

Program Announcement

for the

Defense Health Program

Defense Medical Research and Development Program

Psychological Health/Traumatic Brain Injury Research Program

Department of Defense

Congressionally Directed Medical Research Programs

Clinical and Rehabilitative Medicine Research Program/Joint Program Committee 8

Neurosensory and Rehabilitation Research Award

Funding Opportunity Number: W81XWH-14-CRMRP-NSRRA

Catalog of Federal Domestic Assistance Number: 12.420

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application Deadline:** 5:00 p.m. Eastern time (ET), December 10, 2014
- **Invitation to Submit an Application:** January 5, 2015
- **Application Submission Deadline:** 11:59 p.m. ET, February 13, 2015
- **End of Application Verification Period:** 5:00 p.m. ET, February 17, 2015
- **Peer Review:** April 2015
- **Programmatic Review:** May 2015

The CDMRP eReceipt System has been replaced with the electronic Biomedical Research Application Portal (eBRAP). Principal Investigators and organizational representatives should register in eBRAP as soon as possible. All pre-applications must be submitted through eBRAP. In addition, applications submitted through Grants.gov will now be available for viewing, modification, and verification in eBRAP prior to the end of the application verification period.

This Program Announcement/Funding Opportunity is one of two documents with instructions to prepare and submit an application for this funding opportunity. The second document, the General Application Instructions, is available for downloading from Grants.gov.

TABLE OF CONTENTS

I. Funding Opportunity Description.....	3
A. Program Description	3
B. Award Information.....	3
C. Eligibility Information	10
D. Funding	10
II. Submission Information	12
A. Where to Obtain the Application Package.....	13
B. Pre-Application Submission and Content Form	13
C. Application Submission Content and Forms	15
D. Verification of Grants.gov Application in eBRAP	25
E. Submission Dates and Times	26
F. Other Submission Requirements.....	26
III. Application Review Information	26
A. Application Review and Selection Process.....	26
B. Application Review Process	26
C. Recipient Qualification	29
D. Application Review Dates	29
E. Notification of Application Review Results	29
IV. Administrative Actions.....	29
A. Rejection	29
B. Modification.....	30
C. Withdrawal.....	30
D. Withhold	31
V. Award Administration Information.....	31
A. Award Notice	31
B. Administrative Requirements	31
C. National Policy Requirements	31
D. Reporting.....	31
E. Award Transfers.....	32
VI. Agency Contacts.....	32
A. CDMRP Help Desk.....	32
B. Grants.gov Contact Center.....	32
VII. Application Submission Checklist.....	33

I. FUNDING OPPORTUNITY DESCRIPTION

A. Program Description

Applications to the Fiscal Year 2014/2015 (FY14/15) Defense Medical Research and Development Program (DMRDP) and Psychological Health/Traumatic Brain Injury Research Program (PH/TBIRP) are being solicited for the Defense Health Agency, Research, Development, and Acquisition (DHA RDA) Directorate, by the U.S. Army Medical Research Acquisition Activity (USAMRAA). As directed by the Office of the Assistant Secretary of Defense for Health Affairs, the DHA RDA Directorate manages and executes the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriation. The executing agent for this Program Announcement/Funding Opportunity is the Congressionally Directed Medical Research Programs (CDMRP).

The goal of the DMRDP is to advance the state of medical science in those areas of most pressing need and relevance to today's battlefield experience. The objectives of the DMRDP are to discover and explore innovative approaches to protect, support, and advance the health and welfare of military personnel, families, communities, and the general public; to accelerate the transition of medical technologies into deployed products; and to accelerate the translation of advances in knowledge into new standards of care for injury prevention, treatment of casualties, rehabilitation, and training systems that can be applied in theater or in the clinical facilities of the Military Health System. 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.

The PH/TBIRP mission is to establish, fund, and integrate both individual and multiagency research efforts that will lead to improved prevention, detection, and treatment of PH/TBI. The vision of the PH/TBIRP is to prevent, mitigate, and treat the effects of traumatic stress and traumatic brain injury on function, wellness, and overall quality of life for Service Members as well as their caregivers and families. The DMRDP leverages PH/TBIRP funding to complement core Department of Defense (DoD) research and development funding assigned to study PH and TBI.

The Clinical and Rehabilitative Medicine Research Program (CRM RP) is one of six major program areas within the DMRDP. DMRDP and PH/TBIRP research funding is administered through CRM RP with oversight from Joint Program Committee 8 (JPC-8), which consists of DoD and non-DoD medical and military technical experts relevant to the program area. The CRM RP mission is to focus on definitive and rehabilitative care innovations required to reset our wounded warriors, both in terms of duty performance and quality of life.

B. Award Information

The FY14/15 CRM RP Neurosensory and Rehabilitation Research Award (NSRRA) is intended to support both applied (preclinical) research and clinical trials **addressing TBI** within specific Focus Areas of pain management, hearing loss/dysfunction, balance disorders, tinnitus, vision, or physical rehabilitation. It is the responsibility of the PI to select the appropriate research modality,

applied or clinical trial, for their project. Applications proposing research outside of the Focus Areas listed below should **not** be submitted in response to this Program Announcement.

