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

Cognitive Resilience and Readiness Research Award

Funding Opportunity Number: W81XWH-16- PHTBIRP-CR3A

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

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application Submission Deadline:** 5:00 p.m. Eastern time (ET), June 27, 2016
- **Invitation to Submit an Application:** July 2016
- **Application Submission Deadline:** 11:59 p.m. ET, September 7, 2016
- **End of Application Verification Period:** 5:00 p.m. ET, September 13, 2016
- **Peer Review:** November 2016
- **Programmatic Review:** December 2016 – January 2017

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 3
A. Program Description 3
B. FY16 PH/TBIRP CR3A Topic Areas 4
C. Award Information 5
D. Eligibility Information 7
E. Funding 8
II. Submission Information 9
A. Where to Obtain the Grants.gov Application Package 10
B. Pre-Application Submission Content 10
C. Full Application Submission Content 13
D. Applicant Verification of Grants.gov Submission in eBRAP 26
E. Submission Dates and Times 26
F. Other Submission Requirements 26
III. Application Review Information 26
A. Application Review and Selection Process 26
B. Application Review Process 27
C. Recipient Qualification 30
D. Application Review Dates 30
E. Notification of Application Review Results 31
IV. Administrative Actions 31
A. Rejection 31
B. Modification 31
C. Withdrawal 31
D. Withhold 32
V. Award Administration Information 32
A. Award Notice 32
B. Administrative Requirements 32
C. National Policy Requirements 33
D. Reporting 33
E. Award Transfers 33
VI. Version Codes and Agency Contacts 33
A. Program Announcement/Funding Opportunity and General Application Instructions Version 33
B. CDMRP Help Desk 33
C. Grants.gov Contact Center 34
VII. Application Submission Checklist 35

I. FUNDING OPPORTUNITY DESCRIPTION

A. Program Description

Applications to the Fiscal Year 2016 (FY16) 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 the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriation. The U.S. Army Medical Research and Materiel Command (USAMRMC) Congressionally Directed Medical Research Programs (CDMRP) provides PH/TBIRP management support 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 by the CDMRP with strategic oversight from JPC-5/MOMRP.

The PH/TBIRP was established by Congress in FY07 in response to the devastating impact of traumatic brain injury (TBI) and psychological health (PH) issues, including post-traumatic stress disorder (PTSD), on our deployed Service members in Iraq and Afghanistan. The PH/TBIRP mission is to establish, fund, and integrate both individual and multiagency research efforts that will lead to improved prevention, detection, and treatment of PH issues and TBI. The vision of the PH/TBIRP is to prevent, mitigate, and treat the effects of traumatic stress and TBI on function, wellness, and overall quality of life for 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 six major research program areas within the DHA RDA Directorate. DHP RDT&E research funding is administered through JPC-5/MOMRP with oversight from JPC-5, which consists of Department of Defense (DoD) and non-DoD medical and military technical experts whose knowledge is relevant to the program area. The JPC-5/MOMRP manages an extensive portfolio of research aimed at developing effective countermeasures against training and operational stressors to maximize health, performance, and well-being of Service members and their families throughout the deployment and military life cycle. The JPC-5/MOMRP health research includes maximizing the cognitive well-being of Service members, which is critical to force health, performance, and readiness.

Cognitive resilience is a critical facet of overall Service member resilience, specifically described as "the capacity to overcome the negative effects of setbacks and associated stress on cognitive function or performance."[1] As an extension, cognitive readiness can be described as the ability of a Service member to maintain the cognitive resilience necessary to perform prescribed duties in training and operational settings. This involves a number of factors, including, psychological/cognitive aptitude, physical fitness, as well as social interactions. The

[1] Bolton AE, Yaroush RA, Staal MA, and Bourne LE Jr. 2008. Cognitive performance and resilience to stress. In: *Biobehavioral Resilience to Stress* (Tepe V and Lukey BJ, Eds.). CRC Press, Boca Raton 259–299.

deployment of personnel in varied operational settings requires individuals to possess cognitive tools and skills allowing them to remain agile and adaptive in complex environments across the range of military operations. Therefore, biomedical research to support cognitive resilience and readiness is necessary for success on the battlefield of tomorrow due to the ever-increasing cognitive demands placed on Service members. For these reasons, tools and strategies contributing to cognitive resilience and readiness are of great interest as they would confer robustness and adaptability to Service member function. A greater understanding of the biological/biomedical basis and mechanisms of cognitive resilience and cognitive readiness in individuals is critical for the prevention of performance decrements and psychological injury. Translating and optimizing individualized cognitive resilience strategies into military operational impact will lead to improvements in cognitive readiness. Cognitive readiness, in turn, will contribute to long term improvements in the health of the force.

