

# **Program Announcement**

**For**

**Defense Health Program (DHP)**

**Defense Medical Research and Development Program (DMRDP)**

**Department of Defense (DoD)**

**Assisted by**

**Combat Casualty Care Research Program (CCCRP)**

**and**

**Joint Program Committee 6 (JPC 6)**

## **Psychological Health and Traumatic Brain Injury Research Program**

**Traumatic Brain Injury Research Award (TBIRA)**

**Funding Opportunity Number: W81XWH-12-PHTBI-TBIRA**

**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), September 21, 2012
- **Invitation to Submit an Application:** by October 19, 2012
- **Application Submission Deadline:** 11:59 p.m. ET, December 3, 2012
- **Peer Review:** January 2013
- **Programmatic Review:** March 2013

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## I. FUNDING OPPORTUNITY DESCRIPTION

### A. Program Description

Applications to the Fiscal Year 2012 (FY12) Psychological Health and Traumatic Brain Injury (PH/TBI) Research Program (RP) are being solicited for the Assistant Secretary of Defense for Health Affairs, Defense Health Program (DHP) by the United States Army Medical Research Acquisitions Activity (USAMRAA). The PH/TBI Research Program was established in FY07 for the purpose of complementing ongoing Department of Defense (DoD) efforts toward 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, their family members, Veterans, and other beneficiaries of the Military Health System (MHS).

The Defense Medical Research and Development Program (DMRDP) expects to fund up to five FY12 PH/TBI RP Traumatic Brain Injury Research Award (TBIRA) 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, \$4.8M in FY12 funds are available. The executing agent for this announcement is the Office of the Congressionally Directed Medical Research Programs (CDMRP).

### B. Award Information

**Overview:** The PH/TBI RP TBIRA mechanism is being offered for the first time in FY12. This funding mechanism encourages research efforts focused on knowledge gathering and geared toward solving specific questions. The TBIRA mechanism **DOES NOT ALLOW Clinical Trials**. The intent of the TBIRA mechanism is to:

- promote new/innovative ideas that are still in the early stages of development and have the potential to yield highly impactful data and new avenues of investigation to further the research field of interest;
- advance knowledge regarding the theoretical construct surrounding the TBI Research Area of interest to increase scientific understanding of certain phenomena or behaviors;
- propose new paradigms or challenging existing paradigms; and
- address the technical feasibility of promising new products, pharmacologic agents, behavioral and rehabilitation interventions, diagnostic and therapeutic techniques, clinical guidance, and/or emerging approaches and technologies.

**Research Area:** All applications to the FY12 PH/TBI RP TBIRA mechanism **MUST** specifically address the Research Area listed below:

- **Identify and Characterize Mechanisms of Traumatic Brain Injury-related Neurodegenerative Diseases** including chronic traumatic encephalopathy, with

emphasis on those mechanisms of injury that may be amenable to targeted therapy approaches, including biomarkers that would identify mechanistic targets of therapeutic approaches.

***Applications focused on research areas other than the one listed above should NOT be submitted in response to this Program Announcement/Funding Opportunity. If the proposed research is not relevant to the advertised Research Area, the government will administratively withdraw the application.***

**DoD Collaboration and Alignment Encouraged:** Military relevance 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 Animal Study Models:** Introduction of any new animal models will require clear justification.

**Partnering PI Option:** The TBIRA mechanism encourages applications that include meaningful and productive collaborations between two investigators. The Partnering PI Option under the TBIRA mechanism is structured to accommodate two PIs who will each receive a separate award. One partner is identified as the Initiating PI and the other PI is identified as the Partnering PI. The Initiating and Partnering PIs have different submission requirements; however, both PIs should contribute to the preparation of a single application. The collaborative partners may have expertise in similar or disparate scientific disciplines, but each partner is expected to bring different strengths to the project. New collaborations are encouraged, but not required. It is the responsibility of the collaborating investigators to describe how their combined expertise synergizes to better address the research question and explain why the work should be done together rather than through separate efforts. The PIs are expected to be equal partners in the research.

### **C. Eligibility Information**

- Independent investigators at all academic levels (or equivalent).
- Each individual may submit only one pre-application as a PI or Initiating PI, and each individual may be named as Partnering PI on only one pre-application.
- Cost sharing/matching is not an eligibility requirement.
- Refer to the General Application Instructions, Appendix 1, for general eligibility information.