Applied Research Focus Areas: Applied research is defined as work that refines concepts and ideas into potential solutions with a view toward evaluating technical feasibility of diagnostic and therapeutic techniques, clinical guidance, emerging approaches and technologies, promising new products, and/or pharmacologic agents. To meet the intent of the FY14/15 CRM RP NSRRA mechanism, all applied research applications **must** specifically address one or more of the **TBI-related Focus Areas** listed below.

Pain Management

- **Strategies for management of chronic pain under the care of a clinician in non-deployed settings**
 - Applied research on alternative analgesic drugs
 - Preclinical research, including comparative effectiveness studies, on non-pharmacological therapies, such as integrative medicine and rehabilitative modalities
 - Studies to determine optimal patient populations for various modalities of pain management
 - Studies to evaluate and validate tools for standardized assessment of pain and risk factors for common treatments such as opioids
 - Studies to evaluate methods to increase compliance by providers with Clinical Practice Guidelines (CPGs)
- **Identification of pain generators**
 - Research studies to evaluate novel analgesics and mechanisms of pain in relevant animal models
 - Applied research on non-neuronal cells as they relate to pain
 - Applied research to identify pain biomarkers and their utility
- **Strategies for management of acute pain under the care of a clinician in non-deployed settings**
 - Research to determine acute pain impact on the development of chronic pain
 - Studies to determine the comparative effectiveness of anesthetic/analgesic techniques on pathophysiological processes
 - Preclinical research, including comparative effectiveness studies, on non-pharmacological therapies, such as integrative medicine and rehabilitative modalities

Hearing Loss/Dysfunction, Balance Disorders, and/or Tinnitus

- **Etiology of injury**
 - Studies to better understand the primary/secondary (e.g., mechanical/injury progression) effects of blast exposure on the auditory and vestibular systems
 - Preclinical (non-human primate highly encouraged) research to improve the understanding of the pathophysiology of central auditory processing disorders (CAPDs)
 - Studies evaluating the short- and long-term effects of different types of noise exposure (blast, impulse, intermittent, steady-state) on the auditory and/or vestibular systems
 - Studies to increase the understanding of the mechanisms underlying tinnitus
- **Diagnostics**
 - Studies to develop an objective diagnostic tool for tinnitus
 - Studies to derive a more sensitive, valid, reproducible baseline and post-injury measurement of auditory function
 - Preclinical research focused on improved methods to identify and characterize central auditory processing disorders (CAPDs)
 - Studies to identify biomarkers to aid behavioral testing models in the diagnosis of hearing loss and CAPDs
 - Studies to develop a device capable of accurately measuring hearing in theater
 - Studies to create hardened, mobile devices to test balance that can be administered by corpsman-level medical personnel
 - Studies to identify biomarkers to diagnose inner ear dysfunction
- **Mitigating dysfunction**
 - Studies developing early interventions or rescue treatments for acute sensorineural hearing loss, vestibular injury, and/or tinnitus
 - Studies to define the role and timing of mitigation strategies (e.g., pharmacological approaches, devices, rehabilitative techniques)
 - Mitigation strategies for mechanisms causing conductive hearing loss
- **Restoration and/or rehabilitation**
 - Preclinical research focused on restorative strategies (e.g., hair cell regeneration, stem cells, neural regeneration)
 - Preclinical research on vestibular system molecular/cellular/physiological restoration

- Studies to develop methods to evaluate the interaction between balance/movement and localization/hearing (e.g., conduct localization or speech recognition experiments while moving and maintaining balance)

Vision Dysfunction

- **Mitigation and treatment of visual dysfunction associated with TBI**
 - Screening, evaluation, and diagnosis
 - Treatments (including but not limited to photophobia, light sensitivity, disorders of ocular alignment and motility, disorders of accommodation, difficulties with stereopsis and spatial perception, decreases in visual acuity, visual field loss, visual attention and cognitive processing, and reading difficulties)
 - Diagnostic methods and biomarkers
 - Targeted therapies for gene expression profiles for different parts of the brain and visual system
 - Treatments for traumatic optic neuropathy
 - Novel models for visual dysfunction following blast and concussive trauma

Clinical Trial Research Focus Areas: A clinical trial is defined as a prospective accrual of human subjects where an intervention (e.g., device, drug, biologic, surgical procedure, rehabilitative modality, behavioral intervention, or other) is tested on a human subject for a measurable outcome with respect to exploratory information, safety, effectiveness, and/or efficacy. This outcome represents a direct effect on the human subject of that intervention or interaction. To meet the intent of the FY14/15 CRM RP NSRRA mechanism, all clinical trial research applications *must* specifically address one or more of the **TBI-related Focus Areas** listed below.

