Program Announcement

for the

Defense Health Program

Defense Medical Research and Development Program

Department of Defense

Military Operational Medicine (MOM) Joint Program Committee 5 (JPC-5)

Psychological Health/Traumatic Brain Injury Research Program

Basic/Applied Psychological Health Award

Funding Opportunity Number: W81XWH-13-PHTBI-BAPHA

Catalog of Federal Domestic Assistance Number: 12.420

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application Submission Deadline:** 5:00 p.m. Eastern time (ET), April 16, 2013
- **Invitation to Submit an Application:** May 30, 2013
- **Application Submission Deadline:** 11:59 p.m. ET, July 23, 2013
- **Peer Review:** To be determined
- **Programmatic Review:** To be determined

This Program Announcement 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 2013 (FY13) Psychological Health and Traumatic Brain Injury (PH/TBI) Research Program are being solicited for the Assistant Secretary of Defense for Health Affairs, Defense Health Program (DHP), by the U.S. Army Medical Research Acquisitions Activity (USAMRAA). The PH/TBI Research Program was initiated in 2007 for the purpose of complementing ongoing Department of Defense (DoD) efforts towards promoting a better standard of care for PH (including post-traumatic stress disorder [PTSD]) and TBI in the areas of prevention, detection, diagnosis, treatment, and rehabilitation. This includes research to benefit service members, Family members, Veterans, and other beneficiaries of the Military Health System (MHS).

The Defense Medical Research and Development Program (DMRDP) expects to fund approximately 5-10 FY13 PH/TBI Basic and Applied Psychological Health Award (BAPHA) applications, depending on the quality and number of applications received and the total cost of applications approved for funding. Funding of applications received in response to this Program Announcement/Funding Opportunity is contingent upon the availability of Federal funds for this Program. Funding allotted for this Program Announcement/Funding Opportunity is approximate and subject to change. Currently, we anticipate that up to $15 million (M) in FY13-14 funds may be available. The executing agent for this announcement is the Office of the Congressionally Directed Medical Research Programs (CDMRP).

B. FY13 PH/TBI BAPHA Topic Areas

All applications to the FY13 PH/TBI BAPHA mechanism ***must*** specifically address one or more of the Topic Areas listed below. Applications can address basic science and/or applied research needs related to these specific topics. Definitions of Basic and Applied Science are provided below in Section I.C. Applications for topics other than those listed below should ***not*** be submitted in response to this Program Announcement/Funding Opportunity.

- Research and develop assessment tools, methods, assistive devices, training strategies, and clinical applications (specifically those which target return-to-duty, cognitive self-management, evidence-based retraining focused on compensatory strategies, and/or daily functioning) that show promise in ameliorating cognitive deficits due to TBI and/or its co-morbidities such as stress disorders.
- Understand and prevent or address psychological injuries (depression, anxiety, PTSD, suicide, etc.) and psychosocial issues (relationships, fertility issues, vocational) associated with dismounted combat injuries (DCI; urogenital system damage/loss).
- Research to elucidate combat-related psychological issues unique to women and develop specific interventions as indicated.
- Research to understand and prevent or address psychosocial issues related to sexual trauma (males and females).
- Develop and validate military-relevant standards for making return-to-duty decisions that are related to PH issues.

- Understand and address unique military-related issues associated with gender and gender orientation (lesbian, gay, bisexual, transgender) with consideration in the context of the Don't Ask Don't Tell repeal and to include the impact on family (e.g., parents, partner, children).
- Understand, prevent, and address violence within the military (targeted/radicalized violence within the workplace, sexual trauma).
- Develop methods to improve use of pre-deployment resilience-focused sleep interventions, and post-deployment use of non-pharmacologic, behavioral sleep interventions as a primary treatment for sleep difficulties, obviating the use of hypnotics.
- Employ implementation science and translational research approaches to provide methods for motivating families to engage in health-promoting behaviors; population level skills-based family resilience training and education (communication, parenting, relationship, etc.) for military families to promote adaptation, flexibility, and reduce cumulative stress burden.
- Research to optimize dissemination and foster provider adoption and use of evidence-based treatments for deployment-related psychological health problems (e.g., depression, adjustment disorder, anxiety, PTSD) requires strong military collaboration.
- Address prevention and treatment of alcohol and substance abuse in the military, including evaluation of effectiveness of current Service prevention programs as well as adaptation and validation of screening, brief intervention, and referral to treatment approaches for use within the military.

