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/Traumatic Brain Injury Research Program

Comprehensive Universal Prevention/Health Promotion Interventions Award

Funding Opportunity Number: W81XWH-15-PHTBIRP-CUPHPI
Catalog of Federal Domestic Assistance Number: 12.420
Military Medical Research and Development

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application Deadline:** 5:00 p.m. Eastern time (ET), October 12, 2015

- **Invitation to Submit an Application:** November 16, 2015

- **Application Submission Deadline:** 11:59 p.m. ET, January 14, 2016

- **End of Application Verification Period:** 5:00 p.m. ET, January 18, 2016

- **Peer Review:** February 2016

- **Programmatic Review:** April 2016

The CDMRP eReceipt System has been replaced with the electronic Biomedical Research Application Portal (eBRAP). Principal Investigators and organizational representatives should register in eBRAP as soon as possible. All pre-applications must be submitted through eBRAP. In addition, applications submitted through Grants.gov will now be available for viewing, modification, and verification in eBRAP prior to the end of the application verification period.

This Program Announcement/Funding Opportunity is one of two documents with instructions to prepare and submit an application for this funding opportunity. The second document, the General Application Instructions, is available for downloading from Grants.gov.

TABLE OF CONTENTS

I. FUNDING OPPORTUNITY DESCRIPTION

A. Program Description

Applications to the Fiscal Year 2015 (FY15) Psychological Health and Traumatic Brain Injury Research Program (PH/TBIRP) are being solicited for the Defense Health Agency, Research, Development, and Acquisition (DHA RDA) Directorate, by the U.S. Army Medical Research Acquisition Activity (USAMRAA). As directed by the Office of the Assistant Secretary of Defense for Health Affairs (OASD[HA]), the DHA RDA Directorate manages and executes 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 execution management support aligned with specific DHA RDA Directorate research program areas, including Joint Program Committee-5/Military Operational Medicine Research Program (JPC-5/MOMRP). This Program Announcement/Funding Opportunity and subsequent awards will be managed and executed by the CDMRP with strategic oversight from JPC-5/MOMRP.

The PH/TBIRP was established by Congress in Fiscal Year 2007 (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 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/TBI. The vision of the PH/TBIRP is to prevent, mitigate, and treat the effects of traumatic stress and traumatic brain injury on function, wellness, and overall quality of life for Service members as well as their caregivers and families. The DHA RDA Directorate leverages PH/TBIRP funding to complement DHP core research and development funding assigned to study PH and TBI.

The JPC-5/MOMRP is one of the six major research program areas within the DHA RDA Directorate. The JPC-5/MOMRP manages an extensive portfolio of research aimed at developing effective countermeasures against stressors to maximize health, performance, and well-being throughout the deployment cycle. JPC-5/MOMRP psychological health and resilience research portfolio is focused on prevention, treatment, and recovery of Service member and military family behavioral health, which is critical to force health and readiness. Applications from investigators within the military services are highly encouraged, as are applications involving multidisciplinary collaborations among academia, industry, the military services, the U.S. Department of Veterans Affairs (VA), and other Federal Government agencies.

B. Award Description

The intent of the FY15 PH/TBI Comprehensive Universal Prevention/Health Promotion Interventions (CUP/HPI) Award is to support research focused on the development, adaptation, efficiency or optimization, and testing of comprehensive universal prevention/health promotion interventions and systems-level approaches for use within the military context. This Program Announcement/Funding Opportunity seeks research applications that are designed to have positive effects on multiple target behaviors and outcomes.

Research should address shared common antecedents or precursors and shared risk and protective factors and interventions that have an effect on multiple outcomes. Interventions and systems-level approaches should increase protective factors and positive outcomes and reduce risk factors and negative outcomes that are relevant to the needs of Service members, their families, and their communities. Applications should be limited to prevention interventions and systems-level approaches that are within the military's legal and operational control. Examples of negative outcome targets of interest include, but are not limited to:

- Risky behaviors (e.g., substance use, misuse, and abuse [including alcohol, tobacco, and other substance use, non-medical use, misuse, and abuse of prescription drugs], aggressive and other unsafe driving, and health-risking sexual behaviors [HRSB] related to HIV/AIDS)

- Aggression/violence

- Sexual assault

- Suicidal ideation and behaviors

- Depression

- Anxiety

- Sleep

Health promotion/positive health outcomes include, but are not limited to, adequate physical activity, sleep, and nutrition; supportive social relationships; resilience and holistic wellness; vocational promotion; cognitive and skill enhancement; and cognitive flexibility. Approaches that integrate physical and psychological wellness are encouraged.

The FY15 PH/TBI CUP/HPI Award is intended to support both applied research and clinical trials within specific Topic Areas addressing the prevention and treatment of military-relevant psychological health issues. Applications proposing research outside of the Topic Areas listed in Section I.E. should not be submitted in response to this Program Announcement/Funding Opportunity.

Applied research is defined as work that refines concepts and ideas into potential solutions with a view toward evaluating technical feasibility of behavioral and rehabilitation interventions, diagnostic and therapeutic techniques, clinical guidance, emerging approaches and technologies, promising new products, and/or pharmacologic agents. Applied research may involve human subjects.

A clinical trial is defined as a prospective accrual of human subjects where an intervention (e.g., device, drug, biologic, surgical procedure, rehabilitative modality, behavioral intervention, or other) is tested on a human subject for a measurable outcome with respect to exploratory information, safety, effectiveness, and/or efficacy. This outcome represents a direct effect on the human subject of that intervention or interaction.

C.   Background

Research on civilians has shown that risk behaviors for negative health and behavioral outcomes (e.g., substance use and abuse, aggression, intimate partner violence, HRSB) tend to co-occur in childhood, adolescence, and adulthood (Bailey, 2009; Ellickson et al., 2009). These negative behavioral outcomes share common antecedents and risk and protective factors (Bogart et al., 2006; Jessor and Jessor, 1977). Testing and replication of universal prevention interventions funded by the Prevention Research Branch (PRB) at the National Institute on Drug Abuse (NIDA) has led to a growing body of long-term follow-up studies examining differences in life-course outcomes of intervention and control group participants over time, some into late adolescence and adulthood. Evidence from this body of work indicates that (1) it is possible to intervene early in development on proximal risk and protective factors to have an impact on a broad array of distal outcomes; (2) interventions can have effects, some of which are unanticipated positive effects on outcomes not specifically targeted by the intervention; and (3) those at greatest risk can benefit the most from prevention interventions.

