I. OVERVIEW OF THE FUNDING OPPORTUNITY

Program Announcement for the Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

Joint Program Committee 8 /
Clinical and Rehabilitative Medicine Research Program

Psychological Health/Traumatic Brain Injury Research Program

Complex Traumatic Brain Injury Rehabilitation Research Clinical Trial Development Award

Announcement Type: Initial

Funding Opportunity Number: W81XWH-18-CTRR-CTDA

Catalog of Federal Domestic Assistance Number: 12.420 Military Medical Research and Development

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application Submission Deadline:** 5:00 p.m. Eastern time (ET), September 24, 2018
- **Invitation to Submit an Application:** October 2018
- **Application Submission Deadline:** 11:59 p.m. ET, December 17, 2018
- **End of Application Verification Period:** 5:00 p.m. ET, December 20, 2018
- **Peer Review:** February 2019
- **Programmatic Review:** April 2019

This Program Announcement must be read in conjunction with the General Application Instructions, version 20180329. The General Applications Instructions document is available for downloading from the Grants.gov funding opportunity announcement by selecting the "Package" tab, clicking "Preview," and then selecting "Download Instructions."

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II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY

***New for 2018*: Application submission by extramural organizations through Grants.gov requires use of the Workspace interface, which separates the application package into individual forms. Applicants must create a Workspace in Grants.gov, complete the required forms, and submit their application Workspace package.**

II.A. Program Description

Applications to the Fiscal Year 2018 (FY18) Psychological Health/Traumatic Brain Injury Research Program (PH/TBIRP) are being solicited for the Defense Health Agency (DHA) J9, Research and Development Directorate, by the U.S. Army Medical Research Acquisition Activity (USAMRAA) using delegated authority provided by United States Code, Title 10, Section 2358 (10 USC 2358). As directed by the Office of the Assistant Secretary of Defense for Health Affairs (OASD[HA]), the DHA manages the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriation. The U.S. Army Medical Research and Materiel Command (USAMRMC) Congressionally Directed Medical Research Programs (CDMRP) provides execution management support for DHP research program areas, including the Joint Program Committee 8/Clinical and Rehabilitative Medicine Research Program (JPC-8/CRMRP). The execution management agent for this Program Announcement is the CDMRP with strategic oversight from the JPC-8/CRMRP.

The PH/TBIRP was established by Congress in FY07 in response to the devastating impact of traumatic brain injury (TBI) and psychological health (PH) issues, including post-traumatic stress disorder (PTSD), on our deployed Service members in Iraq and Afghanistan. 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 issues and TBI. The vision of the PH/TBIRP is to prevent, mitigate, and treat the effects of traumatic stress and TBI on function, wellness, and overall quality of life for Service members as well as their caregivers and families.

The JPC-8/CRMRP seeks to implement long-term strategies to develop knowledge and materiel products to reconstruct, rehabilitate, and provide definitive care for injured Service members. The ultimate goal is to return Service members to duty and improve their quality of life. Additional information about the JPC-8/CRMRP can be found at https://crmrp.amedd.army.mil/.

Through the Complex TBI Rehabilitation Research (CTRR) initiative, the PH/TBIRP and JPC-8/CRMRP seek innovative rehabilitation research that has the potential to make a significant impact on improving the health and well-being of military Service members, Veterans, and other individuals with TBI. The programs challenge the clinical and scientific communities to design innovative research that will foster new directions for, and address neglected issues in, the field of TBI rehabilitation research. Applications from investigators within the military Services, and applications involving multidisciplinary collaborations among academia, industry, the military Services, the Department of Veterans Affairs (VA), and other Federal Government agencies are highly encouraged.

II.A.1. FY18 PH/TBIRP CTRR-CTDA Focus Areas

The FY18 PH/TBIRP Complex TBI Rehabilitation Research – Clinical Trial Development Award (CTRR-CTDA) seeks research focused on potential interventions relevant to the mission of the JPC-8/CRMRP. ***To meet the intent of the award mechanism, applications must be responsive to one or both of the following FY18 PH/TBIRP CTRR-CTDA focus areas:***

1. **Cognitive Rehabilitation:** Supports the development of clinical trials that will evaluate the effectiveness of novel or standard-of-care rehabilitation interventions. Proposed trial should target remediation of cognitive deficits including but not limited to memory, processing speed, or executive functioning after TBI. Applications proposing clinical trial development efforts that address barriers to participation in Service members with TBI are strongly encouraged. Investigators are encouraged to propose pragmatic trial designs that compare both novel and standard-of-care cognitive rehabilitation practices, include diverse (but militarily relevant) populations of study participants, recruit patients from heterogeneous practice settings (e.g., DoD and VA), and collect data across a broad range of functioning including standard-of-care DoD outcome measures. Applications that address one or more of the following treatment elements are encouraged:

    - Optimal cognitive rehabilitation delivery/prescription patterns (to include frequency, intensity, time, and type); optimization, validation, and implementation of manualized treatment approaches; and/or validation of optimal treatment modality type.
        - Strategies should propose cognitive rehabilitation practice solutions that are feasible for integration into DoD cognitive rehabilitation practice patterns.
    - Evaluation of how existing, manualized standard of care interventions may predict successful outcomes for return to productivity, military duty, employment, volunteering, and school.
    - Identification of patient characteristics that affect outcomes and/or effectiveness of therapies.
        - Trials utilizing practice-based evidence or pragmatic trial designs are encouraged.

2. **Exercise Tolerance Testing and Progressive Return to Activity Treatment:** Supports the development of clinical trials leading to new knowledge informing the systematic assessment and treatment of activity-induced post-concussive symptoms (e.g., headache, dizziness, nausea, motion intolerance) for the purpose of expediting return to full function and participation level activities. Competitive applications will propose development of clinical trials assessing both subjective and objective measures of exercise intolerance that can assist providers in quantifying the severity of the patient's symptom response. Proposed clinical trial development efforts should lead to future clinical trials that delineate a systematic approach to progressively return Service members to full function and include treatment parameters and a general exposure progression concept that is sufficient to judge the merits of the approach. Competitive applications will include planning for inclusion of concussed Warfighters as at least one cohort in the study design.

II.B. Award Information

The FY18 PH/TBIRP CTRR-CTDA mechanism is being offered for the first time in FY18 and is intended to support the development of clinical trials focused on TBI rehabilitation interventions in the FY18 PH/TBIRP CTRR-CTDA focus areas described in II.A.1. Development of clinical trials focusing on rehabilitation strategies in patients with mild TBI is highly encouraged. The proposed research must be relevant to active duty Service members, Veterans, and their beneficiaries. It is expected that any research findings will also provide benefit to the general population.

The PH/TBIRP CTRR-CTDA mechanism supports the design and development of the research resources necessary to serve as a foundation for investigator-initiated clinical trials under future PH/TBIRP CTRR-Clinical Trial Award with the potential to develop knowledge and material products for rehabilitation and restoration of function following TBI. Principal Investigators (PIs) should explain how the proposed future clinical trial will inform the development, refinement, and/or revision of existing standards of care, clinical recommendations, or guidelines.

TBI is defined as being caused by (1) a direct blow or impact to the head, (2) a penetrating head injury, or (3) exposure to external forces such as blast waves that disrupt the function of the brain. Not all blows to the head or exposure to external forces result in a TBI. The severity of TBI may range from "mild," a brief change in mental status or consciousness, to "severe," an extended period of unconsciousness or confusion after the injury. Classification of TBI severity can be found in Table 1 of the VA/DoD Clinical Practice Guideline for the Management of Concussion-Mild Traumatic Brain Injury.

The anticipated total (direct and indirect) costs budgeted for the entire period of performance for an FY18 PH/TBIRP CTRR-CTDA will not exceed **$200,000**. Refer to Section II.D.5, Funding Restrictions, for detailed funding information.

