CBT-I for Psychosis: Guidelines, Preliminary Efficacy, and Functional Outcomes

NCT02535923

Study protocol

Date of upload: 4/19/2022; Most recent Continuing Review approval date: 1/25/2022

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HP-00074686 Introduction Page_V2

Introduction Page

1 * Abbreviated Title:
CBT-I_Trial

2 * Full Title:
CBT-I for Psychosis: Guidelines, Preliminary Efficacy, and Functional Outcomes-Trial

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

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.***
Elizabeth Klingaman

CITI Training: ID00003385

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:
Kirsten Harvey

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	Kelly Lloyd	yes	yes	Research Team Member	no	
View	Ralf Schneider	no	no	Research Team Member	no	
View	Gabriella Coakley	yes	yes	Research Team Member	no	
View	Maddison Taylor	yes	yes	Research Team Member	no	
View	Philip Gehrman	no	no	Research Team Member	no	
View	Belinda Kauffman	no	no	Research Team Member	no	ID00009489
View	Letitia Travaglini	no	no	Research Team Member	no	
View	Mary Katherine Howell	no	no	Research Team Member	no	
View	Tracy Robertson	no	no	Research Team Member	no	
View	Melanie Bennett	yes	yes	Research Team Member	no	ID00006944
View	Alicia Lucksted	no	no	Research Team Member	no	ID00001635
View	Lynn Calvin	no	no	Research Team Member	no	
View	Deborah Medoff	no	no	Research Team Member	no	ID00006254
View	Lijuan Fang	no	no	Statistician	no	
View	Amanda Peeples	no	no	Research Team Member	no	
View	Jeanette Robinson	no	no	Research Team Member	no	ID00008752
View	Lorrianne Kuykendall	no	no	Research Team Member	no	
View	Clayton Brown	no	no	Statistician	no	ID00000679
View	Richard Goldberg	no	no	Research Team Member	no	ID00008960
View	LAN LI	no	no	Statistician	no	

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

ID: VIEW4DF85C16F2800
Name: v2_Research Team Information

HP-00074686 Resources_V2

Resources

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

1 * Describe the time that the Principal Investigator will devote to conducting and completing the research:
Dr. Klingaman will devote a portion 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 serious mental illness. 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 Drs. Klingaman and Gehrman.

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

3 Please discuss any additional information regarding funding below:
Funding will be provided by the VA Rehabilitation Research and Development Service.

ID: VIEW4DF85DF452400
Name: v2_Funding Information

HP-00074686

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

* Address 1:
810 Vermont Ave NW

Address 2:

* City:
Washington

* State:
DC

* Zip Code:
20420

* Contact Person:
Shirley Groer

* Phone Number:
202-443-5767

* Federal Agency Email:

Grant Number 1 (if applicable):
1IK2RX001836-01A1- OR - Check here if Grant 1 is not assigned a number. ☐

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

PI of Grant 1:
Elizabeth Klingaman

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-00074686 Research Protocol_V2

Research Protocol

1 * Do you have a research protocol to upload?

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

2 If Yes, upload the research protocol:

Name	Created	Modified Date
There are no items to display		

ID: VIEW4E00563F8D000
Name: v2_Research Protocol

HP-00074686

Risk Level_V2

Risk Level

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

* Choose One:

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

ID: VIEW4E02805225800
Name: v2_Risk Level

HP-00074686

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-00074686

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.

Insomnia is a highly prevalent problem for Veterans with serious mental illness (SMI) that is linked to significant distress and poor functioning and is a critical obstacle to rehabilitation and recovery (Cohrs, 2008; Kaplan & Harvey, 2013). The VHA has made treatment of insomnia a high priority and has initiated a nationwide dissemination of Cognitive Behavioral Therapy for Insomnia (CBT-I)–an evidence-based practice and the first-line standard of care for insomnia treatment (Buysse, 2013). While CBT-I is the gold-standard for insomnia treatment in the general population, only several small studies have evaluated the efficacy of CBT-I for Veterans with psychotic or bipolar disorders.

Although CBT-I has the potential to greatly benefit Veterans, practical and illness-related factors are challenges to using CBT-I with Veterans with SMI (i.e., psychotic and bipolar disorders). Prior research shows that while CBT-I may be helpful for some people with psychotic or bipolar disorders, guidelines are needed to aid clinicians in the clinical tailoring of CBT-I for this population (Dopke, Lehner, & Wells, 2004). Our research team has developed guidelines for clinicians to tailor CBT-I so that it meets the unique needs of Veterans with SMI. Randomized controlled trials are now needed to assess the extent to which CBT-I is indeed efficacious in populations with SMI, when compared with treatment they receive in usual care (a focus on health and wellness more broadly). The purpose of this study is to examine the acceptability and preliminary efficacy of CBT-I when compared to an intervention focused on health and wellness.

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:

Aims/Objectives: The purpose of this study is twofold:

(1) In Phase 1 (Acceptability Trial), we will establish the acceptability of CBT-I for Veterans with psychotic disorders and insomnia when delivered using guidelines developed for its use. To do this, we will complete an open trial of CBT-I with six Veterans with psychotic disorders and insomnia (including schizophrenia disorders and bipolar and major depression with psychotic features). Acceptability will be demonstrated by participants' satisfaction with CBT-I and its overall utility, via quantitative assessments and qualitative interviews. Refinements to the guidelines will be made based on this information.

(2) In Phase 2 (RCT), we will test the preliminary efficacy of CBT-I for Veterans with psychotic/bipolar disorders and insomnia when delivered using these refined guidelines. To do this, we will complete a small randomized controlled feasibility and preliminary efficacy trial comparing CBT-I (n=30) to a Health and Wellness control intervention (n=30), evaluating sleep and functioning outcomes. Specifically, feasibility will be demonstrated by adequate rates of recruitment, initial intervention engagement, attendance at intervention sessions, and therapist fidelity. We hypothesize that compared to a general Health and Wellness Intervention, CBT-I will result in significant a) decreases in insomnia symptoms and b) increases in functioning. Regarding exploratory aims, using data collected from the RCT, we will explore whether baseline clinical and sleep characteristics, physical comorbidities, medications, and health behaviors (e.g., smoking, caffeine use) 1) moderate the impact of CBT-I on insomnia and functioning or 2) change as a result of participation in CBT-I, and whether 3) insomnia symptoms mediate the effect of CBT-I on functioning. Lastly, we will (4) preliminarily assess durability of effects of CBT-I on insomnia symptoms and functioning at a 3-month follow-up visit.

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.:

Phase 1 (Acceptability Trial): This phase includes an open acceptability trial and Veteran qualitative interviews. There is no randomization or control group.

Phase 2 (RCT): We will implement an RCT of CBT-I with random assignment to: (1) CBT-I, or (2) Health and Wellness (comparison) group. Participants will complete assessments at baseline, post-treatment, and 3-month follow-up. We will measure symptom and functional outcomes and evaluate potential mediators and moderators of outcomes including cognitive ability, attitudes and beliefs, mental illness symptoms, physical health, and health behaviors. We will also do Veteran qualitative interviews to understand their experiences in the CBT-I treatment.

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

We collected qualitative and quantitative data on sleep related problems, behaviors and treatments among 60 Veterans with serious mental illnesses, including psychotic and bipolar disorders, receiving mental health clinic services at the VA Maryland Healthcare System, as well as providers. Of these, 73.7% reported symptoms of insomnia rated as moderately severe or severe. Veterans in this study expressed dissatisfaction with medication due to side effects, and feelings of hopelessness that medication is the "only way to get to sleep." Desire for non-pharmacological alternatives to improve sleep was a common theme. Providers felt ill-equipped to offer CBT-I to Veterans with psychosis or those with a history of mania (e.g., bipolar disorder).

In a non-VA sample of pilot data, we assessed 30 people with schizophrenia regarding problems related to sleep and the relationship between sleep and other health behaviors. Many reported difficulty falling asleep at night (30%) or experiencing excessive daytime sleepiness (17%), and it was alarming to find that 47% reported taking medication to help with sleep at least three times per week. This figure, in a sample not selected for sleep problems, is highly suggestive that sleep is an important problem for people with psychosis. Second, we examined relationships between insomnia and functioning in a sample of Veterans with SMI (e.g., severe depression, bipolar, and psychotic disorders). These Veterans overwhelmingly reported significant sleep distress on the Insomnia Severity Index; 82% were dissatisfied or very dissatisfied with their sleep, 65% reported worry about sleep problems, almost 40% reported that sleep problems were impairing quality of life, and most (64.8%) considered sleep problems to be interfering with their functioning including concentration and ability to complete daily tasks.

CBT-I addresses maladaptive cognitions about sleep, behaviors perpetuating poor sleep, and learned associations underlying conditioned arousal. Like non-SMI samples, participants in our pilot data endorsed maladaptive cognitions related to sleep and worry about not sleeping. Overall, our findings show that, for individuals with psychotic and bipolar disorders, insomnia is an all too common problem. Importantly, our pilot data indicate that Veterans worry about sleep and the impact their poor sleep will have on their ability to function in their lives and communities.

Sleep Characteristics of Veterans with SMI have Informed Guidelines for Clinical Tailoring of CBT-I: There are a number of ways that CBT-I may not fully consider the challenges experienced by Veterans with psychotic/bipolar disorders and insomnia. Our pilot efforts have revealed a range of practical and motivational challenges, including but not limited to cognitive impairment, motivational deficits, dealing with distress from delusions and hallucinations, medications that cause daytime sleepiness and nighttime restlessness, and needing structured daytime activities to stay awake during the day. Our guidelines for using CBT-I with this population address each of these challenges. In addition, in pilot work, we have asked Veterans with SMI and insomnia to review these guidelines. Our data reveal that Veterans with psychosis and/or bipolar disorder and insomnia perceive these guidelines to be comprehensive in addressing their self-reported sleep challenges and that they would be willing to try this treatment if these guidelines were used.

Summary: These findings highlight the importance of addressing insomnia in Veterans with psychosis and/or bipolar disorder. Specifically: (1) Insomnia is highly prevalent in Veterans with psychosis and/or bipolar disorder, (2) Poor sleep is related to impaired functioning in a number of important domains, (3) CBT-I is relevant to Veterans with psychosis and/or bipolar disorder and insomnia, in that they experience many cognitive and behavioral challenges to sleep, (4) Guidelines for the clinical tailoring of CBT-I for this population are necessary (5) Guidelines we have developed based on pilot data are perceived as comprehensive, important, and likely useful by Veterans with psychosis and/or bipolar disorder and insomnia, and (5) People with psychosis and/or bipolar disorder are willing and able to effectively engage in research on sleep needs and health behavior interventions.

