Recovery Bridge: A Peer Facilitated Intervention to help bridge the transition from psychiatric inpatient hospitalized to living in the community

NCT05758376

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Introduction Page

1 * Abbreviated Title:
Recovery Bridge

2 * Full Title:
Recovery Bridge: A Peer facilitated intervention to help bridge the transition from psychiatric inpatient hospitalization to living in the community

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.***
Richard Goldberg

CITI Training: ID00008960

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	Lijuan Fang	no	no	Statistician	no	ID00019454
View	Juhi Patel	no	no	Research Team Member	no	
View	Alicia Lucksted	no	no	Sub-Investigator	no	ID00001635
View	Howard Turner	no	no	Research Team Member	no	
View	Tracy Robertson	no	no	Research Team Member	no	

	Name	Edit Submission	cc on Email	Research Role	Has SFI?	CITI Training
View	LAN LI	no	no	Research Team Member	no	ID00019102
View	Clayton Brown	no	no	Statistician	no	ID00000679

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

ID: VIEW4DF85C16F2800
Name: v2_Research Team Information

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. Richard Goldberg will devote approximately 5.5 hours per week of his VA time to conduct and complete this research study.

2 * Describe the facilities where research procedures are conducted:
Recruitment will take place at the VA Maryland Health Care System (VAMHCS) inpatient psychiatric program. Study activities will be conducted in person, by video meeting using the VA approved video platform Microsoft Teams, or by phone at the participants' convenience. The informed consent meeting, the baseline assessment meeting, and the first session with a peer specialist will all occur in person on the inpatient unit in a private room at the Baltimore VAMC. Subsequent sessions with peer specialist will be in person in a private room within the VA Maryland Health Care System (VAMHCS), by VA approved Video meeting via Microsoft teams, or by phone, at the participants convenience. The post treatment assessment will be done via VA approved video meeting via Microsoft teams or by phone.

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 as a result of their participation in this study. However, the VA does provide medical and/or psychological treatment for participants who take part in VA research.

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, the study assessments, qualitative interviewing, 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 semiannual 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 Dr. Goldberg and staff.

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:

- ☑ **Federal**
- ☐ Industry
- ☐ Department / Division / Internal
- ☐ Foundation

- [ ] Private
- [ ] State Agency

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

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

3 Please discuss any additional information regarding funding below:
VA ORD HSR&D funded PPO 22-004

ID: VIEW4DF85DF452400
Name: v2_Funding Information

DHHS Funded Study

You indicated that this is a Federally funded study.

1 * Is this study sponsored by a Department of Health and Human Services (DHHS) agency?
○ Yes ● **No**

2 You may upload any grant documents here:

Name	Created	Modified Date
There are no items to display		

ID: VIEW4DF87B9560800
Name: v2_DHHS Funded Study

Federal Agency Sponsor Contact Information

You indicated that this is a Federally funded study.

1 * Agency Name:
VA Health Services Research and Development

* Address 1:
810 Vermont Ave, N.W.

Address 2:

* City:
Washington, D.C.

* State:
DC

* Zip Code:
20040

* Contact Person:
Robert O'Brien

* Phone Number:
202-555-1212

* Federal Agency Email:
Robert.O'Brien2@va.gov

Grant Number 1 (if applicable):
- 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:
"Recovery Bridge: A Peer facilitated intervention to help bridge the transition from psychiatric inpatient hospitalization to living in the community."
PI of Grant 1:
Richard Goldberg

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

Research Protocol

1 * Do you have a research protocol to upload?

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

2 If Yes, upload the research protocol:

Name	Created	Modified Date
There are no items to display		

ID: VIEW4E00563F8D000
Name: v2_Research Protocol

Risk Level

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

* Choose One:

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

ID: VIEW4E02805225800
Name: v2_Risk Level

Exempt Categories

You indicated on the "Risk Level" page that this study is Minimal Risk.

1 * Please review the following categories to determine if your research may be Exempt from IRB oversight. If you believe that your study qualifies as Exempt, select the Category under which it qualifies. If your research does not qualify as Exempt, select **"The research does not qualify as Exempt".**

☐ **Category 1**: Research, conducted in established or commonly accepted educational settings that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

☐ **Category 2**: Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

i. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects.
ii. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation.
iii. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by .111(a)(7).

☐ **Category 3**: Research involving benign behavioral interventions (brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and not offensive or embarrassing) in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

i. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects.
ii. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation.
iii. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by .111(a)(7).

☐ **Category 4**: Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

i. The identifiable private information or identifiable biospecimens are publicly available.
ii. Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects.
iii. The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E [HIPAA], for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b).
iv. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

☐ **Category 5**: Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

☐ **Category 6**: Taste and food quality evaluation and consumer acceptance studies:

i. If wholesome foods without additives are consumed, or
ii. If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the FDA or approved by the EPA or the Food Safety and Inspection Service of the U.S.D.A.

- [x] **The research does not qualify as Exempt.**

ID: VIEW8D50FF499486A05
Name: v2_Exempt Categories

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

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.

The time following discharge from psychiatric hospitalization is a high-risk period and has been associated with a range of negative outcomes including high rates of hospital readmission and suicide. The purpose of the current study is to complete an open trial to examine the feasibility, acceptability of a VA Peer Specialist facilitated web-based intervention called Recovery Bridge. The study will also examine outcomes including hospital re-admission rates, as well as improvement in measures of hope, recovery orientation and quality of life.

The study will also involve completing open-ended interviews with a range of stakeholders to examine intervention fidelity, feasibility, acceptability as well as barriers, and facilitators associated with future implementation of the Recovery Bridge intervention.

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:

The time following discharge from psychiatric hospitalization is a high-risk period and has been associated with a range of negative outcomes including high rates of hospital readmission. The evidence for transitional discharge interventions with bridging components (i.e., provided prior to discharge and continued beyond inpatient care) is mixed in terms of whether they improve rates of readmission and enhance individual outcomes such recovery-orientation, hope, and quality of life. Relatedly, questions remain regarding the effects of peer support in enhancing this care transition.

The VA currently employees over 1,200 Peer Specialists (PS), Veterans with lived mental health experience who, per existing VA directives, should play a major role in supporting Veteran recovery and informing the delivery of recovery-oriented services in inpatient mental health settings. Although peer support holds promise as a component of transitional discharge interventions, there are only a handful of studies that examine the impact peer support has on readmission and recovery-oriented outcomes. Further, results from these studies are mixed, few were performed in the United States, and none were with Veterans. Peer-facilitated recovery action planning, including the My Recovery Plan tool that is freely available online for Veterans, are seen as useful to Veterans but to date no studies have examined their effectiveness in improving post-hospital discharge outcomes. Also, there are no studies looking at how to best combine recovery planning tools (such as My Recovery Plan) with the other effective bridging strategies that address the emotional and personal elements associated returning to the community (e.g. psychoeducation and the establishment of therapeutic relationships that persist across the care transition).
To address these gaps, the Specific Aims of this proposal are to:

Specific Aim 1: Integrate the My Recovery Plan tool and existing PS tools and strategies to develop a manualized intervention called Recovery Bridge for use by VA PS working to help Veterans make the transition from acute inpatient psychiatric hospitalization to community living.