Investigators awarded a PH/TBIRP CTRR-CTDA are expected to apply to the PH/TBIRP CTRR-Clinical Trial Award in the program year following completion of their CTDA (i.e., FY18 PH/TBIRP CTRR-CTDA awardees would apply for an FY20/21 or FY21/22 PH/TBIRP CTRR-Clinical Trial Award, if that award is offered). The FY20/21 or FY21/22 PH/TBIRP CTRR-Clinical Trial Award application would include the results of the completed CTDA project. Award of an FY18 PH/TBIRP CTRR-CTDA does not assure funding for a future PH/TBIRP award(s). The funding of FY20/21 or FY21/22 PH/TBIRP CTRR-Clinical Trial Awards will be contingent upon the availability of federal funds for the program and competitive selection. ***Note that if an Investigational New Drug (IND) or Investigational Device Exemption (IDE) is required for the conduct of the proposed future clinical trial, submission of the IND or IDE application to the U.S. Food and Drug Administration (FDA) should occur prior to submitting an application to a PH/TBIRP CTRR-Clinical Trial Award. If applicable, plans for regulatory filings should be included in the CTDA application.***

Important tasks to consider in an FY18 PH/TBIRP CTRR-CTDA application include, but are not limited to:

- Planning for appropriate regulatory approvals (for example, Institutional Review Board [IRB] submissions and FDA submissions such as IND/IDE applications)
- Establishing access to appropriate patient populations or resources
- Composing the research team and initiating collaborations necessary for the proposed future clinical trial
- Developing the research plan and statistical design
- Developing the clinical protocol
- Developing training procedures
- Planning for potential intellectual or material property issues
- Developing a transition plan with associated resources and collaborations to continue to the next phase of research, including involvement of industry partners, if applicable
- Developing a data analysis/statistical plan and/or modeling for adaptive trial design
- Note: Past and current PH/TBIRP CTRR-Clinical Trial Award Program Announcements have required extensive descriptions of clinical trial components. FY18 PH/TBIRP CTRR-CTDA applicants are encouraged to reference the FY18 PH/TBIRP CTRR-Clinical Trial Award Program Announcement to become familiar with its requirements to help direct proposed activities during the CTRR-CTDA period of performance. The FY18 PH/TBIRP CTRR-Clinical Trial Award Program Announcement (W81XWH-18-CTRR-CTA) can be accessed at http://cdmrp.army.mil/funding/.

The FY18 PH/TBIRP CTRR-CTDA does not support actual conduct of a clinical trial. As stated in Section II.H.2.c, Withdrawal, CTRR-CTDA applications that propose a clinical trial in the CTRR-CTDA period of performance may be administratively withdrawn. Investigators seeking funding for a clinical trial should apply to the FY18 PH/TBIRP CTRR-Clinical Trial Award (W81XWH-18-CTRR-CTA).

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 safety, effectiveness, and/or efficacy. This outcome represents a direct effect on the human subject of that intervention or interaction. For more information on clinical trials and clinical research, a Human Subject Resource Document is provided at https://ebrap.org/eBRAP/public/Program.htm.

Research Involving 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 USAMRMC Office of Research Protections (ORP), Human Research Protection Office (HRPO), prior to research implementation. This administrative review requirement is in addition to the local IRB or Ethics Committee (EC) review. Local IRB/EC 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/EC. ***Allow a minimum of 2 to 3 months for HRPO regulatory review and approval processes***. Additional time for regulatory reviews may be needed for clinical studies taking place in international settings. When possible, protocols should be written for research with human subjects and/or human anatomical substances that are specific to the DoD-supported effort outlined in the submitted application as a stand-alone study. Submission to HRPO of protocols involving more than the scope of work in the DoD-funded award will require HRPO review of the entire protocol (DoD and non-DoD funded). DoD human subjects protection requirements may be applied to non-DoD funded work and necessitate extensive revisions to the protocol. Refer to the General Application Instructions, Appendix 1, and the Human Subject Resource Document available on the electronic Biomedical Research Application Portal (eBRAP) "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) for additional information.

If the IRB determines that a trial presents greater-than-minimal risk to human subjects, the DoD requires an independent research monitor with expertise consistent with the nature of the risk(s) identified within the research protocol. If applicable, refer to the General Application Instructions, Appendix 1, for more information on study reporting authorities and responsibilities of the research monitor.

Federal Interagency TBI Research (FITBIR) Informatics System: For proposed future clinical trials that will enroll TBI subjects, the DoD requires that awardees make data available to the TBI research community by depositing de-identified research data into the 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 collaborate with others doing similar research. While use of FITBIR presents 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 costs and manpower needs 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/).

- Global Unique Identifier (GUID): FITBIR encourages collaboration between laboratories, as well as interconnectivity with other informatics platforms. Such community-wide sharing requires common data definitions and standards. 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 the FITBIR GUID system facilitates repeated and multi-user access to data without the need to personally identify data sources. In order to generate a GUID for a subject, the following personally identifiable information (PII) ***must be collected in the proposed research:***

- Complete legal given (first) name of subject a birth
- Complete legal additional name of subject at birth (if subject has a middle name)
- Complete legal family (last) name of subject at birth
- Day of birth
- Month of birth
- Year of birth
- Name of city/municipality in which subject was born
- Country of birth

Note that this PII is never sent to the FITBIR system. PII cannot be extracted from the GUID. Information on GUID compliance with HIPAA regulations can be found at https://fitbir.nih.gov/content/global-unique-identifier.

- Common Data Elements (CDEs): Data elements must be reported using the National Institute of Neurological Disorders and Stroke (NINDS) TBI CDEs or entered into the FITBIR data dictionary as new, unique data elements (UDEs). For the most current version of the NINDS TBI CDEs, see 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. 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. ***Use of UDEs is strongly discouraged and subject to program approval.***

TBI Outcomes Reporting: PIs are highly encouraged to use the Neurobehavioral Symptom Inventory (NSI), a measure of post-TBI symptom severity, and the Patient Global Impression of Change (PGIC), a global outcome measure of patient experience of care. The NSI and PGIC achieved unanimous concurrence by DoD and VA TBI stakeholders in September 2013 as core TBI outcome measures. More information on the NSI and PGIC is available at the respective links below:

NSI: http://dvbic.dcoe.mil/sites/default/files/DVBIC_-_NSI_Information_Paper_Final.pdf

PGIC: http://dvbic.dcoe.mil/sites/default/files/DVBIC_-_PGIC_Information_Paper_Final.pdf

Use of DoD or VA Resources: If the proposed future clinical trial involves access to active duty military patient populations and/or DoD resources or databases, the application must describe the access and ensure that it will be available at the time of the future CTRR-Clinical Trial Award application submission and should develop a plan for maintaining access as needed throughout the proposed future clinical trial. Future access to target active duty military patient population(s) and/or DoD resource(s) or database(s) should be confirmed by obtaining, as part of

the activities of this award, a letter of support signed by the lowest-ranking person with approval authority.

If the proposed future clinical trial involves access to VA patient populations, VA study resources and databases, and/or VA research space and equipment, VA PIs must develop a plan for obtaining and maintaining access throughout the proposed future clinical trial. Future access to VA patients, resources, and/or VA research space should be confirmed by obtaining as part of the activities of this award a letter of support from the VA Facility Director(s) or individual designated by the VA Facility Director(s), such as the Associate Chief of Staff for Research and Development (ACOS/R&D) or Clinical Service Chief. If appropriate, the future application should identify the VA-affiliated non-profit corporation (NPC) as the applicant institution for VA PIs. If the VA NPC is not identified as the applicant institution for administering the funds, award activities should include obtaining a letter from the VA ACOS/R&D confirming this arrangement and identifying the institution that will administer the funds associated with the proposed future clinical trial.

Access to certain DoD or VA patient populations, resources, or databases may only be obtained by collaboration with a DoD or VA investigator who will have a substantial role in the proposed future clinical trial and may not be available to a non-DoD or non-VA investigator if the resource is restricted to DoD or VA personnel. Investigators should be aware of which resources are available to them if the proposed future clinical trial involves a non-DoD or non-VA investigator collaborating with the DoD and/or VA. If access cannot be confirmed at the time of submission of the future CTRR-Clinical Trial Award application, the Government reserves the right to withdraw or revoke funding until the PI has demonstrated support for and access to the relevant population(s) and/or resource(s). Refer to Section II.D.2.b.ii, Full Application Submission Components, for detailed information.

Military Relevance: Collaboration with the DoD and/or VA is encouraged. A list of websites that may be useful in identifying additional information about ongoing DoD and VA areas of research interest or potential opportunities for collaboration can be found in Appendix 2.

The types of awards made under the Program Announcement will be assistance agreements (grants or cooperative agreements). The level of involvement on the part of the Department of Defense (DoD) during project performance is the key factor in determining whether to award a grant or cooperative agreement.

Extramural Organizations: An assistance agreement (grant or cooperative agreement) is appropriate when the Federal Government transfers a "thing of value" to a "state, local government," or "other recipient" to carry out a public purpose of support or stimulation authorized by a law of the United States, instead of acquiring property or service for the direct benefit and use of the U.S. Government. An assistance agreement can take the form of a grant or cooperative agreement. If "no substantial involvement" on the part of the funding agency is anticipated, a grant award will be made (31 USC 6304). Conversely, if substantial involvement on the part of the funding agency is anticipated, a cooperative agreement will be made (31 USC 6305) and the award will identify the specific substantial involvement. Substantial involvement may include collaboration, participation, or intervention in the research to be performed under

the award. The award type, along with the start date, will be determined during the negotiation process.

The CDMRP intends that information, data, and research resources generated under awards funded by this Program Announcement 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 2, Section K.

Awards will be made no later than September 30, 2019. For additional information refer to Section II.F.1, Federal Award Notices.