Indeed, universal drug abuse prevention interventions have been shown to have long-term effects on multiple behaviors, including substance abuse (Kellam et al., 2008), psychological health problems (e.g., Mason et al., 2007; Kellam et al., 2008), suicidal ideation and attempts (Hawkins et al., 2005; Wilcox et al., 2008), delinquent, violent, and criminal behaviors (Hawkins et al., 1999; Beets et al., 2009), HRSB related to HIV/AIDS (Kellam et al., 2014; Hill et al., 2014; Spoth et al., 2014), high school completion (Kellam et al., 2014), and college attendance and employment (Hawkins et al., 2005). Interventions have been shown to be protective against genetic vulnerability to risky behaviors and positively affect biological functioning (Fisher et al., 2007; Brody et al., 2009).

Systems-level approaches include models for implementing evidence-based prevention intervention throughout a setting or service system (e.g., throughout a military base, or within a health care setting), or interventions that are targeted to multiple levels of individuals within a setting or service system (e.g., health promotion interventions that target multiple levels of military personnel within a military setting).

U.S. Service members and their families endure many challenges (e.g., multiple, prolonged, and sustained combat deployments since September 11, 2001). Specialized and sustained combat operations resulted in Service members experiencing increased numbers and lengths of deployments and greater exposure to stressors, including exposure to death, risk to life, sustained threat of injury or actual injury, and the day-to-day and family stress inherent in all phases of the military lifecycle and transitions. In addition, Service members and their families experience many of the same stressors as civilian communities (e.g., economic downturns). Negative life stress has been shown to be a major contributor to both the onset and exacerbation of substance abuse and psychological health problems and to be related to a variety of negative physical health outcomes, including cardiovascular disease, cancer, and asthma (Smith et al., 2014; LeardMann et al., 2013; Crum-Cianflone et al, 2014; Granado et al., 2009; Sandweiss et al., 2011; LeardMann et al., 2009). Exposure to combat has shown an increased risk for impacting physical health, and those in poorer psychological and physical health are at increased risk for psychological difficulties. This is consistent with other findings in the literature on comorbidities, such as substance abuse, in Service members (e.g., 2011 Department of Defense

Health Related Behaviors Survey of Active Duty Military Personnel; McClernonet al., 2013). Moreover, positive health behaviors such as physical activity, proper nutrition, adequate sleep, and improvements to social relationships, all have been shown to both reduce stress and improve physical and psychological health outcomes.

Universal prevention interventions are designed to be administered to an entire population (Institute of Medicine and National Research Council, 2009) (e.g., a group of Service members entering the military [basic combat training], existing units, military spouses, an entire military installation [base, post, combat training]) and present a good opportunity to intervene with Service members because no one individual is singled out or stigmatized. Current prevention approaches in the military focus on topic-specific training that is typically delivered either online or via group in-person training sessions (e.g., substance abuse prevention training; sexual harassment/assault response and prevention training; suicide prevention training). This Program Announcement/Funding Opportunity seeks to expand available models by taking a comprehensive and integrative approach that is designed to have an impact on multiple behaviors and outcomes.

D.   Research Objectives

Applications should focus on the development, adaptation, efficiency or optimization, implementation and/or testing of prevention interventions and systems-level approaches. Research should target malleable shared common antecedents and risk and protective factors, and include both negative and positive outcomes. Examples of risk reduction target outcomes of interest may include, but are not limited to;

- Risky behaviors (e.g., aggressive and other unsafe driving, HRSB related to HIV/AIDS)
- Substance use, misuse, and abuse (alcohol, tobacco, and other substance use, including non-medical use, misuse, and abuse of prescription drugs)
- Aggression/violence
- Military sexual assault
- Suicidal ideation and behaviors
- Depression
- Anxiety

Examples of health promotion/positive health outcomes may include physical activity, adequate sleep, nutrition, improvements in social relationships, coping, resilience, etc. Interventions and systems-level approaches should have some evidence demonstrating an effect on multiple behaviors, and/or a theoretically based justification for why an effect on multiple behaviors is anticipated. Applications should include follow-up to evaluate durability of effects and longitudinal outcomes.

The approaches should be relevant and appropriate for military Service members, families, and/or their communities. This Program Announcement/Funding Opportunity is interested in interventions that are applicable to all branches of the military (Army, Navy, Air Force, Marines)

as well as Special Forces and Reserve Component (Reserves/National Guard). Collaborations with the military are very important, and applications are encouraged to include letters of support and evidence of an established military collaboration. While Veterans are a very important population, this Program Announcement/Funding Opportunity is not focused on Veterans.

Applications may have broad utilization across the military lifecycle or may be focused on a particular phase. Prevention researchers should consider the timing, dosing, quantity, and delivery method of interventions, for example, to coincide with important military lifecycle stages or transitions. When relevant, limits related to confidentiality concerning research data that involves reporting of illegal behavior by Active Duty Service members and/or their families need to be carefully addressed.

Prevention interventions and systems-level approaches should focus on decreasing malleable risk factors and increasing malleable protective factors that share common antecedents or precursors. This can include increasing competency of skills that promote resilience and intrapersonal, interpersonal, and familial functioning in order to prevent multiple negative outcomes and increase positive outcomes. It may also include other types of systems-level interventions that produce desirable outcomes (e.g., empathy training; emotional literacy training; values-based education; character development) versus reduction of maladaptive behaviors as an alternative way to understand how to optimize human functioning. Interventions should be sensitive to the time and contextual constraints associated with military training and families. Thought should also be given to ensuring that the interventions will be not only acceptable to the target audience and military context, but also engaging and interactive. Studies should consider ways to integrate content into the everyday existence of Service members, families, or small units to decrease burden and increase buy-in. Thought should also be given to the complexities of distributing and sustaining innovation in universal prevention intervention in military organizations.

Partnering PI Option: The FY15 PH/TBI CUP/HPI Award includes an option for up to four Principal Investigators (PIs). One PI will be identified as the Initiating PI and will be responsible for the majority of the administrative tasks associated with application submission. The other PI(s) will be identified as Partnering PI(s). Initiating and Partnering PIs each have different submission requirements, as described in Section II; however, all PIs should contribute significantly to the development of the proposed research project. If recommended for funding, each PI will receive his or her own award.