B. FY16 PH/TBIRP CR3A Topic Areas

The JPC-5/MOMRP is seeking applications for the FY16 PH/TBIRP Cognitive Resilience and Readiness Research Award (CR3A). The general focus of this Program Announcement/Funding Opportunity is to build and sustain cognitive resilience in Service members and to ensure short- and long-term readiness of the force. The expectations of a successful project will be to demonstrate utility of cognitive resilience tools and promote Service member readiness. These expectations will be met through the discovery and transition/translation of scientific findings for performance sustainment and health protection in training and operational environments. The application must address one or more of the topics below:

- Cognitive resilience: Tools and strategies to confer robustness and adaptability in cognitive performance
    - Cognitive resilience measures to:
        - Determine physiological correlates of cognitive performance
        - Monitor neuropsychological indices of cognitive performance
        - Set and validate standards of cognitive performance and resilience in individuals
    - Technologies and applications to:
        - Sustain robust cognitive function in Service members under acute operational psychological and physiological stressors
        - Promote adaptability to novel demands and improve cognitive function in Service members over the course of a training cycle or career
- Cognitive readiness: Translating cognitive resilience to military operational performance and Service member health
    - Tools and strategies that:
        - Correlate measures of cognitive resilience to Service member health under acute stressors scalable throughout a Service member's deployment and life cycle

        - Support cognitive readiness and sustain military operational performance for a number of skills and contexts under acute stressors and/or throughout a Service member's deployment and life cycle
    - Cognitive readiness measures to:
        - Validate cognitive readiness assessment tools and strategies for relevant military training and/or in operational environments
        - Set and validate standards of cognitive resilience in individuals and small (e.g., operational) groups
    - Cognitive resilience and readiness training program implementation:
        - Development of training exercises to improve and maintain cognitive readiness in training and operational environments

Examples of cognitive resilience tools and strategies may include, but are not limited to: computer- or mobile-based cognitive training platforms, novel cognitive adaptation strategies, and physiological/neuropsychological biomarkers for cognitive performance assessment.

Examples of cognitive readiness translations to support operational performance sustainment and fitness for duty include, but are not limited to: improvement of cognitive processes such as attention, memory, processing speed, mental flexibility, adaptive problem-solving strategies and decision-making, emotional intelligence/quotient (EI/EQ), attention management, etc.

Standardization and validation of performance and health products criteria will provide a biomedical framework to quantify temporal changes in performance due to short- and long-term health effects (e.g., psychological stress over time) and will provide a structure to translate force health protection challenges (e.g., mild TBI, psychological health) into operational impacts on Service member performance and help establish objective return-to-duty criteria following injury.

C. Award Information

The FY16 PH/TBIRP CR3A seeks to support research that will increase our understanding of what and how key scientific and biomedical elements influence and correlate with cognitive skills assessment, enhancement, and training for Service members, and related specialty occupations. This Program Announcement/Funding Opportunity is focused on delivering solutions for Service member performance sustainment and health protection and should demonstrate broader potential public use benefit of the research. Novel approaches which contribute to cognitive resilience and readiness are encouraged. Solutions that can be translated from laboratory environments and integrated into existing military training and practice with minimal disruption (noninvasive) to existing routine operations are encouraged. Both applied (preclinical) research and clinical trials within specific topic areas addressing the prevention of military-relevant psychological health issues and enhancement of operational performance are allowed. Research focused outside of the FY16 CR3A Topic Areas, including studies addressing post-injury diagnosis and treatment, should not be included in the response to this Program Announcement/Funding Opportunity. **Studies involving animal research do not meet the intent of this award mechanism.**

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 in which 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 safety, effectiveness, and/or efficacy. This outcome represents a direct effect on the human subject of that intervention or interaction.

