

# Program Announcement

for the

Defense Health Program

Defense Medical Research and Development Program

Department of Defense

Military Operational Medicine Research Program/Joint Program Committee 5

## Psychological Health/Traumatic Brain Injury Research Program

### Psychological Health Research Award

Funding Opportunity Number: W81XWH-14-PHTBI-PHRA

Catalog of Federal Domestic Assistance Number: 12.420

#### SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application Deadline:** 5:00 p.m. Eastern time (ET), September 4, 2014
- **Invitation to Submit an Application:** October 2, 2014
- **Application Submission Deadline:** 11:59 p.m. ET, November 13, 2014
- **End of Application Verification Period:** 5:00 p.m. ET, November 18, 2014
- **Peer Review:** January 2015
- **Programmatic Review:** March 2015

***Change for Fiscal Year 2014:*** 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.***

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## **I. FUNDING OPPORTUNITY DESCRIPTION**

### **A. Program Description**

Applications to the Fiscal Year 2014 (FY14) Defense Medical Research and Development Program (DMRDP) are being solicited for the Assistant Secretary of Defense for Health Affairs, Defense Health Program (DHP), by the U.S. Army Medical Research Acquisition Activity (USAMRAA). The executing agent for this Program Announcement/Funding Opportunity is the Congressionally Directed Medical Research Programs (CDMRP).

The goal of the DMRDP is to advance the state of medical science in those areas of most pressing need and relevance to today's battlefield experience. The objectives of the DMRDP are to discover and explore innovative approaches to protect, support, and advance the health and welfare of military personnel, families, communities, and the general public; to accelerate the transition of medical technologies into deployed products; and to accelerate the translation of advances in knowledge into new standards of care for injury prevention, treatment of casualties, rehabilitation, and training systems that can be applied in theater or in the clinical facilities of the Military Health System. Applications from investigators within the military services are highly encouraged, as are applications involving multidisciplinary collaborations among academia, industry, the military services, the Department of Veterans Affairs (VA), and other Federal Government agencies.

The Military Operational Medicine Research Program (MOMRP) is one of six major program areas within the DMRDP. The MOMRP is administered with oversight from Joint Program Committee 5 (JPC-5), which consists of Department of Defense (DoD) and non-DoD medical and military technical experts relevant to the program area. 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. MOMRP psychological health and resilience research is focused on prevention, treatment, and recovery of Soldiers' and Families' behavioral health which is critical to force health and readiness.

### **B. Award Information**

The FY14 MOMRP Psychological Health and Traumatic Brain Injury (PH/TBI) Psychological Health Research Award (PHRA) is intended to support both applied (preclinical) 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 below should *not* be submitted in response to this Program Announcement.

Applied research is defined as work that refines concepts and ideas into potential solutions with a view towards 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.

To meet the intent of the FY14 MOMRP PH/TBI PHRA mechanism, all applications *must* specifically address one or more of the Topic Areas listed below.

- **Military-related grief, guilt, or loss issues, moral injury, and/or anger, rage or aggression issues.**
  - Efficacy of evidence-based civilian interventions and translation to a military application to address military-related Service Member and/or family grief, guilt, and loss issues, moral injury, and/or anger/aggression issues.
  - Of particular interest are universal and selective interventions that are aimed at equipping leaders, units, Service Members and/or Families with skills to handle situations that may invoke grief, guilt or anger and prevent the development of a negative trajectory.
- **Interdisciplinary and comprehensive prevention and life-skills training strategies to improve brain health.**
  - Efficacy of cognitive training approaches to promote resilience and prevent/mitigate acute negative responses to psychological and physical trauma (this does not include treatment interventions for chronic symptoms).
  - Efficacy of a life-skills (e.g., communication, interpersonal, problem solving, reframing) universal training approach that emphasizes transferability of skills to improve brain health and promoting resilience in Service Members and Families and reduce negative behavioral health outcomes.
- **Military-related psychosocial/psychological health challenges unique to persons of non-traditional sexual orientation [i.e., lesbian, gay, bisexual, and transgender (LGBT)].**
  - Research to determine support needs during transition periods/deployment as well as inclusion and isolation issues with the goal of developing interventions targeting these factors.
  - Prevention approaches aimed at addressing unique needs related to psychological health issues (e.g., sexual harassment/assault, suicide).
- **Sexual assault and trauma related issues in a military context.**
  - Integration of the use of technology and telemedicine assessment, prevention, and treatment approaches to address psychological symptoms or sequelae associated with sexual assault.
  - Research to determine the factors related to positive and negative psychological outcomes/trajectories of sexual assault survivors with the goal of developing interventions targeting these factors.
  - Research on potential gender differences in mental health and sexual assault/harassment victim response (treatment, support), preferences, expectations, treatment efficacy and factors associated with patient/victim satisfaction, experience and outcomes.
  - Efficacy of prevention programs and initiatives to decrease incidence of sexual assault and harassment.

