

Program Announcement

for the

Defense Health Program

Defense Medical Research and Development Program

Department of Defense

Assisted by

Combat Casualty Care Research Program

and

Joint Program Committee 6

Psychological Health and Traumatic Brain Injury Research Program

Traumatic Brain Injury Research Award

Funding Opportunity Number: W81XWH-13-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), February 27, 2013
- **Invitation to Submit an Application:** By April 11, 2013
- **Application Submission Deadline:** 11:59 p.m. ET, May 30, 2013
- **Peer Review:** To Be Determined
- **Programmatic Review:** To Be Determined

This Program Announcement is one of two documents with instructions to prepare and submit an application for this funding opportunity. Refer also to the General Application Instructions, available for downloading from Grants.gov.

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I. FUNDING OPPORTUNITY DESCRIPTION

A. Program Description

Applications to the Fiscal Year 2013 (FY13) Psychological Health and Traumatic Brain Injury (PH/TBI) Research Program (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 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, 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 six FY13 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. As of the release date of this Program Announcement/Funding Opportunity, the FY13 Defense Appropriations Bill has not been passed and there is no guarantee that any funds will be made available to support this Program Announcement/Funding Opportunity. The potential funding estimated for this Program Announcement/Funding Opportunity is approximate and subject to change. Up to \$12 million (M) in FY13 funds may be available, of which \$9M is expected to be reserved for approximately three clinical studies and \$3M may be reserved for approximately three applied and or mechanistic (pre-clinical) studies. The executing agent for this Program Announcement/Funding Opportunity is the Office of the Congressionally Directed Medical Research Programs (CDMRP).

B. Award Information

Overview: The PH/TBI RP TBIRA funding mechanism encourages research efforts focused on knowledge gathering and geared toward solving specific questions. The intent of the FY13 PH/TBI RP TBIRA mechanism is to:

- Promote new/innovative ideas that 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 devices, behavioral and rehabilitation interventions, therapeutic techniques, clinical guidance, and/or emerging approaches and technologies.

Research Area: All applications to the FY13 PH/TBI RP TBIRA mechanism *must* specifically address the Research Area listed below:

Translation/Clinical Research Area:

Development of interventions or therapies to protect and/or restore neuronal function following TBI in the acute (first week), subacute (>1 week to 3 months), and chronic (\geq 3 months from time of injury) phases of care. Neuronal function, commonly referred to as “neuroplasticity,” is defined by D.G. Stein in *Brain Injury Medicine Principles and Practice (Demos Medical Publishing 2007)* as referring to “verifiable examples of functional and adaptive recovery after brain injury.” Additionally, the concept of structural plasticity is included, as studies have shown that functional and adaptive changes occur via structural changes in or between neurons and glia.

Plasticity-driven solutions should demonstrate maintenance or improvement of function, as applicable, until such point that less or no further intervention is required. Such solutions should be non-invasive, as in not requiring implantation or other invasive procedures to execute.

Applications should be designed to:

- Provide objective evidence of induction of structural and functional changes in the brain following TBI that correlate with improved functional outcomes;
- Maximize functional outcomes, as well as define the mechanisms involved in the structural and functional improvements; and
- Validate methods to objectively assess structural and functional recovery. It is recognized that in some cases it may not be possible to precisely define mechanisms or to conduct testing in an animal model. In such cases, objective measures of improvement in the human condition are paramount.

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 Department of 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/>

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>

Uniformed Services University of the Health
Sciences
<http://www.usuhs.mil/>

Center for Neuroscience and Regenerative
Medicine
<http://www.usuhs.mil/cnrm/>

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

Navy and Marine Corps Public Health
Center
<http://www.nmcpbc.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. (For example, do not propose to develop an animal model for TBI unless it is demonstrably necessary to have a new model in order to describe a specific mechanism. The fact that one's lab doesn't have "x" model and wishes to have "x" model is not sufficient given the number and locations of labs with validated TBI models. In such cases, collaborations are recommended.)