C. Award Information

The FY13 PH/TBI BAPHA Program Announcement/Funding Opportunity is focused on specific research Topic Areas of PH and well-being of military personnel and their families as outlined in Section I.B. Research projects should include a well-formulated, testable hypothesis based on a strong scientific rationale. Experimental interventions are strongly encouraged, but are not explicitly required. The FY13 PH/TBI BAPHA seeks to fund basic and applied research (including early phase clinical trials). Preliminary data are required for applied research applications. Descriptions of Basic and Applied Research categories are provided below:

Basic Research is defined as research directed toward acquiring increased knowledge and understanding of fundamental principles of science and medicine. Basic research should promote new/innovative ideas that are still in the early stages of development and have the potential to yield highly impactful outcomes and new avenues of investigation to further the research field of interest. Basic research should strive to attain greater knowledge regarding the theoretical construct surrounding the topic of interest and to increase scientific understanding of certain phenomena or behaviors but not seek to immediately solve or treat these problems. The research should propose new paradigms or challenge existing paradigms. Basic research should have the potential to clarify basic mechanisms of military-relevant disease or injury, and/or enable the discovery of potential new avenues for research. Applications may include clinical studies.

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. Applications may include early Phase I clinical trials, but ***not*** advanced development, or late Phase II large-scale effectiveness clinical trials.

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.

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 its investigational use, evidence that an Investigational New Drug (IND) exemption application has been submitted or will be submitted within 60 days of award is required. If the proposed study involves an Investigational Device that has not been approved or cleared by FDA for its investigational clinical use, the study may be required to comply with the FDA Investigational Device Exemption (IDE) regulations. ***If applicable, evidence that an IDE has been submitted or will be submitted within 60 days of the award date, or that the device is exempt from an IDE, is required.*** The Government reserves the right to withdraw funding if the documented status of the IND or IDE has not been obtained within 6 months of the award date.

Use of Human Subjects and Human Anatomical Substances: All DoD-funded research involving new and ongoing research with human subjects and human anatomical substances 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. Time and level of effort for local IRB approval(s) should be considered in planning. The HRPO is mandated to comply with specific laws and directives governing all research involving human subjects that is supported by the DoD. These laws and directives are rigorous and detailed, and will require information in addition to that supplied to the local IRB. In addition to time for local IRB approval(s), allow for a minimum of 2 months for HRPO review and approval processes. Refer to the General Application Instructions, Appendix 5, for more information.

Multi-Institutional Research: Multidisciplinary and multi-institutional 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, Principal Investigators (PIs) are strongly encouraged to collaborate, integrate, and/or align their research projects with military and/or Veterans Affairs (VA) research laboratories and programs. The following websites may be useful in identifying information about ongoing DoD areas of research interest:

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

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

Defense Centers of Excellence for Psychological Health and Traumatic Brain Injury
http://www.dcoe.health.mil

Defense and Veterans Brain Injury Center
http://www.dvbic.org/

Center for Deployment Psychology
http://www.deploymentpsych.org/

Deployment Health Clinical Center
http://www.pdhealth.mil/

DoD PH/TBI Research Program Investigator-Initiated Research Award & Center for the Study of Traumatic Stress
http://www.cstsonline.org/

National Center for Telehealth and Technology
http://www.t2health.org/

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

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

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

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

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

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

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

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

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

U.S. Army Medical Research Acquisition Activity
https://www.usamraa.army.mil/

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

U.S. Department of Defense Blast Injury Research Program
https://blastinjuryresearch.amedd.army.mil

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

Use of Active Duty Military and VA Populations: If the proposed research plan involves access to Active Duty Military and/or VA patient population(s), the PI is responsible for establishing access to such populations. 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 Active Duty military, Veterans, military and/or VA controlled study materials, and military and/or VA databases.

Data Sharing: The DoD requires that awardees make TBI data generated via this award mechanism available to the research community by depositing de-identified research data into the Federal Interagency TBI Research (FITBIR) Informatics System on a quarterly basis. The FITBIR Informatics system is a free resource to the research community designed to accelerate comparative effectiveness research on brain injury diagnosis and treatment. Data reporting to FITBIR is an opportunity for investigators to facilitate their own research and to collaborate with others doing similar research. While use of the informatics system has no direct cost to the user, a project estimation tool (https://fitbir.nih.gov/jsp/contribute/fitbir-costs.jsp) is available to help estimate indirect cost and manpower needs for PIs. To contribute to FITBIR, researchers should contact the FITBIR Operations Center ahead of time to arrange for data entry support and to ensure all data has been made compatible with the system. FITBIR guidance and policies, as well as the considerable advantages of FITBIR use to the researcher, are detailed at FITBIR: Federal Interagency Traumatic Brain Injury Research Informatics System (http://fitbir.nih.gov/).