Research Involving Human Anatomical Substances, Human Subjects, or Human Cadavers: All DoD-funded research involving new and ongoing research with human anatomical substances, human subjects, or human cadavers must be reviewed and approved by the USAMRMC Office of Research Protections (ORP), Human Research Protection Office (HRPO), in addition to the local Institutional Review Board (IRB) of record. Local IRB 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. ***Allow a minimum of 2 to 3 months for HRPO regulatory review and approval processes***. Refer to the General Application Instructions, Appendix 5, and the Human Subject Resource Document available on the eBRAP

"Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) for additional information.

Investigational New Drug/Investigational Device Exemption (IND/IDE): If the clinical trial involves the use of a drug that has not been approved by the U.S. Food and Drug Administration (FDA) for the proposed investigational use, evidence that an IND application that meets all requirements under the Code of Federal Regulations, Title 21, Part 312 (21 CFR 312) has been submitted or will be submitted to the FDA within 60 days of award is required. If the investigational product is a device, evidence that an IDE application that meets all requirements under 21 CFR 812 has been submitted or will be submitted to the FDA within 60 days of award, or that the device is exempt from an IDE, is required. The Government reserves the right to withdraw funding if the IND or IDE application has not been submitted to the FDA within 60 days of the Department of Defense (DoD) award date or if the documented status of the IND or IDE has not been obtained within 6 months of the award date.

E.   Topic Areas

To meet the intent of the FY15 PH/TBI CUP/HPI Award, applications must propose research to develop, adapt, optimize, test, and/or implement universal prevention interventions and systems-level approaches, specifically addressing one or more of the Topic Areas listed below:

- Life skills training/competence enhancement and resilience-building approaches.

- Holistic and integrated approaches to physical and psychological well-being.

- Interventions and systems-level approaches that target and strengthen the impact of context at different levels (e.g., evaluating the role that policy, leadership, unit norms, or military culture plays at different levels within the military structure and context on the outcomes of prevention interventions and systems-level approaches).

- Research to boost efficacy of prevention interventions through optimization (e.g., multiphase optimization strategy [MOST], http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2062525/).

- Construction/dismantling studies and adaptive designs that systematically examine the impact of program components, alone and together, to determine mechanisms and critical elements of program effectiveness.

- Evaluation of the efficacy of resilience, prevention, and/or mandatory training programs and strategies that are untested but currently being used in military health promotion and prevention programming.

- Optimizing delivery of evidence-based interventions with the goal of improving learning outcomes (e.g., user-friendly formats, optimization of trainer characteristics, train-the-trainer, adjuncts or alternatives to traditional didactic and computer instruction).

The JPC-5/MOMRP and CDMRP intend 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. JPC-5/MOMRP strongly encourages the

applicant to incorporate Common Data Element measures from the Core and Specialty collections, which are available in the Mental Health Research Collection (Psychiatric, Psychosocial, Alcohol, Tobacco, and other substances as well as Substance Abuse and Addiction) of the PhenX Toolkit https://www.phenxtoolkit.org/index.php into all studies involving human subjects as applicable. For additional guidance, refer to the General Application Instructions, Appendix 3, Section L.

F. Eligibility Information

- Independent investigators at all academic levels (or equivalent) are eligible to submit applications.

- Cost sharing/matching is not an eligibility requirement.

- Eligible investigators must apply through an organization. Organizations eligible to apply include national, international, for-profit, nonprofit, public, and private organizations.

- Refer to the General Application Instructions, Appendix 1, for general eligibility information.

G. Funding

For applied research applications:

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

- The anticipated direct costs budgeted for the entire period of performance will not exceed **$1.5M**. Indirect costs are to be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the Government exceeding **$1.5M** direct costs or using an indirect rate exceeding the organization's negotiated rate.

- All direct and indirect costs of any subaward (subgrant or subcontract) 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 clinical trial applications:

- The maximum period of performance is **4** years.

- The anticipated direct costs budgeted for the entire period of performance will not exceed **$3M**. Indirect costs are to be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the Government exceeding **$3M** direct costs or using an indirect rate exceeding the organization's negotiated rate.

Partnering PI: The anticipated combined direct costs budgeted for the entire period of performance for the Initiating PI and the Partnering PI(s) applications will not exceed **$1.5M (applied research) and $3M (clinical trials)**. If the budget of the Initiating PI or Partnering PI contains a subaward (or multiple subawards) all direct and indirect costs of the subaward(s) must be included in the direct costs of the primary award. Collaborating

organizations should budget indirect costs in accordance with each organization's negotiated rate. The combined budgeted direct costs approved by the Government will not exceed **$1.5M (applied research) or $3M (clinical trials)** or use an indirect rate exceeding each organization's negotiated rate.

- For the Partnering PI Option, no additional funds will be provided.

- A separate award will be made to each PI's organization.

- The PIs are expected to be equal partners in the research, and direct cost funding should be divided accordingly, unless otherwise warranted and clearly justified.

Refer to the General Application Instructions, Section II.C.5., for budget regulations and instructions for the Research & Related Budget. ***For all Federal agencies or organizations collaborating with Federal agencies, budget restrictions apply as are noted in Section II.C.5. of the General Application Instructions***.

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

- Travel costs for the PI(s) to disseminate project results at one DoD sponsored, 2 day meeting. 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

- Clinical research costs

- Support for multidisciplinary collaborations

- Travel between collaborating organizations

- Travel costs to attend scientific/technical meetings

Intramural (DoD), other Federal agency, and extramural investigators are encouraged to apply to this Program Announcement/Funding Opportunity. An intramural investigator is defined as a DoD military or civilian employee working within a DoD laboratory or medical treatment facility, or working in a DoD activity embedded within a civilian medical center. Intramural applicants and collaborators are reminded to coordinate receipt and commitment of funds through their respective resource managers. It is permissible for an intramural investigator to be named as a collaborator on an application submitted by an extramural investigator. ***In such cases, the extramural investigator must include a letter from the intramural collaborator's Commander or Commanding Officer that authorizes the involvement of the intramural collaborator.***

As required of all applicants to this Program Announcement/Funding Opportunity, if PIs from Federal agencies submit applications, they must submit through Grants.gov. Therefore, Federal applicants must be familiar with Grants.gov requirements, including the need for an active System for Award Management (SAM) registration and a Data Universal Numbering System

(DUNS) number. Refer to Section II.A. of the General Application Instructions for further information regarding Grants.gov requirements.

