Program Announcement

for the

Department of Defense

Defense Health Program

Defense Medical Research and Development Program

Combat Casualty Care Research Program/Joint Program Committee 6

Psychological Health and Traumatic Brain Injury Research Program

TBI Endpoints Development Award

Funding Opportunity Number: W81XWH-13-PHTBI-TED

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), December 6, 2013
- **Invitation to Submit an Application:** January 2, 2014
- **Application Submission Deadline:** 11:59 p.m. ET, February 13, 2014
- **Peer Review:** April 2014
- **Programmatic Review:** May 2014

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.

TABLE OF CONTENTS

I. FUNDING OPPORTUNITY DESCRIPTION

A. Program Description

Applications to the Fiscal Year 2013 (FY13) Psychological Health and Traumatic Brain Injury Research Program (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 Research Acquisitions Activity (USAMRAA). The executing agent for this Program Announcement/Funding Opportunity is the Congressionally Directed Medical Research Programs (CDMRP).

The PH/TBI Research Program was initiated 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) and TBI in the areas of prevention, detection, diagnosis, treatment, and rehabilitation. This includes research to benefit Service Members, Veterans, their family members, and other beneficiaries of the Military Health System.

The Combat Casualty Care Research Program (CCCRP) seeks to prevent mortality and reduce morbidities caused by battlefield injuries. The CCCRP is administered as part of the Defense Medical Research and Development Program (DMRDP) with oversight from Joint Program Committee 6 (JPC-6), which consists of DoD and non-DoD medical and military technical experts relevant to the program areas. Areas of focus include hemorrhage and resuscitation, traumatic brain injury (TBI), forward surgical and intensive care, and treatments for tissue injury. The CCCRP works to leverage cutting-edge research and knowledge to address existing and emerging gaps in combat casualty care. Applications from investigators within the military services are highly encouraged, as are applications involving multidisciplinary collaborations among academia, industry, the military services, the Department of Veterans Affairs (VA), and other Federal Government agencies.

B. Award Information

The FY13 PH/TBI Research Program TBI Endpoints Development (TED) Award mechanism supports the establishment of a collaborative, multidisciplinary research team to advance endpoints for use in trials involving diagnosis and treatment of mild to moderate TBI (mTBI to modTBI). While a number of potentially useful endpoints for mTBI to modTBI diagnostics and therapeutics exist, a majority of them have not been validated and qualified for use as a reference measure of diagnostic or therapeutic effectiveness. The TED research team will address a critical need within the TBI research community by developing clinically relevant endpoints that can support regulatory approvals and be applicable for use in research tests and clinical trials. (Please see the draft guidance from the U.S. Food and Drug Administration [FDA] for more information http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM230597.pdf). The goal is to improve diagnosis, treatment, and rehabilitation strategies for mTBI to mod TBI. ***This award is not intended to support the direct development of new TBI therapeutic or diagnostic agents and/or devices.***

The critical components of this award mechanism are:

Research Objectives: To meet the intent of the award mechanism, the proposed research must focus on mTBI to modTBI, as defined by the DoD/VA and noted in the table below.

Table I. DoD/VA definitions for TBI severity [a]

	mTBI	modTBI	Severe TBI
Structural imaging	Normal	Normal or abnormal	Normal or abnormal
Loss of consciousness	0-30 minutes	>30 minute and <24 hours	>24 hours
Alteration of consciousness	Up to 24 hours	>24 hours. Severity based on other criteria.	
Post-traumatic amnesia	Up to 1 day	>1 day and <7 days	>7 days
Glasgow Coma Scale	13-15	9-12	<9

[a] http://www.healthquality.va.gov/mtbi/concussion_mtbi_full_1_0.pdf

Research focused on severe TBI should not be included in the response to this Program Announcement/Funding Opportunity. The research should align with the intent of the National Research Action Plan (NRAP; http://www.whitehouse.gov/sites/default/files/uploads/nrap_for_eo_on_mental_health_august_2013.pdf) in seeking to fill an important gap by providing a sensitive and comprehensive assessment of functional outcomes and quality of life following TBI treatment while also being brief, freely accessible, and reliable. Additional background references and resources that may inform the research objectives can be found in the TBI Endpoints Development Award Reference document at https://cdmrp.org/Program_Announcements_and_Forms/.

The proposed research plan should:

- Develop a phased approach involving key research milestones to identify endpoints that would be acceptable to the FDA in their regulatory review of drugs and devices that are being developed for use in the clinical setting to diagnose or treat mTBI to modTBI.
- Demonstrate a solid understanding of the FDA regulatory review process, including the various regulatory pathways for drugs and devices as well as the FDA pre-submission process designed to aid in the development of clinical trial protocols. It is expected that successful conduct of the research plan will involve substantive communication with the FDA.
- Address endpoints for both diagnostics and therapeutics, which may include specific domains associated with TBI such as balance, vision, cognition, attention, executive function, and behavior.
    - The focus should be on existing primary endpoints and how they relate to potential secondary outcome measures. Patient-reported outcomes are not considered a focus area of this effort.