Pain Management

- **Strategies for management of chronic pain under the care of a clinician in non-deployed settings**
 - Clinical research, including comparative effectiveness studies, on non-pharmacological therapies, such as integrative medicine and rehabilitative modalities
 - Studies to determine optimal patient populations for various modalities of pain management

Hearing Loss/Dysfunction, Balance Disorders, and/or Tinnitus

- **Diagnostics**
 - Studies to develop standardized metrics for vestibular assessment and monitoring for return to duty (e.g., CPGs, provider and patient mobile applications)

- Studies to develop and/or standardize behavioral testing in the evaluation of hearing loss
- **Restoration and/or rehabilitation**
 - Studies to develop effective rehabilitation strategies for mild TBI (mTBI) patients with auditory/vestibular dysfunction
 - Studies to improve and compare the outcomes of surgical and non-surgical rehabilitative strategies
 - Studies to determine whether training improves auditory function
 - Studies to develop techniques that combine multisensory rehabilitation strategies (e.g., hearing and balance)
 - Studies to evaluate the most effective rehabilitation for single-sided deafness
 - Studies to evaluate and standardize balance rehabilitation techniques
 - Studies to develop acute retraining paradigms for early rehabilitation and return to duty
 - Studies to assess, improve, and/or develop training/therapy/devices to augment or enhance vestibular function

Neuromusculoskeletal Rehabilitation

- Assessment of current clinical standards using interactive computer training for cognitive rehabilitation
- Clinical validation of rehabilitation treatment modes in the mTBI population with multiple functional deficits (e.g., balance, functional vision, and cognition)
- Evaluation of clinical efficacy of service animals in rehabilitation treatment paradigms for patients after mTBI
- Predictive modeling of rehabilitation outcomes with comorbid TBI and limb trauma

Vision Restoration

- **Vision restoration following traumatic injury**
 - Prostheses for the visual system following injury or degeneration

If the proposed study involves the use of a drug or biologic that has not been approved by the U.S. Food and Drug Administration (FDA) for the proposed investigational use, evidence that an Investigational New Drug (IND) application that meets all requirements under the Code of Federal Regulations, Title 21, Part 312 (21 CFR 312) has been submitted or will be submitted to the FDA ***within 180 days of award*** is required. If the investigational product is a device, evidence that an Investigational Device Exemption (IDE) application that meets all requirements under 21 CFR 812 has been submitted or will be submitted to the FDA ***within 180 days of award***, or that the device is exempt from an IDE, is required. The Government reserves the right to withdraw funding if the IND or IDE application has not been submitted to the FDA within 180

days of the DoD award date or if the documented status of the IND or IDE has not been obtained within 12 months of the award date.

Use of Human Anatomical Substances, Human Subjects, or Human Cadavers: All DoD-funded research involving new and ongoing research with human anatomical substances, human subjects, or human cadavers must be reviewed and approved by the U.S. Army Medical Research and Materiel Command (USAMRMC) Office of Research Protections (ORP), Human Research Protection Office (HRPO), in addition to the local Institutional Review Board (IRB) of record. Local IRB approval at the time of submission is *not* required. The HRPO is mandated to comply with specific laws and requirements governing all research involving human anatomical substances, human subjects, or human cadavers that is supported by the DoD. These laws and requirements will necessitate information in addition to that supplied to the IRB. Allow a minimum of 2 to 3 months for HRPO regulatory review and approval processes. Refer to the General Application Instructions, Appendix 6, for additional information.

Multi-Institutional Research: Multi-institutional research projects are encouraged when combining the resources of two or more organizations will strengthen the research application. If the proposed research is multi-institutional, plans for communication and data transfer between the collaborating institutions, as well as how data, specimens, and/or imaging products obtained during the study will be handled, must be included in the Project Narrative. A separate intellectual and material property plan agreed upon by all participating institutions is also required for multi-institutional research. Participating institutions must be willing to resolve potential intellectual and material property issues and to remove any barriers that may interfere with achieving high levels of cooperation to ensure successful completion of this award.

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

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

Clinical and Rehabilitative Medicine
Research Program
<https://crmrp.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 Health Research Center
<http://www.med.navy.mil/sites/nhrc>

Naval Medical Research Center
<http://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
<https://www.nrl.navy.mil/>

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

Use of Military and VA Populations or Resources: If the proposed research involves access to military and/or VA population(s) and/or resource(s), the PI is responsible for establishing access. If possible, access to target 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 military 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).

FITBIR 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 there is no direct charge to users of the FITBIR informatics system, a project estimation tool (<https://fitbir.nih.gov/jsp/contribute/fitbir-costs.jsp>) is available to help estimate costs and manpower needs that may be associated with data submission. 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/) (<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.

Reporting Guidelines: Proposed research projects should adhere to a core set of reporting standards for rigorous study design. The CRM RP strongly encourages investigators to follow the ARRIVE (Animal Research: Reporting *In Vivo* Experiments) guidelines (http://www.elsevier.com/_data/promis_misc/622936arrive_guidelines.pdf). While these standards are written for animal studies, the basic principles of randomization, blinding, sample-size estimation, and data handling derive from well-established best practices in clinical studies and should be applied to those projects as well.

The CRM RP 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 L.

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, 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.
- Eligible investigators must apply through an organization. Organizations eligible to apply include national, international, for-profit, non-profit, public, and private organizations.
- Refer to the General Application Instructions, Appendix 1, for general eligibility information.

D. Funding

For applied research applications:

- The maximum period of performance is **3** years.
- The maximum allowable total costs for the entire period of performance are **\$1.5 million (M)**.
- All direct and indirect costs of any subaward (subgrant or subcontract) must be included in the total direct costs of the primary award.
- The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum **3** years.

- 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.

For clinical trial applications:

- The maximum period of performance is **4** years.
- The maximum allowable total (direct and indirect) costs for the entire period of performance are **\$3M**.
- All direct and indirect costs of any subaward (subgrant or subcontract) must be included in the total direct costs of the primary award.
- The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum **4** years.
- Regardless of the period of performance proposed, the applicant may not exceed the maximum allowable total costs. Indirect costs shall be proposed in accordance with the organization's negotiated rate agreement.