Specific Aim 2: Complete an open pilot trial (n=15) to examine the feasibility, fidelity, and acceptability of the Recovery Bridge intervention in relation to well specified benchmarks supporting continued and expanded investigation

Specific Aim 3: As part of the open pilot trial: 1) explore the impact of the intervention on readmission rates (at 30 and 90 days), and connection to outpatient care compared to a control group (n of up to 60) identified from administrative data, and; 2) explore the change in recovery and Quality of Life measures over time in the intervention participants.

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.:
This is a feasibility and acceptability pilot study and all Veteran participants will receive the intervention; no human subjects control or placebo group will be used.

3 * Describe the relevant prior experience and gaps in current knowledge. Describe any relevant preliminary data:
More knowledge and evidence is needed regarding the use of peer facilitated interventions that support the transition from inpatient mental health hospitalization to living in the community.

As such the overarching purpose of the current study is to optimize existing materials to develop a manualized transitional discharge intervention called Recovery Bridge. The study will also complete an open trial and collect qualitative interview data from a range of stakeholders to examine preliminary outcomes and inform future research to more broadly disseminate and implement the Recovery Bridge Intervention.

4 * Provide the scientific or scholarly background, rationale, and significance of the research and how it will add to existing knowledge:
The time following discharge from psychiatric hospitalization is a high-risk period and has been associated with a range of negative outcomes including high rates of hospital readmission and suicide. Among Veterans at high risk for suicide who are discharged from inpatient psychiatric care, 30% are readmitted within one year. Even more alarmingly, among Veterans who are high psychiatric service users, 79.8% of Veterans are readmitted to psychiatric inpatient units within two years of discharge. The VHA has made concerted efforts to increase outpatient follow-up within 7 days of psychiatric discharge; in fact, seven-day follow-up rates increased from 39% to 75% between 2005 and 2010. Unfortunately, this increase had no impact on 90-day psychiatric readmission rates. Recent survey data indicate that over two thirds of Veterans discharged from psychiatric inpatient units are not receiving their preferred type of care during post-hospitalization follow-up, with support from a Veteran peer specifically named as a preferred service. These data indicate that different and more effective interventions are needed at this critical care transition.

There is some empirical support for the effectiveness of selected interventions for reducing psychiatric hospital readmission, but the evidence is limited. Two recent systematic reviews/meta-analyses summarize this broad yet extremely heterogeneous literature. The general consensus is that interventions that involve making contact with service users after discharge (e.g., letters) or introducing new roles to oversee aspects of the discharge process are not effective in reducing rates of readmission. Interventions that provide psychoeducation to service users and/or family members may improve some service-level outcomes such as readmission. The conclusions were mixed on the potential effectiveness of interventions that aim to bridge the boundaries between the hospital and community (e.g., Critical Time Intervention, Transitional Discharge Model), though an emphasis on a strong therapeutic relationship with a consistent provider across the care transition may be critical. Although psychoeducation and strong rapport with a therapeutic support person appear to be important, additional high-quality research is required to definitively establish the effectiveness of transitional discharge interventions that rely on these strategies.

Peer support, or support from others with lived experience of mental illness, provides exposure to credible role models who enhance hope and motivation. Per social modeling theory, when an individual interacts with a peer who they perceive to be doing better or having progressed further than themselves, this leads to upward social comparison (e.g., “If they can do it, I can do it too!”) which instills hope and motivation. VA PS, who are Veterans with lived experience of mental illness with specialized training to use their recovery story to support that of others, use their lived experience and “been there” interpersonal approach to support individuals with mental illnesses. This is particularly critical for those experiencing acute crises resulting in psychiatric hospitalization and facing transitions back to the community where common triggers may still exist. Peers are particularly adept at engendering hope, empowerment, and self-efficacy among the individuals they work with, thereby promoting proactive self-management and successful treatment engagement. It follows that PS employed by the VA are well prepared to assist with transitional discharge support for hospitalized Veterans.

Research suggests that involving peers in transitional discharge support interventions is most effective when peers are providing structured support. Unstructured peer support and encouragement for individuals during the discharge transition was examined as a primary or exclusive component of discharge support, or as part of studies of multicomponent interventions. None of these interventions had an impact on hospital readmission. In contrast, in a recent large RCT (n=441) from the UK, peers with a lived experience of mental illness worked with individuals recently discharged from psychiatric inpatient settings to engage in structured one-on-one recovery planning; the intervention was associated with a significant decrease in one-year acute readmission rates compared to an active control condition.

Peer-facilitated recovery planning provides psychoeducation and structured peer support in the context of a strong supportive relationship. By incorporating the most promising practices from the transitional discharge literature, providing a type of service specifically preferred by Veterans, and leveraging the power of social modeling and social comparison, this type of intervention holds great promise for post-psychiatric transitional discharge support. Peer-facilitated recovery planning programs such as Wellness Recovery Action Planning (WRAP) or SAMHSA Action Planning for Prevention and Recovery, which include action planning modules in multiple subcategories such as daily wellness, managing triggers and early warning signs, and what to do when things breakdown, are associated with myriad positive outcomes including improvements in depression, anxiety, hope, empowerment, social connectedness, patient self-advocacy, reduced use and need for crisis interventions, and, as aforementioned, psychiatric hospital readmission rates. Although these last studies are promising regarding how peers can deliver structured support that impacts readmission rates, more research is needed in US treatment settings (particularly inpatient) including the VA.

My Recovery Plan is a peer-facilitated, web-based recovery planning tool created by Veterans for Veterans. Adhering to the SAMHSA Action Planning for Prevention and Recovery program, this tool was created through an OMHSP project, with a multidisciplinary development team led by Mr. Charles Moss, VA Peer Specialist and Subject Matter Expert (who is also a consultant on the current proposal). A team of PS, clinicians, and software developers created and tested the tool, obtaining user feedback from Veterans on the VISN 16 Consumer Advisory Board. Launched earlier this year, My Recovery Plan can be accessed from any device that has access to the Internet. The user-friendly interface allows Veterans to create a recovery plan that can then be printed, saved, or e-mailed for easy access anytime. Mr. Moss has developed materials to facilitate peer delivery of the material in both individual and group modalities. Although a robust evidence base supports peer-facilitated recovery planning more broadly, no programs of research have been initiated to explore how to best use the tailored VA version called My Recovery Plan. The purpose of the present proposal is to optimize use of the My Recovery Plan tool and related care transition strategies widely used by PS to develop a manualized transitional discharge intervention called Recovery Bridge. A large workforce (over 1200 to date) of VA PS are available to support Veterans in the critical care transition from acute inpatient psychiatric hospitalization to community living; this proposal will begin to develop the tools for them to do so.

