

Effectiveness and Implementation of  
eScreening in Post 9/11 Transition  
Programs

NCT04506164

Protocol

June 6, 2021

## Human Protocol (Version 1.7)

### General Information

**\*Please enter the full title of your protocol:**

Effectiveness and Implementation of eScreening in Post 9/11 Transition Programs

**\*Please provide a short name (nickname) to reference this protocol:**

Implementation of eScreening

\* This field allows you to enter an abbreviated version of the Protocol Title to quickly identify this protocol.

### Add Site(s)

**VA Site (\*\*\*\*\* DO NOT ADD OR CHANGE, just save and continue \*\*\*\*\*):**

**Primary  
Dept?**

**Department Name**



**VASDHS - VASDHS**

### Identify protocol staff members

**\*Please add a Principal Investigator for the study:**

Pittman, James O. E., PhD

**3.1 Add all other VA research staff personnel (if name is not in the list, please contact Research Staffing to confirm appointment status)**

A) Additional Investigators

Afari, Niloofar, PhD

Co-Investigator

Depp, Colin A., PhD

Co-Investigator

Lindamer, Laurie A., PhD

Co-Investigator

Rabin, Adrienn Borsika, PhD

Co-Investigator

B) Research Support Staff

Almklov, Erin L., PhD

Lab Manager

Andrew, Sheba S, LCSW

Research Associate

Gault, John, MS  
Clinical Research Associate  
Hernandez, Jeffrey  
Study Coordinator  
Lee, Michael Wah  
Research Associate

**\*Please select the Research Contact(s)**

Almklov, Erin L., PhD  
Pittman, James O. E., PhD

The Research Contact(s) will receive all important system notifications along with the Principal Investigator. (Research Contacts are typically Study Coordinators or the Principal Investigator themselves).

## VASDHS IRB Human Subjects Protocol

v20190121

### Section 1 - Preliminaries

*Principal Investigator:*

James O. E. Pittman, PhD

*Protocol Title:*

Effectiveness and Implementation of eScreening in Post 9/11 Transition Programs

*IRB Protocol Number:*

H200052

*Protocol Nickname:*

Implementation of eScreening

*Form Template Version:*

v20150115

*Date Prepared:*

06/03/2021

*Please be advised that this protocol application form has changed as a result of the 2018 Common Rule. There are new questions and sections, and you may be required to provide additional information to previous sections.*

**1a) Is this study considered human research?**

- ☒ Yes  
☐ No  
☐ I don't know

**1b) Please select:**

- ☒ This is an application for a NEW human subject research protocol  
☐ This is a revision of an existing protocol

## Section 2 - Research Subjects

### 2a) What is the total planned number of VA-consented subjects?

Include the total number of subjects who will prospectively agree to participate in the study (e.g., documented consent, oral consent, or other).

45

### 2b) What is the total number of VA subjects who WILL NOT be consented?

Include the total number of subjects that will be included without consent (e.g., chart review). *Note: Data about people are still considered "human subjects" by the IRB, so even if you do not intend to contact the patients whose charts you will review, you still should enter the number of charts as your "planned subjects."*

27600

## Section 2.1 Consented Subject Groups

### 2.1) For each of the subject categories listed below, indicate whether or not these subject groups will participate in the study:

2.1a) Children under the age of 18

*Note: If neonates or children will be involved in this study, certification by the Medical Center Director will be required. Only minimal risk research may be performed with children. Only non-invasive monitoring and/or prospective observational and retrospective record review studies that are minimal risk can be conducted in VA involving neonates.*

☐ Yes ☒ No

2.1b) Pregnant women

☐ Yes ☒ No

2.1c) Individuals with cognitive/decisional impairment

☐ Yes ☒ No

2.1d) Non-English-speaking individuals

☐ Yes ☒ No

2.1e) Prisoners of War (explicitly targeting this group)

☐ Yes ☒ No

2.1f) Non-Veterans (Note: Justification for inclusion of non-Veterans will be required)

☒ Yes ☐ No

2.1g) Incarcerated individuals (Note: VA CRADO approval will be required)

☐ Yes ☒ No

2.1h) VA employees - including VA paid, IPA, or WOC (Note: Union review and authorization may be required)

☒ Yes ☐ No

2.1i) Students of the institution (e.g., resident trainees) or of the investigator

☐ Yes ☒ No

2.1j) Patients with cancer (or high cancer risk) [explicitly targeting this group]

☐ Yes ☒ No

## Section 2.2 Subject Categories without consent

2.2) Indicate if data or specimens only will be used without enrollment consent for each category listed below:

2.2a) Non-Veterans

☐ Yes ☒ No

2.2b) Prisoners

☐ Yes ☒ No

2.2c) Neonates or Children

Note: If neonates or children will be involved, certification by the Medical Center Director will be required. Only minimal risk research may be performed with children. Only non-invasive monitoring and/or prospective observational and retrospective record review studies that are minimal risk can be conducted in VA involving neonates.

☐ Yes ☒ No

## Section 3 - Study Features (these items default to "No" for convenience)

3) This section consists of several Yes/No questions addressing protocol characteristics. Click on *Save and Continue*.

### Section 3.1 Protocol Basics

Select all that apply

3.1a) The research **intends to change** the participant.

☐ Yes ☒ No

3.1b) **Interactions** with living participants to collect data or specimens with no intent to change them.

☒ Yes ☐ No

3.1c) This is a study that **never** has any **subject contact and does not collect subject identifiers**

☐ Yes ☒ No

3.1d) This is a **chart review** study involving retrospective or prospective medical records.

☒ Yes ☐ No

3.1e) This is a **multi-site** study occurring in-part or in-full at other locations.

☐ Yes ☒ No

3.1f) There is an **international** component to this research. *International research includes sending or receiving human derived data or specimens (identifiable, limited data set, coded, or deidentified) to or from an international source. International research does not include studies in which VA is only one of multiple participating sites where the overall study-wide PI is not a VA investigator.*

☐ Yes ☒ No

3.1g) This study includes **off-station activity** (not including VA-leased space or CBOC clinics) conducted under VASDHS IRB approval. *Note: this does not include research conducted by a collaborator at their home institution under their institutional approval.*

☒ Yes ☐ No

3.1h) VA subjects will **participate** in part or in full **at other locations** (not including VA-leased space or clinics) under VASDHS IRB approval.

☒ Yes ☐ No

## Section 3.2 Specimen Use and Data Repository

Indicate whether or not each of the following applies to this protocol

3.2a) Involves specimens that are left over from pathological or diagnostic testing (**non-research specimens**)

☐ Yes ☒ No

3.2b) Involves **specimens collected for research purposes only**

☐ Yes ☒ No

3.2c) This study includes **specimen banking** (specimens are retained for use outside of the purposes of this protocol)

☐ Yes ☒ No

3.2d) The study involves **DNA** genotyping or other **genetic analysis**

☐ Yes ☒ No

3.2e) Biological **specimens/material** will be sent outside of the VA.

☐ Yes ☒ No

3.2f) A **data repository** is maintained (data are retained after completion of the protocol for other uses, IMPORTANT: see ? before checking "yes")

☐ Yes ☒ No

3.2g) **Data will be shared outside** of the VA (identifiable, coded, limited data set, or deidentified)

☒ Yes ☐ No

## Section 3.3 Treatment and Clinical Trials

Indicate whether or not each of the following applies to this protocol

3.3a) Includes a **treatment** component (a research treatment)

☒ Yes ☐ No

3.3b) Study is a **clinical trial**. *Note: 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 the interventions on biomedical or behavioral health-related outcomes.*

☒ Yes ☐ No

3.3c) Has a data safety monitoring board (**DSMB**) or data safety monitoring committee.

☐ Yes ☒ No

3.3d) Has a **data safety monitoring plan** (but not a DSMB) (this is not the data security plan, it is a safety plan).

☐ Yes ☒ No

## Section 3.4 Drugs and Devices

Indicate whether or not each of the following applies to this protocol

3.4a) **Drugs** that require **FDA** action such as an Investigational New Drug (IND) approval or exemption or 510(k) approval.

☐ Yes ☒ No

3.4b) Other drugs, supplement, etc. that **do not require FDA** action for inclusion in the study.

☐ Yes ☒ No

3.4c) Medical **devices requiring FDA** IDE approval or waiver

☐ Yes ☒ No

3.4d) **Other medical devices**

☐ Yes ☒ No

## Section 3.5 Risk and Hazards

Indicate whether or not each of the following applies to this protocol

3.5a) Study places subjects at **greater than minimal risk** (do not include risks that are due to standard care)

☐ Yes ☒ No

3.5b) Human subjects are exposed to **radioisotopes** (do not include standard care).

☐ Yes ☒ No

3.5c) Subjects have other **radiation exposure** (e.g., x-rays) (do not include standard clinical use).

☐ Yes ☒ No

3.5d) Target population has psychiatric diagnosis or behavioral complaint.

☐ Yes ☒ No

## Section 3.6 Clinical Facilities and Standard Care

Indicate whether or not each of the following applies to this protocol

3.6a) Study **uses VA clinical services** (e.g., adds required tests run in the VA lab for study purposes; research procedures concurrent with clinical care)

☐ Yes ☒ No

3.6b) Includes procedures or drugs that will be considered **part of standard care**.

☐ Yes ☒ No

3.6c) Involves **lab tests done for research** purposes.

☐ Yes ☒ No

## Section 3.7 Subject Expenses and Compensation

Indicate whether or not each of the following applies to this protocol

3.7a) There may be expense or added **costs to the subject** or the subject's insurance.

☐ Yes ☒ No

3.7b) This is a **qualifying cancer treatment trial** and subjects may be billed for study drugs or procedures.

☐ Yes ☒ No

3.7c) This is a cancer treatment trial but **subjects will not be billed** for study drugs or procedures.