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

Scientific/Scholarly Background: Among people with psychotic and/or bipolar disorder disorders, 30-80% report sleep disturbances (Cohrs, 2008; Klingaman et al., 2015). Both objective (e.g., polysomnography, actigraphy) and subjective (e.g., self-report) data identify insomnia as a pervasive concern. People with psychosis and/or bipolar disorder have less total sleep time, reduced sleep efficiency (sleep time divided by time in bed), and take longer to fall asleep compared to healthy controls and 30% to 44% meet criteria for moderate to severe insomnia. Insomnia is one of the most frequent reasons for mental health referrals in the VHA and insomnia is known to cause considerable distress for Veterans.

Given the detrimental impact of insomnia on symptoms and functioning among people with psychosis and/or bipolar disorder, an effective cognitive behavioral approach for this group is desperately needed. Other evidence-based cognitive behavioral therapies with administration guidelines addressing the cognitive and other deficits associated with SMI have shown good efficacy for a range of symptoms and behavioral domains. Cognitive Behavioral Therapy for Insomnia (CBT-I), led by a trained interventionist, is a well-established evidence-based practice, and is classified by the National Institutes of Health (NIH) as a first-line treatment for insomnia. Unfortunately, there is little research examining the efficacy of CBT-I for individuals with SMI (e.g., psychosis and bipolar disorder) and therefore little information available to practitioners wishing to use CBT-I with this group. There have been only three small non-controlled studies of CBT-I in people with psychotic disorders and/or

bipolar disorder. Authors of these studies stressed the need to attend to the symptoms and experiences of these individuals when administering CBT-I. All studies simplified intervention materials and explanations. Neither team tailored the delivery of CBT-I in a standardized manner, to base changes on empirical evidence, or to document guidelines for clinicians using CBT-I with this population in the future. The authors noted comprehension difficulties for some participants suggesting the need for more accommodation to cognitive deficits. They also noted need for building in more practice and motivational enhancement to help clients use behavioral strategies consistently. In sum, while these trials provide preliminary support for the utility of CBT-I among people with SMI, each highlights the need for guidelines for the clinical tailoring of CBT-I with this population.

Rationale and Significance: Veterans with SMI are at elevated risk of disability, high health care spending, reduced quality of life, and early mortality. Thus there is an urgent need to develop and test empirically-derived guidelines for the clinical use of VA EBPs which would target functional outcomes for this population. Insomnia treatment for Veterans with SMI is imperative in this regard. Insomnia is prevalent among people with SMI, causes them significant distress, and is associated with long-term negative consequences for their physical, emotional, psychosocial, and cognitive recovery. It is also one of the most frequent reasons for mental health referrals in the VHA. Further, insomnia represents a significant obstacle to the recovery of Veterans who have psychosis and/or bipolar disorders. CBT-I is classified by the NIH as a first-line treatment for insomnia, and the VHA is disseminating CBT-I as a national evidence-based practice for VA clinicians. Although CBT-I is the gold standard treatment for insomnia, there has been little work to determine how to make it most effective and accessible for Veterans with SMI. The CBT-I manual specifically states potential difficulties in using CBT-I with this population but provides very limited guidance on addressing them. As a result, during the VA Evidence-Based Psychotherapy (EBP) consultation process, providers are currently routinely advised to avoid using CBT-I with Veterans with psychotic or manic symptoms. Thus it is likely that most Veterans with psychosis and/or bipolar disorder, and insomnia are not offered this evidence-based intervention. The VHA Uniform Mental Health Services Handbook clearly states that Veterans with SMI must be offered quality interventions comparable to the care received by other Veterans.

This project addresses this inequity through the testing and iterative refinement of guidelines for the use of CBT-I with this population, and evaluation of the efficacy of this treatment. This can ultimately improve uptake within VA both by encouraging VA EBP trainers to recommend use of CBT-I with people with psychosis and/or bipolar disorder, and by making VA clinicians feel more prepared to use it. The coauthors of the VA CBT-I manual have agreed to use the resulting guidelines in future editions of the VA CBT-I manual that is disseminated to all VA clinicians learning CBT-I, thereby immediately bridging development to implementation.

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Name: v2_Justification, Objective, & Research Design

HP-00074686

Supporting Literature_V2

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.***

Veterans with SMI (i.e., psychosis and bipolar disorder) and insomnia have many sleep challenges. Even after adjusting for illness severity and medication side effects, insomnia symptoms are strongly associated with many functional difficulties experienced by people with psychotic and bipolar disorders. Poor sleep quality predicts dissatisfaction with social relationships, daily activities, emotional functioning, and quality of life (Hofstetter, Lysaker, & Mayeda, 2005; Klingaman, et. al, 2016). Chronic insufficient sleep causes deficits in cognitive functioning generally (Basner, Rao, Goel, & Dinges, 2013), which are exacerbated among people with schizophrenia (Basner, et al., 2013). Among people with other chronic medical and mental health conditions, randomized controlled trials (RCTs) demonstrate that successful insomnia treatment can lead to significantly improved sleep; cognitive (Miro, et al., 2011), social (Talbot, et al., 2014), and daily functioning, psychiatric symptoms, and health-related quality of life (Martinez, et al., 2013). People with psychosis and/or bipolar disorders also find improved psychotic symptoms and/or functioning with better sleep (Kaplan & Harvey, 2013; Myers, Startup, & Freeman, 2011; Dopke, Lehner, & Wells, 2004).

Sedative-hypnotic and antipsychotic medications are typically used to treat insomnia among people with psychotic and bipolar disorders (Kantrowitz, Citrome, & Javitt, 2009; Kaplan & Harvey, 2013). While FDA-approved, sedative-hypnotic medications are not fully effective at improving sleep, and dependence, withdrawal, and side-effects are important risks (3). Psychotropic medications (e.g., quetiapine) have limited efficacy and cause daytime sleepiness and weight gain which further detract from quality of life and functioning (Krystal, Goforth, & Roth, 2008). As such, pharmacological treatments alone fail to adequately address insomnia and its functional consequences among people with SMI.

Behavioral treatments have shown substantial effectiveness for insomnia while avoiding the above-mentioned adverse effects. Cognitive Behavioral Therapy for Insomnia (CBT-I), led by a trained interventionist, is a well-established evidence-based practice, and is classified by the National Institutes of Health (NIH) as a first-line treatment for insomnia (Siebern & Manber, 2011). Compared to pharmacotherapy, CBT-I provides similar effects on short term insomnia symptoms (Morin, et al., 2006), and better long-term improved sleep efficacy (Mitchell, Gehrman, Perlis, & Umscheid, 2012; Buysse, 2013). Effect sizes for CBT-I are robust; a meta-analysis of 23 RCTs found medium to large effects on sleep latency, sleep quality, wakefulness after sleep onset, and sleep efficiency (Irwin, Cole, & Nicassio, 2006). Systematic review of 85 CBT-I treatment studies documented sustained improvement for 3 years post-treatment (Morin, et al., 2006). The Veterans Health Administration (VHA) disseminates and supports its CBT-I manual as one of its rollouts of Evidence-Based Psychotherapies. CBT-I has high potential to be particularly efficacious for Veterans with SMI, as there is strong evidence for cognitive behavioral therapies in the treatment of other health problems faced by this population (Dixon, et al., 2010). Several studies (Dopke, et al., 2004; Myers, et al., 2011; Kaplan & Harvey, 2013) have tried CBT-I with individuals with psychosis and/or bipolar disorder and found preliminary efficacy for the intervention. They described a need to clinically tailor the intervention to the cognitive and symptomatic challenges experienced with this population, yet they did not fully document any suggested guidelines. Based on our previous pilot data on the perspective of both Veteran clients and VA providers, we have developed guidelines for the clinical tailoring of CBT-I. This study will test the acceptability and feasibility of conducting CBT-I delivered in accordance with these guidelines, make refinements to the guidelines based on qualitative feedback, and evaluate the preliminary efficacy of CBT-I used in conjunction with these refined guidelines.

2 If available, upload your applicable literature search:

Name	Created	Modified Date
References IRB.docx(0.02)	4/3/2017 11:45 AM	1/23/2019 12:29 PM

ID: VIEW4E02805A7E400
Name: v2_Supporting Literature

HP-00074686

Study Procedures_V2

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:

This study has two phases:

Phase 1 (Acceptability Trial) has two parts:

Part 1:
Consent and Time Point 1 Assessments (n= 20) and
Part 2:
CBT-I Treatment, Qualitative Interviews, and Time Point 2 Assessment Battery (n=6; invited from the 20 in Part 1).

Part 1: Consent and Time Point 1 Assessments. For all participants consented, chart review data will be collected on: 1) mental health and medical diagnoses, and 2) medications (for the purpose of recording sleep aids/ medications that contribute to sleep disturbances). Participants in Part 1 will be asked to complete a demographic form and an insomnia screening measure [Insomnia Severity Index (ISI)]. Completion of these measures will take approximately 10 minutes. Participants who complete the ISI and score lower than 15 will not be eligible to continue in the study and will be paid $5 for their participation.

Participants who complete the ISI and score 15 or higher will be asked to wear a VA-approved activity watch Actiwatch (Philips Respironics) that records activity level as well as complete weekly sleep diaries for two weeks. The purpose of the watch and diary is to track participants' level of activity. The watch will be worn all times except during bathing or swimming. Data are stored internally and are off-loaded to a computer via a cable. Study staff will offload data to a computer via a cable and use Actiwatch custom software to derive patterns of activity. Results will be saved onto a FIPS 140-2 validated and encrypted VA-issued thumb drive and then immediately transferred behind the VA firewall. If a participant returns an Actiwatch and repairs need to be completed on the Actiwatch we will send the Actiwatch back to Phillips Respironics, however, this company will not access any of the non-sensitive information stored in the Actiwatch.