### **D. Data Sharing**

The DoD intends that data and research resources generated via this award mechanism be made available to the research community (which includes both scientific and consumer advocacy communities) and to the public at large. At a minimum, required data elements will be reported utilizing the National Institute of Neurological Disorders and Stroke TBI Common Data Elements (CDE) (see <http://www.commondataelements.ninds.nih.gov>). If the proposed research is not compatible with the required CDEs, the investigators must supply a detailed justification why these measures will not be incorporated into the research. Additionally, reporting is required via the Federal Interagency Traumatic Brain Injury Research ([fitbir.nih.gov/tbi-portal/](http://fitbir.nih.gov/tbi-portal/)) data repository quarterly, and others as appropriate. Specific requirements will be detailed with the Invitation to Submit an Application in October 2012.

### **E. Funding**

#### **Applications with a single PI**

- The maximum period of performance is 3 years
- The maximum allowable direct costs for the entire period of performance are \$500,000 plus indirect costs.

- All direct and indirect costs of any subaward (subgrant or subcontract) must be included in the total direct costs of the primary award.
- Regardless of the period of performance proposed, the applicant may not exceed the maximum allowable direct costs. Indirect costs shall be proposed in accordance with the organization's negotiated rate agreement.
- The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum 3 years.

### **Applications with Partnering PIs**

- The maximum allowable direct costs for the entire period of performance are increased to \$600,000 plus indirect costs.
- 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. Direct cost funding should be divided accordingly, unless otherwise warranted and clearly justified.

Refer to the General Application Instructions, Section II.C., for budget regulations and instructions for the Research & Related Budget. In addition, for this award mechanism, direct costs:

#### **Must be** requested for Travel costs:

- Each PI 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 program reviews will be held in the National Capitol Region for approximately 2 days.
- In addition, each PI must request travel funds, up to \$1,800, to attend one DoD-sponsored meeting during the award period of performance.

#### **May be** requested for (not all-inclusive):

- Salary
- Research supplies
- Equipment
- Travel between collaborating organizations
- Travel costs of up to \$1,800 per year to attend scientific/technical meetings

Intramural (DoD) and extramural investigators are encouraged to apply to this Program Announcement/Funding Opportunity. Funding cannot be applied toward government or federal salaries. Therefore, intramural investigators wishing to submit independently, or with an extramural partner must have a non-federal organization submit the application. In addition, non-DoD federal agency investigators wishing to submit independently, or with an extramural partner, must have a non-federal organization submit the application.

Direct transfer of funds to a government organization or agency is not allowed except under very limited circumstances.

***The DoD DHP Joint Program Committee 6( JPC-6) expects to allot up to \$4.8M to fund approximately 5 TBIRA 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 multi-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/>).

**Partnering PI Option:** The TBIRA mechanism is structured to accommodate up to two PIs. When there are two 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 will be identified as the Partnering PI. 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 the Partnering PI. The Partnering PI will then be notified separately by email. The 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. The letter will provide the information necessary to begin application submission thru grants.gov.

### **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-12-PHTBI-TBIRA.

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

All pre-application components must be submitted 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. `

**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 a change in PI or organization is necessary after submission of the pre-application, the PI must contact the CDMRP Help Desk at [help@cdmrp.org](mailto:help@cdmrp.org) or 301-682-5507.

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**

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

- **Partnering PI Option:** The Initiating PI must enter the contact information for the 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. The Preproposal Narrative should include the following:

- **Rationale:** Present the ideas and reasoning behind the proposed study, to include relevant literature citations. State how this project meets the intent of the award mechanism and the intent of the program.
- **Hypothesis or Objective:** State the hypothesis to be tested or the objective to be reached.
- **Research Strategy:** Concisely state the project's objective and specific aims. Describe the proposed methods and how they will accomplish the project's aims.
- **Research Area:** Explain how the proposed work addresses the required research area.
- **Military Benefit:** State explicitly how the proposed work will have an impact on the health care needs of warriors, veterans, families, caregivers, and/or communities related to military-relevant TBI issues.

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

- **Quad Chart:** This document must be submitted by the pre-application submission deadline. The Quad Chart is a PowerPoint file that must be downloaded from the CDMRP eReceipt System and saved using Adobe Acrobat Reader as a PDF file. The Quad Chart must include the following sections:
  - Objective(s)
  - Research Area
  - Problem and Relevance: Provide a bulleted summary of the problem to be studied and its relevance to the FY 12 TBIRA Research Area.