☐ Yes ☒ No

3.7d) Subjects will be **compensated** (either in cash or other means such as a gift certificate).

☐ Yes ☒ No

## Section 3.8 Subject Activities

Indicate whether or not each of the following applies to this protocol

3.8a) Involves **surveys or questionnaires** completed by subjects

☒ Yes ☐ No

3.8b) Includes the use of **recruitment materials** such as flyers, advertisements, or letters

☐ Yes ☒ No

3.8c) Involves facial **photographs** or audio or video **recordings of patients**

☒ Yes ☐ No

## Section 3.9 Sponsors and Collaboration

Indicate whether or not each of the following applies to this protocol

3.9a) This research is a funded research project (**commercial (industry) sponsor, NIH, VA, other**).

☒ Yes ☐ No

3.9b) Other **commercial (industry) non-financial support** is provided (e.g., drugs or supplies).

☐ Yes ☒ No

3.9d) The protocol has **Department of Defense** involvement (e.g., subjects or funding).

☐ Yes ☒ No

3.9c) The PI or other study staff member has a financial interest or other **real or potential conflict** related to this study.

☒ Yes ☐ No

3.9e) This study involves **collaborative** research activities (research conducted at other institutions under the authorities or approvals of the other institution/s). *Note: this may include other VA and/or non-VA institutions, but does not include off-site VA research.*

☒ Yes ☐ No

## Section 4 - Estimated Duration

4) What is the estimated duration of the entire study? (From IRB approval to IRB closure)

5 years

## Section 5 - Lay Language Summary

**5) Provide a summary or synopsis of the proposed study using non-technical language (not more than 1 paragraph)**

Electronic screening is effective for timely detection of, and intervention for, suicidal ideation and other mental health symptoms. The VA eScreening program is a patient self-report electronic screening system that has shown promise for the efficient and effective collection of mental and physical health information among veterans. However, additional effectiveness and implementation research is warranted to evaluate the impact of eScreening within VHA. This study will address questions of the impact of eScreening compared to screening as usual, while evaluating a multi-component implementation strategy (MCIS) for optimal enterprise rollout of eScreening in VA Transition Care Management clinics.

## Section 6 - Specific Aims

**6) Provide a statement of specific aims and hypotheses that serve as the basis for this protocol. Emphasize those aspects that justify the use of human subjects.**

The specific aims of the study are to:

Aim 1: Evaluate eScreening, compared to paper and verbal screening (TAU), guided by the RE-AIM (Reach, Efficacy, Adoption, Implementation, and Maintenance) outcomes of the Practical, Robust Implementation and Sustainability Model (PRISM) in 8 Transition Care Management (TCM) programs, using a cluster randomized, stepped wedge design.

- Hypothesis 1 (Reach): Compared to TAU, eScreening will result in a significantly higher proportion of Veterans being screened.

- Hypothesis 2 (Effectiveness): 2a: Compared to TAU, eScreening will result in significantly less time from enrollment to mental health and suicide screening. 2b: Compared to paper and verbal screening, eScreening will result in a significantly higher proportion of Veterans being referred to needed care.

Aim 2: Evaluate the feasibility, acceptability, and potential impact of the Multi-Component Implementation Strategy (MCIS), guided by the RE-AIM outcomes of PRISM, adoption, implementation, and maintenance using mixed methods.

Aim 3: Describe and compare high and low eScreening reach sites guided by contextual constructs of PRISM using qualitative comparative analysis to explore factors influencing the reach of eScreening and the use of the eScreening MCIS.

## Section 7 - Background and Significance

**7) Provide a succinct discussion of relevant background information to justify performing the proposed study.**

Veterans disproportionately account for 22% of all known suicides in the U.S. Screening for suicide risk at the first contact with a health system is a best practice in the national Zero Suicide framework, and vital to enhancing access to appropriate care. Transition Care Management (TCM) programs in the VHA are positioned to screen newly enrolling post-9/11 Veterans at the critical moment of enrollment in health care. Unfortunately, many Veterans (51% in our pilot data) who present for the first time in VHA with recent suicidal thoughts do not receive same-day comprehensive suicide risk evaluation. Suicide risk is increased for Veterans diagnosed with mental health disorders, including posttraumatic stress disorder (PTSD), depressive disorders, and alcohol use disorders. Systematic mental health screening can improve detection of these mental health disorders and identify those who should be targeted for a [suicide risk screening & evaluation](#). However, the current screening and documentation process is inefficient, requiring clinical interviews or paper forms to be completed by Veterans and then entered manually into the medical record.

Our pilot study using electronic screening (eScreening) in TCM with 1,372 post-9/11 Veterans significantly increased rate and speed of screening completion, referral and participation in care, and rate of suicide risk evaluation by 15% compared to paper screening. The VHA eScreening program is a unique and generalizable web-based screening system for Veterans that provides actionable real-time scoring and feedback and integrates into CPRS/Vista. Developed with user-centered design methodology from Veteran and staff input, eScreening was named a Gold Standard Promising Practice for Diffusion by the Under Secretary for Health. However, diffusion of eScreening was unsuccessful at the two of three sites. Our pilot data showed that lack of training, support, and adequate workflow/staffing processes are barriers to successful implementation. To address these barriers, we developed and piloted a multicomponent

implementation strategy (MCIS) for eScreening, which includes eScreening software provision; training; a Rapid Process Improvement Workshop (RPIW), an often used VHA performance improvement strategy; and ongoing blended facilitation. Our pilot data showed that this strategy was effective for implementation and sustained use of eScreening in TCM settings.

Electronic screening is effective for timely detection of and intervention for suicidal ideation and other mental health symptoms, but additional effectiveness and implementation research is warranted to evaluate the impact of eScreening within VHA.

## Section 9 - Design and Methods

**9) Describe the research design and the procedures to be used to accomplish the specific aims of the project. Provide a precise description of the planned data collection (include what systems or databases will be used/accessed to gather data), analysis and interpretation. For chart review studies, include the timeframe of collection. Address sample size, inclusion of women and minorities. Define in clear terms exactly what will be done to the human subjects.**

This study will evaluate the effectiveness and implementation of an electronic screening program called eScreening compared to standard of care paper and/or verbal screening methods in VHA Transition Care Management (TCM) programs. This is a mixed methods hybrid 2, effectiveness-implementation, stepped-wedge (SW) trial of eScreening in eight sites. The following eight sites are implementation sites where no research-related activities will be conducted: Oklahoma City VA Health Care System, Chillicothe VA Medical Center, Orlando VA Medical Center, VA Western Colorado Health Care System, VA Puget Sound Health Care System, Loma Linda VA Health Care System, VA Salt Lake City Health Care System, West Palm Beach VA Medical Center. These sites will implement screening as part of routine clinical care. They will not collect data and will not obtain independent IRB approval.

Study investigators will collect the following data:

EMR data: EMR data will be extracted from the Corporate Data Warehouse (CDW) database. EMR data will consist of 1) the number of Veterans that enrolled in the healthcare system and the date and time they enrolled (144 Veterans average per month across sites), 2) the date and time that they received PC-PTSD-5, PHQ-2, AUDIT-C, CSSR-S, Post 9/11 Screen, Homelessness/Food Insecurity, MST Screen, BTBIS, Tobacco Use, Iraq & Afghan Post Deployment Screen, and the disposition (positive/negative screen), 3) date and time they received comprehensive suicide risk evaluation (CSRE), and 4) health care referrals including mental health (BHIP/PTSD), suicide prevention coordinators, hospitalizations, substance use treatment, and dual diagnosis. These data will be used to calculate the overall rate of screening completion and referral to health care and the average length of time to screening completion. We will also collect age, sex, race, and ethnicity data to include as covariates in our models.

eScreening system: we will use the eScreening reports functionality to pull eScreening usage data for the sites.

Staff participants: approximately 4-8 staff (primarily social workers, but could include Medical Support Assistants or other professionals) at each of the 8 VHA sites who have direct or indirect involvement with implementation of eScreening will be asked to take part in this research. Participation will involve one 30-minute individual telephone survey/interview, two 60-minute individual telephone interviews, and three 10-15 minute online surveys. The interviews and surveys will focus on assessing the feasibility and acceptability of the eScreening implementation strategy; factors affecting adoption, implementation, and sustained use of eScreening; and post implementation outcomes. All data from staff will be collected virtually.

Co-Investigators at VA Los Angeles and VA Boston will help provide oversight of qualitative data (e.g., staff interviews), but will not have access to identifying information. A limited dataset of EMR data collected from the VA Medical Record via the VA Corporate Data Warehouse will be extracted by a Co-Investigator at VA Pittsburgh and provided to VASDHS research staff for analysis. The Centralized Transcription Service Program (CTSP) at the VA Salt Lake City (Co-Investigator) will transcribe all staff interview data and provide it to VASDHS research staff. Additional information is provided in section 23.

**The following is a detailed description of the study procedures, timeline, data, and analyses.**

After a 6-month start up period involving planning and site randomization, the stepped-wedge trial will begin. This stepped-wedge trial relies on sequential roll-out to participating sites over time, while using other sites as controls until they begin implementation and facilitation. The eight participating sites will be stratified by size (a combination of number of TCM staff and average number of post-9/11 Veterans enrolled per month) and block randomized to four step/crossover cohorts of two sites each. All step/crossover cohorts will go through a 3-month pre-implementation (Pre-Imp) phase, followed by a 9-month active implementation using our eScreening MCIS. The eScreening MCIS will begin with a 3-month period that will include eScreening software provision, training, RPIW, and blended facilitation followed by 6

months of ongoing blended facilitation (9 months total). After the active implementation, all sites will have a 9-month sustainment period. Multiple types of data will be collected, including electronic medical record data, staff measures and interviews, field notes, and time motion tracking (described below). Data collection will begin at pre-implementation for each site and continue through sustainment.