    - If the proposed study involves development of new TBI direct endpoints, the application must clearly articulate how the proposed study would produce an end product that is significantly more advanced than existing endpoints.
    - Surrogate endpoints that have the potential to support the regulatory pathway may be considered as a secondary objective.
    - Exploratory outcome measures may be proposed if appropriately justified.
    - Investigators may consider advancing proprietary endpoints; however, applications proposing proprietary endpoints must have a well-structured plan to share data and disseminate the research results as well as provide public access for use of any scoring algorithms.
- Outline pilot and large-scale validation studies for selected endpoints. Consideration should be given for endpoints with high feasibility of implementation in regulatory studies.
- Integrate input from a variety of experts to inform study design.
    - Investigators will be required to plan and host two TBI endpoints development-focused workshops (to be held during Stage I) to solicit input from relevant stakeholders into the study plan and future research.
    - Workshops may host up to approximately 150 individuals (per workshop) from appropriate stakeholder communities across multiple disciplines (e.g., experts from measurement, neurotrauma, rehabilitation, systems engineering, regulatory clinical practice, and other relevant communities).
- Include wide dissemination of research results through peer-reviewed publications and presentation/discussions at scientific meetings.

This award is not intended to support the direct development of a new TBI therapeutic or diagnostic agent and/or device.

Collaborative Team: The TED research team should be multidisciplinary and involve collaborations across multiple research institutions to incorporate expertise in areas such as:

- Endpoints and outcome measures
- System-based approaches
- VA research and care domains
- Clinical rehabilitation and care

It is expected that the research team will leverage existing TBI resources, infrastructure, collaborations, and ongoing initiatives including the VA, DoD, other Federal agencies (e.g., National Institutes of Health [NIH], FDA, etc.), and relevant non-Federal entities (e.g., international collaborations, academic institutions, non-profit organizations, and/or industry). Applicants should consider collaborations with personnel affiliated with established TBI resources.

The Principal Investigator (PI) should have demonstrated experience in successfully leading large, focused projects and collaborative efforts. The PI must present a clear plan for how he/she

would manage and facilitate meaningful collaboration among the research team members to enable successful completion of the proposed research. Participating organizations must be willing to resolve potential intellectual and material property issues and remove institutional barriers to achieving high levels of cooperation. The application should include an organizational chart identifying the roles of all team members and the workflow within and between key components. The required Statement of Work (SOW) should indicate specific milestones and how specific aims toward these milestones will be staged or integrated. Key decision points in the organizational/work flow chart and SOW should be clearly defined, and their impact on the overall project should be clear.

Oversight and Options: A Government Steering Committee (GSC) comprised of personnel from the DoD and other Federal agencies (e.g., VA, FDA, NIH) will be established by the U.S. Army Medical Research and Materiel Command (USAMRMC) and provide oversight for the TED research team. The GSC will review progress and provide the collaborative team with scientific and programmatic feedback and guidance on strategic coordination with other relevant initiatives. The GSC will provide approval recommendations regarding proposed selection of endpoints for development and may recommend areas of future focus. The PI and key members of the TED research team must present written and oral briefings to the GSC and USAMRMC staff at twice-yearly 1-day meetings to be held in the National Capital Region. Based on these reports and presentations, the GSC and USAMRMC staff will evaluate progress, provide feedback, and invoke modifications as needed to facilitate the success of the TED research team. The PI is expected to maintain monthly or more frequent contact with a Government-appointed Grants Officer Representative (GOR), who will maintain full documentation of interactions.

The TED Award will be supported in two Stages. Stage I (Years 1-2) will enable the team to lay the groundwork for the research and conduct studies required to advance the most promising endpoints. Stage II (Years 3-5) will allow the expansion of the project to proceed to larger-scale validation studies. Before moving from Stage I to Stage II, the PI and key team members will be required to present an update on progress toward accomplishing the goals of the project at a one-day Milestone Meeting to be held in the National Capital Region. The Milestone Meeting will be held in conjunction with a GSC briefing meeting and attended by members of the GSC, USAMRMC staff, and the USAMRAA Grants Officer. With consideration of GSC and USAMRMC staff recommendations, the final approval for advancing to Stage II will be issued by the USAMRAA Grants Officer.

In addition, five percent of the total costs of the award (Stages I and II) must be reserved (Year 1) in the budget for "seed projects," i.e., the development of new ideas that may emerge during the course of the award. These seed projects should enable the TED research team to explore new high-impact ideas for the development of endpoints that were not part of the original application, but that develop during the project and are within the scope of the overall vision of the research. Applications should include a description of plans to externally peer review and prioritize the most relevant seed projects for review and selection by the GSC. Seed projects must be submitted for GSC review and approval prior to implementation. Details regarding the process for submittal will be outlined in the award document. Funds for seed projects will be restricted for use until approved for release by the Grants Officer and may not be used for equipment or travel. (See Section I.D., Funding below.)