FITBIR allows for de-identification and storage of data (medical imaging clinical assessment, environmental and behavioral history, etc.) of various types (text, numeric, image, time series, etc.). Use of FITBIR's Global Unique Identifier (GUID) system facilitates repeated and multi-user access to data without the need to personally identify data sources. FITBIR encourages collaboration between laboratories, as well as interconnectivity with other informatics platforms. Such community-wide sharing requires common data definitions and standards.

Data elements must be reported using the National Institute of Neurological Disorders and Stroke (NINDS) TBI Common Data Elements (CDEs) or entered into the FITBIR data dictionary as new, unique data elements. For the most current version of the NINDS TBI CDEs, go to http://www.commondataelements.ninds.nih.gov. Assistance will be available to help the researchers map their study variables to specific CDEs and ensure the formats of the CDEs collected are compatible with the FITBIR informatics system. If the proposed research data cannot be entered as in CDE format, the investigators must supply a proposal for an alternative data submission or data sharing vehicle and justification for use. Use of the TBI CDEs is required wherever possible in an effort to create standardized definitions and guidelines about the kinds of data to collect and the data collection methods that should be used in clinical studies of TBI.

D. Eligibility Information

- Independent investigators at all academic levels (or equivalent).
- Cost sharing/matching is desirable but not an eligibility requirement.
- Organizations eligible to apply include national, international, for-profit, non-profit, public, and private organizations. Both intramural (i.e., U.S. Federal Government

agency, department, laboratory, medical treatment facility [MTF], or a U.S. Government activity embedded within a civilian medical center) and extramural investigators are encouraged to apply to this Program Announcement/Funding Opportunity.

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

E. Funding

All Applications:

- The maximum period of performance is **4** years.
- Applications can be either basic research, applied research, or a combination of basic and applied research.
    - For basic research awards, the maximum allowable direct costs for the entire period of performance is **$1M** plus indirect costs.
    - For applied research and combined awards, the maximum allowable direct costs for the entire period of performance cannot exceed **$4M** plus indirect costs.
    - Applications requesting the higher level of funding that do not include applied research will have their budget reduced as appropriate.
- 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(s) 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(s) 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.***

In addition, for this award mechanism, direct costs:

Must be requested for:

- PI(s) must request travel funds 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 2 days.

May be requested for (not all-inclusive):

- Salary
- Research-related subject costs
- Clinical research costs
- Support for multidisciplinary collaborations
- Travel between collaborating organizations
- Travel costs of up to $1,800 per year to attend scientific/technical meetings (in addition to the required meeting described above)

Intramural and extramural investigators are encouraged to apply to this Program Announcement/ Funding Opportunity. As required of all applicants to this Program Announcement, if PIs from Federal agencies submit full applications, they must submit through Grants.gov. Therefore, Federal applicants must be familiar with Grants.gov requirements, including the need for System for Award Management (SAM) 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 organizations will be executed through a Military Interdepartmental Purchase Request (MIPR) or Funding Authorization Document (FAD) process. Direct transfer of funds from the recipient to a Federal organization or agency is not allowed except under very limited circumstances. ***The DMRDP Military Operational Medicine Joint Program Committee 5 expects to allot approximately $15M of FY13-14 appropriations to fund approximately 5-10 Basic/Applied Psychological Health 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 CDMRP eReceipt System (https://cdmrp.org/) and (2) application submission through Grants.gov (http://www.grants.gov/).

The PH/TBI BAPHA 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 CDMRP eReceipt 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 multiple applications that are essentially identical or propose essentially the same research project to this Funding Opportunity or other Funding Opportunities within the same program and fiscal year is prohibited and will result in administrative withdrawal of the duplicative application(s).

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-13-PHTBI-BAPHA.

B. Pre-Application Submission Content and Form

All pre-application components must be submitted by the Initiating PI through the CDMRP eReceipt System (https://cdmrp.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. The title should be detailed enough to accurately reflect the work that will be done in the study.

Partnering PI Option: ***The Initiating PI is responsible for submission of all pre-application components.***

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

When starting the pre-application, PIs should ensure that they have selected the appropriate application category, i.e., "Basic Research" OR "Applied/Combined Research."