Participants who have not had a sleep apnea screening study in the past 6 months and who do not use a device for sleep apnea management (such as a Continuous Positive Airway Pressure-CPAP device) will also be invited to complete sleep apnea screening. This screening entails a one-night home sleep test for sleep apnea using the WatchPAT (Itamar Medical, Inc), an FDA-approved and VA-approved device for detecting sleep apnea. This is a non-invasive, lightweight device which collects information on arterial pulsatile volume changes at the fingertip and blood oxygen level through a wristwatch connected to a pulse oximeter. For participants invited to partake in the sleep apnea screening, the RA will first explain and demonstrate use of the WatchPAT. Next, the RA will ask the participant to practice using the device while the RA watches and assists until the participant can do so independently and all questions are answered. Participants will be given a card with direction reminders and contact information for the PI and RA in case of questions using the device at home. The participant will then use the equipment for 1 night and will be required to return the equipment the following day. Data are stored internally and are off-loaded to a computer via a cable. Study staff will use WatchPAT custom software to derive an apnea-hypopnea index (AHI) score. Results will be saved onto a FIPS 140-2 validated and encrypted VA-issued thumb drive and then immediately transferred behind the VA firewall. After data offload and processing, each Veteran's AHI will be categorized as absent to mild (AHI less than 15), or moderate to severe (AHI 20 or greater). Typically, one night of WatchPAT use is sufficient to determine the AHI score; participants may be asked to repeat use if their initial reading was invalid. Each participant asked to use a WatchPAT will be paid $75 once their participation in the home sleep apnea screening is complete.

At the end of two weeks of Actiwatch and sleep diary use, participants will be asked to complete an assessment battery that will take approximately 150 minutes. The assessment battery includes measures that assess sleep, health behaviors, and cognitive functioning. Participants will be paid $30 for completion of the Actiwatch, weekly sleep diaries, and assessment battery.

Participants who regularly use a device to manage sleep apnea per responses on the assessment battery will be invited to participate in Part 2. Participants who do not use a device to manage sleep apnea will be invited to participate in Part 2 if they have had a sleep apnea screening study in the past 6 months that indicated absent to mild sleep apnea. Those who had a sleep apnea screening study in the past 6 months that indicated moderate to severe sleep apnea and who do not regularly use a device for sleep apnea management will not be eligible to continue in the study. Individuals with elevated AHI (20 or greater) per results on the WatchPAT home sleep apnea screening will be excluded from Part 2 participation and will be referred to their treatment provider, who will be given information on referral sources for the client to obtain formal sleep testing and possible treatment. Similarly, if any evidence of a significant sleep disorder is noted the participant will undergo a similar referral process.

Part 2: CBT-I Treatment. Participants will be recruited for Part 2 until 6 participants are screened eligible and have agreed to participate in CBT-I. We anticipate screening 20 records and participants in order to recruit 6 participants for Part 2. Interventionists will be master's level clinicians hired based on their qualifications. Prior to beginning sessions, we will screen participants' charts to understand how to best tailor the treatment for them. Participants may be asked to wear a VA-approved activity watch Actiwatch (Philips Respironics) that records activity level as well as complete weekly sleep diaries. The purpose of the watch and diary is to track participants' activity while in treatment. The watch will be worn all times except during bathing or swimming. Data are stored internally and are off-loaded to a computer via a cable. At the culmination of CBT-I, participants will be required to return the activity watch monitor. Study staff will offload data to a computer via a cable and use Actiwatch custom software to derive patterns of activity. Results will be saved onto a FIPS 140-2 validated and encrypted VA-issued thumb drive and then immediately transferred behind the VA firewall. Participants will attend approximately 10 treatment sessions over the span of approximately 4 months. The number of sessions may vary per participant depending on how many sessions are required to reduce each individual's insomnia symptoms. During each session, participants will also complete the Insomnia Severity Index (ISI) and the Sleep Need Questionnaire (SNQ). We will use approximately 10 minutes at the end of every CBT-I session to pose open-ended questions to attending participants about reactions to that week's session content, recommendations for changes, and their views of the usefulness of the session to them as Veterans with psychosis.

Qualitative Interviews. At the end of their participation in CBT-I, participants in Part 2 will complete a qualitative interview that will take approximately 60 minutes regarding their sleep experiences and feedback about CBT-I materials and guidelines. The qualitative interview will be audiorecorded. Audiorecordings will be transcribed by an experienced VA-approved transcriptionist. The transcriptionist will not know the identities of the participants on the recordings and recordings will not include any identifying information. Research staff will ensure that the audiorecordings are transferred in a secure manner (encrypted) to the transcriptionist. Participants will be paid $40 for completion of the qualitative interview.

Time Point 2 Assessment Battery. At the end of their participation in CBT-I, participants in Part 2 will also complete the ISI and the assessment battery administered in Part 1 Time Point 1 Assessment Battery. Participants will be paid $30 for participation in this assessment battery.

Phase 2 (RCT) has two parts:

Part 1: Consent and Time Point 1 Assessments (n=190) and
Part 2: Treatment with CBT-I or Health and Wellness, Time Point 2 Assessment Battery, and Time Point 3 (Follow Up) Assessment Battery (n=60; invited from the 190 in Part 1), Qualitative Interview (n=30)

Part 1: Consent and Time Point 1 Assessments. Part 1 will follow the same assessment procedures as Phase 1, Time Point 1 with the exception that all participants who complete the ISI and score 15 or higher will receive a WatchPAT device. If participants are unable to obtain a valid reading on the WatchPAT device but they have had a

VA sleep apnea screening study in the past 6 months that generated an apnea hypopnea index (AHI) score, this number will be used in place of the unattainable WatchPAT reading. Participants who complete the ISI and score lower than 15 will not be eligible to continue in the study and will be paid $5 for their participation. Participants who complete the Time Point 1 Assessment Battery will be paid $30. Each participant will be paid $75 when they participate in the home sleep apnea screening.

Part 2: Treatment with CBT-I or Health and Wellness. Participants will be recruited for Part 2 until 60 participants are screened eligible and have agreed to participate. We anticipate screening 190 records and participants in order to recruit 60 participants for Part 2. Participants will be randomized to either the CBT-I (treatment) condition or the Health and Wellness (control) condition. Procedures for Part 2, Treatment are otherwise the same as in Phase 1, Treatment, with the exception that we will not pose open-ended questions to participants about recommendations for changes to the treatment.

Time Point 2 Assessment Battery. The Time Point 2 Assessment Battery will follow the same assessment procedures as in Phase 1. Approximately two weeks prior to the Time Point 2 (Post) Assessment date, participants may be given an Actiwatch and will be given sleep diaries to complete. Participants will be paid $30 for participation in the post quantitative assessment battery. If a Veteran is unable to complete the study assessment at a VAMC and does not wish to complete the full assessment battery via telephone, then we will offer to conduct the 7-item Insomnia Severity Index (ISI) measure over the phone and strongly encourage the Veteran to choose a confidential location for this questionnaire.

Time Point 3 (Follow up) Assessment Battery. At 3 months following the intervention, participants will complete the Time Point 3 (Follow Up) Assessment Battery used in Time Points 1 and 2. Approximately two weeks prior to the Time Point 3 (Follow Up) Assessment date, participants may be given an Actiwatch and will be given sleep diaries to complete. Participants will be paid $30 for participation in the follow up quantitative assessment battery. If a Veteran is unable to complete the study assessment at a VAMC and does not wish to complete the full assessment battery via telephone, then we will offer to conduct the 7-item Insomnia Severity Index (ISI) measure over the phone and strongly encourage the Veteran to choose a confidential location for this questionnaire.

Qualitative Interview: Those participants randomized to the CBT-I intervention may also be invited to complete an additional interview shortly after completing the treatment sessions. Up to 30 participants will be asked to complete qualitative interviews. This interview will include questions about their experiences while in CBT-I, as well as their opinion of how this treatment could be improved upon. We will also ask for their input to help us think about how to best offer this intervention to others. The interview will take about 1 hour and will be audio recorded. Participants who complete this additional interview will be paid $40 for participation in the qualitative interview.

OPTION FOR TELEPHONE-BASED SESSIONS:
For the intervention sessions, the qualitative interview, and the self-report surveys administered at all timepoints, if participants are unable to participate in person, they will have the option of completing these activities by phone. Participants completing the self-report measures or qualitative interviews by phone will be mailed their participation compensation funds. As there is one assessment measure (MATRICS) that must be completed in person, participant compensation for assessment time points will be divided if they complete self report measures over the phone ($20) and the MATRICS in person ($10). Due to COVID-related safety issues with having participants complete the MATRICS in person, any participants who had a post or follow up in the COVID era will not be completing the MATRICS or receiving the corresponding $10 for participating in the MATRICS. We will use VA email to communicate with veteran participants during the RCT in order to send electronic copies of resources, blank worksheets, and/or response cards for participants to use during phone sessions. We will only send 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, and that any emails to veteran participants will be deleted upon receipt to help ensure security. For instance,

Hello,
As you requested, attached are the response cards you will use if completing the assessment at home via phone. 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 [VA phone number] 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. All emails will be deleted upon receipt to help ensure security.
Thank you and have a great day!
The VA Research Study Team

and

Hello,
As you requested, attached are blank electronic copies of the worksheets/resources we discussed. Our next call is scheduled for [day], [date] at [time]. Research staff will call you at your preferred number. Please contact the research study team at [VA phone number] 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. All emails will be deleted upon receipt to help ensure security.
Thank you and have a great day!
The VA Research Study Team

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

3 * Describe the duration of an individual participant's participation in the study:
Phase 1: Acceptability Trial.
Part 1. Consent and Time Point 1 Assessments: 10-150 minutes and one overnight sleep apnea screening test, depending on meeting eligibility criteria.
Part 2. CBT-I Treatment: Participants attending 60 minute individual sessions = over approximately 4 months.
Part 3. Qualitative Interviews: 60 minutes.
Part 4. Time Point 2 Assessment Battery: 150 minutes.

Phase 2: RCT.
Part 1. Consent and Time Point 1 Assessments: 10-150 minutes and one overnight sleep apnea screening test, depending on meeting eligibility criteria.
Part 2. Treatment with CBT-I or Health and Wellness: Participants attending 60 minute individual sessions = over approximately 4 months.
Part 3. Time Point 2 Assessment Battery: 150 minutes.
Part 4. Time Point 3 (Follow up) Assessment Battery: 150 minutes.
Part 5. Qualitative Interview: 60 minutes.

4 * Describe the amount of time it will take to complete the entire study:
The entire study will last approximately 3 years.

5 * Describe any additional participant requirements:
N/A

ID: VIEW4E0280585B400
Name: v2_Study Procedures

Sample Size and Data Analysis

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

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

Phase 1 (Acceptability Trial): Due to the estimated rates of insomnia and sleep apnea in prior literature on Veterans with psychotic disorders, we have determined the sample size of 20 to be an appropriate number to attain a final sample size of 6. We determined the sample size of 6 to be feasible for the purpose of an acceptability trial.