II.C. Eligibility Information

II.C.1. Eligible Applicants

II.C.1.a. Organization: All organizations, including international organizations, are eligible to apply.

Government Agencies Within the United States: Local, state, and Federal Government agencies are eligible to the extent that applications do not overlap with their fully funded internal programs. Such agencies are required to explain how their applications do not overlap with their internal programs.

As applications for this Program Announcement may be submitted by extramural and intramural organizations, these terms are defined below.

Extramural Organization: An eligible non-DoD organization. Examples of extramural organizations include academic institutions, biotechnology companies, foundations, Government, and research institutes.

Intramural DoD Organization: A DoD laboratory, DoD military treatment facility, and/or DoD activity embedded within a civilian medical center.

Note: Applications from an intramural DoD organization or from an extramural Federal organization may be submitted through a research foundation.

The USAMRAA makes awards to eligible organizations, not to individuals.

II.C.1.b. Principal Investigator

Independent investigators at all academic levels (or equivalent) are eligible.

An eligible PI, regardless of ethnicity, nationality, or citizenship status, must be employed by, or affiliated with, an eligible organization.

The CDMRP encourages all PIs to participate in a digital identifier initiative through Open Researcher and Contributor ID, Inc. (ORCID). Registration for a unique ORCID identifier can be done online at http://orcid.org/.

II.C.2. Cost Sharing

Cost sharing/matching is not an eligibility requirement.

II.C.3. Other

Organizations must be able to access **.gov** and **.mil** websites in order to fulfill the financial and technical deliverable requirements of the award and submit invoices for payment.

There are no limitations on the number of applications for which an investigator may be named as a PI.

For general information on required qualifications for award recipients, refer to the General Application Instructions, Appendix 3.

Refer to Section II.H.2, Administrative Actions, for a list of administrative actions that may be taken if a pre-application or application does not meet the administrative, eligibility, or ethical requirements defined in this Program Announcement.

II.D. Application and Submission Information

Extramural Submission is defined as an application submitted by an organization to Grants.gov.

Intramural DoD Submission is defined as an application submitted by a DoD organization to eBRAP.

II.D.1. Address to Request Application Package

eBRAP is a multifunctional web-based system that allows PIs to submit their pre-applications electronically through a secure connection, to view and edit the content of their pre-applications and full applications, to receive communications from the CDMRP, and to submit documentation during award negotiations and period of performance.

Extramural Submissions: Pre-application content and forms must be accessed and submitted at eBRAP.org. Full application packages must be accessed and submitted at Grants.gov.

Intramural DoD Submissions: Pre-application content and forms and full application packages must be accessed and submitted at eBRAP.org.

Contact information for the CDMRP Help Desk and the Grants.gov Contact Center can be found in Section II.G, Federal Awarding Agency Contacts.

II.D.2. Content and Form of the Application Submission

Submission is a two-step process requiring both ***pre-application*** and ***full application*** as indicated below. The submission process should be started early to avoid missing deadlines. There are no grace periods.

Pre-Application Submission: All pre-applications for both extramural and intramural organizations must be submitted through eBRAP.org.

Full Application Submission: Full applications must be submitted through the online portals as described below.

Submitting Extramural Organizations: Full applications from extramural organizations must be submitted through a Grants.gov Workspace. Applications submitted by extramural organizations (e.g., research foundations) on behalf of intramural DoD or other Federal organizations or investigators will be considered extramural submissions. Applications from extramural organizations, including non-DoD Federal organizations, received through eBRAP will be withdrawn. See definitions in Section II.C.1, Eligible Applicants.

Submitting Intramural DoD Organizations: Intramural DoD organizations may submit full applications to either eBRAP or Grants.gov. Intramural DoD organizations that are unable to submit to Grants.gov should submit through eBRAP. Intramural DoD organizations with the capability to submit through Grants.gov may submit following the instructions for extramural submissions through Grants.gov or may submit to eBRAP.

For Both Extramural and Intramural Applicants: A key feature of eBRAP is the ability of an organization's representatives and PIs to view and modify the full application submissions associated with them. eBRAP will validate full application files against the specific Program Announcement requirements, and discrepancies will be noted in an email to the PI and in the "Full Application Files" tab in eBRAP. It is the applicant's responsibility to review all application components for accuracy as well as ensure proper ordering as specified in this Program Announcement.

The application title, eBRAP log number, and all information for the PI, Business Official(s), performing organization, and contracting organization must be consistent throughout the entire pre-application and full application submission process. Inconsistencies may delay application processing and limit or negate the ability to view, modify, and verify the application in eBRAP. If any changes need to be made, the applicant should contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507 prior to the application submission deadline.

II.D.2.a. Step 1: Pre-Application Submission Content

During the pre-application process, each submission is assigned a unique log number by eBRAP. This unique eBRAP log number is required during the full application submission process.

To begin the pre-application process, first select whether the submitting organization is extramural or intramural, then confirm your selection or cancel. **Incorrect selection of extramural or intramural submission type will delay processing.**

If an error has been made in the selection of extramural versus intramural and the pre-application submission deadline has passed, the PI or Business Official must contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507 to request a change in designation.

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.

Applicant organizations and associated PIs 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.

PIs with an ORCID identifier should enter that information in the appropriate field in the "My Profile" tab in the "Account Information" section of eBRAP.

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):

- **Tab 1 – Application Information**

  Submission of application information includes assignment of primary and secondary research classification codes, which may be found at https://ebrap.org/eBRAP/public/Program.htm. Note that the codes have recently been revised. Applicants are strongly encouraged to review and confirm the codes prior to making their selection.

- **Tab 2 – Application Contacts**

  Enter contact information for the PI. Enter the organization's Business Official responsible for sponsored program administration (the "person to be contacted on matters involving this application" in Block 5 of the Grants.gov SF424 (R&R) Form). The Business Official must be either selected from the eBRAP list or invited in order for the pre-application to be submitted.

  Select the performing organization (site at which the PI will perform the proposed work) and the contracting organization (organization submitting on behalf of the PI, which corresponds to Block 5 on the Grants.gov SF424 (R&R) Form), and click on "Add Organizations to this Pre-application." The organization(s) must be either selected from the eBRAP drop-down list or invited in order for the pre-application to be submitted.

  It is recommended that PIs identify an Alternate Submitter in the event that assistance with pre-application submission is needed.

- **Tab 3 – Collaborators and Key Personnel**

  Enter the name, organization, and role of all collaborators and key personnel associated with the application.

  FY18 PH/TBIRP CTRR Programmatic Panel members should not be involved in any pre-application or application. For questions related to panel members and pre-applications or

applications, refer to Section II.H.2.c, Withdrawal, or contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507.

To preserve the integrity of its peer and programmatic review processes, the CDMRP discourages inclusion of any employee of its review contractors having any role in pre-application or application preparation, research, or other duties for submitted pre-applications or applications. For FY18, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (http://cdmrp.army.mil/about/2tierRevProcess). Pre-applications or applications that include names of personnel from either of these companies will be administratively withdrawn unless plans to manage conflicts of interest (COIs) are provided and deemed appropriate by the Grants Officer. Refer to the General Application Instructions, Appendix 3, for detailed information.

- **Tab 4 – Conflicts of Interest**

  List all individuals other than collaborators and key personnel who may have a COI in the review of the application (including those with whom the PI has a personal or professional relationship). Refer to the General Application Instructions, Appendix 3, Section C, for further information regarding COIs.

- **Tab 5 – Pre-Application Files**

  Note: Upload documents 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 (two-page limit):** The Preproposal Narrative page limit applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. 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 pre-application.

    The Preproposal Narrative should include the following:

    - **Alignment:** Note specifically which of the FY18 PH/TBIRP CTRR-CTDA focus area(s) the proposed work addresses. Describe how the proposed future clinical trial will evaluate rehabilitation intervention effectiveness in remediating cognitive impairments and functional limitations after TBI.

    - **Research Idea:** Describe the reasoning on which the proposed clinical trial development is based; include relevant literature citations. Briefly describe the level of scientific evidence that supports the progression of this research to a clinical trial. State the hypothesis to be tested and/or the objectives to be attained. Clearly specify which type (e.g., drug, device, surgical) of clinical trial is being proposed and indicate the phase of trial and/or class of device and regulatory status, as appropriate. Briefly describe the intended patient population(s) to be recruited for the clinical trial.

- **Development Plan:** Concisely state the specific aims and tasks to be accomplished in the 12-month period of performance of the FY18 PH/TBIRP CTRR-CTDA. Include a description of planned interactions with the FDA and local IRB, as appropriate, and how the planned tasks will support obtaining any IND/IDE approvals, as needed, for initiation of the proposed future clinical trial. Include a description of how the planning period will be used to build the research team, establish access to the proposed subject population(s), develop the research plan, clinical protocol, statistical plans, plans for subject recruitment, and perform other tasks necessary to support the proposed future clinical trial.