**Partnering PI Option:** The FY14 MOMRP PH/TBI PHRA mechanism 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.

If the proposed study involves the use of a drug or biologic that has not been approved by the Food and Drug Administration (FDA) for the proposed investigational use, evidence that an Investigational New Drug (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 Investigational Device Exemption (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 DoD award date or if the documented status of the IND or IDE has not been obtained within 6 months of the award date.

**Use of Human Anatomical Substances and Human Subjects:** All Department of Defense (DoD)-funded research involving new and ongoing research with human anatomical substances and human subjects must be reviewed and approved by the U.S. Army Medical Research and Materiel Command (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. In addition to time for local IRB approval(s), allow a minimum of 2 to 3 months for HRPO regulatory review and approval processes. Refer to the General Application Instructions, Appendix 6, for additional information.

**Multi-Institutional Research:** Multi-institutional research projects are encouraged when combining the resources of two or more organizations will strengthen the research application. If the proposed research is multi-institutional, plans for communication and data transfer between the collaborating institutions, as well as how data, specimens, and/or imaging products obtained during the study will be handled, must be included in the Project Narrative. A separate intellectual and material property plan agreed upon by all participating institutions is also required for multi-institutional research. Participating institutions must be willing to resolve potential intellectual and material property issues and to remove any barriers that may interfere with achieving high levels of cooperation to ensure successful completion of this award.

**DoD Collaboration and Alignment Encouraged:** Relevance to the health care needs of the Armed Forces, their Family members, and/or the U.S. Veteran population is a key feature of this award. Therefore, PIs are strongly encouraged to collaborate, integrate, and/or align their research projects with military and/or VA research laboratories and programs. The following websites may be useful in identifying information about ongoing DoD areas of research interest:

Air Force Research Laboratory <a href="http://www.wpafb.af.mil/afrl">http://www.wpafb.af.mil/afrl</a>	Navy and Marine Corps Public Health Center <a href="http://www.nmcphc.med.navy.mil/">http://www.nmcphc.med.navy.mil/</a>
Center for Deployment Psychology <a href="http://www.deploymentpsych.org/">http://www.deploymentpsych.org/</a>	Office of Naval Research <a href="http://www.onr.navy.mil/">http://www.onr.navy.mil/</a>
Center for the Study of Traumatic Stress <a href="http://www.cstsonline.org/">http://www.cstsonline.org/</a>	Office of the Under Secretary of Defense for Acquisition, Technology and Logistics <a href="http://www.acq.osd.mil/">http://www.acq.osd.mil/</a>
Congressionally Directed Medical Research Programs <a href="http://cdmrp.army.mil">http://cdmrp.army.mil</a>	U.S. Army Medical Research and Materiel Command <a href="https://mrmc.amedd.army.mil">https://mrmc.amedd.army.mil</a>
Defense Centers of Excellence for Psychological Health and Traumatic Brain Injury <a href="http://www.dcoe.health.mil">http://www.dcoe.health.mil</a>	U.S. Army Research Laboratory <a href="http://www.arl.army.mil">http://www.arl.army.mil</a>
Defense Technical Information Center <a href="http://www.dtic.mil">http://www.dtic.mil</a>	U.S. Naval Research Laboratory <a href="http://www.nrl.navy.mil/">http://www.nrl.navy.mil/</a>
Defense and Veterans Brain Injury Center <a href="http://www.dvbic.org/">http://www.dvbic.org/</a>	Defense Advanced Research Projects Agency: <a href="http://www.darpa.mil/default.aspx">http://www.darpa.mil/default.aspx</a>
Deployment Health Clinical Center <a href="http://www.pdhealth.mil/">http://www.pdhealth.mil/</a>	U.S. Army Medical Research Acquisition Activity <a href="https://www.usamraa.army.mil/">https://www.usamraa.army.mil/</a>
National Center for Telehealth and Technology <a href="http://www.t2health.org/">http://www.t2health.org/</a>	U.S. Department of Veterans Affairs, Office of Research and Development <a href="http://www.research.va.gov/">http://www.research.va.gov/</a>
Military Operational Medicine Research Program <a href="https://momrp.amedd.army.mil">https://momrp.amedd.army.mil</a>	U.S. Department of Defense Blast Injury Research Program <a href="https://blastinjuryresearch.amedd.army.mil">https://blastinjuryresearch.amedd.army.mil</a>
Naval Health Research Center <a href="http://www.med.navy.mil/sites/nhrc/Pages/default.aspx">http://www.med.navy.mil/sites/nhrc/Pages/default.aspx</a>	

**Use of Military and VA Populations or Resources:** If the proposed research involves access to military and/or VA population(s) and/or resource(s), the PI is responsible for establishing access. If possible, access to target military and/or VA patient 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 military Service Members, Veterans, military and/or VA-controlled study materials, and military and/or VA databases. Use Attachment 2 to provide this documentation (see Section II.C., Application Submission Content and Form, Supporting Documentation).

***MOMRP and CDMRP intend that 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 4, Section L.***

### C. Eligibility Information

- Independent investigators at all academic levels (or equivalent).
- Cost sharing/matching is not an eligibility requirement.
- Eligible investigators must apply through an organization. Organizations eligible to apply include national, international, for-profit, non-profit, public, and private organizations.
- Refer to the General Application Instructions, Appendix 1, for general eligibility information.

### D. Funding

#### *For applied research applications:*

- The maximum period of performance is **3** years.
- The maximum allowable direct costs for the entire period of performance are **\$1.5 million (M)**.
- 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.
- Regardless of the period of performance proposed, the applicant may not exceed the maximum allowable direct costs. Indirect costs shall be proposed in accordance with the organization's negotiated rate agreement.

#### *For clinical trial applications:*

- The maximum period of performance is **4** years.
- The maximum allowable direct costs for the entire period of performance are **\$3M**.
- 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 **4** years.
- Regardless of the period of performance proposed, the applicant may not exceed the maximum allowable direct costs. Indirect costs shall be proposed in accordance with the organization's negotiated rate agreement.

#### *Applications with the Partnering PI Option:*

- 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.4., 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.4. of the General Application Instructions.***

For this award mechanism, direct costs:

Must be requested for:

- Travel costs for the PI(s) to attend one program review per year during the award period of performance. For planning purposes, it may be assumed that these program reviews will be held in the National Capital Region for approximately two days.

May be requested for (not all-inclusive):

- Salary
- Research supplies
- Research-related subject costs
- Clinical research costs
- Support for multidisciplinary collaborations
- Travel between collaborating organizations
- Travel costs of up to \$1,800 per year 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 Appendix 3 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 will be executed through 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.4. Research & Related Budget, for additional information on budget considerations for applications involving federal agencies.

***The MOMRP expects to allot approximately \$15M of the FY14 PH/TBIRP and FY15 DMRDP appropriations to fund approximately 4-5 Psychological Health 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. 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/>).

**New for FY14: The CDMRP has replaced its eReceipt System with eBRAP.** Submission remains a two-step process requiring both pre-application and application submission.