Awards to extramural organizations will be issued as a cooperative agreement. Awards and/or subawards 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 TED research team is encouraged to apply for additional complementary research funding through other DoD award mechanisms and/or award mechanisms offered through other funding agencies during the performance period of this award. It is expected that the team will submit to other agencies for additional funding in order to expand the breadth of research and support the research team's efforts beyond the 5-year performance period of the award.

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 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: This award mechanism highly encourages multidisciplinary and multi-institutional projects to strengthen the research application and achieve the award mechanism objectives. For multi-institutional research, 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.

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

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

Combat Casualty Care Research Program
https://ccc.amedd.army.mil/

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

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

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

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

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

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

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

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

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

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

U.S. Naval Research Laboratory
www.nrl.navy.mil

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

National Institute of Neurological Disorders and Stroke
http://www.ninds.nih.gov

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

Centers for Disease Control and Prevention
http://www.cdc.gov/traumaticbraininjury

American Psychological Association
http://www.apa.org

Brain Injury Association of America
http://www.biausa.org

National Institute on Disability and Rehabilitation Research
http://www2.ed.gov/programs/nidrr

Use of Military and VA Populations or Resources: If the proposed research involves access to Active Duty military and/or VA population(s) and/or resource(s), the PI is responsible for establishing access. If possible, access to target Active Duty military and/or VA patient population(s) should be confirmed at the time of application submission. A letter of support, signed by the lowest ranking person with approval authority, should be included for studies involving Service Members, Veterans, military and/or VA-controlled study materials, and military and/or VA databases. Use Attachment 2 to provide this documentation (see Section II.C., Application Submission Content and Form, Supporting Documentation).

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 have 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 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.

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

C. Eligibility Information

- Independent investigators at all academic levels (or equivalent) are eligible to submit applications.
- Cost sharing/matching is 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.

D. Funding

- The maximum period of performance is **5** years.
- The maximum allowable total (direct and indirect) costs for the entire period of performance are **$17 million** (M) (for Stage I, Stage II, and seed projects).
- 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 total costs. Indirect costs shall be proposed in accordance with the organization's negotiated rate agreement.

- The applicant may request up to **$5M** in total (direct and indirect) costs for Years 1-2 (Stage I). Stage I will be funded using allocations from the FY13 PH/TBI Research Program Congressional appropriation.
- The applicant may request up to **$12M** in total (direct and indirect) costs for option Years 3-5 (Stage II).). The option period may be funded with future Congressional appropriations, if available. A total of one option period may be allowed.
- The combined total costs for Stage I and II will not exceed **$17M**.
- Exercising the option for Stage II will be contingent on receipt of sufficient Congressional appropriations, submission and approval of written progress reports, and acceptable performance of the recipient as determined by the GOR. Milestones outlining acceptable performance in the option period will be finalized during award negotiations and incorporated into the approved SOW. Before moving from Stage I to Stage II, the PI(s) will be required to present an update on progress toward accomplishing the goals of the project at a Milestone Meeting to be held in the National Capital Region. The Milestone Meeting will be attended by members of the GSC, USAMRMC staff, and the USAMRAA Grants Officer. ***Failure to complete each milestone may result in forfeiture of the subsequent installment of TED Award funding.***
- Five percent of the total costs must be allocated and reserved for funding "seed projects," i.e., the development of new ideas that emerge during the course of the award. Direct costs for these seed projects should be allocated into the "other direct cost" category of the Year 1 budget. These funds will be restricted for use until approved for release by the USAMRAA Grants Officer. Funds for seed projects may not be used for equipment or travel.
- The applicant must submit a comprehensive budget, broken down by year, that details the projected funding needed for the entire period of performance, to include Stages I and II and the seed projects.
- 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:

- Travel costs for the PI and up to three key TED research team personnel to attend two GSC review meetings 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 1-2 days.
- Travel for the PI and up to three key TED research team personnel to attend one DoD-sponsored research meeting during the period of performance.

- Costs associated with hosting two TBI endpoints development-focused workshops to be held during Year 1 and Year 2 of the award period of performance.

May be requested for (not all-inclusive):

- Salary of non-Government personnel (includes contract research personnel at Government facilities)
- Research supplies
- Equipment
- Research-related subject costs
- Clinical research costs
- Purchase or support of datasets and/or databases
- Support for multidisciplinary collaborations
- Travel between collaborating organizations
- Travel costs of up to $1,800 per year per person for the PI and up to three key TED research team personnel to attend scientific/technical meetings (in addition to the required meetings described above)

Intramural (DoD) 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 be issued as a cooperative agreement. Awards and/or subawards 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 CCCRP/JPC-6 expects to allot approximately $5M of the FY13 PH/TBI Research Program appropriation to fund Stage I of approximately one TED Award application, depending on the quality and number of applications received. The funding estimated for this Program Announcement/Funding Opportunity is approximate and subject to realignment. Funding of applications received in response to this Program Announcement/Funding Opportunity is contingent upon the availability of federal funds for this program.