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

FITBR 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 FITBR's Global Unique Identifier (GUID) system facilitates repeated and multi-user access to data without the need to personally identify data sources. FITBR 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 FITBR 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 FITBR informatics system. If the proposed research data cannot be entered as in CDE format, the investigators must supply a proposal for an alternative data submission or data sharing vehicle and justification for use. Use of the TBI CDEs is required wherever possible in an effort to create standardized definitions and guidelines about the kinds of data to collect and the data collection methods that should be used in clinical studies of TBI.

C. Eligibility Information

- Independent investigators at all academic levels (or equivalent) are eligible.
- Cost sharing/matching is desirable but not an eligibility requirement.
- Organizations that are eligible to apply include those in the national, international, public, private, military, and civilian sectors. For all federal organizations, applications must be submitted through a non-federal organization. Both intramural (i.e., DoD) 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 **3** years.
- The maximum allowable total costs for the entire period of performance are \$3M inclusive of indirect costs for clinical studies including clinical trials and \$1M inclusive of indirect costs for applied and or mechanistic studies (the government reserves the right to determine if funding is appropriate to type of study) .
- 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 the entire maximum funding amount for a project that may have a period of performance less than the maximum 3 years.

Refer to the General Application Instructions, Section II.C., for budget regulations and instructions for the Research & Related Budget. ***For all federal organizations, special budget restrictions apply and are so 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(s) 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.
- Travel costs for the PI(s) to attend one DoD-sponsored meeting. Costs associated with travel to this meeting, up to \$1,800, should be included in Year 2 of the budget. For planning purposes, it can be assumed that the meeting will be held in the National Capitol Area. These travel costs are in addition to those allowed for annual scientific/technical meetings.

May be requested for (not all-inclusive):

- Salary
- Research supplies
- Clinical research costs
- Equipment
- Support for multidisciplinary collaborations
- Travel between collaborating organizations
- Travel costs of up to \$1,800 per year to attend scientific/technical meetings in addition to the travel costs for the required meeting 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/Funding Opportunity, 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) registration and a Data Universal Numbering System (DUNS) number. Refer to Appendix 3 of the General Application Instructions for further information regarding Grants.gov requirements.

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 \$12M to fund approximately six TBIRA applications, three clinical and three applied and or mechanistic

studies, 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/>).

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 rejection 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-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.

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 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**
- **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:

- **References Cited** (two-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).

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

- **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:**

Pre-applications will be screened based on technical merits, relevance to the DoD mission, and adherence to the intent of the FY13 PH/TBI RP TBIRA mechanism 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 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/>).

Application Components:

Grants.gov application package components: For the FY13 PH/TBI RP 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 (10-page limit):** Upload as “ProjectNarrative.pdf.” The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings, etc.) used to describe the project. Including URLs that provide additional information to expand the Project Narrative and could confer an unfair competitive advantage are prohibited and will result in administrative withdrawal of the application. *Describe the proposed project 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 experimental design, methods, and analyses including appropriate controls in sufficient detail for analysis. Address potential problem areas and present alternative methods and approaches.

For Clinical Trials:

- Identify intervention to be tested and describe the projected outcomes.
- Define the study variables and describe how they will be measured. Include a description of appropriate controls and the endpoints to be tested.
- Describe the methods that will be used to recruit a sample of human subjects from the accessible population (e.g., convenience, simple random, stratified random).

- Describe the human subject-to-group assignment process (e.g., randomization, block randomization, stratified randomization, age-matched controls, alternating group, or other procedures), if applicable. Explain the specific actions to accomplish the group assignment (e.g., computer assignment, use of table of random numbers).
- o **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 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.***
 - o 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).
 - o List of Abbreviations, Acronyms, and Symbols: Provide a list of abbreviations, acronyms, and symbols.
 - o Facilities, Existing Equipment, and Other Resources: Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate if Government-furnished facilities or equipment are proposed for use. If so, reference should be made to the original or present Government award under which the facilities or equipment items are now accountable. There is no form for this information.
 - o 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.
 - o 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.
 - o 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.
 - o Intellectual and Material Property Plan (if applicable):