PIs must be registered in eBRAP in order to submit a pre-application and receive notification of the status of a pre-application or application. A key feature of eBRAP is that an organization's representatives and PIs are able to view and modify the Grants.gov application submissions associated with them, but only if the organization, Business Officials, and PIs are registered and affiliated with the organization in eBRAP (see *eBRAP User Guide* at <https://ebrap.org/eBRAP/public/UserGuide.pdf>). Upon completion of an organization's registration in eBRAP and approval by the CDMRP Help Desk, the organization name will be displayed in eBRAP to assist the organization's business officials and PIs as they register.

**Note:** Submission of either the pre-application to eBRAP or application to Grants.gov does not require registering an organization and affiliating its Business Officials and PIs in eBRAP; however, the ability to view and modify the Grants.gov application in eBRAP is contingent upon the registration and affiliation. ***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.*** If verification is not completed by the end of the application verification period, the application will be reviewed as submitted through Grants.gov, provided there is no cause for administrative rejection of the application (see [Section IV.A., Rejection](#)).

The FY14 MOMRP PH/TBI PHRA mechanism is structured to accommodate up to a maximum of four PIs. One Partner 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 grant application package with that of the Initiating PI. If an application is invited, only the Initiating PI will receive notification of invitation via email from CDMRP.

Submission of applications that are essentially identical or propose essentially the same research project to different funding opportunities within the same program and fiscal year is prohibited and will result in administrative withdrawal of the duplicative application.

#### **A. Where to Obtain the Application Package**

To obtain the complete application package, including all required forms, perform a Grants.gov (<http://www.grants.gov/>) basic search using the Funding Opportunity Number: W81XWH-14-PHTBI-PHRA.

#### **B. Pre-Application Submission and Content Form**

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](mailto: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**
  - It is recommended that PIs identify an Alternate Submitter in the event that assistance with pre-application submission is needed.
  - The Business Official's contact information or an invitation to a Business Official to register in eBRAP is required.
- **Collaborators and Conflicts of Interest (COI) – Tab 3**

FY14 PH/TBI PHRA Working Group members should not be involved in any pre-application or application. For questions related to FY14 PH/TBI PHRA Working Group members and pre-applications or applications, refer to Section IV.C., Withdrawal, or contact the CDMRP Help Desk at [help@eBRAP.org](mailto:help@eBRAP.org) or 301-682-5507.

**Partnering PI Option:** The Initiating PI must enter the contact information for each Partnering PI in the Partnering PI section.

- **Required Files – Tab 4**

**Notes:** *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 FY14 MOMRP PH/TBI PHRA 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, Veterans, 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 Preproposal Narrative.
- **Key Personnel Biographical Sketches (four-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 5**

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 MOMRP, pre-applications will be screened based on the following criteria:

- **Alignment with Topic Areas:** How well the project addresses at least one of the FY14 MOMRP PH/TBI PHRA 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. How the endpoints are appropriate for the proposed study. Whether the proposed methodology is appropriate.
- **Personnel:** How 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 and Veterans 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. Application Submission Content and Forms**

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

Each application submission must include the completed application package of forms and attachments provided in Grants.gov for this Program Announcement/Funding Opportunity. The application package is submitted by the Authorized Organizational Representative through the Grants.gov portal (<http://www.grants.gov/>).

***New for FY14: Applications submitted through and validated by Grants.gov will be retrieved and processed by eBRAP to allow for review, modification, and verification.*** The PI and organizational representatives will receive an email request from eBRAP to review, modify, and verify the application submitted to Grants.gov. During this verification period, the PI may

upload missing files (excluding those listed in [Section IV.A., Rejection](#)), replace files, and re-categorize files. These modifications must be completed by the end of the verification period.

**Note:** *Changes to either the Project Narrative or Budget are not allowed in eBRAP*; if such changes are required, the entire application package must be submitted through Grants.gov as a “Changed/Corrected Application” with the Previous Grants.gov Tracking ID *prior to the application submission deadline (which occurs earlier than the end of the application verification period)*.

