HUMAN SUBJECTS RESEARCH PROTOCOL

TEMPLATE INSTRUCTIONS
03/19/2019

Project Title: Designing a Mobile App to Support Academic Success for Student Veterans

Protocol Version and Date: Version 1.0; 4/5/2022

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1.0 Objective and Specific Aims:

In 2018, over 669,922 Veterans used military benefits to pursue higher education, with 75% enrolled as full-time students. For these Veterans, advancing their education is an important step toward their continued community reintegration, including improved employment opportunities, stable housing, family and social roles, and other outcomes. Though Veterans bring multiple strengths to academic settings, transitioning to the new culture of higher education may also involve significant challenges that impact their academic performance. Specifically, student Veterans experience higher rates of health risk behaviors (e.g., substance use), self-reported difficulties adjusting to campus life, and interpersonal difficulties with faculty than their civilian peers. These issues can lead to lower enrollment rates and slower degree attainment, which seriously impede Veterans' successful adjustment to civilian life and vocational success.

One particular concern is that Veterans transitioning back to civilian life have diagnosed mental health conditions at elevated rates compared to civilian students. As a result, Veterans face difficulties related to cognitive (e.g., attention), physical (e.g., pain), or emotional/behavioral (e.g., PTSD, depression, substance use) issues. Many Veterans do not report psychiatric problems and do not seek treatment, and over half of Veterans who have a mental health issues may not perceive a need for mental health. Lack of services and treatment is especially concerning for student Veterans, who have higher rates of mental health symptoms and suicide than non-Veteran students, but lower rates of treatment. Even for Veterans seeking treatment for academic and psychiatric issues, there can be many barriers such as time, transportation, and perhaps most importantly, not understanding the process for becoming connected to existing VA and campus services.

The VA has invested in many in-person resources for academic support and mental health treatment, using a catalogue of supported education options for Veterans embedded in Compensated Work Therapy (CWT), Veteran Integration to Academic Leadership (VITAL), and mental health clinics. Preliminary evidence from supported education pilots such as VITAL- Supported Education (VITAL-SEd) have not only shown promise in assisting Veterans with their educational success, but have also gathered feedback from Veterans on specific areas of treatment that assisted them. However, in-person supported education is not available to all – and Veterans across the spectrum of academic and mental health concerns could benefit from an asynchronous, mobile application providing a one-stop shop for student Veteran support.

Studies with non-Veteran student populations have shown that targeted mobile platforms to orient students to the culture of higher education, while also focusing on their mental health, can increase students' retention and course engagement. Unfortunately, there is no VA mobile app specifically aimed toward student Veterans. We plan to develop a personalized academic success app, *VetEd*, with content based in past research, educational literature, and Veteran feedback, to address a variety of academic and psychiatric symptom-related educational barriers for student Veterans. Specifically, *VetEd* will provide services to student Veterans who may not yet have access to supported education services by 1) promoting the creation and execution of educational planning and goals, 2) providing opportunities for Veterans to learn new academic and coping skills such as course organization, task completion, and stress management, and 3) connecting Veterans with VA resources based off their personal needs, such as information on mental health counseling, existing college resources like obtaining educational accommodations, and Post-9/11 GI Bill coverage.

Primary Aims:

Aim 1. Develop a Veteran-centered educational support app by conducting focus groups [(3 focus groups, n=8, n=8, n=5, total n= 21)] of student Veterans with mental health disorders to identify their perceived academic needs, app preferences, and evaluate Veteran-centered content.

Aim 2. Test and iteratively revise the *VetEd* app (3 waves of n= 5, total n =15) by assessing app software, content, human-computer interface, usability, satisfaction data, and preliminary exploration of changes in educational functioning (course activity completion, academic self-efficacy, and retention).

> **Hypotheses:** Although we are underpowered to detect statistically significant changes in educational functioning scores, we will utilize non-parametric analyses to assess for potential changes from pre- and post-app use related to academic functioning (academic self-efficacy, course task completion, and perceived retention/course completion) and community reintegration (M2C-Q).

Secondary Aims: N/A

2.0 Background and Significance

2.1 Background

Higher education has a vital, lasting impact on Veteran's functioning and quality of life. As service members transition out of active duty, many decide to pursue higher education as the next step toward secure employment and a higher quality of life, with financial support for college often cited as a primary motivator for enlisting in the military.[1] In 2018, over 669,922 Veterans used military benefits to pursue higher education, with 75% enrolled as full-time students.[2] Since the Post 9/11 GI Bill was introduced in 2009, more than 1.4 million Veterans, service members, and their families have used it to fund their education.[3] Many Veterans view education as a necessary step toward vocational success, as people with higher levels of education are more likely to be employed[4] and earn more over their lifetime.[5] Quality of life is also improved with educational success, as Veterans with at least some college show improved employment opportunities, stable housing, and family and social roles.[6,7,8]

Student Veterans with mental health disorders need additional resources to meet academic goals. While Veterans bring multiple strengths to academic settings, transitioning to the culture of higher education can be complicated by challenges impacting daily functioning and academic performance. One particular concern is

that Veterans have mental health conditions at elevated rates compared to civilians.[9] This is particularly concerning for student Veterans, who have higher rates of mental health symptoms and suicide than non-Veteran students, but lower rates of treatment,[10] with up to 50% not engaged in mental health care.[11] Student Veterans with mental health conditions can have additional problems meeting the educational goals, as they experience higher rates of health risk behaviors (e.g., substance use), difficulties adjusting to campus life,[11] and interpersonal concerns with faculty.[12] These Veterans can face difficulties related to cognitive (e.g., attention), addictive (e.g., alcohol), or emotional/behavioral issues (e.g., PTSD, depression), leading to lower enrollment rates[13] and slower degree attainment[14] which in turn impede Veterans' successful adjustment to civilian life and vocational success. Unfortunately, many Veterans with mental health concerns neither report problems nor seek treatment,[10] and more than 50% do not perceive a need for services.[15] Even for Veterans seeking treatment for academic and psychiatric issues, there are many barriers such as time, transportation, and perhaps most importantly, not understanding how to get connected to existing resources.[16]

Though in-person educational services exist to help student Veterans, there are many barriers to their use. The VA has invested significant resources to address student success and mental health, using a catalogue of in-person treatments options for Veterans. Many of these are based in the tenets of Supported Education (SEd), a well-studied and effective approach for students who, because of psychiatric disabilities, face challenges in achieving educational goals.[17] This framework focuses on improving educational competencies related to academic settings (e.g., literacy, study skills, time management), successful navigation of the university environment (e.g., financial assistance), and improved attitude and motivation. VA resources currently available to student Veterans include Veterans Integration To Academic Leadership (VITAL) which provides information regarding education benefits, on-campus clinical care coordination, case management, and training; VetSuccess On Campus (VSOC) which provides on campus academic services; and Compensated Work Therapy (CWT) Supported Education (SEd) program, which provides individualized support for Veterans engaged in education and training programs as well as linkages with educational facilities.[17,18]

Though these program can be highly successful in assisting student Veterans, they are only effective to the extent that student Veterans can access them. Face-to-face resources are often unavailable due to geographical issues and a lack of trained supported education staff, or unappealing due to the multiple time constraints student Veterans manage.[19] Furthermore, there are many reasons student Veterans may not seek supported education interventions, including the stigma attached to having mental health problems, the desire to be resilient and build on strengths associated with military services, and distrust of the Veterans Health Administration (VHA).[20,21] Failures and delays in accessing or entering needed treatment can result in clinical, financial, and personal losses, as well as negative impacts on community reintegration.[22, 23]

Mobile application are a promising way to provide support and resources to those unable or unwilling to access in-person services. Innovative strategies to reach student Veterans with mental health concerns are needed to circumvent inaccessibility and stigma, in order to increase the acquisition of coping and academic skills. Although one such intervention, Veterans Integration to Academic Leadership-Supported Education (VITAL-SEd; described in further detail below) has shown promise in pilots and RCTs, the typical time from standard in-person treatment development to implementation can take 20 years.[24] Consequently, VA efforts to provide web- and app-based resources for intervention programming have increased. Mobile interventions have the potential to reach Veterans who might otherwise not have access to VA clinical care, as 81% of adults have access to smartphones.[25] Following initial technology development, mobile app interventions are relatively easy to implement within clinical settings compared to in-person

interventions, as they do not require training staff.[26] Once developed, an app to support Veterans' transition to the student role could provide psychoeducation, skill building, and connection to VA services both directly to Veteran users and as a complement to VA-provided services. [However, engagement - both initial and sustained - remains a problem for health apps. Studies suggest that engagement with behavioral apps can be improved by factors including positive perceptions of usefulness, motivation to pursue a goal, and visualizing user data in the app[43,44] suggesting the importance of Veteran input early in development and testing. Additionally, adoption and engagement of apps may be bolstered if the app is recommended by a source the target user trusts and finds credible, such as VITAL staff.[45] To improve both initial and sustained engagement, both target-use (Veteran) and future app referral sources (e.g., VA staff and college staff) should be involved in development, assessment, and future dissemination planning.

