I. OVERVIEW OF THE FUNDING OPPORTUNITY

Program Announcement for the Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

**Joint Program Committee-6/Combat Casualty Care
Research Program**

Psychological Health and Traumatic Brain Injury Research Program

Federal Interagency Traumatic Brain Injury Research Analysis Award

Announcement Type: Initial

Funding Opportunity Number: W81XWH-19-PHTBIRP-FITBIRA

**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), July 10, 2019

- **Application Submission Deadline:** 11:59 p.m. ET, August 1, 2019

- **End of Application Verification Period:** 5:00 p.m. ET, August 6, 2019

- **Peer Review:** October 2019

- **Programmatic Review:** December 2019

This Program Announcement must be read in conjunction with the General Application Instructions, version 20190218. The General Application 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

II.A. Program Description

Applications to the Fiscal Year 2019 (FY19) Psychological Health and 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) CDMRP provides management support for DHP research program areas, including the Joint Program Committee-6/Combat Casualty Care Research Program (JPC-6/CCCRP). The execution management agent for this Program Announcement is the Congressionally Directed Medical Research Programs (CDMRP) with strategic oversight from the JPC-6/CCCRP.

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, on deployed Service members in Iraq and Afghanistan. The PH/TBIRP mission is to establish, fund, and integrate both individual and multi-agency 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-6/CCCRP is one of six major core research program areas within the DHP. JPC-6 is a committee of Department of Defense (DoD) and non-DoD medical and military technical experts in combat casualty care-related program areas. JPC-6/CCCRP's mission is to drive medical innovation through development of knowledge and materiel solutions for the acute and early management of combat-related trauma on current and future battlefields including point of injury, far forward, and prolonged, en route, and early facility-based care. Innovations developed by JPC-6/CCCRP-supported research are applied in-theater across the roles of care and within the prehospital and critical care clinical facilities within the Military Health System. These solutions not only help to minimize the morbidity and mortality of combat-related injuries sustained by the Warfighter, they also are often translatable to civilian care. For additional information on JPC-6/CCCRP, the program's previous and current successes, and other documents related to the program's long-term planning efforts, please visit the JPC-6/CCCRP official website at https://ccc.amedd.army.mil/Pages/default.aspx.

The JPC-6/CCCRP Neurotrauma Portfolio's mission is focused on closing military-relevant gaps across a broad range of research areas to improve the prevention, diagnosis, management, and treatment of TBI and related sequelae from point of injury through recovery. The goal is to decrease morbidity and mortality from neurotrauma, mitigate secondary brain injury across all TBI severities and all roles of care, advance materiel and knowledge development, and expand and develop clinical guidelines, care algorithms, therapies, devices, and procedures that advance

the decision-making capabilities of medical personnel, enabling earlier intervention and improved outcomes.

II.A.1. FY19 JPC-6/CCCRP FITBIR Analysis Award Topics of Interest

The JPC-6/CCCRP has identified the following Topics of Interest for funding under the FY19 Federal Interagency Traumatic Brain Injury Research (FITBIR) Analysis Award. Applicants are not restricted to this list and may propose other retrospective studies of FITBIR data that align to the intent of the mechanism. However, funding for the FITBIR Analysis award will only support studies that utilize existing FITBIR data. The FY19 FITBIR Analysis Award Topics of Interest include, but are not limited to:

- Identification of unique clinical outcomes for civilians and Service members

- Utilization of FITBIR data to inform clinical practice guidelines for TBI

- Examination of treatment responders vs. non-responders to better understand the profiles of injury

- Analysis of how TBI outcomes relate to quality of life, employment, and other psychosocial measures

- Correlation of injury severity and response to treatment in patients with varying TBI severities (mild, moderate, severe)

- Exploration of chronic (more than one year post injury) patient characteristics (e.g., psychiatric symptoms, sleep disturbance, cognitive deficits) that suggest particular treatment approaches