II. SUBMISSION INFORMATION

Submission is a two-step process requiring both (1) pre-application submission through the CDMRP eReceipt System (https://cdmrp.org/) and (2) application submission through Grants.gov (http://www.grants.gov/).

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

A. Where to Obtain the Application Package

To obtain the complete application package, including all required forms, perform a Grants.gov (http://www.grants.gov/) basic search using the Funding Opportunity Number: W81XWH-13-PHTBI-TED.

B. Pre-Application Submission Content and Form

All pre-application components must be submitted by the 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.

PIs and organizations identified in the pre-application should be the same as those intended for the subsequent application submission. If any changes are necessary after submission of the pre-application, the PI must contact the CDMRP Help Desk at help@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**

  FY13 CCCRP Neurotrauma Steering Committee members should not be involved in any pre-application or application. For questions related to FY13 CCCRP Neurotrauma Steering Committee members and pre-applications or applications, refer to Section IV.C., Withdrawal, or contact the CDMRP Help Desk at help@cdmrp.org or 301-682-5507.

- **Required Files – Tab 4**

  Pre-Application Narrative (three-page limit): The Pre-Application Narrative page limit applies to text and any figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, and cartoons. Inclusion of URLs that provide additional information to expand the Pre-Application Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the

application. ***Note: At this time, eReceipt is unable to read files made with Adobe Acrobat PDFMaker version 9.0 and higher.***

The Pre-Application Narrative should include the following:

- **Rationale:** State the ideas and reasoning on which the proposed research is based. Describe how the preliminary data and rationale support the research idea. State how this project meets the intent of the award mechanism.
- **Hypothesis or Objective:** State the hypothesis to be tested or the objective to be reached.
- **Research Strategy:** Clearly describe the research being proposed. Concisely state the project's objectives, specific aims, and ultimate endpoints. Describe the proposed methods and how they will accomplish the project's aims.
- **Personnel:** Briefly state the qualifications of the PI and collaborators/key personnel to perform the described project. Outline the overall organization of the research team and each team member's role in the project.
- **Military Benefit:** Describe how the proposed work would impact the health care needs of Service Members and/or Veterans recovering from TBI as well as their families, caregivers, and/or communities.

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 Pre-Application Narrative using a standard reference format that includes the full citation (i.e., author(s), year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).
- **List of Abbreviations, Acronyms, and Symbols:** Provide a list of abbreviations, acronyms, and symbols used in the Pre-Application Narrative.
- **PI and Key Personnel Biographical Sketches** (four-page limit per individual).
- **Quad Chart:** The Quad Chart template is a one-page PowerPoint file that must be downloaded from the CDMRP eReceipt System at https://cdmrp.org/Program_Announcements_and_Forms/, completed, and saved as a PDF file using Adobe Acrobat Reader.

- **Submit Pre-Application – Tab 5**

  This tab must be completed for the pre-application to be accepted and processed by the 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 DHP, the DMRDP, and the CCCRP, pre-applications will be screened based on the following criteria:

  - **Research Plan:** How well the proposed project addresses the intent of the award mechanism and the program. To what degree the rationale, objectives, and specific aims support the research idea. Whether the proposed methodology is appropriate.
  - **Personnel:** How the qualifications and expertise of the PI and key personnel are appropriate to perform the proposed work.
  - **Military Benefit:** How the proposed work would ultimately benefit the health care needs of Service Members and/or Veterans recovering from TBI as well as their families, caregivers, and/or communities.

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

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

C. Application Submission Content and Form

Applications will not be accepted unless the 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/).

Grants.gov application package components: For the FY13 PH/TBI Research Program TED Award, the Grants.gov application package includes the following components (refer to the General Application Instructions, Section II.C., for additional information on application submission):

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

2. **Attachments Form**

   - **Attachment 1: Project Narrative (20-page limit):** Upload as "ProjectNarrative.pdf." The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings, etc.) used to describe the project. Inclusion of URLs that provide additional information to expand the Project Narrative and could confer an

unfair competitive advantage is prohibited and will result in administrative withdrawal of the application.

Describe the proposed project in detail using the outline below.