Phase 2 (RCT): Due to the estimated rates of insomnia and sleep apnea in prior literature on Veterans with psychotic and bipolar disorders, we have determined the sample size of 190 to be an appropriate number to attain a final sample size of 60. After considering time and resources available with this CDA-2, we believe it will be feasible to randomize 30 individuals per condition, thus the total sample size of 60. With 25% anticipated loss to follow-up at PT, we anticipate outcome assessments at PT for approximately 22-23 participants per condition. We expect 35% loss to follow-up at the follow-up visit, leaving 19-20 per condition). With the anticipated 22-23 per condition with complete data at post-treatment, power is estimated to be at least .80 for detecting between "medium" and "large" effect sizes (d=.60) with the ANCOVA analysis, assuming BL to PT correlation in the response variable is r=0.7. Assuming r=0.6, the detectable effect size increases to d=.67 (with power=.80). Up to 30 participants within the CBT-I condition will be asked to complete the qualitative interview. This will allow us to gain a rich understanding of the variety of experiences participants within the CBT-I condition have had with the treatment.

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:

Phase 1 (Acceptability Trial): Interviews with Veterans will be audiorecorded and transcribed. Transcripts will be read and discussed by the PI and study team, creating a brief summary that captures our best understanding of what the interviewee sought to convey. We will organize themes, variations, and interrelationships among the ideas, views, and experiences conveyed by the interviews. We will pay particular attention to ideas/themes that can contribute to intervention effectiveness and implementation. In doing so, we will consider interviewee's personal reflections and will pay close attention to their personal experiences with using or providing treatment services. The study team will discuss the results to consider refining guidelines for CBT-I in accordance with the unique needs of these Veterans. Resulting suggestions and recommendations will be used to refine CBT-I guidelines and materials for the RCT evaluating the efficacy of CBT-I delivered to Veterans with SMI in accordance with these guidelines.

Phase 2 (RCT): Specific Aim 3, Hypothesis 1 (H1). CBT-I intervention feasibility will be demonstrated by adequate rates of recruitment, initial intervention engagement, attendance at intervention sessions, and therapist fidelity. Analysis: We will use descriptive statistics to summarize the feasibility of CBT-I by: Calculating (a) the rate of recruitment (# consented divided by # approached and # randomized divided by # consented) and compare these to recruitment goals; (b) the percent who engaged in treatment (% of randomized who attend first 3 sessions), median (and inter-quartile range [IQR]) of the total number of sessions attended and treatment dropout rates (# who dropped out prior to completing treatment divided by # who engaged); (c) the median (and IQR) of the number of reminders and outreach contacts made for each participant; (d) the mean (and SD) of the CBT-I Treatment Components Adherence Scale assessed at post-treatment; and (e) the percent of participants who turned in completed sleep logs and percent of the total number of treatment sessions in which completed sleep logs were turned in. To assess therapist fidelity to CBT-I, we will compute percent of sampled sessions in which interventionists were adequately adherent as defined by the rollout criteria of the VA CBT-I EBP of an average rating equal to 2 ("satisfactory"), in addition to no items at a score of 0 ("poor") on the Assessment Competency Rating Scale and the Therapy Competency Rating Scale. For the Health and Wellness condition, we will also compute percentages of sampled sessions with adequate adherence on our Health and Wellness Therapist Adherence and Competence rating scales with parallel criteria for adequacy (i.e. average score equal to "acceptable" and no items scored as "unacceptable").

Specific Aim 3, Hypotheses 2a-b (H2a,b). Compared to a general Health and Wellness Intervention, CBT-I will show significant a) decreases in insomnia symptoms (as measured by the ISI) and b) increases in functioning (as measured by the VR-36). Analysis: For the two outcomes for H2a and H2b we will use the mixed model described above. For example, to assess the effect of CBT-I on insomnia severity as measured by variable Y= ISI, the model will be: Y_j=β_0+β_1 "Y" _1+β_2 P"T + " β_3 "FU + " β_4 "CBT-I +" β_5 "CBT-I·POST + " β_6 "CBTI·FU + " e_j , where j = 2, 3 are the PT and FU assessment points respectively, Y1 is the baseline value, and POST, FU, and CBT-I are indicator variables for the PT and FU time-points and the CBT-I intervention condition (versus the control condition). β_5 in the model, equal to the group differences at PT (i.e. treatment effect) and FU, will be tested against the Null hypothesis that that β_5=0. As mentioned above an important out-of-balance covariate and potential confounder could also be included in the model.

Secondary Aims. In secondary analyses, actigraphy outcomes will include the length of time between target bedtime (via sleep log information) and sleep onset (sleep latency), and the number of awakenings after sleep onset. The right-hand-side of the model for Specific Aim 3 will also be used for these outcomes, however the type of longitudinal model may differ. For example, a Poisson or Negative Binomial model using generalized estimating equations (GEE) would likely be a better fit for testing the treatment effect on the count variable, number-of-awakenings.

Exploratory Aims (EA). We will explore whether clinical and sleep characteristics, physical comorbidities, and other health behaviors: moderate the effect of CBT-I on insomnia and functional outcomes (EA1), and/or improve as a result of participation in CBT-I (EA2). Analysis: For EA1, we would add the three-way interaction terms between the baseline health behavior variable, the CBT-I indicator, and either the PT or FU indicator to estimate differential effects depending on health behavior status or level at PT and FU, respectively. For EA2, we would use a model parallel to the model for H2a, b except the health behavior variable would be the response variable. For a categorical health behavior variable a logit regression model using GEE would be used (e.g. logistic regression). For EA3, if CBT-I improves functioning (H2b), we will explore whether the data indicate that improvement in sleep/insomnia symptoms mediates the effect of CBT-I on functioning. Analysis: We will use standard methods for mediation analysis. For EA4 (durability of effects), we will examine treatment effects at the follow-up visit (i.e. test the significance of β_6) in the comprehensive mixed model specified above for primary aim 3. Here, durability is operationally defined as significantly better outcome at FU (CBT-I vs Control) for those outcomes that were significantly better at PT. This approach (versus testing for no change in effect between PT and FU) allows for the possibility of significantly better outcome at FU even while there is attenuation relative to the PT effect.

Qualitative Interviews. Analysis for Phase 2 (RCT) qualitative interviews will follow the same procedure as those in Phase 1 (Acceptability Trial).

ID: VIEW4E02806052800
Name: v2_Sample Size and Data Analysis

HP-00074686 Sharing of Results_V2

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:

For both Phases 1 and 2: Participants can request overall results of this study if interested. Results of this study will be shared through publications. Participants' test results and progress in the intervention may be shared with their VA medical providers in order to coordinate the delivery of this intervention with the rest of participants' medical care.

ID: VIEW4E02808CBD800
Name: v2_Sharing of Results

HP-00074686

Behavioral Methods and Procedures_V2

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

• MIRECC Demographic Form
• Insomnia Severity Index (ISI)
• Sleep Need Assessment
• Pittsburgh Sleep Quality Index (PSQI)
• Morningness-Eveningness Questionnaire
• Sleep Hygiene Behaviors
• MIRECC Instrument to Measure Self-Management
• Dysfunctional Beliefs and Attitudes about Sleep Scale
• Pre Sleep Arousal Scale
• Sleep Related Behaviors Questionnaire
• Sleep Associated Monitoring Index
• Sleep Self-efficacy scale
• Fear of Sleep Inventory
• PROMIS-SF Anxiety
• PROMIS-SF Depression
• Sleep readiness to change scale
• Dissociative Experiences Scale
• Social Readjustment Rating Scale
• Specific psychotic experiences questionnaire
• Coping Strategies Scale
• Difficulties in Emotion Regulation Scale
• Brief Irritability Test
• Illness Management and Recovery Scale: Consumer Self-Rating
• PROMIS Fatigue measure
• Functional Outcomes of Sleep Questionaire-10
• Motivation and Pleasure Scale
• World Health Organization Disability Assessment Schedule (WHO-DAS 2.0)
• WHO-DAS-Insomnia
• Veterans RAND 36-item Health Survey (VR-36)
• Veterans RAND Health Survey-Insomnia Items
• Eating/physical activity readiness to change items
• Smoking History Form (SHF)
• Fagerstrom Tolerance Scale (FTS)
• Ready Willing and Able Smoking questionnaire
• ASI/AUDIT Questionnaires
• Suicide Behaviors Questionnaire-Revised
• Brief Resilience Scale
• Glasgow Sleep Effort Scale
• Satisfaction with Treatment Form
• Iowa Sleep Disturbances Inventory-Unusual Experiences Subscale,
• Sleep Diary (CSD-Core) with instructions
• Sleep Diary (CSD-Core) - Trial - we included this modified form of the Sleep Diary (CSD-Core) to include more detailed information regarding when participants removed the Actiwatch device.
• Sleep Diary (CSD-Core) - Trial with medications- we included this modified form of the Sleep Diary (CSD-Core) to include more detailed information regarding when participants removed the Actiwatch device and medications used to help with sleep.
• Sleep Diary (CSD-Core) - Eligibility - we included this modified form of the Sleep Diary (CSD-Core) to include more detailed information regarding when participants removed the Actiwatch device and when participants wore the WatchPAT device for home sleep screening CBT-I Treatment Components Adherence Scale (TCAS)
• STOP-BANG Sleep Apnea Measure (STOP-BANG)
• Participant Application of Sleep Strategies
• Sleep Knowledge Check
• International Restless Leg Syndrome Screen and Measure

2 * Upload a copy of all questionnaires/surveys:

Name	Created	Modified Date
International Restless Led Syndrome Screen and Measure(0.02)	11/5/2018 4:09 PM	1/7/2019 11:10 AM
CBT-I Treatment Components Adherence Scale (TCAS).doc(0.03)	4/12/2017 11:42 AM	12/13/2018 10:37 AM
Sleep Diary and Instructions (CSD-Core)- Trial with medications(0.01)	5/8/2018 9:23 AM	5/8/2018 9:23 AM
22. Difficulties in Emotion Regulation Scale.pdf(0.02)	3/29/2018 8:34 AM	5/8/2018 9:17 AM
14. Fear of Sleep Inventory.docx(0.02)	3/29/2018 8:31 AM	5/8/2018 9:16 AM
26. Functional Outcomes of Sleep Questionnaire.docx(0.02)	3/29/2018 8:35 AM	5/8/2018 9:16 AM
19. Revised Social Readjustment Rating Scale.docx(0.02)	3/29/2018 8:33 AM	5/8/2018 9:15 AM
41. Sleep Knowledge Check.doc(0.02)	3/30/2018 10:36 AM	5/8/2018 9:13 AM
11. Sleep Related Behaviors Questionnaire.doc(0.02)	3/29/2018 8:30 AM	5/8/2018 9:12 AM
Sleep Diary and Instructions (CSD-Core) - Eligibility.doc(0.02)	12/12/2017 10:19 AM	5/8/2018 9:11 AM