- 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/or*
 - Provide a plan for resolving intellectual and material property issues among participating organizations; *and/or*
 - Describe the commercialization plan, if applicable. The plan should include intellectual property, market size, financial analysis, strengths and weaknesses, barriers to market, competitors and management team. Discuss the significance of this development effort, when it can be anticipated, and the potential commercial use for the technology being developed.
- Data 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 National Institute of Neurological Disorders and Stroke TBI CDEs (see <http://www.commondataelements.ninds.nih.gov>). If the proposed research is not compatible with the required CDEs, the investigators must supply a justification as to why these measures will not be incorporated into the research. Additionally, reporting is required via the FITBIR (<http://fitbir.nih.gov/tbi-portal/>) data repository quarterly. The Government reserves the right to identify additional data sharing requirements and or repositories for submission of data for archive.
- **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 FY13 PH/TBI RP 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.
- **Attachment 6: Military Benefit Statement (one-page limit):** Upload as “MilitaryBenefit.pdf.”
 - Describe how the studies will have impact on accelerating the development of promising interventions or treatments for the FY13 PH/TBI RP 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 FY13 PH/TBI RP TBIRA Research Area.
- **Attachment 7: Innovation Statement (one-page limit):** Upload as “Innovation.pdf.”

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

 - Study concept: Investigation of a novel idea and/or research question that could have a significant impact on the 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.
- **Attachment 8: Transition Plan (one-page limit).** Upload as “Transition.pdf.”

Provide information on the methods and strategies proposed to move the product to the next phase of research or delivery to the military or civilian market after successful completion of the award. The transition plan should include the components listed below.

 - Details of the funding strategy that will be used to bring the outcomes to the next level (e.g., specific potential industry partners, specific funding opportunities to be pursued).
 - A description of collaborations and other resources that will be used to provide continuity of development.
 - A brief schedule and milestones for bringing the outcome(s) to the next level.
 - The involvement of appropriate intellectual property, licensing, and/or business professionals.

- A risk analysis for cost, schedule, manufacturability, and sustainability.
- **Attachment 9: Intervention (for Clinical Trials):** Upload as “Intervention.pdf.” The Intervention attachment should include the components listed below.
 - a. **Description of the Intervention:** The description of the intervention should include the following components as appropriate to the type of intervention: complete name and composition of medication or device, storage and handling information, source, dose, schedule, administration route, washout period, duration of the intervention, and concomitant medications allowed.

Summarize key preclinical findings that examine the safety of the intervention. Information on treatment safety, including anticipated side-effects, and any antidotes or available treatments should also be provided. Description of devices should include detailed operational instructions, any potential risks to users, and intended benefits. Other types of interventions should be fully described. If applicable, provide documentation of submission for IND/IDE or approved IND/IDE number.
 - b. **Study Procedures:** Describe the interaction with the human subject to include the study intervention that he/she will experience. Provide sufficient detail in chronological order for a person uninvolved in the study to understand what the human subject will experience. Provide a schedule (e.g., flowchart or diagram) of study evaluations and follow-up procedures. Discuss how compliance with Good Clinical Practices, Good Manufacturing Practices, and other regulatory considerations will be established, monitored, and maintained, as applicable.
- **Attachment 10: IND/IDE Documentation (if applicable):** If submitting multiple documents, start each document on a new page. Combine and upload as a single file named “IND-IDE.pdf.”
 - Complete the IND/IDE Documentation Form, which is available for download on the Full Announcement page for this Program Announcement/Funding Opportunity on Grants.gov.
 - If an IND or IDE is required for this study, an application must be submitted to the FDA prior to grant submission. If an IND or IDE has been submitted, an explanation of the status of the IND or IDE should be provided (e.g., past the critical 30-day period, pending response to questions raised by the Agency, on clinical hold). Inclusion of a copy of the Agency meeting minutes is encouraged but not required. If an IND or IDE is not required for the proposed study, provide evidence in the form of communication from the FDA or the IRB of record to that effect.
- **Attachment 11: Data Management (if applicable):** 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 providers, 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.
- **Laboratories performing evaluations and special precautions.** Identify the laboratory performing each evaluation, as well as any special precautions that should be taken in handling the samples. Special precautions that should be taken by the human subject before, during, or after the laboratory procedure should be clearly defined. If transport of samples is required, describe provisions for ensuring proper storage during transport.