Civilian studies have shown that targeted mobile platforms designed to orient students to the culture of higher education, while also focusing on their mental health, can increase student retention and course engagement.[27] However, the majority of publicly-available education apps are extensions of learning-management systems for specific courses,[28] and do not provide resources that would specifically assist Veterans with mental health concerns and academic skills acquisition. Extending what current, effective civilian student apps provide (course management options) and adding Veteran-specific features (academic skill training, stress management exercises, connection to VA services) could thus provide an important, easily accessed resource to support Veterans. Unfortunately, there is no widely available VHA mobile app for student Veterans, and no accessible targeted intervention for student Veterans with mental health disorders - a substantial gap, given the high rate of difficulties these Veterans face.

An academic support app for student Veterans could improve current educational functioning and future employment. Readily available, mobile assistance with academic and psychiatric issues could provide student Veterans with the knowledge, skills, and resources to help them graduate. In the proposed project, we plan to develop a personalized academic success app, *VetEd*, with content based in past research, supported educational literature, and Veteran feedback, to address a variety of academic and psychiatric symptom-related educational barriers for student Veterans. Specifically, *VetEd* would provide services to student Veterans who may not have access to VA education interventions by 1) promoting the creation and execution of educational planning and goals, 2) providing opportunities for Veterans to learn new skill sets like course organization, task completion, and stress management, and 3) connecting Veterans with additional VA resources based off their personal needs, such as providing information on mental health counseling, obtaining educational accommodations, and Post-9/11 GI Bill coverage

2.2 Preliminary Studies

Our team includes researchers with expertise in student Veterans, technology, and mental health from the VISN 1 Mental Illness Research, Education, and Clinical Center (MIRECC) and the Center for Healthcare Organization and Implementation Research (CHOIR). The core research team includes **PI Dr. Erin Reilly,** with expertise in educational technologies, student development, and the creation and testing of mobile interventions for mental health, insomnia, and chronic pain; **Co-I Dr. Lisa Mueller**, specialist in Veterans' supported education, career development, and mental health interventions; and **Co-I Dr. Megan Kelly**, with expertise in development and usability testing of mobile programs for Veterans with mental health concerns. Our project will draw on the following preliminary studies:

VetSEd: The Veteran Supported Education (VetSEd) manualized treatment[29,30] provided personalized supported education for Veterans with academic goals. A small VetSEd RCT pilot was conducted with 33 Veterans with PTSD who had higher education goals.[31] Despite a small sample and matched attention control that could have diluted effects, significant positive differences were found, with the intervention group spending greater amounts of time on educational activities (p =.0.002). However, the high intervention attrition rate (30%) suggested difficulties accessing the in-person program.

VITAL-SEd: The Veterans Integration to Academic Leadership-Supported Education (VITAL-SEd) program[32] was developed using psychiatric rehabilitation and supported education principles. Based partially on VetSEd, both the pilot trial and RCT (PI: Dr. Ellison; CO-I's: Drs. Reilly and Mueller) provided critical data on the particular needs of student Veterans with unmet psychiatric issues. In the pilot study for VITAL-SED, 8 Veterans with mental health disorders (e.g., PTSD, substance use) reported high levels of satisfaction with treatment in relation to perceived academic issues (Table 1).[46] Following this pilot, a larger RCT (n=43) was completed in 2020. Preliminary findings showed that, compared to the control group, Veterans in VITAL-SEd reported significant improvement in completing academic tasks (p = 0.02), psychosocial functioning (p = 0.04), and a reduction in psychiatric symptoms on the PCL-5 (p =0.03) and PHQ-15 (p = 0.02).

2.3 Significance

This development project and exploratory study will combine mobile app technology with empirically-supported educational interventions for student Veterans struggling with mental health concerns. The app will provide opportunities for academic and psychiatric self-management to increase educational success for student Veterans, allowing for greater access and virtual care options for Veteran care coordination and educational development. Additionally, a resource that improves educational and vocational outcomes could help decrease disability payments and increase Veteran lifetime earnings. This project will create a resource for student Veterans that 1) provides a novel and accessible alternative to in-person education services that could help Veterans complete their academic path, and 2) advance our understanding app-delivered educational and psychiatric interventions. In addition, Dr. Shana Bakken (*National Director, Compensated Work Therapy*) and Dr. Khamkay Chitaphong (National Director, *Veterans Integration To Academic Leadership*), our operational partners, have dissemination team with several years of experience, which will make it easy to disseminate the *VetEd* app. Successful completion of the project will lead to the development of a Merit Review assessing *VetEd's* academic impact and effectiveness using a larger scale RCT.

3.0 Research Design and Methods

3.1 Drug/Device Information

N/A

3.2 Type of Study

This study will be a quantitative and qualitative research study in which we will hold focus groups with Veterans and then conduct field-based usability testing of the initial *VetEd* mobile app. Focus groups will be qualitative in nature, and usability testing will be both quantitative and qualitative.

3.3 Study Procedures

a. Sub-Study Participation

N/A

b. Study Related Procedures

<u>Phase 1 Focus Groups and Development</u> (10 months)

This phase will focus on preliminary app development using focus groups to revise, add, or remove potential content already identified as potential areas of app content (focus groups, n=8, n=8, n=5). . Following the informed consent process, we will audio record sessions if completed in-person or video-record if completed via remote teleconferencing, as this will assist with transcription for remote sessions. Focus group participants will be provided with drafted versions of potential app content related to the content areas below. At a minimum, Veterans in the focus group will be 1) given general information about the aims of the *VetEd* app in terms of its purpose, 2) given the opportunity to discuss their own educational experiences related to barriers and facilitators of their academic success, 3) presented with a general framework for how the mobile app will work, look, and function, 3) be presented with the exercises below as potential options for in-app content. At each stage of this focus group, Veterans will be encouraged to both provide feedback on specific content, looks, usability, and perceived appropriateness or "fit" with Veteran populations, and 2) to brainstorm potential additional content options for future app inclusion, such as resources, exercises, or options for customization. We will

VetEd Content. The *VetEd* app content provided to focus groups participants for feedback will be an adaptation and extension of the successfully piloted VITAL-SEd program) The overarching goals of this intervention will be to (1) orient student Veterans with mental health disorders to successfully transition to the role of student as defined by their self-created educational roadmap while providing services related to (2) academic skills, (3) mental health management, and (4) up-to-date information on psychiatric, academic, and financial resources to help them successfully complete courses and increase educational and psychiatric functioning. To achieve these goals, the intervention components presented to Veterans will cover four specific areas of student development (Table 2). Additionally, to assist with app- engagement, we will embed app-notifications prompting users to complete or explore different app content.