### **Study Start up (0 to 6 months):**

**Randomization and internal facilitators.** Sites will be stratified by size, block randomized into four step /crossover cohorts, and engaged in selecting the **internal facilitators**, who will be serving as site eScreening implementation champions during the study. During site selection, we identified champions who support the use of eScreening and who have established relationships with the TCM team.

**Finalize Materials.** The qualitative lead co-investigator along with the PI and the implementation science expert will guide the development and pilot testing of the study questionnaires, time and adaptation trackers, and interview guides using PRISM.

**Lean/Six Sigma RPIW training.** Our team has over 7 years of experience implementing eScreening in diverse clinical settings, using the RPIW approach. To prepare for formal RPIW facilitation, two external facilitators will be trained to facilitate eScreening RPIWs, including the primary facilitator (master's level) and a backup (the PI) by a blackbelt level Lean/Six Sigma expert in the Systems Redesign program at San Diego Healthcare System. As part of the training, the external facilitators will facilitate two formal eScreening RPIWs with implementation sites not participating in the study.

**Finalize training materials.** Our team has developed an eScreening VA Pulse Site to make accessing technical information and training materials easy for staff. The site includes frequently asked questions, tutorial videos, a technical manual and user guide, a large amount of training information, and the eScreening playbook. In collaboration with our eScreening OIT team, we will update these materials to include the most recent information on eScreening and to support the training protocol.

**Stakeholder Meeting:** Building upon several preliminary meetings with national and facility stakeholders, we will host a formal teleconference start-up meeting with National TCM leadership, site internal facilitators, VA OIT eScreening Program Manager, VA Innovations staff, and the PI and co-investigators and research staff. The aim of this meeting is to orient everyone to the goals of the study, communicate the national stakeholder preferences for the content and frequency of interactions, and identify and address possible logistical barriers and facilitators. The 2-hour meeting will use a storyboard format to describe procedures and generate discussion through a structured focus group format employed in our prior work. These meetings will occur every six months during the study. An external VHA advisory group, which includes Veterans, will review the research materials and plan.

### **Stepped-Wedge Trial (7 to 45 months):**

Based on our preliminary work, we anticipate a sample of 45 staff will be enrolled in this study. Patient level data will be collected from EMR (for which we will apply for a HIPPA waiver), and no Veterans will directly participate. Recruitment procedures will be reviewed, and adjusted, if needed, in the startup period, but the proposed procedure will be as follows: 1) Internal facilitators, TCM staff and eScreening implementation-related stakeholder staff at each site will be invited to participate in the study; 2) An informational session about the study's leadership and purpose, selection of participants, and use of data will be conducted. Potential staff participants will be informed that their participation is entirely voluntary and their decision about participation will not affect their employment, merit, or promotion. Following this informational session, research staff consent interested participants. After consent has been signed, enrolled staff members will receive a link to an online survey and will be scheduled for a preliminary interview by the evaluation lead. If staff turnover occurs, we will attempt to assess the staff member prior to leaving and replace and train another participant with similar functions within the clinic. Each of the four step/crossover cohorts will go through the following phases sequentially during the study.

**Pre-implementation (Pre-IMP) phase.** This phase will last 3 months during which the research team will work with the internal facilitators to: 1) gather pre-implementation information including detailed information on the processes in place for TCM screening upon enrollment ; 2) identify points of contact for iPads and other logistical needs; 3) establish communication with TCM staff and others working with the TCM staff; 4) recruit staff participants for the study; and 5) begin ongoing tracking of process data from field notes and time motion tracking. TCM staff names, clinic names, note titles, scheduling the RPIW, and clinical reminders completed by program staff will be gathered and used for subsequent development of user accounts and content customization during the implementation phase. The implementation team will also provide psychoeducation to the staff on the importance of screening. This phase will serve as an attention control condition to which the baseline control and intervention conditions will be compared.

During pre-implementation, TCM teams will continue usual screening procedures. These involve interview or self-report, paper-based collection of post-9/11 screening measures, including the system-wide standardized assessments of depression, PTSD, alcohol use, and suicide (PHQ-2, PCPTSD, Audit-C and C-SSRS, respectively). Veterans who are positive on C-SSRS then receive a Comprehensive Suicide Risk Evaluation and are referred for appropriate follow-up. A detailed description and flow map of the current

screening process at each site will be developed by the external facilitator (research team) and internal facilitator (site staff) with information from the TCM staff prior to the implementation phase.

**Active Implementation (MCIS):** The eScreening MCIS was developed over the past seven years and consists of: 1) eScreening software provision, 2) training, 3) RPIW, and 4) ongoing blended facilitation. We developed our MCIS to address specific eScreening implementation barriers we found in our prior research. In order to address system level barriers related to OIT support, we developed a technical support infrastructure for eScreening using existing VA IT resources (see LOS) as part of eScreening provision. The training component addresses educational barriers regarding eScreening use and the research available. Blended facilitation also addressed educational barriers as well as, technology related and other unforeseen challenges. The RPIW process will address, leadership support, staff buy-in, resources needed and by engaging all stakeholders in the process and developing a site-specific and clear plan for implementation. The RPIW specifically includes a section where the team generates possible barriers and solutions in day 2.

**eScreening.** eScreening is a VHA program that allows Veterans to answer self-report screening questions via an iPad connected to the VHA secure Wi-Fi. eScreening reads from and writes to the VHA EMR. The highlighted features of eScreening include: 1) the ability for Veterans to enter screening information directly without the involvement of a clinician; 2) immediate scoring of measures; 3) an editable note generated in the EMR; and 4) clinician alerts for positive mental health screens that require follow-up for suicide risk.

**Training.** eScreening training will be virtual and asynchronous and include a 1-hour instructional PowerPoint that will be presented by the external facilitator. The PowerPoint is followed by an hour of tutorial videos showing all steps of (creating assessments, adding Veterans, saving to VistA, searching for assessments, creating scheduled appointment assessments, accessing reports). Hands-on training for users will be available in group format or individually by the training staff as requested by the TCM site staff. Additional training materials can be accessed via the eScreening Pulse site which include a series of quick guides to address eScreening customization, assessment set-up and dashboard use. Frequently asked questions will also be available on the Pulse site.

**RPIW.** The 3-day RPIW will be facilitated virtually by the external facilitator with assistance from the onsite internal facilitator and will include the TCM team, related staff (i.e., medical support staff, clerks), and other site stakeholders. The first day of the process will train participants in the RPIW principles and will introduce a summary of the information gathered in the Pre-Implementation Phase, including a graphic of the current state process map which will then be refined and finalized. The second day consists of collective efforts to map a targeted future state, conduct a gap analysis, and identifying relevant factors and barriers unique to the site. The third day is dedicated to the repetition of action planning, execution, and reevaluation to finalize the targeted state and identify clinically meaningful goals for improvement. Using a Plan-Do-Study-Act (PDSA) framework, the plans to achieve the target state are enacted with a detailed plan that includes who, what, when for each step in the plan. Due to the flexibility of eScreening and the implementation strategy, each TCM program may choose to integrate eScreening into their workflow based on the specific needs of their program, available resources, and other factors.

**Blended facilitation.** Blended facilitation will include a primary external facilitator from the eScreening team who will work with the site internal facilitator to schedule meetings, training sessions, and phone calls. The external facilitator will be the main point of contact for implementation-related questions. The internal facilitator, selected during the startup period, will work with the external facilitator to navigate internal site systems (i.e., local leadership, OIT, logistics) and serve as a champion for the eScreening project at each site.

### **Overview of Data Sources & Timing for Data Collection:**

Our study will use a mixed-methods design and will collect a combination of quantitative and qualitative data from multiple stakeholders and at multiple time points. A general overview of the data sources and data collection time points are provided in this section. More specific data collection and analysis considerations are provided under each aim.

**Quantitative data sources and timing for data collection.** Quantitative data collection includes data from the EMR, the eScreening system, and surveys that will be completed by staff participants. We will extract EMR data at the beginning and end of Pre-Imp, at the end of the MCIS period, and at 9 months post-MCIS. We will use the eScreening reports functionality to pull eScreening usage data for each cohort after the MCIS period and 9 months post-MCIS. We will conduct a Pre-Imp individual telephone survey /interview using the feasibility and acceptability scales developed by Weiner et al (2017). We will also use a secure online survey system (i.e., Qualtrics) to collect survey elements based on the PRISM and its RE-AIM outcomes during Pre-Imp, at the end of the MCIS period, and at 9 months post-MCIS.

**Qualitative data sources and timing for data collection.** Qualitative data will be collected using field notes and interviews. We will take field notes using a structured template during telephone meetings/calls throughout the pre-implementation and implementation stages including initial contact, during the RPIW,

and the facilitation contact sessions. Research staff will take extensive field notes to describe the clinical environment, work flows, patient population, and relational atmosphere. Individual telephone interviews will be conducted with purposefully selected site staff during pre-implementation (survey/interview), post-implementation (telephone interview), and the sustainment (telephone interview) phases. Interviews will focus on factors affecting adoption, implementation, and sustained use of eScreening. Both mindset and practical issues will be explored to illustrate implementation issues, challenges, and underpinnings of success. A specific set of probes will outline, and diagram tasks involved step-by-step to document barriers and facilitators and when communication and coordination were needed.

### **Aim 1 Data collection and analyses:**

Aim 1: Evaluate eScreening, compared to paper and verbal screening, guided by the RE-AIM outcomes of PRISM in 8 TCM programs, using a cluster randomized, stepped wedge design. Hypothesis 1 (Reach): Compared to paper and verbal screening, eScreening will yield a significantly higher rate of screening. Hypothesis 2 (Effectiveness): 2a: Compared to paper and verbal screening, eScreening will result in significantly less time for mental health and suicide screening. 2b: Compared to paper and verbal screening, eScreening will result in significantly higher rate of referral to needed care.