Investigational New Drug/Investigational Device Exemption (IND/IDE): If the proposed study 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 proposed study involves the use of a device that has not been approved by the FDA for the proposed investigational use, 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 or qualifies for an abbreviated 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 IDE has not been obtained within 6 months of the award date.

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 6, 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.

Use of Military and Department of Veterans Affairs (VA) Populations or Resources: If the proposed research involves access to Active Duty military and/or VA population(s) and/or resource(s), the Principal Investigator (PI) is responsible for establishing access. If possible, access to target Active Duty 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 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., Full Application Submission Content, Supporting Documentation).

DoD Collaboration and Alignment Encouraged: Relevance to the healthcare 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. Agencies listed below are potential resources and do not represent an all-inclusive list of work in the target research area.

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

U.S. Army Research Institute
https://sslweb.hqda.pentagon.mil/ari/

U.S. Army Resiliency Directorate
http://www.army.mil/readyandresilient/

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

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

Defense Technical Information Center
http://www.dtic.mil

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

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

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

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

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

U.S. Army Aeromedical Research Laboratory
www.usaarl.army.mil

U.S. Army Center for Environmental Health Research
http://usacehr.amedd.army.mil

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

U.S. Army Research, Development and Engineering Command
www.army.mil/rdecom

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

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

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

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

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

Walter Reed Army Institute of Research
http://wrair-www.army.mil

The CDMRP intends that information, data, and research resources generated under awards funded by this Program Announcement/Funding Opportunity be made available to the research community (which includes both scientific and consumer advocacy communities) and to the public at large. For additional guidance, refer to the General Application Instructions, Appendix 4, Section K.

D. Eligibility Information

- Independent intramural (DoD) and extramural 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 Federal agencies, national, international, for-profit, nonprofit, public, and private organizations.
- 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. Submissions from intramural (DoD) organizations are allowed and encouraged for this Program Announcement/Funding Opportunity. Applicants submitting through their intramural organizations are reminded to coordinate receipt and commitment of funds through their respective resource managers. ***If an investigator at an intramural organization is named as a collaborator on an application submitted through an extramural organization, the application must include a letter from the collaborator's Commander or Commanding Officer at the intramural organization that authorizes the collaborators involvement.***
- Refer to the General Application Instructions, Appendix 1, for general eligibility information.

E. Funding

- The maximum period of performance is **3** years.
- The anticipated total costs budgeted for the entire period of performance will not exceed **$2.5 million (M)**. Indirect costs are to be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the Government exceeding **$2.5M** total 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.

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 disseminate results of the project at one DoD In-progress Review (IPR) meeting per year. For planning purposes, it should be assumed that this will be a two-day meeting 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
- Clinical trial costs
- Equipment
- Research supplies
- Support for multidisciplinary collaborations, including travel
- Travel costs for up to 2 investigators to travel to 1 scientific/technical meeting per year in addition to the required IPR meeting described above.

Shall not be requested for:

- Animal research studies

Awards to extramural organizations will consist solely of assistance agreements (Cooperative Agreements and Grants). Awards to intramural (DoD) agencies and other Federal agencies may be managed through a direct fund transfer (e.g., the Military Interdepartmental Purchase Request [MIPR]; Funding Authorization Document [FAD] process; or DD Form 1144 Support Agreement). Direct transfer of funds from the recipient to a DoD agency is not allowed except under very limited circumstances. Refer to the General Application Instructions, Section II.C.4., for budget regulations and instructions for the Research & Related Budget. ***For Federal agencies or organizations collaborating with Federal agencies, budget restrictions apply as are noted in Section II.C.4. of the General Application Instructions***.

The JPC-5/MOMRP expects to allot approximately $5M of the $125M FY16 PH/TBIRP appropriation to fund approximately 2 CR3A applications, depending on the quality and number of applications received. In addition to the FY16 appropriation, FY17 funds may be allotted to fund one (1) additional award, if FY17 funds become available. As of the release date of the Program Announcement/Funding Opportunity, the FY17 Defense Appropriations Bill has not been passed and there is no guarantee that any additional funds will be made available to support this program. The funding estimated for this Program Announcement/ Funding Opportunity is approximate and subject to realignment. 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.

The pre-application and application submission process should be started early to avoid missing deadlines. There are no grace periods. 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.

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.

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

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.*** Prior to the full application deadline, a corrected or modified full application package may be submitted. Other application components may be changed until the end of the application verification period. After the end of the application verification period, the full application cannot be modified.