Name	Created	Modified Date
36. ASI_Audit Combined (without response cards).docx(0.02)	3/29/2018 8:38 AM	5/8/2018 9:09 AM
42. Iowa Sleep Disturbances Inventory - Unusual Experiences Subscale.doc(0.01)	3/30/2018 1:01 PM	3/30/2018 1:01 PM
44. Participant Application of Sleep Strategies.pdf(0.01)	3/30/2018 10:36 AM	3/30/2018 10:36 AM
40. Satisfaction with Treatment Form.docx(0.01)	3/29/2018 8:39 AM	3/29/2018 8:39 AM
39. Glasgow Sleep Effort Scale.pdf(0.01)	3/29/2018 8:39 AM	3/29/2018 8:39 AM
38. Brief Resilience Scale.docx(0.01)	3/29/2018 8:39 AM	3/29/2018 8:39 AM
35. Ready Willing Able-Smoking Version.pdf(0.01)	3/29/2018 8:39 AM	3/29/2018 8:39 AM
37. Suicide Behaviors Questionnaire Revised (SBQ-R).docx(0.01)	3/29/2018 8:38 AM	3/29/2018 8:38 AM
5. Morningness-Eveningness Scale.docx(0.01)	3/29/2018 8:38 AM	3/29/2018 8:38 AM
21. Coping Strategies Scale.doc(0.01)	3/29/2018 8:38 AM	3/29/2018 8:38 AM
32. Eating and Physical Activity Readiness to Change.docx(0.01)	3/29/2018 8:36 AM	3/29/2018 8:36 AM
31. Veterans RAND Insomnia version.docx(0.01)	3/29/2018 8:36 AM	3/29/2018 8:36 AM
28_29. WHODAS 2.0 36 Interview Questions_Insomnia.docx(0.01)	3/29/2018 8:36 AM	3/29/2018 8:36 AM
25. PROMIS Fatigue Measure.pdf(0.01)	3/29/2018 8:35 AM	3/29/2018 8:35 AM
27. The Motivation and Pleasure Scale.docx(0.01)	3/29/2018 8:35 AM	3/29/2018 8:35 AM
24. Illness Management and Recovery Scale - Consumer Outcome Survey.docx(0.01)	3/29/2018 8:35 AM	3/29/2018 8:35 AM
23. Brief Irritability Test.docx(0.01)	3/29/2018 8:34 AM	3/29/2018 8:34 AM
4. Sleep Need Assessment.docx(0.01)	3/29/2018 8:34 AM	3/29/2018 8:34 AM
20. Specific Psychotic Experiences Questionnaire_formatted.docx(0.01)	3/29/2018 8:33 AM	3/29/2018 8:33 AM
18. Dissociative Experiences Scale.docx(0.01)	3/29/2018 8:32 AM	3/29/2018 8:32 AM
17. Sleep Readiness to Change.docx(0.01)	3/29/2018 8:31 AM	3/29/2018 8:31 AM
16. PROMIS Depression Measure.pdf(0.01)	3/29/2018 8:31 AM	3/29/2018 8:31 AM
15. PROMIS Anxiety Measure.pdf(0.01)	3/29/2018 8:31 AM	3/29/2018 8:31 AM
13. Sleep Self Efficacy Scale.docx(0.01)	3/29/2018 8:31 AM	3/29/2018 8:31 AM
12. Sleep Associated Monitoring Index.docx(0.01)	3/29/2018 8:30 AM	3/29/2018 8:30 AM
10. Pre Sleep Arousal Scale.pdf(0.01)	3/29/2018 8:30 AM	3/29/2018 8:30 AM
9. Dysfunctional Beliefs about Sleep.pdf(0.01)	3/29/2018 8:30 AM	3/29/2018 8:30 AM
8. MIRECC Instrument to Measure Self-Management.pdf(0.01)	3/29/2018 8:30 AM	3/29/2018 8:30 AM
7. Sleep Hygiene Behaviors.docx(0.01)	3/29/2018 8:29 AM	3/29/2018 8:29 AM
Sleep Diary and Instructions (CSD-Core) - Trial.doc(0.01)	12/12/2017 10:19 AM	12/12/2017 10:19 AM
Sleep Diary and Instructions (CSD-Core).doc(0.04)	4/12/2017 12:12 PM	6/28/2017 8:27 AM
STOP-BANG_edited.docx(0.01)	4/12/2017 12:13 PM	4/12/2017 12:13 PM
Smoking History Form (SHF).docx(0.01)	4/12/2017 11:43 AM	4/12/2017 11:43 AM
Fagerstrom (FTS).pdf(0.01)	4/12/2017 11:42 AM	4/12/2017 11:42 AM
WHODAS2.0_36items_interview (WHODAS2.0).pdf(0.01)	4/4/2017 5:30 PM	4/4/2017 5:30 PM
VR-36 FORM Version 1.0 (VR-36).doc(0.01)	4/4/2017 5:30 PM	4/4/2017 5:30 PM
Pittsburgh Sleep Quality Index PTSD (PSQI).docx(0.01)	4/4/2017 5:29 PM	4/4/2017 5:29 PM
Insomnia Severity Index (ISI).pdf(0.01)	4/3/2017 3:49 PM	4/3/2017 3:49 PM
Demographic Form (DEMO).pdf(0.01)	4/3/2017 3:49 PM	4/3/2017 3:49 PM

3 * What is the total length of time that each survey is expected to take?
Surveys will take approximately 90 minutes.

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

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

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

ID: VIEW4E09460F5EC00
Name: v2_Surveys/Questionnaires

HP-00074686 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
Qual Interview_RCT.docx(0.01)	3/27/2018 11:44 AM	3/27/2018 11:44 AM
Qualitative.docx(0.01)	4/3/2017 3:55 PM	4/3/2017 3:55 PM

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

For both Phase 1 (Acceptability Trial) and Phase 2 (RCT): approximately 60 minutes

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

For both Phase 1 (Acceptability Trial) and Phase 2 (RCT):The data will be recorded as written responses on the interview form, audiorecordings of interviews, and transcripts of the audiorecorded interviews.

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-00074686

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)

Phase 1 and 2: We are recording qualitative interviews for the purpose of capturing main themes and perspective of Veterans.
Phases 1 and 2: We are recording treatment sessions for supervision and quality assurance purposes.

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?

Phases 1 and 2: Audiorecordings will not be labeled with any identifying information and will be kept in a locked storage area behind a locked door. Electronic audiofiles will be stored behind the VA firewall. Audio recordings of interviews will be transcribed by an outside VA-approved transcription agency, so as to not have the actual audio recording be the only copy of this research data.

ID: VIEW4E094C128C800
Name: v2_Audio or Video Recording / Photographs

Behavioral Intervention

You indicated that this study involves psychosocial or behavioral interventions.

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

CBT-I is a well-established evidence-based intervention delivered in approximately 10 sessions, each lasting approximately 1 hour. CBT-I addresses cognitive, arousal and behavioral factors relating to sleep difficulties. Each CBT-I session is led by a trained interventionist using a manualized curriculum. Sessions combine assessment, problem conceptualization, education, behavioral strategies and cognitive therapy.

The comparison condition will be a Health and Wellness self-management intervention providing education and support related to the management of physical and emotional well-being. The curriculum will be based on an existing program developed by other VISN 5 MIRECC investigators that is being used in other MIRECC/VA-funded trials. Similar in structure to CBT-I, Health and Wellness is delivered in approximately 10 sessions, each lasting approximately 1 hour. Each Health and Wellness session is led by a trained interventionist using a manualized curriculum. Sessions will focus on health and wellness issues and education on ways to better manage health-related concerns following a basic structure that includes: review of the previous session's material, new educational content, and discussion/application. Topics will include: an overview, physical activity, nutrition and healthy eating, relaxation, stress management, substance use, medication and side effects, and a review.

ID: VIEW4E0BC12A9F800
Name: v2_Behavioral Interventions

HP-00074686 Testing_V2

Testing

You indicated that this study involves neuropsychological or psychophysiological testing.

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

1 * List all of the tests to be used in the study, including both standardized and non-standardized assessments:
The MATRICS consensus cognitive battery measures 7 domains of cognitive functioning through the use of 10 brief measures. Eight of those will be administered in the current study.

2 * Describe procedures related to all testing:
1. Symbol-Coding: Timed paper-and-pencil test in which respondent uses a key to write digits that correspond to nonsense symbols
2. Category Fluency- Animal Naming: Oral test in which respondent names as many animals as she/he can in 1 minute
3. Trail Making Test: Part A: Timed paper-and-pencil test in which respondent draws a line to connect consecutively numbered circles placed irregularly on a sheet of paper
4. Continuous Performance Test—Identical Pairs (CPT-IP)* : Computer-administered measure of sustained attention in which respondent presses a response button to consecutive matching numbers
5. Wechsler Memory Scale®—3rd Ed. (WMS®-III): Spatial Span : Using a board on which 10 cubes are irregularly spaced, respondent taps cubes in same (or reverse) sequence as test administrator
6. Letter-Number Span: Orally administered test in which respondent mentally reorders strings of number and letters and repeats them to administrator
7. Hopkins Verbal Learning Test—Revised™ (HVLT-R™): Orally administered test in which a list of 12 words from three taxonomic categories is presented and the respondent is asked to recall as many as possible after each of three learning trials
8. Neuropsychological Assessment Battery® (NAB®): Mazes: Seven timed paper-and-pencil mazes of increasing difficulty that measure foresight and planning

THE MATRICS consensus cognitive battery must be completed in person. If participants are completing other study procedures via telephone sessions, they will be asked to come into the VAMHCS to complete the MATRICS. Participants can decline to participate in this in-person portion of the assessment and can still continue with other study procedures.

3 * Upload relevant testing materials:

Name	Created	Modified Date
MATRICS Score Sheet_1 20 2010.doc(0.01)	4/14/2017 12:07 PM	4/14/2017 12:07 PM
MATRICS cognitive battery.doc(0.01)	4/14/2017 12:07 PM	4/14/2017 12:07 PM

4 * What is the individual duration of each test and what is the entire duration of all tests?
60 minutes

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

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

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

ID: VIEW4E0BC1E3C2800
Name: v2_Testing

HP-00074686

Data Collection_Record_V2

Data Collection/Record Review

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

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

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

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

○ Yes ● **No**

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

○ Yes ● **No**

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

ID: VIEW4E0E25A8CA400
Name: v2_Data Collection / Record Review

HP-00074686

Prospective Data_V2

Prospective Data

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

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

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

1.1 If Other, please specify:

2 * What data fields will you have access to/collect for the study? For example, name, initials, date of birth, Social Security number, income, demographic information, family units, housing, etc.