Table 2. Fundamental *VetEd* Mobile App Areas for Student Development

Area	Description	Potential Content*
1. Creating & Following an Educational Roadmap	Activities to help orient to the student role, reflect on educational and career goals, and organize academic choices into a roadmap with actionable education goals.	▪ *Education Tactics Plan* ▪ *Campus Resources Assessment Worksheet* ▪ *Creating a School Schedule*
2. Learning Strategies for Success	Short, informational activities and modules focused on the skills necessary to effectively complete course work.	▪ *Study Strategies* ▪ *Time Management Strategies* ▪ *Managing Interpersonal Conflict*
3. Coping with Stressors	Activities and guidance for mental health issues, stress management, and coping strategies for difficult thoughts and feelings.	▪ *Relaxation Activities* ▪ *Dealing with Stressful Thoughts* ▪ *Centering Before You Study*
4. Connecting to Resources	Resources and information for academic concerns, [mental health issues for multiple populations], and VBA/GI-Bill benefits information modeled off the VA Inquiry Routing & Information System (IRIS).	▪ *Exploring Course Accommodations* ▪ *GI Bill Concerns* ▪ *Mental Health Services* ▪ *Enrolling in the VA* ▪ *Center for Women Veterans (CWV)*

*based on VITAL-SED, consultant, and provider feedback; to be revised as needed using focus group data

Focus Group Procedure and Analysis. We will hold 3 focus groups of Veterans with mental health disorders (n=21) using a semi-structured interview guide. Our target of 3 groups is based on research suggesting that approximately 80% of all themes (i.e., thematic saturation) in focus groups are discoverable withing 2 – 3 focus groups[47], thus reaching point of "diminishing returns" in discovering new insights for preliminary app content.[48] Focus groups will either be conducted virtually on in person. We will not mix participants in virtual vs. in person focus groups – all participants in virtual groups will participate virtually and all participants in in person focus groups will participate in person. Focus groups will include Veterans enrolled in at least two courses in a setting of higher education in the past year, whether or not they are currently enrolled students. This will allow for a wider range of feedback on potential content and student Veteran needs, which may not be captured if only currently enrolled and successful student Veterans are recruited due to survivorship bias.

Following the informed consent process, participants will complete a 1.5 hour audio (if in person) or video-recorded (if virtual) focus group. Dr. Reilly will follow a similar protocol used for previous focus groups for educational interventions (PI: Marsha Ellison) and mobile apps (PI: Megan Kelly). This will include questions assessing Veterans' reasons for pursuing higher education, exercises they find helpful for learning academic skills (e.g., task management), messages that motivate them to complete course work, barriers related to mental health that impede successful course completion, and potential app resources to improve their academic functioning. Preliminary app content will be presented via PowerPoint and mobile app mock-ups for review and feedback, including discussing additional elements Veterans would find helpful in the app. Interviews will be transcribed by the VA Centralized Transcription Services Program. We will use Rapid Assessment Procedures (RAP),[33] an effective, widely used rapid data collection process. Coding will include the creation of summary points into a data matrix that organizes these points for each main topic of inquiry. This will allow the research team to systematically assess similarities, differences, and trends in responses across the focus groups. Finally, after a discussion of matrix contents, we will create a final memo summarizing findings and noting key themes for content. We will use this information to understand factors that that may improve acceptability of a *VetEd* app as well as features to revise or create.

Phase 2 Pilot Usability Testing (9 months): The goals of this phase are to: 1) gain feedback on the *VetEd* mobile app via Veteran usability testing; 2) assess Veteran interest, satisfaction, and usability of *VetEd*; 3) iteratively address any technological concerns, and 4) collect preliminary information on the impact of the *VetEd* app on academic functioning (retention, perceived course task ability, and educational self-efficacy) and community reintegration. We will conduct pilot usability testing with 15 Veterans who meet eligibility criteria, conducted in three waves. Each usability testing wave will include 5 participants, based on the finding that approximately 80% of usability problems can be detected using a sample of 4 to 5 participant per wave.[34]

Usability testing procedures. Following the consent process, participants will complete a series of baselines assessments (approximately 2.5 hours total) related to their academic experiences, technology acceptance, mental health functioning and symptomology, and community integration. Participants will then be provided with the app and log-in information for *VetEd*, with instructions on how to utilize the app at home over a four-week period. During this Phase, we will access information about enrolled participants via their VA Health CPRS and/or VISTA.

such as diagnoses, progress notes, medications, and specific information concerning substance use, to determine how other treatments are influencing outcomes for this study related to their mental health and academic functioning. During that time, they will complete at least two in-app tasks within

per week, with instructions provided specifically about which to access in Weeks 1, 2, 3, and 4. These will include setting up an educational roadmap, tracking course assignments, learning about successful study strategies, completing a coping exercise, and finding information related to GI Bill benefits. There will also be a quick midpoint assessment (45 minutes). Participants will complete surveys following this 4-week app piloting, and to evaluate the app in the following areas: (a) app usefulness: whether users can successfully complete designated tasks on the app, (b) effectiveness: the ability to accomplish assigned educational app tasks quickly and easily, (c) learnability: the ability to meet pre-determined app navigation goals (e.g. accessing and inputting information into the education roadmap), (d) satisfaction: users' feelings and opinions about the app related to their educational functioning and alignment with mental-health needs, and (e) engagement: initial and sustained interaction between a user and a mobile application. Usability measures will include two quantitative system usability scales (SUS; AES), task completion (quantitative), app log-in and use information (engagement). Perceived usefulness, engagement, and overall satisfaction will also be assessed through a post-app qualitative interview (survey + interview will be 2 hours total). After each round of testing (4-5 participants per wave, total n = 15), the investigative team will work with the programming team to improve the app.

3.4 Data Collection

We will use several qualitative and quantitative assessments during the usability testing of the veteran student app, *VetEd* (Phase 2, see Table 3 below).

Table 3. Veteran Completed Assessments for the Evaluation of *VetEd*

Measure*	Screen	Baseline	Midpoint	Post-App Follow-up	Purpose
Demographics	X	X			Eligibility, Sample Description
SCID-5		X			Eligibility, Sample Description
PCL5		X		X	Sample Description
PHQ-9		X		X	Sample Description
SUS			X	X	Usability
AES			X	X	Feasibility, Acceptability, Usability
ASES		X	X	X	Academic Outcome
CWBS		X	X	X	Academic Outcome
M2C-Q		X		X	Community Reintegration Outcome
Post-App Interview				x	Usability Feedback & Academic Outcomes

**Note. Full names and descriptions of measures are listed below.*

Demographics, functional health, and pain measures. Demographic measures will include age, gender, race and ethnicity, and education. These measures will take approximately 10 minutes.

Mobile App Utilization. We will collect information on *VetEd* usage, including the duration of use (minutes), number of logins, completion of in-app activities, and the percentage of participants who complete the program.

Mental Health Symptom Measures. To assess for important psychological co-morbidities in chronic pain treatment, we will administer the 9 - item Patient Health Questionnaire-9 (PHQ-9)[61] to assess for depressive symptoms, and 20-item PTSD Checklist-5 (PCL-5).[41] These surveys will take approximately 7 minutes.

Mental Health Diagnostic Measure: The *Structured Clinical Interview for the DSM (SCID-5)*[35] is a reliable semi-structured instrument that is the gold standard for diagnosing mental health disorders. The utilized SCID modules will take approximately 30 minutes.

System Usability Scale (SUS)*:* The SUS[36] is a 10-item measure, scored on a 5-point Likert scale, that assesses human-computer interaction. A SUS score above 58 is regarded as above average, and a SUS score above 80 is regarded as high and a score above which participants are likely to recommend the product to friends. The SUS generates a subjective evaluation score using a globally accepted scale and to understand if the system in its current form is sufficiently usable. This survey will take approximately 3 minutes

Acceptability E-Scale (AES): The AES[37] is a 5-item validated measure of the acceptability of mobile interventions, which has a cut-off of 80% for acceptability covering overall and specific component satisfaction. It will take approximately 2 minutes.

Academic Functioning Outcomes: Increased academic function is the primary non-usability related goal of the *VetEd* app. Consequently, preliminary educational functioning information related to academic self-efficacy, preparedness for course tasks, and perceived confidence in course completion/retention will also be collected and described. In line with educational research suggesting non-GPA factors can be stronger predictors of educational success and graduation[39], we will specifically assess self-reported academic self-efficacy using:

- *The Academic Self-Efficacy Scale[40](ASES*), an eight-item rapid assessment instrument to assess respondent self-efficacy regarding several academic skills related to academic achievement, such as time management, taking notes, taking tests, and general academic ability.
- *The Coping With Education Barriers Subscale[41]*(*CWBS)*, a subscale of the full 28 item scale that includes 2 subscales, the Coping with Career-Related Barriers (not administered for this study) and the Coping with Educational Barriers scale (20 items), assessing participants' degree of confidence in overcoming potential educational barriers (both internal and external).
- We will also assess self-reported confidence in completing coursework and academic retention (qualitative interview).