- **Research Team:** Provide a description of the research team that clearly demonstrates appropriate background and expertise to accomplish the proposed work.

- **Impact and Military Benefit:** Describe how the proposed future clinical trial would impact healthcare for military Service members, Veterans, and other individuals recovering from TBI in conjunction with symptoms associated with cognitive dysfunction.

- **Pre-Application Supporting Documentation:** The items to be included as supporting documentation for the pre-application ***must be uploaded as individual files*** and are limited to the following:

  - 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, reference title, and reference source, including 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 (six-page limit per individual): ***All biographical sketches should be uploaded as a single combined file.*** Biographical sketches of the PI and key personnel should be used to demonstrate background and expertise through education, positions, publications, and previous work accomplished.

  - Quad Chart: Provide a Quad Chart for the proposed project. The Quad Chart template is a one-page PowerPoint file that must be downloaded from eBRAP at https://ebrap.org/eBRAP/public/Program.htm, completed and saved as a PDF file using Adobe Acrobat Reader.

- **Tab 6 – Submit Pre-Application**

  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 and the JPC-8/CRMRP, pre-applications will be screened based on the following criteria:

  - Alignment: How well the project plans to address at least one of the FY18 PH/TBIRP CTRR-CTDA focus areas. How well the project addresses the intent of the award mechanism.

  - Research Idea: How well the rationale is supported, and how well the background provided indicates the research is ready to move into a clinical trial development.

  - Development Plan: How well the proposed future clinical trial preparations are designed. The degree to which the proposed activities will successfully prepare the study for application to a PH/TBIRP CTRR-Clinical Trial Award Program Announcement and subsequent clinical trial initiation.

  - Research Team: Whether the qualifications and expertise of the PI and key personnel are appropriate to perform the proposed research.

  - Impact and Military Benefit: To what degree the proposed work would impact healthcare for military Service members, Veterans, and other individuals recovering from TBI in conjunction with symptoms associated with cognition dysfunction.

- **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 in Section I, Overview of the Funding Opportunity. Invitations to submit a full application are based on the Pre-Application Screening Criteria listed above.

II.D.2.b. Step 2: Full Application Submission Content

Applications will not be accepted unless the PI has received notification of invitation.

The CDMRP cannot make allowances/exceptions to its policies for submission problems encountered by the applicant organization using system-to-system interfaces with Grants.gov.

Each application submission must include the completed full application package for this Program Announcement. The full application package is submitted by the Authorized Organizational Representative through Grants.gov (http://www.grants.gov/) for extramural organizations or through eBRAP (https://ebrap.org/) for intramural organizations. See Table 1 below for more specific guidelines.

II.D.2.b.i. Full Application Guidelines

Extramural organizations must submit full applications through Grants.gov. Applicants must create a Grants.gov Workspace for submission, which allows the application components to be completed online and routed through the applicant organization for review prior to submission. Applicants may choose to download and save individual PDF forms rather than filling out webforms in the Workspace. A compatible version of Adobe Reader **must** be used to view, complete, and submit an application package consisting of PDF forms. If more than one person is entering text into an application package, the ***same version*** of Adobe Reader software should be used by each person. Check the version number of the Adobe software on each user's computer to make sure the versions match. Using different versions of Adobe Reader may cause submission and/or save errors – even if each version is individually compatible with Grants.gov. Refer to the General Application Instructions, Section III, and the "Apply For Grants" page of Grants.gov (https://www.grants.gov/web/grants/applicants/apply-for-grants.html) for further information about the Grants.gov Workspace submission process. Submissions of extramural applications through eBRAP may be withdrawn.

Table 1. Full Application Submission Guidelines

Extramural Submissions	Intramural DoD Submissions
Application Package Location	
Download application package components for W81XWH-18-CTRR-CTDA from Grants.gov (http://www.grants.gov) and create a Grants.gov Workspace. The Workspace allows online completion of the application components and routing of the application package through the applicant organization for review prior to submission.	Download application package components for W81XWH-18-CTRR-CTDA from eBRAP (https://ebrap.org).
Full Application Package Components	
SF424 (R&R) Application for Federal Assistance Form: Refer to the General Application Instructions, Section III.A.1, for detailed information.	**Tab 1 – Summary:** Provide a summary of the application information. **Tab 2 – Application Contacts:** This tab will be pre-populated by eBRAP; add Authorized Organizational Representative.
Descriptions of each required file can be found under Full Application Submission Components: • Attachments • Research & Related Personal Data • Research & Related Senior/Key Person Profile (Expanded) • Research & Related Budget • Project/Performance Site Location(s) Form	**Tab 3 – Full Application Files:** Upload files under each Application Component in eBRAP. Descriptions of each required file can be found under Full Application Submission Components: • Attachments • Key Personnel • Budget • Performance Sites

Extramural Submissions	Intramural DoD Submissions
• R&R Subaward Budget Attachment(s) Form (if applicable)	**Tab 4 – Application and Budget Data:** Review and edit proposed project start date, proposed end date, and budget data pre-populated from the Budget Form.
Application Package Submission	
Create a Grants.gov Workspace. Add participants (investigators and Business Officials) to the Workspace, complete all required forms, and check for errors before submission. **Submit a Grants.gov Workspace Package.** An application may be submitted through Workspace by clicking the "Sign and Submit" button on the "Manage Workspace" page, under the "Forms" tab. Grants.gov recommends submission of the application package **at least 24-48 hours prior to the close date** to allow time to correct any potential technical issues that may disrupt the application submission. Note: If either the Project Narrative or the budget fails eBRAP validation or if the Project Narrative or the budget needs to be modified, an updated Grants.gov application package must be submitted via Grants.gov as a "Changed/Corrected Application" with the previous Grants.gov Tracking ID prior to the application submission deadline.	**Submit package components to eBRAP (https://ebrap.org).** **Tab 5 – Submit/Request Approval Full Application:** After all components are uploaded and prior to the full application submission deadline, enter your password in the space provided next to "Enter Your Password Here" and press the "Submit Full Application" button. eBRAP will notify your Resource Manager/Comptroller/Task Area Manager or equivalent Business Official by email.
Application Verification Period	
The full application package submitted to Grants.gov may be viewed and modified in eBRAP until the end of the application verification period. During the application verification period, the full application package, ***with the exception of the Project Narrative and Budget Form,*** may be modified.	After eBRAP has processed the full application, the organizational Resource Manager/Comptroller/Task Area Manager or equivalent Business Official and PI will receive email notification of this status and will be able to view and modify application components in eBRAP. During the application verification period, the full application package, ***with the exception of the Project Narrative and Budget Form,*** may be modified. Your Resource Manager/Comptroller/Task Area Manager or equivalent Business Official should log into eBRAP to review and to approve prior to the application verification deadline.

Extramural Submissions	Intramural DoD Submissions
Further Information	
Tracking a Grants.gov Workspace Package. After successfully submitting a Workspace package, a Grants.gov Tracking Number is automatically assigned to the package. The number will be listed on the "Confirmation" page that is generated after submission. Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.	Refer to the General Application Instructions, Section IV, for further information regarding eBRAP requirements.

Application viewing, modification, and verification in eBRAP are strongly recommended, but not required. ***The Project Narrative and Budget cannot be changed after the application submission deadline.*** Prior to the full application deadline, a corrected or modified full application package may be submitted. Other application components may be changed until the end of the application verification period. Verify that subaward budget(s) and budget justification forms are present in eBRAP during the application verification period. If these components are missing, upload them to eBRAP before the end of the application verification period. After the end of the application verification period, the full application cannot be modified.

Material submitted after the end of the application verification period, unless specifically requested by the Government, will not be forwarded for processing.

The full application package must be submitted using the unique eBRAP log number to avoid delays in application processing.

II.D.2.b.ii. Full Application Submission Components

- **Extramural Applications Only**

  SF424 (R&R) Application for Federal Assistance Form: Refer to the General Application Instructions, Section III.A.1, for detailed information.

- **Extramural and Intramural Applications**

  Attachments:

  Each attachment to the full application components must be uploaded as an individual file in the format specified and in accordance with the formatting guidelines listed in the General Application Instructions, Appendix 4.

  For all attachments, ensure that the file names are consistent with the guidance. Attachments will be rejected if the file names are longer than 50 characters or have incorrect file names that contain characters other than the following: A-Z, a-z, 0-9, underscore, hyphen, space,

and period. In addition, there are file size limits that may apply in some circumstances. Individual attachments may not exceed 20 MB, and the file size for the entire full application package may not exceed 200 MB.

- **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) 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 may result in administrative withdrawal of the application.

  Describe the proposed project in detail using the outline below.

