I. OVERVIEW OF THE FUNDING OPPORTUNITY

Program Announcement for the Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

Joint Program Committee 5 Military Operational Medicine Research Program

Psychological Health and Traumatic Brain Injury

Research Program

Peer Support Program Translational Research Award

Announcement Type: Initial

Funding Opportunity Number: W81XWH-17-PHTBIRP-TRA

Catalog of Federal Domestic Assistance Number: 12.420 Military Medical Research and Development

SUBMISSION AND REVIEW DATES AND TIMES

- Pre-Application Submission Deadline: 5:00 p.m. Eastern time (ET), January 5, 2018
- Application Submission Deadline: 11:59 p.m. ET, January 19, 2018
- End of Application Verification Period: 5:00 p.m. ET, January 24, 2018
- **Peer Review:** March 2018
- **Programmatic Review:** May 2018

This Program Announcement must be read in conjunction with the General Application Instructions, version 20170516. The General Applications Instructions document is available for downloading from the Grants.gov funding opportunity announcement by selecting the "Package" tab, clicking "Preview," and then selecting "Download Instructions."

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II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY

II.A. Program Description

Applications to the Fiscal Year 2017 (FY17) Psychological Health and Traumatic Brain Injury Research Program (PH/TBIRP) are being solicited for the Defense Health Agency (DHA) J9, Research and Development Directorate, by the U.S. Army Medical Research Acquisition Activity (USAMRAA) using delegated authority provided by United States Code, Title 10, Section 2358 (10 USC 2358). As directed by the Office of the Assistant Secretary of Defense for Health Affairs (OASD[HA]), the DHA manages the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriation. The U.S. Army Medical Research and Materiel Command (USAMRMC) Congressionally Directed Medical Research Programs (CDMRP) provides PH/TBIRP management support for DHA research program areas, including the Joint Program Committee-5/Military Operational Medicine Research Program (JPC-5/ MOMRP). The execution management agent for this Program Announcement/Funding Opportunity is the CDMRP with strategic oversight from the JPC-5/MOMRP.

The PH/TBIRP was established by Congress in FY07 in response to the devastating impact of traumatic brain injury (TBI) and psychological health (PH) issues, including post-traumatic stress disorder (PTSD), on our deployed Service members (SMs) in Iraq and Afghanistan. The PH/TBIRP mission is to establish, fund, and integrate both individual and multiagency research efforts that will lead to improved prevention, detection, and treatment of PH issues and TBI. The vision of the PH/TBIRP is to prevent, mitigate, and treat the effects of traumatic stress and TBI on function, wellness, and overall quality of life for SMs as well as their caregivers and families.

The JPC-5/MOMRP is one of six major research program areas within the DHA Research and Development Directorate. DHP RDT&E funding is administered through JPC-5/MOMRP, which consists of DoD and non-DoD medical and military technical experts relevant to the program area. The JPC-5/MOMRP PH and resilience research portfolio is focused on developing effective medical countermeasures against operational stressors and to prevent physical and psychological injuries during training and operations in order to maximize the health, readiness, and performance of SMs and their families, which are critical to force health and readiness. The proposed research must be relevant to active duty Service members, Veterans, other military beneficiaries, and the American public.

II.A.1. Background and Intent

In addition to the typical civilian stressors, SMs and their families face military-unique challenges, including frequent disruptive moves, deployments, traumatic exposures, disruptions in family routines, and compromised co-parenting.¹ Although most SMs adequately cope with, and may thrive when faced with, these challenges, a significant number experience individual and family psychosocial difficulties (e.g., interpersonal problems, suicide, substance abuse) that threaten military readiness.^{2, 3, 4, 5} Suicide remains a serious military health concern and focus on prevention, intervention, and postvention is critical.

Despite efforts to increase accessibility and utilization of behavioral health services, significant barriers exist to SMs seeking and utilizing care. Many SMs have a strong preference for self-reliance and for seeking the help of peers instead of professionals or formal help resources. In April 2017, the Defense Equal Opportunity Management Institute completed a brief survey of 4,438 active duty respondents and asked who they preferred to talk to when feeling stressed or overwhelmed; the three most popular responses were a friend outside of the military (54%), a spouse/intimate partner (54%), or a military peer (48%). The four least popular responses were mental health provider (7%), medical provider (4%), military family life consultant (4%), and attorney (1%). The *Status of the Forces Survey*⁶ found that active duty respondents who self-reported suicide ideation and attempts sought help from mental health professionals/significant others (48%), and military friends not in chain of command (43%), suggesting that peers are relied upon as a significant source of support. In 2016, the Center for Naval Analysis completed a series of focus groups with active duty members about stigma and found similar results with SMs preferring to seek help from a peer over a medical or mental health provider.

Military culture emphasizes teamwork and peer support⁷ and operational peer support is a focus of developing and enhancing well-being, resiliency, and readiness.⁸ Connecting with peers can improve quality of life, promote wellness, and build resiliency.⁹ Social support is a key aspect of healthy functioning, and its absence is associated with both increased risk for and problems recovering from psychological disorders, including PTSD, substance abuse, and suicide.^{10, 11, 12} Peer support can be characterized as practical, social, and emotional support from a person with shared affiliation, lived experiences, or situations. The *Ontario Peer Development Initiative*¹³ defines peer support as: "… a naturally occurring, mutually beneficial support process, where people who share a common experience meet as equals, sharing skills, strengths and hope, allowing people to learn ways of coping from each other."

Peer support is widely used in formal and informal programs both in the military and civilian communities, and can positively impact individuals with shared diseases, conditions, or situations.¹⁴ Peer support programs implemented in law enforcement and other emergency service agencies have contributed to an increase in professional mental health referrals and a decrease in on-the-job suicides, sick days, and poor work performance.¹⁵ Peer support programs have been applied in the military to address combat and operational stress and enhance resiliency (e.g., California National Guard Peer-to-Peer Support Program, Canadian Operational Stress Injury Social Support, Deployment Safety and Resiliency Team), suicide prevention, and recovery. Similarly, the VA is using peer-to-peer programs in the management of PTSD and substance use disorder by having peer supporters serve as an example of how to overcome injuries and offer support as someone who has "been there."

Current Evidence Base for Peer Support

The Defense Suicide Prevention Office (DSPO) requested the Tri-West Healthcare Alliance to conduct a systematic review of the scientific evidence on the effectiveness of peer support interventions in suicide prevention. Their review identified 18 relevant published studies that collectively show that peer support can be effective for engaging people into care, reducing the use of emergency rooms and hospitals, and reducing mental health symptoms. Social support, experiential knowledge, trust, confidentiality, and easy access appear to be common components of effective peer support programs. However, current research is limited by lack of comparison

groups, small sample sizes, and inconsistency of peer support provider roles. Research often involved multi-faceted interventions in which peer-to-peer approaches were one component, which makes quality assessment of peer-to-peer approaches difficult to achieve.

Challenges and Considerations for Peer Support Programs

One source of peer support is a group of helpers described as peer support providers, such as peer educators, mentors, navigators, advocates, assistants, coaches, providers, buddies, and community health workers. Topics of importance and inconsistency in the peer support literature include peer support provider training, supervision, the degree of autonomy and responsibility, and the content of their actual work. Training and supervision for peer support providers engaged in suicide prevention efforts are especially important as this domain is sensitive and involves safety concerns. Clearly defining the peer support provider role is critical to success^{16, 17} and consideration should be given to the settings in which peer providers are located, what services they provide, and how well they are integrated into the mental healthcare teams.^{18, 19} The key functions of peer support include assistance in daily management of health-related behaviors, social and emotional support, linkage to clinical care, and longitudinal or ongoing support.

The skills required and the types of expectations that could define successful fulfillment of the peer support provider role have also been mentioned in the literature. Peer training should include methods to manage the vicarious trauma, frustrations, and inevitable setbacks involved in this work.²⁰ The values and principles underlying peer support have been explored, but an understanding of its mechanisms of action is lacking.²¹ Many authors point out that peer support should enhance rather than supplant needed traditional mental health services.²¹

Current Peer Support Practices in the Military

The military has a longstanding tradition of leveraging peer support interventions that aim to support SMs' capabilities through fostering positive outcomes and reducing risk. Examples of programs developed for military populations include:

- Be There Outreach Center (DSPO) (<u>https://www.betherepeersupport.org/</u>)
- Defender's Edge (Air Force)
- Conquering Stress Through Strength (Marine Corps)
- Buddy-to-Buddy (Michigan Army National Guard) (<u>http://buddytobuddy.org/</u>)

While peer support practices are popular, there is a dearth of evidence on their effectiveness in promoting healthy behaviors and reducing problem behaviors like suicide.

II.B. Award Information

The FY17 JPC-5/MOMRP PH/TBIRP Peer Support Program (PSP) Translational Research Award Funding Opportunity seeks applications to support examinations of efficacy and *effectiveness of peer-to-peer support interventions to translate and integrate content into the everyday routines of SMs to enhance psychological health readiness and mitigate negative behavioral health issues including suicide behaviors.* Applications should focus on research to evaluate the efficacy and effectiveness of peer support programs that could be implemented in the military. Such interventions should leverage public health paradigms such as the socialecological model, behavior change theory, and adult learning theory. Considerations such as how peer-to-peer support would accommodate military culture, including varied ranks and structure, gender, and occupation requirements should be taken into account. Interventions should be sensitive to the time and contextual constraints associated with occupation and lifestyle. Interventions that include an electronic or virtual component will be considered, but applicants should demonstrate that such components will ensure the interventions are interactive and engaging. Studies should consider ways to integrate content into the everyday routines of SMs to decrease burden and increase buy-in.

Applications should evaluate the peer support program, including peer support providers' roles, using but not limited to the following criteria:

- 1. Tasks: Observable activities peer support providers are expected to perform in support of peers; interventions should specify which tasks are visible to peers and which tasks are helpful to peers but considered "behind-the-scenes."
- 2. Responsibilities: Categories that group similar tasks together; tasks can be organized by knowledge or skill area, peer support setting, type of peer, frequency in which task is performed, or other common themes.
- 3. Traits: Knowledge, skills, abilities, attitudes, and other attributes that peer support providers need to have prior to assuming work role responsibilities; interventions should specify what level of education or types of experiences may be necessary for a peer support provider to have in order to execute the intervention; in addition, interventions should address the importance of whether peer support providers need to have the same rank or belong to the same career field as the peers.
- 4. Peer-to-Peer Environment: Interventions should specify the range of environments in which peer support is executed; peer-to-peer environment descriptions should address the following questions:
 - a. How much autonomy and supervision do peer support providers need after initial training?
 - b. What is the intervention modality (in-person, virtual, both)?
 - c. What is the environment? Do peers need to belong to the same team or unit or be aligned to the same workplace (installation)?
 - d. How many peers should be involved in a peer support session?
 - e. When can the intervention occur (duty hours, off-duty hours, i.e., during work, after work, or both)?

