Introduction Page

1 * Abbreviated Title:
Evidence-Based Multidimensional Pain Self-Management Planning: Personalized by and for Veterans via Web-Based Application

2 * Full Title:
Evidence-Based Multidimensional Pain Self-Management Planning: Personalized by and for Veterans via Web-Based Application

3

* Select Type of Submission:

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

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

4 Original Version #:
HP-00086659

Research Team Information

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

CITI Training:

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

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

CITI Training:

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

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

	Name	Edit Submission	cc on Email	Research Role	Has SFI?	CITI Training
View	Bernadette Siaton	no	no	Research Team Member	no	ID00000046
View	Chad Wessinger	yes	yes	Study Coordinator	no	
View	Heidi Ortmeyer	yes	yes	Research Team Member	no	
View	Alice Ryan	yes	yes	Research Team Member	no	ID00012869

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

ID: VIEW4DF85C16F2800
Name: v2_Research Team Information

Resources

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

1 * Describe the time that the Principal Investigator will devote to conducting and completing the research:
Dr. Hogans will be devoting 35% effort to this research project, the work is slotted for support by a VHA eSPiRE research grant.

2 * Describe the facilities where research procedures are conducted:
VA Maryland Health Care System.

This study consists of three phases: focus group, pre-pilot, and pilot phases.

The focus group study will occur at the Loch Raven VA where there is a GEROFIT exercise program. We have previously met informally with some Veterans in this program as part of preparatory to research queries. This facility include a gym and meeting space. We will meet with the focus group Veterans in the meeting space adjacent to the gym.

The pre-pilot phase will involve one-on-one interviews with Veterans. The Veterans will be recruited from the Empower Veterans Program, meeting at the Loch Raven VA, and from the Women's clinic at Fort Meade. The Veteran will be invited to attend a one-on-one interview session at the VAMHCS main hospital. The GRECC is based there and there are private counseling rooms available for these sessions. In the event that the study participant is not comfortable with coming to the VAMHCS main building, we will identify alternative sites that meet the criteria for the participant's comfort and privacy.

The pilot phase will involve one-on-one interviews with Veterans as well as phone interviews. The Veteran will be invited to attend a one-on-one interview sessions at the VAMHCS main hospital. The GRECC is based there and there are private counseling rooms available for these sessions. In the event that the study participant is not comfortable with coming to the VAMHCS main building, we will identify alternative sites that meet the criteria for the participant's comfort and privacy.

This research project is based in the Maryland VA GRECC located in 4B area of the VAMHCS main building. The PI and co-investigators have dedicated office and meeting space as well as computational resources and access to statistical consulting.

3 * Describe the availability of medical and/or psychological resources that subjects might need as a result of anticipated consequences of the human research:
The study will be carried out by Dr. Hogans and staff in the context of the VAMHCS Geriatric Research Education and Clinical Center (GRECC). In addition to GRECC resources which include IRB support-staff and recruitment and study coordination staff, the project has paid effort from Dr. Lavin, director of the pain center at VAMHCS and two clinical psychologists, Dr. Perra and Dr. Buenaver.

The VA does provide medical and/or psychological treatment for participants who take part in VA research, as outlined in the mandated VA consent form. In this minimal risk study, we do not anticipate that participants will need any additional treatment.

4 * Describe the process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions:
Study staff working on this protocol will have been specially trained in working with participants with chronic pain. Their assigned duties on this project will be described to them in detail prior to working with research participants. They will then be consistently guided through ongoing study team meetings and trainings. All staff listed on the protocol are extensively trained on obtaining informed consent, as well as study assessments and App use. Study staff practice study procedures beforehand and are observed a number of times prior to meeting with research participants independently. Supervision of staff is always of the highest quality and remains a top priority for our research group.

Sites Where Research Activities Will Be Conducted

1 * Is this study a:

- ○ Multi-Site
- ● **Single Site**

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

○ Yes ● **No**

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

○ Yes ● **No**

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

Name	Created	Modified Date

There are no items to display

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

○ Yes ● **No**

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

○ Yes ● **No**

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

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

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

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

Funding Information

1 * Indicate who is funding the study:

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

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

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

3 Please discuss any additional information regarding funding below:

DHHS Funded Study

You indicated that this is a Federally funded study.

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

○ Yes ● **No**

2 You may upload any grant documents here:

Name	Created	Modified Date
VASpecific Aims and _Research_Plan final 2019MAR11.pdf(0.01)	8/16/2019 1:57 PM	8/16/2019 1:57 PM

ID: VIEW4DF87B9560800
Name: v2_DHHS Funded Study

Federal Agency Sponsor Contact Information

You indicated that this is a Federally funded study.

1

* Agency Name:
VA Office of Research and Development

* Address 1:
810 Vermont Ave NW

Address 2:

* City:
Washington

* State:
DC

* Zip Code:
20571

* Contact Person:
kristy.benton-grover@va.gov

* Phone Number:
2024435728

* Federal Agency Email:
kristy.benton-grover@va.gov

Grant Number 1 (if applicable):
RX003169-01A1- OR - Check here if Grant 1 is not assigned a number. ☐

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

PI of Grant 1:

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

If Grant 2 has no number, please provide the following information:
Title of Grant 2:

PI of Grant 2:

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

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

PI of Grant 3:

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

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

PI of Grant 4:

Research Protocol

1 * Do you have a research protocol to upload?

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

2 If Yes, upload the research protocol:

Name	Created	Modified Date
There are no items to display		

ID: VIEW4E00563F8D000
Name: v2_Research Protocol

Risk Level

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

* Choose One:

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

ID: VIEW4E02805225800
Name: v2_Risk Level

Exempt Categories

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

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

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

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

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

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

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

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

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

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

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

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

☑ **The research does not qualify as Exempt.**

Type of Research

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

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

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

(●) **Yes** ( ) No

Lay Summary

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

Chronic low back pain is the #1 cause of disability and low quality of life in Veterans. Pain is a huge burden- stealing enjoyment, fulfillment, and time. Sometimes surgery, injections, or medications can help but sometimes not. Although no one solution fixes chronic low back pain, there are many treatments that can reduce pain impact and restore quality of life. These treatments involve: movement, psychology, mind-and-body therapies, sleep, and environmental factors. The challenge is how to best coordinate these treatments for chronic low back pain. We've built a prototype mobile application that delivers the latest information to Veterans so they can work with healthcare providers to build their own pain self-management plans. With this new tool, the Veteran has data at hand and choses their preferred pain self-management activities, making a coordinated plan that can be shared with their healthcare team. Our goal is giving Veterans the knowledge and power to 'plan the work and work the plan' for chronic low back pain: restoring value, fulfillment, and meaning.

ID: VIEW4E02805CF7000
Name: v2_Lay Summary

Justification, Objective, & Research Design

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

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

The purpose of this study is to develop and pilot test a novel App, in tablet-based form, to engage Veterans and providers in developing personalized, pro-active C-MEPPS for chronic low back pain. Our vision is an appealing user interface that increases Veteran access to self-management strategies, reliable information, and improved rehabilitative outcomes. The goal is to reduce pain impact and increase functional outcomes. This SPiRE effort will build and pilot test a web-based application empowering Veterans to overcome cLBP with a coordinated multidimensional evidence-based plan for pain self-management created by the Veteran. The specific aims of this project are aligned with primary Veterans Health Administration (VHA) strategic objectives, especially Strategy 1.1.2: "VA focuses on outcomes to tailor Veteran choice"; and: "Online navigator tools/information empowers Veterans to make decisions". This project responds to Rehabilitation Research and Development priorities: "Non-pharmacological activity-based interventions for chronic pain impacting outcomes that may include pain reduction… and QoL." Our secondary goal is to provide primary care and specialty services at VHA a novel, innovative, technologically appropriate, informative, and readily available tool in the fight against debility and poor health in Veterans with chronic low back pain.