Refer to the General Application Instructions, Section II.C.4., for budget regulations and instructions for the Research & Related Budget. ***For all Federal agencies or organizations collaborating with Federal agencies, budget restrictions apply as are noted in Section II.C.4. of the General Application Instructions.***

For this award mechanism, direct costs:

Must be requested for:

- Travel costs for the PI(s) to attend one program review per year during the award period of performance. For planning purposes, it should be assumed that the meeting will be held in the National Capital Area for approximately 2 days.

May be requested for (not all-inclusive):

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

Intramural (DoD), other Federal agency, and extramural investigators are encouraged to apply to this Program Announcement/Funding Opportunity. An intramural investigator is defined as a DoD military or civilian employee working within a DoD laboratory or medical treatment facility, or working in a DoD activity embedded within a civilian medical center. Intramural

applicants and collaborators are reminded to coordinate receipt and commitment of funds through their respective resource managers. It is permissible for an intramural investigator to be named as a collaborator on an application submitted by an extramural investigator. ***In such cases, the extramural investigator must include a letter from the intramural collaborator's Commander or Commanding Officer that authorizes the involvement of the intramural collaborator.***

As required of all applicants to this Program Announcement/Funding Opportunity, if PIs from Federal agencies submit applications, they must submit through Grants.gov. Therefore, Federal applicants must be familiar with Grants.gov requirements, including the need for an active System for Award Management (SAM) registration and a Data Universal Numbering System (DUNS) number. Refer to Appendix 3 of the General Application Instructions for further information regarding Grants.gov requirements.

Awards to extramural organizations will consist solely of assistance agreements (Cooperative Agreements and Grants). Awards to intramural agencies and other Federal agencies will be executed through the Military Interdepartmental Purchase Request (MIPR) or Funding Authorization Document (FAD) process. Direct transfer of funds from the recipient to a Federal agency is not allowed except under very limited circumstances. Refer to the General Application Instructions, Section II.C.4. Research & Related Budget, for additional information on budget considerations for applications involving Federal agencies.

The CRMRP expects to allot approximately \$19M of the FY14 PH/TBI appropriation to fund approximately 9-10 NSRRA applications, depending on the quality and number of applications received. In addition to the FY14 appropriation, it is anticipated that up to \$19M in FY15 funds may be available to fund approximately 9-10 additional awards. As of the release date of this Program Announcement/Funding Opportunity, the FY15 Defense Appropriations Bill has not been passed and there is no guarantee that any additional funds will be made available to support this program. The funding estimated for this Program Announcement/Funding Opportunity is approximate and subject to realignment. Funding of applications received in response to this Program Announcement/Funding Opportunity is contingent upon the availability of federal funds for this program.

II. SUBMISSION INFORMATION

Submission is a two-step process requiring both (1) pre-application submission through the electronic Biomedical Research Application Portal (eBRAP) (<https://eBRAP.org/>) and (2) application submission through Grants.gov (<http://www.grants.gov/>).

The CDMRP has replaced its eReceipt System with eBRAP. Submission remains a two-step process requiring both pre-application and application submission.

PIs must be registered in eBRAP in order to submit a pre-application and receive notification of the status of a pre-application or application. A key feature of eBRAP is that an organization's representatives and PIs are able to view and modify the Grants.gov application submissions associated with them, but only if the organization, Business Officials, and PIs are registered and affiliated with the organization in eBRAP (see *eBRAP User Guide* at

<https://ebrap.org/eBRAP/public/UserGuide.pdf>). Upon completion of an organization's registration in eBRAP and approval by the CDMRP Help Desk, the organization name will be displayed in eBRAP to assist the organization's business officials and PIs as they register.

Note: Submission of either the pre-application to eBRAP or application to Grants.gov does not require registering an organization and affiliating its Business Officials and PIs in eBRAP; however, the ability to view and modify the Grants.gov application in eBRAP is contingent upon the registration and affiliation. ***Application viewing, modification, and verification in eBRAP is strongly recommended, but not required. The Project Narrative and Budget cannot be changed after the application submission deadline. Any other application component cannot be changed after the end of the application verification period.*** If verification is not completed by the end of the application verification period, the application will be reviewed as submitted through Grants.gov, provided there is no cause for administrative rejection of the application (see [Section IV.A., Rejection](#)).

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-14-CRMRP-NSRRA.

B. Pre-Application Submission and Content Form

All pre-application components must be submitted by the PI through eBRAP (<https://eBRAP.org/>). Because the invitation to submit an application is based on the contents of the pre-application, investigators should not change the title or research objectives after the pre-application is submitted.

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

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

- **Application Information – Tab 1**
- **Application Contacts – Tab 2**
 - It is recommended that PIs identify an Alternate Submitter in the event that assistance with pre-application submission is needed.
 - The Business Official's contact information or an invitation to a Business Official to register in eBRAP is required.
- **Collaborators and Conflicts of Interest (COI) – Tab 3**

FY14/15 CRMRP NSRRA Working Group members should not be involved in any pre-application or application. For questions related to Working Group members and pre-applications or applications, refer to [Section IV.C., Withdrawal](#), or contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507.