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

Supporting Literature

1 * Provide a summary of current literature related to the research: ***If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer box below.***
1. Newton-Scanlon, J, Hancock, N, Honey, A. (2017). Evaluation of peer-delivered, transitional and post-discharge support program following psychiatric hospitalization. BMC Psychiatry, 17:307-15.
2. Tyler, N., Wright, N., & Waring, J. (2019). Interventions to improve discharge from acute adult mental health inpatient care to the community: systematic review and narrative synthesis. BMC Health Services Research, 19(1), 1-24.
3. Hegedüs, A., Kozel, B., Richter, D., & Behrens, J. (2020). Effectiveness of transitional interventions in improving patient outcomes and service use after discharge from psychiatric inpatient care: a systematic review and meta-analysis. Frontiers in Psychiatry, 10, 969:1-11.
4. Department of VA: VHA Directive 1163—Psychosocial Rehabilitation and Recovery Services. Aug 13, 2019.
5. Department of VA: VHA Handbook 1160.06—Inpatient Mental Health Services. Sep. 16, 2013

6. Forchuk, C, Martin, M, Chan, Y, Jensen, E. Therapeutic relationships form psychiatric hospital to community (2005). Journal of Psychiatric Mental Health Nursing, 12:556-64
7. Reynolds, W., Lauder, W, Sharkey, S., et al. (2004). The effects of a transitional discharge model for psychiatric patients, Journal of Psychiatric and Mental Health Nursing, 11:82-88,
8. Sledge, W. H., Lawless, M., Sells, D., Wieland, M., O'Connell, M. J., & Davidson, L. (2011). Effectiveness of peer support in reducing readmissions of persons with multiple psychiatric hospitalizations. Psychiatric Services, 62(5), 541-544.
9. Simpson, A, Flood, C, Rowe, J, et al. (2014). Results of a pilot randomized controlled trial to mesure the clinical and cost effectiveness of peer support in increasing hope and quality of life in mental health patients, BMC Psychiatry, 14-30.
10. Kidd, S, Mutschler, C, Lichtenstein, S. et al. (2021). Randomized trial of a brief peer support intervention for individuals with schizophrenia transitioning from hospital to community. Schizophrenia Research, 231:214-220
11. Johnson, S., Lamb, D., Marston, L., Osborn, D., Mason, O., Henderson, C., ... & Lloyd-Evans, B. (2018). Peer-supported self-management for people discharged from a mental health crisis team: a randomised controlled trial. The Lancet, 392(10145), 409-418.
12. Bernet, A. C. (2013). Predictors of psychiatric readmission among veterans at high risk of suicide: the impact of post-discharge aftercare. Archives of Psychiatric Nursing, 27(5), 260-261.
13. Bowersox, N. W., Saunders, S. M., & Berger, B. D. (2012). Predictors of rehospitalization in high-utilizing patients in the VA psychiatric medical system. Psychiatric Quarterly, 83(1), 53-64.
14. Pfeiffer, P. N., Ganoczy, D., Zivin, K., McCarthy, J. F., Valenstein, M., & Blow, F. C. (2012). Outpatient follow-up after psychiatric hospitalization for depression and later readmission and treatment adequacy
15. Pfeiffer, P. N., Bowersox, N., Birgenheir, D., Burgess, J., Forman, J., & Valenstein, M. (2016). Preferences and barriers to care following psychiatric hospitalization at two veterans affairs medical centers: A mixed methods study. The Journal of Behavioral Health Services & Research, 43(1), 88-103.
16. Albert Bandura (1965) Influence of Models-reinforcement contingencies on the acquisition of imitative response. J of Personality and Social Psychology. 1965:1:589-595
17. Davidson, L., & Guy, K. (2012). Peer support among persons with severe mental illnesses: a review of evidence and experience. World Psychiatry, 11(2), 123-128.
18. Cook, J., Copeland, M., Jonikas, J., Hamilton, M., Razzano, L., Grey, D., Floyd, C., Hudson, W., Macfarlane, R., Carter, T, Boyd, S. (2012). Results of a randomized controlled trial of mental illness self-management using Wellness Recovery Action Planning. Schizophrenia Bulletin. 38(4): 881-891
19. Cook, J.Jonikas, Goldrick, Steigman, Grey, Burke, Copeland. (2013) Impact of Wellness Recovery Action Planning on Service Utilization and Need in a Randomized Controlled Trial. Psychiatric Rehabilitation Journal. 35: 250-257
20. Moss Moss, C. & Hodges, L. (2021). My Recovery Plan. VA National Peer Support Webinar Series. March 3.
21. Dvagov.sharepoint.com/sites/VACO Mental Health/Peer Support
22. The Client Satisfaction Questionnaire-8. In M. Maruish (Ed.), The use of psychological testing for treatment planning and outcome assessment (3rd Ed.). Mahwah, NJ: Lawrence Erlbaum Associates, 2004: 799-811.
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29. Groenland, E. (2016). Using the matrix method for the analysis of deductive, qualitative research data. An introduction with an annotated illustration. Qualitative Research Data. An Introduction with an Annotated Illustration (April 25, 2016).
30. Averill, J. B. (2002). Matrix analysis as a complementary analytic strategy in qualitative inquiry. Qualitative health research, 12(6), 855-866.

2 If available, upload your applicable literature search:

Name	Created	Modified Date

There are no items to display

ID: VIEW4E02805A7E400
Name: v2_Supporting Literature

Study Procedures

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

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

15 (N=15) Veterans, who are slated for discharge from the VAMHCS inpatient psychiatric unit, will participate in a pilot study to examine the feasibility and acceptability of Recovery Bridge (a web-based tool) as a transitional discharge intervention designed to decrease inpatient re-admission rates and improve Veteran's hope, recovery orientation, and quality of life. Our research staff will monitor the census of the inpatient unit every day and recruit Veterans as early as possible during their stay. Study staff will approach Veterans to explain the study and allow ample time for questions and evaluation of capacity to provide consent. Those consented will be asked to complete a brief (30-45 min) quantitative, baseline assessment. The two PS working on the project will also be available to meet the Veteran at the hospital during the recruitment and assessment process to help establish and build rapport. The consent meeting and the baseline assessment will be done in person on the inpatient unit. They will be conducted in a private and confidential space.

All enrolled Veterans will participate in the Recovery Bridge intervention which will take place over approximately five, 30-75 minute sessions. The first session will take place in-person on the inpatient unit (with the peer specialist using a government issued laptop to access the web-based program) in a private and confidential space. The remaining sessions will occur either in person, over the VA approved video platform, Microsoft Teams, or over the phone, at the participants' convenience. The web-based Recovery Bridge intervention will include instructions on how to tailor and apply myriad Peer Specialist skills and strategies to the context of working with Veterans transitioning from inpatient psychiatric hospitalization to community living. It will also include tailored instructions for using the tools modules relating to:1) Daily wellness; 2) managing triggers and early warning signs, and; 3) what to do when things breakdown (including crisis and safety plans developed in concert with licensed independent providers). Veterans will be able to access the intervention with assistance from the peer specialist who will have a government issued laptop. Sessions may be audio or video recorded for fidelity purposes.

Veteran Participants:

Approximately 7 days following the final intervention session, all Veteran participants will complete a 30-45 minute quantitative, post-assessment along with a 30-60 minute qualitative interview regardless of the number of intervention sessions attended in order to understand barriers and facilitators to engaging in the intervention. This final assessment along with the qualitative interview will be done over the phone or via VA approved Video platform, Microsoft Teams.

Peer and Non-Veteran Participants:
To assess perceptions of the barriers and facilitators to implementation of the Recovery Bridge intervention, stakeholders [including the PS interventionists, a local recovery coordinator (LRC), PS supervisors, and clinician/administrators who work in both inpatient and outpatient mental health settings] will be enrolled into the study and qualitative interviews will be conducted (30-60 minutes). These interviews will be done over the phone or VA approved video platform, Microsoft teams.