Specific Aims:

1) To develop and pilot test a web-based application for Veterans, including women Veterans and older Veterans, applying User-Centered Design principles, empowering Veterans to build and use coordinated multidimensional evidence-based plans for pain self-management, aligned with each Veteran's preferences, interests, and strengths.

2) To promote behavior change targeting rehabilitative outcomes by identifying potential barriers to App use, e.g., usability and use, and by acquiring pilot data regarding future direction rehabilitative outcomes, including objective measures, e.g., physical activity, sleep duration, and patient-reported outcomes such as pain interference and improved quality of life.

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

This is a mixed-methods pilot study to further develop and test a novel custom-built web-based application, to assist Veterans and their providers in developing coordinated multi-dimensional evidence-based plans for pain self-management (C-MEPPS).

Procedures:

Phase 1: Veteran focus group

• Single occasion, focus group discussion: Up to five Veterans, recently graduated from the Empowering Veterans Program at the Baltimore-Loch Raven VA will meet during the first quarter of funding for this program. The group will be introduced to the prototype App on tablet computers. Using open semi-structured interviews, we will explore their use of non-pharmacological pain self-management strategies, with special attention to understanding use of language and how existing strategies link to labels and the values they associate with each. A total of five interface options will be included, to assess appeal, perceived navigability of these options, and input on design features and usability. Brief questionnaires will be completed at the end of the focus group session and compensation for participation will be distributed. (Site: Loch Raven VA)

Phase 2: Veteran Pre-pilot group

• Single one-on-one interview: Using open semi-structured interviews, we will explore their use of non-pharmacological pain self-management strategies, with special attention to understanding use of language and how existing strategies link to labels and the values they associate with each. A total of five interface options will presented to the interview subjects and rated for appeal, perceived navigability, design features, and usability. Validated questionnaires will be completed, see details below. Compensation for participation will be distributed.

o Five Veterans from Empowering Veterans Program at the Baltimore-Loch Raven VA; (Site: Loch Raven VA)

o Five female Veterans from the Women's health clinic; (Sites: Baltimore VAMHCS and Fort Meade VA)

Our pre-pilot objective is to reach two groups of Veterans: 1) 5 Veterans completing the EVP (Empower Veterans Program) and 2) 5 Veterans attending the Women's Health Clinic, in collaboration with Dr. Staropoli, Director of Women's Health for VAMHCS. This will provide important feedback for the experience of two different groups: the first group is experienced with non-pharmacological, values-based, approaches to pain management including CBT, ACT, MBSR, and others. The Women's Health Clinic group may not have had formal exposure to non-pharmacological pain management and may require additional information or resources to attain maximal benefit from C-MEPPS. The goal is an App that is useful to the broadest number of Veterans. We will include at least 4 older Veterans among the 10 recruited so the App can be developed with input from older Veterans accessing whole-health integrative approaches to pain self-management.

Phase 3: Veteran Formal pilot testing group

• Multiple visits, phone interviews, and activity monitoring. Once feedback from the pre-pilot group is obtained and further modifications incorporated into READY-GO Pain, the App will be tested with a pilot group.

• 20 Veterans with cLBP a balance of middle-aged and older male and female veterans.

• The study procedures will include:

o Recruitment: the study will be introduced to potential study subjects by the PI, study investigators, colleagues, or the study coordinator

o Consent: the study will be described in detail to the potential study subjects by PI, study investigators, or the study coordinator. If the study subject agrees to participation, they will be given a pain diary to bring back at the time of the initial visit in 2 weeks time.

o Initial visit: the study subject will be introduced to the tablet App and instructed in use, all questions will be answered. The study subject will complete brief questionnaires pertaining to pain, sleep, quality of life, prior App experience, and pain interference. The study subject will be fitted with an actigraph and instructed in the use of the device.

o 1st followup phone call: The study subject will be contact by phone one week after the initial visit. Coaching on App use and troubleshoot of App and actigraph use will be provided. Brief pain and pain interference questionnaires will be administered.

o 1st follow up visit: the study subject will be introduced to the tablet App and instructed in use, all questions will be answered. The study subject will complete brief questionnaires pertaining to pain, sleep, quality of life, prior App experience, and pain interference. The study subject will be fitted with an actigraph and instructed in the use of the device.

o 2nd followup phone call: The study subject will be contact by phone one week after the initial visit. Coaching on App use and troubleshoot of App and actigraph use will be provided. Brief pain and pain interference questionnaires will be administered.

o 3rd followup phone call: The study subject will be contact by phone one week after the initial visit. Coaching on App use and troubleshoot of App and actigraph use will be provided. Brief pain and pain interference questionnaires will be administered.

o 4th followup phone call: The study subject will be contact by phone one week after the initial visit. Coaching on App use and troubleshoot of App and actigraph use will be provided. Brief pain and pain interference questionnaires will be administered.

o Final visit: the study subject will be introduced to the tablet App and instructed in use, all questions will be answered. The study subject will complete brief questionnaires pertaining to pain, sleep, quality of life, prior App experience, and pain interference. The study subject will be fitted with an actigraph and instructed in the use of the device.

o Final follow up phone call: The subject will be briefly interviewed two weeks after final visit for final thoughts about the App use experience and any plans to change behaviors as a result of using the App for activity planning.

We will examine pilot data on usability, App use, and behavior change, and assess barriers to implementing changes planned by the Veteran through the App (failure mode analysis). The vision is that this will lead to future research on rehabilitation-oriented outcomes such as: functional measures, QoL, and pain.

Actigraph is a widely used activity meter, that non-invasively assesses the physical activity of the wearer. It is non-painful and non-invasive. It can be put in place and taken off by the study participant at will. As noted by the manufacturer: "ActiGraph is ISO-13485:2016 certified, and our activity monitors are FDA 510(k) cleared Class II medical devices in the U.S. and adhere to regulatory standards worldwide."

Because Veteran privacy is a major concern for all VA research, we have designed this study to take additional steps to protect Veteran privacy. In this pilot study, we will not use the internet to deliver or receive information to/from our study participants. The pain self-management App in this study will be provided on a tablet that will not transmit information.

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

Coordinated pain self-management planning reduces reliance on opioids: using instead physical activity, mental health strategies, mind-body practices such as Yoga, sleep optimization, medication safety, and improvements in environmental factors such as social supports and home safety.12-16,18-21 Coordination of care is a time-intensive clinical activity that is highly dependent on practitioner education, experience, and proficiency.13 This is a novel, scalable solution to a major public health problem impacting Veterans of all ages.

The value of an App for chronic pain self-management was examined in preliminary studies. We gathered preliminary impressions about the experience of potential users, utilizing the prototype App. There was tremendous enthusiasm on the part of clinicians for a solution to promote patient engagement with effective pain self-management activities. One provider said “Wow, this would be really great to have for use with my patients”. Providers were excited to learn about the evidence-based studies that have recently reported on effectiveness of pain self-management, Table 4. They were very interested to have a tool that would link patients to evidence-based practices and wanted to be able to use the app themselves to encourage patients in using effective non-pharmacological activities. We’ve had interest from CLC, primary care, and specialty care providers. Next, we met informally with a group of several Veterans, during a coffee break at the VAMHCS GRECC GeroFit program. These older Veterans navigated the App prototype easily and quickly grasped the concept of putting together a plan. They described it as ‘helpful’, ‘liked the diary/tracker’, and liked the colorful interface. Several Veterans wanted to know: “When will the App be available?”