- Proposed Solution: Provide a bulleted summary of the objectives of the work based on the Preproposal Narrative.
- Picture: Insert a picture/graphic that is representative of the work to be done; this may, for example, show some aspect of the research to be performed.
- Timeline and Cost: Identify the major planned activities or phases of the work and their duration on the chart provided and provide the estimated direct costs by year.
- **References Cited** (five-page limit): List relevant references using a standard reference format including the full citation (i.e., author(s), year published, and title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate). The inclusion of Internet URLs to references is encouraged.
- **PI and Key Personnel Biographical Sketches** (four-page limit per individual):
- **Submit Pre-Application – Tab 5:** Must be completed for the pre-application to be accepted and processed by CDMRP.
- **Other Documents Tab:** No additional documents are required.

**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 FY 12 TBIRA mechanism, pre-applications will be screened based on adherence to the intent of the award mechanism.

- **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-applications.

The Pre-application notification date 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 Single 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/>).

For the TBIRA, additional application components are also required and should be submitted as directed below.

***Partnering PI Option: The CDMRP requires separate Grants.gov application package submissions for the Initiating PI and the Partnering PI. Initiating and Partnering PI will 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 Initiating PIs under the Partnering PI Option:**

**Grants.gov application package components:** For the FY12 TBIRA, 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 (ten page limit):** Upload as “ProjectNarrative.pdf.”
    - Describe the proposed project using the following outline:
    - **Background:** Present the ideas and reasoning behind the proposed work. Cite relevant literature and any available preliminary data. Describe previous experience most pertinent to this 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 study design, methods, and analyses, including appropriate controls, in sufficient detail for analysis. Address potential problem areas and present alternative methods and approaches
    - **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.
    - **Military Benefit:** Describe how the proposed studies build on the research goals in order to maximally benefit the target population(s). Describe how the studies will have impact on accelerating the movement of promising treatments for the target Research Area.
    - **Study Personnel:** Describe the background and expertise of investigators. Briefly describe their roles on the project.
  - **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 component unless otherwise noted. Include only those components described below; inclusion of items not requested may result in administrative rejection 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-owned facilities or equipment are proposed for use. Reference should be made to the original or present 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) (two-page limit per letter): Provide a letter (or letters, if applicable), signed by the Department Chair or appropriate organization official, reflecting the laboratory space, equipment, and other resources available for the project.
- Letters of Collaboration (if applicable) (two-page limit per letter): Provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed work.
- Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations.
- **Attachment 3: Technical Abstract (one-page limit):** Upload as “TechAbs.pdf.”
  - Use 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 (if applicable): Briefly describe how the proposed project is innovative.
  - Military Benefit: Briefly explain the applicability of the proposed research to the FY 12 TBIRA Research Area and describe how the proposed project will have an immediate or potential long term impact on the health and well being of service members, veterans, and their family members.

- **Attachment 4: Lay Abstract (one-page limit):** Upload as “LayAbs.pdf”  
Clearly describe, in a manner readily understood by lay persons, the rationale and objective for the proposed project. Do not duplicate the technical abstract.
  - Describe the ultimate applicability and impact of the research.
  - Describe the potential ultimate applicability and impact of the research on the target population.
- **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.

***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 should be noted for each task.***

- **Attachment 6: Military Benefit Statement (one-page limit):** Upload as “MilitaryBenefit.pdf.”
  - Describe how the studies will have impact on accelerating the movement of promising treatments for the FY12 TBIRA Research Area.
  - Describe how the proposed research addresses the FY12 TBIRA Research Area.
  - Describe how the proposed project, if successful, will lead to immediate advancements and/or have the potential to significantly accelerate progress in the FY12 TBIRA Research Area.
- **Attachment 7: Innovation Statement [if applicable] (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 aspect of TBI 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.