All Participants:
All qualitative interviews will be conducted by video meeting, or phone and audio-recorded following IRB/ORD approved informed consent procedures via Microsoft Teams. For the Veterans enrolled in the study, the qualitative guidelines will have already been discussed and agreed to during the informed consent process. For the stakeholders and Peer Specialists who will be interviewed, they will be provided an information sheet relaying all the information of the portion of the study they will take part. They will read and discuss with study staff before agreeing to the interview. Recordings of all interviews will be transcribed verbatim by a VA & IRB approved service (Microsoft Teams) then proofread against the recording (and anonymized in the process) by members of the study team.

An administrative data only control sample will be established to pull matched services data for up to an additional 60 Veterans

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:
Veteran subjects participation will last approximately two months. Peer Support Specialist and interventionist and stakeholder participation (as human subjects to complete a single qualitative interview) will last 30-60 minutes each.

4 * Describe the amount of time it will take to complete the entire study:
The entire study will be completed within 18 months.

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:
Our goal is to collect quantitative and qualitative information on proof of concept through a small scale open pilot trial. We have determined that implementing Recovery Bridge with 15 Veterans and conducting qualitative interviews with all Veteran participants, 2 PS interventionists, and up to five or six key stakeholder will be sufficient to determine feasibility and acceptability. We will also collect administrative data (described in companion protocol HP-00110495-Suplemental Administrative Data Protocol) to create a matched group sample of up to 60 to compare services outcomes. As a open-trial this small pilot is not powered.

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:
Exploratory Outcomes and Analysis for the Active Sample: The Hope Scale (HS), a twelve-item measure that measures hopefulness (23). Research has found HS scores to be positively associated with goal related activities and coping strategies (24) The WHOQOL-BREF. This brief instrument allows for ratings across 8 quality of life dimension and has strong psychometric properties (25). The Maryland Assessment of Recovery: is a brief self-report measure of recovery orientation and has strong psychometric properties (26). The above scales will be assessed during the inpatient stay (baseline) after the patient has signed consent to participate in the study and after the final session of the Recovery Bridge intervention (follow-up) which will be done over video (Microsoft Teams) or the phone. Exploratory analysis of these measures will primarily be descriptive. Effect sizes (mean change ÷ baseline standard deviation) will be calculated but due to small sample size will have a high standard error, hence will not be used to power a larger study

Exploratory Services Related Outcomes Using Active and Control Sub-Samples.

The active sample (n=15) will be compared to a randomly selected contemporaneous (or near-contemporaneous) group-matched sample (n of up to 60) from administrative data on a couple of post-discharge metrics. The first is the SAIL post-discharge engagement metric of 3 outpatient visits within 30 days (or if flagged for suicide risk, 4 outpatient visits within 30 days). The second metric will be whether the patient is re-admitted to in-patient psychiatric hospitalization within 30 days. Matching will be based on diagnostic grouping, age group, and gender. In addition to descriptive statistics (proportions by group), matched pairs analyses (McNemar's test and matched-pairs OR's with 95% confidence intervals) will be used to compare the active sample to the administrative sample on (1) proportion meeting the post-discharge engagement metric, and (2) proportion with inpatient re-hospitalization within 30 days. These analyses are exploratory given limited power and precision of 95% confidence intervals. All quantitative study data will be password protected and stored in a VA REDCap database

Qualitative Analyses: For qualitative data, we will utilize a rapid analysis summary approach. To begin, we will create a summary template with deductively identified key domains (or topics) of interest. We will iteratively refine the summary template by independently summarizing the first few transcripts and then meeting as a team to discuss the summaries, establish agreement, and revise the template with inductively identified domains. When the template is finalized, each of the remaining transcripts will be summarized by an individual and audited by a second person, with disagreements brought to the larger team for discussion. Data from the summaries will be entered into a matrix to begin analysis and identification of common themes. Utilizing this rapid approach will allow us to quickly and efficiently assess the data for the primary outcome of acceptability.

ID: VIEW4E02806052800
Name: v2_Sample Size and Data Analysis

Sharing of Results

1 * Describe whether results (study results or individual subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings) will be shared with subjects or others (e.g., the subject's primary care physicians) and if so, describe how it will be shared:
No study data will be shared with subjects or others

ID: VIEW4E02808CBD800
Name: v2_Sharing of Results

Psychological/Behavioral/Educational Methods & Procedures

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

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

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

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

Surveys/Questionnaires

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

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

1 * List all questionnaires/surveys to be used in the study, including both standardized and non-standardized assessments:
• Client Satisfaction Questionnaire (CSQ-8)
• Hope Scale (HS)
• WHOQOL-BREF
• The Maryland Assessment of Recovery
Demographics

2 * Upload a copy of all questionnaires/surveys:

Name	Created	Modified Date
Demographic Form Recovery Bridge.docx(0.01)	11/15/2023 1:23 PM	11/15/2023 1:23 PM
Maryland Assessment of Recovery (MARS) (0.01)	11/22/2021 2:37 PM	11/22/2021 2:37 PM
WHOQOL-BREF(0.01)	11/22/2021 2:36 PM	11/22/2021 2:36 PM
Hope Scale (0.01)	11/22/2021 2:35 PM	11/22/2021 2:35 PM
CSQ survey (0.01)	11/22/2021 2:35 PM	11/22/2021 2:35 PM

3 * What is the total length of time that each survey is expected to take?
7-12 minutes each
30-45 minutes in total

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?
Q26 on the WHOQOL does not directly elicit information related to the potential for harm to self or others. However, if someone endorses a response of 3 or higher, our

RAs are trained to conduct a risk assessment based on our MIRECC safety SOP and to follow up with the appropriate clinician(s). The PI and a key Co-investigator are both licensed psychologists, and per our safety SOP, are both able to respond as needed.

ID: VIEW4E09460F5EC00
Name: v2_Surveys/Questionnaires

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
Qualitative Interview Guides (0.01)	11/22/2021 2:40 PM	11/22/2021 2:40 PM

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

All Veterans, Peer Specialist, and stakeholder participants will participate in one, 30-60 qualitative interview.

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

All interviews will be audio-recorded following IRB/ORD approved informed consent procedures. Recordings of all Veteran and PS interviews will be transcribed verbatim (and anonymized in the process) by VA & IRB approved professionals, then the transcript proofread against the recording by members of the study team. Each stakeholder interview will be led by Dr. Luckstead or another staff member, and attended by a second study team member as note-taker. Immediately after, the interviewer and note-taker will debrief about the interview and the note-taker will add a field note summarizing this conversation to that interview's notes.

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

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**
- ☑ **Audio**
- ☐ Still Photo
- ☐ Other

1.1 If Other, specify:

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

We are recording qualitative interviews to ensure that we are capturing main themes and perspectives. We are also recording all inpatient sessions and other subsequent sessions for treatment fidelity.

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?

All electronic files of audio/video recordings will be labeled with a code number. The link between code and participant name is password-protected, stored behind the VA

firewall, and only accessible to study staff listed on this project. Any transcriptions created will be deidentified and stripped of any PHI or PII.