  - **Future Clinical Trial:** State the relevance of the research to at least one of the FY18 PH/TBIRP CTRR-CTDA focus areas. Describe briefly the rationale for the proposed future clinical trial and include a literature review, preliminary studies, and preclinical data that led to its development.

    - Describe the hypothesis and/or objectives of the proposed future clinical trial.

    - Specify the anticipated target population for the proposed future clinical trial, and the availability of access, or how access will be obtained, to such a population.

    - Explain the research question to be addressed and/or intervention to be tested. If an intervention will be tested, include relevant information about its source, FDA approval/review status (as applicable), availability, efficacy, dosing (if applicable), and mechanism of action (if known).

  - **Development Plan:** Describe the work to be conducted during the FY18 PH/TBIRP CTRR-CTDA period of performance, clearly stating how each task is necessary for the initiation of the proposed future clinical trial. Where relevant, identify potential problems and potential alternative approaches.

    - Describe the overarching goals of the work to be done in the FY18 PH/TBIRP CTRR-CTDA period of performance.

    - Describe the military/VA target populations or resources (e.g., active duty or reserve military, Veterans, or military family members; military- or VA-controlled study materials; databases; and/or restricted facilities) necessary for the proposed future clinical trial. Describe planning activities during the FY18 PH/TBIRP CTRR-CTDA period of performance to obtain access to the populations or resources.

    - Provide a timeline and plans for coordination of IRB submission and approval at each study site, as applicable.

    - If applicable, describe detailed plans for carrying out the IND/IDE application process, including timelines, milestones, and planned interactions with the FDA.

The path to FDA application and approval (IND/IDE or other) for the proposed future clinical trial should be outlined as clearly as possible.

- If applicable, describe planning for safety and clinical monitoring, including compliance with Good Clinical Practice (GCP) guidelines, if applicable.

- Describe the timeline and plans to finalize the experimental design and develop applicable clinical protocol and related documents (e.g., consent form, questionnaires) for the proposed future clinical trial, as applicable.

- Describe how sample size estimates will be calculated, how a plan for statistical analyses will be developed, and how a human subjects recruitment plan, if applicable, will be formulated. Include plans to engage a statistician and other experts as appropriate.

- Describe plans to develop applicable data collection/monitoring procedures, a data analysis plan, and other data collection tools.

- Describe how a plan to share and disseminate data and other resources created by the proposed future clinical trial with the greater research community will be developed.

- Describe how any other preparatory activities will be accomplished.

– **Study Team:** Describe the PI's background and expertise in TBI and cognitive rehabilitation research and in conducting clinical studies. Describe the experience and contributions of other key study team members.

- Describe plans for developing the research team and obtaining any research resources or professional collaborations for the proposed future clinical trial, if applicable. Include plans for training team members, as appropriate. Address any involvement of DoD or VA clinicians and scientists.

○ **Attachment 2: Supporting Documentation:** Combine and upload as a single file named "Support.pdf". Start each document on a new page. If documents are scanned to PDF, the lowest resolution (100 to 150 dpi) should be used. The Supporting Documentation attachment should not include additional information such as figures, tables, graphs, photographs, diagrams, chemical structures, or drawings. These items should be included in the Project Narrative.

There are no page limits for any of these components unless otherwise noted. Include only those components described below; inclusion of items not requested or viewed as an extension of the Project Narrative will result in the removal of those items or may result in 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 Patents: Include a list of relevant publication URLs and/or patent abstracts. If publications are not publicly available, then copies of up to five published manuscripts may 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 support not requested in the Program Announcement, such as those from members of Congress, do not impact application review or funding decisions.

- Regulatory Communications: Include any communications with the FDA or local IRB relevant to tasks to be completed in the FY18 PH/TBIRP CTRR-CTDA period of performance, including any documents relevant to obtaining required IND/IDE approvals.

- 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. If an investigator at an intramural organization is named as a collaborator on an application submitted through an extramural organization, the application must include a letter from the collaborator's Commander or Commanding Officer at the intramural organization that authorizes the collaborator's involvement.

- Intellectual Property: Information can be found in Code of Federal Regulations, Title 2, Part 200.315 (2 CFR 200.315), "Intangible Property."

    - Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations.

    - Commercialization Strategy (if applicable): Describe the commercialization plan. The plan should include intellectual property, market size, financial analysis, strengths and weaknesses, barriers to the 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 and Research Resources Sharing Plan: Describe how data and resources generated during the performance of the project will be shared with and made available to the research community.

  - If applicable, describe the plan to make data available to the TBI research community through the FITBIR Informatics System. If an alternative data-sharing vehicle will be employed, provide justification for its use.

  - Refer to the General Application Instructions, Appendix 2, Section K, for more information about the CDMRP expectations for making data and research resources publicly available. Additionally, the Government reserves the right to identify archival repositories for submission of data. Any costs associated with submission will be addressed during award negotiations.

- Quad Chart: Provide a Quad Chart for the proposed project. The format for the quad chart is available on the eBRAP "Funding Opportunities & Forms" web page at https://ebrap.org/eBRAP/public/Program.htm

- **Attachment 3: Technical Abstract (one-page limit):** Upload as "TechAbs.pdf". The technical abstract is used by all reviewers. Abstracts of all funded research projects will be posted publicly. ***Do not include proprietary or confidential information.*** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

  Technical abstracts should be written using the outline below. The technical abstract should provide an appropriate description of the project's key aspects; clarity and completeness within the space limits of the technical abstract are highly important.

  - **Background:** State how the proposed research addresses one or both of the FY18 PH/TBIRP CTRR-CTDA focus areas. Present the ideas and reasoning behind the proposed future clinical trial.

  - **Objective/Hypothesis:** State the objective to be reached/hypothesis to be tested by the proposed future clinical trial. Describe the overall research goals for the study.

  - **Development Plan:** Briefly describe how the work proposed for the FY18 PH/TBIRP CTRR-CTDA period of performance will lead to the future proposed clinical trial.

  - **Impact and Military Relevance:** State briefly how the proposed future clinical trial, if successful, will have an immediate or potential long-term impact on the health and well-being of military Service members, Veterans, and other individuals living with complex TBI.

- **Attachment 4: Lay Abstract (one-page limit):** Upload as "LayAbs.pdf". The lay abstract is used by all reviewers. Abstracts of all funded research projects will be posted publicly. ***Do not include proprietary or confidential information***. Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

  Lay abstracts should be written using the outline below. ***Do not duplicate the technical abstract.***

  - Clearly describe the objectives and rationale for the proposed study and intervention in a manner readily understood by readers without a background in science or medicine.
  - Describe the ultimate applicability and impact of the proposed future clinical trial.
    - What types of patients will it help, and how will it help them?
    - What are the potential clinical applications and benefits?
    - What is the projected timeline it may take to achieve the expected patient-related outcome?
  - What are the likely contributions of the proposed future clinical trial to advancing the field of complex TBI research, patient care, and/or quality of life?

- **Attachment 5: Statement of Work (SOW) (three-page limit):** Upload as "SOW.pdf". The suggested SOW format and examples specific to different types of research projects are available on the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm). For the CTRR-CTDA mechanism, use the SOW format example titled, "SOW (Statement of Work) Generic Format." The SOW must be in PDF format prior to attaching.

  The SOW should include a list of major tasks that support the proposed specific aims, followed by a series of subtasks outlined related to the major tasks and milestones within the period of performance. The SOW should describe only the work for which funding is being requested by this application and, as applicable, should also:

  - Include the name(s) of the key personnel and contact information for each study site/ subaward site.
  - Indicate the number (and type, if applicable) of research subjects projected or required for each task and at each site. Indicate quarterly enrollment targets. Refer to the General Application Instructions, Appendix 1, for additional information regarding regulatory requirements.
  - Identify cell line(s) and commercial or organizational source(s) to be used. If human anatomical substances (including cell lines) will be used, specify whether or not identifiable information is accessible to the research team by any means.

- If applicable, indicate timelines required for regulatory approvals relevant to human subjects research (e.g., IND or IDE applications) by the FDA or other Government agency.

- Briefly state the methods to be used.

- **Attachment 6: Impact and Military Benefit Statement (two-page limit):** Upload as "Impact.pdf". Describe the short- and long-term impact of the future clinical trial on the field of complex TBI research, patient care, and/or quality of life, including an assessment of the likelihood that a successful outcome of the proposed clinical trial will lead to a practical application in individuals recovering from military-relevant injuries incident to military service as well as injuries occurring in the general public. Address the impact on one or both of the FY18 PH/TBIRP CTRR-CTDA focus areas. Although not all-inclusive, the following are examples of ways in which research projects may have an impact, if successful:

  - The project has the potential to advance research in the field of complex TBI.

  - The research would contribute to the development or validation of evidence-based policy or guidelines for patient evaluation and care.

  - Describe any relevant controversies or treatment issues that will be addressed by the proposed research.