Both quantitative scales will take approximately 15 minutes. The qualitative interview, which will be combined with the mobile app feedback interview, will take approximately 30 minutes.

Community Reintegration: The Military to Civilian questionnaire (M2C-Q)[49] is a 16-item intended to measure dimensions of community reintegration related to productivity (in education, work, and domestic life); social relations; community engagement; and perceived meaning in life, self-care, and leisure. It will take approximately 5 minutes.

Data Management. Gesiel Software, Inc. will collect app utilization data for all participants. When data collection is complete, we will lock the database, conduct quality checks, and perform the data analyses described below. Paper research files will be kept at the VA Bedford HCS in a locked cabinet where data will be encoded with deidentified ID numbers and on an encrypted, secure VA server space that will be used solely for this study.

3.5 Analysis Plan

Data analysis plan. The main Phase 2 quantitative measures of acceptability and usability will be the Acceptability E-Scale and the System Usability Scale (SUS), respectively. We expect that Acceptability E-Scale and SUS ratings will increase across the 3 waves of app revision, and that by the third wave we will reach the benchmark of 80% on the Acceptability E-Scale and a 68 on the SUS (good acceptability). Additional data will be provided by the qualitative interviews after app use, using RAP processes outlined in Phase 1. We will also assess feasibility and engagement by measuring the proportion of

individuals who successfully complete the 4-week app testing, with at least 5 completed activities (of requested 8, 2 per week) or 63% of the program completed, in line with the mean number of completed sessions found in previous mobile interventions for chronic conditions.[42]

We will also assess academic functioning (academic self-efficacy, course task completion, and perceived retention/course completion) and community reintegration (M2C-Q) pre- and post-app use for each student Veteran specifically to 1) characterize the sample in terms of baseline academic functioning and community reintegration, 2) assess for possible changes in academic functioning and community reintegration, and 3) test the feasibility of these measures in anticipation of a larger, future RCT. This assessment will include testing the hypothesis that app use may lead to improvements in academic self-efficacy (ASES) and ability to complete courses tasks (CWBS), or potentially improvements in community reintegration (M2C-Q) mental health symptoms (PCL5, PHQ-9). To evaluate this, we will conduct non-parametric. Within subject statistical analyses between pre and post-app use scores on these two measures (using Wilcoxon Signed Rank Test), which is appropriate for small sample testing and outcomes that may thus not be normally distributed. We will use caution in our interpretation of inferential analyses.

4.0 Human Subjects

4.1 General Characteristics

Focus Groups. Participants will be 21 Veterans recruited from the Bedford VAMC and the community. Veterans at the Bedford VAMC will be identified for recruitment using a CPRS and/or VISTA chart review, hearing about the study from providers, or will be self-referred. Potential participants will be pre-screened by phone to determine whether eligibility criteria are met. In order to develop a Veteran student app that meets the needs of many Veterans with mental health concerns, we will also recruit from a diversity of clinics (e.g., VITAL, Women's Health Clinic, LGBTQ program, MHICM, mental health outpatient programs, domiciliary, social work services), and programs that serve different military cohorts (e.g., Vietnam Veteran groups, OEF/OIF program).

Usability Testing: Participants will be 15 Veterans recruited from the Bedford VAMC and the community. Veterans at the Bedford VAMC will be identified using CPRS chart review and/or VISTA, hear about the study from providers, or be self-referred. We will recruit from advertising on the Bedford VAMC Facebook page, Bedford VAMC Twitter account, Veteran newsletter, and Craigslist. All potential participants will be pre-screened by phone to determine whether basic study eligibility criteria are met.

4.2 Inclusion of Vulnerable Subjects

The study population may be considered vulnerable because they may be economically disadvantaged. The veteran population includes individuals who are economically or educationally disadvantaged. The study keeps payments to participation at a minimum in order to avoid coercion based on economic conditions. In addition, the informed consent is written at a grade-school level of education to minimize the vulnerability of the educationally disadvantaged.

Vulnerable participants will also include those with diagnosed mental health disorders. These individuals may have impaired decision–making abilities. Acute exacerbations of psychiatric illness may

substantially impair decision-making abilities by decreasing level of understanding and reasoning. However, the level of capacity in those that are stabilized is likely to be much higher. This study is not focused on treatment for acute exacerbation and thus, plans to include veterans who are not in an acute symptomatic exacerbation. Therefore, the decision-making capacity is likely to be intact and will be assessed via the planned phone screen.

Another population to be included is that of the Veterans themselves. They are accustomed to taking and following direct orders, thus introducing a further need for researchers to prevent coercion either directly or indirectly. Veterans will be given ample time to read and consider informed consent, with other treatment options presented by investigators. Family members, significant others, and primary treatment teams may also be involved in the decision-making process if the Veteran wishes. They are also informed that refusal to participate will be accepted without hesitation at any time and will not change their eligibility for VA services, treatment, disability payments, or other related VA benefits. Research staff will evaluate each subject at the end of the phone screen (focus group and formative evaluation phases), focus group, or usability testing session to insure that they have not experienced significant distress or exacerbation of their symptoms as a result of their participant. The evaluation will consist of asking the subject about (1) feelings of distress and (2) desire for additional support because of distress. Anyone experiencing distress and desiring support will be provided with informal support and if necessary taken to formal providers (see Protection Against Risk section).

4.3 Inclusion of Pregnant Women

Pregnant women will not be excluded because the *VetEd app* may still be helpful to them, and their perspective should have the opportunity to be included in the development of this mobile resource. In addition, the risk to the fetus is not greater than minimal and pregnant women may have specific academic needs that deserve to be included in this app, per the VA's mission to provide quality services to all who have served, and also aligns with Senate passed legislation *The Protecting Moms Who Served Act of 2021*. Obtaining this information requires that Veteran women who are pregnant or become pregnant may provide important feedback on potential app content.

4.3 Inclusion of Incompetent Subjects

We will not enroll incompetent subjects.

4.4 Inclusion/Exclusion Criteria

Phase One: Focus Groups
Inclusion criteria:
1) Enrolled in a minimum of at least 2 courses in a higher education setting within the past year
2) Current DSM-5 mental health disorder
3) Competent to provide informed consent
4) Owns a smart phone capable of supporting mobile apps
5) Are willing and able to read in English
6) Ages 18 and older

Exclusion Criteria:

1) Current or recent (within 1 month of study entry) moderate or severe DSM-5 alcohol or drug use disorder
2) Cognitive impairment that would interfere with participation
3) Severe suicidal ideation or a psychiatric hospitalization within the past month

Phase Two: Pilot Usability Testing
Inclusion criteria:
1) Currently enrolled in a minimum of at least 2 courses in a higher education setting
2) Current DSM-5 mental health disorder
4) Competent to provide informed consent
5) Owns a smart phone capable of supporting mobile apps
6) Are willing and able to read in English
7) Ages 18 and older
8) Self-report struggling with current course activities

Exclusion Criteria:
1) Not currently enrolled as a student
2) Current or recent (within 1 month of study entry) moderate or severe DSM-5 alcohol or drug use disorder
3) Cognitive impairment that would interfere with participation
4) Severe suicidal ideation or a psychiatric hospitalization within the past month

No subjects will be excluded based on their race, religion, ethnicity, gender or HIV status, as applicable.

4.5 Recruitment Procedures

We will recruit 60 Veterans in total (to meet study goals of max N=36 Veterans in the study) from the VA Bedford HCS (focus group=21 and pilot usability testing= 15
) and the community. Participants will be recruited throughout VA Bedford.

The PI will not be a provider of services to any participant recruited into the study. The PI will not call participants prior to enrollment, unless they contact the PI and express interest in the study or they do not call after receiving a letter about the study to indicate that they are not interested in the study (see below).