**Data collection.** We will obtain a HIPAA waiver to collect the following data: 1) the number of Veterans that enrolled in the healthcare system and the date and time they enrolled (144 Veterans average per month across sites), 2) the date and time that they received PC-PTSD-5, PHQ-2, AUDIT-C, CSSR-S, Post 9/11 Screen, Homelessness/Food Insecurity, MST Screen, BTBIS, Tobacco Use, Iraq & Afghan Post Deployment Screen, and the disposition (positive/negative screen), 3) date and time they received comprehensive suicide risk evaluation (CSRE), and 4) health care referrals including mental health (BHIP/PTSD), suicide prevention coordinators, hospitalizations, substance use treatment, and dual diagnosis. These data will be used to calculate the overall rate of screening completion and referral to health care during the baseline control period and the average length of time to screening completion. The same data will be collected for the previous nine months post-implementation and sustainment. Based on the average enrollment data for our sites over the past year, approximately 27,600 Veterans will enroll in VA healthcare during the 27-month baseline control, Pre-Imp, post MCIS, and Sustainment data time-periods.

**Sample size and power calculation:** We powered the study for the intervention effect of the effectiveness outcomes in Aim 1. We assumed a common intervention effect across all cohorts/steps and Hierarchical Linear Modeling (HLM) to account for clustering, including a fixed effect for cohort/step of crossover to account for secular trends and an indicator of intervention phase change (e.g., control vs. intervention) to provide intervention effects. Power was calculated based on established methods for SW trials. We set type I error rate  $\alpha = 0.05$ , Cohen's  $d$  (or  $h$  for binary outcomes) effect size = 0.1, power = 0.8, and assumed an intraclass correlation (ICC) = 0.20, which is a conservative estimate based similar studies. Under these assumptions, the estimated sample size needed for the proposed study is approximately  $N = 5,000$  participants. Data from our pilot study show effect sizes that are all above this detectable effect sizes. Given that 144 new post-9/11 Veterans are enrolled on average across implementation sites each month and we will collect data at each site over a 24-month period, the study is sufficiently powered to detect effect sizes observed in similar studies.

**Statistical analysis and hypothesis testing.** Data analyses will proceed in stages and will follow the recommendations of the Prevention Science and Methodology Group for randomized field trials. Preliminary data screening and cleaning will require examination of the data distributions for normality and missing data patterns at both the univariate and multivariate level. Missing data are expected to be limited and are readily incorporated in HLM if the data can be assumed to be missing at random using Maximum Likelihood estimation. If the data are determined not to be missing at random, missing data mechanisms will be built into the target statistical models. HLM will be used as the primary statistical model due to the nested (or clustered) structure of the data (veterans [level 1] nested within TCM clinics [level 2] nested within implementation site [level 3]), with random assignment occurring at the implementation site level. HLM is a flexible modeling strategy that allows for the integration of fixed and random effects in nested/clustered data structures with normal and non-normal response variables. Demographic information about participants during the MCIS and control phases will be statistically compared within and between sites to ensure comparability. Any characteristics that differ between the intervention and control groups will be included as covariates in subsequent models to minimize bias. Fixed effects will be included in each model to account for study phase (i.e., baseline control, Pre-Imp/attention control, MCIS, and sustainment) and step/crossover cohort, to account for secular trends. We will also be able to test interactions between study phase and step to determine whether intervention effects differed by cohort and whether intervention effects varied between TCM clinics within implementations sites. Separate models will be tested to determine whether a greater proportion of Veterans were screened for mental health and suicide risk (Reach) and referred to care (Effectiveness) during the MCIS and/or sustainment phases relative to the baseline and/or attention control phases. Additional models will test whether the mean number of days between enrollment and screening were lower (Effectiveness) during the MCIS and/or sustainment phases relative to the baseline and attention control phases. In all analyses, we will set statistical significance at  $\alpha = 0.05$  and use Holm-Bonferroni adjustments for  $\leq 5$  tests and false discovery rate methods for  $> 6$  tests. When multiple correlated outcomes (dependent outcomes) are analyzed with each hypothesis, corrections

will be calculated based on the effective number of independent tests when applying the multiple comparison procedures

## **Aim 2 Data collection and analyses:**

**Aim 2:** Evaluate the feasibility, acceptability, and potential impact of the MCIS, guided by the RE-AIM outcomes of PRISM, adoption, implementation, and maintenance using mixed methods.

**Data collection.** We will use a mixed methods approach and collect both quantitative and qualitative data guided by the RE-AIM outcomes of PRISM. For the replication cost, we will use the a time tracker previously used for VA implementation efforts. The tool will be customized for this study and used to incrementally capture all facilitation activity by the external facilitator. Activities will then be quantified and used to develop a replication cost estimate by site.

**Quantitative data analysis.** We will use descriptive statistics to summarize quantitative measures for each PRISM outcome using 50% as a benchmark. **Adoption** will be calculated as the overall number and proportion of TCM clinics that are willing to initiate eScreening, relative to the total number of TCM clinics across implementation sites and within each implementation site, as well as the overall number and proportion of providers who are willing to adopt eScreening relative to the total number of providers across implementation sites, across TCM clinics at each implementation site, and within each TCM clinic. **Implementation** will be calculated as the proportion of TCM clinics and providers within clinics who implement eScreening. We will also calculate mean ratings of the acceptability and feasibility of the MCIS across providers within TCM clinics and across implementation sites. Time tracker data will be analyzed using the VA general ledger, which includes all labor costs including employee benefits and employer contributions to taxes. Indirect costs should be incurred in proportion to direct costs and will be estimated based on VA Health Economics Resource Center (HERC) guidance. **Maintenance** will be calculated as the proportion of TCM clinics and providers within clinics who implement eScreening during the sustainment phase (i.e., the 9-month period following initial implementation).

**Qualitative data analysis.** Study investigators or an experienced, trained member of the study team will conduct semi-structured interviews. Interviews will be audio recorded, transcribed by the VA CTSP, and entered into the qualitative software program, ATLAS.ti. A key aspect to this analysis is to answer these questions: What influences adoption of eScreening by providers? What factors influenced the implementation of eScreening? What factors promote maintenance? The analysis will also answer the bigger question of why providers do or do not implement eScreening, including understanding any practical clinic work flow reasons for use or non-use, or key underlying characteristics of eScreening program or provider. The analysis will consider emergent themes using an editing approach. Two project team members will independently code the semi-structured interview data collected. A third team member will assess coding quality and resolve conflicts.

**Convergent analysis.** Using a mixed-methods convergent design, the qualitative research core team will analyze the data concurrently with the quantitative data to explain and support/refute the quantitative data and add to insights regarding future implementation research and dissemination efforts.

## **Aim 3 Data collection and analyses:**

**Aim 3:** Describe and compare high and low eScreening reach sites guided by contextual constructs of PRISM using qualitative comparative analysis to explore factors influencing the reach of eScreening and the use of the eScreening MCIS. In Aim 3, qualitative data from contextual elements of PRISM will be used to construct comparative analysis between high and low eScreening reach sites. Questions and measures assessing the PRISM contextual dimensions will be included in the proposed interviews and field notes (qualitative data) and will also be informed by the proposed surveys and EMR data (quantitative data).

**Data analysis.** Qualitative data will be analyzed as described for aim 2, but we will use a template approach for the analysis using constructs from contextual factors. We will use codes identified and created based on the PRISM constructs and other emergent themes to tag the relevant transcript quotations. Quotation reports will list the associated quotations verbatim by site. Sites will be divided by high vs. low reach using a cutoff score of 30% (from Aim 1), based on prior work. Qualitative comparative analysis (QCA) will allow us compare high and low eScreening reach sites to identify factors influencing the implementation of eScreening and the impact of the MCIS using systematic cross-case comparison to better understand causal complexity. We will list and count different combinations of variables in our data set, and then apply logical inference rules to evaluate whether alternative inferences are supported by the data. Using our outcome of interest (i.e. high reach) and a list of conditions (i.e. contextual factors) that may be associated with that outcome we will develop calibration metrics using a crisp dichotomous set. Calibration involves considering how each site is related to our pre-defined PRISM concept using specific decision rules. We will establish a codebook detailing the conditions and decision rules. Third, we will calibrate the data. Specifically, using coded data, each site will be calibrated dichotomously as either "having" (1.0) or "not having" (0.0) each condition. After our sites are calibrated, we will construct a truth table, using Stata, to analyze logical combinations of conditions to determine if specific combinations share the outcome. Using Boolean logic, we will minimize the truth table to arrive at pathways to the outcome.

The pathways will then be assessed using the consistency and coverage parameters of fit. A thematic analysis of site interview data will be used to supplement QCA findings.

## Section 9.8 Questionnaires & Surveys

**9.8) Provide the name and a reference for questionnaires/surveys that are standard or identify them here and attach a copy of the questionnaire/survey. *Questionnaires or surveys that are not clinical standard references must be uploaded. Reference the help link for additional information related to surveys administered to VA personnel and approved platforms for web-based surveys.***

Acceptability and Feasibility scale/interview developed by Weiner et al., 2017; investigator created online survey; and interview guides (post-implementation and sustainment phase). All attached.

## Section 9.11 Pictures and Audio/Video Recordings of Patients

**9.11) Describe the purpose of photographs (facial), or audio, or video recordings of patients. Describe whether the recordings will contain, or potentially contain, identifiers. *Note: use of photographs or recordings must be covered in the informed consent process and documented consent documents (e.g., consent form, information sheets, telephone screen scripts).***

Interviews will be conducted with purposefully selected site staff focused on factors affecting adoption, implementation, and sustainment before and after the active implementation phase. Both mindset and practical issues will be explored to illustrate implementation issues, challenges, and underpinnings of success. A specific set of probes will outline, and diagram tasks involved step-by-step to document barriers and facilitators and when communication and coordination were needed.