Awards to extramural organizations will consist solely of assistance agreements (Cooperative Agreements and Grants). Awards to intramural agencies and other Federal agencies may be executed through a direct fund transfer (e.g., the Military Interdepartmental Purchase Request [MIPR] or Funding Authorization Document [FAD] process). Direct transfer of funds from the recipient to a Federal agency is not allowed except under very limited circumstances. Refer to the General Application Instructions, Section II.C.5. Research & Related Budget, for additional information on budget considerations for applications involving Federal agencies.

The JPC-5/MOMRP expects to allot approximately $7.5M of the FY15 PH/TBIRP appropriation to fund approximately 2-4 Comprehensive Universal Prevention/Health Promotion Intervention 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.   SUBMISSION INFORMATION

Submission is a two-step process requiring both (1) pre-application submission through the electronic Biomedical Research Application Portal (eBRAP) (https://eBRAP.org/) and (2) application submission through Grants.gov (http://www.grants.gov/). Refer to the General Application Instructions, Section II.A. for registration and submission requirements for eBRAP and Grants.gov.

eBRAP is a multifunctional web-based system that 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. A key feature of eBRAP is the ability of an organization's representatives and PIs to view and modify the Grants.gov application submissions associated with them. eBRAP will validate Grants.gov 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.

PIs should ensure that their name and email address are the same as the name and email address that will be provided on the SF-424 Form of the Grants.gov application package submitted to Grants.gov. The organization, Business Officials, PI(s), and eBRAP log number named in the full application submitted to Grants.gov must match those named in the pre-application in eBRAP.

Application viewing, modification, and verification in eBRAP is strongly recommended, but not required. The Project Narrative and Budget cannot be changed after the application submission deadline. Any other application component cannot be changed after the end of the application verification period.

The FY15 PH/TBI CUP/HPI Award is structured to accommodate up to a maximum of four PIs. One PI will be identified as the Initiating PI and will be responsible for the majority of the administrative tasks associated with application submission. The other PI(s) will be identified as Partnering PI(s). Initiating and Partnering PIs each have different submission requirements; however, all PIs should contribute significantly to the development of the proposed research project including the Project Narrative, Statement of Work, and other required components. The Initiating PI must complete the pre-application submission process and submit the contact information for each Partnering PI. Each Partnering PI will then be notified of the pre-application submission separately by email. ***Each Partnering PI must follow the link in this email and register with eBRAP in order to associate his/her Grants.gov application package with that of the Initiating PI.*** Do not delay completing these steps. If this is not completed, the Partnering PI will not be able to view and modify his/her application submission in eBRAP.

A.   Where to Obtain the Grants.gov Application Package

To obtain the Grants.gov application package, including all required forms, perform a basic search using the Funding Opportunity Number W81XWH-15-PHTBIRP-CUPHPI in Grants.gov (http://www.grants.gov/).

B.   Pre-Application Submission Content

All pre-application components must be submitted by the Initiating PI through eBRAP (https://eBRAP.org/). Because the invitation to submit an application is based on the contents of the pre-application, investigators should not change the title or research objectives after the pre-application is submitted.

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 help@eBRAP.org 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):

- **Application Information – Tab 1**

- **Application Contacts – Tab 2**
  - 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 SF-424 form). The Business Official must either be selected from the eBRAP 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.

- **Collaborators and Key Personnel – Tab 3**

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

  ○ FY15 PH/TBIRP CUP/HPI Programmatic Review Panel members should not be involved in any pre-application or application. For questions related to Programmatic Review Panel members and pre-applications or applications, refer to Section IV.C., Withdrawal, or contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507.

  ○ The Initiating PI must enter the contact information for each Partnering PI in the Partnering PI section.

- **Conflicts of Interest (COIs) – Tab 4**

  ○ 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).

- **Pre-Application Files – Tab 5**

  Note: Upload document(s) as individual PDF files unless otherwise noted. eBRAP will not allow a file to be uploaded if the number of pages exceeds the limit specified below.

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

  The Preproposal Narrative should include the following:

  ○ **Rationale:** State the ideas and reasoning on which the proposed applied research or clinical trial is based. Describe how the preliminary data and rationale support the research idea. State how this project meets the intent of the award mechanism.

  ○ **Topic Area:** Note specifically what FY15 PH/TBI CUP/HPI Topic Area(s) the proposed work addresses.

  ○ **Hypothesis or Objective:** State the hypothesis to be tested or the objective to be reached.

  ○ **Research Strategy:** Clearly describe the research or clinical trial being proposed, and indicate the phase of trial and/or class of device and regulatory status as appropriate. Concisely state the project's objectives, specific aims, and ultimate endpoints. Describe the proposed methods and how they will accomplish the project's aims.

  ○ **Personnel:** Briefly state the qualifications of the PI and key personnel to perform the described research or clinical trial.

- ○ **Military Benefit:** Describe how the proposed work would impact the psychological health and well-being of Service members and/or their family members.

  Pre-Application Supporting Documentation: The items to be included as supporting documentation for the pre-application *must be uploaded as individual documents* and are limited to:

  - ○ References Cited (one-page limit): List the references cited (including URLs if available) in the Preproposal 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 used in the Pre-proposal Narrative.

  - ○ Key Personnel Biographical Sketches (five-page limit per individual).

  - ○ Quad Chart: The Quad Chart template is a one-page PowerPoint file that must be downloaded from the eBRAP "Program Announcement and Forms" web page (https://ebrap.org/eBRAP/public/Program.htm), completed, and saved as a PDF file using Adobe Acrobat Reader.

- **Submit Pre-Application – Tab 6**
  - ○ This tab must be completed for the pre-application to be accepted and processed.

Pre-Application Screening

- **Pre-Application Screening Criteria**

  To determine the technical merits of the pre-application and the relevance to the mission of the DHP and the JPC-5/MOMRP, pre-applications will be screened based on the following criteria:

  - ○ **Alignment with Research Objectives and Topic Areas:** How well the project aligns with the FY15 PH/TBI CUP/HPI Research Objectives and whether the project addresses at least one of the Topic Areas.