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.):
The Recovery Bridge intervention will be a combination of the My Recovery Plan tool and existing Peer Specialist tools and strategies. The My Recovery Plan tool includes an action planning module that helps Veterans set specific, action-oriented things they can do daily and goals to help them remain healthy and stable. Examples and recommendations are available to help Veterans build action plans across three subcategories: daily wellness; managing triggers and early warning signs, and what do when things breakdown. All sessions would last 30-75 minutes for a total of approximately 5 sessions.

ID: VIEW4E0BC12A9F800
Name: v2_Behavioral Interventions

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

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)
- ☑ **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.
Name, address, telephone number, last 4 of SSN, inpatient admission and discharge date and notes, outpatient and inpatient encounters scheduled after hospital discharge, and suicide safety plan

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

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

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
NCT05758376

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.***
150

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:
84

Worldwide - the number being enrolled total at all sites (including local enrollment):
84

3 * Gender:
☑ **Male**
☑ **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

Vulnerable Populations

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

- [x] **Employees or Lab Personnel**
- [ ] Children (Minors)
- [ ] Cognitively Impaired/ Impaired Decision Making Capacity
- [ ] Pregnant Women/Fetuses
- [ ] Wards of the State
- [ ] Students

- [ ] Prisoners
- [ ] Nonviable Neonates or Neonates of Uncertain Viability
- [ ] Economically/Educationally Disadvantaged
- [ ] None of the above

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

ID: VIEW4E0E519917800
Name: v2_Vulnerable Populations

Vulnerable Populations - Employees or Lab Personnel

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

1 * Describe how you will ensure particiption in this research will not affect employment and prevent undue influence:
There will be no specific risks associated with study participation for Employees or Lab Personnel. The study's IRB-approved information sheet will be reviewed and research procedures for the interviews will be conducted in the same manner as for other participants. Employees will be told that their participation in the study is completely voluntary. Employees will also be told that their employment status will not be affected by their decision to participate or not to participate in this study.

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

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_Veteran v4 TC.docx(0.01)	2/20/2024 3:06 PM	2/20/2024 3:06 PM
Eligibility Checklist_Veteran v4(0.04)	11/12/2021 12:10 PM	2/20/2024 3:06 PM
Eligibility Checklist__Non Veteran_Key Stakeholder.docx(0.02)	11/12/2021 12:10 PM	10/23/2023 4:22 PM
Eligibility Checklist__Non Veteran_Peer Specialist.docx(0.02)	11/12/2021 12:10 PM	10/23/2023 4:22 PM

1.2 If No, create an eligibility checklist below:

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

Number	Criteria
There are no items to display	

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

Number	Criteria
There are no items to display	

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

Eligibility Checklist for HP-00098903_7 v2-20-2024-1708459598384(0.01)

ID: VIEW4E0E5185F9000
Name: v2_Eligibility

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.):
Veteran Participants:
Potential participants will be patients on the Baltimore VAMC inpatient psychiatry unit (commonly referred to as the 6A unit). Our research staff will monitor the census of the inpatient unit every day and recruit Veterans as early as possible during their stay. Our study staff will work closely with the staff that works on the 6A unit. Participants will be identified by two methods: (1) CPRS chart review and screening of the 6A unit census via use of partial HIPAA waiver, (2) VA clinician referrals, from those who work on the 6A unit, of participants who meet inclusion criteria and who might be interested in participating. No cold calling of Veterans would take place.

Prior to research staff contact with potential Veteran, 6A staff will mention the study to Veterans who meet inclusion criteria to gauge an initial interest. Study staff may also inquire about Veterans on the 6A census via CPRS to see if the 6A staff would recommend, and then 6A staff will mention the study to the Veteran.

If the Veteran expresses interest, 6A staff will inform study staff that the Veteran is open to a phone call. Initial contact with Veterans would then be made via the phone on the 6A unit. Study staff may use provided script to call the Veteran on the 6A unit phone to describe the study and schedule a consent session to take place in person. Study staff can also approach Veterans while on the unit to explain the study, and allow ample time for questions and evaluation of capacity to provide consent (a consent appointment). Those consented will be asked to complete a brief (20-30 min) assessment including measures of the outcomes noted below. The two PS working on the project will also be available to meet the Veteran during the recruitment and assessment process to help establish and build rapport.

Research assistants who will interact with participants are all specially trained to work with persons with 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.

Peer Specialist Participants:
Both Peer Specialists working as interventionists on the project will be directly asked to participate in a 30-60 minute qualitative interview. If interested, a project information sheet will be reviewed and the participant will have the opportunity to ask questions before deciding whether to participate.

Key Stakeholder Participants:
We will conduct recruitment through convenience sampling and identify Individuals already known to the study team to be involved in providing and coordinating care across the transition from psychiatric inpatient to outpatient care to participate in a 30-60 minute qualitative interview. If interested, a project information sheet will be reviewed and the participant will have the opportunity to ask questions before deciding whether to participate.

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

Veteran Participants:
Our research team has extensive experience recruiting and obtaining informed consent from individuals with serious mental illness. Research staff is 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.

Peer Specialists and Key Stakeholder Participants:

Peer Specialists and Key Stakeholders will be told that their participation in this study is completely voluntary. They will also be told that their decision to participate or not participate in the study will have no impact on their employment at the VAMHC. The procedures will be reviewed with them prior to participation via information sheet.

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
Veteran Phone Script_clean.docx(0.02)	3/14/2024 4:10 PM	3/21/2024 4:05 PM
Recovery Bridge Recruitment phone script_Peer Specialists and Stakeholders.docx(0.01)	11/26/2021 4:04 PM	11/26/2021 4:04 PM
Recovery Bridge Recruitment email script__Peer Specialists and Stakeholders.docx(0.01)	11/26/2021 4:04 PM	11/26/2021 4:04 PM

ID: VIEW4E0BCAA0A6C00
Name: v2_Recruitment

Advertising

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

(●) **Yes** ( ) No

ID: VIEW4E0BCCF811000
Name: v2_Advertising

Advertising Detail

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

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

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

1.1.1 If Other, specify:

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

We are looking for Veterans who want help focusing on their recovery and wellness during the transition period after hospitalization. Recovery Bridge is a Peer Specialist facilitating a technology-supported intervention, and it helps Veterans develop recovery plans while transitioning into the community.

Please call Juhi Patel 443-240-0734 or talk to your inpatient team to learn more information. You will be paid for your participation.

This research is conducted under
Richard Goldberg, Ph.D.
VISN 5 Mental Illness Research, Education, and Clinical Center
VA Maryland Health Care System (VAMHCS)

1.3 * Upload advertisement(s) here:

Name	Created	Modified Date
Recovery Bridge Flyer(0.01)	1/26/2024 10:45 AM	1/26/2024 10:45 AM

ID: VIEW4E0BCE82B8C00
Name: v2_Advertising Detail

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) 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 data confidentiality and security. Hard copies of the consent forms will be stored in a locked cabinet behind locked doors at the MIRECC offices within the VAMHCS. Electronic research data that contain PHI or PII, including the file that links participants' identities to an anonymous study code, are kept on a secure VA computer network (behind the VA 'firewall'). The network and computer files are password protected and passwords are only known to authorized study team members. Electronic research files are backed up regularly.