- f. Where should the peer support intervention take place (on-base in barracks, on-base at work site, off-base at home, or off-base at other locations)?
- g. Is the same location needed to execute the intervention?

This funding opportunity seeks applications that support clinical trials of non-medical (behavioral health) interventions.

A clinical trial is defined as a prospective accrual of human subjects in whom an intervention (e.g., behavioral intervention, device, drug, biologic, surgical procedure, rehabilitative modality, or other) is tested for a measurable outcome with respect to safety, effectiveness, and/or efficacy. This outcome represents a direct effect on the subject of that intervention or interaction. Behavioral health interventions should be applicable to all DoD Service branches (Army, Navy, Air Force, Marines) as well as Special Operations Communities and the Reserve Component (Reserves/National Guard). Military collaborations are encouraged. *Veterans are an important population, but this Program Announcement/Funding Opportunity is not focused on Veterans.* The expectation of this research is to demonstrate the utility of these peer-to-peer support interventions to benefit our SMs and the public at large.

The proposed research may have broad applicability across the military life cycle or may be focused on a particular phase. Applications should consider the timing, quantity, and delivery method of training and interventions, for example, to coincide with important military life cycle stages or transitions. When relevant, limits related to confidentiality concerning research data that involves reporting of illegal behavior by current SMs need to be carefully addressed.

Research should specify resilience, wellness, and behavioral health and risk outcomes in addition to suicide risk and protective factors that peer support interventions are targeting. Examples of modifiable suicide risk and protective factors may include but are not limited to: resilience, help seeking, hopelessness, burdensomeness, belongingness, social isolation, access to lethal means, perceived organizational support, leader supportive behaviors, finding purpose, and financial/ relationship/legal problems.

Applications should NOT focus on peer support interventions that consist primarily of referrals to clinical care. This funding opportunity is not interested in interventions that employ gatekeeper training approaches such as the Applied Suicide Intervention Skills Training (ASIST) or Ask-Care-Escort (ACE) intervention. Interventions should include a skill-building component for the peer support provider through a train-the-trainer module as well as for the peer being helped by the peer support provider.

Examples of skills to target in both peer support providers and peers may include but are not limited to preventive maintenance, emotion regulation, social problem solving, healthy coping, adaptive thinking, stress management, team building, supportive leadership behaviors, overcoming stigma associated with help seeking, and understanding and mitigating implicit or unconscious biases.

Examples of skills to target for peer support providers may include but are not limited to peer influencing, proactive bystander intervention, active listening, empathy, and overcoming resistance to help seeking. Examples of skill-building activities that interventions may address

are motivational interviewing, cognitive-behavioral techniques, Specific-Measurable-Attainable-Realistic-Timely (S.M.A.R.T.) goal setting, Strength-Weakness-Opportunity-Threat (S.W.O.T.) planning, crisis response planning, role playing or scenario learning, and stress inoculation training.

Interventions should have some evidence demonstrating an effect on suicide-related behaviors, their risk correlates, protective factors, and/or a theoretically based justification for why an effect on behaviors in non-clinical, military populations is anticipated. Applications should include repeated measurements to evaluate implementation fidelity, durability of effects, sustainability, and longitudinal outcomes. Baseline, mid-, and post-intervention measures of peer support provider and peer outcomes of interest for DoD include behavioral assessments of learned skills from peers, transfer of learned skills from peer support setting to work and personal life settings, utilization of help-seeking resources by peers, measures of hopelessness, burdensomeness, belongingness, suicide ideation, non-suicidal self-injury, suicide plans, and suicide attempts. Mid-intervention measures may occur as early as one-fourth and as late as halfway through the intervention. Post-intervention measures may occur immediately after the peer-to-peer intervention occurs. If the proposed intervention has no discrete end date, then the application may define what the initial timeframe for the intervention is and have a measure that coincides with the end date for that timeframe. Follow-up measures may take place no sooner than 30 days after the initial post-intervention measure.

Given the challenges in defining peer support provider roles and responsibilities, applications should explain how work role requirements for peer support providers are defined. This funding opportunity is interested in applications that will help DoD come to a consensus on the work role requirements for peer support providers (see Dierdhorff and Morgeson, 2007, for a review and empirical investigation²²).

The JPC-5/MOMRP expects to allot approximately \$6M of the FY17 PH/TBIRP appropriation to fund approximately 2 to 3 PSP Translational Research Award applications, depending on the quality and number of applications received. Funding of applications received in response to this Program Announcement/Funding Opportunity is contingent upon the availability of Federal funds for this program. The maximum period of performance is 3 years. For additional funding information, see Section II.D.5, Funding Restrictions.

This Program Announcement/Funding Opportunity is focused on delivering solutions for SM health and should demonstrate broader potential public use benefit of the research. Peer support interventions may have broad utilization across the military life cycle or may be focused on a particular phase. When relevant, limits related to confidentiality concerning research data that involves reporting of illegal behavior by SMs and/or their families need to be carefully considered and addressed within the application.

Use of Military Populations or Resources:

If the proposed research involves access to active duty military and/or resource(s), the PI is responsible for demonstrating such access. If possible, access to target active duty military population(s) should be confirmed at the time of application submission. A letter of support, signed by the lowest-ranking person with approval authority, should be included for studies

involving SMs, military-controlled study materials, and military databases. If access cannot be confirmed at the time of application submission, the Government reserves the right to withdraw or revoke funding until the PI has demonstrated support for and access to the relevant population(s) and/or resource(s).

If the proposed research requires access to Military Health System (MHS) data managed by the DHA, the PI is required to follow the guidance on the official website of the MHS, <u>https://health.mil/Military-Health-Topics/Privacy-and-Civil-Liberties/Submit-a-Data-Sharing-Application</u>.

DoD and other Federal Agencies Collaboration and Alignment Encouraged: Relevance to the healthcare needs of the Armed Forces, their family members, and their communities is a key feature of this award. Therefore, PIs are strongly encouraged to collaborate, integrate, and/or align their research projects with DoD or other Federal Agencies' research laboratories and programs. Agencies listed in <u>Appendix 3</u> are potential resources and do not represent an all-inclusive list of work in the target research area.

Use of Common Data Elements and Data Sharing: The National Research Action Plan (NRAP) requires the use of common data elements (CDEs) to facilitate sharing of data to promote collaboration, accelerate research, and advance knowledge on characterization, prevention, diagnosis, and treatment of PH disorders and PTSD. The USAMRMC strongly encourages applicants to incorporate CDE measures appropriate to each field of study, such as the PhenX Core and Specialty collections (e.g. Suicide Specialty collections), which are available in the Mental Health Research, Substance Abuse and Addiction, and Research Domains Collections of the PhenX Toolkit, <u>https://www.phenxtoolkit.org/index.php</u>, into all studies involving human subjects as applicable.

For studies that will enroll subjects with psychological health disorders, awardees may be requested to submit data to the National Institute of Mental Health Data (NDA) Archive <u>https://data-archive.nimh.nih.gov</u> or another data repository to be identified by the Government.

The CDMRP intends that information, data, and research resources generated under awards funded by this Program Announcement/Funding Opportunity be made available to the research community (which includes both scientific and consumer advocacy communities) and to the public at large. For additional guidance, refer to the General Application Instructions, Appendix 2, Section K.

Research Involving Human Subjects: All Department of Defense (DoD)-funded research involving new and ongoing research with human subjects must be reviewed and approved by the USAMRMC Office of Research Protections (ORP), Human Research Protection Office (HRPO) prior to research implementation. This administrative review requirement is in addition to the local Institutional Review Board (IRB) or Ethics Committee (EC) review. Local IRB/EC approval at the time of submission is not required. The HRPO is mandated to comply with specific laws and requirements governing all research involving human anatomical substances, human subjects, or human cadavers that is supported by the DoD. These laws and requirements will necessitate information in addition to that supplied to the IRB/EC. Allow a minimum of 2 to 3 months for HRPO regulatory review and approval processes. When possible, protocols should

be written for research with human subjects and/or human anatomical substances that are specific to the DoD-supported effort outlined in the submitted application. Submission to HRPO of protocols covering more than the scope of work in the DoD-funded award will require HRPO review of the entire protocol as DoD-supported research and may include extensive modifications to meet DoD human subjects protection requirements. Refer to the General Application Instructions, Appendix 1, and the Human Subject Resource Document available on the electronic Biomedical Research Application Portal (eBRAP) "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) for additional information.

Awards will be made no later than September 30, 2018. For additional information refer to <u>Section II.F.1, Federal Award Notices</u>.

II.C. Eligibility Information

II.C.1. Eligible Applicants

II.C.1.a. Organization: All organizations, including international organizations, are eligible to apply.

Government Agencies within the United States: Local, state, and Federal Government agencies are eligible to the extent that applications do not overlap with their fully funded internal programs. Such agencies are required to explain how their applications do not overlap with their internal programs.

As applications for this Program Announcement may be submitted by extramural and intramural organizations, these terms are defined below.

Extramural Organization: An eligible non-(DoD) organization. Examples of extramural organizations include academia, biotechnology companies, foundations, Government, and research institutes.

Intramural DoD Organization: A DoD laboratory, DoD military treatment facility, and/or DoD activity embedded within a civilian medical center.

Note: Applications from an intramural organization or from an extramural non-DoD Federal organization may be submitted through a research foundation.

The USAMRAA makes awards to eligible organizations, not to individuals.

II.C.1.b. Principal Investigator: Independent investigators at all academic levels (or equivalent) are eligible to submit applications.

An eligible Principal Investigator, regardless of ethnicity, nationality, or citizenship status, must be employed by, or affiliated with, an eligible organization.