The qualitative interview data will generate digital voice files, which are considered identifiers. To minimize risk, during recorded interviews participants will only be identified using their project ID number, and there will be no mention of their name or other identifiers.

## Section 9.12 Off Station Activities

**9.12) Describe each off-station activity including where it occurs, subject involvement, and any additional required protections. *Note: if the off-station activity is being conducted under the approval authority of another institution, this is not VA offsite research and should be described as collaborative research effort. Please contact the HRPP office if you have any questions***

Staff participants will be recruited from each of the 8 implementation sites and will complete the study-related surveys and interviews at each of their own facilities.

## Section 10 - Human Subjects

**10) Describe the characteristics of the proposed subject population. Include age, gender, ethnicity, and health status as appropriate. *Note: Data about people are still considered "human subjects" by the IRB, so even if you do not intend to contact the patients whose charts you will review, you still describe the characteristics related to the subjects whose charts you will review.***

- Provide inclusion and exclusion criteria as appropriate. Provide a statement how non pregnancy is confirmed if pregnancy is an exclusion criteria.
- For multisite studies, provide the total number of subjects from all sites and include description of the local site's role as a coordinating center if applicable.
- Indicate the number of VA participants to be studied.
- Indicate the estimated number of consented subjects that will fail the screening process, if any.

There are five main sources of data for this study (previously described): 1) Quantitative administrative electronic medical record (EMR) data, 2) Quantitative data from the eScreening system, 3) Quantitative survey data, 4) Qualitative interview data, and 5) Field notes. EMR data will be collected to capture patient level data, including rates of screening completion and referral to mental health care. However, no Veterans will directly participate. We will obtain a HIPAA waiver to collect EMR data. Quantitative (surveys) and qualitative (interviews) data will be collected from a sample of approximately 45 staff who will be enrolled in this study.

**Inclusion Criteria:**

1. Direct or indirect involvement with implementation of eScreening at the site
2. Capable of informed consent.

**Exclusion Criteria:**

1. Not involved in or directly impacted by eScreening involvement at each site

Participants will be recruited from both genders and each ethnic group in proportions representative of those in the respective pool at each site. No children will be involved in any aspect of this study. There is no screening process for consented participants.

## Section 10.1 Non-Veteran Subjects

**10.1a) Recruitment of non-Veterans cannot be for the sake of convenience for this study. Provide the objective and justification for the inclusion of non-Veteran subjects. Identify how the research results will be generalizable to the Veteran population.**

*NEW: ORD now requires completion of a Request to Enroll Non-Veterans form (available in the help section of OnRAMP) for any VA studies requesting to enroll non-Veterans. This form will be reviewed by the local RDC before the application may be considered by the IRB. Complete the form and upload with this submission.*

The purpose of the research is to evaluate effectiveness and implementation of an electronic screening program called eScreening compared to standard of care paper and verbal based screening methods in VHA Transition Care Management (TCM) program sites. Staff at the 8 implementation sites are need to provide valuable information related to the eScreening implementation strategy that will help to inform scale up efforts and will ultimately improve the speed and rate at which Veterans are screened for suicide risk and mental health disorders and referred for mental health treatment.

**10.1b) Non-Veterans must be given a copy of the VA Notice of Privacy Practices (NOPP) and sign the acknowledgement form. The Privacy Officer must be notified when a non-Veteran is enrolled in the study and be provided with a copy of the signed NOPP. If CPRS notes are entered, and the acknowledgement must also be scanned into CPRS. The NOPP, Acknowledgement form, and instructions to provide the completed form to the PO are available under the ? at the top right corner of this page.**

☒ Agree ☐ Disagree

## Section 10.6 Avoiding coercion of students or employees

**10.6) Indicate how coercion of students and/or employees will be avoided:**

Participation will be voluntary and will in no way affect employment or performance ratings.

## Section 11 - Recruitment

**11) Describe, step-by-step, the plans for recruitment of subjects (or selection of subjects as in record review). This description must include how, when, and where potential subjects are approached as well as procedures for identifying potential participants (through medical records, physician referral, third-party sources, etc.). Include how selection is equitable. Indicate if vulnerability to coercion may be present and if so plans to ensure voluntary participation.**

Approximately 4-8 staff at each of the 8 VHA implementation sites who have direct or indirect involvement with implementation of eScreening will be asked to take part in this research (for a total of 45 participants across all sites).

No recruitment materials will be used. During the study start-up period, Transition Care Managers at each of the implementation sites (8 total) will identify staff who will be involved in the implementation of eScreening at their facility. The research team will then contact these individuals via phone or email and invite them to participate in the research portion of the study (i.e., interviews and surveys). Potential staff participants will be informed that their participation is entirely voluntary and their decision about participation will not affect their employment, merit, or promotion.

## Section 12 - Informed Consent

**12) Indicate whether or not each category of consent is involved in this study:**

12a) Will the study team obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without (or prior to) obtaining informed consent of the prospective subject or the prospective subject's LAR?

☐ Yes ☒ No

12b) **Signed** informed consent

☒ Yes ☐ No

12c) Waiver of documented consent (e.g., **oral** consent) for all or part of the study.

☐ Yes ☒ No

12d) Request for a **waiver** of consent for all or some study activities.

☒ Yes ☐ No

12e) Alteration of **other required elements** of consent.

☐ Yes ☒ No

12f) **Child** assent to participate (Director approval will be required)

☐ Yes ☒ No

12g) Will any language **other than English** be used by those obtaining consent and understood by the prospective participant or the legally authorized representative?

☐ Yes ☒ No

12h) **Decisional Capacity Assessment** to determine if participants have the capacity to consent for themselves.

☐ Yes ☒ No

12i) **Surrogate** consent (legally authorized representative)

☐ Yes ☒ No

### Section 12.1 Informed Consent Process

**12.1a) Will consent be obtained before any study procedures are performed (including screening procedures except screening procedures with Consent/HIPAA waiver approval)?**

☒ Yes ☐ No

**12.1b) Will the information being communicated to the participant or legally authorized representative during the consent process include exculpatory language through which the participant or legally authorized representative is made to waive or appear to waive any of the participant's legal rights or release or appear to release the Researcher, Sponsor, the VA or its agents from liability for negligence.**

☐ Yes ☒ No

**12.1c) A master list of all VA subjects consented (written or not) under this protocol will be maintained.**

☒ Agree ☐ Disagree

**12.1d) Identify the circumstances under which consent will be obtained including where the process will take place; any waiting period between describing the research and obtaining consent including sufficient time for the prospective participant to consider participation, and any steps taken to minimize the possibility of coercion or undue influence.**

Participants who are appropriate for inclusion will meet virtually using Teams with a project staff member who will describe the study, including information about the content of the surveys and interviews, as well as the longitudinal nature of the study. Following this informational session, research staff will obtain consent electronically from interested participants. Fully informed consent will be obtained by all participating staff, and Dr. Pittman and other co-investigators will be directly available to answer questions. All participating staff will be provided with a copy of the consent document and a copy of the Experimental Subject's Bill of Rights. Informed consent will be documented with the VA IRB-approved written consent form that each participant will sign and submit electronically via VA email or screenshot prior to participation. Signed and witnessed consent forms will be kept on file in a specially secured cabinet.

To avoid coercion, potential staff participants will be informed verbally, and in the consent form, that: 1) The research team will not reveal to leadership at any level if the staff member decided to participate or not in the research study. 2) participation is entirely voluntary and their decision about participation will not affect their employment, merit, or promotion. 3) They may withdraw at any time, skip any questions they choose not to answer, and that the information they provide will not affect their position at the VA or relationships with VA staff and leadership.

## Section 12.4 Waiver of Informed Consent

**12.4a) Is it practicable to conduct the research without the waiver or alteration of consent?**

☐ Yes ☒ No

**12.4b) Does the research examine public benefit or service programs and is subject to state or local government approval?**

☐ Yes ☒ No

**12.4c) Will the research involve greater than minimal risk?**

☐ Yes ☒ No

**12.4d) Will waiving or altering informed consent adversely affect the subjects' rights and welfare?**

☐ Yes ☒ No

12.4e) Is it appropriate to provide pertinent information to subjects later BUT this information will NOT be provided?

☐ Yes ☒ No

12.4f) Identify to what aspects of the study you are requesting a waiver of consent (i.e., full study or specific aspects). Describe the waiver or alteration needed and why it can be granted (include why the research is not practical without the waiver or alteration and how the waiver enables conducting the study).

Waiver of informed consent or alteration of consent elements may be allowed if the IRB documents these findings and approves waiver or alteration.

A waiver of informed consent is needed to obtain quantitative administrative electronic medical record (EMR) data. EMR data will be collected to capture patient level data. No Veterans will directly participate.

Specifically, EMR data will be extracted from the cooperate data Wearhouse by the Pittsburg VA Co-I and provided to VASDHS for analysis. Data that must be accessed are the veterans who enrolled into the healthcare system during specific dates at each of the performance sites. Data that will be collected and used are: 1) date and time of enrollment, 2) the date and time of completed PC-PTSD-5, PHQ-2, AUDIT-C, CSSR-S, post-911 screen, homelessness/food insecurity screen, MST screen, BTBIS, Tobacco Use, and Iraq & Afghan post deployment screen, and the score (positive/negative screen), 3) date and time of comprehensive suicide risk evaluation (CSRE), 4) number and type of health care referrals, 5) demographic variables sex, age, race and ethnicity, and 6) performance site. In addition, we will need to access veterans unique Vista IEN in order to collect the data specified above.

12.4g) Explain why the research could not practicably conducted without using identifiable information.

It is not feasible to collect the amount of data needed and meet the study aims without a waiver.