- **Background:** Present the ideas and reasoning behind the proposed work. State how the proposed work meets the intent of the FY13 PHTBI Research Program TED Award. Cite relevant literature and pilot or preliminary data (if available).
- **Objectives/Specific Aims/Hypotheses:** Provide a description of the purpose and objectives of the study with detailed specific aims and/or study questions/hypotheses.
- **Research Strategy:** Describe the experimental design, methods, and analyses including appropriate controls in sufficient detail for analysis. Present a detailed plan that identifies critical milestones, outlines the collaborations and technical solutions that will be implemented to accomplish the milestones, and explains how the ultimate outcomes will be translated to individuals affected by traumatic brain injury. Address potential problem areas and present alternative methods and approaches.
  - Describe how the research strategy supports regulatory considerations.
  - Include a plan for investigator-hosted workshops.
  - Describe how the study would address various domains (e.g., vision, hearing, pain, balance, etc.) relating to diagnostic and therapeutic mTBI to modTBI endpoints.
  - Propose a framework for developing and executing pilot studies (Stage I).
  - Propose the framework and rationale for a larger-scale validation study that may be executed as an option to the work (Stage II).
  - Outline a strategic plan for wide-dissemination of the research results and materials of this study and discuss integration within the appropriate regulatory processes (e.g., FDA utilization).
- **Research Team and Environment:** Describe how the PI's research experience and leadership skills make him/her well-qualified to coordinate this effort. Discuss the qualifications of the multidisciplinary research team and how it will provide the appropriate expertise necessary to address the research question. Include an organizational chart identifying the roles of all team members. Describe how the collaborative team will leverage existing efforts relating to TBI endpoint measures. Present an overall management plan to facilitate group interactions, data and material sharing, adherence to regulatory requirements, administrative support, and oversight. Describe the research environment(s) and how the facilities and resources will support the research requirements and the project.
- **Statistical Plan and Data Analysis:** Describe the statistical model and data analysis plan with respect to the study objectives as appropriate to type of study. For clinical studies or trials, specify the approximate number of human subjects

that will be enrolled. If multiple study sites are involved, state the approximate number to be enrolled at each site. Include a complete power analysis to demonstrate that the sample size is appropriate to meet the objectives of the study.

- **Attachment 2: Supporting Documentation.** Start each document on a new page. Combine and upload as a single file named "Support.pdf." If documents are scanned to pdf, the lowest resolution (100 to 150 dpi) should be used. ***There are no page limits for any of these components unless otherwise noted. Include only those components described below; inclusion of items not requested may result in the removal of those items or administrative withdrawal of the application.***
  - References Cited: List the references cited (including URLs if available) in the project narrative using a standard reference format that includes the full citation (i.e., author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).
  - List of Abbreviations, Acronyms, and Symbols: Provide a list of abbreviations, acronyms, and symbols.
  - Facilities, Existing Equipment, and Other Resources: Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate whether or not Government-furnished facilities or equipment are proposed for use. If so, reference should be made to the original or present Government award under which the facilities or equipment items are now accountable. There is no form for this information.
  - Publications and/or Patent Abstracts (five-document limit): Include relevant publication URLs and/or patent abstracts. If publications are not publicly available, then a copy/copies of the published manuscript(s) must be included in Attachment 2. Extra items will not be reviewed.
  - Letters of Organizational Support (two-page limit per letter): Provide a letter (or letters, if applicable), signed by the Department Chair or appropriate organization official, confirming the laboratory space, equipment, and/or other resources available for the project.
  - Letters of Collaboration (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. Address any existing history of collaboration and/or collaborations that leverage ongoing TBI initiatives.
  - Letter(s) of Support for Use of Military and VA Populations or Resources (if applicable) (two-page limit per letter): Provide a letter(s) signed by the lowest ranking person with approval authority for studies involving Service Members, Veterans, military and/or VA-controlled study materials, and military and/or VA databases.
  - Intellectual and Material Property Plan:

- Provide a list of all background intellectual property relevant to the project. Identify any proprietary information that will be provided to the Government and whether the applicant will require a waiver of Government purpose rights; ***and***
- 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 expectations for making data and research resources publically available. Include plans for utilizing the NINDS 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 in the pre-application. If no changes have been made to the project, the same Quad Chart submitted with the pre-application may be used.

- **Attachment 3: Technical Abstract (one-page limit):** Upload as "TechAbs.pdf."

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

  - Background: State how the proposed research addresses the intent of the FY13 PH/TBI Research Program TED Award. Present the ideas and reasoning behind the proposed work.
  - Objective/Hypothesis: State the objective/hypothesis to be tested. Provide evidence or rationale that supports the objective/hypothesis.
  - Specific Aims: State the specific aims of the study.
  - Study Design: Briefly describe the study design, including appropriate controls.
  - Military Benefit: Briefly explain how the proposed project will have an immediate or potential long-term impact on the health and well-being of Service Members, Veterans, and/or their family members.

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

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

  - Describe the objectives and rationale for the application in a manner that will be readily understood by readers without a background in science or medicine.
    - Do not duplicate the technical abstract.

- Describe the ultimate applicability of the research.
  - What types of patients will it help, and how will it help them? (Include the current available statistics to the related injury/condition.)
  - What are the potential clinical applications, benefits, and risks?
  - What is the projected timeline it may take to achieve the expected patient-related outcome?
- Briefly describe how the proposed project will benefit Service Members, Veterans, and/or their family members.