  - ○ **Research Plan:** How well the proposed applied research or clinical trial addresses the intent of the award mechanism and the program. To what degree the rationale, objectives, and specific aims support the research idea. Whether the endpoints are appropriate for the proposed study. Whether the proposed methodology is appropriate.

  - ○ **Personnel:** Whether the qualifications and expertise of the PI and key personnel are appropriate to perform the proposed research or clinical trial.

  - ○ **Military Benefit:** How the proposed work would benefit the psychological health care needs of Service members as well as their families, caregivers, and/or communities.

- **Notification of Pre-Application Screening Results**

  Following the pre-application screening, Initiating PIs will be notified as to whether or not they are invited to submit applications; however, they will not receive feedback (e.g., a critique of strengths and weaknesses) on their pre-application. The estimated timeframe for notification of invitation to submit an application is indicated on the title page of this Program Announcement/Funding Opportunity.

C.   Full Application Submission Content

Applications will not be accepted unless the Initiating PI has received notification of invitation.

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 Grants.gov application package provided in Grants.gov for this Program Announcement/Funding Opportunity. The Grants.gov application package is submitted by the Authorized Organizational Representative through the Grants.gov portal (http://www.grants.gov/).

Note: The Project Narrative and Budget Form cannot be changed after the application submission deadline. If either the Project Narrative or the budget fails eBRAP validation or if the Project Narrative or Budget Form needs to be modified, an updated Grants.gov application package must be submitted via Grants.gov as a "Changed/Corrected Application" with the previous Grants.gov Tracking ID *prior to the application submission deadline*.

The CDMRP requires separate Grants.gov application package submissions for the Initiating PI and each Partnering PI, even if the PIs are located within the same organization. Initiating and Partnering PIs will each be assigned unique log numbers by eBRAP. Each Grants.gov application package must be submitted using the unique log number.

Note: All associated applications (Initiating and each Partnering PI) must be submitted by the Grants.gov deadline.

Application Components for the Initiating PI:

Grants.gov application package components: For the FY15 PH/TBI CUP/HPI Award, the Grants.gov application package includes the following components (refer to the General Application Instructions, Section II.C., for additional information on application submission):

1. **SF-424 (R&R) Application for Federal Assistance Form:** Refer to the General Application Instructions, Section II.C., for detailed information.

2. **Attachments Form**

   Each attachment to the Grants.gov application forms must be uploaded as an individual PDF file in accordance with the formatting guidelines listed in Appendix 2 of the General Application Instructions. For all attachments, ensure that the file names are

consistent with the guidance. Grants.gov will reject attachments with file names 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, Grants.gov has file size limits that may apply in some circumstances. Individual attachments may not exceed 20 MB and the file size for the entire Grants.gov application package may not exceed 200 MB.

- **Attachment 1: Project Narrative (30-page limit): Upload as "ProjectNarrative.pdf."** The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings, etc.) 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.

  ○ **Background:** State the relevance of the applied research or clinical trial to at least one of the FY15 PH/TBI CUP/HPI Topic Areas and explain the applicability of the anticipated findings. Present the ideas and reasoning behind the proposed work. Cite relevant literature and pilot or preliminary data. Describe previous experience most pertinent to this project. Discuss the unique contribution of the proposed research as compared to the conventional wisdom/previous research.

    For clinical trials:

    – Provide a summary of relevant clinical trials and distinguish how the proposed study differs from other relevant or recently completed clinical trials. Include a discussion of any current clinical use of the intervention under investigation, and/or details of its study in clinical trials for other indications (as applicable).

    – Clearly support the choice of study variables and explain the basis for the study questions and/or study hypotheses.

  ○ **Personnel:** Briefly state the qualifications of the PI(s) and key personnel to perform the described research or clinical trial. Provide an organizational chart identifying key members of the study team including institution/center/ department. Briefly describe their roles on the project. A medical monitor (external to the study) and study coordinator(s) should be included for all clinical interventions.

  ○ **Objectives/Specific Aims/Hypotheses:** Provide a description of the purpose and objectives of the study with detailed specific aims and/or study questions/hypotheses.

  ○ **Research Strategy:** Describe the experimental design, methods, and analyses including appropriate controls in sufficient detail for analysis. Address potential problem areas and present alternative methods and approaches.

For clinical trials and applied research involving human subjects:

- − 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 of human subjects from the accessible population (e.g., convenience, simple random, stratified random).

- − 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 psychometric measures, if applicable. Include critical survey questions, if applicable. The use of standardized psychometric instruments is strongly encouraged when available.

For clinical trials:

- − Identify the intervention to be tested and describe the projected outcomes.

- ○ **Statistical Plan and Data Analysis:** Describe the statistical model and data analysis plan with respect to the study objectives as appropriate to the type of study. For clinical trials and applied research involving human subjects, specify the approximate 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 of the study.

- • **Attachment 2: Supporting Documentation.** Start each document on a new page. Combine and upload as a single file named "Support.pdf." If documents are scanned to pdf, the lowest resolution (100 to 150 dpi) should be used. *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 Patent Abstracts: 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: 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 Collaboration: 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.

- ○ Letter(s) of Support for Use of Military Populations or Resources (if applicable): Provide a letter(s) signed by the lowest ranking person with approval authority for studies involving military Service members, military - controlled study materials, and military databases.

- ○ Intellectual Property

  - – Background and Proprietary Information: All software and data first produced under the award are subject to a Federal purpose license. Provide a list of all background intellectual property to be used in the project or provide a statement that none will be used. If applicable, state and identify the proprietary information that will be provided to the Government and indicate whether the applicant will require a waiver of the Federal purpose license.

  - – Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations and/or Partnering PIs.

- ○ Data and Research Resources Sharing Plan: Describe 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 3, Section L for more information about the CDMRP expectations for making data and research resources publicly available.

- ○ Current Quad Chart: Provide a current Quad Chart in the same format as in the pre-application. If no changes have been made, the same Quad Chart submitted with the pre-application can be used.