Chart Review data to be collected include name, address, dates, telephone numbers, email addresses, mental health and medical diagnoses, VA sleep clinic sleep study Apnea Hypopnea Index (AHI) and Respiratory Disturbance Index (RDI) scores, and name, dosage, and amount of time on current medications.

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-00074686

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-00074686

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

NCT02535923

ID: VIEW4E093BF1D0800
Name: v2_Clinical Trial Registration Information

Participant Selection

1 * How many local potential participants (or specimens/charts) do you anticipate will be screened for this study? ***Screening includes determining potential participants' initial eligibility for and/or interest in a study.***
1500

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:
210

Worldwide - the number being enrolled total at all sites (including local enrollment):
210

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-00074686

Vulnerable Populations_V2

Vulnerable Populations

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

- [ ] 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
- [x] **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

HP-00074686 Eligibility_V2

Eligibility

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

● **Yes** ○ No

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

Name	Created	Modified Date
Eligibility Checklist-Phase 2 RCT.doc(0.04)	4/5/2017 4:10 PM	1/7/2019 9:44 AM
Eligibility Checklist-Phase 1 Acceptability.doc(0.02)	4/5/2017 4:10 PM	4/21/2017 11:33 AM

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-00074686_15 v1-7-2019-1546872282490(0.01)

ID: VIEW4E0E5185F9000
Name: v2_Eligibility

HP-00074686

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 outpatient clinics/programs within the VA Maryland Health Care System (VAMHCS). Potential Veteran participants will be identified by several methods: (1) CPRS chart review and screening via use of 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.

To recruit participants, we will first screen medical records in order to identify Veterans who meet preliminary eligibility criteria of current diagnosis of a psychotic disorder or bipolar disorder per medical record review [meeting criteria established by the VA Serious Mental Illness Treatment Research and Evaluation Center (SMITREC): schizophrenic disorders, bipolar disorder, or depression with psychotic features, age 18 or older, and receiving outpatient VA mental health services. Following a positive chart review screen, the RA will contact the individual, explain the study, and obtain informed consent.

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

We may also send a recruitment letter and postcard to let prospective participants know that they may be eligible for one of our studies. The letter will offer the client the option of calling research staff about the study or they can check yes on an enclosed stamped postcard indicating that it is okay for research staff to call them to see if they have any interest in being part of a study. They may also check no on the postcard if they are not interested. If we do not hear back from the clients after a few days one of our research staff will call them to make sure they have received the letter.

Further, it should be re-iterated that research assistants who will interact with participants are all specially trained to work with persons with serious mental illnesses. Research staff will first consult the participant's treatment team for permission to begin the consent process. This will help avoid approaching people who may be in crisis or may not be able to comprehend the study procedures, risks, and benefits.

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 serious mental illness. Research staff are trained to recognize symptoms of serious mental illness 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
Follow up reminder template(0.01)	11/5/2018 4:31 PM	11/5/2018 4:31 PM
CBT-I Post Card.doc(0.02)	7/31/2017 12:51 PM	3/26/2018 12:54 PM
Recruitment Letter- CBT-I_Acceptability Trial and RCT- Coakley revised.doc(0.02)	7/31/2017 12:51 PM	3/26/2018 12:54 PM

ID: VIEW4E0BCAA0A6C00
Name: v2_Recruitment

HP-00074686 Advertising_V2

Advertising

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

● Yes ○ No

ID: VIEW4E0BCCF811000
Name: v2_Advertising

HP-00074686

Advertising Detail_V2

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

1.1.1 If Other, specify:

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

Are you bothered by sleep problems? We are looking for Veterans (age 18 and older) who are dissatisfied with their sleep and who have been diagnosed with a serious mental illness (ex. Schizophrenia Disorders, Bipolar Disorder, or Depression with Psychosis) to partake in a research study on Insomnia Treatment. Research will be conducted at the Baltimore/Perry Point VA. Please call Gabriella Coakley at 410-637-1426 to see if you are eligible. You will be paid for your participation. This research is conducted under Elizabeth Klingman, Ph.D., VISN 5 Mental Illness Research, Education, and Clinical Center VA Maryland Health Care System (VAMHCS). Grab a number below and call us for more details!

1.3 * Upload advertisement(s) here:

Name	Created	Modified Date
advertisement_CBT-I_PPVA- Coakley 1.03.19.pdf(0.02)	12/12/2017 10:10 AM	1/7/2019 9:43 AM
advertisement_CBT-I_BaltimoreVA- Coakley 1.03.19.pdf(0.02)	12/12/2017 10:10 AM	1/7/2019 9:43 AM
CBT-I Handouts 1.03.19.pdf(0.02)	6/13/2018 4:15 PM	1/7/2019 9:43 AM

ID: VIEW4E0BCE82B8C00
Name: v2_Advertising Detail

HP-00074686

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:

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

(3) 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 serious mental illnesses 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.

(4) Participants may feel some discomfort with discussing their cognitions related to sleep or with restructuring their nighttime routines to accommodate the activity structuring involved in CBT-I (moderate likelihood, low degree of seriousness). Likewise, participants may feel some discomfort with discussing their health behaviors in the Health and Wellness intervention. However the CBT-I and the Health and Wellness intervention protocols are not generally considered unpleasant and more severe reactions are uncommon based on prior studies using CBT-I and Health and Wellness.

(5) Potential loss of confidentiality (small likelihood, moderate degree of seriousness). All project staff are thoroughly trained in issues relating to maintaining confidentiality of research data. 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 VA Maryland Health Care System, MIRECC suite (209 W. Fayette Street, Baltimore, MD). All hard copies of research assessment forms will be stored in a locked cabinet in a locked office in 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 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 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), and behind the VA firewall. In the event of any incidents, unauthorized access of sensitive data or storage devices or noncompliance with security controls, the PI or another member of the research staff will immediately contact the VAMHCS Information Security Officer, Privacy Officer and the VAMHCS Research Compliance Officer and the University of Maryland IRB.

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

(7) Some participants may experience skin irritation as a result of wearing the watch (small likelihood, low degree of seriousness). During consent and when being assigned the watch, participants are informed of this potential risk and that if this were to happen to them, they should remove the watch and discontinue use. Participants will be informed that they can call study staff and/or their physician should they have any concerns at any time. Participants who inform study staff of an adverse reaction to the watch will not be asked to use it at subsequent visits.

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:
Participants in this study may learn strategies/tools and receive resources to reduce their insomnia symptoms.

2 * Describe the importance of the knowledge expected to result from the study:
Participation in this study may benefit other individuals and Veterans with SMI (i.e., psychotic and bipolar disorders) through the development of evidence-based guidelines, tools, and educational materials to significantly reduce insomnia symptoms and therefore facilitate functional recovery.

Phase 1 (Acceptability Trial): This study aims at examining the acceptability of CBT-I as delivered with guidelines for Veterans with psychosis. Knowledge derived from this study could help us better understand vital components of the guidelines which need to be refined to optimize the provision of evidence-based services to Veterans with psychotic disorders. The resulting guidelines will be used in future RCTs of CBT-I, will be published in the VA CBT-I manual and will enable us to better implement CBT-I for Veterans with psychosis in VA hospitals nationwide.

Phase 2 (RCT): This study aims to examine the feasibility and preliminary efficacy of CBT-I. Knowledge derived from this study could inform future efforts to design interventions to improve Veterans' rehabilitation and enhance functioning and recovery due to sleep 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 CBT-I can be tailored to the needs of Veterans with psychotic and bipolar disorders and learning new strategies/tools and resources to reduce insomnia symptoms. This understanding will be used to underlie the development of new strategies to optimize sleep treatment for people with serious mental illness.

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

HP-00074686

Withdrawal of Participants_V2

Withdrawal of Participants

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

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

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 trained 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

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 informed consent form.
2. Coded data: (2a) hard copies of assessment forms, (2b) coded electronic data
3. Audiofiles

(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). The file that links participant names to their project ID number will be stored behind the VA Firewall. Access to the link file will be limited to only study staff listed on this protocol. 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.

(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 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.

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

(3) Audiofiles
Audiofiles may be listened to for supervision purposes by the PI and the other members of the research staff. All CD's and DVD's of audio/video recordings will be collected at the VA and 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). Electronic audio files will be stored securely behind the VA Firewall. All audio/video recordings will be identified by codes only, and will not contain participants' names. The link file connecting the participant's name to their ID number will be kept electronically, in a password protected file behind the VA firewall.

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 MIRECC Share Drive: BAL_MIRECC_Share-->CBT-I Study--> Acceptability and RCT. 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 Division of Psychology, Department of Psychiatry, University of Maryland, School of Medicine, or the Division of Psychiatric Services Research (737 W. Lombard Street, Suite 570, Baltimore, MD 21201) or 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.

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) Audiofiles

All audio files will be stored behind the VA firewall in a restricted folder: BAL_MIRECC_Share-->CBT-I Study--> Audio Files and Session Notes. Audio files will be identified by codes only.

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

Audio recorded CBT-I sessions will be stored electronically behind the VA firewall: BAL_MIRECC_Share-->CBT-I Study--> Audio Files and Session Notes. Philip Gehrman, Ph.D., at the University of Pennsylvania School of Medicine and the Philadelphia VA will be given access to these recordings behind the VA firewall, as he provides consultation and quality assurance monitoring to our study staff. Dr. Gehrman is a VA National CBT-I Trainer and Consultant and a member of this study team. These audiorecordings are purely being used for training and fidelity purposes.

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?

All data collected for this study will be destroyed in accordance with the VA Records Control Schedule (RCS 10-1).

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 initial contact with veterans must be made in person or by phone prior to email 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-00074686

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

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:
Elizabeth Klingaman

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

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**
- [ ] 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:
Review of the research data specified above by the protocol safety monitor will occur on an ongoing basis throughout the duration of the study.

5 * Safety monitoring results will be reported to:

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

5.1 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.