- **Attachment 12: Human Subject Recruitment and Safety Procedures (for Clinical Trials):** Upload as “HumSubProc.pdf.” The Human Subject Recruitment and Safety Procedures attachment should include the components listed below.
 - a. **Study Population:** Describe the target population (to whom the study findings will be generalized) and the nature, approximate number, and pertinent demographic characteristics of the accessible population at the study site (population from which the sample will be recruited/drawn). Demonstrate that the research team has access to the proposed study population. Furthermore, discuss past efforts in recruiting human subjects from the target population for previous clinical trials (if applicable). Address any potential barriers to accrual including those specific to recruitment from military and/or Veteran populations (if applicable). Provide 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. Ensure that the compensation plan is fair and does not provide undue inducement. If the study requires multiple visits, a plan for pro-rating payments in the event of human subjects’ withdrawal should be considered.
 - Describe the recruitment and advertisement materials. The recruitment materials should not be coercive or offer undue inducements and should accurately reflect the study.
 - Include a description of any considerations unique to recruitment from military or Veterans medical treatment facilities, if applicable.
 - 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. Ensure that the benefits are not overstated. ***NOTE: Payment and/or other compensation for participation are not considered to be benefits and must be addressed in a separate section.***

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 direct and indirect costs combined, the budget cannot exceed \$3M for clinical studies or \$1M for applied/mechanistic studies.
- 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 subaward 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 compares applications to each other and makes recommendations for funding to the Commanding General, U.S. Army Medical Research and Materiel Command (USAMRMC), for concurrence, and then to the Office of the Assistant Secretary of Defense for Health Affairs for final approval based on technical merit, the relevance to the mission of the DHP and 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. Panel members sign a non-disclosure statement certifying 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. 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 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 FY13 PH/TBI RP TBIRA Research Area.
- The potential contribution of the proposed study to research aligned with the FY13 PH/TBI RP TBIRA 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, recruitment of appropriate subjects, and identifies sampling methods to gain a representative sample from the population(s) of interest.
- How well the statistical plan, including sample size projections and power analysis, is adequate for the study.
- How well a transition plan has been formulated to take the research to the next level taking into consideration a future funding strategy, collaborations, and milestones.
- For studies utilizing human subjects, how well plans for addressing ethical and regulatory considerations have been developed.
- How well the PI has outlined a plan for management of research data as appropriate for type of study.

- **Innovation**

- How the research proposes new paradigms or challenges existing paradigms in one or more of the following ways: concept or question, research methods or

technologies, adaptations of existing methods or technologies, and clinical interventions.

- How the proposed research represents more than an incremental advance upon published data.
- How the potential gain justifies the perceived risk.

- **Personnel**

- How the background and expertise of the investigator(s) demonstrate his/her 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**

- To what extent the writing, clarity, and presentation of the application components influenced the review.

- **Budget**

- Whether the budget is appropriate for the proposed research and within the limitations of this Program Announcement/Funding Opportunity.

2. Programmatic Review: To determine the application's relevance to the mission of the DoD, DMRDP, 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 DMRDP
- 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 peer review summary statement on the strengths and weaknesses of the application.

IV. ADMINISTRATIVE ACTIONS

After receipt of pre-applications from CDMRP eReceipt or applications from Grants.gov, the following administrative actions may occur:

A. Rejection

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

- Preproposal Narrative exceeds page limit.
- Preproposal Narrative is missing.

The following will result in administrative rejection of the application:

- 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.

B. Modification

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

C. Withdrawal

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

- A FY13 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 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 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, 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 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

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

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

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 Statement (MilitaryBenefit.pdf) as Attachment 6.	
	Upload Innovation Statement (Innovation.pdf) as Attachment 7.	
	Upload Transition Plan (Transition.pdf) as Attachment 8.	
	Upload Intervention (Intervention.pdf) , if applicable, as Attachment 9.	
	Upload IND/IDE Documentation (IND-IDE.pdf), if applicable, as Attachment 10.	
	Upload Data Management (Data_Manage.pdf), if applicable, as Attachment 11.	
	Upload Human Subject Recruitment and Safety Procedures (HumSubProc.pdf), if applicable, as Attachment 12.	
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.	