- **Attachment 3: Technical Abstract (one-page limit): Upload as "TechAbs.pdf."** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

- ○ Background: State how the proposed research addresses a FY15 PH/TBI CUP/HPI Topic Area(s). Present the ideas and reasoning behind the proposed work.
- ○ 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.
- ○ Study Design: Briefly describe the study design, including appropriate controls.
- ○ Military Benefit: Briefly explain how the proposed project will have an immediate or potential long-term impact on the psychological health and well-being of Service members and/or their family members.

- **Attachment 4: Lay Abstract (one-page limit): Upload as "LayAbs.pdf."** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.
  - ○ Describe the objectives and rationale for the application in a manner that will be in clear layperson terms by readers without a background in science or medicine.
    - – Do not duplicate the technical abstract.
  - ○ Describe the ultimate applicability of the research.
    - – What types of populations will it help, and how will it help them? Include currently available statistics to the related injury/condition.
    - – What are the potential clinical applications, benefits, and risks?
    - – What is the projected timeline it may take to achieve the expected patient-related outcome?
    - – What are the likely contributions of this study to advancing the field of psychological health research or patient care?
  - ○ Briefly describe how the proposed project will benefit Service members, and/or their family members.

- **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 (https://ebrap.org/eBRAP/public/Program.htm). For the FY15 PH/TBI CUP/HPI mechanism, use the SOW format example titled "SOW Generic Format" or "SOW for Clinical Research"." The SOW must be in PDF format prior to attaching. Refer to the General Application Instructions, Section II.C.3., for detailed guidance on creating the SOW.

  Each PI must submit an identical copy of a jointly created SOW. The contributions of the Initiating PI and Partnering PI(s) should be noted for each task.

- **Attachment 6: Impact and Military Benefit Statement (one-page limit): Upload as "MilBen.pdf."**
  - Describe how the proposed study is responsive to the health care needs of Service members with military-relevant psychological health problems. Provide information about the incidence and/or prevalence of the disease or condition to be studied in Service members if appropriate and available.
  - If Active Duty Military will be used in the proposed research project, describe the population(s), the appropriateness of the population(s) for the proposed study, and the feasibility of accessing the population. If a non-military population will be used for the proposed research project, explain how the population simulates Service members.

  For studies including a clinical intervention:
  - Identify the volunteer population(s) that will participate in the proposed intervention, and describe the potential impact of the proposed clinical trial on the psychological health and well-being of Military Service members and their families.
  - Describe the short-term impact: Detail the anticipated outcomes that will be directly attributed to the results of the proposed clinical trial. Outcomes should be specific and measurable and should include a definition of the end user.
  - Describe the long-term impact: Explain the long-range vision for implementation of the intervention in the clinic or field and describe the anticipated long-term benefits for the targeted population.
  - Compare the proposed intervention to pharmacologic agents, devices, and/or clinical guidance currently available, if applicable.

- **Attachment 7: Transition Plan (one-page limit).** Upload as "Transition.pdf."

  Provide information on the methods and strategies proposed to move the product to the next phase of research or delivery to the military or civilian market after successful completion of the award. The transition plan should include the components listed below.
  - Details of the funding strategy that will be used to bring the outcomes to the next level (e.g., specific potential industry partners, specific funding opportunities to be pursued).
  - A description of collaborations and other resources that will be used to provide continuity of development.
  - A brief schedule and milestones for bringing the outcome(s) to the next level.
  - The involvement of appropriate intellectual property, licensing, and/or business professionals.
  - A risk analysis for cost, schedule, manufacturability, and sustainability.

- **Attachment 8: Human Subject Recruitment and Safety Procedures (if applicable; 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.

  a. **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/drawn). Demonstrate that the research team has access to the proposed study population. Furthermore, discuss past efforts in recruiting human subjects from the target population for previous clinical trials (if applicable). Address any potential barriers to accrual and plans for addressing unanticipated delays. Include justification of any age, race, ethnicity, or sex limitations provided.

  b. **Inclusion/Exclusion Criteria:** List the inclusion and exclusion criteria for the proposed clinical trial. 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 from the clinical trial.

  c. **Description of the Recruitment Process:** Explain methods for identification of potential human subjects (e.g., medical record review, obtaining sampling lists, health care 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.

  d. **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.

- 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.

- Describe the plan for the consent of the individual's Legally Authorized Representative (LAR) to be obtained prior to the human subject's participation in the study. State law defines who may act as the LAR. The local IRB of record should be consulted for guidance regarding who can serve as LAR for research at the study site. Note: The PI must describe a clear intent to benefit for human subjects who cannot give their own consent to participate in the proposed clinical trial to be in compliance with Title 10 United States Code Section 980 (10 USC 980) (http://www.gpo.gov/fdsys/pkg/USCODE-2011-title10/pdf/USCODE-2011-title10-subtitleA-partII-chap49-sec980.pdf). If applicable, please refer to the General Application Instructions, Appendix 5, for more information.

- *Assent.* If minors or other populations that cannot provide informed consent are included in the proposed clinical trial, a plan to obtain assent (agreement) from those with capacity to provide it, or a justification for a waiver of assent, should be provided. PIs should consult with their local IRB to identify the conditions necessary for obtaining assent.

e. **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. Please 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.

f. **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 in the clinical trial. 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. Include safeguards and planned responses such as dose reduction or stopping criteria based on toxicity grading scales or other predetermined alert values.
  - ○ 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 (e.g., medication washout periods, dietary restrictions, hydration, fasting, pregnancy prevention).
  - ○ Describe any special care (e.g., wound dressing assistance, transportation due to side effects of study intervention impairing ability to drive) or equipment (e.g., thermometers, 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 (if applicable; required for all studies recruiting human subjects; no page limit): Upload as "Data_Manage.pdf."** The Data Management attachment should include the components listed below.

  a. **Data Management:** 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, local, and federal 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 or diagnostic tests performed as part of the study.

- **Attachment 10: Intervention (if applicable; required for clinical trials; no page limit): Upload as "Intervention.pdf."** The Intervention attachment should include the components listed below.

    a. **Description of the Intervention:** As applicable, the description of the intervention should include the following components: complete name and composition, storage and handling information, source, dose, schedule, administration route, washout period, duration of the intervention, and concomitant medications allowed.