The recruitment process will include the following:

1) We will ask providers to mention the study to potential participants if they think it might be of interest to the participant, and provide a brochure or flyer if they are interested. We will ask providers to tell participants to call us if they are interested. Providers are not recruiting study participants, only providing information about the study and referring potential participants to the study flyer for more information. Although we will specifically target providers from VITAL, Vocational Rehabilitation, Veterans Community Care Center (VCCC), Mental Health Clinic (MHC), the Veterans Mental Health and Addictions Program, Primary Care Behavioral Health (PCBH), Veterans Services Coordinators,

Primary Care, the Community Residential Center (CRC), and the VASH program, we will provide information to any clinicians who are interested in learning about it.
2) We will also provide information to veterans and providers at a Crossroads event at the VA Bedford HCS, where information (e.g., flyers) about the present study and other investigators' studies will be distributed at a table in a highly frequented area of the Hospital.
3) We will also distribute flyers throughout the hospital, with research staff study contact information.
4) The names of Veterans from a medical record review coming to the following clinics for appointments: VITAL, Tobacco Cessation Program, Veterans Community Care Center (VCCC), Mental Health Clinic (MHC), the Veterans Mental Health and Addictions Program, Women's Health Clinic, Primary Care, Primary Care Behavioral Health (PCBH),the Compensated Work Therapy (WCT) program, the Community Residential Center (CRC), and the VASH program. These names will be obtained by searching CPRS and/or VISTA for entry/provider codes associated with these programs.
a. The research staff will access these patients' medical records only to determine whether they meet the study inclusion criteria and obtain address and phone contact information. We will also access SSNs ensure that we are identifying the right patient for contact. We will not open flagged records.
b. We will then send a letter to the Veteran to invite him/her to learn more about the study (attached to this application). The letter will contain contact information for the research team so the patient can contact the research team for more information. It will state that if we don't hear from the patient within two weeks, that we will call them about the study. It will also state that if patients do not want to be called, they can call our research staff and let us know. The identifiable information will be used only by members of the research team. This information will not be disclosed to anyone outside the VA.
5. Will obtain a list from the business office?

c. If the potential participant is interested in remote participation in the study after the phone conversation, we may use Azure RMS to send them the Informed Consent Information Sheet, study flyer, and study information by email.

Psychology menu option

Bed Mh Sw Vitl Cs Mgmt
BED MH TELE SW VITAL
BED MH TELE VITAL PSO 1
BED MH VITL PSO 3 IND
BED MH VITL PSO GRP

Alissa, christina, kate

We will also post our study flyer information on the VA Bedford Facebook page, VA Bedford Twitter account, in the VetNetNews newsletter, and Craigslist.

It is expected that recruitment will be enhanced by the VA Bedford's extensive treatment networks, recognition for expertise in vocational rehabilitation, and lack of competing studies, and subject payment. If continuous review of recruitment data suggest imbalance in gender distribution, we will target our recruitment toward clinics that serve higher numbers of women (e.g., women!'s clinics).

We will call a potential participant three times, and if we do not hear back from them from any of these attempts, we will discontinue contact attempts. However, if a potential participant does call back and leaves a message, we will reinitiate the three call rule (i.e., call them three more times and discontinue if we do not hear from them). If potential participants are not available, research staff will leave a message, saying "My name is Dr./Mr./Ms. And I am calling from the Bedford VA Hospital. We are calling about a research study and would like to check if you are interested in participating in this study. If you would like more information, please give us a call back at 781-687-XXXX. Thank you." If we reach someone by phone who is not the potential participant, we will ask the person to write down our contact information for the potential participant (name and number), but will not indicate where we are from or the purpose of our call to maintain confidentiality.

4.5.1 Subject Identification and Pre-Enrollment Screening:

We will obtain information through oral communication (telephone screening) with the prospective subject. The investigator will also obtain identifiable private information by accessing records (via CPRS or VISTA) to determine eligibility. Thus the exception to informed consent applies and no waiver of informed consent is necessary.

4.5.1a Use of PHI for Recruitment and/or Screening before consent is obtained:

We will request a waiver of HIPAA authorization for recruitment/screening.

A request to use identifiable information in the conduct of this research study under a waiver of authorization for recruitment and screening was submitted with this protocol. The identifiable information being requested is:

To use during the recruitment process:

- To conduct brief screenings with veterans who express interest in the study after learning about it through study presentations, flyers, letters, phone calls, or providers. This will involve asking the veterans questions based on study inclusion/exclusion criteria (i.e., academic status, substance use history). These are included on the study screening form.

- The names of veterans coming to the following clinics for appointments: Veteran Integration to Academic Leadership (VITAL), Veterans Community Care Center (VCCC), Mental Health Clinic (MHC), the Community Stabilization Program (CSP), Primary Care Behavioral Health (PCBH), Women's Health Clinic, Primary Care, the Community Residential Center (CRC), the Compensated Work Therapy Program (CWT), and the VASH program. These names will be obtained by searching CPRS or VISTA for entry/provider codes/clinic codes associated with these programs.

    - The research staff will access these veterans medical records only to determine whether they meet the study inclusion criteria and obtain address and phone contact information. We will also access SSNs to ensure that we are identifying the right patient for contact (e.g., patients with the same name but different SSN). We will not

open flagged records. We will also obtain email addresses if potential participant wants to be sent information through Azure RMS.

- We will then send a letter to the patient to invite him/her to learn more about the study (attached to this application). The letter will contain contact information for the research team so the patient can contact the research team for more information. It will state that if we don't hear from the patient within two weeks, that we will call and contact them about the study. It will also state that if patients do not want to be called, they can call our research staff and let us know. The identifiable information will be used only by members of the research team. This information will not be disclosed to anyone outside the VA.

The identifiable information will be used or disclosed only by members of the research team. This information will not be disclosed to anyone outside the VA.

The proposed study poses minimal risk to the privacy of the subjects because:

a. The identifiable information will be protected from improper use or disclosure by:

- For screening purposes only, this study will maintain a contact log. This log will contain the identifying information for veterans who are identified by research staff via medical record review or who contact research staff after learning about the study. It will contain the patient's name, social security number, contact information, and status (No Response, Screened In, Screened Out, Pending, No-Show, Chose not to participate). This log will be stored on our designated secure server space, accessible only to approved study staff. This log will be used until the end of the recruitment period in order to prevent ineligible or uninterested veterans from being contacted again by letters from research staff. All information will be kept according to VA Records Retention Policy.

- Study screening forms will be coded, and will not contain the participant's name, social security number, or date of birth.

- All identifying information will be maintained in locked file cabinets in locked offices or on a the study's secure VA server space.

- Only identifying information for candidates who meet the diagnostic eligibility criteria will be recorded.

- Identifying information for these patients will be recorded electronically on the VA server space, and will be password protected.

- If patients are not interested, we will transfer their information to a log of non-interested participants which will also be recorded electronically on a secure VA server space: \\R04BEDNAS21.v01.med.va.gov

- This log will be used until the end of the recruitment period. This will be done to prevent uninterested patients from being contacted again by letters from research staff. All information will be kept according to VA Records Retention Policy.

- This information will be only be used for scientific research purposes.

- Only Bedford VA study team members will have access to this information.

- The study team will not identify, directly or indirectly, any individual participant in any report of such research or otherwise disclose participant identities in any manner.

4.5.1b Consent for Recruitment and/or Screening:

We will conduct brief screenings with interested veterans will enable the research staff to more efficiently achieve the enrollment goal.

This recruitment method is the only way we will achieve sample size goals and the goal of a representative sample of veterans who are eligible for this study. It is essential that we specifically offer the study to all patients who meet criteria for the study in order to obtain a representative sample, rather than relying solely on self or provider referrals. If the research team relies on provider identification of eligible patients, it is likely that they will fail to identify all patients who meet diagnostic criteria for the study. Just relying on provider and self-referrals may result in a biased sample, as it is likely providers would only refer veterans to the study who they considered good candidates for this study, rather than all candidates who are eligible for the study. By having the research team identify potential candidates beforehand and then sending letters to potential candidates to use to contact the patient, and following up for those who do not opt out, we can ensure that the largest sample of veterans possible can be invited to participate in the study.

The inclusion criteria for the study are very broad and were expressly designed to allow greatest access possible to the study. For this study, it is important that we recruit our sample from a broad population of patients who smoke, and not just those identified only by providers or themselves as eligible. Veterans who decide they want to participate will go through the Informed Consent Information Sheet process prior to entering the study. Written information provided to participants and it will provide detailed information about study procedures and potential risks and benefits.