The CDMRP encourages all PIs to participate in a digital identifier initiative through Open Researcher and Contributor ID, Inc. (ORCID). Registration for a unique ORCID identifier can be done online at <u>http://orcid.org/</u>.

II.C.2. Cost Sharing

Cost sharing/matching is not an eligibility requirement.

II.C.3. Other

Organizations must be able to access **.gov** and **.mil** websites in order to fulfill the financial and technical deliverable requirements of the award and submit invoices for payment.

Each investigator may submit only one FY17 PH/TBIRP PSP Translational Research Award application as a PI; however, there are no limits on the number of applications for which an investigator may be named as a co-investigator.

For general information on required qualifications for award recipients, refer to the General Application Instructions, Appendix 3.

Refer to <u>Section II.H.2</u>, <u>Administrative Actions</u>, for a list of administrative actions that may be taken if a pre-application or application does not meet the administrative, eligibility, or ethical requirements defined in this Program Announcement/Funding Opportunity.

II.D. Application and Submission Information

Extramural Submission is defined as an application submitted by a non-DoD organization to Grants.gov.

Intramural Submission is defined as an application submitted by a DoD organization for an intramural investigator, who is a DoD military or civilian employee working within a DoD laboratory or military treatment facility, or working in a DoD activity embedded within a civilian medical center.

II.D.1. Address to Request Application Package

The multifunctional web-based system eBRAP allows PIs to submit their pre-applications electronically through a secure connection, to view and edit the content of their pre-applications and full applications, to receive communications from the CDMRP, and to submit documentation during award negotiations and period of performance.

Submitting Extramural and Intramural Organizations: Pre-application content and forms can be accessed at <u>https://eBRAP.org</u>.

Submitting Extramural Organizations: Full application packages can be accessed at Grants.gov.

Submitting Intramural DoD Organizations: Full application packages can be accessed at eBRAP.org.

Contact information for the CDMRP Help Desk and the Grants.gov Contact Center can be found in <u>Section II.G, Federal Awarding Agency Contacts</u>.

II.D.2. Content and Form of the Application Submission

Submission is a two-step process requiring both *pre-application* and *full application* as indicated below. The submission process should be started early to avoid missing deadlines. There are no grace periods.

Pre-application Submission: All pre-applications for both extramural and intramural organizations must be submitted through eBRAP (<u>https://eBRAP.org/</u>).

Full Application Submission: Full applications must be submitted through the online portals as described below.

Submitting Extramural Organizations: Full applications from extramural organizations must be submitted through Grants.gov. Applications submitted by extramural organizations (e.g., research foundations) on behalf of intramural DoD or other Federal organizations or investigators will be considered extramural submissions.

Submitting Intramural DoD Organizations: Intramural DoD organizations may submit full applications to either eBRAP or Grants.gov. Intramural DoD organizations that are unable to submit to Grants.gov should submit through eBRAP. Intramural DoD organizations with the capability to submit through Grants.gov may submit following the instructions for extramural submissions through Grants.gov or may submit to eBRAP. Applications from extramural organizations, including non-DoD Federal organizations, received through eBRAP may be withdrawn. See definitions in Section II.C.1, Eligible Applicants.

For both Extramural and Intramural applicants: A key feature of eBRAP is the ability of an organization's representatives and PIs to view and modify the full application submissions associated with them. eBRAP will validate full application files against the specific Program Announcement/Funding Opportunity requirements and discrepancies will be noted in an email to the PI and in the Full Application Files tab in eBRAP. It is the applicant's responsibility to review all application components for accuracy as well as ensure proper ordering as specified in this Program Announcement/Funding Opportunity.

The application title, eBRAP log number, and all information for the PI, Business Official(s), performing organization, and contracting organization must be consistent throughout the entire pre-application and application submission process. Inconsistencies may delay application processing and limit or negate the ability to view, modify, and verify the application in eBRAP. If any changes need to be made, the applicant should contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507 prior to the application deadline.

II.D.2.a. Step 1: Pre-Application Submission Content

During the pre-application process, each submission is assigned a unique log number by eBRAP. This unique eBRAP log number will be needed during the full application submission process.

To begin the pre-application process, first select whether the submitting organization is extramural or intramural, then confirm your selection or cancel. **Incorrect selection of extramural or intramural submission type may result in delays in processing.**

If an error has been made in the selection of extramural versus intramural and the pre-application submission deadline has passed, the PI or Business Official must contact the CDMRP Help Desk at <u>help@eBRAP.org</u> or 301-682-5507.

All pre-application components must be submitted by the Initiating PI through eBRAP (<u>https://eBRAP.org/</u>).

PIs and organizations identified in the pre-application should be the same as those intended for the subsequent application submission. If any changes are necessary after submission of the pre-application, the PI must contact the CDMRP Help Desk at <u>help@eBRAP.org</u> or 301-682-5507.

The pre-application consists of the following components, which are organized in eBRAP by separate tabs (refer to the General Application Instructions, Section II.B, for additional information on pre-application submission):

• Tab 1 – Application Information

• Tab 2 – Application Contacts

Enter contact information for the PI. Enter the organization's Business Official responsible for sponsored program administration (the "person to be contacted on matters involving this application" in Block 5 of the Grants.gov SF424 (R&R) Form). The Business Official must be either selected from the eBRAP list or invited in order for the pre-application to be submitted.

Select the performing organization (site at which the PI will perform the proposed work) and the contracting organization (organization submitting on behalf of the PI, which corresponds to Block 5 on the Grants.gov SF424 (R&R) Form), and click on "*Add Organizations to this Pre-application*." The organization(s) must be either selected from the eBRAP drop-down list or invited in order for the pre-application to be submitted.

It is recommended that PIs identify an Alternate Submitter in the event that assistance with pre-application submission is needed.

• Tab 3 – Collaborators and Key Personnel

Enter the name, organization, and role of all collaborators and key personnel associated with the application.

FY17 PH/TBIRP PSP Programmatic Panel members must not be involved in any preapplication or application. For questions related to Panel members and pre-applications or applications, refer to <u>Section II.H.2.c</u>, <u>Withdrawal</u>, or contact the CDMRP Help Desk at <u>help@eBRAP.org</u> or 301-682-5507. To preserve the integrity of its peer and programmatic review processes, the CDMRP discourages inclusion of any employee of its review contractors having any role in preapplication or application preparation, research, or other duties for submitted pre-applications or applications. For FY17, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (<u>http://cdmrp.army.mil/about/</u><u>2tierRevProcess</u>). Pre-applications or applications that include names of personnel from either of these companies will be administratively withdrawn unless plans to manage conflicts of interest (COIs) are provided and deemed appropriate by the Grants Officer. Refer to the General Application Instructions, Appendix 3, for detailed information.

• Tab 4 – Conflicts of Interest

List all individuals other than collaborators and key personnel who may have a COI in the review of the application (including those with whom the PI has a personal or professional relationship). Refer to the General Application Instructions, Appendix 3, Section C, for further information regarding COIs.

• Tab 5 – Pre-Application Files

- Letter of Intent (LOI) (one-page limit): Provide a brief description of the research to be conducted. LOIs are used for program planning purposes only (e.g., reviewer recruitment) and will not be reviewed during either the peer or programmatic review sessions.
- List of Individuals Providing Confidential Letters of Recommendation: Enter contact information for describe number and type of individuals, who will provide letters of recommendation. Each individual will receive an email generated from eBRAP containing specific instructions on how to upload his/her letter.

• Tab 6 – Submit Pre-Application

This tab must be completed for the LOI to be accepted and processed.

II.D.2.b. Step 2: Full Application Submission Content

All contributors and administrators to the application must use matching compatible versions of Adobe software when editing and preparing application components. The use of different software versions will result in corruption of the submitted file. Refer to the General Application Instructions, Section III, for details on compatible Adobe software.

The CDMRP cannot make allowances/exceptions to its policies for submission problems encountered by the applicant organization using system-to-system interfaces with Grants.gov.

Each application submission must include the completed full application package for this Program Announcement/Funding Opportunity. The full application package is submitted by the Authorized Organizational Representative through Grants.gov (<u>http://www.grants.gov/</u>) for extramural organizations or through eBRAP (<u>https://ebrap.org/</u>) for intramural organizations. See Table 1 below for more specific guidelines.

II.D.2.b.i. Full Application Guidelines

Extramural organizations, including non-DoD Federal agencies, must submit full applications through Grants.gov. Submissions of extramural applications through eBRAP may be withdrawn.

Extramural Submissions	Intramural DoD Submissions			
Application Package Location				
Download application package components for W81XWH-17-PHTBIRP-TRA from Grants.gov (<u>http://www.grants.gov</u>).	Download application package components for W81XWH-17- PHTBIRP-TRA from eBRAP (<u>https://ebrap.org</u>).			
Full Application Package Components				
SF424 (R&R) Application for Federal Assistance Form: Refer to the General Application Instructions, Section III.A.1, for detailed information.	Tab 1 – Summary: Provide a summary of the application information.Tab 2 – Application Contacts: This tab will be pre-populated by eBRAP; add Authorized Organizational Representative.			
 Descriptions of each required file can be found under Full Application Submission Components: <u>Attachments</u> <u>Research & Related Senior/Key Person</u> <u>Profile (Expanded)</u> <u>Research & Related Budget</u> <u>Project/Performance Site Location(s) Form</u> <u>R&R Subaward Budget Attachment(s)</u> <u>Form</u> (if applicable) 	 Tab 3 – Full Application Files: Upload files under each Application Component in eBRAP. Descriptions of each required file can be found under Full Application Submission Components: <u>Attachments</u> <u>Key Personnel</u> <u>Budget</u> <u>Performance Sites</u> Tab 4 – Application and Budget Data: Review and edit proposed project start date, proposed end date, and budget data pre-populated from the Budget Form. 			
Application Package Submission				
Submit package components to Grants.gov (http://www.grants.gov). If either the Project Narrative or the budget fails eBRAP validation or if the Project Narrative or the budget need to be modified, an updated Grants.gov application package must be submitted via Grants.gov as a "Changed/Corrected Application" with the	Submit package components to eBRAP (<u>https://ebrap.org</u>). Tab 5 – Submit/Request Approval Full Application: After all components are uploaded and prior to the full application submission deadline, enter your password in the space provided "Enter Your Password Here" and press the "Submit			

Table 1. Full Application Submission Guidelines

Extramural Submissions	Intramural DoD Submissions		
previous Grants.gov Tracking ID prior to the application submission deadline.	Full Application" button. eBRAP will notify your Resource Manager/ Comptroller or equivalent Business Official by email.		
Application Verification Period			
The full application package submitted to Grants.gov may be viewed and modified in eBRAP until the end of the application verification period. During the application verification period, the full application package, <i>with the exception of the Project Narrative and</i> <i>Budget Form</i> , may be modified.	After eBRAP has processed the full application, the organizational Resource Manager/Comptroller or equivalent Business Official and PIs will receive an email notification of this status and will be able to view and modify application components in eBRAP. During the application verification period, the full application package, <i>with the exception</i> <i>of the Project Narrative and Budget</i> <i>Form,</i> may be modified. Your Resource Manager/Comptroller or equivalent Business Official should log into eBRAP to review and to approve prior to the application verification deadline.		
Further Information			
Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.	Refer to the General Application Instructions, Section IV, for further information regarding eBRAP requirements.		