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

Chronic low back pain (cLBP) causes more disability than any other condition worldwide and affects 33% of Veterans1-3 impairing functional capacity, quality of life, and mental health, while increasing medication reliance and substance abuse.4,5 In Veterans, co-occurrence of chronic pain with mental health and substance use conditions, and opioid treatment increases suicide and inadvertent death5-7. Severe cLBP, defined as interfering greatly with normal activity and present on most or all days, affects 20% of Veterans with cLBP.1

Interventions to improve functional outcomes and reduce health burdens are a major priority for VA.8 Despite cLBP having a profound impact on health, it is not well understood and simple therapies have not worked. One potential key is that cLBP is a form of chronic pain, i.e. pain that persists beyond the period of normal healing. Prevalent in older adult and women Veterans, chronic pain leads to poor mental and physical health, is devastating to cognition and function, and importantly requires informed management.1,9-16

Conceptual Framework. In the last year, systematic reviews have laid a new foundation for pain self-management. Now, there is a huge unmet need for innovative tools for knowledge transfer to patients and providers: i.e., a roadmap to coordinate evidence-based pain-reducing activities into daily life.11-16 The need is acute because as we’ve shown previously, medical graduates have little or no training in pain and pain self-management.17 Although single self-management activities, e.g. moderate exercise, may decrease pain slightly, multi-dimensional evidence-based pain self-management has superior outcomes.10,18,19 The goal of comprehensive pain management is connecting patients with personalized coordinated multi-dimensional evidence-based plans for pain self-management (C-MEPPS).16,20 Pain self-management usually occurs through collaboration between patient and provider; the patient acquires a tailored, multidimensional evidence-based plan leading to pain consuming less of the patient’s life, Figure 1.12,13,21 Positive, health-focused, value-based activities become the focus of attention. In the process, pain becomes a footnote in the patient’s life, not gone, but no longer dominant20. C-MEPPS can be an important element of successful management of chronic pain including low back pain, headache, and arthritis.18-21 By contrast, unstructured self-management shows lower efficacy.20

Current status. Right now, creating C-MEPPS requires patient and provider to invest hours of effort to work through the activities appropriate for pain self-management, and to assemble the options in a coordinated manner. One major component is time to discuss how various options impact pain outcomes, another component is discovering what activities appeal to the patient. Creating C-MEPPS in the traditional manner is severely limited by health system constraints22, amplified by the absence of training in comprehensive pain management17. Although the VA “supports self-management as the foundation for all steps of pain care…”, at present, innovative evidence-based tools supporting pain self-management are a major need. 22-25

Our solution: A novel, scalable roadmap for pain self-management using peer-reviewed evidence; aligned with values-oriented approaches, like those of the Atlanta VA Empower Veterans Program.26 Our goals are: a) empowering Veterans to learn about appealing and effective choices for pain self-management, b) supporting Veterans in combining appropriate activities for coordinated pain self-management and c) engaging Veterans in planning change and effective lifestyle management, creating C-MEPPS through use of a mobile App: READY-GO Pain. The App currently exists as a hyperlinked graphical interface but requires further development and pilot testing during the period of this SPiRE proposal. Web-encoding has already started with GRECC seed funds. The App will provide Veterans with brief psychoeducation about chronic pain self-management, evidence-based options for pain control, a concrete Veteran-designed plan, a simple way to track activities, and reports to share with the healthcare team.

Supporting Literature

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

Low back pain affects 1 in 3 Veterans. Surgery isn't appropriate for most back pain and interventional care has limited impact on long-term outcomes. Robust evidence supports broader use of non-pharmacological therapies such as physical activity, mind-body activities, psychoeducation, and strategies such as pacing and sleep hygiene for chronic pain. Potentially, the most effective approach is referral to a comprehensive pain management program involving an interprofessional team of physicians, nurses, pharmacists, physical therapists, clinical psychologists and others. These programs lead to creation of coordinated multi-dimensional, evidence-based plans for pain self-management (C-MEPPS) tailored to each patient. This approach, while effective, is extremely resource intensive; and access is limited by health system factors.

Because the number of patients with chronic low back pain (cLBP) far outstrips the health system capacity for comprehensive management, novel scalable solutions that increase patient access to effective therapies are of high priority. One approach is to train primary care providers to engage patients in multidimensional evidence-based plans for pain self-management, and to negotiate the development of C-MEPPS in the context of a primary care visit. While hypothetically appealing, the feasibility of multiple 40-minute counseling sessions in primary practice where the typical visit lasts less than 20 minutes and needs to address a full spectrum of medical needs is not tenable. Alternatives are essential. Our program aims to accelerate knowledge transfer and support primary care providers and patients in pain self-management. We will connect patients and providers to the broader spectrum of evidence-based therapies and facilitate positive behavior change.

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2 If available, upload your applicable literature search:

Name	Created	Modified Date

There are no items to display

Study Procedures

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

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

Patients will be recruited from multiple clinics and intentionally include older and female Veterans. The study coordinator will recruit and consent Veterans. There are three study groups including focus group, one-on-one interview group, and pilot study group. Veterans will be recruited separately for each of these study groups, necessitating separate consent forms.

Procedures:

Phase 1: Veteran focus group
• Single occasion, focus group discussion: Up to five Veterans, recently graduated from the Empowering Veterans Program at the Baltimore-Loch Raven VA will meet during the first quarter of funding for this program. The group will be introduced to the prototype App on tablet computers. Using open semi-structured interviews, we will explore their use of non-pharmacological pain self-management strategies, with special attention to understanding use of language and how existing strategies link to labels and the values they associate with each. A total of five interface options will be included, to assess appeal, perceived navigability of these options, and input on design features and usability. Brief questionnaires will be completed at the end of the focus group session and compensation for participation will be distributed. (Site: Loch Raven VA)

Phase 2: Veteran Pre-pilot group
• Single one-on-one interview: Using open semi-structured interviews, we will explore their use of non-pharmacological pain self-management strategies, with special attention to understanding use of language and how existing strategies link to labels and the values they associate with each. A total of five interface options will presented to the interview subjects and rated for appeal, perceived navigability, design features, and usability. Validated questionnaires will be completed, see details below. Compensation for participation will be distributed.
o Five Veterans from Empowering Veterans Program at the Baltimore-Loch Raven VA; (Site: Loch Raven VA)
o Five female Veterans from the Women's health clinic; (Sites: Baltimore VAMHCS and Fort Meade VA)

Our pre-pilot objective is to reach two groups of Veterans: 1) 5 Veterans completing the EVP (Empower Veterans Program) and 2) 5 Veterans attending the Women's Health Clinic, in collaboration with Dr. Staropoli, Director of Women's Health for VAMHCS. This will provide important feedback for the experience of two different groups: the first group is experienced with non-pharmacological, values-based, approaches to pain management including CBT, ACT, MBSR, and others. The Women's Health Clinic group may not have had formal exposure to non-pharmacological pain management and may require additional information or resources to attain maximal benefit from C-MEPPS. The goal is an App that is useful to the broadest number of Veterans. We will include at least 4 older Veterans among the 10 recruited so the App can be developed with input from older Veterans accessing whole-health integrative approaches to pain self-management.