4.5.2 Enrollment:

60 participants will potentially be consented in the study to reach our goals for participation in focus groups (n = 21) and the formative evaluation, (n=15). A participant will be enrolled in the study immediately after the informed consent process. Participants in the focus group will immediately participate in the focus group after an informed consent process. For participants in the usability pilot testing, participation will take place immediately after an informed consent process.

4.5.2a HIPAA Authorization:

We are requesting a HIPAA waiver for all parts of the project as most participants will be remote and it would be impractible to do it through the mail, as consent will be done remotely with a waiver of documentation of informed consent.

4.5.2b Informed Consent:

Verbal informed consent will be obtained from each participant prior to entering the study. The information sheet provided to Veterans will explain in simple terms, before the patient is entered into the study, the risks and benefits to the patient. Verbal consent will be obtained after a thorough explanation of the study by the PI or other study personnel (e.g., research assistant, postdoctoral fellow, PI), and an opportunity for the participant to ask questions about the study. This discussion will take place under conditions in which the participant has adequate time to consider the benefits and risks associated with his/her participation in the study. We have decided to allow participants to choose between in-person and remote study visits for the focus group and formative evaluation portions of the study. For those that choose remote visits, the informed consent process will be done over VA-approved video-conferencing software.

After screening, if a Veteran indicates interest in the study, study staff will mail or email the study participant the informed consent information sheet if they prefer remote visits, or we will hand the Veteran an informed consent information sheet if they prefer in-person visits. A wavier of documentation of informed consent will be requested, to accommodate Veterans who complete all procedures remotely and for all participants to maintain consistency, as most will be remote.

After the potential research subject has reviewed the informed consent information sheet and indicated interest in participating, a study staff member will speak with the Veteran in-person or by phone or using VA-approved video-conferencing software to review the informed consent with them. Study staff will ask if they have any questions. We will assure the privacy of participants by asking them to use a private space if we are doing the consent process remotely, rather than a shared office or common area, to speak with us. If they come to the VA to do the process in-person, we will use a private space for the informed consent where we cannot be overheard. The informed consent document contain all required elements of informed consent and will explain in simple terms, the risks and benefits to the patient and that participation is voluntary and the patient is free to withdraw from the study at any time with no consequences. Consent will be obtained after a thorough explanation of the study by the PI or other study personnel (e.g., research assistant, postdoctoral fellow, PI), and an opportunity for the participant to ask questions about the study. This discussion will take place under conditions in which the participant has adequate time to consider the benefits and risks associated with his/her participation in the study.

Only participants capable of giving informed consent will be admitted into the study. Informed consent will be obtained by trained and highly qualified research personnel. The research staff member that conducts the informed consent process will ask each participant to verify that the information in the consent form is understood. The staff member will review understanding of the consent form, including information pertinent to study participation. During the informed consent process, we will assess whether the Veteran is competent to provide informed consent. We will determine whether the Veteran

is oriented to time, place, and person. We will ask questions to understand whether the Veteran understands the basics about what the study protocol involves. We will assess whether the consequences of participating in the study are understood. We will also assess whether the Veteran is able to clearly and voluntarily express his or her preference for participating in the study. If the Veteran is not able to do these things, we will determine that the Veteran is not competent to provide informed consent and we will end the informed consent process. Only once all questions have been answered and the participant understands the purpose of the study and study procedures will the participant give verbal consent, which we shall document in a secure excel file recording the participant providing consent and the date the provided consent. . A waiver of documentation of informed consent will be requested as individuals will be consented verbally. The informed consent process will be completed prior to the initiation of any study procedures

A discussion of the study's purpose, research procedures, risks and potential benefits, and the voluntary nature of participation as part of the informed consent process will continue throughout the research experience.

It will be the responsibility of the PI to assure that informed consent is obtained from each participant prior to the performance of any protocol procedures and in accordance with current state and federal regulations.

4.5.2c Master List

A participant will be added to the master list of subjects when s/he is consented. This master list will be kept on the secure VA shared drive (only accessible to study staff) for this study. Only staff that are part of the study and have access to the shared drive, and thus will have access to this master list.

4.5.2d VHA Health Records

A VHA health record will not be created and updated for this study.

4.5.2e Certificate of Confidentiality

We will obtain a certificate of confidentiality for this research study.

4.6 Risk/Benefit Ratio

4.6.1 Potential Risks and Methods to be Used to Minimize Risks:

1) During the study assessments and treatment, participants may experience some discomfort from discussing personal material and completing self-report questionnaires. Likewise, some participants may feel uncomfortable about having the study assessments and qualitative interviews related to *VetEd* app usage.

2) There is a risk of breach of confidentiality and loss of privacy, which great care will be taken to prevent. As discussed below, we will take precautions to ensure that potential risks are minimized.

Protection Against Risk

1) In order to minimize anxiety during the study assessments, focus groups, or usability testing, the PI and study staff will make every attempt to help participants feel comfortable when discussing sensitive material or talking aloud during focus groups and qualitative interviews. The PI is a licensed clinical psychologist with 10 years of clinical experience, particularly with regard to treating student mental health concerns, PTSD, and depression.

2) Initial and continuing participation of the participant in these protocols will be strictly voluntary; the participant will remain free to terminate participation at any time.

3) Potential study participants will be screened initially over the phone for eligibility. For screening purposes only, this study will maintain a contact log. This log will contain the identifying information for veterans who are identified by research staff via medical record review or who contact research staff after learning about the study. It will contain the veteran's name, social security number, contact information, and status (No Response, Screened In, Screened Out, Pending, Chose not to participate). This log will be securely stored on a VA shared drive. This log will be maintained until the end of the recruitment period in order to prevent ineligible or uninterested veterans from being contacted again by letters from providers or by research staff. The identifiable information will be used only by members of the research team. This information will not be disclosed to anyone outside the VA. The proposed study poses minimal risk to the privacy of the subjects because:

- Study screening forms will be coded, and will not contain the veteran's name, social security number, or date of birth.
- All identifying information will be maintained in locked file cabinets in locked offices or on the study's secure VA server space.
- Only identifying information for candidates who meet the diagnostic eligibility criteria will be recorded.
- Identifying information for these veterans will be recorded electronically on the secure VA shared drive.
- If Veterans are not interested, we will transfer their information to a log of non-interested participants which will also be recorded electronically on the study's secure space on the VA server.
- This information will be only be used for scientific research purposes.
- Only VA study team members will have access to this information.
- The study team will not identify, directly or indirectly, any individual participant in any report of such research or otherwise disclose participant identities in any manner.

Following this initial screening, potential study candidates will be consented and then participate in a detailed psychiatric screening interview at the first study visit with trained project staff who are closely supervised by Dr. Reilly. Effective screening will exclude Veterans who would be at greater risk because of psychiatric conditions revealed by this process. Dr. Reilly has used the aforementioned screening criteria successfully in the past with behavioral intervention studies. If at any point there are significant adverse reaction during the screening process, the participant will be removed from the study and appropriate treatment implemented. This could include immediate assessment to a local emergency room.

4) There is a possibility that study participants will not improve their academic functioning after testing the mobile app. All participants who fail to respond to treatment or withdraw prematurely will be referred for alternative treatment. If withdrawal from the study is necessary, we will provide appropriate alternative treatments (e.g., placing a consult with the VITAL program or Mental Health Clinic). Dr. Reilly will discuss the study, alternative treatments, or any concerns about the study with participants if requested by the participant or health care provider.

5) Participants may possibly experience clinical deterioration during the study. However, Dr. Reilly will be available to participants by phone, or in person if necessary, to discuss any concerns throughout the treatment period. Drs. Reilly, Kelly, and Mueller are all licensed psychologists, and will be available to study participants in the event of a clinical emergency; participants may also go to Bedford VA walk-in clinic if a clinical emergency occurs. This will be clearly communicated orally and in writing to study participants. Participants will be withdrawn from the study if their clinical condition deteriorates substantially. Participants may also be withdrawn if, in the judgment of the study investigators, remaining in the study poses a substantial risk to the participant or a higher level of care is needed.