The pre-application consists of the following components, which are organized in the CDMRP eReceipt System 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**
- **Collaborators and Conflicts of Interest (COI) – Tab 3**

  FY13 MOM JPC-5 members should not be involved in any pre-application or application. For questions related to JPC-5 members and pre-applications or applications, refer to Section IV.C., Withdrawal, or contact the CDMRP Help Desk (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**

  Pre-application Narrative (three-page limit): The Preproposal Narrative page limit applies to text and any figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, and cartoons. Including URLs that provide additional information to expand the Project Narrative and could confer an unfair competitive advantage

are prohibited and will result in administrative withdrawal of the application. ***Note: At this time, the CDMRP eReceipt System is unable to read files made with Adobe Acrobat PDFMaker version 9.0 and higher.***

The Preproposal Narrative should include the following:

- **Military Benefit:** State explicitly how the proposed work will have an impact on the prevention, detection, diagnosis, and/or treatment of military-relevant psychological health issues. Describe how the proposed work is responsive to the health care needs of Warriors, Veterans, Families, caregivers, and/or communities.
- **Rationale:** Present the problem and proposed solution. Present the ideas and reasoning behind the proposed study to establish the evidence-based need for the proposed project, to include relevant literature citations and/or pilot data.
- **Hypothesis or Objective:** State the aims and hypothesis to be tested.
- **Research Strategy:** Describe the proposed design and methods and how they will accomplish the project aims. Identify the most important metrics to be used; name commercially available measurement instruments and provide a brief description of non-published metrics.
- **Relevance:** State how this project meets the intent of the award mechanism and what will be delivered at the end of the project.

Quad Chart: The Quad Chart template is a one-page PowerPoint file that must be downloaded from the CDMRP eReceipt System at https://cdmrp.org/Program_Announcements_and_Forms/, completed, and saved using Adobe Acrobat Reader as a PDF file.

Pre-Application Supporting Documentation: The items to be included as supporting documentation for the pre-application 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).

- **Submit Pre-Application – Tab 5**

  This tab must be completed for the pre-application to be accepted and processed by the CDMRP.

- **Other Documents Tab**

  If applicable, provide letters of support related to recruitment and/or collaboration.

Pre-Application Screening

- **Pre-Application Screening Criteria**

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

  - **Military Benefit:** What impact these studies will have on the outcomes of Warriors, Veterans, Families, caregivers, and/or communities within the specified Topic Areas listed in Section I.B.
  - **Research Idea and Rationale:** How the proposed project addresses the intent of the award mechanism and one or more of the specified Topic Areas. How the proposed project would likely advance scientific understanding of the specified Topic Area(s) based on the evidence presented in the application. How well delineated and appropriate is/are the hypothesis(es) to be tested or the objective(s) to be reached.
  - **Research Strategy:** How well the research plan supports the project aims, rationale, and objectives. Is the proposed project designed to yield accurate data and valid conclusions?
    - **Personnel:** How the qualifications and expertise of the PI and key personnel are appropriate to accomplish the proposed research.

- **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 Form

Applications will not be accepted unless the PI or 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/).

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 the CDMRP eReceipt System. Each Grants.gov application package must be submitted using the unique log number.

Application Components for Single PIs or for Initiating PIs under the Partnering PI Option:

Grants.gov application package components: For the FY13 PH/TBI BAPH 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 (15-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. Including URLs that provide additional information to expand the Project Narrative and could confer an unfair competitive advantage are prohibited and will result in administrative withdrawal of the application.

     Describe the proposed project in detail using the outline below.

     - **Background:** State explicitly how the proposed work will have an impact on the prevention, detection, diagnosis, and/or treatment of military-relevant psychological health issues. Describe how the proposed work is responsive to the health care needs of Warriors, Veterans, Families, caregivers, and/or communities. Present the ideas and rationale supporting the proposed work with references to relevant literature and discussion of any available preliminary data. 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 approach, study design, methods (including appropriate controls or comparison groups as applicable), and analyses in sufficient detail for evaluation of scientific rigor. Describe or define measures and instruments. Address potential problem areas and present alternative methods and approaches. If human subjects or human anatomical samples will be used, include a detailed plan for the recruitment of subjects or the acquisition of samples. Describe the statistical plan, if appropriate, for the research proposed.

     Submissions that include clinical interventions and/or clinical research:

     Submissions that include clinical research will be evaluated using additional review criteria, which are outlined in Section III.B.1. of this Program Announcement/ Funding Opportunity. Therefore, the following items should also be described within the Project Narrative:

- **Study Design:**
  - Identify and describe the intervention or research to be tested and describe the projected outcomes with sufficient detail to replicate the critical elements of the project.
  - Define the study variables and describe how they will be measured. Include a description of appropriate controls and comparison groups 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 Clinician Administered PTSD Scale (CAPS) and/or PTSD Checklist – Military Version (PCL-M) (pre- and post-intervention) are specifically required for PTSD interventions.
- **Statistical Plan and Data Analysis:** Include a complete power analysis to demonstrate that the sample size is appropriate to meet the objectives of the study. Specify the approximate number of human subjects that will be enrolled and estimate the number in each comparison group. Specify the most important comparisons and how they relate to their hypothesis. If multiple study sites are involved, state the projected number to be enrolled at each site. Describe the data analysis plan in a manner that is consistent with the study objectives.