## Section 12.9 HIPAA Authorization

For each category below, indicate whether or not this study involves the indicated process:

12.9a) Signed HIPAA Authorization. *\*\*New Template is available in the [? Help section](#)\*\**

☐ Yes ☒ No

12.9b) HIPAA waiver to cover the entire study

☐ Yes ☒ No

12.9c) HIPAA waiver for recruitment, screening, and/or for a portion of the study.

☒ Yes ☐ No

12.9d) HIPAA Authorization or waiver is **not required** for some or all of the study subjects (e.g. no health data).

☒ Yes ☐ No

## Section 12.10 HIPAA Waivers and Alterations

12.10a) Describe the purpose/nature of the HIPAA waiver or alteration and **list specifically, what identifiers and health information are being requested under the waiver/alteration and identify whether the waiver is for access, use, and/or collection of this information.**

A HIPAA waiver is needed to obtain quantitative administrative electronic medical record (EMR) data. EMR data will be extracted from the cooperate data Wearhouse by the Pittsburg VA Co-I and provided to VASDHS for analysis. Data that must be accessed are the veterans who enrolled into the healthcare system during specific dates at each of the performance sites.

Data that will be collected and used are: 1) date and time of enrollment, 2) the date and time of completed PC-PTSD-5, PHQ-2, AUDIT-C, CSSR-S, post-9/11 screen, homelessness/food insecurity screen, MST screen, BTBIS, Tobacco Use screen, and Iraq & Afghan post deployment screen, and the score (positive/negative screen), 3) date and time of comprehensive suicide risk evaluation (CSRE), 4) number and type of health care referrals, 5) demographic variables sex, age, race and ethnicity, and 6) performance site.

In addition, we will need to access veterans unique Vista IEN in order to collect the data specified above.

**12.10b) The proposed access, use, and/or disclosure of PHI involves no more than a minimal risk to the privacy of individuals.**

☒ Agree ☐ Disagree

**12.10c) The plan to protect the identifiers from improper use and disclosure is adequate.**

☒ Agree ☐ Disagree

Describe the plan

Several steps have been taken to minimize risk related to loss of privacy. All staff will have been trained or will receive training in ethical conduct of research. The electronic data from the EMR limited dataset will be stored on the secure VASDHS research drive within the PI's protocol specific folder(R:\PI\Folders\Pittman).

**12.10d) An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law.**

☒ Agree ☐ Disagree

12.10d2) Describe the plan:

Only a limited dataset of Veteran data collected from the Corporate Data Warehouse will be stored, including performance site, date/time, score of results, referral to MH clinics, and covariate variables (age, sex, race, ethnicity). No other patient identifiers will be stored.

**12.10e) By signing this protocol for submission, the PI is providing written assurance that the PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted by the Privacy Rule. 38 U.S.C. 7332 Information: If the waiver of HIPAA authorization is for the use of 38 USC 7332 information (applicable to drug abuse, alcohol abuse, HIV infection, and sickle cell anemia records), by signing this protocol for submission the PI is providing written assurance that the purpose of the data is to conduct scientific research and that no personnel involved may identify, directly or indirectly, any individual patient or subject in any report of such research or otherwise disclose patient or subject identities in any manner. (Ref: 38 U.S.C. 7332(b)(2)(B))**

☒ Agree ☐ Disagree

**12.10f) The research could not practicably be conducted without the waiver or alteration.**

☒ Agree ☐ Disagree

12.10f2) Describe how the waiver/alteration enables the research to be conducted

A HIPAA waiver will allow investigators to access the large amount of quantitative EMR data needed to meet study aims.

**12.10g) The research could not practicably be conducted without access to and use of the PHI.**

☒ Agree ☐ Disagree

12.10g2) Describe why it would be impracticable to conduct this research without the PHI described 12.10a. (v3/8/18)

It is not feasible to collect the amount of data needed without a waiver.

## Section 13 - Alternatives to Participation

### 13) Describe the alternatives to participation in this research study (see ? for guidance)

For Staff the alternative to participation is to not participate in the study.

## Section 14 - Potential Risks

### 14) Describe any potential or known risks or discomforts and assess their likelihood and seriousness (see ? for guidance)

Potential risks associated with participation in the study are 1) loss of confidentiality and 2) feeling discomfort during their participation, both of which are research risks as this project involves no medical or psychological treatment intervention. These risks apply only to participating site staff. Such risks are not likely and would not lead to serious consequences. All data obtained from the EMR and eScreening system will not be traceable to PII and thus pose no risk to Veterans.

Research Risk. As stated in the potential risks, participation may result from loss of confidentiality due to unforeseen circumstances (fire or flood that may compromise locked data). Every effort will be made to protect the confidentiality of staff participant records. However, a risk for potential loss of a participant's confidentiality exists. This is highly unlikely given the precautions taken in the data management plan, but the possibility is not zero. In addition, there is minimal research risk to TCM participants during the training and interviews, such as feeling discomfort during their participation, but our team has not experienced this as a notable issue for past research that has involved similar techniques.

## Section 15 - Risk Management

### 15) Describe the procedures for protecting against or minimizing any potential risks/discomforts, and the adequacy of resources for conducting the study and resources participants may need as a consequence of the research. When applicable, include detail of the following safety measures: (a) The type of safety information to be collected, including AEs; (b) Frequency of safety data collection; (c) Frequency or periodicity of review of cumulative safety data; (d) Statistical tests for analyzing the safety data to determine if harm is occurring; and (e) Conditions that trigger an immediate suspension of the research. See ? for further requirements.

To minimize the risk of staff participant discomfort, confidentiality will be stressed, participants will be informed that they have the right to refuse to answer questions or to terminate their participation in the study at any time without prejudice, and everyone who interacts with participating staff will be highly trained.

The following steps are taken to minimize the risk to confidentiality. Electronic data will be stored on a secure research drive on our VA network, accessible only to VA research personnel associated with the proposed study. Electronic records will include a password-protected key linking participant numbers with subject names. Paper records will be coded by participant number only and will not include names. All paper records will be kept in locked cabinets in a locked room. A special custom-tailored database system will be developed for this project to ensure the highest possible data reliability. Data entry programs will include double data entry, item prompts, skip patterns, range checks, and logical validity routines. Copies of audio files from staff qualitative interviews will be stored on the VA secure server. The qualitative interviews will generate digital voice files, which are considered identifiers. To minimize risk, during recorded interviews participants will only be identified using their project ID number, and there will be no mention of their name or other identifiers. All digitally recorded interviews will be transcribed by CTSP. The transcription will not include any identifying information accidentally disclosed in interviews. Participants will be instructed not to state any names or other identifying information in their interviews. Any identifying information found in voice files from the qualitative interviews would be accidental and rare; no identifying information will be found in transcripts. The transcription files will be stored on a VA server behind the VA firewall.

Members of the investigative team will be well educated regarding the protection of patients' rights to confidentiality. Identities of participants will not be revealed in the publication or presentation of any results from this project. Procedures specified in the consent forms are consistent with HIPAA regulations.

All investigators and research staff will complete the VA human subject's certification requirements, as well as certification in HIPAA regulations.

## Section 17 - Potential Benefits

**17) Discuss benefits that may be gained by the subject as well as potential benefits to society in general (see ? for guidance)**

There are no direct benefits to participating staff. However, eScreening may improve the speed and rate at which Veterans are screened for suicide risk and mental health disorders and referred for mental health treatment. eScreening may have several advantages over usual screening, including time savings for providers and use of fewer organizational resources.

## Section 18 - Risk/Benefit Analysis

**18) Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and in relation to the importance of the knowledge that may reasonably be expected to result.**

While there are risks in participation, these risks are optimally minimized through the outlined risk management measures. Potential risks are not likely and would not lead to serious consequences. The potential benefits from this study appear to outweigh the minimal risks.

## Section 21 - Responsibilities and Qualifications

**Here are the identified study staff members**

James O. E. Pittman, PhD

Adrienn Borsika Rabin, PhD, Colin A. Depp, PhD, Laurie A. Lindamer, PhD, Niloofar Afari, PhD, John Gault, MS, Jeffrey Hernandez, Erin L. Almklov, PhD, Michael Wah Lee, Sheba S Andrew, LCSW

**21) For each staff member listed above, describe their role and qualifications. Also indicate which of the study staff are authorized to obtain consent, when applicable to the study.**

Dr. Pittman is an licensed clinical social worker and holds clinical privileges within the social work scope of practice at the VASDHS. He is also Associate Director of Education and Dissemination in CESAMH. As the PI, he will be responsible for oversight of all aspects of the project

Niloofar Afari, Ph.D.(Co-Investigator) is Associate Chief of Staff for Mental Health at VA San Diego Healthcare System and Vice Chair of Veterans Affairs at the Department of Psychiatry, UCSD School of Medicine. Dr. Afari will (1) Co-lead the CESAMH eScreening Core staff, (2) Oversee the overall scientific integrity of the proposed trial, (3) Assist in the writing of manuscripts for publication.

Laurie Lindamer, Ph.D. (Co-Investigator) has a joint appointment with the VA San Diego Healthcare System (VASDHS) as a Research Psychologist and Director of Education and Dissemination for the VA Center of Excellence in Stress and Mental Health (CESAMH) and with the University of California, San Diego (UCSD) as a Clinical Professor of Psychiatry. She will (1) Co-lead implementation planning and preparation with Dr. Pittman, and (2) Act as a point of contact for the research staff when Dr. Pittman is not available to collaborate.

Colin Depp, Ph.D (Co-Investigator) is a licensed clinical Staff Psychologist in the VA San Diego Healthcare System (VASDHS) and Associate Professor of Psychiatry at the University of California, San Diego (UCSD). On the proposed project, he will (1) lend his experience in suicidology and technology to oversee the overall scientific integrity of the proposed trial. He will also (2) assist in interpretation of study results, development of scientific publications arising from the study.