- **Required Files – Tab 4**

Notes: *Upload document(s) as individual PDF files unless otherwise noted. eBRAP will not allow a file to be uploaded if the number of pages exceeds the limit specified below.*

Preproposal Narrative (three-page limit): The Preproposal 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 Preproposal Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application.

The Preproposal Narrative should include the following:

- **Rationale:** State the ideas and reasoning on which the proposed applied research or clinical trial is based. Describe how the preliminary data and rationale support the research idea. State how this project meets the intent of the award mechanism.
- **Focus Area:** Note specifically what TBI-related Focus Area(s) the proposed work addresses and whether it involves a clinical trial.
- **Hypothesis or Objective:** State the hypothesis to be tested or the objective to be reached.
- **Research Strategy:** Clearly describe the research or clinical trial being proposed, and indicate the phase of trial and/or class of device and regulatory status as appropriate. 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 key personnel to perform the described research or clinical trial.
- **Military Benefit:** Describe how the proposed work would impact the health care needs of Service Members and/or U.S. Veterans recovering from traumatic injury 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 *must be uploaded as individual documents* and are limited to:

- **References Cited (one-page limit):** List the references cited (including URLs if available) in the Preproposal Narrative using a standard reference format that includes the full citation (i.e., author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).
- **List of Abbreviations, Acronyms, and Symbols:** Provide a list of abbreviations, acronyms, and symbols used in the Preproposal Narrative.
- **Key Personnel Biographical Sketches** (four-page limit per individual).
- **Quad Chart:** The Quad Chart template is a one-page PowerPoint file that must be downloaded from eBRAP 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.

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, DMRDP, PH/TBIRP, and CRM RP, pre-applications will be screened based on the following criteria:

- **Alignment with TBI-related Focus Areas:** How well the project addresses at least one of the FY14/15 CRM RP NSRRA Focus Areas and advances the field of TBI research or patient care.
- **Research Plan:** How well the proposed applied research or clinical trial addresses the intent of the award mechanism and the program. To what degree the rationale, objectives, and specific aims support the research idea. How the endpoints are appropriate for the proposed study. Whether the proposed methodology is appropriate.
- **Personnel:** How the qualifications and expertise of the PI and key personnel are appropriate to perform the proposed research or clinical trial.
- **Military Benefit:** How the proposed work would benefit the health care needs of Service Members and U.S. Veterans recovering from traumatic injury 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 Forms

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/>).

New for FY14: Applications submitted through and validated by Grants.gov will be retrieved and processed by eBRAP to allow for review, modification, and verification. The PI and organizational representatives will receive an email request from eBRAP to review, modify, and verify the application submitted to Grants.gov. During this verification period, the PI may upload missing files (excluding those listed in [Section IV.A., Rejection](#)), replace files, and re-categorize files. These modifications must be completed by the end of the verification period.

Note: Changes to either the Project Narrative or Budget are not allowed in eBRAP; if such changes are required, the entire application package must be submitted through Grants.gov as a “Changed/Corrected Application” with the Previous Grants.gov Tracking ID **prior to the application submission deadline (which occurs earlier than the end of the application verification period).**

Grants.gov application package components: For the FY14/15 CRM RP Neurosensory and Rehabilitation Research 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.
 - **Background:** State the relevance of the applied research or clinical trial to at least one of the FY14/15 CRM RP NSRRA Focus Areas and the relevance to TBI. Present the ideas and reasoning behind the proposed work and explain the applicability of the proposed findings. Cite relevant literature and pilot or preliminary data. Describe previous experience most pertinent to this project.

For clinical trials:

 - Provide a summary of relevant clinical trials and distinguish how the proposed study differs from other relevant or recently completed clinical trials. Include a discussion of any current clinical use of the intervention under investigation, and/or details of its study in clinical trials for other indications (as applicable).
 - Clearly support the choice of study variables and explain the basis for the study questions and/or study hypotheses.
 - **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 the intervention to be tested and describe the projected outcomes.

For clinical trials and applied research involving human subjects:

- Define the study variables and describe how they will be measured. Include a description of appropriate controls and the endpoints to be tested.
- Describe the methods that will be used to recruit a sample 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).
- **Statistical Plan and Data Analysis:** Describe the statistical model and data analysis plan with respect to the study objectives as appropriate to the type of study. For clinical trials and applied research involving human subjects, specify the approximate number of human subjects that will be enrolled. If multiple study sites are involved, state the approximate number to be enrolled at each site. Include a complete power analysis to demonstrate that the sample size is appropriate to meet the objectives 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: Provide a letter (or letters, if applicable), signed by the Department Chair or appropriate organization official, confirming the laboratory space, equipment, and other resources available for the project.
- Letters of Collaboration (if applicable): Provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed work.
- Letter(s) of Support for Use of Military and VA Populations or Resources (if applicable): Provide a letter(s) signed by the lowest ranking person with approval authority for studies involving military Service Members, Veterans, military and/or VA-controlled study materials, and military and/or VA databases.
- Intellectual Property Statement
 - Background and Proprietary Information: All software and data first produced under the award are subject to a Federal purpose license in accordance with applicable DoD Grant and Agreement Regulations (DoDGAR) requirements. Provide a list of all background intellectual property to be used in the project or provide a statement that none will be used. If applicable, state and identify the proprietary information that will be provided to the Government and indicate whether the applicant will require a waiver of the Federal purpose license.
 - Intellectual and Material Property (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations.
- Data and Research Resources Sharing Plan: Describe how data and resources generated during the performance of the project will be shared with the research community. Refer to the General Application Instructions, Appendix 4, Section L, for more information about the CRMRRP expectations for making data and research resources publicly available.
- Current Quad Chart: Provide a current Quad Chart in the same format as in the pre-application. If no changes have been made 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 an FY14/15 CRMRRP NSRRA Focus Area. 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.”
Use the outline below. Do not duplicate the technical abstract. 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.
 - Describe the ultimate applicability of the clinical 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) (three-page limit):** Upload as “SOW.pdf.” Refer to the General Application Instructions, Section II.C.2., for detailed guidance on creating the SOW.