The organization's Business Official or Authorized Organization Representative (or Resource Manager/Comptroller) should approve/verify the full application submission prior to the application verification deadline.

Application viewing, modification, and verification in eBRAP are strongly recommended, but not required. *The Project Narrative and Budget cannot be changed after the application submission deadline.* Prior to the full application deadline, a corrected or modified full application package may be submitted. Other application components may be changed until the end of the application verification period. After the end of the application verification period, the full application cannot be modified.

Material submitted after the end of the application verification period, unless specifically requested by the Government, will not be forwarded for processing.

The full application package must be submitted using the unique eBRAP log number to avoid delays in application processing.

II.D.2.b.ii. Full Application Submission Components:

• Extramural Applications Only –

SF424 (R&R) Application for Federal Assistance Form: Refer to the General Application Instructions, Section III.A.1, for detailed information.

• Extramural and Intramural Applications -

Attachments:

Each attachment to the full application components must be uploaded as an individual file in the format specified and in accordance with the formatting guidelines listed in the General Application Instructions, Appendix 4.

For all attachments, ensure that the file names are consistent with the guidance. Attachments will be rejected if the file names are longer than 50 characters or incorrect file names that contain characters other than the following: A-Z, a-z, 0-9, underscore, hyphen, space, and period. In addition, there are file size limits that may apply in some circumstances. Individual attachments may not exceed 20 MB and the file size for the entire full application package may not exceed 200 MB.

• Attachment 1: Project Narrative (20-page limit): Upload as

"ProjectNarrative.pdf." The page limit of the Project Narrative applies to text and nontext elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs that provide additional information to expand the Project Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application.

Describe the proposed project in detail using the outline below.

- Alignment to Award Mechanism: State the relevance of the proposed research to the intent of the award mechanism in <u>Section II.B</u>, <u>Award Information</u>, and explain the potential impact of peer-to-peer support interventions to translate and integrate content into the everyday routines of SMs to enhance psychological health readiness and mitigate negative behavioral health issues including suicide behaviors to benefit SMs and the public at large.
 - Describe the resilience and behavioral health and risk outcomes in addition to suicide risk and protective factors that peer support interventions are targeting.
 - Describe the effect of the PSP on suicide-related behaviors, their risk correlates, protective factors, and/or a theoretically based justification for the anticipated effect on behaviors in non-clinical, military populations.
 - Explain how the proposed approach utilizes designs to develop a knowledge base about "how" interventions are translated to military practice settings that go beyond distribution of information about the intervention.

- Describe how well the proposed approach includes models for implementing peer-to-peer support interventions throughout the DoD or interventions that target multiple levels of military personnel within a military environment.
- Explain how peer-to-peer support will accommodate the diverse nature of the targeted population, including gender and occupations. Interventions should be sensitive to the time and contextual constraints associated with occupations and lifestyles of SMs and their families.
- Describe the timing and delivery methods of training and interventions, and how they coincide with important military life cycle stages or transitions.
- Describe the skill-building component for the peer support providers through a train-the-trainer module as well as for the peer being helped by the peer support provider.
- Describe how the interventions studied will be interacting and engaging to decrease burden and increase buy-in.
- Explain how work role requirements for peer support providers are defined and how these work role requirements will benefit the DoD.
- Elucidate the extent to which the proposed approach addresses the potential immediate or long-term PH and well-being of SMs, their families, and/or communities and the extent to which the proposed approach may be applicable and beneficial to the general public.
- Hypotheses/Objectives and Specific Aims: Provide a description of the hypotheses for the proposed research. Present the ideas and reasoning behind the proposed work. Cite relevant literature and pilot or preliminary data. Describe previous experience most pertinent to this research. Explain how the research will evaluate the peer support programs including peer support providers' roles in the following ways:
 - Tasks: Observable activities peer support providers are expected to perform in support of peers; interventions should specify which tasks are visible to peers and which tasks are helpful to peers but considered "behind-the-scenes."
 - Responsibilities: Categories that group similar tasks together; responsibilities can organize tasks by knowledge or skill area, peer support setting, type of peer, frequency in which task is performed, or other common themes.
 - Traits: Knowledge, skills, abilities, attitudes, and other attributes that peer support providers need to have prior to assuming work role responsibilities; interventions should specify the level of education or types of experiences that may be necessary for a peer support provider to have in order to execute the intervention; in addition, interventions should address the importance of whether peer support providers need to have the same rank or belong to the same career field as the peers.

- Peer-to-Peer Environment: Descriptions of interventions should specify the range of environments in which peer support is executed; peer-to-peer environment descriptions should address the following questions:
 - How much autonomy and supervision do peer support providers need after initial training?
 - ♦ What is the intervention modality (in-person, virtual, both)?
 - Do peers need to belong to the same unit or be aligned to the same installation?
 - How many peers should be involved in a peer support session?
 - When can the intervention occur (duty hours, off-duty hours, i.e., during work, after work, or both)?
 - Where should the peer support intervention take place (on-base in barracks, on-base at work site, off-base at home, off-base at other locations)?
 - ✤ Is the same location needed to execute the intervention?
- **Project Milestones:** Identify timelines for critical events that must be accomplished in order for the project to be successful.
- **Research Strategy:** Describe objectives, specific aims, experimental design, methods, and analyses.
 - Align the methods and procedures with the research aims. State how they will be developed and integrated into the project and their feasibility to address the need(s) described.
 - Identify any potential problems and address alternative approaches.
 - Define the study variables and describe how they will be measured. Include a description of appropriate controls and the endpoints to be tested.
 - Describe the methods that will be used to recruit a sample cohort from the accessible population (e.g., convenience, simple random, stratified random).
 - Describe access to the subject population(s) with a viable plan for recruitment, consent, screening, and retention of appropriate subjects, and identify sampling methods to gain a representative sample from the population(s) of interest.
 - Describe the human subject-to-group assignment process (e.g., randomization, block randomization, stratified randomization, age-matched controls, alternating group, or other procedures), if applicable. Explain the specific actions to

accomplish the group assignment (e.g., computer assignment, use of table of random numbers).

• Describe the reliability and validity of assessment measures, if applicable. Include critical survey questions, if applicable.

PIs and collaborating organizations may not use, employ, or subcontract for the use of any human participants, including the use of human data, until applicable regulatory documents are approved by the USAMRMC ORP HRPO to ensure that DoD regulations have been met.

Refer to the General Application Instructions, Appendix 1, for additional regulatory requirements information.

- Statistical Plan and Data Analysis: Describe the statistical model(s) and data analysis plan with respect to the study objectives and endpoints as appropriate to the type of study. For research involving human subjects, specify the number of human subjects that will be enrolled. If multiple study sites are involved, state the approximate number to be enrolled at each site. Include a complete power analysis to demonstrate that the sample size is appropriate to meet the objectives and endpoints of the study.
- **Personnel:** Describe how the background, experience and expertise of the PI(s) and other key personnel demonstrate their ability to perform the proposed research and the appropriate composition of the research or study team (e.g., study coordinator, statistician).
 - Demonstrate the extent to which the PI has formed a multidisciplinary team of scientists and stakeholders.
 - Describe the levels of effort by the PI(s) and other key personnel.
 - State whether each key investigator's record of accomplishments demonstrates his/her understanding of working with military populations.
- Attachment 2: Supporting Documentation: Combine and upload as a single file named "Support.pdf." Start each document on a new page. If documents are scanned to PDF, the lowest resolution (100 to 150 dpi) should be used. The Supporting Documentation attachment should not include additional information such as figures, tables, graphs, photographs, diagrams, chemical structures, or drawings. These items should be included in the Project Narrative. Any additional material viewed as an extension of the Project Narrative will be removed or may result in administrative withdrawal of the application.

There are no page limits for any of these components unless otherwise noted. Include only those components described below; inclusion of items not requested will result in the removal of those items or may result in administrative withdrawal of the application.

- References Cited: List the references cited (including URLs, if available) in the Project Narrative using a standard reference format that includes the full citation (i.e., author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).
- List of Abbreviations, Acronyms, and Symbols: Provide a list of abbreviations, acronyms, and symbols.
- Facilities, Existing Equipment, and Other Resources: Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate whether or not Government-furnished facilities or equipment are proposed for use. If so, reference should be made to the original or present Government award under which the facilities or equipment items are now accountable. There is no form for this information.
- Publications and/or Patents: Include a list of relevant publication URLs and/or patent abstracts. If publications are not publicly available, then copies of up to five published manuscripts may be included in Attachment 2. Extra items will not be reviewed.
- Letters of Organizational Support (one-page limit per letter): Provide a letter (or letters, if applicable), signed by the Department Chair or appropriate organization official, confirming the laboratory space, equipment, and other resources available for the project. Letters of support not requested in the Program Announcement, such as those from members of Congress, do not impact application review or funding decisions.
- Letter(s) of Support for Use of Military Populations or Resources (if applicable, 1-page limit per letter is recommended): If the proposed research plan involves access to active duty military patient populations or resources, include a letter(s) of support, signed by the lowest-ranking person with approval authority, confirming such access. If access cannot be confirmed at the time of application submission, the Government reserves the right to withhold or revoke funding until the PI has demonstrated support for and access to the relevant population(s) and/or resources
- Letters of Collaboration (if applicable) (one-page limit per letter): Provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed work. If an investigator at an intramural organization is named as a collaborator on an application submitted through an extramural organization, the application must include a letter from the collaborator's Commander or Commanding Officer at the intramural organization that authorizes the collaborator's involvement.