Electronic research data derived from research assessments (e.g., interviews, medical record abstractions), which are identified only by an anonymous study code assigned to each research participant, are kept on a secure VA computer network (behind the VA 'firewall'). The network and computer files are password protected and passwords are only known to authorized study team members. Electronic research files are backed up regularly. Any hard copies of data will be kept in a locked cabinet in a locked room in the MIRECC suite located on the 7th floor of the Baltimore ANNEX (209 W Fayette St. Baltimore MD) 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.

(5) Potential loss of privacy (small likelihood, moderate degree of seriousness). Some participants may be concerned that they may be identified as a study participant and/or that others may overhear them sharing information pertinent to the study during assessment procedures or intervention sessions. Research staff are thoroughly training to protect the privacy of research participants. To minimize this risk, we meet with participants in private rooms with closed doors at the VA Maryland Health Care System (VAMHCS), and all designated assessment rooms are equipped with sound machines to minimize the likelihood of other building occupants overhearing participants. If meeting over the phone, study team members will verify that the participant is alone in a quiet room with adequate privacy during study visits. If using telehealth, study team members will "lock" the virtual room in addition to verifying the privacy of the room.

(6) Some participants may feel uncomfortable with being audio or video recorded (small likelihood, low degree of seriousness). Participants will be told that the recording device may be turned off at any time during the research visit if this occurs. 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 digital audio/video recording files using an anonymous study code only. All digital recordings and the file that links participants' identities to their anonymous study code are stored on a secure VA computer network (behind the VA 'firewall'). The network and computer files are password protected and passwords are only known by authorized study team members. All digital files are stored in restricted folders, accessible only to authorized study team members. Electronic research files are backed up regularly.

ID: VIEW4E1B52509F000
Name: v2_Research Related Risks

Potential Benefits and Alternatives

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

1 * Describe the potential direct benefit(s) to participants:
Participation in this study may provide no direct benefits to participants. However, Veteran participants may learn skills and strategies to use as they transition from inpatient psychiatric hospitalization to community living.

2 * Describe the importance of the knowledge expected to result from the study:
We hope to determine the feasibility and acceptability of Recovery Bridge as a transitional discharge intervention designed to decrease inpatient readmission rates and improve Veteran's hope, recovery orientation, and quality of life. Additionally, we expect to learn more about the perceptions of the barriers and facilitators to implementation of the Recovery Bridge interventions.

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 the Recovery Bridge intervention might be used in health behavior change efforts for people with mental illness who are transitioning from inpatient mental health hospitalization to community living.

4 * Describe the alternatives to participation in this study. If there are no alternatives, state that participation is voluntary and the alternative is not to participate. For intervention studies, describe appropriate alternative clinical procedures or courses of treatment available to subjects.
Participation in this study is voluntary. The alternative is not to participate.

ID: VIEW4E1B5251B0400
Name: v2_Potential Benefits and Alternatives

Withdrawal of Participants

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

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

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 decides to withdraw from the research, all data already collected will remain in the database, but no new data will be collected from the participant.

ID: VIEW4E1B52531F800
Name: v2_Withdrawal of Participants

Privacy of Participants

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

1 * Describe how you will ensure the privacy of potential participants throughout the study ***(privacy refers to persons and their interest in controlling access to themselves):***
Research staff are thoroughly training to protect the privacy of research participants. We meet with participants in private rooms with closed doors at the VAMHCS. If using telehealth, study team members will "lock" the virtual room to ensure privacy and will verify that the participant is alone in a quiet room with adequate privacy during study visits. If using the phone, study team members will verify that the participant is alone in a quiet room with adequate privacy during study visits.

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:
Peer Specialists and Key Stakeholder participants will be provided research information over phone, email, or in person. Interested Veterans will be provided study information over the phone or in person on the inpatient unit. The study team member will ensure that the participant is in a private location where they are comfortable discussing sensitive information.

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.)
Hard copies of the consents will be kept in a locked cabinet in a locked room in the MIRECC suite located on the 7th floor of the Baltimore ANNEX (209 W Fayette St. Baltimore MD). Electronic research data that contain PHI or PII, including the file that links participants' identities to an anonymous study code, electronic data derived from research interviews, and all digital recordings are stored on a secure VA computer network (behind the VA 'firewall'). The file that links participant names to their project ID number will be stored behind the VA firewall on the MIRECC Share Drive (\\r04balnas21.v05.med.va.gov\BAL_Groups\BAL_MIRECC_Share). Electronic data derived from research interviews and digital audio recordings will be stored behind the VA firewall on the MIRECC Restricted Share Drive (\\r04balnas21.v05.med.va.gov\BAL_MIRECC_Restricted_Share).

3 * How will such data be secured?
The hard copy consents will be kept in a locked cabinet in a locked room in the MIRECC suite located on the 7th floor of the Baltimore ANNEX (209 W Fayette St. Baltimore MD to which one study staff member has access. The network and computer files are password protected and passwords are only known by authorized study team members. All digital audio files and electronic data derived from research interviews are stored in restricted folders, accessible only to authorized study team members. All digital audio files and electronic research data derived from research interviews are labeled using an anonymous study code only. Electronic research files are backed up regularly. No VA sensitive information will leave the VA protected environment.

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.

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 cannot be deleted however, VA data must be destroyed according to the VHA Records Control Schedule (RCS) 10-1)***
● **Yes** ○ No

6.1 If Yes, what data (e.g., all data, some recordings, interview notes), when and how?
The investigator's VA research records and any VA participant identifiers will be retained until the maximum retention period is reached, as defined by the Dept. of Veterans Affairs Records Control Schedule (RCS 10-1). When the maximum retention period is reached, the VA data may be destroyed using the most current data destruction methodologies that are available at the time of data destruction.

7 Do you plan to obtain a Certificate of Confidentiality?
○ Yes ● **No**

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

Name	Created	Modified Date
There are no items to display		

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

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

ID: VIEW4E1B5265E0400
Name: v2_Confidentiality of Data

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:
Richard Goldberg, Ph.D.

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

3 * What data will be reviewed?

- ☑ **Adverse Events**
- ☑ **Enrollment Numbers**
- ☑ **Patient Charts/Clinical Summaries**
- ☐ Laboratory Tests
- ☐ Medical Compliance
- ☑ **Procedure Reports**
- ☑ **Raw Data**
- ☑ **Outcomes (Primary, Secondary)**
- ☑ **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.

4 * What will be the frequency of the review?

- ● **Annually**
- ○ Bi-Annually
- ○ Other

4.1 If Other, specify:

5 * Safety monitoring results will be reported to:

- ☑ **IRB**
- ☐ GCRC
- ☐ Sponsor

☐ Other

5.1 If Other, specify:

ID: VIEW4E1B026A2A400
Name: v2_Monitoring Plan - Individual

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:

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

1.2.2	Name	Created	Modified Date
	compensation for research-related injury language.docx(0.01)	11/12/2021 3:59 PM	11/12/2021 3:59 PM

ID: VIEW4E1B629EEC000
Name: v2_Compensation for Research-Related Injury

Payment/Reimbursement to Participants

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

● **Yes** ○ No

ID: VIEW4E1C52A5D7800
Name: v2_Payment to Participants

Payment/Reimbursement Detail

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

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

- ☐ Travel
- ☐ Parking
- ☐ Meals
- ☐ Lodging
- ☑ **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.***

60.00

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

Veterans will be reimbursed $25 at baseline (for completion of the assessment battery) and $35 dollars for the follow-up assessment and qualitative interview.