  - The proposed research would address potential issues that might limit the impact of the proposed research.

  - If an active duty military, Veteran, or military family member population(s) will be used in the proposed research project, the application describes the population(s), the appropriateness of the population(s) for the proposed research, and the feasibility of using the population. If a non-military population will be used for the proposed research project, the application explains how the results will be relevant to active duty military, Veteran, or military family member population(s).

- **Attachment 7: Representations, if applicable (extramural submissions only):** Upload as "MandatoryReps.pdf". All extramural applicants must complete and submit the Required Representations template available on eBRAP (https://ebrap.org/eBRAP/public/Program.htm). For more information, see the General Application Instructions, Appendix 5, Section B, Representations.

- **Attachment 8: DoD Military Budget Form(s), if applicable:** Upload as "MFBudget.pdf". If a military facility (Military Health System facility, research laboratory, medical treatment facility, dental treatment facility, or a DoD activity embedded with a civilian medical center) will be a collaborator in performance of the project, complete the DoD Military Budget Form, available for download on the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm), including a budget justification, for each military facility as instructed. The costs per year should be included on the Grants.gov Research and Related Budget

form under subaward costs. Refer to the General Application Instructions, Section III.A.7, for detailed information.

- **Extramural and Intramural Applications**

  To evaluate compliance with Title IX of the Education Amendments of 1972 (20 USC A§1681 et seq.), the DoD is collecting certain demographic and career information to be able to assess the success rates of women who are proposed for key roles in applications in science, technology, engineering, or mathematics (STEM) disciplines. To enable this assessment, each application must include the following forms completed as indicated.

  Research & Related Personal Data: For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.3, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.2, for detailed information.

  Research & Related Senior/Key Person Profile (Expanded): For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.4, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.2, for detailed information.

  - PI Biographical Sketch (six-page limit): Upload as "Biosketch_LastName.pdf". The suggested biographical sketch format is available on the "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) in eBRAP. The National Institutes of Health Biographical Sketch may also be used. All biographical sketches should be submitted in the PDF format that is not editable.

  - PI Previous/Current/Pending Support (no page limit): Upload as "Support_LastName.pdf".

  - Key Personnel Biographical Sketches (six-page limit each): Upload as "Biosketch_LastName.pdf".

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

  Research & Related Budget: For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.4, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.3, for detailed information.

  Budget Justification (no page limit): Upload as "BudgetJustification.pdf". The budget justification for the entire period of performance must be uploaded to the Research & Related Budget after completion of the budget for Period 1.

  Project/Performance Site Location(s) Form: For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.5, and for intramural

submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.4, for detailed information.

- **Extramural Applications Only**

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

  - **Extramural Subaward:** Complete the Research & Related Subaward Budget Form through Grants.gov. (Refer to the General Application Instructions, Section III.A.6, for detailed information.) Verify subaward budget(s) and budget justification forms are present in eBRAP during the application verification period. If these components are missing, upload them to eBRAP before the end of the application verification period.

  Intramural DoD Collaborator(s): Complete the DoD Military Budget Form and upload to Grants.gov attachment form as Attachment 8. (Refer to the General Application Instructions, Section III.A.7, for detailed information.) Intramural DoD Collaborator(s) costs per year should be included on the Grants.gov Research and Related Budget form under subaward costs.

II.D.3. Dun and Bradstreet Data Universal Numbering System (DUNS) Number and System for Award Management (SAM)

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. Verify the status of the applicant's organization's Entity registration in SAM well in advance of the application submission deadline. Allow 3 to 4 weeks to complete the entire SAM registration process. If an applicant has not fully complied with the requirements at the time the Federal awarding agency is ready to make a Federal award, the Federal awarding agency may determine that the applicant is not qualified to receive a Federal award and use that determination as a basis for making a Federal award to another applicant. Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.

New Requirement: In March 2018, the General Services Administration (GSA) implemented fraud prevention security measures in the SAM that require every ***new*** contractor registrant to provide a written (hard copy), notarized letter confirming the entity's Administrator authorized to register the entity in the SAM database or to make changes to its registration. Effective April 29, 2018, the notarized letter process is now mandatory on all ***current*** registrants at SAM who have a requirement to update data on their SAM record. The notarized letter is mandatory and is required before the GSA Federal Service Desk (FSD) will activate the entity's registration. The Office of the Secretary of Defense and GSA realize the length of time needed to transmit, receive, process, and approve the notarized letters presents a significant impact on the ability of the contracting activity to make timely awards, but these steps must be taken to mitigate fraud concern. ***Notarized letters are required for all new and existing SAM-registered entities.*** The notarized letters must be postal service mailed (not emailed or faxed) to the "Federal Service Desk" and must contain the information outlined in the SAM-posted Frequently

Asked Questions (FAQs) at https://www.gsa.gov/about-us/organization/federal-acquisition-service/office-of-systems-management/integrated-award-environment-iae/sam-update. Instructions for domestic entities and instructions for international entities with embedded templates for use are also provided within the SAM Update notice with frequently asked questions at https://www.gsa.gov/about-us/organization/federal-acquisition-service/office-of-systems-management/integrated-award-environment-iae/sam-update.

II.D.4. Submission Dates and Times

All submission dates and times are indicated in Section I, Overview of the Funding Opportunity. Pre-application and application submissions are required. The pre-application and application submission process should be started early to avoid missing deadlines. There are no grace periods. Failure to meet either of these deadlines will result in submission rejection.

Applicant Verification of Full Application Submission in eBRAP

Following retrieval and processing of the full application, eBRAP will notify the organizational representatives and PI by email to log into eBRAP to review, modify, and verify the full application submission. eBRAP will validate retrieved files against the specific Program Announcement requirements and discrepancies will be noted in both the email and in the "Full Application Files" tab in eBRAP. eBRAP does not confirm the accuracy of file content. It is the applicant's responsibility to review all application components and ensure proper ordering as specified in the Program Announcement. ***If either the Project Narrative or the budget fails eBRAP validation or needs to be modified, an updated full application package must be submitted prior to the application submission deadline.*** The Project Narrative and Budget Form cannot be changed after the application submission deadline.

Extramural Submission: The full application package submitted to Grants.gov may be viewed and modified in eBRAP until the end of the application verification period. During the application verification period, the full application package, ***with the exception of the Project Narrative and Budget Form***, may be modified.

Intramural DoD Submission: After eBRAP has processed the full application, the organizational Resource Manager/Comptroller/Task Area Manager or equivalent Business Official and PI(s) will receive email notification of the status and will be able to view and modify application components in eBRAP. During the application verification period, the full application package, ***with the exception of the Project Narrative and Budget Form***, may be modified. The Resource Manager/Comptroller/Task Area Manager or equivalent Business Official should log into eBRAP to review and to approve prior to the application verification deadline.

For All Submissions: Verify that subaward budget(s) with budget justification are present in eBRAP during the application verification period. If these components are missing, upload them to eBRAP before the end of the application verification period.

II.D.5. Funding Restrictions

The maximum period of performance is **12 months**.

The anticipated **total (direct + indirect)** costs budgeted for the entire period of performance will not exceed **$200,000**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the Government exceeding **$200,000** total costs or using an indirect cost rate exceeding the organization's negotiated rate.

All direct and indirect costs of any subaward or contract 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 **12 months**.

For this award mechanism, direct costs must be requested for:

- Travel costs for the PI(s) to present project information or disseminate project results at one DoD PH/TBIRP CTRR In-Progress Review meeting during the period of performance should be requested. For planning purposes, it should be assumed that the meeting will be held in the National Capital Area. These travel costs are in addition to those allowed for annual scientific/technical meetings.

- Travel costs for the PI(s) to present project information or disseminate project results at one DoD-sponsored scientific meeting (e.g., Military Health System Research Symposium) during the period of performance. These travel costs are in addition to those allowed for annual scientific/technical meetings.

For this award mechanism, direct costs may be requested for (not all-inclusive):

- Salary
- Administrative costs
- Support for establishing collaborations
- Database generation
- Software development
- Costs associated with IRB and/or FDA applications and reviews
- Travel between collaborating organizations

Awards made to extramural organizations will consist solely of assistance agreements (grants and cooperative agreements). For extramural awards with an intragovernmental component, direct transfer of funds from an extramural award recipient to a DoD or other Federal agency is not allowed except under very limited circumstances. Funding to intramural DoD and other Federal agencies will be managed through a direct fund transfer. Intramural applicants are responsible for coordinating through their agency's procedures the use of contractual or assistance funding awards or other appropriate agreements to support extramural collaborators.

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

The JPC-8/CRMRP expects to allot approximately $800,000 of the FY18 PH/TBIRP appropriation to fund approximately four CTRR-Clinical Trial Development Award applications, depending on the quality and number of applications received. Funding of applications received in response to this Program Announcement is contingent upon the availability of Federal funds for this program.