- **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 if 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 (if applicable): 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.
- Letters Confirming Access to Target Military or VA Patient Population(s) (one-page limit) (if applicable): Provide a letter(s) signed by the lowest ranking person with approval authority for studies involving Active Duty military, Veterans, military and/or VA-controlled study materials, and military and/or VA databases.
- Intellectual Property
  - Background and Proprietary Information (if applicable): 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. Identify any 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, for more information about the expectations for making data and research resources publicly available. Include plans for utilizing the National Institute of Neurological Disorders and Stroke TBI CDEs (see http://www.commondataelements.ninds.nih.gov). If the proposed research is not compatible with the required CDEs, the investigators must supply a justification as to why these measures will not be incorporated into the research. Additionally, reporting is required via the FITBIR (http://fitbir.nih.gov/tbi-portal/) data repository quarterly. The Government reserves the right to identify additional data sharing requirements and or repositories for submission of data for archive.

- Current Quad Chart: Provide a current Quad Chart in the same format as 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."

  Technical abstracts should be written using the outline below.

  - Background: 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.
  - Innovation: Briefly describe how the proposed project is innovative.
  - Impact: Briefly describe how the proposed project will have an impact on psychological health research or patient care.

- **Attachment 4: Lay Abstract (one-page limit):** Upload as "LayAbs.pdf."

  Lay (public) abstracts should be written using the outline below.

  - Clearly describe, in a manner readily understood by lay persons, the rationale and objective for the proposed work.
    - 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?
    - What are the potential clinical applications, benefits, and risks?
    - What is the projected time it may take to achieve a patient-related outcome?
    - What are the likely contributions of this study to advancing the field of psychological health research or patient care?
  - If the research is too basic for clinical applicability, describe the interim outcomes.

- **Attachment 5: Statement of Work (SOW) (three-page limit):** Upload as "SOW.pdf." Refer to the General Application Instructions, Section II.C., for detailed information, including guidance on appropriate SOW formats.

  For the Partnering PI Option: 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 military Service Members and Veterans with deployment-related psychological health problems. Provide information about the incidence and/or prevalence of the disease or condition to be studied in military 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., military 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, detection, diagnosis, and/or treatment of military-relevant psychological health issues. Describe how the proposed work is responsive to the health care needs of Warriors, 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: Innovation Statement (one-page limit):** Upload as "Innovation.pdf."

  Summarize how the proposed research is innovative. Investigating the next logical step or incremental advancement on published data is not considered innovative. The following examples of ways in which research may be innovative, although not all-inclusive, are intended to help PIs frame the innovative features of their applications:

  - Study concept: Investigation of a novel idea and/or research question that could have a significant impact on the Topic Area selected for study.
  - Research method or technology: Use of novel research methods or new technologies.
  - Existing methods or technologies: Application or adaptation of existing methods or technologies for novel research, or for research that differ fundamentally from those originally intended.

- **Attachment 9: Transition Plan (two-page limit).** Upload as "Transition.pdf." Provide information on the methods and strategies proposed to move the product to the next level (e.g., next phase of clinical trials and/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 applied for).
- A description of collaborations and other resources that will be used to provide continuity of development.
- A brief schedule and milestones for bringing the outcome(s) to the next level of development.
- A risk analysis for cost, schedule, manufacturability, and sustainability.

- **Attachment 10: Human Subject Recruitment and Safety Procedures (required for studies with clinical interventions and/or clinical research) (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 which 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 study. 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 study.

  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.
- If accessing Active Duty Service Members, describe how this special population will be approached and what steps will be taken to avoid the introduction of potential bias in recruiting subjects. Consider the use of an Ombudsman during recruitment and informed consent procedures.
- If accessing Veterans through the VA Medical System, ensure that potential subjects are made aware that their ongoing health care is not dependent upon participation in the study. Consider the use of an Ombudsman during recruitment and informed consent procedures.
- 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 study to be in compliance with Title 10 United States Code Section 980 (10 USC 980) (http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=browse_

usc&docid=Cite:+10USC980). 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 study, 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, Active Duty Service Members and/or Veterans, or society.