Phase 3: Veteran Formal pilot testing group
• Multiple visits, phone interviews, and activity monitoring. Once feedback from the pre-pilot group is obtained and further modifications incorporated into READY-GO Pain, the App will be tested with a pilot group.
• 20 Veterans with cLBP a balance of middle-aged and older male and female veterans.
• The study procedures will include:
o Recruitment: the study will be introduced to potential study subjects by the PI, study investigators, colleagues, or the study coordinator
o Consent: the study will be described in detail to the potential study subjects by PI, study investigators, or the study coordinator. If the study subject agrees to participation, they will be given a pain diary to bring back at the time of the initial visit in 2 weeks time.
o Initial visit: the study subject will be introduced to the tablet App and instructed in use, all questions will be answered. The study subject will complete brief questionnaires pertaining to pain, sleep, quality of life, prior App experience, and pain interference. The study subject will be fitted with an actigraph and instructed in the use of the device. A 6-minute walk test will be completed. The Veteran will be given the tablet, loaded with the App, to take home and bring back at the follow-up and final visits.
o 1st followup phone call: The study subject will be contact by phone one week after the initial visit. Coaching on App use and troubleshoot of App and actigraph use will be provided. Brief pain and pain interference questionnaires will be administered.
o 1st follow up visit: the study subject will be coached regarding the tablet App and actigraph use, all questions will be answered. The study subject will complete brief questionnaires pertaining to pain, sleep, quality of life, prior App experience, and pain interference. The study subject will be fitted with an actigraph and instructed in the use of the device.
o 2nd followup phone call: The study subject will be contact by phone 3 weeks after the initial visit. Coaching on App use and troubleshoot of App and actigraph use will be provided. Brief pain and pain interference questionnaires will be administered.
o 3rd followup phone call: The study subject will be contact by phone 4 weeks after the initial visit. Coaching on App use and troubleshoot of App and actigraph use will be provided. Brief pain and pain interference questionnaires will be administered.
o 4th followup phone call: The study subject will be contact by phone 5 weeks after the initial visit. Coaching on App use and troubleshoot of App and actigraph use will be provided. Brief pain and pain interference questionnaires will be administered.
o Final visit, in person 6 weeks after the initial visit: the study subject will be debriefed regarding tablet App, all questions will be answered. The study subject will complete brief questionnaires pertaining to pain, sleep, quality of life, prior App experience, and pain interference. The study subject will be debriefed on use of the Actigraph device. The devices will be collected. A 6-minute walk test will be completed.
o Final follow up phone call: The subject will be briefly interviewed two weeks after final visit for final thoughts about the App use experience and any plans to change behaviors as a result of using the App for activity planning.
o Veterans from Empowering Veterans Program at the Baltimore-Loch Raven VA; (Site: Loch Raven VA)
o Female Veterans from the Women's health clinic; (Sites: Baltimore VAMHCS and Fort Meade VA)

We will examine pilot data on usability, App use, and behavior change, and assess barriers to implementing changes planned by the Veteran through the App (failure mode analysis). The vision is that this will lead to future research on rehabilitation-oriented outcomes such as: functional measures, QoL, and pain.

Importantly, there will be no remote, network transmission of data using the tablet app during this study. Instead, completely de-identified information (i.e. data without any of the 18 HIPAA identifiers) will be entered and stored on the tablet for subsequent download when participants arrive at the VAMHCS facility for their planned in-person visits. Hence, there is no chance that VA sensitive information could be accidentally divulged by using the tablet in the manner detailed for this pilot study.

The data collected from participants with tablet APP is de-identified data. The tablet APP and tablet itself are VA approved so authorized connected to the VA network (WiFi and Wired).

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

N/A

3 * Describe the duration of an individual participant's participation in the study:
The individual's participation in the study will not exceed 8 weeks.

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

5 * Describe any additional participant requirements:
Inclusion criteria include: Veterans receiving care at the VAMHCS, frequent or persistent low back pain (> 3 months), pain >=3 on a 0-10 numeric rating scale, willing to participate in trial of non-pharmacological therapies for pain; ability to speak, read, and write as needed for study. Stable treatment.

Sample Size and Data Analysis

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

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

This study is not powered to find statistically significant differences. Qualitative data interpretation will follow from a priori hypothesis development, in brief: specific design features, e.g. simple design, clear navigation, will improve Veteran experience. Quantitative aspects are not anticipated to attain statistical significance and will be descriptive.

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

Both qualitative and quantitative methods of research analysis will be used. Data analysis will be performed utilizing a standard statistical analysis package, SAS and excel will be used to evaluate program development, implementation, qualitative instrument development, complex analytical methods, mixed methods research, and survey methodology.

Qualitatively, the current pilot study is designed to identify common barriers to App use.

Quantitatively, this study will obtain statistical information to guide the development of outcome measures for a Merit-level research proposal to determine the potential effectiveness of this multi-dimensional approach to pain self-management in an App.

Sharing of Results

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

Safety monitoring will report incidental findings to the patient's primary care provider. The individual subject results will not be shared with the subjects. Aggregated data will be reported through oral and written presentations.

ID: VIEW4E02808CBD800
Name: v2_Sharing of Results

Psychological/Behavioral/Educational Methods & Procedures

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

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

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

Surveys/Questionnaires

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

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

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

Pain (basic)
Pain scale (DoD/VA-based) diary

Pain-related function, interference, purpose and self-efficacy:
PROMIS-29 Profile v2
PROMIS SF v1.0 Self-Effic-General
PROMIS SF v1.0 Self-Effic-ManagSymptoms
PROMIS SF v1.0 Meaning-Purpose

Pain (detail)
Body pain diagram
FM diagnostic criteria survey
FM Patient pain location report
Widespread pain index

Function and quality of life
EQ-5D-5L
SF-6D
katz-ADL: activities of daily living
Lawton-IADL: independent activities of daily living
Life Space Questionnaire - Maryland

Sleep
Pittsburgh Sleep Quality Index
Insomnia Severity Index
Epworth Sleepiness Scale

Diet
ASA 24 dietary recall

App specific instruments
System Usability Scale (SUS))
Change Assessment in Pain Self-management

2 * Upload a copy of all questionnaires/surveys:

Name	Created	Modified Date
4f. SPiRE_Accelerometer Activity Log wrist.docx(0.01)	5/31/2022 4:02 PM	5/31/2022 4:02 PM
1a. DoD-VA Pain Scale.pdf(0.01)	2/25/2022 12:55 PM	2/25/2022 12:55 PM
1b. Daily Pain Diary Cover Page_1.31.22.docx(0.01)	2/25/2022 12:55 PM	2/25/2022 12:55 PM
1c. Daily Pain Diary Pages_1.31.22.docx(0.01)	2/25/2022 12:55 PM	2/25/2022 12:55 PM
2a. PROMIS-29_Profile_v2.1_2-7-2018.pdf(0.01)	2/25/2022 12:54 PM	2/25/2022 12:54 PM
2b. PROMIS SF v1.0 - Self Effic-General 4a 9-1-17.pdf(0.01)	2/25/2022 12:54 PM	2/25/2022 12:54 PM
2c. PROMIS SF v1.0 - Self-Effic-ManagSymptoms 4a_6-21-2017.pdf(0.01)	2/25/2022 12:54 PM	2/25/2022 12:54 PM
2d. PROMIS_SF_v1.0_-_Meaning-Purpose_4a_6-27-2017.pdf(0.01)	2/25/2022 12:54 PM	2/25/2022 12:54 PM
3a. Body Pain Diagram with SML scoring sheet 2022FEB.docx(0.01)	2/25/2022 12:54 PM	2/25/2022 12:54 PM
3b. FM Diagnostic Criteria Survey Questionnaire (2013)_0.pdf(0.01)	2/25/2022 12:54 PM	2/25/2022 12:54 PM
3c. FM Patient Pain Location Report.pdf(0.01)	2/25/2022 12:53 PM	2/25/2022 12:53 PM
3d. Widespread Pain Index PDF.pdf(0.01)	2/25/2022 12:53 PM	2/25/2022 12:53 PM
4a. EQ-5D-5L Paper Self-Complete v1.1.docx(0.01)	2/25/2022 12:52 PM	2/25/2022 12:52 PM
4b. SF-6D_SF12-RCH.pdf(0.01)	2/25/2022 12:52 PM	2/25/2022 12:52 PM
4c. katz-adl.pdf(0.01)	2/25/2022 12:52 PM	2/25/2022 12:52 PM
4d. lawton-iadl.pdf(0.01)	2/25/2022 12:52 PM	2/25/2022 12:52 PM
4e. Life Space Questionnaire with Citation_Modified-Maryland.pdf(0.01)	2/25/2022 12:51 PM	2/25/2022 12:51 PM
5a. PSQI.pdf(0.01)	2/25/2022 12:51 PM	2/25/2022 12:51 PM