ID: VIEW4E1B026A2A400
Name: v2_Monitoring Plan - Individual

HP-00074686

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(0.02)	4/5/2017 5:33 PM	4/19/2017 11:17 AM

ID: VIEW4E1B629EEC000
Name: v2_Compensation for Research-Related Injury

HP-00074686

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-00074686

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)

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

1.1 If Other, specify:

2 * What is the total dollar value of the payments/reimbursements over the duration of the study? ***Total payment(s) for participation in research of $600 or more in a calendar year is required to be reported on an IRS Form 1099.***
up to $205

3 * Describe the timing and distribution plan for the payment/reimbursement (schedule, means, etc.)?
If a participant expresses to study staff they he or she is having difficulty attending study appointments due to lack of transportation then a bus token, or equivalent travel voucher, will be offered to the participant.

Phase 1 (Acceptability Trial)

Part 1 Consent and Time Point 1 Assessments:
20 participants at $5 each for demographic and ISI form (if deemed ineligible due to ISI score); $30 each for Time Point 1 Assessment Battery and $75 each for sleep apnea screening, depending on meeting eligibility criteria.

Part 3 Qualitative Interviews:
6 participants at $40 each for qualitative interviews.

Part 4 Time Point 2 Assessment Battery:
6 participants at $30 each for Time Point 2 Assessment Battery.

Phase 2 (RCT)

Part 1 Consent and Time Point 1 Assessments:
140 participants at $5 each for demographic and ISI form (if deemed ineligible due to ISI score); $30 each for Time Point 1 assessment battery, and $75 each for sleep apnea screening, depending on meeting eligibility criteria.

Part 3 Time Point 2 Assessment Battery:
60 participants at $30 each for Time Point 2 Assessment Battery.

Part 4 Time Point 3 (3-month Follow-Up) Assessment Battery:
60 participants at $30 each for Time Point 3 Assessment Battery.

Part 5 Qualitative Interview:
30 participants at $40 each for RCT Qualitative Interview.

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:
If completing in person they will be given a VA voucher that they can take to the VA agent cashier and redeem for cash, or be sent a check from the VA Cashier or electronic gift card. A check from the VA Cashier or electronic gift card will be sent to Veterans if they are completing study procedures over the phone. Participants will be given bus tokens or equivalent travel voucher as needed.

If participants did not complete the MATRICS in-person due to safety issues surrounding COVID, they only received $20 instead of $30 for completion of the assessment over the phone.

ID: VIEW4E1C54A6ACC00
Name: v2_Payment Detail

HP-00074686 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

ID: VIEW4E1B0A2114400
Name: v2_HIPAA

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:

Our research staff are carefully trained on obtaining consent from participants with mental illness and supervised by senior staff members. If a potential participant indicates interest in participating, the study interviewer will meet the participant, introduce him/herself to the participant, provide an overview of the project, and invite him/her to participate. Interested participants are provided an informed consent form. Staff members are trained to recognize symptoms of severe mental illness and cognitive impairment that could undermine a participant's ability to provide informed consent. The consent form is reviewed in detail with all participants. Research staff are trained in strategies for interacting with people with severe and persistent mental illness, including speaking slowly and clearly, stopping to summarize frequently, and providing time for questions.

After the consent form has been summarized and reviewed and all questions 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 research office. 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 be reviewed and 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 the original is kept in the research office.

In keeping with the requirements put forth in the Department of Veterans Affairs: a) 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 initial contact with veterans must be made in person or by phone prior to email contact; d) verification of the study will be provided following the guidelines set forth in HRPP/IRB policies and procedures 10G.

Request to Waive Documentation of Consent:
A waiver of documentation of consent is being requested because a participant developed some skin irritation under the wristband of one of the watches used in the protocol. For this new risk, we will request verbal consent by informing current participants of the risk as soon as possible, either via telephone or an in-person appointment, whichever would occur first, so they do not have to wait until their next study appointment to receive the information. Since this is believed to be a minimal risk, we wanted to minimize the burden that would be placed on participants to complete a written reconsent process. We also believe that this new information will not change participants' willingness to continue participation, as we will not ask them to continue wearing the watch should this situation arise. Study staff will use the script provided in "additional documents" and document this in participants' study records. If other anticipated risks would occur, this process will be evaluated on a case-by-case basis.

A waiver of written documentation of consent is being requested to inform participants of the option to complete assessments, the interview, and intervention sessions via telephone if needed, as well as to be emailed resources, materials, and/or response cards. We will request verbal consent by informing current participants as soon as possible, either via telephone or an in-person appointment, whichever would occur first, so they do not have to wait until their next study appointment to receive the information. Since this is believed to be minimal risk, we wanted to minimize the burden that would be placed on participants to complete a written reconsent process. We also believe that this new information will not change participants' willingness to continue participation, as we are broadening their options for remote participation. Study staff will use the script provided in "additional documents" and document this in participants' study records.

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 in 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:
A private office or room within the VAMHCS.

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

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

ID: VIEW4E1C661D0AC00
Name: v2_Informed Consent Process

Waiver of Documentation of Consent

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

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

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

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

A waiver of documentation of consent is being requested because a participant developed some skin irritation under the wristband of one of the watches used in the protocol. For this new risk, we will request verbal consent by informing current participants of the risk as soon as possible, either via telephone or an in-person, whichever would occur first, so they do not have to wait until their next study appointment to receive the information. Since this is believed to be a minimal risk, we wanted to minimize the burden that would be placed on participants to complete a written reconsent process. We also believe that this new information will not change participants' willingness to continue participation, as we will not ask them to continue wearing the watch should this situation arise. Study staff will use the script provided in "additional documents" and document this in participants' study records. If other anticipated risks would occur, this process will be evaluated on a case-by-case basis.

A waiver of written documentation of consent is being requested to inform participants of the option to complete self-report assessments, the interview, and intervention sessions via telephone if needed, as well as to be emailed resources, materials, and/or response cards. We will request verbal consent by informing current participants as soon as possible, either via telephone or an in-person appointment, whichever would occur first, so they do not have to wait until their next study appointment to receive the information. Since this is believed to be minimal risk, we wanted to minimize the burden that would be placed on participants to complete a written reconsent process. We also believe that this new information will not change participants' willingness to continue participation, as we are broadening their options for remote participation. Study staff will use the script provided in "additional documents" and document this in participants' study records.

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.

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.

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.

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
VAMHCSConsent_Acceptability_CBT-I_8-16-19 clean.docx(0.02)	8/16/2019 1:02 PM	8/16/2019 2:29 PM
CBT-I RCT ICF 3-24-20 track changes.docx(0.03)	3/16/2020 4:52 PM	3/24/2020 12:32 PM
VAMHCSConsent_Acceptability_CBT-I_8-16-19 track changes.docx(0.02)	8/16/2019 1:02 PM	8/16/2019 2:29 PM
CBT-I RCT ICF 3-24-20 clean version_updated(0.01)	12/2/2020 10:31 AM	12/2/2020 10:31 AM

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
CBT-I RCT ICF 3-24-20 clean.docx(0.03)	3/16/2020 4:52 PM	3/24/2020 12:32 PM
CBT-I RCT ICF 8-28-19 track changes.docx(0.03)	8/16/2019 12:55 PM	8/28/2019 11:29 AM
CBT-I RCT ICF 8-28-19 clean.docx(0.03)	8/16/2019 12:56 PM	8/28/2019 11:29 AM
CBT-I RCT ICF 8-14-19 clean.docx(0.01)	8/16/2019 12:55 PM	8/16/2019 12:55 PM
VAMHCSConsent_RCT_CBT-I _5.09.18_clean.docx(0.05)	9/13/2017 9:36 AM	1/7/2019 2:38 PM
VAMHCSConsent_RCT_CBT-I _5.09.18 tracked changes.docx(0.05)	3/30/2018 10:47 AM	1/7/2019 2:37 PM
VAMHCSConsent_Acceptability_CBT-I_9.12.17.docx(0.03)	9/13/2017 9:36 AM	10/23/2017 3:25 PM

2 Upload any HIPAA authorization forms here:

Acceptability HIPAA.pdf(0.01)	8/23/2017 10:31 AM	8/23/2017 10:31 AM
RCT HIPAA.pdf(0.01)	8/23/2017 10:31 AM	8/23/2017 10:31 AM

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

ID: VIEW4E1C7712D3000
Name: v2_Consent Forms - Draft

Organization Review Requirements (other than IRB)

Answer the following questions to determine additional organizational review requirements:

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

Psychiatry

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

VA-Specific Criteria

1 * What is the relevance of this research to the mission of VA and the Veteran population that it serves*?

Veterans with SMI (serious mental illness; i.e., psychosis and bipolar disorders) are at elevated risk of disability, high health care spending, reduced quality of life, and early mortality. Thus there is an urgent need to develop empirically-derived guidelines for the clinical use of VA EBPs which would target functional outcomes for this population. Insomnia treatment for Veterans with SMI is imperative in this regard. Insomnia is prevalent among people with SMI, causes them significant distress, and is associated with long-term negative consequences for their physical, emotional, psychosocial, and cognitive recovery. It is also one of the most frequent reasons for mental health referrals in the VHA. Further, insomnia represents a significant obstacle to the recovery of Veterans with psychosis and bipolar disorders specifically. As a result, during the VA Evidence-Based Psychotherapy (EBP) consultation process, providers are currently routinely advised to avoid using CBT-I with Veterans with these symptoms. Thus it is likely that most of these Veterans are not offered this evidence-based intervention. The VHA Uniform Mental Health Services Handbook clearly states that Veterans with SMI must be offered quality interventions comparable to the care received by other Veterans. This research will address this inequity by testing and refining guidelines for the use of CBT-I with these Veterans and test the preliminary efficacy of CBT-I delivered to Veterans with SMI in accordance with these guidelines.

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.):

Non-Veterans will not be enrolled in this study.