- **Attachment 11: Data Management (required for studies with clinical interventions and/or clinical research) (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: Study Personnel and Organization (required for studies with clinical interventions and/or clinical research (no page limit):** Upload as "Personnel.pdf." The Study Personnel and Organization attachment should include the components listed below.

  a. **Principal Investigator/Study Staff:** 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.

  b. **Study Management Plan:** Provide a plan for ensuring the standardization of procedures among staff and across sites (if applicable). If the proposed clinical study 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, should be included. Provide a plan for real-time communication among collaborating institutions (if applicable).

- **Attachment 13: Intervention (required for studies with clinical interventions) (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. If applicable, summarize key preclinical findings and other clinical studies that examine the safety of the intervention. Description of devices should include detailed operational instructions, and any potential risks to users, and intended benefits. Other types of interventions should be fully described.

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

- **Attachment 14: Surveys, Questionnaires, and Other Data Collection Instruments (if applicable; required for studies with clinical interventions) (no page limit):** Upload as "Surveys.pdf." The Surveys, Questionnaires, and Other Data Collection Instruments attachment should include a copy of the most recent version of surveys, questionnaires, data collection forms, rating scales, interview guides, or other instruments. For each instrument, describe how the information collected is related to the objectives of the study.

- **Attachment 15: IND/IDE Documentation Form (if applicable):** If submitting multiple documents start each documents 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/IDE has been submitted, an explanation of the status of the IND/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/IDE application is not yet submitted, provide evidence that an IND/IDE will be submitted within 60 days of award. Examples include a pre-IND/IDE meeting with the FDA, a pre-IND/IDE meeting request to the FDA, or other communication with the FDA. Provide the anticipated date of IND/IDE submission. If an IND/IDE is not required for the proposed study, provide evidence in the form of official communication from the FDA or the IRB of record to that effect.

3. **Research & Related Senior/Key Person Profile (Expanded):** Refer to the General Application Instructions, Section II.C., for detailed information.

   - PI Biographical Sketch (four-page limit): Upload as "Biosketch_LastName.pdf."
   - PI 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 the Initiating and Partnering PI(s).
   - Key Personnel Current/Pending Support (no page limit): Upload as "Support_LastName.pdf."
     - Include current/pending support for the Initiating and Partnering PI(s).

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

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

   For the Partnering PI Option: Initiating and Partnering PIs must each submit a budget and justification specific to their own portion of the effort as part of their separate Grants.gov application packages. The Research & Related Budget for the Initiating PI should not include budget information for the Partnering PI(s), even if they are located within the same organization. The combined total direct costs for the Initiating and Partnering PIs' budgets cannot exceed the maximum allowable amounts indicated in Section I.E., Funding.

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

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

Application Components for the Partnering PI(s,) if applying under the Partnering PI Option:

Each Partnering PI must follow the link in the email from the CDMRP eReceipt System 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., 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 effort 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 total direct costs for the Initiating and Partnering PIs' budgets cannot exceed the maximum allowable amounts indicated in Section I.E., Funding.

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

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

D. 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 any one of the deadlines will result in application rejection.

E. 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 Data Universal Numbering System (DUNS) number to submit applications to Grants.gov. The applicant organization must also be registered in the Entity Management functional area of the System for Award Management (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 applications are evaluated by scientists, clinicians, and consumer advocates using a two-tier review process. The first tier is a peer review of applications against established criteria for determining technical merit. The second tier is a programmatic review that makes recommendations for funding to the Commanding General, USAMRMC, for concurrence, and then to the Office of the Assistant Secretary of Defense for Health Affairs for final approval, based on technical merit, the relevance to the mission of the DHP and MOM JPC-5 and the specific intent of the award mechanism. The highest-scoring applications from the first tier of review are not automatically recommended for funding. Additional information about the twotier review process used by the MOM JPC-5 can be found at http://cdmrp.army.mil/about/fundingprocess.

All MOM JPC-5 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 Criteria

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

    - **Impact**
        - How the proposed study addresses at least one of the FY13 PH/TBI BAPHA Topic Areas.
        - The potential unique contribution of the proposed study to research and/or patient care in the FY13 PH/TBI BAPHA Topic Areas.

- **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.
    - How well the PI acknowledges potential problems and addresses alternative approaches.
    - How the PI describes the population(s) of interest, demonstrates access to these populations, and identifies sampling methods to gain a representative sample from the population(s) of interest.
- **Innovation**
    - How the research proposes new paradigms or challenges existing paradigms in one or more of the following ways: concept or question, research methods or technologies, adaptations of existing methods or technologies, and clinical interventions.
    - How the proposed research represents more than an incremental advance upon published data.
    - How the potential gain justifies the perceived risk.
- **Transition Plan**
    - Whether the funding strategy described to bring the outcome(s) to the next phase of clinical trials and/or delivery to the military and/or civilian market is appropriate.
    - Whether appropriate collaborations and other resources for providing continuity of development are established and/or well described.
    - How the schedule and milestones for bringing the outcome(s) to the next level of development are appropriate.
    - 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.
- **Personnel**
    - How the background and expertise of the PI and other key personnel demonstrate their ability to perform the proposed work.
    - How the levels of effort by the PI and other key personnel are appropriate to ensure success of this project.
    - How the PI's record of accomplishment demonstrates his/her ability to accomplish the proposed work.