- Intellectual Property: Information can be found in Code of Federal Regulations, Title 2, Part 200.315 (2 CFR 200.315), "Intangible Property."
 - Intellectual and Material Property Plan: Indicate whether or not there are any intellectual property rights relevant to the study. If applicable, provide a plan for resolving intellectual and material property issues among participating organizations.
- Data and Research Resources Sharing Plan: Indicate whether common data elements (CDEs) will be incorporated into the study (if applicable) and how data and resources generated during the performance of the project will be shared with the research community. Refer to the General Application Instructions, Appendix 2, Section K, for more information about expectations for making data and research resources publicly available.
- Quad Chart: Provide a Quad Chart for the proposed project. The format for the quad chart is available on the eBRAP "Funding Opportunities & Forms" web page at <u>https://ebrap.org/eBRAP/public/Program.htm.</u>
- Attachment 3: Technical Abstract (one-page limit): Upload as "TechAbs.pdf." The technical abstract is used by all reviewers. Abstracts of all funded research projects will be posted publicly. *Do not include proprietary or confidential information*. Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

Technical abstracts should be written using the outline below. The technical abstract should provide an appropriate description of the project's key aspects; clarity and completeness within the space limits of the technical abstract are highly important.

- Background: State the ideas and reasoning on which the proposed work is based. Describe how the study rationale examines the efficacy and effectiveness of peer-topeer support interventions to translate and integrate content into the everyday routines of SMs to enhance psychological health readiness and mitigate negative behavioral health issues including suicide behaviors.
- **Objective/Hypothesis:** State the objective/hypothesis to be tested. Provide evidence or rationale that supports the objective/hypothesis.
- **Specific Aims:** State the specific aims of the study and how they support the proposed work.
- **Study/Project Design:** Briefly describe the study/project design, including controls.
- Impact and Military Benefit: Briefly explain the potential impact of peer-to-peer support interventions to translate and integrate content into the everyday routines of SMs to enhance psychological health readiness and mitigate negative behavioral health issues including suicide behaviors to benefit our SMs and the public at large.

Attachment 4: Lay Abstract (one-page limit): Upload as "LayAbs.pdf." The lay abstract is used by all reviewers. Abstracts of all funded research projects will be posted publicly. *Do not include proprietary or confidential information*. Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

Lay abstracts should be written using the outline below. Minimize use of acronyms and abbreviations, where appropriate. The lay abstract is an important component of the application review process because it addresses issues of particular interest to the consumer community. Do not duplicate the technical abstract.

- Describe the objectives and rationale for the application in a manner that will be readily understood by readers without a background in psychological health or military readiness.
- Describe the efficacy and effectiveness of peer-to-peer support interventions to translate and integrate content into the everyday routines of SMs to enhance psychological health readiness and mitigate negative behavioral health issues including suicide behaviors.
- Briefly describe how the proposed project will benefit SMs and the public at large.
- Attachment 5: Statement of Work (SOW) (three-page limit): Upload as "SOW.pdf." The suggested SOW format and examples specific to different types of research projects are available on the eBRAP "Funding Opportunities & Forms" web page (<u>https://ebrap.org/eBRAP/public/Program.htm</u>). For the PSP Translational Research Award mechanism, use the SOW format example titled "SOW for Clinical Research (Including Trials, Special Populations)." The SOW must be in PDF format prior to attaching.

The SOW should include a list of major tasks that support the proposed specific aims, followed by a series of subtasks outlined related to the major tasks and milestones within the period of performance. The SOW should describe only the work for which funding is being requested by this application and, as applicable, should also:

Include the name(s) of the key personnel and contact information for each study site/ subaward site.

Indicate the number (and type, if applicable) of research subjects (animal or human) and/or human anatomical samples projected or required for each task and at each site. Refer to the General Application Instructions, Appendix 1, for additional information regarding regulatory requirements.

Briefly state the methods to be used.

For studies with prospective accrual of human subjects, indicate quarterly enrollment targets.

Indicate timelines required for regulatory approvals relevant to human subjects research.

• Attachment 6: Impact and Military Benefit Statement (three-page limit): Upload as "Impact.pdf."

- Describe how the proposed work enhances psychological health care for SMs. Show how the proposed study complements ongoing peer-to-peer support research and potentially will improve training and education interventions.
- How will peer-to-peer support accommodate the diverse nature of the targeted populations, including gender and occupations, especially in military populations? Include the current available statistics to the related population of concern.
- What are the likely contributions of this study to advancing peer-to-peer support throughout the DoD as well as the potential benefit for the general public?
- Describe how the proposed approach addresses the resilience and behavioral health and risk outcomes in addition to suicide risk and protective factors that peer support interventions are targeting.
- Describe how the proposed approach addresses the effect of the PSP on suiciderelated behaviors, their risk correlates, protective factors, and/or a theoretically based justification for the anticipated effect on behaviors in non-clinical, military populations.
- Describe how the proposed approach utilizes designs to develop a knowledge base about "how" interventions are translated to military practice settings that go beyond distribution of information about the intervention.
- Describe how peer-to-peer support accommodates the diverse nature of the targeted population, including gender and occupations. Interventions should be sensitive to the time and contextual constraints associated with occupations and lifestyles of SMs and their families.
- Describe how the proposed approach addresses the timing and delivery methods of training and interventions, and how they coincide with important military life cycle stages or transitions.
- Describe how the proposed approach addresses the skill-building component for the peer support providers through a train-the-trainer module as well as for the peer being helped by the peer support provider.
- Explain to what extent the interventions studied will be interactive and engaging to decrease burden and increase buy-in.
- Describe how the proposed approach addresses the work role requirements for peer support providers and how the work role requirements will benefit the DoD.

• Attachment 7: Translation Plan (one-page limit): Upload as "Translation.pdf."

Clearly state the methods and strategies to move the anticipated research outcomes to the next phase of research or delivery to the military practice or civilian community after successful completion of the award. The translation plan should include the components listed below:

- Describe the funding, schedule, and milestones that will be used to bring the training and education interventions to the next level of development (e.g., specific funding opportunities to be pursued). Detail the timelines toward implementation.
- Describe collaborations and other resources that will be used to facilitate translation of the proposed training and education interventions.
- Describe the management of and access to intellectual property, licensing, and/or business professionals, if applicable.
- Attachment 8: Human Subject Recruitment and Safety Procedures required for all studies recruiting human subjects; no page limit: Upload as "HumSubProc.pdf." The Human Subject Recruitment and Safety Procedures attachment should include the components listed below:
 - Study Population: Describe the target population (to whom the study findings will be generalized) and the nature, approximate number, and pertinent demographic characteristics of the accessible population at the study site (population from whom the sample will be recruited). Demonstrate that the research team has access to the proposed study population. Furthermore, discuss past efforts in recruiting human subjects from the target population. Address any potential barriers to accrual and plans for addressing unanticipated delays. Include justification of any age, race, ethnicity, or sex limitations provided.
 - **Inclusion/Exclusion Criteria:** List the inclusion and exclusion criteria for the proposed research. Inclusion/exclusion criteria should take into consideration the specific risk profile of the studies to be conducted and the standard of care for that patient population. Provide detailed justification for exclusions.
 - Inclusion of Women and Minorities in Study: Consistent with the Belmont Report, "Ethical Principles and Guidelines for the Protection of Human Subjects," and Congressional legislation, special attention is given to inclusion of women and/or minorities in studies funded or supported by the USAMRMC. This policy is intended to promote equity both in assuming the burdens and in receiving the benefits of human subjects research. Include an appropriate justification if women and/or minorities will be excluded.
 - **Description of the Recruitment Process:** Explain methods for identification of potential human subjects (e.g., medical record review, obtaining sampling lists, and healthcare provider identification).

- Describe the recruitment process in detail. Address who will identify potential human subjects, who will recruit them, and what methods will be used to recruit them.
- Include a detailed description of and justification for the compensation plan if the human subjects will be compensated for participation in the study.
- Describe the recruitment and advertisement materials. The recruitment materials should not be coercive or offer undue inducements and should accurately reflect the study.
- **Description of the Informed Consent Process:** Specifically describe the plan for obtaining informed consent from human subjects.

For the proposed study, provide a draft, in English, of the Informed Consent Form.

- Identify who is responsible for explaining the study, answering questions, and obtaining informed consent. Include a plan for ensuring that human subjects' questions will be addressed during the consent process and throughout the trial.
- Include information regarding the timing and location of the consent process.
- Address issues relevant to the mental capacity of the potential human subject (e.g., altered capacity due to administration of any mind-altering substances such as tranquilizers, conscious sedation or anesthesia, brain injury, stress/life situations, or human subject age), if applicable.
- Address how privacy and time for decision-making will be provided and whether or not the potential human subject will be allowed to discuss the study with anyone before making a decision.
- Address whether research data will be de-identified to minimize risks to privacy when shared with data repositories.
- Consider the need for obtaining ongoing consent or for re-assessing capacity over the course of a long-term study, and describe any relevant procedures to assure continued consent.
- Screening Procedures: List and describe any evaluations (e.g., laboratory procedures, history, or physical examination) that are required to determine eligibility/suitability for study participation and the diagnostic criteria for entry. Note that some screening procedures may require a separate consent or a two-stage consent process. Informed consent must be obtained prior to initiation of any procedures for the purpose of determining eligibility.

- Risks/Benefits Assessment:

- Foreseeable risks: Clearly identify all study risks. Study risks include any risks that the human subject is subjected to as a result of participation. Consider psychological, legal, social, and economic risks as well as physical risks. If the risks are unknown, this should be stated. If applicable, any potential risk to the study personnel should be identified.
- Risk management and emergency response:
 - Describe all safety measures to minimize and/or eliminate risks to human subjects and study personnel or to manage unpreventable risks.
 - Discuss the overall plan for provision of emergency care or treatment for an adverse event for study-related injuries, to include who will be responsible for the cost of such care.
 - Address any special precautions to be taken by the human subjects before, during, and after the study.
 - Describe any special care or equipment (e.g., monitors, telemedicine equipment) needed for human subjects enrolled in the study.
- **Potential benefits:** Describe known and potential benefits of the study to the human subject, a specific community, or society.
- Attachment 9: Data Management (no page limit): Upload as "DataManage.pdf." The Data Management attachment should include the components listed below.