    Summarize key preclinical pharmacological findings, dosage studies, and other clinical studies (if applicable) that examine the safety of the intervention. Description of devices should include detailed operational instructions, any potential risks to users, and intended benefits. Other types of interventions should be fully described.

    b. **Study Procedures:** Describe the interaction with the human subject to include the study intervention that he/she will experience. Provide sufficient detail in chronological order for a person uninvolved in the study to understand what the human subject will experience. Provide a schedule (e.g., flowchart or diagram) of study evaluations and follow-up procedures. Discuss how compliance with Good Clinical Practices, Good Manufacturing Practices, and other regulatory considerations will be established, monitored, and maintained, as applicable.

- **Attachment 11: Collaborating DoD Military Facility 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 Collaborating DoD Military Facility Budget Form (available for download on the eBRAP "Funding Opportunities & Forms" web page), including a budget justification, for each Military Facility as instructed. Refer to the General Application Instructions, Section II.C.8., for detailed information**.**

3. **Research & Related Senior/Key Person Profile (Expanded):** Refer to the General Application Instructions, Section II.C.4., 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 (https://ebrap.org/eBRAP/public/Program.htm) in eBRAP. The five-page National Institutes of Health Biographical Sketch may also be used.

- 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."

4. **Research & Related Budget:** Refer to the General Application Instructions, Section II.C.5., 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.

- Applications with Partnering PI Option: Initiating and Partnering PIs must each submit a budget and justification specific to their own portion of the efforts as part of their separate Grants.gov application packages. The Research & Related Budget for the Initiating PI should not include budget information for Partnering PI(s), even if they are located within the same organization. The anticipated combined direct costs budgeted for the entire period of performance for the Initiating PI and the Partnering PI(s) applications will not exceed **$1.5M (applied research) and $3M (clinical trials)**.

5. **Project/Performance Site Location(s) Form:** Refer to the General Application Instructions, Section II.C.6., for detailed information.

6. **R & R Subaward Budget Attachment(s) Form (if applicable):** Refer to the General Application Instructions, Section II.C.7., for detailed information.

Application Components for the Partnering PI(s):

Each Partnering PI MUST follow the link in the email from eBRAP and complete the registration process prior to the application submission deadline in order to associate his/her Grants.gov application package with that of the Initiating PI.

The application submission process for Partnering PI(s) uses an abbreviated Grants.gov application package that includes:

1. **SF-424 (R&R) Application for Federal Assistance Form**

2. **Attachments Form**
   - **Attachment 5: Statement of Work (SOW) (three-page limit):** Upload as "SOW.pdf." Refer to the General Application Instructions, Section II.C.3., for detailed information on completing the SOW. *Each PI must submit an identical copy of a jointly created SOW. The contributions of the Initiating PI and Partnering PI(s) should be noted for each task.*

3. **Research & Related Budget:** Refer to the General Application Instructions, Section II.C.5., for detailed information.

- Budget Justification (no page limit): Upload as "BudgetJustification.pdf."

- Initiating and Partnering PIs must each submit a budget and justification specific to their own portion of the efforts as part of their separate Grants.gov application packages. The Research & Related Budget for the Partnering PI(s) should not include budget information for the Initiating PI, even if they are at the same organization. The anticipated combined direct costs budgeted for the entire period of performance for the Initiating PI and the Partnering PI(s) applications will not exceed **$1.5M (applied research) and $3M (clinical trials)**.

4. **Project/Performance Site Location(s) Form:** Refer to the General Application Instructions, Section II.C.6., for detailed information.

5. **R & R Subaward Budget Attachment(s) Form (if applicable**): Refer to the General Application Instructions, Section II.C.7., for detailed information.

D. Applicant Verification of Grants.gov 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 an application submitted to Grants.gov. Following retrieval and processing of the Grants.gov application, eBRAP will notify the organizational representatives and PI by email to log into eBRAP to review, modify, and verify the Grants.gov 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, an updated Grants.gov application package must be submitted via Grants.gov as a "Changed/Corrected Application" with the previous Grants.gov Tracking ID prior to the application submission deadline.*** The Project Narrative and Budget Form cannot be changed after the application submission deadline.

E. Submission Dates and Times

All submission dates and times are indicated on the title page of this Program Announcement/ Funding Opportunity. Pre-application and application submissions are required. Failure to meet either of these deadlines will result in application rejection.

F. Other Submission Requirements

Refer to the General Application Instructions, Appendix 2, for detailed formatting guidelines.

All applications must be submitted through Grants.gov. 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. Refer to the General Application Instructions, Section II.A., for information on Grants.gov registration requirements.

III. APPLICATION REVIEW INFORMATION

A. Application Review and Selection Process

All applications are evaluated by scientists, clinicians, and consumer advocates using a two-tier review process. The first tier is peer review of applications against established criteria for determining technical merit. The second tier is a programmatic review that makes recommendations for funding to the DHA RDA Directorate and OASD(HA) based on (a) technical merit and (b) the relevance to the mission of the DHP and JPC-5/MOMRP and to the specific intent of the award mechanism. The highest-scoring applications from the first tier of review are not automatically recommended for funding. Additional information about the twotier 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 merit-based selection process. Panel members sign a nondisclosure 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 Title 18 United States Code 1905.

B. Application Review Process

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

    - **Impact and Military Benefit**
        - Whether the proposed study addresses at least one of the FY15 PH/TBI CUP/HPI Topic Areas and how well it aligns with the Research Objectives.
        - The potential unique contribution of the proposed study to psychological health research and/or clinical care as related to at least one of the FY15 PH/TBI CUP/HPI Topic Areas.
        - The potential immediate or long-term benefit and usability of the proposed research on the psychological health and well-being of Service members, their families, and/or communities.

    - **Research Strategy and Feasibility**
        - How well the preliminary data and scientific rationale supports the research project.

- How well the hypotheses or objectives, aims, experimental design, methods, and analyses are developed and integrated into the project and how well they address the need(s) described.
- How consistent the methods and procedures are with sound research design.
- How well the PI acknowledges potential problems and addresses alternative approaches.
- How well the PI has outlined a plan for management and sharing of research data as appropriate for the type of study.

For clinical trials and applied research involving human subjects:

- How well the PI describes the population(s) of interest, demonstrates access to these populations, has a viable plan for recruitment, consent, screening, and retention of appropriate subjects, and identifies sampling methods to gain a representative sample from the population(s) of interest.
- How well plans for addressing ethical and regulatory considerations have been developed, including mitigation of risk, consideration of privacy issues, and process for obtaining informed consent.
- If applicable, whether there is evidence demonstrating availability of the device/intervention from its source for the duration of the proposed 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 adequate for the study and all proposed correlative studies.