Applications that <u>include</u> clinical interventions or clinical research will also be evaluated (as appropriate for the type of proposed clinical study) according to the following additional scored criteria, which are of equal importance:

- **Impact of Clinical Intervention (if applicable)**
  - How well the sample population represents the targeted patient population that might benefit from the proposed intervention.
  - How the potential outcomes of the proposed clinical trial will provide/improve the short-term benefits for individuals.
  - How significantly the long-term benefits for implementation of the intervention may impact patient care and/or quality of life.
- **Ethical Considerations**
  - How the level of risk to human subjects is minimized and whether there is sufficient evidence of a monitoring plan that is appropriate for the level of risk.
  - How well the evidence shows that the procedures are consistent with sound research design and, when appropriate, that these procedures are already in use for diagnostic or treatment purposes.
  - To what degree privacy issues are appropriately considered.
  - To what degree the process for seeking informed consent is appropriate and whether safeguards are in place for vulnerable populations.
- **Intervention (if applicable)**
  - Whether there is evidence of support, indicating availability of the device/ intervention from its source, for the duration of the proposed clinical trial (if applicable).
  - 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.
  - How the intervention advances prevention and patient care beyond the currently available interventions.
  - Whether a member of the study team holds the IND/IDE and whether the timeline proposed for IND/IDE application is appropriate (if applicable).
- **Recruitment, Accrual, and Feasibility**
  - How well the PI addresses the availability of human subjects for the clinical study and the prospect of their participation.
  - Whether the PI has demonstrated access to the proposed human subjects population.
  - The degree to which the recruitment, informed consent, screening, and retention processes for human subjects will meet the needs of the proposed clinical study.
  - How well the application identifies possible delays (e.g., slow accrual, attrition) and presents adequate contingency plans to resolve them.

- To what extent the proposed clinical study affects the daily lives of the individual human subjects participating in the study (e.g., Will human subjects still be able to take their regular medications while participating in the clinical study? Are human subjects required to stay overnight in a hospital?).

- **Research Strategy/Study Design**
  - How well the scientific rationale for testing the intervention or hypothesis is supported by the preliminary data, critical review and analysis of the literature, and/or laboratory/preclinical evidence.
  - How well the study aims, hypotheses or objectives, experimental design, methods, data collection procedures, and analyses are designed to achieve the study endpoints.
  - How well the inclusion and randomization criteria meet the needs of the proposed clinical research.
  - How well the exclusion criteria are justified.
  - How appropriate are the questionnaires, surveys, and other tools included in the study, and how well described are their psychometrics.

For studies including a clinical intervention:

  - How well the research design incorporates treatment outcome as the metric of primary importance and compares factors including patient compliance, treatment satisfaction, optimizing patient match to treatment modality, ease of treatment delivery, provider/patient safety issues, cost, program management issues, and a resultant "best practice guide to implementation."
  - How well the applicant demonstrates an ability to adequately screen, assess, monitor, and manage risk of suicide and suicide-related behavior.

- **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 the study and all proposed correlative studies.

- **Personnel**
  - Whether the composition of the study team (e.g., study coordinator, statistician) is appropriate.
  - To what degree the study team's background and expertise are appropriate to accomplish the proposed work (e.g., statistical expertise, expertise in the disease, and clinical studies).
  - How the levels of effort of the study team members are appropriate for successful conduct of the proposed study.
  - How well the logistical aspects of the proposed clinical study (e.g., communication plan, data transfer and management, standardization of procedures) meet the needs of the proposed clinical study.

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

- **Environment**
  - The appropriateness of the scientific environment for the proposed research.
  - How the research requirements are supported by the availability of and accessibility to facilities and resources (including collaborative arrangements).
  - The quality and extent of institutional support are appropriate for the proposed research.
- **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 influenced the review.