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.

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-16-PHTBIRP-CR3A in Grants.gov (http://www.grants.gov/).

B. Pre-Application Submission Content

All pre-application components must be submitted by the 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.

A change in PI or organization after submission of the pre-application may be allowed after review of a submitted written appeal (contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507) and at the discretion of the USAMRAA Grants Officer.

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

- **Tab 1 – Application Information**
- **Tab 2 – Application Contacts**
  - Enter contact information for the PI. Enter the organization's Business Official responsible for sponsored program administration (the "person to be contacted on matters involving this application" in Block 5 of the Grants.gov SF424 (R&R) Form). The Business Official must 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.
- **Tab 3 – Collaborators and Key Personnel**
  - Enter the name, organization, and role of all collaborators and key personnel associated with the application.
  - FY16 PH/TBIRP CR3A Programmatic Panel members should not be involved in any pre-application or full application. For questions related to the FY16 PH/TBIRP CR3A Programmatic 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.
  - To preserve the integrity of its peer and programmatic review processes, the CDMRP discourages inclusion of any employee of its review contractors having any role in application preparation, research, or other duties for submitted applications. For FY16, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (http://cdmrp.army.mil/about/2tierRevProcess). Applications that include names of personnel from either of these companies will be administratively withdrawn unless plans to manage conflicts of interest (COIs) are provided and deemed appropriate by the Government. Refer to the General Application Instructions, Appendix 1, for detailed information.
- **Tab 4 – Conflicts of Interest (COIs)**
  - List all individuals other than collaborators and key personnel who may have a COI in the review of the application (including those with whom the PI has a personal or

professional relationship). Refer to Appendix 1, Section C, of the General Application Instructions for further information regarding COIs.

- **Tab 5 – Pre-Application Files**

  Note: Upload documents 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 (3-page limit): The Preproposal Narrative page limit applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs that provide additional information to expand the 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:** Concisely state the ideas and reasoning on which the proposed work is based. Correlate the study rationale to enhancement of cognitive skills contributing to resilience and performance in high-stress military training and occupational environments.
  - **Hypothesis or Objective:** Clearly describe a research hypothesis or objective to be achieved under the proposed work.
  - **Alignment with Topic Areas:** State how the project addresses at least one of the FY16 CR3A Topic Areas. Describe why the proposed approach is appropriate and important for addressing the identified topic area(s).
  - **Research Strategy**: Describe the proposed approach. Briefly describe how prior work supports the proposed approach, targeted population, and any tools, exercises, measures, strategies, etc., which would be used to address the topic area(s).
  - **Personnel:** Briefly state the qualifications of the PI and key personnel to perform the described research project.
  - **Military Benefit and Impact:** Describe how the proposed work impacts Service member training, performance, and resilience as well as the potential benefit for the general public.

  Pre-Application Supporting Documentation: The items to be included as supporting documentation for the pre-application must be uploaded as individual files 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 (five-page limit per individual). All biographical sketches should be uploaded as a single combined file. Biographical sketches should be used to demonstrate background and expertise through education, positions, publications, and previous work accomplished.
- Quad Chart: Complete and upload the Quad Chart template available from the eBRAP "Funding Opportunities and Forms" web page (https://ebrap.org/eBRAP/public/Program.htm).

- **Tab 6 – Submit Pre-Application**
  - 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:

  - **Rationale:** How well the rationale supports enhancement of cognitive skills contributing to resilience and performance in military training and occupational environments.
  - **Hypothesis or Objective:** How well the research hypothesis or objective is presented.
  - **Topic Areas:** Whether the project addresses at least one of the FY16 CR3A Topic Areas.
  - **Research Strategy:** Whether the proposed approach is supported by prior work and is appropriate in target populations.
  - **Personnel:** How the qualifications of the PI and key personnel are appropriate to achieve the proposed research.
  - **Military Benefit and Impact:** How well the proposed work impacts Service member training, performance, and resilience, and demonstrates potential benefit for the general public.

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

  Following the pre-application screening, 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. Invitations to submit a full application are based on the Pre-Application Screening Criteria as published above.