Describe all methods used for data collection to include the following:

- **Identifiers:** Describe the unique identifiers or specific code system to be used to identify human subjects, if applicable.
- **Confidentiality:** Explain measures taken to protect the privacy of study human subjects and maintain confidentiality of study data. Strategies to protect the privacy and confidentiality of study records, particularly those containing identifying information, should be addressed.
 - Address who will have access to study records, data, and specimens, including an acknowledgment that representatives of USAMRMC are eligible to review study records.
 - Address requirements for reporting sensitive information to state or local authorities.

- **Disposition of data:** Describe where data (both electronic and hard copy) will be stored, who will keep the data, how the data will be stored, and the length of time data will be stored.
- Sharing study results: In cases where the human subject could possibly benefit medically or otherwise from the information, explain whether or not the results of screening and/or study participation will be shared with human subjects or their primary care provider, to include results from any screening tests performed as part of the study.
- Attachment 10: DoD Military Budget Form(s), if applicable: Upload as "MFBudget.pdf." If a military facility (military health system facility, research laboratory, treatment facility, dental treatment facility, or a DoD activity embedded with a civilian medical center) will be a collaborator in performance of the project, complete the DoD Military Budget Form, available for download on the eBRAP "Funding Opportunities & Forms" web page (<u>https://ebrap.org/eBRAP/public/Program.htm</u>), including a budget justification, for each military facility as instructed. The costs per year should be included on the Grants.gov Research and Related Budget form under subaward costs. Refer to the General Application Instructions, Section III.A.7, for detailed information.
- Extramural and Intramural Applications –

Research & Related Senior/Key Person Profile (Expanded): For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.3, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.2, for detailed information.

- PI Biographical Sketch (five-page limit): Upload as "Biosketch_LastName.pdf." The suggested biographical sketch format is available on the "Funding Opportunities & Forms" web page (<u>https://ebrap.org/eBRAP/public/Program.htm</u>) in eBRAP. The National Institutes of Health Biographical Sketch may also be used. All biographical sketches should be submitted in the portable document format (PDF) that is not editable.
- PI Previous/Current/Pending Support (no page limit): Upload as "Support_LastName.pdf."
- Key Personnel Biographical Sketches (five-page limit each): Upload as "Biosketch_LastName.pdf."
- Key Personnel Previous/Current/Pending Support (no page limit): Upload as "Support_LastName.pdf."

Research & Related Budget: For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.4, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.3, for detailed information.

Budget Justification (no page limit): Upload as "BudgetJustification.pdf." The budget justification for the entire period of performance must be uploaded to the Research & Related Budget after completion of the budget for Period 1.

Project/Performance Site Location(s) Form: For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.5, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.4, for detailed information.

• Extramural Applications Only –

R&R Subaward Budget Attachment(s) Form (if applicable): Refer to the General Application Instructions, Section III.A.6, for detailed information.

- **Extramural Subaward:** Complete the Research & Related Subaward Budget Form through Grants.gov. (Refer to the General Application Instructions, Section III.A.6, for detailed information.)
- Intramural DoD Collaborator(s): Complete the DoD Military Budget Form and upload to Grants.gov as Attachment 10. (Refer to the General Application Instructions, Section III.A.7, for detailed information.) Intramural DoD Collaborator(s) costs per year should be included on the Grants.gov Research and Related Budget form under subaward costs.

II.D.3. Dun and Bradstreet Data Universal Numbering System (DUNS) Number and System for Award Management (SAM)

Applicant organizations and all subrecipient organizations must have a DUNS number to submit applications to Grants.gov. The applicant organization must also be registered in the Entity Management functional area of the SAM with an "Active" status to submit applications through the Grants.gov portal. Verify the status of the applicant's organization's Entity registration in SAM well in advance of the application submission deadline. Allow 3 to 4 weeks to complete the entire SAM registration process. If an applicant has not fully complied with the requirements at the time the Federal awarding agency is ready to make a Federal award, the Federal awarding agency may determine that the applicant is not qualified to receive a Federal award and use that determination as a basis for making a Federal award to another applicant. Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.

II.D.4. Submission Dates and Times

All submission dates and times are indicated in <u>Section I, Overview of the Funding Opportunity</u>. Pre-application and application submissions are required. The pre-application and application submission process should be started early to avoid missing deadlines. There are no grace periods. Failure to meet either of these deadlines will result in submission rejection.

Applicant Verification of Full Application Submission in eBRAP

Prior to the end of the application verification period, PIs and organizational representatives can review and modify in eBRAP certain components of a submitted application. Following retrieval and processing of the full application, eBRAP will notify the organizational representatives and PI by email to log into eBRAP to review, modify, and verify the full application submission. eBRAP will validate retrieved files against the specific Program Announcement/Funding Opportunity requirements and discrepancies will be noted in both the email and in the Full Application Files tab in eBRAP. eBRAP does not confirm the accuracy of file content. It is the applicant's responsibility to review all application components and ensure proper ordering as specified in the Program Announcement/Funding Opportunity. *If either the Project Narrative or the budget fails eBRAP validation or needs to be modified, an updated full application package must be submitted prior to the application submission deadline.* The Project Narrative and Budget Form cannot be changed after the application submission deadline.

II.D.5. Funding Restrictions

The maximum period of performance is **3** years.

The anticipated **total** costs (direct and indirect) budgeted for the entire period of performance will not exceed **\$3M**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the Government exceeding **\$3M** total costs or using an indirect cost rate exceeding the organization's negotiated rate.

All direct and indirect costs of any subaward or contract must be included in the total direct costs of the primary award.

The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum 3 years.

For this award mechanism, direct costs must be requested for:

• Travel costs for the PI(s) to disseminate project results at one DoD in-progress review meeting annually. For planning purposes, it should be assumed that the meeting will be held in the National Capital Area. These travel costs are in addition to those allowed for annual scientific/technical meetings.

May be requested for (not all-inclusive):

- Salary
- Research-related subject costs
- Support for multidisciplinary collaborations
- Equipment

- Clinical trial costs
- Travel between collaborating organizations
- Travel costs for up to two investigators to travel to one scientific/technical meeting per year in addition to the required in-progress review meetings described above.

Must not be requested for:

• Animal studies

Extramural (non-Federal) awards will consist solely of assistance agreements (Cooperative Agreements and Grants). For extramural awards with an intragovernmental component, direct transfer of funds from an extramural award recipient to a DoD or other Federal agency is not allowed except under very limited circumstances. Funding to intramural DoD and other Federal agencies will be managed through a direct fund transfer. Intragovernmental only funding to intramural DoD and other Federal agencies will be managed through a direct fund transfer. Intragovernmental only funding to intramural applicants are responsible for coordinating through their agency's procedures the use of contractual or assistance funding awards or other appropriate agreements to support extramural collaborators.

Refer to the General Application Instructions, Section III.A.4, for budget regulations and instructions for the Research & Related Budget. *For Federal agencies or organizations collaborating with Federal agencies, budget restrictions apply as are noted in the General Application Instructions, Section III.A.4.*

The JPC-5/MOMRP expects to allot approximately \$6M of the FY17 PH/TBIRP appropriation to fund approximately 2 to 3 PSP Translational Research Award applications, depending on the quality and number of applications received. Funding of applications received in response to this Program Announcement/Funding Opportunity is contingent upon the availability of Federal funds for this program.

II.D.6. Other Submission Requirements

Refer to the General Application Instructions, Appendix 4, for detailed formatting guidelines.

II.E. Application Review Information

II.E.1. Criteria

II.E.1.a. Peer Review

To determine technical merit, all applications will be evaluated according to the following scored criteria, which are of equal importance:

• Impact

- How well the proposed work enhances psychological health care for SMs and complements ongoing DoD and VA research to potentially improve training and education interventions.
- To what extent the proposed approach includes models for implementing peer-to-peer support interventions throughout the DoD or interventions that target multiple levels of military personnel within a military environment.
- To what extent the proposed approach addresses the potential immediate or long-term PH and well-being of SMs, their families, and/or communities, and to what extent the proposed approach may be applicable and beneficial to the general public.
- How well the proposed approach describes the resilience and behavioral health and risk outcomes in addition to suicide risk and protective factors that peer support interventions are targeting.
- How well the proposed approach describes the effect of the PSP on suicide-related behaviors, their risk correlates, protective factors, and/or a theoretically based justification for the anticipated effect on behaviors in non-clinical, military populations.
- How well the proposed approach utilizes designs that develop a knowledge base about "how" interventions are translated to military practice settings that go beyond distribution of information about the intervention.
- To what extent peer-to-peer support will accommodate the diverse nature of the targeted population, including gender and occupations. Interventions should be sensitive to the time and contextual constraints associated with occupations and lifestyles of SMs and their families.
- How well the proposed approach describes the timing and delivery methods of training and interventions, and how they coincide with important military life cycle stages or transitions.
- How well the proposed approach describes the skill-building component for the peer support providers through a train-the-trainer module as well as for the peer being helped by the peer support provider.
- To what extent the interventions studied will be interactive and engaging to decrease burden and increase buy-in.
- How well the proposed approach describes the work role requirements for peer support providers and how the work role requirements will benefit the DoD and the public at large.
- How well the proposed research impacts peer-to-peer support interventions to translate and integrate content into the everyday routines of SMs and the public at large.

• How well those interventions enhance psychological health readiness and mitigate negative behavioral health issues including suicide behaviors to benefit SMs and the public at large.