- Definition and analysis of outcomes related to post-concussion syndrome, from weeks, months, or years after injury

- Determine the best classification parameters for initial injury based on evolving clusters of symptoms or sequelae

- Correlation of the time between injury and initial treatment with long-term outcomes

- Correlation of TBI assessment/diagnostic devices with diagnosis and outcomes

- Analysis of the exacerbation or regression of specific sequelae or symptoms at intermediate and long-term time points

- Identification of signs and symptoms of neurodegenerative disease during follow-up

- Generation of data on signs of neurodegenerative disorders that appear during follow-up and how these signs may affect long-term outcome

- Exploration of the relationship between intensity of emergency, critical, and acute care to long-term disability

II.A.2. Award Background

In August 2012 Executive Order 13625, *Improving Access to Mental Health Services for Veterans, Service Members, and Military Families*, was released to direct government agencies to create a National Research Action Plan (NRAP) to describe the planned intragovernmental coordination to further knowledge, diagnostic, and therapeutic capabilities regarding post-traumatic stress disorder, TBI, suicide, and related injuries. Within that document, government agencies were directed to "improve data sharing between agencies and academic and industry researchers to accelerate progress and reduce redundant efforts without compromising privacy". As part of the efforts to be responsive to the Executive Order, the FITBIR informatics system was developed and action items related to FITBIR were included in the NRAP released in August 2013.

FITBIR is an informatics system created through a collaborative effort between the USAMRMC and the National Institute of Neurological Disorders and Stroke (NINDS) of the National Institutes of Health (NIH). Based on the award-winning Biomedical Research Informatics Computing System (BRICS) platform, FITBIR serves as the premier platform to share human subject data across the TBI field. The goal of FITBIR is to accelerate research progress by allowing for re-analysis, aggregation, and rigorous comparison of deidentified data to facilitate new insights in the understanding, diagnosis, and treatment of TBI. FITBIR's usefulness is facilitated by the use of Global Unique Identifiers (GUIDs) and common data elements (CDEs). GUIDs are unique alpha-numeric identifiers for study participants that facilitate deidentified data sharing and tracking across multiple research sites and studies. A GUID is generated from a subject's personally identifiable information (PII) using a complex algorithm; the PII cannot be reverse engineered from the GUID. Only a subject's GUID is shared with FITBIR and the subject's PII remains protected. CDEs, developed as part of an initiative led by NINDS, are a set of data collection standards within the neuroscience research community. CDEs are identified and defined by subject matter experts. CDE development is an ongoing process that evolves with the needs of the field.

Currently, FITBIR contains over 3.7 million (M) data records for over 70,000 subjects from studies funded by the DoD and NINDS. This comprehensive dataset includes demographics, outcome assessments, imaging, and biomarkers. During an award's period of performance, the study data are in a sequestered state. However, after the period of performance ends, the data are shared publicly to all researchers with active FITBIR data access accounts. As of May 2019, data from 15 completed studies and over 4,500 research subjects are shared publicly. Please visit the FITBIR website at https://fitbir.nih.gov/ for more information on FITBIR, currently available data, and policies for accessing shared data.

II.B. Award Information

The intent of the FY19 FITBIR Analysis Award is to leverage this data to identify actionable insights for the diagnosis, management, and treatment of TBI. The proposed research must be relevant to active duty Service members, Veterans, military beneficiaries, and/or the American public.

The anticipated total costs budgeted for the entire period of performance for an FY19 JPC-6/CCCRP PH/TBI FITBIR Analysis Award will not exceed **$750,000**. Refer to Section II.D.5, Funding Restrictions, for detailed funding information.

The JPC-6/CCCRP expects to allot approximately $3M of the FY19 PH/TBIRP appropriation to fund approximately 4 FITBIR Analysis Award applications. Funding of applications received is contingent upon the availability of Federal funds for this program as well as the number of applications received, the quality and merit of the applications as evaluated by scientific and programmatic review, and the requirements of the Government. 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. It is anticipated that awards made from this FY19 FITBIR Analysis Award funding opportunity will be funded with FY19 funds, which will expire for use on September 30, 2025.