C. Full Application Submission Content

The application process should be started early on Grants.gov to avoid missing deadlines. There are no grace periods. Verify the status of the applicant's organization's Entity registration in the

SAM well in advance of the application submission deadline. Allow 3 to 4 weeks to complete the entire SAM registration process. Refer to the General Application Instructions, Section II, for additional information.

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

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

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

Each application submission must include the completed Grants.gov application package 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***.

Grants.gov application package components: For the FY16 PH/TBIRP CR3A, 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. **SF424 (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 (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 may result in administrative withdrawal of the application.

Describe the proposed project in detail using the outline below.

- **Background:** State the relevance of the proposed research to at least one of the FY16 PH/TBIRP CR3A 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.
- **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 (including applicable tools and measures), and analyses. Include appropriate controls in sufficient detail for analysis. Address potential problem areas and present alternative methods and approaches. Describe how proposed measures, applications, strategies, or technologies contribute to cognitive resilience and readiness in military settings. Discuss how research specific to military training and/or operational environments are generalizable to the overall military population and the general public. If applicable, detail how the proposed approach would be evaluated in appropriate populations. Address the technical maturity of the proposed approach and how the research strategy advances the knowledge base towards fielding a solution. As applicable to the proposed research, describe in detail the regulatory strategy and plan and demonstrate compliance with Good Manufacturing Practice (GMP), Good Laboratory Practice (GLP), and Good Clinical Practice (GCP), etc.

  For 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 cohort 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 assessment measures, if applicable. Include critical survey questions, if applicable.

- **Statistical Plan and Data Analysis:** Describe the statistical model(s) and data analysis plan with respect to the study objectives and endpoints as appropriate to the type of study. For research involving human subjects, specify the 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 and endpoints of the study.
- **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 in the project. A medical monitor (external to the study) and study coordinator(s) should be included for all clinical trials.

- **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: (1-page limit per letter is recommended): Provide a letter (or letters, if applicable), signed by the Department Chair or appropriate organization official, confirming the laboratory space, equipment, and other resources available for the project. Letters of support not requested in the Program Announcement/Funding Opportunity will be removed.

- Letter(s) of Support for Use of Military and VA Populations or Resources (if applicable, 1-page limit per letter is recommended): If the proposed research plan involves access to active duty military and/or VA patient populations or resources, include a letter(s) of support, signed by the lowest ranking person with approval authority, confirming such access. If access cannot be confirmed at the time of application submission, the Government reserves the right to withhold or revoke funding until the PI has demonstrated support for and access to the relevant population(s) and/or resources.
- Letters of Collaboration (if applicable, 1-page limit per letter is recommended): Provide a signed letter from each collaborating individual or organization that demonstrates that the PI has the support or resources necessary for the proposed work. For applications that include an intramural collaborator, include a letter from the collaborator's Commander or Commanding Officer at the intramural organization that authorizes the collaborator's involvement.
- Intellectual Property
  - Intangible property acquired, created or developed under this award will be subject to all rights and responsibilities established at 2 CFR 200.315. Should the applicant intend to use, in the performance of this program, pre-existing, legally protected and perfected intangible property and for which no Federal funds had been used in the development of said property, the applicant must:
    - Clearly identify all such property;
    - Identify the cost to the Federal government for use or license of such property, if applicable; or
    - Provide a statement that no property meeting this definition will be used on this project.
  - 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 K, 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."** The technical abstract is used by all reviewers. Abstracts of all funded research projects will be posted publicly. ***Do not include proprietary or confidential information.*** Use only characters available on a standard QWERTY

keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

- Background: State how the proposed research addresses at least one of the FY16 PH/TBIRP CR3A Topic Areas. 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 cognitive health and operational readiness of Service members, Veterans, and/or their family members.

- **Attachment 4: Lay Abstract (one-page limit): Upload as "LayAbs.pdf."** The lay abstract is used by all reviewers. Abstracts of all funded research projects will be posted publicly. ***Do not include proprietary or confidential information.*** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.
  - ***Do not duplicate the technical abstract.*** Lay abstracts should be written using the following outline.
  - 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.
  - Describe the ultimate applicability of the research.
    - What populations will it help, and how will it help them? (Include currently available statistics to the related population of concern.)
    - What are the potential clinical applications, benefits, and risks?
    - What is the projected timeline it may take to achieve the expected outcome?
    - What are the likely contributions of this study to improving cognitive functioning and resilience in military populations during military training and/or operational environments?
  - Briefly describe how the proposed project will benefit Service members, Veterans, and/or their family members.