Name	Created	Modified Date
5b. Insomnia Severity Index (ISI).pdf(0.01)	2/25/2022 12:51 PM	2/25/2022 12:51 PM
5c. Epworth Sleepiness Scale (ESS).pdf(0.01)	2/25/2022 12:51 PM	2/25/2022 12:51 PM
6a. ASA24_About Pages.pdf(0.01)	2/25/2022 12:50 PM	2/25/2022 12:50 PM
7b. Change Assessment in Pain Self-Management_2022FEB25.docx(0.01)	2/25/2022 12:50 PM	2/25/2022 12:50 PM
7a. System usability scale for App 2021DEC13.docx(0.03)	8/16/2019 2:37 PM	2/25/2022 12:50 PM

3 * What is the total length of time that each survey is expected to take?
5 minutes each for a total of 60 minutes for first and last round of survey. The pain diary questionnaire will be answered daily during the study.

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

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

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

ID: VIEW4E09460F5EC00
Name: v2_Surveys/Questionnaires

Interviews

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

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

○ Yes ● **No**

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

Name	Created	Modified Date
Script for follow up phone interview.docx(0.01)	5/31/2022 4:09 PM	5/31/2022 4:09 PM
RGP App Phone Screen & Script rev.docx(0.01)	5/31/2022 4:07 PM	5/31/2022 4:07 PM

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

25 minutes each for a total of 2.5 hours

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

Research assistant will record interview responses, with telephonic audio recording

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

● **Yes** ○ No

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

If there is a concerning answer to the question: "Are there any problems you're having that we need to be aware of?", this will be reviewed by the safety team and the participants PCP will be alerted to relevant concerns.

Focus Groups

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

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

○ Yes ● **No**

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

Name	Created	Modified Date
Script for focus groups(0.02)	8/9/2019 2:38 PM	8/14/2019 3:28 PM

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

90 minutes

4 * How will the data be recorded?

Notes and audio recording

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

○ Yes ● **No**

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

ID: VIEW4E094A8F91800
Name: v2_Focus Groups

Audio or Video Recording/Photographs

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

1

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

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

1.1

If Other, specify:

2

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

Ensure correct transcription of interview and focus group responses.

3

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

- ○ Yes
- ● **No**

4

* How will individuals' identities be protected?

All recordings will be stored only on secure encrypted computers and destroyed at the end of the study period.

Observation

You indicated that this study involves individual or group behavioral observations.

1 * Please describe what is being observed.
Individual behavior will be assessed using examination and actigraphy recordings.

2 * Are any of the observations likely to cause harm if confidentiality were breached? (i.e., Illegal activities)
○ Yes ● **No**

3 * How will individuals identities be protected?
All recordings will be stored only on secure encrypted computers and archived according to VA policy at the end of the study period.

4 * How will observations be recorded?
Observations will be recorded in writing, electronic records, and audio recording.

Behavioral Intervention

You indicated that this study involves psychosocial or behavioral interventions.

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

Utilization of an Application to assist in care coordination. This will involve daily interaction with the tablet-based App during the 6 week period of the study. The interaction with the App itself could take a few minutes but during planning and education activities could take longer periods such as 30 minutes. The study participants will be coached in using the App. The intention is that the App will assist study participants in planning more healthful activities such as moderate daily exercise and improved sleep habits with an overarching goal of reducing pain intensity and interference.

The pilot phase study participants will meet with study staff multiple times during the study.

Phase 1: Veteran focus group
• Single occasion, focus group discussion: Up to five Veterans, recently graduated from the Empowering Veterans Program at the Baltimore-Loch Raven VA will meet during the first quarter of funding for this program. The group will be introduced to the prototype App on tablet computers. Using open semi-structured interviews, we will explore their use of non-pharmacological pain self-management strategies, with special attention to understanding use of language and how existing strategies link to labels and the values they associate with each. A total of five interface options will be included, to assess appeal, perceived navigability of these options, and input on design features and usability. Brief questionnaires will be completed at the end of the focus group session and compensation for participation will be distributed. (Site: Loch Raven VA). Duration 90 minutes, planning activities with an aim of reducing chronic pain intensity and interference will be discussed.

Phase 2: Veteran Pre-pilot group
• Single one-on-one interview: Using open semi-structured interviews, we will explore their use of non-pharmacological pain self-management strategies, with special attention to understanding use of language and how existing strategies link to labels and the values they associate with each. A total of five interface options will presented to the interview subjects and rated for appeal, perceived navigability, design features, and usability. Validated questionnaires will be completed, see details below. Compensation for participation will be distributed.
o Five Veterans from Empowering Veterans Program at the Baltimore-Loch Raven VA; (Site: Loch Raven VA)
o Five female Veterans from the Women's health clinic; (Sites: Baltimore VAMHCS and Fort Meade VA)

Our pre-pilot objective is to reach two groups of Veterans: 1) 5 Veterans completing the EVP (Empower Veterans Program) and 2) 5 Veterans attending the Women's Health Clinic, in collaboration with Dr. Staropoli, Director of Women's Health for VAMHCS. This will provide important feedback for the experience of two different groups: the first group is experienced with non-pharmacological, values-based, approaches to pain management including CBT, ACT, MBSR, and others. The Women's Health Clinic group may not have had formal exposure to non-pharmacological pain management and may require additional information or resources to attain maximal benefit from C-MEPPS. The goal is an App that is useful to the broadest number of Veterans. We will include at least 4 older Veterans among the 10 recruited so the App can be developed with input from older Veterans accessing whole-health integrative approaches to pain self-management. Duration 90 minutes, planning activities with an aim of reducing chronic pain intensity and interference will be discussed.