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

- ☐ Cash
- ☑ **Check**
- ☐ Money Order
- ☑ **Gift Certificate/Gift Card**
- ☑ **Other**

4.1 If Other, specify:

VA-issued voucher

ID: VIEW4E1C54A6ACC00
Name: v2_Payment Detail

HIPAA (Health Insurance Portability and Accountability Act)

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

• At UMB, this includes UMB schools designated as covered entities (School of Medicine and School of Dentistry) and entities

under the University of Maryland Medical System (UMMS). The Baltimore VA Medical Center is also a covered entity.

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

(●) **Yes** ( ) No

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

(●) **Yes** ( ) No

ID: VIEW4E1B0A2114400
Name: v2_HIPAA

Protected Health Information (PHI)

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

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

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

2 * Why is the PHI necessary for this research?

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

The PHI is necessary in order to identify and screen for study eligibility criteria. We collect names, addresses, last four of SSN, and phone numbers to be able to contact participants for all aspects of their participation in the study, and to be able to send them a letter if needed. Veteran dates of birth is collected in order to verify age and identify them in our study database. Each participant in the study is assigned an ID number that will be linked to their name, so identifying number/code has been checked for this purpose.

Voiceprints are collected through our audio recordings and these are used to collect data and for training and supervision of staff. Full-face images may be collected via video recording of sessions. These recordings are used for fidelity purposes only.

We will be accessing the Veteran Participants Safety plan that is entered into their CPRS record as a note. This will be done with the Veteran's knowledge after enrollment. No changes to the safety plan will be made.

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

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

4 * Provide written assurance that Protected Health Information will not be reused. (Note: this refers to re-use on another study or for a purpose which has not been approved, not to the re-use of screening data during the current study).
PHI collected for this study will only be used for the purposes described in this protocol. This information will not be reused or disclosed to any other entity outside this study.

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

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

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

Name	Created	Modified Date

There are no items to display

ID: VIEW4E1B0A24AA400
Name: v2_Protected Health Information

Waiver/Alteration of Authorization

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

1 * Provide rationale for how the research presents no more than minimal risk to the privacy of individuals:
For Veteran participants:
We request a partial HIPAA waiver for recruitment. This waiver of HIPAA authorization for recruitment purposes is justified because the use of information includes no more than minimal risk to the confidentiality of the participants' information. Information collected through this waiver will only be used by study staff listed in this protocol and will not be shared with anyone outside of the project.
For Non-Veteran/Staff Participants:
We are requesting a full waiver for non-Veteran/Staff participants to be able to enroll and interview non-Veteran staff who do not live in the area and could not provide wet signature. The procedures for non-veteran/Staff are a one time interview and no more than minimal risk to their privacy, as they will provide only their name and be recorded, but will be assigned a PID to de-identify them. The interview will also be transcribed and voiceprints will be deleted.

2 * Describe the plan to ensure the protection of PHI collected during this study from improper use and disclosure:
For Veteran and Non Veteran participants:
The information requested for use in our waiver of HIPAA Authorization will be protected by study staff from improper use and disclosure. This information will not be reused or disclosed to any other person or entity outside of this research project. This information will be stored on a password protected computer behind the VA firewall. Only study staff will have access to this information.

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

For Non Veteran participants: Any PHI collected from non Veteran participants will be destroyed within 6 months of closing the study.

4 * Why could the research not practicably be done without access to and use of this PHI?
For Veteran participants:
This research could not practicably be conducted without access to and use of this PHI. Access to this PHI allows research staff to screen medical records and determine eligibility prior to approaching Veterans about the study. Without access to this PHI we would be placing an undue burden on Veterans by approaching those who may not be eligible for this research study. A burden would also be placed on study staff whose time would be wasted by approaching non-eligible Veterans. This information is needed in order be able to contact participants for all aspects of their participation in the study.

For Non-Veteran participants: Most of the interviews/procedures could not be carried out without the full waiver of HIPAA because of the location of the desired participants.

5 * Why could the research not practicably be done without the waiver or alteration?
For Veteran participants:
This waiver for recruitment allows us to screen medical records for study eligibility criteria and then only approach those Veterans who appear eligible based on this screening. Without this waiver we would be placing an undue burden on Veterans by approaching those who may not be eligible for this research study. A burden would also be placed on study staff whose time would be wasted by approaching non-eligible Veterans. The alteration of HIPAA to obtain verbal authorization would limit the amount of close contact and allow for the safety and comfort of our participants and research staff during the COVID-19 pandemic. Having written HIPAA authorization would also require an additional form with the participants name that identifies them as a study participant which could increase the risk of breach of confidentiality.

For Non-Veteran/Staff Participants:
We are requesting a full waiver for non-Veteran/Staff participants to be able to interview and enroll those who do not live in the area.

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

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

ID: VIEW4E1B0A2896400
Name: v2_Waiver/Alteration of Authorization

Informed Consent Process

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

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

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

2 * Describe the Informed Consent process in detail:

For Non-Veteran/Staff/Peer Specialist Participants:
We would like to request to waive documentation of the informed consent process for Non-Veteran/Peer Specialist and Key Stakeholder qualitative interviews. Study team members will review the study's IRB-approved information sheet with each potential participant prior to the start of any study activity. This process will allow an opportunity for potential participants to ask questions as well as make an informed decision about participating in the study. The information sheet for the specialists and stakeholders can be found under the additional documents section. We are requesting this due to location of participants would not allow for wet signature.

For Veteran Participants only:
Written informed consent will be secured from all participants. Our research staff are carefully trained on obtaining consent from participants with serious mental illness and supervised by senior staff members. The study interviewer will provide an overview of the project, and invite him/her to participate. Potential participants are provided a combined HIPAA and informed consent form. Staff members are trained to recognize symptoms of severe mental illness and cognitive impairment that could undermine a participant's ability to provide informed consent. The consent form is summarized to all participants in detail, and participants are given time to ask any questions they may have and to discuss the form and its contents with the research staff.

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

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

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:

Veteran participants: A private office or room, in line with procedures for talking with Veterans who are patients on inpatient psychiatric units.

Non-Veteran/PS and Key Stakeholder participants: The information sheet review will take place using VA approved video Microsoft teams or over the phone. Study team members ensure privacy for themselves and will verify that the participant is alone in a quiet room with adequate privacy. If consent is conducted over the phone study team members will verify that the participant is alone in a quiet room with adequate privacy during the review.

7 * Describe the provisions for assessing participant understanding:

Veteran participants must correctly answer a set of questions regarding the study. If they do not answer all of the questions correctly after 2 attempts, they will not be eligible to participate.

Non-Veteran/PS and Key Stakeholder participants will not be assessed for understanding.

8 * Describe the consideration for ongoing consent:
Veteran participants: Staff will review and remind the participant 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 the last assessment and interview. If they are unable to provide continued consent, they will be removed from the study.

Non-Veteran/PS/Key stakeholder participation is a one time meeting.

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:
Non Veteran Staff:
A waiver of documentation of written consent for non-Veteran participants is being requested for this study. We are requesting a full waiver for non-Veteran/Staff participants so we can interview staff members/stakeholders who do not live in the area and are unable to provide a wet signature. The procedures in which they participate in are a one time interview and minimal risk.