- **Attachment 5: Statement of Work (SOW) (four-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 FY16 PH/TBIRP CR3A mechanism, use the SOW format example titled "SOW for Clinical Research" or "SOW for Advanced Tech Development Research." The SOW must be in PDF format prior to attaching. Refer to the General Application Instructions, Section II.C.2., for detailed guidance on creating the SOW.

- **Attachment 6: Impact and Military Benefit Statement (one page limit): Upload as "MilBen.pdf."**
    - Describe how the proposed study is responsive to the cognitive health needs of Service members in a military training or operational environment. Provide available information about the current skills and training in Service members and/or Veterans, if appropriate and available. Show how the proposed study complements ongoing DoD and VA research, if applicable.
    - 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).
    - State explicitly how the proposed work will have an impact on the cognitive functioning, training, and enhancement of Service members in an operational environment. Describe how the proposed work is responsive to the healthcare needs of Service members, Veterans, families, caregivers, and/or communities. State how the proposed work may be applicable to and beneficial to the general public.

    For studies including a clinical trial:

    - 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 define the intended 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 anticipated research outcomes to the next phase of research or delivery to the military practice 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 of development (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, such as proposed development or modification of clinical practice guidelines and a plan for dissemination of practitioner and patient educational tools.
- A description of continued efforts required to validate any newly developed or non-standard utilization of assessment measures, tools, and technologies.
- 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 research. Inclusion/exclusion criteria should take into consideration the specific risk profile of the studies to be conducted and the standard of care for that patient population. Provide detailed justification for exclusions.

  Inclusion of Women and Minorities in Study. Consistent with the Belmont Report, "Ethical Principles and Guidelines for the Protection of Human Subjects," and Congressional legislation, special attention is given to inclusion of women and/or minorities in studies funded or supported by the USAMRMC. This policy is intended to promote equity both in assuming the burdens and in receiving the benefits of human subjects research. Include an appropriate justification if women and/or minorities will be excluded from the clinical research/trial.

  c. Description of the Recruitment Process: Explain methods for identification of potential human subjects (e.g., medical record review, obtaining sampling lists, and healthcare provider identification).

  - Describe the recruitment process in detail. Address who will identify potential human subjects, who will recruit them, and what methods will be used to recruit them.

- Include a detailed description of and justification for the compensation plan if the human subjects will be compensated for participation in the study.
- Describe the recruitment and advertisement materials. The recruitment materials should not be coercive or offer undue inducements and should accurately reflect the study.

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) (https://www.gpo.gov/fdsys/pkg/USCODE-2011-title10/pdf/USCODE-2011-title10-subtitleA-partII-chap49-sec980.pdf). If applicable, refer to the General Application Instructions, Appendix 6, 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. 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 study or 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, and 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 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.
- **Data reporting:** Describe how data will be reported and how it will be assured that the documentation will support a regulatory filing with the FDA, if applicable.
- **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 10: Intervention (if applicable; required for clinical trials; no page limit):** Upload as "Intervention.pdf." The Intervention attachment should include the components listed below.
    - **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.
    - **Study procedures and regulatory strategy:** 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. Outline the regulatory strategy. Discuss how compliance with Good Clinical Practices (GCP), Good Manufacturing Practices (GMP), and other regulatory considerations will be established, monitored, and maintained, as applicable.

- **Attachment 11: 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 eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm).
    - If an IND or IDE application has been submitted, provide an explanation of the status of the IND or IDE application (e.g., past the critical 30-day period, pending response to questions raised by the Agency, on clinical hold). Provide a summary of previous meetings with the FDA on development of this product, if appropriate. A copy of the Agency meeting minutes should be included if available. Provide copies of communications from the FDA relevant to the most recent status of the IND or IDE application.
    - 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 results and minutes of 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 clinical trial, or if it qualifies for an abbreviated IDE, provide evidence in the form of communication from the FDA or the IRB of record to that effect. Devices qualifying for an

abbreviated IDE must comply with the abbreviated IDE requirements but do not require submissions of an IDE application to the FDA.

- **Attachment 12: 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.7., 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. All biographical sketches should be submitted in the portable document format (pdf) that is not editable.