Funds to be obligated on any award resulting from this funding opportunity will be available for use for a limited time period based on the fiscal year of the funds. The time is considered when establishing the award's period of performance. It is anticipated that awards made from this funding opportunity will be funded with FY18 funds, which will expire for use on September 30, 2024.

II.D.6. Other Submission Requirements

Refer to the General Application Instructions, Appendix 4, for detailed formatting guidelines.

II.E. Application Review Information

II.E.1. Criteria

II.E.1.a. Peer Review

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

- **Potential Military Benefit and Clinical Impact**
    - How well the proposed future clinical trial addresses one or both of the FY18 PH/TBIRP CTRR-CTDA focus areas.
    - How the anticipated outcomes of the proposed future clinical trial, if successful, will be relevant to individuals with complex TBI.
    - How the anticipated outcomes of the proposed future clinical trial will provide/improve the short-term benefits for individuals with complex TBI.
    - How significantly the long-term benefits for implementation of the intervention may impact patient care and/or quality of life.
    - The degree to which the results of the proposed clinical trial are expected to affect clinical practice.

- If the anticipated study population does not include Service member or Veteran participants as all or a portion of the future study population, how applicable the results will be to these populations.

- **Research Question**

  - How well the preliminary data and scientific rationale support the proposed future clinical trial and demonstrate sufficient evidence for moving into the proposed stage of research at the end of the FY18 PH/TBIRP CTRR-CTDA.

  - How well the hypothesis or objectives of the proposed future clinical trial are described.

- **Development Plan Strategy and Feasibility**

  - To what degree the work proposed for the FY18 PH/TBIRP CTRR-CTDA period of performance is justified as necessary to enable the proposed future clinical trial.

  - To what extent the proposed tasks are feasible as described and achievable within the FY18 PH/TBIRP CTRR-CTDA period of performance.

  - How well the proposed tasks for the FY18 PH/TBIRP CTRR-CTDA period of performance support the successful initiation of the proposed future clinical trial, including:

    – How well constructed the plans are to develop the experimental design and develop any required clinical protocols and associated documents for the proposed future clinical trial.

    – How the plans to develop data collection and monitoring tools and data analyses are appropriate for the scope of the proposed future clinical trial.

    – How well the application addresses considerations such as statistical support, planning, and intellectual and materiel property agreements.

    – To what extent the plans for obtaining all necessary regulatory approvals (e.g., IRB and IND/IDE application and review processes) and plans for safety and clinical monitoring, including compliance with GCP, if applicable, are feasible and likely to lead to success.

    – How well the plan addresses the availability of human subjects for the proposed future clinical trial and the prospect of their participation.

    – How well the plan addresses access to the human subjects population in the proposed future clinical trial.

    – How well the plan addresses inclusion of data from the proposed future clinical trial in the FITBIR Informatics System.

- How well the plans for other preparatory activities are described and whether they are appropriate to enable the proposed future clinical trial.

- **Personnel**

  - To what extent the background and expertise of the PI and key personnel are appropriate to accomplishing the proposed project.

  - Whether the levels of effort are appropriate for successful conduct of the proposed work.

  - How well the application describes plans to recruit appropriate expertise to the proposed future clinical trial research team.

  - If applicable, to what extent the proposed project includes plans to integrate DoD or VA researchers and clinicians to the future clinical research team.

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

- **Environment**

  - To what extent the scientific environment is appropriate for the proposed project.

  - How well the research requirements are supported by the availability of and accessibility to facilities and resources (including collaborative arrangements).

  - To what extent the quality and level of institutional support are appropriate for the proposed project.

- **Budget**

  - Whether the **total (direct + indirect)** maximum costs are equal to or less than the allowable total maximum costs as published in the Program Announcement.

  - Whether the budget is appropriate for the proposed effort.

- **Application Presentation**

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

II.E.1.b. Programmatic Review

To make funding recommendations and select the application(s) that, individually or collectively, will best achieve the program objectives, the following criteria are used by programmatic reviewers:

- Ratings and evaluations of the peer reviewers

- Relevance to the mission of the DHP, JPC-8/CRMRP, and PH/TBIRP, as evidenced by the following:
    - Adherence to the intent of the award mechanism and alignment with the FY18 PH/TBIRP CTRR-CTDA focus areas
    - Relative impact and military relevance
    - Program portfolio composition

II.E.2. Application Review and Selection Process

All applications are evaluated by scientists, clinicians, and consumers in a two-tier review process. The first tier is peer review of applications against established criteria for determining technical merit. Each application is evaluated for its own merit, independent of other applications. The second tier is a programmatic review that makes recommendations for funding to the Commanding General, USAMRMC, on behalf of the DHA and the OASD(HA), based on technical merit, the relevance to the mission of the DHP, JPC-8/CRMRP, and PH/TBIRP, the specific intent of the award mechanism, and to other specified evaluation criteria in the Program Announcement. Programmatic review is a comparison-based process in which applications with scientific and technical merit compete in a common pool. ***The highest-scoring applications from the first tier of review are not automatically recommended for funding. Funding recommendations depend on various factors as described in Section II.E.1.b, Programmatic Review.*** 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 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 and approval 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 and approval 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 18 USC 1905.

II.E.3. Integrity and Performance Information

Prior to making an assistance agreement award where the Federal share is expected to exceed the simplified acquisition threshold, as defined in 2 CFR 200.88, over the period of performance, the Federal awarding agency is required to review and consider any information about the applicant that is available in the Federal Awardee Performance and Integrity Information System (FAPIIS).

An applicant organization may review FAPIIS, accessible through SAM, and submit comments to FAPIIS on any information about the organization that a Federal awarding agency previously entered and is currently available in FAPIIS.

The Federal awarding agency will consider any comments by the applicant, in addition to other information in the designated integrity and performance system, in making a judgment about the applicant's integrity, business ethics, and record of performance under Federal awards when determining a recipient's qualification prior to award, according to the qualification standards of the Department of Defense Grant and Agreement Regulations (DoDGARs), Section 22.415.

II.E.4. Anticipated Announcement and Federal Award Dates

All application review dates and times are indicated in Section I, Overview of the Funding Opportunity.

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.

II.F. Federal Award Administration Information

II.F.1. Federal Award Notices

Awards will be made no later than September 30, 2019. Refer to the General Application Instructions, Appendix 2, for additional award administration information.

After email notification of application review results through eBRAP, and if selected for funding, a representative from the USAMRAA will contact the business official authorized to negotiate on behalf of the PI's organization.

Only an appointed USAMRAA Grants Officer may obligate the Government to the expenditure of funds. No commitment on the part of the Government should be inferred from discussions with any other individual. The award document signed by the Grants Officer is the official authorizing document.

Federal Organizations: Awards to Federal Government organizations (including intramural DoD organizations) will be executed through the Military Interdepartmental Purchase Request (MIPR) or Funding Authorization Document (FAD) process. Transfer of funds is contingent upon appropriate safety and administrative approvals. Intramural applicants and collaborators are reminded to coordinate receipt and commitment of funds through their respective Resource Manager/Task Area Manager/Comptroller or equivalent Business Official.

After email notification of application review results through eBRAP, and if selected for funding, a representative from the CDMRP will contact the business official authorized to negotiate on behalf of the PI's organization.

II.F.1.a. PI Changes and Award Transfers

As this is a 12-month period of performance award, organizational transfers will not be allowed, and approval of a change of PI will be on a case-by-case-basis at the discretion of the Grants Officer.

Refer to the General Application Instructions, Appendix 2, Section B, for general information on organization or PI changes.

II.F.2. Administrative and National Policy Requirements

If additional conference travel is proposed, prior to the re-budgeting and in advance of the incurrence of the travel costs, the Grants Officer should be consulted to determine the reasonableness of the expense in accordance with 2 CFR 200.407.

For this award mechanism, direct costs must be requested for:

- Travel costs for the PI(s) to present project information or disseminate project results at one DoD PH/TBIRP CTRR In-Progress Review meeting during the period of performance should be requested. For planning purposes, it should be assumed that the meeting will be held in the National Capital Area. These travel costs are in addition to those allowed for annual scientific/technical meetings.

- Travel costs for the PI(s) to present project information or disseminate project results at one DoD-sponsored scientific meeting (e.g., Military Health System Research Symposium) during the period of performance. These travel costs are in addition to those allowed for annual scientific/technical meetings.

Applicable requirements in the DoDGARs found in 32 CFR, Chapter 1, Subchapter C, and 2 CFR, Chapter XI, apply to grants and cooperative agreements resulting from this Program Announcement.

Refer to the General Application Instructions, Appendix 2, for general information regarding administrative requirements.