Hypothesis/Objectives and Specific Aims

- How well the proposed approach describes the hypotheses or objectives, specific aims, experimental design, methods, and analyses for the proposed research.
- How well the proposed approach presents the ideas and reasoning behind the proposed work.
- To what extent the relevant literature and pilot or preliminary data supports the proposed work.
- To what extent the research will evaluate the peer support programs, including peer support providers' roles, in the following ways:
 - Tasks: Observable activities peer support providers are expected to perform in support of peers; interventions should specify which tasks are visible to peers and which tasks are helpful to peers but considered "behind-the-scenes."
 - Responsibilities: Categories that group similar tasks together; tasks under responsibilities can be organized by knowledge or skill area, peer support setting, type of peer, frequency in which task is performed, or other common themes.
 - Traits: Knowledge, skills, abilities, attitudes, and other attributes that peer support providers need to have prior to assuming work role responsibilities; interventions should specify the level of education or types of experiences that may be necessary for a peer support provider to have in order to execute the intervention; in addition, interventions should address the importance of whether peer support providers need to have the same rank or belong to the same career field as the peers.
 - Peer-to-Peer Environment: Descriptions of interventions should specify the range of environments in which peer support is executed; peer-to-peer environment descriptions should address the following questions:
 - How much autonomy and supervision do peer support providers need after initial training?
 - What is the intervention modality (in-person, virtual, both)?
 - Do peers need to belong to the same unit or be aligned to the same installation?
 - How many peers should be involved in a peer support session?
 - When can the intervention occur (duty hours, off-duty hours, i.e., during work, after work, or both)?

- Where should the peer support intervention take place (on-base in barracks, onbase at work site, off-base at home, off-base at other locations)?
- Is the same location needed to execute the intervention?

• Project Milestones

• To what degree the timelines for the critical events required for the project to be successful align with the hypotheses, aims, methods, and analyses.

• Research Strategy and Feasibility

- How consistent the methods and procedures are with sound research design.
- How well the application acknowledges potential problems and addresses alternative approaches.
- How well the application defines the study variables and describes how they will be measured. Whether the controls are appropriate and endpoints achievable.
- How well the methods used to recruit a sample cohort from the accessible population are described.
- How well the human subject-to-group assignment process is described. Whether the specific actions to accomplish the group assignment are realistic/adequate for the proposed study.
- How valid and reliable the assessment measures are.
- How viable the plan is for recruitment, consent, screening, and retention of appropriate subjects. Whether the application plans to use de-identified data for sharing with data repositories.
- To what degree do the sampling methods achieve a representative sample from the population(s) of interest?
- How well the proposed research describes the target population and demonstrates access to the proposed study population.
- How well the inclusion and exclusion criteria are described for the proposed research.
- To what extent are the methods for identification of potential human subjects, recruitment process, informed consent, and compensation plan appropriate for the proposed study?

• Data Sharing Plan

• How well the PI has outlined a plan for use of CDEs and sharing of research data as appropriate for the type of study.

Statistical Plan

- To what degree the statistical model and data analysis plan are suitable for the planned study.
- How the statistical plan, including sample size projections and power analysis, is appropriate to meet the objectives and endpoints of the study.

• Personnel

- How the background and expertise of the PI and other key personnel demonstrate their ability to perform the proposed research in a military population.
- Whether the composition of the research or study team (e.g., study coordinator, statistician) is appropriate and complementary.
- How the levels of effort by the PI and other key personnel are appropriate to ensuring success of this project.
- To what extent the research team's previous experience is pertinent to the proposed work.
- To what extent the PI has formed a multidisciplinary team of scientists and stakeholders.

• Translation Plan and Intellectual Property

- Whether the funding strategy, schedule, and milestones described are appropriate to facilitate translation of the proposed training and education interventions.
- Whether appropriate collaborations, needed to facilitate translation of the proposed training and education interventions, are established and/or well described.
- How well the application identifies intellectual property ownership, describes any appropriate intellectual and material property plan among participating organizations (if applicable), and addresses any impact of intellectual property issues on product development and subsequent Government access and rights to products supported by this funding opportunity.
- If applicable, whether the applicant has demonstrated that he/she has access to all intellectual property rights necessary for development and commercialization and evidence that the Government has access and rights to such products or technologies.

In addition, the following unscored criteria will also contribute to the overall evaluation of the application:

• Budget

- Whether the **total** maximum costs are equal to or less than the allowable total maximum costs as published in the Program Announcement/Funding Opportunity.
- Whether the budget is appropriate for the proposed research.

Application Presentation

• To what extent the writing, clarity, and presentation of the application components influence the review.

• Environment

- How the research requirements are supported by the availability of and accessibility to facilities and resources.
- Whether the quality and extent of institutional support are appropriate for the proposed project.

II.E.1.b. Programmatic Review

To make funding recommendations and select the application(s) that, individually or collectively, will best achieve the program objectives, the following criteria are used by programmatic reviewers:

- Ratings and evaluations of the peer reviewers
- Relevance to the mission of the DHP, JPC-5/MOMRP, and PH/TBIRP, as evidenced by the following:
 - Adherence to the intent of the award mechanism
 - Program portfolio composition
 - Relative impact and military benefit
 - Relative feasibility of translation plan

II.E.2. Application Review and Selection Process

All applications are evaluated by scientists, clinicians, and consumers in a two-tier review process. The first tier is peer review of applications against established criteria for determining technical merit. Each application is evaluated for its own merit, independent of other applications. The second tier is a programmatic review that makes recommendations for funding to the Commanding General, USAMRMC, on behalf of the DHA and the OASD(HA), based on

technical merit, the relevance to the mission of the DHP, JPC-5/MOMRP, and PH/TBIRP, the specific intent of the award mechanism, and to other specified evaluation criteria in the Program Announcement/Funding Opportunity. Programmatic review is a comparison-based process in which applications with scientific and technical merit compete in a common pool. *The highest-scoring applications from the first tier of review are not automatically recommended for funding. Funding recommendations depend on various factors as described in Section II.E.1.b, Programmatic Review.* Additional information about the two-tier process used by the CDMRP can be found at http://cdmrp.army.mil/about/fundingprocess.

All CDMRP review processes are conducted confidentially to maintain the integrity of the meritbased selection process. Panel members sign a statement that application and evaluation information will not be disclosed outside the panel. Violations of confidentiality can result in the dissolving of a panel(s) and other corrective actions. In addition, personnel at the applicant or collaborating organizations are prohibited from contacting persons involved in the review process to gain protected evaluation information or to influence the evaluation process. Violations of these prohibitions will result in the administrative withdrawal of the organization's application. Violations by panel members or applicants that compromise the confidentiality of the review process may also result in suspension or debarment from Federal awards. Furthermore, the unauthorized disclosure of confidential information of one party to another third party is a crime in accordance with 18 USC 1905.

II.E.3. Integrity and Performance Information

Prior to making an assistance agreement award where the Federal share is expected to exceed the simplified acquisition threshold (currently \$150,000) over the period of performance, the Federal awarding agency is required to review and consider any information about the applicant that is available in the Federal Awardee Performance and Integrity Information System (FAPIIS).

An applicant, at its option, may review FAPIIS, accessible through SAM, and submit comments to FAPIIS on any information about itself that a Federal awarding agency previously entered and is currently available in FAPIIS.

The Federal awarding agency will consider any comments by the applicant, in addition to other information in the designated integrity and performance system, in making a judgment about the applicant's integrity, business ethics and record of performance under Federal awards when determining a recipient's qualification prior to award, according to the qualification standards of the Department of Defense Grant and Agreement Regulations (DoDGAR), Section 22.415.

II.E.4. Anticipated Announcement and Federal Award Dates

All application review dates and times are indicated in <u>Section I, Overview of the Funding</u> <u>Opportunity</u>.

Each PI and organization will receive email notification of posting of the funding recommendation in eBRAP. Each PI will receive a peer review summary statement on the strengths and weaknesses of the application.

II.F. Federal Award Administration Information

II.F.1. Federal Award Notices

Awards will be made no later than September 30, 2018. Refer to the General Application Instructions, Appendix 2, for additional award administration information.

Awards are made to organizations, not to individual PIs. The types of awards made under the Program Announcement/Funding Opportunity will be assistance agreements (grants or cooperative agreements). The level of involvement on the part of DoD during project performance is the key factor in determining whether to award a grant or cooperative agreement.

Extramural Organizations: An assistance agreement (grant or cooperative agreement) is appropriate when the Federal Government transfers a "thing of value," to a "state, local government," or "other recipient," to carry out a public purpose of support or stimulation authorized by a law of the United States, instead of acquiring property or service for the direct benefit and use of the U.S. Government. An assistance agreement can take the form of a grant or cooperative agreement. If "no substantial involvement" on the part of the funding agency is anticipated, a grant award will be made (31 USC 6304). Conversely, if substantial involvement on the part of the funding agency is anticipated, a cooperative agreement will be made (31 USC 6305). Substantial involvement may include collaboration, participation, or intervention in the research to be performed under the award. The award type, along with the start date, will be determined during the negotiation process.

After email notification of application review results through the eBRAP, and if selected for funding, a representative from the USAMRAA will contact the business official authorized to negotiate on behalf of the PI's organization.

Only an appointed USAMRAA Grants Officer may obligate the Government to the expenditure of funds. No commitment on the part of the Government should be inferred from discussions with any other individual. The award document signed by the Grants Officer is the official authorizing documents.

Intramural Organizations: Awards to Federal Government organizations (to include intramural DoD organizations) will be executed through the Military Interdepartmental Purchase Request (MIPR) or Funding Authorization Document (FAD) process. Transfer of funds is contingent upon appropriate safety and administrative approvals. Intramural applicants and collaborators are reminded to coordinate receipt and commitment of funds through their respective resource managers (RM).

After email notification of application review results through the eBRAP, and if selected for funding, a representative from the CDMRP will contact the business official authorized to negotiate on behalf of the PI's organization.

II.F.1.a. PI Changes and Award Transfers

Unless otherwise restricted, changes in PI will be allowed at the discretion of the USAMRAA Grants Officer, provided that the intent of the award mechanism is met.

The organization transfer of an award supporting a clinical trial is strongly discouraged and in most cases will not be allowed. Approval of a transfer request will be on a case-by-case basis at the discretion of the Grants Officer. An organization transfer of an award will not be allowed in the last year of the (original) period of performance or any extension thereof.

Refer to the General Application Instructions, Appendix 2, Section B, for general information on organization or PI changes.

II.F.2. Administrative and National Policy Requirements

In addition to written progress reports, in-person presentations at the in-progress review meetings may be requested.

Applicable requirements in the DoDGAR found in 32 CFR, Chapter 1, Subchapter C, and 2 CFR, Chapter XI, apply to grants and cooperative agreements resulting from this Program Announcement/Funding Opportunity.

Refer to the General Application Instructions, Appendix 2, for general information regarding administrative requirements.

Refer to the General Application Instructions, Appendix 5, for general information regarding national policy requirements.