- **Attachment 5: Statement of Work (SOW) (four-page limit):** Upload as "SOW.pdf." Refer to the General Application Instructions, Section II.C., for detailed information, including guidance on appropriate SOW formats.
  - Include a SOW that covers the work proposed for the entire period of performance, to include Stages I and II. Indicate specific milestones, and how specific aims toward these milestones will be staged or integrated. SOWs for seed projects should not be submitted with the application; they should be submitted to the GSC for review, approval, and release of funds as they emerge.
- **Attachment 6: Military Benefit (one-page limit):** Upload as "MilBen.pdf."
  - Describe how the proposed study is responsive to the health care needs of Service Members and Veterans recovering from traumatic injury. Provide information about the incidence and/or prevalence of the disease or condition to be studied in Service Members and/or Veterans, if appropriate and available. Show how the proposed study complements ongoing DoD and VA areas of research interest.
  - If active duty military and/or Veteran population(s) will be used in the proposed research project or clinical trial, 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: Transition Plan (one-page limit).** Upload as "Transition.pdf." Provide information on the methods and strategies proposed to move the product to the next phase of research or delivery to the military or civilian market after successful completion of the award. The transition plan should include the components listed below.
  - Details of the funding strategy that will be used to bring the endpoints to the next level (e.g., specific potential industry partners, specific funding opportunities to be pursued, coordination with appropriate regulatory agencies).
  - A description of collaborations and other resources that will be used to provide continuity of development.
  - A brief schedule and milestones for bringing the outcome(s) to the next level.

- The involvement of appropriate intellectual property, licensing, and/or business professionals.
- A risk analysis for cost, schedule, manufacturability, and sustainability.

- **Attachment 8: Human Subject Recruitment and Safety Procedures (if applicable; required for all studies recruiting human subjects; no page limit):** Upload as "HumSubProc.pdf." The Human Subject Recruitment and Safety Procedures attachment should include the components listed below.

  a. Study Population: Describe the target population (to whom the study findings will be generalized) and the nature, approximate number, and pertinent demographic characteristics of the accessible population at the study site (population from whom the sample will be recruited/drawn). Demonstrate that the research team has access to the proposed study population. Furthermore, discuss past efforts in recruiting human subjects from the target population for previous clinical trials (if applicable). Address any potential barriers to accrual and plans for addressing unanticipated delays. Include justification of any age, race, ethnicity, or sex limitations provided.

  b. Inclusion/Exclusion Criteria: List the inclusion and exclusion criteria for the proposed clinical trial. Inclusion/exclusion criteria should take into consideration the specific risk profile of the studies to be conducted and the standard of care for that patient population. Provide detailed justification for exclusions.

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

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

  - Describe the recruitment process in detail. Address who will identify potential human subjects, who will recruit them, and what methods will be used to recruit them.
  - Include a detailed description of and justification for the compensation plan if the human subjects will be compensated for participation in the study.
  - Describe the recruitment and advertisement materials. The recruitment materials should not be coercive or offer undue inducements and should accurately reflect the study.

  d. Description of the Informed Consent Process: Specifically describe the plan for obtaining informed consent from human subjects.

- ***For the proposed study, provide a draft, in English, of the Informed Consent Form.***
- Identify who is responsible for explaining the study, answering questions, and obtaining informed consent. Include a plan for ensuring that human subjects' questions will be addressed during the consent process and throughout the trial.
- Include information regarding the timing and location of the consent process.
- Address issues relevant to the mental capacity of the potential human subject (e.g., altered capacity due to administration of any mind-altering substances such as tranquilizers, conscious sedation or anesthesia, brain injury, stress/life situations, or human subject age), if applicable.
- Address how privacy and time for decision making will be provided and whether or not the potential human subject will be allowed to discuss the study with anyone before making a decision.
- Consider the need for obtaining ongoing consent or for re-assessing capacity over the course of a long-term study and describe any relevant procedures to assure continued consent.
- Describe the plan for the consent of the individual's Legally Authorized Representative (LAR) to be obtained prior to the human subject's participation in the study. State law defines who may act as the LAR. The local IRB of record should be consulted for guidance regarding who can serve as LAR for research at the study site. Note: The PI must describe a clear intent to benefit for human subjects who cannot give their own consent to participate in the proposed clinical trial to be in compliance with Title 10 United States Code Section 980 (10 USC 980) (http://www.gpo.gov/fdsys/pkg/USCODE-2011-title10/pdf/USCODE-2011-title10-subtitleA-partII-chap49-sec980.pdf). If applicable, please refer to the General Application Instructions, Appendix 5, for more information.
- ***Assent.*** If minors or other populations that cannot provide informed consent are included in the proposed clinical trial, a plan to obtain assent (agreement) from those with capacity to provide it, or a justification for a waiver of assent, should be provided. PIs should consult with their local IRB to identify the conditions necessary for obtaining assent.