2. **Programmatic Review:** To determine the application's relevance to the mission of the DoD and MOM JPC-5, as well as to make funding recommendations, the following equally considered criteria are used by programmatic reviewers:

- **Relative Ratings and Evaluations of the Scientific Peer Reviewers**
  - How the scientific merit, in the context of military relevance and programmatic review, compares to all eligible applications under consideration.
- **Portfolio Balance**
  - How well the proposed study accelerates core research efforts and contributes to overall portfolio balance.
- **Impact on Military Population**
  - How much the proposed project contributes to accelerating the fulfillment of military requirements, if successful.
  - How the plan to access the military populations, if applicable, is appropriate and feasible.
  - How well the research study solves a documented military problem.

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 notification of the funding recommendation. 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 CDMRP eReceipt 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.
- **Partnering PI Option:** All associated (Initiating and each Partnering PI) applications are not submitted by the deadline.

B. Modification

- Pages exceeding the specified limits will be removed prior to review for all documents other than the Project Narrative and Preproposal Narrative.
- Documents not requested will be removed.
- Following the application deadline, the PI may be contacted by CDMRP via email with a request to provide certain missing supporting documents (excluding those listed in Section IV.A., Rejection). The missing documents must be provided by 5:00 p.m. ET on the second full business day following the date the email was sent. Otherwise, the application will be reviewed as submitted.

C. Withdrawal

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

- A FY13 MOM JPC-5 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 document. A list of the FY13 MOM JPC-5 members can be found at http://cdmrp.army.mil/phtbi/panels/panels13_5.

- The application does not conform to this Program Announcement/Funding Opportunity description to an extent that precludes appropriate review.
- 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.
- Submission of multiple applications that are essentially identical or propose essentially the same research project.
- The proposed research project is not relevant to any of the FY13 PH/TBI BAPHA topic areas.
- Human Subject Recruitment and Safety Procedures attachment (Attachment 10) is missing (for clinical intervention or clinical research applications).
- Data Management attachment (Attachment 11) is missing (for clinical intervention or clinical research applications).
- Intervention attachment (Attachment 13) is missing (for clinical intervention applications).
- 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)
- The PI does not meet the eligibility criteria.

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, 2014. Refer to the General Application Instructions, Appendix 4, for additional award administration information.

B. Administrative and National Policy Requirements

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

C. Reporting

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

Quarterly technical progress reports will be required.

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

D. Award Transfers

Changes in PI will only be allowed under extenuating circumstances that will be evaluated on a case-by-case basis and at the discretion of the Grants Officer.

The transfer of an award to another institution is strongly discouraged. A transfer will not be allowed for any institution that includes a study site/clinical trial at its location. Approval of a transfer request from an institution that does not include a study site at its location will be at the discretion of the Grants Officer.

Refer to the General Application Instructions, Appendix 4, Section F, 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 the CDMRP eReceipt System 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@cdmrp.org

B. Grants.gov Contact Center

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

Phone: 800-518-4726

Email: support@grants.gov

Sign up on Grants.gov for "send me change notification emails" by following the link on the Synopsis page for the Program Announcement/Funding Opportunity or by responding to the prompt provided by Grants.gov when first downloading the 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

Grants.gov Application Components	Action	Single PI or Initiating PI Completed	Each Partnering PI Completed
SF-424 (R&R) Application for Federal Assistance Form	Complete form as instructed.		
Attachments Form	Upload Project Narrative (ProjectNarrative.pdf) as Attachment 1.		
	Upload Supporting Documentation (Support.pdf) as Attachment 2.		
	Upload Technical Abstract (TechAbs.pdf) as Attachment 3.		
	Upload Lay Abstract (LayAbs.pdf) as Attachment 4.		
	Upload Statement of Work (SOW.pdf) as Attachment 5.		
	Upload Military Benefit (MilBen.pdf) as Attachment 6.		
	Upload Impact Statement (Impact.pdf) as Attachment 7.		
	Upload Innovation Statement (Innovation.pdf) as Attachment 8.		
	Upload Transition Plan (Transition.pdf) as Attachment 9.		
Attachments Form (as applicable)	Upload Human Subject Recruitment and Safety Procedures (HumSubProc.pdf) as Attachment 10.		
	Upload Data Management Statement (Data_Manage.pdf) as Attachment 11.		
	Upload Study Personnel and Organization Statement (Personnel.pdf) as Attachment 12.		
	Upload Intervention Statement (Intervention.pdf) as Attachment 13.		
	Upload Surveys, Questionnaires, and Other Data Collection Instruments (Surveys.pdf) as Attachment 14.		
	Upload IND/IDE Documentation Form (IND/IDE.pdf) as Attachment 15.		

Grants.gov Application Components	Action	Single PI or Initiating PI Completed	Each Partnering PI Completed
Research & Related Senior/Key Person Profile (Expanded)	Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field.		
	Attach PI 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 Current & Pending Support (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.		