Phase 3: Veteran Formal pilot testing group
• Multiple visits, phone interviews, and activity monitoring. Once feedback from the pre-pilot group is obtained and further modifications incorporated into READY-GO Pain, the App will be tested with a pilot group.
• 20 Veterans with cLBP a balance of middle-aged and older male and female veterans.
• The study procedures will include:
o Recruitment: the study will be introduced to potential study subjects by the PI, study investigators, colleagues, or the study coordinator
o Consent: the study will be described in detail to the potential study subjects by PI, study investigators, or the study coordinator. If the study subject agrees to participation, they will be given a pain diary to bring back at the time of the initial visit in 2 weeks time.
o Initial visit: the study subject will be introduced to the tablet App and instructed in use, all questions will be answered. The study subject will complete brief questionnaires pertaining to pain, sleep, quality of life, prior App experience, and pain interference. The study subject will be fitted with an actigraph and instructed in the use of the device. A 6-minute walk test will be completed.
o 1st followup phone call: The study subject will be contact by phone one week after the initial visit. Coaching on App use and troubleshoot of App and actigraph use will be provided. Brief pain and pain interference questionnaires will be administered.
o 1st follow up visit: the study subject will be coached regarding the tablet App and actigraph use, all questions will be answered. The study subject will complete brief questionnaires pertaining to pain, sleep, quality of life, prior App experience, and pain interference. The study subject will be fitted with an actigraph and instructed in the use of the device.
o 2nd followup phone call: The study subject will be contact by phone 3 weeks after the initial visit. Coaching on App use and troubleshoot of App and actigraph use will be provided. Brief pain and pain interference questionnaires will be administered.
o 3rd followup phone call: The study subject will be contact by phone 4 weeks after the initial visit. Coaching on App use and troubleshoot of App and actigraph use will be provided. Brief pain and pain interference questionnaires will be administered.
o 4th followup phone call: The study subject will be contact by phone 5 weeks after the initial visit. Coaching on App use and troubleshoot of App and actigraph use will be provided. Brief pain and pain interference questionnaires will be administered.
o Final visit: the study subject will be debriefed regarding tablet App, all questions will be answered. The study subject will complete brief questionnaires pertaining to pain, sleep, quality of life, prior App experience, and pain interference. The study subject will be debriefed on use of the Actigraph device. The devices will be collected. A 6-minute walk test will be completed. Duration 90 minutes, planning activities with an aim of reducing chronic pain intensity and interference will be discussed.
o Final follow up phone call: The subject will be briefly interviewed for final thoughts about the App use experience and any plans to change behaviors as a result of using the App for activity planning.

We will examine pilot data on usability, App use, and behavior change, and assess barriers to implementing changes planned by the Veteran through the App (failure mode analysis). The vision is that this will lead to future research on rehabilitation-oriented outcomes such as: functional measures, QoL, and pain.

Data Collection/Record Review

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

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

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

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

○ Yes ● **No**

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

○ Yes ● **No**

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

ID: VIEW4E0E25A8CA400
Name: v2_Data Collection / Record Review

Prospective Data

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

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

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

1.1 If Other, please specify:
Study surveys, observations, actigraphy, and tablet utilization data

2 * What data fields will you have access to/collect for the study? For example, name, initials, date of birth, Social Security number, income, demographic information, family units, housing, etc.
Name, date of birth, gender, race, ethnicity.
6 minute walk test observation, actigraph recording, use of tablet data

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

Name	Created	Modified Date
There are no items to display		

Clinical Trial Registration

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

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

○ Yes ● **No**

2 * Has this trial been registered?

● **Yes** ○ No

ID: VIEW4E093BF078C00
Name: v2_Clinical Trial Registration

Clinical Trial Registration Information

You indicated that this clinical trial has been registered.

1 * Was this trial registered at www.clinicaltrials.gov?
(●) **Yes** ( ) No

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

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

2.2 Provide justification for registering this trial on this site:

3 * Registration Number
NCT04075487

ID: VIEW4E093BF1D0800
Name: v2_Clinical Trial Registration Information

Participant Selection

1 * How many local potential participants (or specimens/charts) do you anticipate will be screened for this study? ***Screening includes determining potential participants' initial eligibility for and/or interest in a study.***
70

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

Local - the number being enrolled at this site:
35

Worldwide - the number being enrolled total at all sites (including local enrollment):
35

3 * Gender:

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

4 * Age(s):

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

5 * Race/Ethnicity:

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

6

* Language(s):

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

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

6.1 Specify Other:

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

○ Yes ● **No**

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

Vulnerable Populations

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

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

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

Eligibility

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

● **Yes** ○ No

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

Name	Created	Modified Date
INCLUSION AND EXCLUSION CRITERIA CHECKLIST MAY2022.docx(0.01)	5/31/2022 4:12 PM	5/31/2022 4:12 PM

1.2 If No, create an eligibility checklist below:

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

Number	Criteria
There are no items to display	

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

Number	Criteria
There are no items to display	

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

Eligibility Checklist for HP-00086659_4 v5-31-2022-1654027941498(0.01)

ID: VIEW4E0E5185F9000
Name: v2_Eligibility

Recruitment

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

Veterans will be recruited from the following clinical populations: Empower Veterans Program, GEROFit participants, Women's health clinic, VAMHCS patients with LBP meeting eligibility criteria.

Recruitment will take place at Baltimore, Loch Raven, Annex, and Fort Meade locations of VAMHCS. Potential VA participants will be identified by several methods: (1) CPRS chart review and screening via use of a partial HIPAA waiver, (2) VA clinician referrals of participants who meet inclusion criteria and who might be interested in participating, (3) Self referrals by participants who hear about the study and are interested in participating or who have participated in other studies and have indicated a willingness to be contacted for studies in the future.

We would also like to perform a computer-based screening using the VISN 5 Corporate Database Warehouse to screen for individuals who have had low back pain for at least three months. As part of this, we will use a data pull with real Social Security Numbers (SSNs) from VA's Information and Computing Infrastructure (VINCI) to enhance recruitment goals within the VISN. Potential subjects from the VISN will be mailed an IRB approved recruitment letter (uploaded in recruitment section), as well as an opt in/opt out post-card (uploaded in recruitment section). Postage will be provided on the opt in/out post-card, which will allow for potential subjects to indicate whether they
would like to be contacted in the future related to the study. The opt in/out post-card will not list the subject's name, but rather will only provide a letter number that we will generate and store in a password protected file on the VA server prior to mailing the letter. If no response is received within two weeks, we will follow up with a phone call to gauge subject interest.

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

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

Per VA protocol, Veterans will be contacted by mail prior to telephone contact.

Our research team has extensive experience recruiting and obtaining informed consent from individuals with chronic pain. Research staff is trained to avoid any actions that might be interpreted as coercive and to recognize anything that could undermine the ability to provide proper informed consent.

Before obtaining consent, the recruiter will assess competency to understand and sign the consent form by asking the individual a set of IRB approved questions (See attached evaluation to sign consent questions in Additional Documents). If the individual is unable to answer the questions correctly the study team member will review aspects of the study that the individual did not understand. They will then ask the questions a second time. If the individual cannot answer them a second time the individual will be judged not competent to give consent, and he or she will not be included in the study. Individuals will be told that their participation is completely voluntary and that they can choose to stop participation at any time without any negative consequences.

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

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

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

Primary care and specialty providers

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

Name	Created	Modified Date
5.31.22 IRB appl Opt In Out PostCard PainApp.pub(0.01)	5/31/2022 4:51 PM	5/31/2022 4:51 PM
VINCI Pain App Recruitment Letter.doc(0.01)	5/31/2022 4:51 PM	5/31/2022 4:51 PM

Advertising

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

● **Yes** ○ No

ID: VIEW4E0BCCF811000
Name: v2_Advertising

Advertising Detail

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

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

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

1.1.1 If Other, specify:
Flyers

1.2 * Provide exact text of all proposed advertisement(s):
Please see the attached flyer

1.3 * Upload advertisement(s) here:

Name	Created	Modified Date
RGP App Flyer_4.27.22 final.docx(0.01)	5/31/2022 4:52 PM	5/31/2022 4:52 PM

Research Related Risks

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

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

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

Potential loss of confidentiality (small likelihood, moderate degree of seriousness). All project staff are thoroughly trained in issues relating to maintaining confidentiality of research data. Statistical analyses will be based on group data; no individual data will be reported. There is a slight risk of a confidentiality breach related to data collected for research purposes. Study participants will be informed that information obtained is confidential; potential risks to data security and the measures we take to protect it will be reviewed with them during the informed consent process. Numerous steps will be taken to ensure data confidentiality and security. Paper records are identified only by an anonymous code number assigned to each research participant and are kept in a locked file cabinet behind a locked office door. Electronic records are stored on password protected computers.