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

Refer to full text of the USAMRAA General Research Terms and Conditions with Institutions of Higher Education, Hospitals, and Non-Profit Organizations: Addendum to the DoD R&D Terms and Conditions and the USAMRAA General Research Terms and Conditions with For-Profit Organizations for further information.

II.F.3. Reporting

Refer to the General Application Instructions, Appendix 2, Section A, for general information on reporting requirements. ***If there are technical reporting requirement delinquencies for any***

existing USAMRAA-sponsored awards at the applicant organization, no new awards will be issued to the applicant organization until all delinquent reports have been submitted.

A final progress report and quad charts will be required. In addition to written progress reports, in-person presentations may be requested. For format examples, refer to the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm).

Awards resulting from this Program Announcement will incorporate additional reporting requirements related to recipient integrity and performance matters. Recipient organizations that have Federal contract, grant, and cooperative agreement awards with a cumulative total value greater than $10,000,000 are required to provide information to FAPIIS about certain civil, criminal, and administrative proceedings that reached final disposition within the most recent 5-year period and that were connected with performance of a Federal award. Recipients are required to disclose, semiannually, information about criminal, civil, and administrative proceedings as specified in the applicable Terms and Conditions (see General Application Instructions, Section III.A.4).

II.G. Federal Awarding Agency Contacts

II.G.1. CDMRP Help Desk

Questions related to Program Announcement content or submission requirements as well as questions related to the pre-application or intramural application submission 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

II.G.2. Grants.gov Contact Center

Questions related to extramural 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; International 1-606-545-5035

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 or by responding to the prompt provided by Grants.gov when first downloading the Grants.gov application package. If the Grants.gov application package is updated or changed, the original version of the application package may not be accepted by Grants.gov.

II.H. Other Information

II.H.1. Program Announcement and General Application Instructions Versions

Questions related to this Program Announcement should refer to the Program name, the Program Announcement name, and the Program Announcement version code 20180329h. The Program Announcement numeric version code will match the General Applications Instructions version code 20180329.

II.H.2. Administrative Actions

After receipt of pre-applications or applications, the following administrative actions may occur:

II.H.2.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.

II.H.2.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.

II.H.2.c. Withdrawal

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

- An FY18 PH/TBIRP CTRR Programmatic Panel 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 FY18 PH/TBIRP CTRR Programmatic Panel members can be found at http://cdmrp.army.mil/phtbi/panels/panels18_ctrra.***

- The application fails to conform to this Program Announcement description to the extent that appropriate review cannot be conducted.

- 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).

- To preserve the integrity of its peer and programmatic review processes, the CDMRP discourages inclusion of any employee of its review contractors having any role in the preparation, research or other duties for submitted applications. For FY18, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (http://cdmrp.army.mil/about/2tierRevProcess). Applications that include names of personnel from either of these companies will be administratively withdrawn unless plans to manage COIs are provided and deemed appropriate by the Grants Officer. Refer to the General Application Instructions, Appendix 3, for detailed information.

- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review or approval process to gain protected evaluation information or to influence the evaluation process.

- Applications from extramural organizations, including non-DoD Federal agencies, received through eBRAP may be withdrawn.

- Applications submitted by an intramural DoD organization may be withdrawn if the intramural organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to extramural collaborators.

- The application includes a clinical trial within the period of performance of the FY18 PH/TBIRP CTRR-CTDA.

II.H.2.d. Withhold

Applications that appear to involve research misconduct will be administratively withheld from further consideration pending organizational investigation. The organization 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.

II.H.3. Application Submission Checklist

Application Components	Action	Completed
SF424 (R&R) Application for Federal Assistance **(Extramural submissions only)**	Complete form as instructed.	
Summary (Tab 1) and Application Contacts (Tab 2) **(Intramural submissions only)**	Complete these tabs as instructed.	
Attachments	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".	
	Impact and Military Benefit: Upload as Attachment 6 with file name "Impact.pdf".	
	Representations (extramural submissions only): Upload as Attachment 7 with file name "MandatoryReps.pdf," if applicable.	
	DoD Military Budget Form(s): Upload as Attachment 8 with file name "MFBudget.pdf," if applicable.	
Research & Related Personal Data	Complete form as instructed.	
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.	

Application Components	Action	Completed
Research & Related Budget **(Extramural submissions only)**	Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field.	
Budget **(Intramural submissions only)**	Complete the DoD Military Budget Form and justification.	
Project/Performance Site Location(s) Form	Complete form as instructed.	
R&R Subaward Budget Attachment(s) Form, if applicable	Complete form as instructed.	

APPENDIX 1: ACRONYM LIST

ACOS/R&D	Associate Chief of Staff for Research and Development
CDEs	Common Data Elements
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
COI	Conflict of Interest
CPG	Clinical Practice Guideline
CRMRP	Clinical and Rehabilitative Medicine Research Program
CTA	Clinical Trial Award
CTDA	Clinical Trial Development Award
CTRR	Complex Traumatic Brain Injury Rehabilitation Research
DHA	Defense Health Agency
DHP	Defense Health Program
DoD	Department of Defense
DoDGARs	Department of Defense Grant and Agreement Regulations
DUNS	Data Universal Numbering System
eBRAP	Electronic Biomedical Research Application Portal
EC	Ethics Committee
eCTD	Electronic Common Technical Document
ET	Eastern Time
FAD	Funding Authorization Document
FAPIIS	Federal Awardee Performance and Integrity Information System
FAQs	Frequently Asked Questions
FDA	U.S. Food and Drug Administration
FITBIR	Federal Interagency Traumatic Brain Injury Research Informatics System
FSD	Federal Service Desk
FY	Fiscal Year
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
GUID	Global Unique Identifier
HRPO	Human Research Protection Office
ICH E6	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use)
IDE	Investigational Device Exemption
IND	Investigational New Drug

IRB	Institutional Review Board
JPC-8	Joint Program Committee 8
LAR	Legally Authorized Representative
M	Million
MIPR	Military Interdepartmental Purchase Request
NIH	National Institutes of Health
NINDS	National Institute of Neurological Disorders and Stroke
NPC	Non-Profit Corporation
NSI	Neurobehavioral Symptom Inventory
OASD(HA)	Office of the Assistant Secretary of Defense for Health Affairs
ORCID	Open Researcher and Contributor ID, Inc.
ORP	Office of Research Protections
PGIC	Patient Global Impression of Change
PH	Psychological Health
PH/TBIRP	Psychological Health/Traumatic Brain Injury Research Program
PI	Principal Investigator
PII	Personally Identifiable Information
PTSD	Post-Traumatic Stress Disorder
RDT&E	Research, Development, Test, and Evaluation
RM	Resource Manager
SAM	System for Award Management
SOW	Statement of Work
STEM	Science, Technology, Engineering, Mathematics
TBI	Traumatic Brain Injury
UDEs	Unique Data Elements
USAMMDA	U.S. Army Medical Materiel Development Activity
USAMRAA	U.S. Army Medical Research Acquisition Activity
USAMRMC	U.S. Army Medical Research and Materiel Command
USC	United States Code
VA	Department of Veterans Affairs

APPENDIX 2: DOD AND VA WEBSITES

PIs are encouraged to integrate and/or align their research projects with DoD and/or VA research laboratories and programs. Collaboration with DoD and/or VA investigators is also encouraged. Below is a list of websites that may be useful in identifying additional information about DoD and VA areas of research interest, ongoing research or potential opportunities for collaboration.

Air Force Office of Scientific Research
http://www.wpafb.af.mil/afrl/afosr/

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

Armed Forces Radiobiology Research Institute
http://www.usuhs.edu/afrri/

Clinical and Rehabilitative Medicine Research Program
https://crmrp.amedd.army.mil

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

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

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

Defense Health Agency
https://health.mil/dha

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

Defense Threat Reduction Agency
http://www.dtra.mil/

Military Health System Research Symposium
https://mhsrs.amedd.army.mil/SitePages/Home.aspx

Military Infectious Diseases Research Program
https://midrp.amedd.army.mil

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

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

Navy Bureau of Medicine and Surgery
http://www.med.navy.mil/

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

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

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

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

Telemedicine and Advanced Technology Research Center
http://www.tatrc.org/

Uniformed Services University
http://www.usuhs.edu/research

U.S. Army Aeromedical Research Laboratory
www.usaarl.army.mil

U.S. Army Center for Environmental Health Research
http://usacehr.amedd.army.mil

U.S. Army Institute of Surgical Research
http://www.usaisr.amedd.army.mil/

U.S. Army Research Institute of Environmental Medicine
http://www.usariem.army.mil/

U.S. Army Medical Research Institute of Infectious Diseases
http://www.usamriid.army.mil/

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

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

U.S. Army Research, Development and Engineering Command
www.army.mil/rdecom

U.S. Army Resiliency Directorate
http://www.army.mil/readyandresilient/

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

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

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

Walter Reed Army Institute of Research
http://www.wrair.army.mil/