**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.”
  - Key Personnel Current/Pending Support (no page limit): Upload as “Support\_LastName.pdf.”
- 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 Single (non-partnered) Applications:** The budget cannot exceed \$500,000 for direct costs.
    - **For Partnered Applications:** 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, even if they are at the same organization. The combined direct costs for the Initiating and partnering PI budgets cannot exceed \$600,000.
- 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, if applying under the Partnering PI Option:**

*The Partnering PI must follow the link in the email from CDMRP eReceipt 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 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 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 \$600,000.
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. Organizations are required to provide a Data Universal Numbering System (DUNS) number and register in the Entity Management functional area of the System For Award Management (SAM) 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 compares applications to each other and 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 DoD and the PH/TBI RP TBIRA mechanism. The highest-scoring applications from the first tier of review are not automatically recommended for funding. Additional information about the two-tier review 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. Each level of review requires panelists to sign a non-disclosure statement attesting that application and evaluation information will not be disclosed outside the panel. Violations of the non-disclosure statement can result in the dissolving of a panel(s) and other corrective actions. Organizational personnel and PIs 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 panelists or PIs that compromise the confidentiality of the review process may also result in suspension or debarment of their employing organizations 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 **bolded** scored criteria, which are of equal importance:

- **Military Benefit**
  - How the proposed study addresses the FY12 TBIRA Research Area.
  - The potential contribution of the proposed study to research aligned with the FY12 TBIRP Research Area.
  - The potential immediate or long term benefit of the proposed research on the health and well being of service members, veterans, and their families.
- **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 (if applicable)**
  - 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.

- **Personnel**
  - How the background and expertise of the investigator(s) demonstrate their ability to perform the proposed work.
  - How the levels of effort by the investigator(s) are appropriate to ensure success of this project.
  - How the investigator(s) record(s) of accomplishment demonstrates his/her ability to accomplish the proposed work.
- **Environment**
  - How the scientific environment is appropriate for the proposed research.
  - How the research requirements are supported by the availability of and accessibility to facilities and resources.
  - How the quality and extent of institutional support are appropriate for the proposed research.

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

- **Application Presentation**
  - How the writing and components of the application influenced the review.
- **Budget**
  - Whether the budget is appropriate for the proposed research and within the limitations of the award mechanism.

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

- Adherence to the intent of the award mechanism
- Programmatic relevance in relation to the priorities of the PH/TBI RP TBIRA
- Ratings and evaluations of the peer reviewers
- Relative translational potential (as applicable)
- Military benefit
- Program portfolio composition

### **C. Recipient Qualification**

Refer to the General Application Instructions, Appendix 1, for additional information on organization and Government agency requirements.

## **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 scientific 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 is missing.

The following will result in administrative rejection of the application:

- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.
- Submission of an application for which a letter of invitation was not received.
- Partnering PI Option: Both associated (Initiating and 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.
- 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 FY12 Neurotrauma Steering Committee 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 FY12 Neurotrauma Steering Committee members can be found at [http://cdmrp.army.mil/phtbi/panels/panels12\\_6](http://cdmrp.army.mil/phtbi/panels/panels12_6).
- 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.

## **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 U.S. Army Medical Research Acquisition Activity (USAMRAA) Contracting/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, 2013. 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 and Quad Charts will be required.

## **D. Award Transfers**

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: 1-301-682-5507

Email: [help@cdmrp.org](mailto: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: 1-800-518-4726

Email: [support@grants.gov](mailto:support@grants.gov)

***Sign up on Grants.gov for “send me change notification emails” by following the link on the Synopsis page for the Program Announcement/Funding Opportunity. If the application package is updated or changed, the original version of the application package may not be accepted by Grants.gov.***

**VII. APPLICATION SUBMISSION CHECKLIST: SINGLE (NON-PARTNERED) APPLICATIONS**

<b>Grants.gov Application Components</b>	<b>Action</b>	<b>Completed</b>
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 Statement (MilitaryBenefit.pdf) as Attachment 6.	
	Upload Innovation Statement (Innovation.pdf) as Attachment 7.	
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 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.	
<b>Additional Application Components</b>	<b>Action</b>	<b>Completed</b>
Confidential Letters of Recommendation	Confirm upload to CDMRP eReceipt System.	

**APPLICATION SUBMISSION CHECKLIST: PARTNERED APPLICATIONS**

<b>Grants.gov Application Components</b>	<b>Action</b>	<b>Initiating PI Completed</b>	<b>Partnering PI Completed</b>
SF-424 (R&R) Application for Federal Assistance 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 Statement (MilitaryBenefit.pdf) as Attachment 6.		
	Upload Innovation Statement (Innovation.pdf) as Attachment 7.		
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.		