**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 Single PIs or Initiating PI under the Partnering PI Option:**

**Grants.gov application package components:** For the Psychological Health Research 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**

- **Attachment 1: Project Narrative (20-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 will 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 FY 14 MOMRP PH/TBI PHRA Topic Areas and explain the applicability of the proposed 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 and what will be delivered at the end of the project.

#### ***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 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 not reimbursed by 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. The use of the Clinician Administered PTSD Scale (CAPS) and/or the PTSD Checklist – Military Version (PCL-M) (pre- and post-intervention) is specifically required for PTSD interventions.

***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 may result in the removal of those items or 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 (five-document limit): Include relevant publication URLs and/or patent abstracts. If publications are not publicly available, then a copy/copies of the published manuscript(s) must 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 and VA Populations or Resources (if applicable): Provide a letter(s) signed by the lowest ranking person with approval authority for studies involving military Service Members, Veterans, military and/or VA-controlled study materials, and military and/or VA databases.
  - Intellectual Property
    - Background and Proprietary Information: All software and data first produced under the award are subject to a federal purpose license in accordance with applicable DoD Grant and Agreement Regulations (DoDGAR) requirements. 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.
  - 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 4, 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 to the project, the same Quad Chart submitted with the pre-application may be used.
- **Attachment 3: Technical Abstract (one-page limit): Upload as “TechAbs.pdf.”**

Use the outline below. (Proprietary or confidential information should *not* be included.)

- Background: State how the proposed research addresses a FY14 MOMRP PH/TBI PHRA Topic Area. 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, Veterans, and/or their Family members.
- **Attachment 4: Lay Abstract (one-page limit): Upload as “LayAbs.pdf.”**

Lay abstracts should be written using the following outline. (Proprietary or confidential information should *not* be included.)

- Describe the objectives and rationale for the application in a manner that will be readily understood 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 patients 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, Veterans, and/or their Family members.
- **Attachment 5: Statement of Work (SOW) (three-page limit): Upload as “SOW.pdf.” Refer to the General Application Instructions, Section II.C.2., for detailed guidance on creating the SOW.**

The suggested SOW format and examples specific to different types of research projects are available on the eBRAP “Program Announcement and Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>). The SOW must be in PDF format prior to attaching. For the PHRA mechanism, use the SOW format example titled “SOW Generic Format” or “SOW for Clinical Research”, as applicable. The SOW must be in PDF format prior to attaching.

*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: 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 and Veterans 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 and/or Veterans, if appropriate and available. Show how the proposed study complements ongoing DoD and VA areas of research interest.
  - If Active Duty Military and/or Veteran population(s) 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 the targeted population (i.e., Service Members or Veterans).
- **Attachment 7: Impact Statement (one-page limit):** Upload as “Impact.pdf.”
  - State explicitly how the proposed work will have an impact on the prevention and/or treatment of Military-relevant psychological health issues. Describe how the proposed work is responsive to the health care needs of Service Members, Veterans, Families, caregivers and/or communities.

***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 personnel 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 8: 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, including proposed development or modification of clinical practice guidelines and a plan for dissemination of practitioner and patient educational tools.
    - 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 9: IND/IDE Documentation (if applicable):** If submitting multiple documents, start each document on a new page. Combine and upload as a single file named “IND-IDE.pdf.”
    - Complete the IND/IDE Documentation Form, which is available for download on the Full Announcement page for this Program Announcement/Funding Opportunity on Grants.gov.
    - If an IND or IDE has been submitted, an explanation of the status of the IND or IDE should be provided (e.g., past the critical 30-day period, pending response to questions raised by the Agency, on clinical hold). Inclusion of a copy of the Agency meeting minutes is encouraged but not required. If the IND or IDE application is not yet submitted, provide evidence that an IND or IDE will be submitted within 60 days of award. Examples include a pre-IND or pre-IDE

meeting with the FDA, a pre-IND/pre-IDE meeting request to the FDA, or other communication with the FDA. Provide the anticipated date of IND/IDE submission. If an IND or IDE is not required for the proposed study, provide evidence in the form of communication from the FDA or the IRB of record to that effect.