6) Participants in the study may report suicidal ideation or suicidal intent. Given that some study participants may present with numerous vulnerabilities (e.g., history of traumatic brain injury, current or past suicidal ideation or behavior), all study staff members will be trained by Dr. Reilly, a licensed psychologist, in procedures for conducting risk assessment and crisis interventions. For participants who in the PI's judgment pose a substantial current risk of suicide but do not consent to having a provider contacted, we will breach confidentiality and contact their provider while notifying the participant of this and explaining our rationale (concern for their safety). At the beginning of the study and each subsequent assessment, participants will be told that the information they share is confidential unless the participant appears in jeopardy of harming themselves or someone else. For actively suicidal participants, or other participants who appear at high risk, who are not currently receiving mental health treatment, we will strongly encourage the participant to obtain mental health treatment. In addition, we will make every effort to find treatment for the participant and facilitate their obtaining treatment in a timely way.

Telephone Risk Assessments. Risk assessment will be conducted with all participants during the initial eligibility screening. Elements of risk assessment will include level of suicidal ideation and suicidal intent, using questions from the University of Washington Risk Assessment Protocol (UWRAP). If the Veteran endorses either of these items, further questions will be asked, including presence and level of specificity of a plan, access to weapons and other means, presence of known risk factors (e.g., recent loss, substance misuse, chronic pain or other serious medical problems), and presence or absence of deterrents. The PI will be notified of all such occurrences immediately. Following the procedures of the Bedford VAMC, if a Veteran is at imminent risk of suicide at the time of a phone screen, the RA will direct the Veteran to Dr. Reilly or their clinician designee via warm telephone transfer. The psychologist will conduct a suicide risk assessment over the telephone in order to determine the Veteran's level of risk. If the psychologist deems the Veteran to be at imminent risk, s/he will call the police and request emergency services via a warm transfer. The psychologist will stay on the line with the Veteran until s/he makes contact with emergency services and care is transferred. In the unanticipated event that a licensed clinical psychologist is not available, and study staff are unable to reach the emergency room at the VA, they will conduct a warm transfer to the Veterans' Crisis Line. If they believe that the Veteran

is not at imminent risk, but may need a welfare check, s/he will coordinate with VA police and the suicide prevention team. We will coordinate with credentialed, clinical research staff at each study site to ensure that there is constant coverage by a licensed clinical psychologist. As necessary, the study team will collaborate with the local suicide prevention coordinator to facilitate care and clinical follow-up. If a potential participant is hospitalized, they will remain potentially eligible and will be invited to participate during or after their hospitalization.

7) Initial and continuing participation of the participant in these protocols will be strictly voluntary; the participant will remain free to terminate participation at any time.

8) All data collected from participants, CPRS/VISTA-review, or the mobile app will be used specifically for the research purposes described in this application. No identifying information will be associated with any information provided by participants as a function of their participation in this study, including their names, addresses, or phone numbers. Each participant in the study will be assigned an arbitrary study number at random and this number will be used for all data for subsequent analyses. Although the consent form will include the name of each participant, it will be filed separately from the actual data files for each participant. To ensure protection of confidential information, all data will be coded and stored in locked files to ensure confidentiality. Audio recordings of and video recordings (dependent on participant's chosen modality) of usability testing and focus groups will be kept at the data management site at the Bedford VA and stored on a secure VA shared drive for this study. Upon completion of the study and data entry and analysis, all data and files will be stored and archived indefinitely under lock and key. Information about substance use will not be made available to any party without the written informed consent of the participant and at the participant's request. Only the PI and the PI's research team will have access to the computerized data. Names will not be included on videotaped portions of the study, in computerized data files, or in any published reports. Case records will be reviewed only by study personnel or, if necessary, by institutional, state, or federal regulatory personnel. Research assistants and others working on this study will be educated about the importance of strictly protecting participants' rights to confidentiality.

9) Numerous safeguards will keep electronic data secure. Each subject will be assigned a code number so that should any non-study personnel gain access to the data, they will not know to whom the data belong. A secure password is required to access computers, and computer networks are on secured servers that meet or exceed federal confidentiality standards.

10) The Bedford VA has institutional policies requiring all clinical investigators and their key personnel to undergo mandatory training in human subjects research. The program includes all clinical researchers regardless of their source of funding. Researchers typically fulfill this requirement by completing Bedford VA research trainings.

4.6.2 Data and Safety Management Plan:
4.6.2.1 Data Security

Although the consent form will include the name of each subject, it will be filed separately from the actual data files for each subject. All consent forms, interview, and questionnaire data will be filed securely under lock and key in file cabinets in the PI's offices at the Bedford VA Hospital (Building 5, 135B). Local data files, designated by an anonymous subject study number, will be stored directly to the

secure VA server designated for this study, be securely maintained, and will be accessible only to research staff directly involved in this project. Upon completion of the study and data entry and analysis, all data and files will be stored and archived indefinitely under lock and key.

Procedures to ensure the privacy of subjects:

Subjects will be asked to come to the PI's program offices, which are located in Building 5, away from busy patient areas. Interviews and questionnaires that take place in person will be completed in the PI's program offices, with the door closed. A white-noise machine will be used to ensure that information from the subject will not be heard outside of program offices. Study visits conducted remotely will utilize only VA-approved teleconferencing systems using secure meeting rooms.

Procedures to maintain the confidentiality of data/information:
All data will be used specifically for the research purposes described in this application. No identifying information will be associated with any information obtained from questionnaires or interview data, including names, addresses, or phone numbers. All data will be kept in accordance with VA regulations. Each participant in the study will be assigned an arbitrary study number at random and this number will be used for all data for subsequent analyses. All data are filed securely under lock and key in file cabinets at the ENRM Veterans Hospital (in Building 5, 135B). Upon completion of the study and data entry and analysis, all de-identified data and files will be stored and archived indefinitely under lock and key. All computers are password-protected. Information will not be made available to any party without the written informed consent of the subject and at the subject's request.

How/where data will be stored (location with room number):
Data will be stored in locked file cabinets in Room 135B in Building 5, a Bedford VA building that is locked during non-business hours. Computerized data files will be stored in password-protected files on a VA serve space designated for this study only.

Who will have access to the data/codes:
Only Dr. Reilly and authorized study personnel will have access to the data/codes onsite at the Bedford VAMC. Codes will be stored on the approved VA server space for this study. Only Bedford study staff will have access to one database, linking the code to the Veteran's name and SSN. This information will be stored on the study VA server space and stored separately from other data. Once a research staff member is no longer working on this protocol, they will no longer have access to data and codes.

What will happen to the data when the research is complete:
All data will be kept in accordance with VA regulations. Upon completion of the study and data entry and analysis, all de-identified data and files will be stored and archived indefinitely under lock and key.

How data will be archived:
The data will be archived. Data will be archived on VA authorized storage media and hard copies of data (i.e., questionnaires and interview data) will be stored in locked file cabinets in Building 5, Room 135B. We will retain a complete record of all data obtained during the VA portion of the research in accordance with privacy requirements, the Federal Records Act, and VHA Records Control Schedule (RCS) 10-1. All disclosures and data transmission will meet privacy and security requirements per VA Directive 6500, VA Handbook 6500, and VHA Handbook 1605.1.

Will data with identifiers be released?
Data with identifiers will not be released, transferred, or shared.

4.6.2.2 Data Safety Monitoring

A DSMB is not required because multiple clinical sites will not be used, the study is not blinded, and interventions are not particularly high risk or vulnerable populations are not included.

Responsibility for Data and Safety Monitoring: Dr. Reilly will have overall responsibility for monitoring the integrity of the study data and participant safety. Any difficulties that arise with Veterans related to self-disclosed safety issues or concerns will be discussed between the PI and the co-investigators (Drs. Kelly and Mueller). Additionally, the safety of research participants will be discussed in meetings with Drs. Reilly, Kelly, and Mueller, respective to their areas of expertise.