Dr. Rabin, Ph.D. is an Implementation Science expert who has extensive experience with implementation Science methodology in the context of the VA nationally. She is a faculty of the CESAMH Education and Dissemination Unit at VASDHS. Dr. Rabin will (1) lead the development of the qualitative and quantitative instruments using the Pragmatic Robust Implementation and Sustainability Model (PRISM), (2) lead the documentation of adaptations by adapting methodology and (3) provide training and ongoing guidance to

the external facilitators and the broader research and frontline team on documentation of modifications to the intervention and implementation strategy throughout the implementation period. She will also (3) Attend regular full project team and smaller implementation team meetings, (4) Be available for blended facilitation-related consultation as needed, (5) Serve as liaison to entities offering additional tools for and approaches to blended facilitation, and (6) Contribute to publications.

Erin Almklov, Ph.D. is a licensed clinical psychologists in the VASDHS. She will provide assistance and oversight for various study-related activities.

Jeffrey Hernandez will be involved in data management, administrative tasks, and IRB requirements.

Michael Lee will assist with study-related administrative tasks and data management.

John Gault, LCSW is a licensed clinical social worker. Under the supervision of the PI, he will be responsible for providing external facilitation for the implementation of eScreening. He will also assist with study coordination and other day-to-day study activities.

Sheba Andrew, LCSW is a license clinical social workers. Under the supervision of the PI, she will be involved with the collection of qualitative study data and other study-related duties.

## Section 22 - Bibliography

**22) List relevant articles that the IRB can use to provide necessary background for the protocol. Do not include an extensive NIH-grant-style bibliography. (Up to 5 recommended, but use more if needed to support the protocol or citations above.)**

Nelson HD, Denneson L, Low A, et al. Systematic review of suicide prevention in veterans. VA Evidence-based Synth Progr Reports. 2015.

Lawrence ST, Willig JH, Crane HM, et al. Routine, Self#Administered, Touch#Screen, Computer#Based Suicidal Ideation Assessment Linked to Automated Response Team Notification in an HIV Primary Care Setting. Clin Infect Dis. 2010.

Holzner B, Giesinger J, Pinggera, J et al. The Computer-based Health Evaluation Software (CHES): A software for electronic patient-reported outcome monitoring. BMC Med Inf Decis. 2012;12(126).

Pittman JOE, Afari N, Floto E, et al. Implementing eScreening technology in four VA clinics: A mixed-method study. BMC Health Serv Res. 2019.

Pittman J, Afari N, Rabin B et al. Empowering Veteran Healthcare with Technology: Veteran, Staff and Stakeholder Engagement to Develop and Implement eScreening. In: Symposium Presented at: 40th Annual Meeting of the Society of Behavioral Medicine. Washington, DC.

## Section 23 - Sponsors and Collaborators

**23) Clarify any industry financial or other support (e.g., NIH funds the study or Company X provides the assay kits). Identify non-VA Research collaborators and their role in this protocol, including whether or not they have access to subjects or identified data.**

Data will be transferred via encrypted VA email to and from study Co-Investigators. In addition, the PI and his approved study staff at VASDHS will be given access to Co-I Mor's (VA Pittsburgh Healthcare System, VAPHS) secure local VA shared study folder in order to directly access study data files containing identifiers from that folder. The data being shared from VA Pittsburgh Co-I will be maintained in their location on the local VA shared study folder. Only approved study staff identified by the PI, Dr. James Pittman, in San Diego, will access them directly from this drive. Data will be maintained on the local shared study folder until compiled and transferred to Dr. Pittman. After transfer, VA San Diego will assume responsibility for maintenance of the data, and local copies stored at VAPHS will be deleted.

Allison Hamilton, Ph.D. (VA Los Angeles; Co-Investigator) is an implementation science and qualitative methods expert. She will help provide oversight of qualitative data (e.g., staff interviews), but will not have access to identified data.

Bo Kim, Ph.D. (VA Boston; Co-Investigator) is a core investigator at CHOIR. She will provide expertise related to blended facilitation and qualitative data. She will not have access to identified data

Maria Mor, PhD (VA Pittsburgh; Co-Investigator) is Director of the CHERP Biostatistics and Informatics Core. She will be responsible for extracting a limited dataset as previously described from the electronic medical record (EMR) via the VA Corporate Data Warehouse and providing it to VASDHS research staff for analysis.

The Centralized Transcription Service Program (CTSP) at the VA Salt Lake City (Co-Investigator) will transcribe all staff interview data and provide it to VASDHS research staff.

Miguel Villodas, Ph.D. (non-VA Research Co-Investigator/Biostatistician) is an Assistant Professor in Department of Psychology at San Diego State University. As a senior biostatistician on this project, he will work closely with the principle investigators and the study team to provide all biostatistical and programming support for the study. He will only have access to aggregate de-identified quantitative data to provide statistical support.

Russell Glasgow, Ph.D. (Non-VA research; Implementation Science Consultant) is a Professor of Family Medicine at the University of Colorado. As a senior implementation science consultant for the proposed project, Dr. Glasgow will help Dr. Rabin and the research team evaluate the implementation, scalability, and sustainability of the eScreening multicomponent implementation strategy. He will also be available to provide ongoing consultation and guidance. He will not have access to identified data.

In the submission form, upload a copy of the grant, subaward, CRADA, etc. as applicable to the study.

## Section 26 - Conflict of Interest

### 26) Describe any financial interests or other conflicts related to this study: (see ? for instructions on this item)

Niloofer Afari, James Pittman, and Elizabeth Floto are named as inventors on a pending provisional patent application that was submitted through the VA Technology Transfer Program (TTP). The VA ID No. is 2018-359 entitled, "Methods And Systems For Comprehensive Patient Screening." Our understanding is that the VA would be the patent owner if the patent is eventually approved as non-provisional.

The claims of the provisional patent application that was submitted by the TTP describe the functionality of a previous version of eScreening. In July 2018, we submitted an application to the TTP for the VA eScreening program, which was sponsored by our ACOS for Research Dr. Gerhard Schulteis. Our intention was to make eScreening available outside the VA consistent with the mission of the VA Technology Transfer Program (TTP): to facilitate the commercialization of VA inventions to benefit Veterans and the American Public. As part of the application we each signed an inventor certification which included the following statement "I hereby voluntarily assign my entire right, title, and interest in and to the above identified invention to the United States Government. I do not desire a Determination of Rights under 37 CFR Part 501."

The eScreening Project does include evaluation of the impact of eScreening on speed and rate of mental health screening for Veterans in the VA (AIM 1), but it is only one of several similar technology based screening systems (Behavioral Health Lab; Mental Health Assistant PRO; Clinical Dashboard) currently used inside and outside the VA. In addition, A 2016 review article by Lyon and colleagues documented 49 similar technology systems available outside the VA. As such, we believe the proposed study results may impact the evidence base related to screening technology, but it will not affect the value of the patent application.

## Section 27 - Privacy, Confidentiality, and Information Security

27a) Provide a brief description of how participant privacy and confidentiality will be protected in this study. Describe the circumstance under which it may be possible for a research team member to identify subjects and any related protections or assurances to prohibit or avoid identification. Describe how the number of people with access to identifiers for research purposes is limited in order to protect a participant's privacy.

All electronic data will be stored within the VA secure network in the PI's VASDHS R: drive folder (R: \PIfolders\Pittman) and will be accessed only by approved study personnel using VA secured workstations. All paper records will be kept in locked cabinets in a locked room. In the event of a real or suspected breach of security, the VA Police, the VA Information Security Officer, and the VA Privacy Officer will be notified.

**27.b) Entry of a CPRS Research Informed Consent Note is required when subjects will be admitted as inpatients or treated as an outpatients for research and the study involves research medical care or may affect medical care.**

- *If a Research consent Note is required, then a Research Progress Note should also be entered for each procedure or intervention.*
- *Scanning the Consent and HIPAA Authorization into CPRS is not required. Linking the Consent to the Research Informed Consent Note may be permitted and can be useful for trials involving the Research Pharmacy or when research will be performed in conjunction with clinical procedures.*
- *For Non-Veterans, if Research Informed Consent Notes are entered, then the NOPP Acknowledgment must be scanned into the record. Otherwise a copy of the signed NOPP must be retained with the Investigator's research records and a copy sent to the Privacy Officer; see the [? Help](#) for more information.*

27.b1) Is entry of CPRS notes required based on the above criteria?

- ☐ CPRS notes are needed for ALL subjects
- ☐ CPRS notes are needed for SOME subjects
- ☒ CPRS notes are NOT needed for any subjects

**27c) Select the VA Sensitive Information (VASI) use category**

- ☐ This study does not collect or use any VASI
- ☐ This study uses but does not save, collect, copy, or record VASI
- ☒ This study does collect or record VASI

## Section 27.1 VA Sensitive Information (VASI)

**27.1a) For each type of VASI, indicate all that apply:**

Indicate which of the following will be collected/recorded:

- ☒ Protected Health Information (PHI)
- ☒ Names
- ☐ Device identifiers and serial numbers
- ☒ E-mail addresses
- ☐ Medical record numbers
- ☐ URLs (Universal Resource Locator)
- ☒ All elements of dates (except year) or any age over 89
- ☐ Health plan beneficiary numbers
- ☐ IP Addresses (Internet Protocol)
- ☒ Telephone numbers
- ☐ Account numbers
- ☐ Biometric Identifiers including finger and voice print
- ☒ Fax numbers
- ☐ Certificate or license numbers
- ☐ Full face photographic images and comparable images
- ☐ All geographic subdivisions smaller than a state
- ☐ Vehicle ID and serial numbers including license plate numbers
- ☐ Social security numbers or scrambled SSNs (describe below)
- ☐ Other unique identifying number, characteristic, or code (describe below)

**27.1b) Consent Forms and/or HIPAA Authorization**

☒ Yes ☐ No

**27.1c) Images with personal identifiers are used for this study (x-rays, MRI images with patient names, record numbers, dates, etc.)?**

☐ Yes ☒ No

**27.1d) Photos with faces or audio video recordings are used for this study.**

☒ Yes ☐ No

27.1d1) Identify the device or devices that will be used to take/make the photographs or recordings.