- **Personnel**
  - How the background and expertise of the PI(s) and other key personnel demonstrate their ability to perform the proposed research or clinical trial.
  - Whether the composition of the research or study team (e.g., study coordinator, statistician) is appropriate.
  - How the levels of effort by the PI(s) and other key personnel are appropriate to ensure success of this project.

- **Transition Plan**
  - Whether the funding strategy described to bring the outcome(s) to the next level of development and/or delivery to the military or civilian market is appropriate.
  - Whether appropriate collaborations and other resources for providing continuity of development are established and/or well described.
  - Whether the schedule and milestones for bringing the outcome(s) to the next level of development are appropriate and feasible.

- How well the potential risk analysis for cost, schedule, manufacturability, and sustainability is developed.
- 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 to products supported by this Program Announcement/Funding Opportunity.

- **Environment**
  - How the scientific environment is appropriate for the proposed research or clinical trial.
  - How the research or trial 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.

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

- **Budget**
  - Whether the budget is appropriate for the proposed research and within the limitations of this Program Announcement/Funding Opportunity.

- **Application Presentation**
  - To what extent the writing, clarity, and presentation of the application components influence the review.

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

   a. **Ratings and evaluations of the peer reviewers**

   b. **Relevance to the mission of the DHP, JPC-5/MOMRP and FY15 PH/TBI CUP/HPI, as evidenced by the following:**
   - Adherence to the intent of the award mechanism
   - Program portfolio composition
   - Military and programmatic relevance
   - Relative impact
   - Relative feasibility of transition plan

C. Recipient Qualification

For general information on required qualifications for award recipients, refer to the General Application Instructions, Appendix 1.

D. Application Review Dates

All application review dates and times are indicated on the title page of this Program Announcement/Funding Opportunity.

E. Notification of Application Review Results

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.

IV. ADMINISTRATIVE ACTIONS

After receipt of pre-applications from eBRAP or applications from Grants.gov, the following administrative actions may occur:

A. Rejection

The following will result in administrative rejection of the pre-application:

- Preproposal Narrative exceeds page limit.
- Preproposal Narrative is missing.

The following will result in administrative rejection of the application:

- Submission of an application for which a letter of invitation was not received.
- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.
- Submission of the same research project to different Funding Opportunities within the same program and fiscal year.
- Partnering PI Option: All associated (Initiating and Partnering PI(s)) applications are not submitted by the deadline

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.

C.   Withdrawal

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

- An FY15 PH/TBIRP CUP/HPI Programmatic Review 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 FY15 PH/TBIRP CUP/HPI Programmatic Review Panel members can be found at http://cdmrp.army.mil/phtbi/panels/panels15_cup**

- 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).

- Inclusion of any employee of CDMRP review contractors in applications for funding without adequate plans to mitigate conflicts of interest. Refer to the General Application Instructions, Section II.B., 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.

- The invited application does not propose the same research project described in the pre-application.

- The proposed research is not relevant to any of the FY15 PH/TBI CUP/HPI Topic Areas listed in Section I.E.

D.   Withhold

Applications that appear to involve research misconduct will be administratively withheld from further consideration pending institutional investigation. The institution 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.

V.   AWARD ADMINISTRATION INFORMATION

A.   Award Notice

Awards will be made no later than September 30, 2016. Refer to the General Application Instructions, Appendix 3, for additional award administration information.

Any assistance instrument awarded under this Program Announcement/Funding Opportunity will be governed by the award terms and conditions, which conform to DoD's implementation of the Office of Management and Budget (OMB) circulars applicable to financial assistance. Terms

and conditions of new awards made after December 26, 2014 may include revisions to reflect DoD implementation of new OMB guidance in the Code of Federal Regulations, Title 2, Part 200, "Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards" (2 CFR part 200).

B.   Administrative Requirements

Refer to the General Application Instructions, Appendix 3 for general information regarding administrative requirements.

C.   National Policy Requirements

Refer to the General Application Instructions, Appendix 4 for general information regarding national policy requirements.

D.   Reporting

Refer to the General Application Instructions, Appendix 3, Section I, for general information on reporting requirements.

Quarterly technical progress reports and quad charts will be required.

In addition to written progress reports, in-person presentations may be requested.

E.   Award Transfers

The institution 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.

Refer to the General Application Instructions, Appendix 3, Section M, for general information on organization or PI changes.

VI. AGENCY CONTACTS

A. CDMRP Help Desk

Questions related to Program Announcement/Funding Opportunity content or submission requirements as well as questions related to the submission of the pre-application 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: help@eBRAP.org

B. Grants.gov Contact Center

Questions related to 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

    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.

VII. APPLICATION SUBMISSION CHECKLIST

Grants.gov Application Components	Upload Order	Action	Initiating PI Completed	Partnering PI Completed
SF-424 (R&R) Application for Federal Assistance		Complete form as instructed.		
Attachments Form	1	Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf.".		
	2	Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf."		
	3	Technical Abstract: Upload as Attachment 3 with file name "TechAbs.pdf."		
	4	Lay Abstract: Upload as Attachment 4 with file name "LayAbs.pdf."		
	5	Statement of Work: Upload as Attachment 5 with file name "SOW.pdf."		
	6	Impact and Military Benefit Statement: Upload as Attachment 6 with file name "MilBen.pdf."		
	7	Transition Plan: Upload as Attachment 7 with file name "Transition.pdf."		
	8	Human Subject Recruitment and Safety Procedures: Upload as Attachment 8 with file name "HumSubProc.pdf."		
	9	Data Management: Upload as Attachment 9 with file name "Date_Manage.pdf."		
	10	Intervention: Upload as Attachment 10 with file name "Invervention.pdf."		
	11	Collaborating DoD Military Facility Budget Form(s): Upload as Attachment 11 with file name "MFBudget.pdf," if applicable.		
Research & Related Senior/Key Person Profile (Expanded)		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.		
Research & Related Budget		Complete form as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field.		
Project/Performance Site Location(s) Form		Complete form as instructed.		
R & R Subaward Budget Attachment(s) Form		Complete form as instructed.		