The suggested SOW format and examples specific to different types of research projects are available on the eBRAP “Program Announcement and Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>). For the FY14/15 CRM RP Neurosensory and Rehabilitation Research Award mechanism, use the SOW format example titled “SOW Generic Format.” The SOW must be in PDF format prior to attaching.

- **Attachment 6: Military Benefit (one-page limit):** Upload as “MilBen.pdf.”
 - Describe how the proposed study is responsive to the health care needs of military Service Members and Veterans recovering from traumatic injury. Provide information about the incidence and/or prevalence of the disease or condition to be studied in military Service Members and/or Veterans, if appropriate and available. Show how the proposed study complements ongoing DoD and VA areas of research interest.
 - If active duty military and/or Veteran population(s) will be used in the proposed research project 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.” Describe/discuss the methods and strategies proposed to move the technology or Knowledge Product to the next phase of development (clinical trials, commercialization, and/or delivery to the civilian or military market) after successful completion of the award. The post-award transition plan should include the components listed below.
 - The development and/or commercialization strategy.
 - Details of the funding strategy to transition to the next level of development and/or commercialization (e.g., partners, internal/external funding opportunities to be applied for).
 - For Knowledge Products, a description of collaborations and other resources that will be used to provide continuity of development including proposed development or modification of CPGs and recommendations, provider training materials, patient brochures, and other clinical support tools, scientific journal publications, models, simulations, and applications. A “Knowledge Product” is a non-materiel product that addresses an identified need, topic area, or capability gap, is based on current evidence and research, aims to transition into medical practice, training, tools, or to support materiel solutions (systems to develop, acquire, provide, and sustain medical solutions and capabilities), and educates or impacts behavior throughout the continuum of care, including primary prevention of negative outcomes.
 - A schedule and milestones for transitioning the technology or Knowledge Product to the next level of development, (next-phase clinical trials, transition to industry, delivery to the military or civilian market, incorporation into clinical practice, or approval by the FDA). Include identification of the FDA regulatory strategy (if appropriate).
 - Ownership rights/access to the intellectual property necessary for the development and/or commercialization of products or technologies supported with this award and the government’s ability to access such products or technologies in the future.
 - A risk analysis for cost, schedule, manufacturability, and sustainability.
- **Attachment 8: 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 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 the IND or IDE application is not yet submitted, provide evidence that an IND or IDE will be

submitted within 180 days of award. Examples include a pre-IND or pre-IDE meeting with the FDA, a pre-IND/pre-IDE meeting request to the FDA, or other communication with the FDA. Provide the anticipated date of IND/IDE submission. If an IND or IDE is not required for the proposed study, provide evidence in the form of communication from the FDA or the IRB of record to that effect.

- **Attachment 9: 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 10: Data Management (if applicable; required for all studies recruiting human subjects; no page limit):** Upload as “Data_Manage.pdf.” The Data Management attachment should include the components listed below.
 - a. Data Management:** Describe all methods used for data collection to include the following:
 - **Identifiers:** Describe the unique identifiers or specific code system to be used to identify human subjects, if applicable.
 - **Confidentiality:**
 - Explain measures taken to protect the privacy of study human subjects and maintain confidentiality of study data. Strategies to protect the privacy and confidentiality of study records, particularly those containing identifying information, should be addressed.
 - Address who will have access to study records, data, and specimens, including an acknowledgment that representatives of USAMRMC are eligible to review study records.
 - Address requirements for reporting sensitive information to state or local authorities.

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

b. Laboratory Evaluations:

- **Specimens to be collected, schedule, and amount.** All specimens that will be collected for study purposes must be clearly stated. The collection schedule and amount of material collected must also be clearly described.
 - **Evaluations to be made.** Describe all evaluations that will be made for study purposes. Explain how the results of laboratory evaluations will be used to meet the objectives of the study (or to monitor safety of human subjects).
 - **Storage.** Describe specimen storage, to include location of storage, how long specimens will be stored, any special conditions required, labeling, and disposition. Outline the plan to store specimens for future use to include considerations for informed consent and providing human subjects with an opportunity to decline participation in the study.
 - **Labs performing evaluations and special precautions.** Identify the laboratory performing each evaluation, as well as any special precautions that should be taken in handling the samples. Special precautions that should be taken by the human subject before, during, or after the laboratory procedure should be clearly defined. If transport of samples is required, describe provisions for ensuring proper storage during transport.
- **Attachment 11: Intervention (if applicable; required for clinical trials; no page limit):** Upload as “Intervention.pdf.” The Intervention attachment should include the components listed below.
 - a. **Description of the Intervention:** As applicable, the description of the intervention should include the following components: complete name and composition, storage and handling information, source, dose, schedule, administration route, washout period, duration of the intervention, and concomitant medications allowed.