- **Attachment 10: 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 11: 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 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 or diagnostic tests performed as part of the study.

**b. Laboratory Evaluations:**

- **Specimens to be collected, schedule, and amount.** All specimens that will be collected for study purposes must be clearly stated. The collection schedule and amount of material collected must also be clearly described.
- **Evaluations to be made.** Describe all evaluations that will be made for study purposes. Explain how the results of laboratory evaluations will be used to meet the objectives of the study (or to monitor safety of human subjects).
- **Storage.** Describe specimen storage, to include location of storage, how long specimens will be stored, any special conditions required, labeling, and disposition. Outline the plan to store specimens for future use to include considerations for informed consent and providing human subjects with an opportunity to decline participation in the study.
- **Labs performing evaluations and special precautions.** Identify the laboratory performing each evaluation, as well as any special precautions that should be taken in handling the samples. Special precautions that should be taken by the human subject before, during, or after the laboratory procedure should be clearly defined. If transport of samples is required, describe provisions for ensuring proper storage during transport.
- **Attachment 12: 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.
- 3. Research & Related Senior/Key Person Profile (Expanded):** Refer to the General Application Instructions, Section II.C.3., for detailed information.
- PI Biographical Sketch (four-page limit): Upload as “Biosketch\_LastName.pdf.”
  - PI Previous/Current/Pending Support (no page limit): Upload as “Support\_LastName.pdf.”
  - Key Personnel Biographical Sketches (four-page limit each): Upload as “Biosketch\_LastName.pdf.”
    - Include biographical sketches for both the Initiating and Partnering PI(s).
  - Key Personnel Previous/Current/Pending Support (no page limit): Upload as “Support\_LastName.pdf.”
    - Include previous/current/pending support for both the Initiating and Partnering PI(s).
- 4. Research & Related Budget:** Refer to the General Application Instructions, Section II.C.4., for detailed information.
- Budget Justification (no page limit): Upload as “BudgetJustification.pdf.”
- Applications with the 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 combined direct costs for the Initiating and Partnering PI(s) budgets cannot exceed \$1.5M for applied research and \$3M for clinical trials.*
- 5. Project/Performance Site Location(s) Form:** Refer to the General Application Instructions, Section II.C.5., for detailed information.
- 6. R & R Subaward Budget Attachment(s) Form (if applicable):** Refer to the General Application Instructions, Section II.C.6., 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 grant application package with that of the Initiating PI.*

The application submission process for Partnering PI(s) uses an abbreviated application package of forms and attachments from Grants.gov 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.2., 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, 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 combined direct costs for the Initiating and Partnering PIs’ budgets cannot exceed \$1.5M for applied research and \$3M for clinical trials.*

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

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

**D. Verification of Grants.gov Application in eBRAP**

For FY14, a new process has been initiated whereby organizational representatives and PIs can view their applications as submitted through Grants.gov and prior to peer review of the application. This will enable applicants to make modifications prior to scientific and programmatic evaluation of applications, provided the modifications are made by either the end of the application verification period or, for changes to the Project Narrative or Budget, by the application submission deadline.

After application submission to Grants.gov, eBRAP will retrieve and validate the application submission. eBRAP will notify the organizational representatives and PI via email and instruct them to log into eBRAP to review, modify, and verify the application. Files that fail eBRAP validation will be noted in both the email and in the Full Application Files tab. eBRAP does not validate the accuracy or completeness of content in the files. PIs are strongly encouraged to review all application components. If either the Project Narrative or the Budget fail eBRAP validation, an updated Grants.gov application package must be submitted via Grants.gov prior to the application submission deadline, which occurs earlier than the end of the application verification period. *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.*