Refer to full text of the <u>USAMRAA General Research Terms and Conditions for Institutions of</u> <u>Higher Education, Hospitals, and Non-Profit Organizations</u> and the <u>USAMRAA General</u> <u>Research Terms and Conditions with For-Profit Organizations</u> for further information.

II.F.3. Reporting

Refer to the General Application Instructions, Appendix 2, Section A, for general information on reporting requirements.

Quarterly, annual, and final technical progress reports and quad charts will be required.

Awards resulting from this Program Announcement/Funding Opportunity will incorporate additional reporting requirements related to recipient integrity and performance matters. Recipient organizations that have Federal contract, grant, and cooperative agreement awards with a cumulative total value greater than \$10,000,000 are required to provide information to FAPIIS about certain civil, criminal, and administrative proceedings that reached final disposition within the most recent 5-year period and that were connected with performance of a Federal award. Recipients are required to disclose semiannually information about criminal, civil, and administrative proceedings as specified in the applicable Terms and Conditions. The applicable Terms and Conditions for institutions of higher education, hospitals, and nonprofit organizations are available in OAR Article I, Section B, in the July 2016 R&D General Terms and Conditions. The applicable Terms and Conditions for for-profit organizations are available in Section 34 of the February 2017 USAMRAA General Research Terms and Conditions with For-Profit Organizations.

II.G. Federal Awarding Agency Contacts

II.G.1. CDMRP Help Desk

Questions related to Program Announcement/Funding Opportunity content or submission requirements as well as questions related to the pre-application or intramural application submission through eBRAP should be directed to the CDMRP Help Desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. ET. Response times may vary depending upon the volume of inquiries.

Phone: 301-682-5507

Email: <u>help@eBRAP.org</u>

II.G.2. Grants.gov Contact Center

Questions related to extramural application submission through Grants.gov portal should be directed to the Grants.gov Contact Center, which is available 24 hours a day, 7 days a week (closed on U.S. Federal holidays). Note that the CDMRP Help Desk is unable to provide technical assistance with Grants.gov submission.

Phone: 800-518-4726; International 1-606-545-5035

Email: support@grants.gov

Sign up on Grants.gov for "send me change notification emails" by following the link on the Synopsis page for the Program Announcement/Funding Opportunity or by responding to the prompt provided by Grants.gov when first downloading the Grants.gov application package. If the Grants.gov application package is updated or changed, the original version of the application package may not be accepted by Grants.gov.

II.H. Other Information

II.H.1. Program Announcement/Funding Opportunity and General Application Instructions Versions

Questions related to this Program Announcement/Funding Opportunity should refer to the Program name, the Program Announcement/Funding Opportunity name, and the Program Announcement/Funding Opportunity version code 20170516f. The Program Announcement/Funding Opportunity numeric version code will match the General Applications Instructions version code 20170516.

II.H.2. Administrative Actions

After receipt of pre-applications or applications, the following administrative actions may occur:

II.H.2.a. Rejection

The following will result in administrative rejection of the application:

- LOI was not submitted.
- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.

II.H.2.b. Modification

- Pages exceeding the specific limits will be removed prior to review for all documents other than the Preproposal Narrative and Project Narrative.
- Documents not requested will be removed.

II.H.2.c. Withdrawal

The following may result in administrative withdrawal of the pre-application or application:

- An FY17 PH/TBIRP PSP Programmatic Panel member is named as being involved in the research proposed or is found to have assisted in the pre-application or application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting documentation. *A list of the FY17 PH/TBIRP PSP Programmatic Panel members can be found at <u>http://cdmrp.army.mil/PHTBIRP/</u>panels/panels17_psp.*
- The application fails to conform to this Program Announcement/Funding Opportunity description to the extent that appropriate review cannot be conducted.
- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- To preserve the integrity of its peer and programmatic review processes, the CDMRP discourages inclusion of any employee of its review contractors having any role in the preparation, research or other duties for submitted applications. For FY17, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (<u>http://cdmrp.army.mil/about/2tierRevProcess</u>). Applications that include names of personnel from either of these companies will be administratively withdrawn unless plans to manage COIs are provided and deemed appropriate by the Grants Officer. Refer to the General Application Instructions, Appendix 3, for detailed information.

- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review process to gain protected evaluation information or to influence the evaluation process.
- Applications from extramural organizations, including non-DoD Federal agencies, received through eBRAP may be withdrawn.
- Applications submitted by an intramural DoD organization may be withdrawn if the intramural organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to extramural collaborators.
- The application does not propose the same research project described in the pre-application.
- Submission of more than one research project to the same Funding Opportunity within the same program and funding cycle

II.H.2.d. Withhold

Applications that appear to involve research misconduct will be administratively withheld from further consideration pending organizational investigation. The organization will be required to provide the findings of the investigation to the USAMRAA Grants Officer for a determination of the final disposition of the application.

II.H.3. Application Submission Checklist

Application Components	Action	Completed
SF424 (R&R) Application for Federal Assistance (Extramural submissions only)	Complete form as instructed.	
Summary (Tab 1) and Application Contacts (Tab 2) (Intramural submissions only)	Complete these tabs as instructed.	
Attachments	 Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf." Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf." Technical Abstract: Upload as Attachment 3 with file name "TechAbs.pdf." Lay Abstract: Upload as Attachment 4 with file name "LayAbs.pdf." Statement of Work: Upload as Attachment 5 with file name "SOW.pdf." Impact and Military Benefit Statement: Upload as Attachment 6 with file name "Impact.pdf." Translation Plan: Upload as Attachment 7 with file name "Translation.pdf." Human Subject Recruitment and Safety Procedure: Upload as Attachment 8 with file name "HumSubProc.pdf," if applicable Data Management: Upload as Attachment 9 with file name "DataManage.pdf." DoD Military Budget Form(s): Upload as Attachment 10 with file name "MFBudget.pdf," 	
Research & Related Senior/Key Person Profile (Expanded)	if applicable. Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field. Attach PI Previous/Current/Pending Support (Support_LastName.pdf) to the appropriate field. Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field. Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person to the appropriate field.	

Application Components	Action	Completed
Research & Related Budget	Complete as instructed. Attach Budget	
(Extramural submissions	Justification (BudgetJustification.pdf) to the	
only)	appropriate field.	
Budget (Intramural	Complete the DoD Military Budget Form and	
submissions only)	justification.	
Project/Performance Site	Complete form as instructed.	
Location(s) Form		
R&R Subaward Budget		
Attachment(s) Form, if	Complete form as instructed.	
applicable		

APPENDIX 1: ACRONYM LIST

ACURO	Animal Care and Use Review Office
CDE	Common Data Element
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
DHA	Defense Health Agency
DHP	Defense Health Program
DoD	Department of Defense
DoDGAR	Department of Defense Grant and Agreement Regulations
DSPO	Defense Suicide Prevention Office
DUNS	Data Universal Numbering System
eBRAP	Electronic Biomedical Research Application Portal
EC	Ethics Committee
ET	Eastern Time
FAD	Funding Authorization Document
FY	Fiscal Year
HRPO	Human Research Protection Office
LOI	Letter of Intent
IRB	Institutional Review Board
JPC	Joint Program Committee
M	Million
MHS	Military Health System
MIPR	Military Interdepartmental Purchase Request
MOMRP	Military Operational Medicine Research Program
NDA	National Institute of Mental Health Data Archive
OASD(HA)	Office of the Assistant Secretary of Defense for Health Affairs
OMB	Office of Management and Budget
ORP	Office of Research Protections
PH	Psychological Health
PH/TBIRP	Psychological Health and Traumatic Brain Injury Research Program
PI	Principal Investigator
PSP	Peer Support Program
PTSD	Post-Traumatic Stress Disorder
RDT&E	Research, Development, Test, and Evaluation
RM	Resource Manager
SAM	System for Award Management
SMs	Service Members
SOW	Statement of Work
TBI	Traumatic Brain Injury
USAMRAA	U.S. Army Medical Research Acquisition Activity
USAMRMC	U.S. Army Medical Research and Materiel Command
USC	United States Code
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APPENDIX 2: CITATIONS

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APPENDIX 3: DOD, VA, AND OTHER FEDERAL AGENCY WEBSITES

Air Force Office of Scientific Research <u>http://www.wpafb.af.mil/afrl/afosr/</u>

Air Force Research Laboratory <u>http://www.wpafb.af.mil/afrl</u>

Army Medicine Armymedicine.mil

Army Resilient Directorate http://www.army.mil/readyandresilient/

Congressionally Directed Medical Research Programs http://cdmrp.army.mil

Defense Advanced Research Projects Agency http://www.darpa.mil/

Defense Technical Information Center <u>http://www.dtic.mil</u>

Department of Veterans Affairs <u>http://www.va.gov/</u>

Military Health System Research Symposium https://mhsrs.amedd.army.mil/SitePages/Ho me.aspx

Military Operational Medicine Research Program https://momrp.amedd.army.mil

National Institutes of Health <u>https://www.nih.gov/</u>

Naval Health Research Center http://www.med.navy.mil/sites/nhrc

Naval Medical Research Center <u>www.med.navy.mil/sites/nmrc</u>

Navy and Marine Corps Public Health Center http://www.nmcphc.med.navy.mil/

Office of Naval Research http://www.med.navy.mil/

Office of the Under Secretary of Defense for Acquisition, Technology and Logistics <u>http://www.acq.osd.mil/</u>

Telemedicine and Advanced Technology Research Center http://www.tatrc.org/

Uniformed Services University of the Health Sciences http://www.usuhs.edu/research

U.S. Army Institute of Surgical Research <u>http://www.usaisr.amedd.army.mil/</u>

U.S. Army Research Institute of Environmental Medicine <u>http://www.usariem.army.mil/</u>

U.S. Army Medical Research Institute of Infectious Diseases <u>http://www.usamriid.army.mil/</u>

U.S. Army Medical Research and Materiel Command http://mrmc.amedd.army.mil/

U.S. Army Research Laboratory <u>http://www.arl.army.mil</u>

U.S. Department of Veterans Affairs, Office of Research and Development <u>http://www.research.va.gov</u>

U.S. Food and Drug Administration <u>http://www.fda.gov</u>

U.S. Naval Research Laboratory <u>http://www.nrl.navy.mil</u>

Walter Reed Army Institute of Research <u>http://www.wrair.army.mil</u>