Summarize key preclinical pharmacological findings, dosage studies, and other clinical studies (if applicable) that examine the safety of the intervention. Description of devices should include detailed operational instructions, any potential risks to users, and intended benefits. Other types of interventions should be fully described.
 - 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.

- 3. Research & Related Senior/Key Person Profile (Expanded):** Refer to the General Application Instructions, Section II.C.3., 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.4., for detailed information.
 - Budget Justification (no page limit): Upload as “BudgetJustification.pdf.”
- 5. Project/Performance Site Location(s) Form:** Refer to the General Application Instructions, Section II.C.5., for detailed information.
- 6. R & R Subaward Budget Attachment(s) Form (if applicable):** Refer to the General Application Instructions, Section II.C.6., for detailed information.

D. Verification of Grants.gov Application in eBRAP

A process has been initiated whereby organizational representatives and PIs can view their applications as submitted through Grants.gov and prior to peer review of the application. This will enable applicants to make modifications prior to scientific and programmatic evaluation of applications, provided the modifications are made by either the end of the application verification period or, for changes to the Project Narrative or Budget, by the application submission deadline.

After application submission to Grants.gov, eBRAP will retrieve and validate the application submission. eBRAP will notify the organizational representatives and PI via email and instruct them to log into eBRAP to review, modify, and verify the application. Files that fail eBRAP validation will be noted in both the email and in the Full Application Files tab. eBRAP does not validate the accuracy or completeness of content in the files. PIs are strongly encouraged to review all application components. If either the Project Narrative or the Budget fail eBRAP validation, an updated Grants.gov application package must be submitted via Grants.gov prior to the application submission deadline, which occurs earlier than the end of the application verification period. ***The Project Narrative and Budget cannot be changed after the application submission deadline. Any other application component cannot be changed after the end of the application verification period.***

E. Submission Dates and Times

All submission dates and times are indicated on the [title page](#) of this Program Announcement/ Funding Opportunity. Pre-application and application submissions are required. Failure to meet either of these deadlines will result in application rejection.

F. 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 DUNS number to submit applications to Grants.gov. The applicant organization must also be registered in the Entity Management functional area of the SAM with an “Active” status to submit applications through the Grants.gov portal. Refer to the General Application Instructions, Appendix 3, for information on Grants.gov requirements.

III. APPLICATION REVIEW INFORMATION

A. Application Review and Selection Process

All applicants are evaluated by scientists, clinicians, and consumer advocates using a two-tier review process. The first tier is 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 DHA RDA Directorate and the Office of the Assistant Secretary of Defense for Health Affairs), based on (a) technical merit and (b) the relevance to the mission of the DHP, DMRDP, PH/TBIRP and CRM RP and to 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 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 Process

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

- **Research Strategy and Feasibility**

- How well the preliminary data and scientific rationale support the research project.
- 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 consistent the methods and procedures are with sound research design.
- How well the PI acknowledges potential problems and addresses alternative approaches.
- How well the PI has outlined a plan for management and sharing of research data as appropriate for the type of study.
- If applicable, how well the animal study (or studies) is designed to achieve objectives, including the choice of model and endpoints/outcome measures to be used.

For clinical trials and applied research involving human subjects:

- How well the PI describes the population(s) of interest, demonstrates access to these populations, has a viable plan for recruitment, consent, screening, and retention of appropriate subjects, and identifies sampling methods to gain a representative sample from the population(s) of interest.
- How well plans for addressing ethical and regulatory considerations have been developed, including mitigation of risk, consideration of privacy issues, and process for obtaining informed consent.
- If applicable, whether there is evidence demonstrating availability of the device/intervention from its source for the duration of the proposed study.

- **Military Benefit**

- The potential immediate or long-term benefit and usability 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 plan 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.

- **Personnel**

- How the background and expertise of the PI and other key personnel demonstrate their ability to perform the proposed research or clinical trial.
- Whether the composition of the research or study team (e.g., study coordinator, statistician) is appropriate.

- How the levels of effort by the PI and other key personnel 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.
- **Transition Plan**
 - Whether the identified next level of development and/or commercialization is realistic.
 - Whether the funding strategy described to bring the technology or Knowledge Product to the next level of development (e.g., specific potential industry partners, specific funding opportunities to be applied for) is reasonable and realistic.
 - Whether the proposed collaborations and other resources for providing continuity of development, including proposed development or modification of CPGs and recommendations, provider training materials, patient brochures, and other clinical support tools, scientific journal publications, models, simulations, and applications are established and/or achievable.
 - Whether the schedule and milestones for bringing the technology or Knowledge Product to the next level of development (next-phase clinical trials, transition to industry, delivery to the military or civilian market, incorporation into clinical practice, or approval by the FDA) are achievable.
 - Whether the potential risk analysis for cost, schedule, manufacturability, and sustainability is realistic and reasonable.
 - 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.
 - Whether the applicant has demonstrated that they have access to all intellectual property rights necessary for development and commercialization and evidence that the government has the ability to access such products or technologies.