e. Screening Procedures: List and describe any evaluations (e.g., laboratory procedures, history, or physical examination) that are required to determine eligibility/suitability for study participation and the diagnostic criteria for entry. Please note that some screening procedures may require a separate consent or a two-stage consent process. Informed consent must be obtained prior to initiation of any procedures for the purpose of determining eligibility.

f. Risks/Benefits Assessment:

- **Foreseeable risks:** Clearly identify all study risks. Study risks include any risks that the human subject is subjected to as a result of participation in the clinical trial. Consider psychological, legal, social, and economic risks as well as physical risks. If the risks are unknown, this should be stated. If applicable, any potential risk to the study personnel should be identified.
- **Risk management and emergency response:**
  - Describe all safety measures to minimize and/or eliminate risks to human subjects and study personnel or to manage unpreventable risks. Include safeguards and planned responses such as dose reduction or stopping criteria based on toxicity grading scales or other predetermined alert values.
  - Discuss the overall plan for provision of emergency care or treatment for an adverse event for study-related injuries, to include who will be responsible for the cost of such care.
  - Address any special precautions to be taken by the human subjects before, during, and after the study (e.g., medication washout periods, dietary restrictions, hydration, fasting, pregnancy prevention).
  - Describe any special care (e.g., wound dressing assistance, transportation due to side effects of study intervention impairing ability to drive) or equipment (e.g., thermometers, telemedicine equipment) needed for human subjects enrolled in the study.
- **Potential benefits:** Describe known and potential benefits of the study to the human subject, a specific community, or society.

- **Attachment 9: Data Management (if applicable; required for research involving human subjects; no page limit):** Upload as "Data_Manage.pdf." The Data Management attachment should include the components listed below.

a. Data Management: Describe all methods used for data collection to include the following:

- **Identifiers:** Describe the unique identifiers or specific code system to be used to identify human subjects, if applicable.
- **Confidentiality:**
  - Explain measures taken to protect the privacy of study human subjects and maintain confidentiality of study data. Strategies to protect the privacy and confidentiality of study records, particularly those containing identifying information, should be addressed.
  - Address who will have access to study records, data, and specimens, including an acknowledgment that representatives of USAMRMC are eligible to review study records.

- Address requirements for reporting sensitive information to state or local authorities.

- **Disposition of data:** Describe where data (both electronic and hard copy) will be stored, who will keep the data, how the data will be stored, and the length of time data will be stored.
- **Sharing study results:** In cases where the human subject could possibly benefit medically or otherwise from the information, explain whether or not the results of screening and/or study participation will be shared with human subjects or their primary care provider, to include results from any screening or diagnostic tests performed as part of the study.

b. Laboratory Evaluations:

- **Specimens to be collected, schedule, and amount.** All specimens that will be collected for study purposes must be clearly stated. The collection schedule and amount of material collected must also be clearly described.
- **Evaluations to be made.** Describe all evaluations that will be made for study purposes. Explain how the results of laboratory evaluations will be used to meet the objectives of the study (or to monitor safety of human subjects).
- **Storage.** Describe specimen storage, to include location of storage, how long specimens will be stored, any special conditions required, labeling, and disposition. Outline the plan to store specimens for future use to include considerations for informed consent and providing human subjects with an opportunity to decline participation in the study.
- **Labs performing evaluations and special precautions.** Identify the laboratory performing each evaluation, as well as any special precautions that should be taken in handling the samples. Special precautions that should be taken by the human subject before, during, or after the laboratory procedure should be clearly defined. If transport of samples is required, describe provisions for ensuring proper storage during transport.

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 Previous/Current/Pending Support (no page limit): Upload as "Support_LastName.pdf."
   - Key Personnel Biographical Sketches (four-page limit each): Upload as "Biosketch_LastName.pdf."
   - Key Personnel Previous/Current/Pending Support (no page limit): Upload as "Support_LastName.pdf."

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

- Budget Justification (no page limit): Upload as "BudgetJustification.pdf."
- Include a budget and justification that covers the work proposed for the entire period of performance, to include Stages I and II.

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.