     Biographical Sketches should be used to demonstrate background and expertise through education, positions, publications, and previous work accomplished.
   - 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.4., 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.

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.

   Collaborating DoD Military Facilities Form: A Military Facility collaborating in the performance of the project should be treated as a subaward for budget purposes. However, do not complete the Grants.Gov R & R Subaward Budget Attachment Form;

instead, complete the Collaborating DoD Military Facility Budget Form (use Attachment 12, Collaborating DoD Military Facility Budget Form) to show all direct and indirect costs. The costs per year should be included on the Grants.gov Research and Related Budget form under subaward costs. Refer to the General Application Instructions, Section 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 or 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 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 submission rejection.

F. Other Submission Requirements

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

All extramural 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 consumers in a two-tier review process. The first tier is peer review of applications against established criteria for determining technical merit. Each application is evaluated for its own merit, independent of other

applications. The second tier is a programmatic review that makes recommendations for funding to the DHA RDA Directorate and the OASD(HA) , based on technical merit, the relevance to the mission of the DHP and JPC-5/MOMRP, to the specific intent of the award mechanism, and to other specified evaluation criteria in the Program Announcement/Funding Opportunity. Programmatic review is a comparison-based process in which applications with scientific and technical merit compete in a common pool. ***The highest-scoring applications from the first tier of review are not automatically recommended for funding. Funding recommendations depend on various factors as described in Section III.B.2., Programmatic Review.*** Additional information about the two-tier process used by the CDMRP can be found at http://cdmrp.army.mil/about/fundingprocess.

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

   - **Research Strategy and Feasibility**
     - How well the proposed approach addresses one or more of the FY16 CR3A Topic Areas and contributes to cognitive resilience and readiness in a military setting.
     - How well the proposed measures, tools, or strategies are described and are appropriate for the target population.
     - To what extent the proposed research is supported by sound scientific rationale as well as previous research data and literature.
     - How well the hypotheses or objectives, aims, experimental design, methods, and analyses are developed and integrated into the project.
     - To what extent the proposed approaches are sufficiently mature and appropriate to address the FY16 CR3A Topic Area(s).
     - How well the PI acknowledges potential problems and addresses alternative approaches.

- Whether the research can be completed within the proposed period of performance.
- How well the PI has outlined an appropriate plan for management and sharing of research data.

- **Impact and Military Benefit**
  - How well the proposed approach is responsive to the needs of Service members in military job categories and corresponding training or operational environments.
  - How well the proposed approach will have an impact on the cognitive resilience and readiness of Service members.
  - To what extent the proposed approach may be applicable and beneficial to the general public.
- **Human Subjects Recruitment (if applicable)**
  - 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.
- **Intervention (if applicable)**
  - Whether there is evidence of support, indicating availability of the intervention from its source, for the duration of the proposed clinical research/trial.
  - To what degree the intervention addresses the need(s) described.
  - To what degree the PI has provided preclinical and/or clinical evidence to support the safety of the intervention.
  - Whether a member of the study team holds the IND/IDE for the indication proposed or whether the timeline proposed for obtaining the IND/IDE is appropriate.
  - For investigator-sponsored INDs, whether there is evidence of appropriate institutional support, including capabilities to ensure monitoring as required by the FDA.
  - Whether plans to comply with GMP (for investigational drug, biological, and device interventions) and GCP guidelines are appropriate.
  - Whether measures are described to ensure the consistency of dosing of active ingredients for nutritional supplements (if applicable).

- **Statistical Plan**
    - To what degree the statistical model and data analysis plan are suitable for the planned study.
    - Whether the statistical plan, including sample size projections and power analysis, is adequate for the study and all proposed correlative studies.
- **Personnel**
    - How well the background and expertise of the PI and other key personnel demonstrate their ability to perform the proposed research, clinical study or trial.
    - Whether the composition of the research or study team (e.g., study coordinator, statistician) is appropriate.
    - Whether the levels of effort by the PI and other key personnel are appropriate to ensure success of this project.
    - Whether each key investigator's record of accomplishment demonstrates his/her understanding of working with military populations.
- **Transition Plan and Intellectual Property**
    - Whether the identified next level of development and/or commercialization is realistic.
    - Whether the funding strategy described to bring the anticipated research outcomes to the next level of development (e.g., specific potential industry partners, specific funding opportunities to be applied for) is reasonable and realistic.
    - As applicable to the proposed research, how the proposed collaborations and other resources for providing continuity of development, including proposed development or modification of Clinical Practice Guidelines and recommendations, provider training materials, patient brochures, and other clinical support tools, scientific journal publications, models, simulations, and applications are established and/or achievable.
    - As applicable to the proposed research, how the schedule and milestones for bringing the anticipated research outcomes to the next level of development (e.g., next-phase clinical trials, transition to industry, delivery to the military or civilian market, incorporation into clinical practice, or approval by the FDA) are achievable.
    - Whether the risk analysis for cost, schedule, manufacturability, and sustainability is realistic and reasonable.
    - How well the application identifies intellectual property ownership, describes an 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.