ID: VIEW4E1B52509F000
Name: v2_Research Related Risks

Potential Benefits and Alternatives

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

1 * Describe the potential direct benefit(s) to participants:
Participation in this study may provide no direct benefits to participants. However, participants may learn about the impact of better coordination of health self-management on reducing chronic pain.

2 * Describe the importance of the knowledge expected to result from the study:
This research will contribute to our understanding of how chronic pain self-management might result in less pain, substantive cost savings, reduction of opioid over-reliance, improved patient quality of life.

3 * Describe how the potential risks to participants are reasonable in relationship to the potential benefits:
Potential risks are truly minimal, this is simply a tool to help patients and providers plan out treatment more effectively. This is intended to speed and facilitate the planning of treatment that should ideally be occurring already. The major risks to participants are mild embarrassment from answering questionnaires and minimal risks to privacy, mitigated extensively by study procedures. These risks are outweighed by the potential benefits to participants include early awareness and self-directed engagement in pain self-management.

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

Withdrawal of Participants

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

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

Participants will be withdrawn without their agreement under the following circumstances:
the subject is too ill to continue in the study,
there is evidence of incorrect use or unanticipated risk,
the subject does not follow instructions from research staff,
the PI or co-investigators decides that the study is not in the best interest of the participant.

These circumstances have been outlined in the VA mandated informed consent form.

2 * Describe procedures for orderly termination:

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

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

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

Privacy of Participants

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

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

Data regarding potential participants will be maintained in a secure and encrypted computer until archived consistent with VA policy upon study completion.

Research staff are thoroughly training to protect the privacy of research participants. We meet with participants in private rooms with closed doors at the VAMHCS.

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

Potential participants will receive research information in a private consultation room, with the door closed, or by telephone.

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

Some Veterans experience stress upon visiting specific VA locations, e.g. main hospital may be stressful for some. For this reason, we will be able to meet with study participants at one of multiple locations.

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

○ Yes ● **No**

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

○ Yes ● **No**

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

ID: VIEW4E1B525B87C00
Name: v2_Privacy of Participants

Confidentiality of Data

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

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

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

The VA electronic data will be stored behind the VA firewall at \\r04balnas20.v05.med.va.gov\VHABALHOGANB$\

The VA paper data will be stored in the Study PI office 4B-188, 10 North Greene Street in a locked cabinet. As this study will meet Veterans at VA settings of their choice, paper records pertaining to that specific record will need to be transported back to the VAMHCS Baltimore location from Loch Raven, Fort Meade, or the Annex. When this occurs, paper records will be transported in a locked case.

3 * How will such data be secured?

No VA sensitive information will leave the VA protected environment. Electronic data for this study will remain securely behind the VA firewall and will only be accessible through secure VA computer accounts. The network and computer files are only accessible by authorized study team members. Electronic research files are backed up regularly. All study paper records and audio recordings will be securely stored in locked file cabinets behind locked doors at the location specified in item 2.

All research related electronic data is stored coded and subject identifiers, such as names, are not stored in the same files that contain the research data.

Importantly, there will be no remote, network transmission of data using the tablet app during this study. Instead, completely de-identified information (i.e. data without any of the 18 HIPAA identifiers) will be entered and stored on the tablet for subsequent download when participants arrive at the VAMHCS facility for their planned in-person visits. Hence, there is no chance that VA sensitive information could be accidentally divulged by using the tablet in the manner detailed for this pilot study.

Again, when research team members transport study paper records from one VA site to another VA site for final storage, a secured briefcase will always be utilized to protect documents.

4 * Who will have access to research data?

Only the PI, co-investigators, and research staff will have access to research data with identifiers. Access to research study data will be removed for study personnel when they are no longer part of the research team.

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

- ( ) Yes
- (●) **No**

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

- (●) **Yes**
- ( ) No

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

The investigator's VA research records and any VA participant identifiers will be retained until the maximum retention period is reached, as defined by the Dept. of Veterans Affairs Records Control Schedule (RCS 10-1). When the maximum retention period is reached, the VA data may be destroyed using the most current data destruction methodologies that are available at the time of data destruction.

7 Do you plan to obtain a Certificate of Confidentiality?

- ( ) Yes
- (●) **No**

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

Name	Created	Modified Date

There are no items to display

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

At this point in the development of the Pain Self-Management App (PS-MA) described here, we do not gather or allow the Veteran to send information to the study team through the App. The Veteran may elect to save information from the App through the mechanism of screen capture, but otherwise, at this point, no information will be sent to the study team from the App. In addition, no HIPAA PHI will be entered into the tablet in this study, the patient will be identified to the tablet by a nickname, with the nickname-participant crosswalk codes secured by the study team.

For those Veterans participating in this early-phase study, they will be provided with a tablet computer, the tablet computer will be password protected. The tablet computer will contain information about the Veteran's use of the application, this information will be reviewed and included in the study data once the Veteran returns the tablet to the study team.

In accordance with VA policy, procedures are in place for reporting incidents, i.e. theft or loss of data or storage media, unauthorized access of sensitive data or storage devices or non-compliance with security controls. Upon learning of such an incident, study staff will immediately report the incident to the VAMHCS PO, ISSO, and R&D Service.

To summarize:

For those Veterans participating in this early-phase study, they will be provided with a tablet computer.
• The tablet computer will be password protected.
• No HIPAA PHI will be entered into the tablet in this study, the patient will be identified to the tablet by a nickname, with the nickname-participant crosswalk codes secured by the study team.
• The tablet computer will contain information about the Veteran's use of the application, but the computer will not collect identifiable information about the study participant.
• The system logging of App use will be included in the study data once that table is returned to the team. This information will be reviewed and included in the study data once the Veteran returns the tablet to the study team. There is the possibility of losing this data if the participant loses the tablet prior to study completion, however, this risk is accepted in order to protect the privacy of the participant's information.

Monitoring Plan Selection

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

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

ID: VIEW4E1B00E30D400
Name: v2_Monitoring Plan Selection

Monitoring Plan - Committee

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

1 * Will the Committee be Internal or External?

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

2 * What data will be reviewed?

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

2.1 If Other, specify:

3 * What will be the frequency of the review?

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

3.1 If Other, specify:

4 * Safety monitoring results will be reported to:

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

4.1 If Other, specify:

Monitoring Plan - Internal DSMB

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

1 * List Internal DSMB Members:

Name
View Dr. Beth Hogans
View Dr. Robert Lavin
View Dr. Ariana Perra
View Dr. Alice Ryan

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

● **Yes** ○ No

3 * Will there be an interim efficacy analysis?

● **Yes** ○ No

3.1 If Yes, when?

End of Year 1

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

Unblinded data will be reviewed by DSMB team members

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

Risk to study subject: physical or mental, due to study continuation.