ID: VIEW4E1C6EF6F5000
Name: v2_Waiver of Documentation of Consent

Consent and HIPAA Authorization Forms - Draft

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

Name	Created	Modified Date
Veteran ICF HP-00098903_v2.docx(0.02)	9/26/2023 11:01 AM	10/2/2023 8:20 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
Veteran ICF HP-00098903_12.8.21.docx(0.01)	12/8/2021 10:24 AM	12/8/2021 10:24 AM
Recovery Bridge disclosure form_Peer Specialist, MH Clinician, and Administrator Stakeholders.docx(0.01)	11/26/2021 4:06 PM	11/26/2021 4:06 PM
Veteran ICF HP-00098903.docx(0.01)	11/26/2021 4:05 PM	11/26/2021 4:05 PM

2 Upload any HIPAA authorization forms here:
There are no items to display

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:

Psych CMHSR General

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** - Please answer the following question to determine whether review by the University of Maryland Greenebaum Comprehensive Cancer Center (UMGCCC) is required:

* Does this protocol involve oncology patients and/or oncology data in any capacity? This includes, but is not limited to, the inclusion of cancer patients, as well as research related to prevention, treatment, or diagnosis of oncological diseases. ○ Yes ● **No**

If Yes, or if you have any questions regarding Cancer Center review, please contact the UMGCCC Regulatory Office at UMGCCCRegulatory@umm.edu.

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*?
the VA is committed to improving care options and a wide range of outcomes for Veterans. This study holds promise for reducing hospital re-admission and improving a range of outcomes (e.g. hope, functioning, quality of life) for Veteran participants

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.):
Some of the targeted stakeholders (all VA employees) may not be Veterans.

2.2 If non-veterans will be enrolled in this study, provide a substantive justification** for the enrollment of non-veterans in this research:
VA employee stakeholder feedback is key to informing the acceptability, feasibility and future implementation of the study intervention.

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

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 data from the other non-VA institution(s)?

ID: VIEW8D5931EAC5B1E6E
Name: v2_Additional VA

VA Maryland Health Care System Review Required

1

Note: Based on the answers provided in your submission, this protocol qualifies as a VA study and therefore requires VA-specific reviews to ensure that all VA regulatory requirements are met. The VAMHCS Research & Development Committee (RDC) review is included in these VA-specific reviews and RDC approval is required prior to engaging in any research activities. **Importantly, you must submit this protocol to the VAMHCS RDC for review within 60 days of IRB approval.** Please see below for a summary of required VA-specific review steps.

****Before you initiate any of the following VA-specific review steps, please contact Kelly Lloyd (Kelly.Lloyd@va.gov), VAMHCS Research Protections Officer (RPO), to ensure full compliance with VA requirements.**

1. Ensure that you have already created a new project shell in IRBNet and that the title matches the title for this IRB application. Before drafting the IRB submission, the PI **should have completed Package 1 – ACOS New Project Review Form** found in the VAMHCS IRBNet library (log in to IRBNet first and then click on link), gotten it signed by the PI's VA Service Chief, and submitted it to the Research Service as a single document package within this project shell in IRBNet.
2. After you have received ACOS sign-off, you may submit your protocol application in CICERO. The application will be routed to designated reviewers including Kelly Lloyd, VAMHCS RPO. She will conduct a VA Administrative Pre-Review and the results will be communicated to the study team through the CICERO platform and may include suggested edits to the application and consent/HIPAA form(s). The study team will be responsible for implementing these edits in CICERO.
3. While the VA Specialty Review is being conducted in CICERO, complete the Information System Security Officer (ISSO) review form and email to Kelly so she can prepare her request for that additional, required review. You can find the form used for ISSO review in the VAMHCS IRBNet library (log in to IRBNet first and then click on link): **RDC – Information Security Officer Review Form.pdf.**
4. After all suggested edits have been made in the CICERO application and consents/HIPAA by the study team, Kelly will then send for VAMHCS ISSO and Privacy Officer (PO) review and the study team will be copied on these correspondences. (Please Note: Kelly will prepare PO review form).
5. Once you receive approval from ISSO and PO, Kelly will finalize her review and send the CICERO application on to the next UMB HRPO-required reviewing body.
6. You will then create another new package in your IRBNet project shell (i.e., the same project shell you already created for ACOS review) to submit the protocol documents for Subcommittee on Research Safety (SRS) review. You can find all applicable submission forms in the VAMHCS IRBNet library (log in to IRBNet first and then click on link). Please use this form within the library as a submission guide: **IRBNet Admin Review Checklist – Used only as a guide for submitters – Does not have to uploaded.**
7. After your protocol has been approved by the IRB, you'll create a third, new package in your IRBNet project shell (i.e., the same project shell you already created for ACOS review and used to submit documents for SRS review) to submit the protocol documents required for Research and Development Committee (RDC) review. You can find all applicable submission forms in the VAMHCS IRBNet library (log in to IRBNet first and then click on link). Please use this form within the library as a submission guide: **IRBNet Admin Review Checklist – Used only as a guide for submitters – Does not have to uploaded.**
8. Only after you have been approved by RDC, you may initiate study activities.

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:

The study involves in vitro fertilization:

The research involves work with embryonic stem cells:

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)

Additional Documents

1 Upload all additional documents here:

Name	Created	Modified Date
HIPAA_Waiver_Request_vha-10-0521-2 _SIGNED.pdf(0.02)	9/29/2023 1:38 PM	10/26/2023 9:07 AM
Recovery Bridge Information Sheet- Non Veterans.docx(0.03)	9/15/2023 2:20 PM	10/23/2023 4:08 PM
CITI cert Harvey 2023.pdf(0.01)	8/9/2023 9:52 AM	8/9/2023 9:52 AM
Privacy and HIPAA Harvey.pdf(0.01)	8/9/2023 9:52 AM	8/9/2023 9:52 AM
Privacy and Info Security Harvey.pdf(0.01)	8/9/2023 9:52 AM	8/9/2023 9:52 AM
Gov Ethics Essentials Harvey.pdf(0.01)	8/9/2023 9:52 AM	8/9/2023 9:52 AM

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

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:
this person has worked as study analyst/statistician with the PI on multiple projects for well more than a decade, has stayed up to date on her requisite training, has years of experience and expertise and the full knowledge and skill set needed to work on this project

Add a Team Member

1 * Select Team Member:
Juhi Patel

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:
Ms. Patel is an experienced research assistant and has the requisite expertise to serve as research team member for the current study.

Add a Team Member

1 * Select Team Member:
Alicia Lucksted

2 Research Role:
Sub-Investigator

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

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

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

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Dr. Lucksted has two decades of related experience and expertise to assume her role and duties on the study team

Add a Team Member

1 * Select Team Member:
Howard Turner

2 Research Role:
Research Team Member

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

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

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

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

Add a Team Member

1 * Select Team Member:
Tracy Robertson

2 Research Role:
Research Team Member

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

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

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

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

Add a Team Member

1 * Select Team Member:
LAN LI

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:
Lan Li performs data management for the study. 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.

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:
this person has worked as study analyst/statistician with the PI on multiple projects for well more than a decade, has stayed up to date on her requisite training, has years of experience and expertise and the full knowledge and skill set needed to work on this project