- If applicable, whether the applicant has demonstrated that he/she has access to all intellectual property rights necessary for development and commercialization and evidence that the government has the ability to access such products or technologies.

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

- **Environment**
  - How the scientific environment is appropriate for the proposed research.
  - How well the research requirements are supported by the availability of and accessibility to facilities and resources (including military Service members, military-controlled study materials, and military databases, if applicable).
- **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 criteria are used by programmatic reviewers:
   a. **Ratings and evaluations of the peer reviewers**
   b. **Relevance to the mission of the DHP and JPC-5/MOMRP, as evidenced by the following:**
      - Adherence to the intent of the award mechanism
      - Program portfolio composition
      - Relative impact and military benefit
      - Relative feasibility of the 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.
- For research involving human subjects, Human Subject Recruitment and Safety Procedures (Attachment 8) is missing.
- For research involving human subjects, Data Management (Attachment 9) is missing.
- For research proposing clinical trials, Intervention (Attachment 10) is missing.

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 FY16 PH/TBIRP CR3A Programmatic Panel member is named as being involved in the research proposed or is found to have assisted in the pre-application or application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting documentation. ***A list of the FY16 PH/TBIRP CR3A Programmatic Panel members can be found http://cdmrp.army.mil/phtbi/panels/panels16_cr3a***.

- The application fails to conform to this Program Announcement/Funding Opportunity description to the extent that appropriate review cannot be conducted.
- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- To preserve the integrity of its peer and programmatic review processes, the CDMRP discourages inclusion of any employee of its review contractors having any role in the preparation, research or other duties for submitted applications. For FY16, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (http://cdmrp.army.mil/about/2tierRevProcess). Applications that include names of personnel from either of these companies will be administratively withdrawn unless plans to manage COIs are provided and deemed appropriate by the Government. Refer to the General Application Instructions, Appendix 1, 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.

D. Withhold

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

V. AWARD ADMINISTRATION INFORMATION

A. Award Notice

Awards will be made no later than September 30, 2017. 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 H, 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 at yearly in-progress reviews may be requested.

E. Award Transfers

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

Refer to the General Application Instructions, Appendix 4, Section L, for general information on organization or PI changes.

VI. VERSION CODES AND AGENCY CONTACTS

A. Program Announcement/Funding Opportunity and General Application Instructions Version

Questions related to this Program Announcement/Funding Opportunity should refer to the Program name, the Program Announcement/Funding Opportunity name, and the Program Announcement/Funding Opportunity version code [20160210i]. The Program Announcement/Funding Opportunity numeric version code will match the General Applications Instructions version code [20160210].

B. 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

C. 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; International 1-606-545-5035

Email: support@grants.gov

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

VII. APPLICATION SUBMISSION CHECKLIST

Grants.gov Application Components	Upload Order	Action	Completed
SF424 (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 the file name "MilBen.pdf"	
	7	Transition Plan: Upload as Attachment 7 with the file name "Transition.pdf"	
	8	Human Subject Recruitment and Safety Procedures: Upload as Attachment 8 with the file name "HumSubProc.pdf," if applicable	
	9	Data Management: Upload as Attachment 9 with the file name "Data_Manage.pdf," if applicable	
	10	Intervention: Upload as Attachment 10 with the file name "Intervention.pdf," if applicable	
	11	IND/IDE Form: Upload as Attachment 11 with the file name "IND-IDE.pdf, if applicable"	
	12	Collaborating DoD Military Facility Budget Form(s): Upload as Attachment 12 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 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.	