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 Office of the Assistant Secretary of Defense for Health Affairs, based on technical merit, the relevance to the mission of the DHP, DMRDP, and the CCCRP 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 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. 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 in decreasing order of importance:

   - **Research Strategy and Feasibility**
     - How the preliminary data (if available) and scientific rationale supports the research project, if available.
     - How well the hypotheses or objectives, aims, experimental design, methods, and analyses are developed and integrated into the project and how well they address the need(s) described.
     - How well the research plan identifies critical milestones, outlines the collaborations and technical solutions that will be implemented to accomplish the milestones (including required workshops), and explains how these solutions will ultimately be translated to individuals with traumatic brain injury.
     - How well the application addresses endpoints for multiple domains (e.g., vision, hearing, pain, balance, etc.) relating to mTBI to modTBI endpoints.
     - How well the application outlines pilot and large-scale validation studies for selected endpoints.
     - How well the PI acknowledges potential problems and addresses alternative approaches.
     - How well the PI demonstrates an understanding of FDA regulatory review requirements.
     - If applicable, how the PI describes the population(s) of interest, demonstrates access to these populations, has a viable plan for recruitment of appropriate subjects, and identifies sampling methods to gain a representative sample from the population(s) of interest.
     - How well plans for addressing ethical and regulatory considerations have been developed.
     - How well the PI has outlined a plan for management and sharing of research data and resources in addition to dissemination of study results as appropriate for the type of study.
   - **Military Benefit**
     - The potential immediate or long-term benefit and impact of the proposed research on the health and well-being of Service Members, Veterans, and/or their families or communities.

- **Statistical Plan**
  - To what degree the statistical model and data analysis plans are suitable for the planned study.
  - How the statistical plan, including sample size projections and power analysis, is adequate for the study and all proposed correlative studies.
- **Transition Plan**
  - Whether the funding strategy described to bring the outcome(s) to the next level of development and/or delivery to the military or civilian market is appropriate.
  - Whether appropriate collaborations and other resources for providing continuity of development and dissemination of results are established and/or well described.
  - How the schedule and milestones for bringing the outcome(s) to the next level of development are appropriate and feasible.
  - How well the potential risk analysis for cost, schedule, manufacturability, and sustainability is developed.
  - How well the application identifies intellectual property ownership, describes any appropriate intellectual and material property plan among participating organizations (if applicable), and addresses any impact of intellectual property issues on product development and subsequent Government access to products supported by this Program Announcement/Funding Opportunity.
- **Personnel**
  - Whether the PI(s) has experience in successfully leading large, focused projects and/or collaborative efforts.
  - How the research team's background and expertise demonstrate their ability to perform the proposed work.
  - How well the composition of the research team represents the appropriate multidisciplinary elements necessary to carry out the proposed work.
  - How the levels of effort by the PI and other key personnel are appropriate to ensure success of this project.
- **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 (including collaborative arrangements).
  - How the quality and extent of institutional support are appropriate for the proposed project.
  - How existing collaborations or funded efforts may be leveraged to support the proposed work.

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

- **Budget**
  - Whether the budget is appropriate for the proposed research and within the limitations of this Program Announcement/Funding Opportunity.
  - Whether the cost estimate for the option period is appropriate for a large-scale validation study.
- **Application Presentation**
  - To what extent the writing, clarity, and presentation of the application components influenced the review.

2. **Programmatic Review:** To make funding recommendations, the following criteria are used by programmatic reviewers:
   - **Ratings and evaluations of the peer reviewers**
   - **Relevance to the mission of the DHP, DMRDP, and the CCCRP as evidenced by the following:**
     - Adherence to the intent of the award mechanism
     - Military relevance
     - Program portfolio composition
     - Relative impact

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 the CDMRP eReceipt System or applications from Grants.gov, the following administrative actions may occur:

A. Rejection

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

- Pre-Application Narrative exceeds page limit.
- Pre-Application Narrative is missing.

The following will result in administrative rejection of the application:

- Submission of an application for which a letter of invitation was not received.
- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.
- Submission of the same research project to different funding opportunities within the same program and fiscal year.

B. Modification

- Pages exceeding the specified limits will be removed prior to review for all documents other than the Pre-Application Narrative and 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 FY13 CCCRP JPC-6 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 FY13 CCCRP JPC-6 Neurotrauma Steering Committee members can be found at http://cdmrp.army.mil/phtbi/panels/panels13_6.
- The application does not conform to this Program Announcement/Funding Opportunity description to an extent that precludes appropriate review.

- Total 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.

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 and updated quad charts will be required.

Attendance and presentation of progress reports at regular GSC and established Milestones Meetings will be required.

D. Award Transfers

The institutional transfer of an award is strongly discouraged and in some cases may not be allowed. Approval of a transfer request will be on a case-by-case basis at the discretion of the Grants Officer.

Refer to the General Application Instructions, Appendix 4, Section 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	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 Transition Plan (Transition.pdf) as Attachment 7.	
	Upload Human Subject Recruitment and Safety Procedures (HumSubProc.pdf) as Attachment 8.	
	Upload Data Management (Data_Manage.pdf) as Attachment 9.	
Research & Related Senior/Key Person Profile (Expanded)	Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field.	
	Attach PI Previous/Current/Pending Support (Support_LastName.pdf) to the appropriate field.	
	Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field.	
	Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person to the appropriate field.	
Research & Related Budget	Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field.	
Project/Performance Site Location(s) Form	Complete form as instructed.	
R & R Subaward Budget Attachment(s) Form	Complete form as instructed.	