Dr. Reilly will be monitoring adverse events involving data loss and adverse events related to the study. Adverse events will be monitored in the following ways:
Procedures for Monitoring Participant Safety: The PI will implement the following procedures to ensure data integrity and the safety of participants during the study:

1) Many elements of the research plan are intended to minimize the risks of study participation. These are detailed in the Research Design and Methods section and 2) "Protection Against Risks" in the Human Participants section above. For example, the study exclusion criteria exclude Veterans who are experiencing clinically significant suicidality or a psychiatric hospitalization within the past month. The PI will carefully monitor participants at each study visit to ensure that they do not experience clinically significant deterioration; if they do, the PI will reevaluate them and, if indicated, refer them for immediate non-study treatment (e.g., pharmacotherapy, counseling, inpatient, or residential treatment). The PI (or covering clinician in her absence) will be available to participants in the event of an emergency. In the event that serious medical or mental health complications should occur, consultation from emergency clinical services is immediately available at the Bedford VA Medical Center.

2) Weekly meetings will be held between Drs. Reilly, Kelly, Mueller, and other study staff. We will discuss and resolve any safety issues more frequently if necessary, as such issues arise, possible participant withdrawal from the study, or any safety concern.

3) Data integrity and confidentiality will be safeguarded as discussed in the Data Management section of the application and under Protection Against Risks above.

Reporting Adverse Events: Reporting of adverse events will occur as follows:

Reporting Adverse Events: Reporting of adverse events will occur as follows:
1) Any death that is both unanticipated and possibly related to the research will be communicated orally to the IRB of the VA Bedford Healthcare System immediately upon becoming aware of the death, and in

writing within 5 business days.

2) Any Serious Adverse Event (e.g., suicide attempt, hospitalization) that is both unanticipated and possibly related to the research will be reported in writing to the IRB within 5 business days. Any serious adverse event that does not appear to be both unanticipated and related to the research, will be recorded and reported at continuing review.

3) Any adverse event that does not appear to be serious, unanticipated or related to the research will be summarized in the VA Bedford IRB annual progress reports that are submitted to the IRB for continuing review.

4.6.3 Potential Benefits:

1) Participants may benefit from a potentially effective mHealth intervention. Veterans may benefit by being able to improve their academic functioning and access to VHA resources for student Veterans.
2) Moreover, the research will help to understand whether mobile, asynchronous interventions for academic issues are beneficial for Veterans also managing mental health concerns, as there is still only limited research on efficacious mobile app interventions for student Veterans
3) The information gained from this study will provide direction for future research studies on mHealth apps for student Veterans and provide important information on the feasibility and acceptability of the *VetEd* app that can be used for a larger trial.

4.6.4 Alternative Procedures:

Participants are free to decline entrance into or withdraw their participation in this study at any time. However, if they decline to participate or withdraw from the study, and they indicate that they desire assistance with their academic functioning, they will be provided with information about VA supported education services and VITAL services. In addition, if Veterans decline to participate or withdraw and reported that they would like additional mental health treatments at the VA, they will be referred to services such as the mental health clinic, and treatment may include individual and group counseling, peer support, and/or medications. Similar treatments are available through programs in the community as well. A decision not to participate in this study or to withdraw from this study will not affect the participant's ability to participate in standard VA treatment for educational assistance or mental health support.

4.7 Costs and Payments

Focus Groups: We will pay subjects $40 each (in the form of a gift card) for their participation in focus groups (1.5 hours). We expect to have a total of 21 Veterans across the three focus groups.

Usability testing: Usability pilot participants will receive $80 for the baseline assessment (2.5 hours), $20 for a mid-point check-in to evaluate any potential usability issues (45 minutes), and $90 for follow-up visit assessments after the pilot testing (2 hours), for a total of $190 per participant.

4.8 Providing for Reuse of Data

Data will not be reused in future studies.

4.9 Creation of a Tissue Bank

A tissue bank will not be created for this study.

5.0 Resources

The PI is the Bedford Education Director of the VISN 1 MIRECC, which provides space and staff for this study. The VISN 1 Mental Illness Research, Education, and Clinical Center (MIRECC) involves several VA medical centers in the New England network, is centrally administered at the Bedford VA. Study activities will take place in the offices of the MIRECC in Buildings 5 and 9.

6.0 Collaborations

To ensure that the developed *VetEd* app is responsive to both Veteran-identified needs and VHA priorities for Veteran educational supports, a *VetEd* advisory panel will also be formed, including the following stakeholders: VACO consultants Dr. Shana Bakken (National Director, Compensated Work Therapy, see support letter) and Dr. Khamkay Chitaphong (National Director, Veterans Integration To Academic Leadership), Alisa Bennett (Bedford VAMC VITAL Program Manager), current VITAL-SEd providers, and Kristine Babcock (Veterans Services Coordinator, Northshore Community College). This will ensure that crucial feedback from senior VACO stakeholders, community partners, and SEd experts guide app content and future *VetEd* app dissemination early in the research process. This group will meet with the research staff quarterly, beginning with a project kick-off upon the start of the project. These panel members will 1) not be involved in the research study as collaborators or co-investigators, 2) not have access to research data. The panel members may be provided with options for changes and additions to the mobile application as informed by Veteran focus groups, for the purposes of making decisions regarding additional app content. This will not include the presentation of Veteran research data.

7.0 Qualifications of the Investigators

Dr. Erin Reilly, Ph.D. is the Education Director, Psychologist, and Investigator with the Mental Illness Research, Education, and Clinical Center (MIRECC), working on technology-assisted interventions using Acceptance and Commitment Therapy (ACT) with Veterans managing chronic mental and physical health concerns. Much of her recent work explores the use of technology to deliver acceptance and mindfulness-based interventions supporting psychological and physical functioning concerns for Veterans, with a particular emphasis on chronic pain, anxiety, and physical health-related functioning. She has also received a Rehabilitation R&D Career Development Award to support the development and evaluation of an online intervention for chronic pain management. She also worked with Dr. Lisa Mueller on the development and testing of the Veteran Integration to Academic Leadership – Supported Education (VITAL-SED) manualized intervention pilot. Her experience with both developing interventions for student Veterans and creating online technologies for students in higher education are uniquely suited to this proposal for the development and iterative evaluation of the VetEd app. She is the named Primary Investigator for the Rehabilitation R&D SPiRE that will fund this development and usability pilot project.

Dr. Megan Kelly, Ph.D. is the Co-Director and the Bedford Site Director of the VISN 1 MIRECC. She has been involved in the psychosocial treatment research for the past 19 years, with a particular focus on the development of behavioral interventions to improve the community reintegration of Veterans with PTSD. She has published on trauma and stress responding, the relationship between trauma and barriers to VA care, and the effects of stress and trauma on OEF/OIF veterans. She has had five VA and NIH-funded projects (including three RR&D funded projects) to develop and evaluate new behavioral interventions for Veterans focused on the improving the psychological health and community reintegration of Veterans. She also has substantial expertise in the development of Veteran-facing mobile interventions, including online websites for tobacco cessation, and mobile app development to address social support issues for Veterans with PTSD. Her research is focused on social functioning in individuals with mental health disorders, and in particular, how social avoidance is an important obstacle to positive life functioning. Thus, she has extensive experience with psychosocial treatment research for Veterans with PTSD and other mental health disorders. She has a demonstrated record of successful and productive projects in the area of individuals with PTSD and her expertise and experience have prepared her to serve as a co-Investigator for the proposed project.

Dr. Lisa Mueller, Ph.D. is the Clinical Director of the Bedford VA Vocational program, and has been part of a team implementing supported education for the past ten years and am an experienced supervisor for this service. She was co-investigator with Dr. Marsha Ellison for her participatory action research study that led to the development of the Veterans Supported Education manual (VetSEd). She has also worked with Dr. Ellison on a number of supported education studies and recently co-led a work group with the VHA Vocational Rehabilitation National Director, Dr. Shana Bakken, for the Office of Mental Health and Suicide Prevention to revise the original VetSEd manual to create the CWT SEd manual. She has presented on the provision of education services to veterans in local, regional, and national presentations for the past eight years and serve as one of the four content experts in the field leading a national quarterly technical assistance call for VA Vocational Rehabilitation programs. As an investigator for the VISN1 Mental Illness Research Education and Clinical Center (MIRECC), she has also conducted qualitative analysis from focus groups and individual interview data on funded research projects and received RR&D VA funding to develop and evaluate a motivational enhancement intervention for veterans with serious mental illness to increase competitive employment outcomes and have contributed to VA funded research in the areas of vocational rehabilitation.

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