Research-Related Costs

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

- ○ No
- ● **Yes**

1.1 If Yes, check all that apply:

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

1.2 If No, who is responsible for payment?

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

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

2.1 If Other, specify:
VA will provide salary support to PI

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

Compensation for Research-Related Injury

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

◯ Yes ● **No**

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

Name	Created	Modified Date
There are no items to display		

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

◯ Yes ● **No**

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

1.2.2

Name	Created	Modified Date
There are no items to display		

Payment/Reimbursement to Participants

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

● **Yes** ○ No

ID: VIEW4E1C52A5D7800
Name: v2_Payment to Participants

Payment/Reimbursement Detail

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

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

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

1.1 If Other, specify:

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

$225

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

$25 payment for travel to and participation in a focus group (Phase 1)

$35 payment for travel to and participation in a one-on-one interview group (Phase 2)

$225 payment for travel to and participation in pilot phase group (Phase 3), this will entail a total of three visits, actigraph and App use over 6 weeks, and 5 phone interviews. The patient will receive a $50 check after completing the first in person session (initial visit) preceded by the two week pain diary period. The patient will receive a second $50 check after completing the second in person session (first follow up) as well as the intervening phone call. The patient will receive a $100 check after completing the third in person session (final visit) as well as the additional two phone calls and a final check for $25 after completing the final follow up phone call.

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

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

4.1 If Other, specify:

HIPAA (Health Insurance Portability and Accountability Act)

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

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

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

● **Yes** ○ No

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

● **Yes** ○ No

ID: VIEW4E1B0A2114400
Name: v2_HIPAA

Protected Health Information (PHI)

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

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

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

2 * Why is the PHI necessary for this research?

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

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

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

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

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

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

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

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

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

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

Name	Created	Modified Date

There are no items to display

Waiver/Alteration of Authorization

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

1 * Provide rationale for how the research presents no more than minimal risk to the privacy of individuals:
All data are retained on VA secure and encrypted computers.

2 * Describe the plan to ensure the protection of PHI collected during this study from improper use and disclosure:
All data are retained on VA secure and encrypted computers.

3 * Describe the plan to destroy the PHI collected during this study at the earliest opportunity consistent with the conduct of the research. If there is a need to retain PHI, provide a justification:
All data will be destroyed upon study completion

4 * Why could the research not practicably be done without access to and use of this PHI?
A partial HIPAA waiver for recruitment is essential in facilitating conduct of this study, by allowing proper screening of participants prior to enrollment.

5 * Why could the research not practicably be done without the waiver or alteration?
This study is based on the recruitment of Veterans with specific characteristics, necessitating a partial HIPAA waiver for recruitment.

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

6.1 If Yes, describe the individuals or entities outside of UM to whom PHI will be disclosed.

ID: VIEW4E1B0A2896400
Name: v2_Waiver/Alteration of Authorization

Informed Consent Process

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

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

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

2 * Describe the Informed Consent process in detail:

Subject will meet with study coordinator or PI who will describe the study, explain the procedures, and answer all questions. The informed consent will occur in a private consultation room. The process of demonstrating the App will be described to the participants, the data security procedures will be explained. Study team member obtaining informed consent will ensure that the participant has a full understanding of the risks and potential benefits of study participation and that the potential participant is fully aware that they may withdraw at any time.
Written consent will be obtained.

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

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

● **Yes** ○ No

4 * Describe who will obtain Informed Consent:

Study coordinator or PI

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

N/A

6 * Describe the setting for consent:

Private consultation room

7 * Describe the provisions for assessing participant understanding:

Verbal discussion

8 * Describe the consideration for ongoing consent:

Subjects will be informed of the right to withdraw at any time at study recruitment.

Consent and HIPAA Authorization Forms - Draft

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

Name	Created	Modified Date
VA Informed Consent 2019SPIRE-Phase 1_FOCUS GROUP-FI 083019 info rev.docx(0.04)	8/27/2019 12:15 PM	9/18/2019 2:03 PM
VA Informed Consent 2019SPIRE-Phase 3_APP USE- FI 083019 info rev.docx(0.05)	8/27/2019 12:15 PM	9/25/2019 12:34 PM
VA Informed Consent 2019SPIRE-Phase 2_INTERVIEW- FI 083019 info rev.docx(0.06)	8/27/2019 12:15 PM	9/18/2019 2:04 PM

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

1A Archived Consent Forms:

Name	Created	Modified Date
VA Informed Consent draft 2019SPIRE Hogans 2019AUG16.docx(0.01)	8/16/2019 2:39 PM	8/16/2019 2:39 PM
draft IC(0.02)	8/12/2019 1:32 PM	8/14/2019 3:28 PM

2 Upload any HIPAA authorization forms here:

There are no items to display

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

ID: VIEW4E1C7712D3000
Name: v2_Consent Forms - Draft

Organization Review Requirements (other than IRB)

Answer the following questions to determine additional organizational review requirements:

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

Veterans Administration Hospital

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

VA-Specific Criteria

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

Chronic low back pain (cLBP) causes more disability than any other condition worldwide and affects 33% of Veterans1-3 impairing functional capacity, quality of life, and mental health, while increasing medication reliance and substance abuse.4,5 In Veterans, co-occurrence of chronic pain with mental health and substance use conditions, and opioid treatment increases suicide and inadvertent death5-7. Severe cLBP, defined as interfering greatly with normal activity and present on most or all days, affects 20% of Veterans with cLBP.1

2 * Describe who will be enrolled in this study:

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

2.1 * If non-veterans will be enrolled in this study, provide a description of non-veterans who will be enrolled (For example: community members, family members/caretakers of Veterans, clinicians/caregivers to Veterans, etc.):

N/A

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

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

- ○ Yes
- ○ No
- ● **N/A**

*

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

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

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

**

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

[VHA Handbook 1200.05 §24]

VA Prohibited Research

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

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

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

ID: VIEW4E1C8AF03A400
Name: v2_VA Prohibited Research

Additional VA

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

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

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

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

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

VA Maryland Health Care System Review Required

1

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

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

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

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

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

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

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

2

Questions answered on 'Organizational Review Requirements' page:

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

Questions answered on 'VA Prohibited Research' page:

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

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

3

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

● **Yes** ○ No

ID: VIEW4E1C8F0D7B000
Name: v2_VA Review Required

Summary of Required Reviews (other than IRB)

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

Name of Related Submission

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

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

Name of Organization	**Review Status**
Veterans Administration Hospital	Complete

Additional Documents

1

Upload all additional documents here:

Name	Created	Modified Date
There are no items to display		

Final Page of Application

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

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

Name of Organization	**Review Status**
Veterans Administration Hospital	Complete

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

Name of Related Submission

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

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

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

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

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

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

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

Add a Team Member

1 * Select Team Member:
Bernadette Siaton

2 Research Role:
Research Team Member

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

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

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

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Dr. Siaton is an experienced clinician with experience with minimal risk studies. Dr. Siaton and the PI have collaborated on numerous research studies. Dr. Siaton has extensive knowledge of the local study sites and culture and society relevant to this study.

Add a Team Member

1 * Select Team Member:
Chad Wessinger

2 Research Role:
Study Coordinator

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

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

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

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Mr. Wessinger is experienced in the conduct of research studies of the type planned here. He is very experienced in the local study site, cultural and societal issues.

Add a Team Member

1 * Select Team Member:
Heidi Ortmeyer

2 Research Role:
Research Team Member

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

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

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

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Dr. Ortmeyer is a senior investigator in exercise physiology with extensive experience in safety procedures, protocol development, and study design. She has several years experience with research at the VAMHCS, including experience with use and implementation of actigraph (activity monitoring) technology in Veterans.

Add a Team Member

1 * Select Team Member:
Alice Ryan

2 Research Role:
Research Team Member

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

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

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

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Dr. Ryan is a senior investigator in exercise physiology with extensive experience in safety procedures, protocol development, and study design. She has many years experience with research at the VAMHCS, including aspects of culture and societal impact.