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

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-00074686

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

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-00074686

VA Review Required_V2

VA Maryland Health Care System Review Required

1

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

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

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

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

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

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

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

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

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

Questions answered on 'VA Prohibited Research' page:

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

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

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

● **Yes** ○ No

ID: VIEW4E1C8F0D7B000
Name: v2_VA Review Required

Summary of Required Reviews (other than IRB)

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

Name of Related Submission

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

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

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

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

HP-00074686

Additional Documents_V2

Additional Documents

1

Upload all additional documents here:

Name	Created	Modified Date
Follow up reminder template_watch.docx(0.01)	1/10/2021 10:58 AM	1/10/2021 10:58 AM
CBT-I Script for Informing Participant of MATRICS Change.docx(0.01)	10/7/2020 8:33 AM	10/7/2020 8:33 AM
Script for informing participants of phone and email options - updated 3.24.20_2.docx(0.04)	3/16/2020 4:50 PM	3/24/2020 12:30 PM
Request for and Authorization to Release Health Information(0.01)	12/31/2019 12:31 PM	12/31/2019 12:31 PM
2010 - HIPAA 125 - Thomas Tsuji.pdf(0.01)	9/3/2019 5:12 PM	9/3/2019 5:12 PM
2010 - HIPAA 201 - Thomas Tsuji.pdf(0.01)	9/3/2019 5:12 PM	9/3/2019 5:12 PM
2019 Privacy and HIPAA Training - Thomas Tsuji.pdf(0.01)	9/3/2019 3:41 PM	9/3/2019 3:41 PM
2019 - VA Privacy and Information Security Awareness and Rules of Behavior - Thomas Tsuji.pdf(0.01)	9/3/2019 3:41 PM	9/3/2019 3:41 PM
2017 VA CITI GCP Refresher_ Thomas Tsuji.pdf(0.01)	9/3/2019 3:41 PM	9/3/2019 3:41 PM
Script for informing participants of new risk.docx(0.01)	8/16/2019 2:40 PM	8/16/2019 2:40 PM
2019 VA_Privacy_Security_Maddison Taylor.pdf(0.01)	4/8/2019 8:39 AM	4/8/2019 8:39 AM
2019 Privacy_HIPAA_Maddison Taylor.pdf(0.01)	4/8/2019 8:39 AM	4/8/2019 8:39 AM
2019 GCP_CITI_Maddison Taylor.pdf(0.01)	4/8/2019 8:39 AM	4/8/2019 8:39 AM
2018 - VA Privacy and Information Security Awareness and Rules of Behavior - Samantha Hack.pdf(0.01)	2/8/2019 2:31 PM	2/8/2019 2:31 PM
2018 - Privacy and HIPAA Training - Samantha Hack.pdf(0.01)	2/8/2019 2:30 PM	2/8/2019 2:30 PM
2018 - VA Privacy and Information Security Awareness and Rules of Behavior - Ralf Schneider.pdf(0.01)	2/8/2019 2:30 PM	2/8/2019 2:30 PM
2018 - Privacy and HIPAA Training - Ralf Schneider.pdf(0.01)	2/8/2019 2:30 PM	2/8/2019 2:30 PM
2017 - VA CITI Refresher - Ralf Schneider.pdf(0.01)	2/8/2019 2:30 PM	2/8/2019 2:30 PM
2018 - VA Privacy and Information Security Awareness and Rules of Behavior - Naomi Stahl.pdf(0.01)	2/1/2019 1:16 PM	2/1/2019 1:16 PM
2018 Privacy and HIPAA Training - Naomi Stahl.pdf(0.01)	2/1/2019 1:16 PM	2/1/2019 1:16 PM
2018 - VA CITI_GCP Basic-Naomi Stahl.pdf(0.01)	2/1/2019 1:16 PM	2/1/2019 1:16 PM
2017 - VA Privacy and Information Security Awareness and Rules of Behavior - Samantha Hack.pdf(0.01)	2/1/2019 1:15 PM	2/1/2019 1:15 PM
2017 - Privacy and HIPAA Training - Samantha Hack.pdf(0.01)	2/1/2019 1:15 PM	2/1/2019 1:15 PM
2016 VA CITI Refresher Training Record - Samantha Hack.pdf(0.01)	2/1/2019 1:15 PM	2/1/2019 1:15 PM
2018 - VA Privacy and Information Security Awareness and Rules of Behavior - Melanie Bennett.pdf(0.01)	2/1/2019 1:15 PM	2/1/2019 1:15 PM
2018 - Mandatory Training for Transient Clinical Staff Non-Trainees - Melanie Bennett.pdf(0.01)	2/1/2019 1:15 PM	2/1/2019 1:15 PM
2016 - VA CITI Refresher - Melanie Bennett.pdf(0.01)	2/1/2019 1:15 PM	2/1/2019 1:15 PM
2018 - VA Privacy and Information Security Awareness and Rules of Behavior - Letitia Travaglini.pdf(0.01)	2/1/2019 1:14 PM	2/1/2019 1:14 PM
2018 Privacy and HIPAA Training - Letitia Travaglini.pdf(0.01)	2/1/2019 1:14 PM	2/1/2019 1:14 PM
2018 VA CITI - GCP refresher training record - Letitia Travaglini.pdf(0.01)	2/1/2019 1:14 PM	2/1/2019 1:14 PM
Zhang CITI(0.01)	12/13/2018 10:38 AM	12/13/2018 10:38 AM
Kuykendall HIPAA Training(0.01)	8/20/2018 3:19 PM	8/20/2018 3:19 PM
Calvin HIPAA Training(0.03)	8/20/2018 3:16 PM	8/20/2018 3:18 PM
Kuykendall CITI(0.01)	8/20/2018 3:17 PM	8/20/2018 3:17 PM
Calvin CITI(0.01)	8/20/2018 3:17 PM	8/20/2018 3:17 PM
Federline CITI(0.02)	5/30/2018 12:21 PM	5/30/2018 12:22 PM
HIPAA Revocation.pdf(0.01)	8/23/2017 10:30 AM	8/23/2017 10:30 AM
infosec_and_privacy_checklist 5-24-17.docx(0.02)	4/26/2017 5:34 PM	5/24/2017 7:44 AM
Goldberg CITI(0.01)	5/17/2017 2:02 PM	5/17/2017 2:02 PM
Fang CITI(0.01)	5/17/2017 2:01 PM	5/17/2017 2:01 PM
Lucksted CITI(0.01)	5/17/2017 2:01 PM	5/17/2017 2:01 PM
Kindred CITI(0.01)	5/17/2017 2:00 PM	5/17/2017 2:00 PM
Gehrman CITI(0.01)	5/17/2017 2:00 PM	5/17/2017 2:00 PM
CBT-I-Trial_Evaluation to Sign Consent.doc(0.01)	4/26/2017 5:31 PM	4/26/2017 5:31 PM

ID: VIEW4E0962513A000
Name: v2_Additional Documents

Final Page of Application

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

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

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

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

Name of Related Submission

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

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

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

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

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

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

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

ID: VIEW4E1B10C500000
Name: v2_Final Page of Application

HP-00074686

IRB - Add a Team Member

Add a Team Member

1 * Select Team Member:
Kelly Lloyd

2 Research Role:
Research Team Member

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

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

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

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Kelly Lloyd has worked with the Mental Illness Research, Education and Clinical Center (MIRECC) at the VAMHCS as a research team member and Director of Human Subjects Protections and Quality Assurance for a number of 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 both the Baltimore and Perry Point VAMCs. She is very familiar and knowledgeable about the study sites, culture and society related to working on this protocol.

HP-00074686

IRB - Add a Team Member

Add a Team Member

1 * Select Team Member:
Ralf Schneider

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:
Ralf Schneider has worked within the Mental Illness Research, Education and Clinical Center (MIRECC) at the VAMHCS for several years. He has served on previous projects involving individuals with serious mental illnesses. Ralf has been involved in research involving this population at the study sites where the proposed research will take place. He is very familiar and knowledgeable about the study sites, culture and society related to working on this protocol.

HP-00074686

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 is a research assistant with the MIRECC at the VAMHCS. 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-00074686

IRB - Add a Team Member

Add a Team Member

1 * Select Team Member:
Maddison Taylor

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:
Maddison Taylor works with the VA Maryland Health Care System as a research team member. She has been specially trained in how to interact with individuals with serious mental illnesses. She is familiar and knowledgeable about the study sites, culture and society related to working on this protocol.

HP-00074686

IRB - Add a Team Member

Add a Team Member

1 * Select Team Member:
Philip Gehrman

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:
Philip Gehrman, Ph.D. is a Psychologist with an established track record in sleep treatment research with a particular focus on insomnia. At the Perelman School of Medicine at the University of Pennsylvania, Dr. Gehrman has served as Clinical Director of the Penn Behavioral Sleep Medicine Program and is currently an Assistant Professor in the Department of Psychiatry. As a clinical psychologist with the Behavioral Health Service at the Philadelphia VA Medical Center and a VA CBT-I Master Trainer and Training Consultant, he is well-equipped to provide expertise in practical issues of the optimal delivery of CBT-I for Veterans with insomnia, including those with co-occurring mental illness.

HP-00074686

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-00074686

IRB - Add a Team Member

Add a Team Member

1 * Select Team Member:
Letitia Travaglini

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:
Letitia Travaglini has worked with the VA Maryland Health Care System as a Research Investigator for over a year. She has worked on several other studies involving people with serious mental illnesses and has significant experience researching sensitive topics with vulnerable populations. She is very familiar and knowledgeable about the study sites, culture and society related to working on this protocol.

HP-00074686

IRB - Add a Team Member

Add a Team Member

1 * Select Team Member:
Mary Katherine Howell

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:
Mary Katherine Howell is working with the VA Maryland Health Care System as a post-doctoral fellow and research team member. She has been specially trained in how to interact with individuals with serious mental illnesses and has worked on several other studies involving this population. She is very familiar and knowledgeable about the study sites, culture and society related to working on this protocol.

HP-00074686

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 is a research staff member with the MIRECC at the VAMHCS. 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-00074686

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 Mental Illness Research, Education and Clinical Center (MIRECC) at 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. She is very familiar and knowledgeable about the study sites, culture and society related to working on this protocol.

HP-00074686

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-00074686

IRB - Add a Team Member

Add a Team Member

1 * Select Team Member:
Lynn Calvin

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:
Lynn Calvin 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. Additionally, she has already worked on numerous VA studies with Veterans at both the Baltimore and Perry Point VAMC's. She is very familiar and knowledgeable about the study sites, culture and society related to working on this protocol.

HP-00074686

IRB - Add a Team Member

Add a Team Member

1 * Select Team Member:
Deborah Medoff

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:
Deborah Medoff 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. Additionally, she has already worked on numerous VA studies with Veterans at both the Perry Point and Baltimore VAMC's. She is very familiar and knowledgeable about the study sites, culture and society related to working on this protocol.

HP-00074686

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-00074686

IRB - Add a Team Member

Add a Team Member

1 * Select Team Member:
Amanda Peeples

2 Research Role:
Research Team Member

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

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

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

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

HP-00074686

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-00074686

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 a number of 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 both the Baltimore and Perry Point VAMC's. She is very familiar and knowledgeable about the study sites, culture and society related to working on this protocol.

HP-00074686

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-00074686

IRB - Add a Team Member

Add a Team Member

1 * Select Team Member:
Richard Goldberg

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

HP-00074686

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.