## **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, Appendix 3, for information on Grants.gov requirements.

## **III. APPLICATION REVIEW INFORMATION**

### **A. Application Review and Selection Process**

All applicants 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 Office of the Assistant Secretary of Defense for Health Affairs, based on (a) technical merit and (b) the relevance to the mission of the DHP, DMRDP, and 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 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 merit-based selection process. Panel members sign a non-disclosure 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**

- How the proposed study addresses at least one of the FY14 MOMRP PH/TBI PHRA Topic Areas.
- The potential unique contribution of the proposed study to psychological health research and/or patient care in at least one of the FY14 MOMRP PH/TBI PHRA 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, Veterans, and/or their Families 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 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 and other key personnel are appropriate to ensure success of this project.
  - How the investigator(s) record(s) of accomplishment demonstrates his/her ability to accomplish the proposed work.
- **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, including proposed development or modification of clinical practice guidelines and a plan for dissemination of practitioner and patient educational tools, are established and/or well described.
  - How 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.
  - How the quality and extent of institutional support are appropriate for the proposed project.
  - If applicable, to what degree the intellectual and material property plan is appropriate.

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, 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, DMRDP, and MOMRP, as evidenced by the following:**
  - Adherence to the intent of the award mechanism
  - Program portfolio balance and composition
  - Military and programmatic relevance
  - Relative impact
  - Relative transition potential

### **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) 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.
- Following application submission to Grants.gov, the PI will receive an email request from eBRAP to review, modify, and verify the application submitted to Grants.gov. During this verification period, the PI may upload missing documents (excluding those listed in [Section IV.A., Rejection](#)), replace files, and re-categorize files. These modifications must be completed by the end of the application verification period; otherwise, the application will be reviewed as submitted.

### C. Withdrawal

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

- A FY14 PH/TBI PHRA Working Group 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 FY14 PH/TBI PHRA Working Group members can be found at <http://cdmrp.army.mil/phtbi/panels/panels14>.

- The application fails to conform to this Program Announcement/Funding Opportunity description to the extent that appropriate review cannot be conducted.
- Direct costs as shown on the Research & Related Budget exceed the maximum allowed by this Program Announcement/Funding Opportunity.
- 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 application does not provide evidence that an IND/IDE has been submitted, or will be submitted within 60 days of the award date, or that the drug/device is exempt from an IND/IDE (if applicable).

#### **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 4, 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 4 for general information regarding administrative requirements.

### **C. National Policy Requirements**

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

### **D. Reporting**

Refer to the General Application Instructions, Appendix 4, Section J, for general information on reporting requirements.

Quarterly technical progress reports and quad charts will be required.

In addition to written progress reports, oral presentations may be requested.

### **E. Award Transfers**

Changes in PI are not allowed, except under extenuating circumstances that will be evaluated on a case-by-case basis and at the discretion of the Grants Officer.

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 4, 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](mailto: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](mailto: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 application package. If the application package is updated or changed, the original version of the application package may not be accepted by Grants.gov.***

## VII. APPLICATION SUBMISSION CHECKLIST

Single PI applicants complete only the “Initiating PI” column:

<b>Grants.gov Application Components</b>	<b>Action</b>	<b>Initiating PI Completed</b>	<b>Partnering PI Completed</b>
SF-424 (R&R) Application for Federal Assistance	Complete form as instructed.		
Attachments Form	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.”		
	Military Benefit Statement: Upload as Attachment 6 with the file name “MilBen.pdf.”		
	Impact Statement: Upload as Attachment 7 with the file name “Impact.pdf.”		
	Transition Plan: Upload as Attachment 8 with the file name “Transition.pdf.”		
	IND/IDE Documentation: Upload as Attachment 9 with the file name “IND-IDE.pdf.” (if applicable)		
	Human Subject Recruitment and Safety Procedures: Upload as Attachment 10 with the file name “HumSubProc.pdf.” (if applicable)		
	Data Management: Upload as Attachment 11 with the file name “Data_Manage.pdf.” (if applicable)		
	Intervention: Upload as Attachment 12 with the file name “Intervention.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.		