Audio recording device - the Pocket Memo Voice Recorder DPM8000 or Olympus 7000 Voice Recorder.

27.1d2) Identify where images will be stored (e.g., in the medical record, with study hardcopy records, with study electronic VASI records)

The digital audio recordings will be uploaded to a folder in the PI's VASDHS R: drive folder (R:\PIfolders\Pitman) immediately following the session for secure storage and the information will be deleted from the recorder. The audio recordings will be transcribed by Dr. Susan Zickmund, a Research Scientist at the Veteran Health Administration Salt Lake City and Director of the VA HSR&D-funded Centralized Transcription Services Program (CTSP). Any named individual or location discussed will be struck from the text record to avoid a potential breach in confidentiality.

**27.1e) Biological specimens with identifiers are used for this study.**

☐ Yes ☒ No

## Section 27.2 Data Collection, Tools, and Resources

**27.2a) Will any specially obtained software be used?**

☒ Yes ☐ No

27.2a1) Describe the software, and identify license requirements and the ownership of the software or license. Identify on what computer/network the software will be used (e.g., VA, VA Research/VMRF, local hard drive) and any data that will be stored in temporary files on the computer's hard drive

We will use a secure online survey system (i.e., Qualtrics) to collect field note data as well as survey elements based on the PRISM and its RE-AIM outcomes. ATLAS.ti software will be used to analyze qualitative data. Stata and SPSS 26.0 will be used to analyze quantitative data.

**27.2b) Will any mobile devices (laptop, tablet, portable hard-drive, etc.) be used in support of this study?**

☒ Yes ☐ No

27.2b1) Provide details of the device/s. Indicate whether the device is FIPS 140-2 encryption validated and confirm that the device is listed in the VA EIL. Provide details regarding the nature of the data that will be stored or transmitted on the device and confirm whether a copy of all data will be stored on the VA network.

The VA eScreening program is a web-based technology that can be accessed using my VA access portal credentials. Individual sites may choose to provide devices such as iPads based on their implementation strategy. These devices are not considered part of the research. Devices used by clinical programs as part of routine care will transmit data using a VA secure VA access portal and do not store data.

**27.2c) Does the study require use of an electronic data capture system?**

☒ Yes ☐ No

27.2c1) Provide the web address, details regarding their security features, the nature of the data involved, and the research purpose. Also include a description of how VA retains a copy of the data entered into the system.

The VA eScreening program allows for de-identified extraction of data originally collected for clinical use. This option will be used for this protocol. When the deidentified export option is selected clinical data are exported directly into a CVS or Microsoft Excel format in accordance with VHA Handbook 1605. Appendix B.

**27.2d) Will any other web-based applications be used (e.g., for recruitment, completing online questionnaires, or processing data)?**

☒ Yes ☐ No

27.2d1) Provide the web address, details regarding their security features, the nature of the data involved, and the research purpose. Also include a description of how VA retains a copy of the data generated using these tools.

We will use a secure VA approved online survey system (i.e., Qualtrics) to collect data from staff participants about implementation and to collect field note data. All electronic data will be stored on a secure research drive on our VA network, accessible only to VA research personnel associated with the proposed study.

**27.2e) Will coded data that excludes personal identifiers be used? Coded data excludes *all* HIPAA identifiers (per VHA Handbook 1605.1 Appendix B), including dates**

☒ Yes ☐ No

27.2e1) Identify where the code key is stored and in what format (electronic, paper).

For staff participant data: electronic records will include a password-protected key linking participant numbers with subject names, which will be stored separately from the data. Paper records will be coded by participant number only and will not include names. All paper records will be kept in locked cabinets in a locked room.

EMR data will not be coded.

## Section 27.3 Data Sharing and Transportation

**27.3a) Does this study involve collecting, sharing or transporting any type of data outside of the local VA?**

☒ Yes ☐ No

**27.3b) This study collects VASI outside of VA (i.e., at a non-VA location).**

☐ Yes ☒ No

**27.3c) VASI is transported outside of VA for any purpose other than sharing.**

☐ Yes ☒ No

**27.3d) PHI may be disclosed to monitoring/auditing agencies by HIPAA Authorization. *Note: The Research Office must be notified when monitors come to audit***

☒ Yes ☐ No

**27.3e) Data may be shared with collaborators or others in the conduct of this protocol.**

☒ Yes ☐ No

27.3e1) Describe the data to be shared or disclosed, the entities to which the data are to be disclosed, how the data are to be transmitted, and how the transmitted data will be stored, retained, destroyed, and/or further disclosed and to whom. This includes data from individual subjects as well as other data developed during the research such as the analytic data and the aggregate data. For PHI and VASI, indicate the authority/ies permitting the sharing or disclosure of data (HIPAA Authorization, Limited Data Set, Data Use Agreement, VA Form 10-5345-Request for and Authorization to Release Health Information., etc.).

A limited dataset of EMR data collected from the VA Medical Record via the VA Corporate Data Warehouse will be extracted by a Co-Investigator at VA Pittsburgh and provided to VASDHS research staff for analysis. In order to feasibly share this data, the PI and his approved study staff at VASDHS will be given access to Co-I Mor's (VA Pittsburgh Healthcare System, VAPHS) secure local VA shared study folder in order to directly access study data files containing identifiers from that folder. The data being shared from VA Pittsburgh Co-I will be maintained in their location on the local VA shared study folder. Only approved study staff identified by the PI, Dr. James Pittman, in San Diego, will access them directly from this drive. Data will be maintained on the local shared study folder until compiled and transferred to Dr. Pittman. After transfer, VA San Diego will assume responsibility for maintenance of the data, and local copies stored at VAPHS will be deleted.

Data collected from staff participants (e.g., interview/survey data) may be shared to be analyzed and interpreted with the previously listed collaborators. This data will contain no identifiers and will be sent via secure VA encrypted email; and while being analyzed, will be stored on a password-protected computer by the collaborators.

## Section 27.4 Research Record Storage and Retention

For each type of record, indicate whether it is collected for this study

### 27.4a) Hardcopy records/data (includes paper, pictures, film, etc.)

☒ Yes ☐ No

27.4a1) Identify precisely where hardcopy data will be stored to include physical site, building, and room number, etc. For each location identify whether VASI or non-sensitive information is stored at that location. For VASI, identify how the data is secured.

Hardcopy data, including VASI, will be stored in a locked cabinet in the PI's locked office (building 1 room 2306A) and in a locked cabinet in the PI's locked lab office (building 1 room 2324).

27.4a2) Are all of the above locations at VA?

☒ Yes ☐ No

### 27.4b) Electronic study records (includes computer files, removable disk files, digital files, etc.).

☒ Yes ☐ No

27.4b1) Identify precisely where **non-sensitive** electronic records/data will be stored to include the full map drive, network location/server name, etc., and a brief description of what data/information is stored at each location.

All non-VASI data will be stored electronically within the VA secure network in the PI's VASDHS R: drive folder (R:\PI-folders\Pittman).

27.4b2) Identify precisely where **VASI** electronic records/data will be stored to include the full map drive, network location/server name, etc., and a brief description of what data/information is stored at each location.

If no VASI is collected or recorded for this study, simply indicate that the "Study does not collect or record VASI".

All VASI data (i.e., names, email addresses, telephone/fax numbers) will be stored electronically within the VA secure network in the PI's VASDHS R: drive folder (R:\PI-folders\Pittman).

27.4b3) Are any of the locations described in 27.4b outside of the VA Secure Network? *Note: this includes storage on a computer local hard drive.*

☐ Yes ☒ No

**27.4c) Record Retention - VHA requires compliance with Records Control Schedule (RCS-10) for retention of electronic and hard copy records. Following study closure, these temporary records must be retained for six years and then destroyed. Longer retention may be permitted if required by other Federal regulations or requirements. Will RCS-10 requirements be followed (i.e., 6-year retention)?**

☒ I will adhere to VHA Records Control Schedule-10 requirements

☐ I request an exception to RCS-10 requirements

## Section 27.5 Additional Privacy or Information Security Details

Provide any other privacy or information security details here.

NA

## Section 27.6 Attestations

In the event of real or suspected breach of security, the Information Security Officer, Privacy Officer, VA Police (if appropriate), and the individual's supervisor will be notified within one hour of learning of the event.

☒ Agree ☐ Disagree

Study staff will be up to date on any required VHA Privacy Policy and Information Security training or they will not be allowed access to VA Sensitive Information.

☒ Agree ☐ Disagree

Access to research sensitive information, if any, will be removed when study personnel are no longer part of the research team.

☒ Agree ☐ Disagree

At least one copy of all study records (whether sensitive or non-sensitive) will be retained under VA control and only destroyed in compliance with the approved Records Control Schedule

☒ Agree ☐ Disagree

The VA retains ownership of the research data. Should the investigator leave the VA, custody of the research records will be assigned to another investigator and the Research Service notified in writing, or custody of the research records will be transferred to the Research Service.

☒ Agree ☐ Disagree

## Section 28 - Protocol Association to New or Existing Project

28) Is this a new R&D Project? Before you go on to complete the *Initial Review Submission Form* (which is used for attachments), please address the association of this Protocol to an R&D Committee Project. This Protocol may represent a new R&D Project, or it may be an additional Protocol under an existing R&D Project (such as when a single grant supports multiple Protocols). Will this Protocol be submitted to the R&D Committee as a new Project?

☒ Yes ☐ No

**The Protocol Application is now complete for a Protocol that will also be a new R&D Committee Project.**

**Next you will go on to the Initial Review Submission Form which is used to package up the Protocol Application and any needed attachments and submit them to the IRB.**

Click on *Save and Continue*