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

- **Environment**
 - How the scientific environment is appropriate for the proposed research or clinical trial.
 - How the research or trial 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 project.

- **Budget**
 - Whether the budget is appropriate for the proposed research and within the limitations of this Program Announcement/Funding Opportunity.
- **Application Presentation**
 - To what extent the writing, clarity, and presentation of the application components influence the review.

2. Programmatic Review: To make funding recommendations, the following criteria are used by programmatic reviewers:

- a. **Ratings and evaluations of the peer reviewers**
- b. **Relevance to the mission of the DHP, DMRDP, PH/TBI, and CRMRP, as evidenced by the following:**
 - Adherence to the intent of the award mechanism
 - Military relevance
 - Program portfolio composition
 - Relative impact
 - Transition potential

C. Recipient Qualification

For general information on required qualifications for award recipients, refer to the General Application Instructions, Appendix 1.

D. Application Review Dates

All application review dates and times are indicated on the [title page](#) of this Program Announcement/Funding Opportunity.

E. Notification of Application Review Results

Each PI and organization will receive email notification of posting of the funding recommendation in eBRAP. Each PI will receive a peer review summary statement on the strengths and weaknesses of the application.

IV. ADMINISTRATIVE ACTIONS

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

A. Rejection

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

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

The following will result in administrative rejection of the application:

- Submission of an application for which a letter of invitation was not received.
- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing. *For clinical trial applications:*
- Attachment 9, Human Subject Recruitment and Safety Procedures, is missing.
- Attachment 10, Data Management, is missing.
- Attachment 11, Intervention, is missing.

B. Modification

- Pages exceeding the specific limits will be removed prior to review for all documents other than the Preproposal Narrative and Project Narrative.
- Documents not requested will be removed.
- Following application submission to Grants.gov, the PI will receive an email request from eBRAP to review, modify, and verify the application submitted to Grants.gov. During this verification period, the PI may upload missing documents (excluding those listed in [Section IV.A., Rejection](#)), replace files, and re-categorize files. These modifications must be completed by the end of the application verification period; otherwise, the application will be reviewed as submitted.

C. Withdrawal

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

- A FY14/15 CRM RP NSRRA Working Group member is named as being involved in the research proposed or is found to have assisted in the pre-application or application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting documentation. A list of the FY14/15 CRM RP NSRRA Working Group members can be found at <http://cdmrp.army.mil/dmrpd/panels/NSRRAPanel14>.
- The application fails to conform to this Program Announcement/Funding Opportunity description to the extent that appropriate review cannot be conducted.
- 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

FY14 awards will be made no later than September 30, 2015. FY15 awards will be made no later than September 30, 2016. Refer to the General Application Instructions, Appendix 4, for additional award administration information.

Any assistance instrument awarded under this Program Announcement/Funding Opportunity will be governed by the award terms and conditions, which conform to DoD's implementation of the Office of Management and Budget (OMB) circulars applicable to financial assistance. Terms and conditions of new awards made after December 26, 2014 may include revisions to reflect DoD implementation of new OMB guidance in the Code of Federal Regulations, Title 2, Part 200, "Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards" (2 CFR part 200).

B. Administrative Requirements

Refer to the General Application Instructions, Appendix 4 for general information regarding administrative requirements.

C. National Policy Requirements

Refer to the General Application Instructions, Appendix 5 for general information regarding national policy requirements.

D. Reporting

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

Quarterly technical progress reports and quad charts will be required.

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

E. Award Transfers

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

Refer to the General Application Instructions, Appendix 4, Section M, 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 eBRAP should be directed to the CDMRP Help Desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. ET. Response times may vary depending upon the volume of inquiries.

Phone: 301-682-5507

Email: help@eBRAP.org

B. Grants.gov Contact Center

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

Phone: 800-518-4726

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	Complete form as instructed.	
Attachments Form	Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf."	
	Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf."	
	Technical Abstract: Upload as Attachment 3 with file name "TechAbs.pdf."	
	Lay Abstract: Upload as Attachment 4 with file name "LayAbs.pdf."	
	Statement of Work: Upload as Attachment 5 with file name "SOW.pdf."	
	Military Benefit: Upload as Attachment 6 with file name "MilBen.pdf."	
	Transition Plan: Upload as Attachment 7 with file name "Transition.pdf."	
	IND/IDE Documentation: Upload as Attachment 8 with file name "IND-IDE.pdf", if applicable.	
	Human Subjects Recruitment and Safety Procedures: Upload as Attachment 9 with file name "HumSubProc.pdf", if applicable.	
	Data Management: Upload as Attachment 10 with file name "Data_Manage.pdf", if applicable	
	Intervention: Upload as Attachment 11 with file name "Intervention.pdf", if applicable.	
Research & Related Senior/Key Person Profile (Expanded)	Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field.	
	Attach PI Previous/Current/Pending Support (Support_LastName.pdf) to the appropriate field.	
	Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field.	
	Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person to the appropriate field.	
Research & Related Budget	Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field.	
Project/Performance Site Location(s) Form	Complete form as instructed.	
R & R Subaward Budget Attachment(s) Form	Complete form as instructed.	