Awards will be made no later than September 30, 2020. For additional information refer to Section II.F.1, Federal Award Notices.

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 DoD during project performance is the key factor in determining whether to award a grant or cooperative agreement.

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.

Proposed research must analyze existing FITBIR data. Funding from the FITBIR Analysis Award will not support animal research or prospective (active) enrollment of human subjects. *Applications may supplement FITBIR data with other public or private data sources.* Applicants are expected to demonstrate access to shared data or restricted data within FITBIR at the time of application submission. *Proof of an approved FITBIR Data Access Request is required at the time of application submission (Attachment 7).* The FITBIR Data Access Request form can be found at https://fitbir.nih.gov/content/get-account.

Research Involving Human Subjects Data: All DoD-funded research involving the use, access, or analysis of human subjects data or records 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 Institutional Review Board (IRB) or Ethics Committee (EC) review. The use of

deidentified human subject data/records may be exempt from IRB review. Exemption must be determined by the office of the institution's IRB of record and confirmed by USAMRMC HRPO. Local IRB/EC approval at the time of submission is *not* required. Investigators must review their institutional requirements and guidelines for filing with the IRB for exempt status.

The HRPO is mandated to comply with specific laws and requirements governing all research involving human subjects 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 research taking place in international settings. When possible, protocols should be written for research with human subjects data/records 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 "Information for Investigators – Research with Data/Specimens" document at https://mrmc.amedd.army.mil/assets/docs/orp/Investigator_Guidance_on_HRPO_Review_of_Use_of_Data_Specimens_07Jun2018.pdf for additional information.

Use of DoD or Department of Veterans Affairs (VA) Resources: If the proposed research supplements FITBIR data with other DoD resources or databases, the application must describe the access at the time of submission and include a plan for maintaining access as needed throughout the proposed research. Access to DoD resource(s) or database(s) should be confirmed by including a letter of support, signed by the lowest-ranking person with approval authority.

If the proposed research supplements FITBIR data with VA study resources and databases, and/or VA research space and equipment, VA Principal Investigators (PI)s/co-PIs must have a plan for obtaining and maintaining access throughout the proposed research. Access to VA resources and/or VA research space should be confirmed by including 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 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, the application should include a letter from the VA ACOS/R&D confirming this arrangement and identifying the institution that will administer the funds associated with the proposed research.

Access to certain DoD or VA resources or databases may only be obtained by collaboration with a DoD or VA investigator who has a substantial role in the research 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 research involves a non-DoD or non-VA investigator collaborating with the DoD and/or VA. If access cannot be confirmed at the time of application submission, 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.

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.

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, other Federal Government organization other than the DoD, 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 Government organization may be submitted to Grants.gov 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 to be named by the organization as the PI on the application.

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 https://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: An application submitted by an organization to Grants.gov.

Intramural DoD Submission: An application submitted by a DoD organization to electronic Biomedical Research Application Portal (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 must be accessed and submitted at eBRAP.org.

- 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 (https://eBRAP.org/).

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

Extramural Organization Submissions: Full applications from extramural organizations must be submitted through 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.

Intramural DoD Organization Submissions: 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: eBRAP allows 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, eBRAP assigns each submission a unique log number. 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/).

The applicant organization 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 Research & Related 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 Research & Related 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 applicants 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.

members should not be involved in any pre-application or application. For questions related to Panel members and pre-applications or applications, refer to , or contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507.

- **Tab 4 – Conflicts of Interest (COIs)**

  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).

- **Tab 5 – Pre-Application Files**

  Letter of Intent (LOI) (one-page limit): Provide a brief description of the research to be conducted. If applicable, identify the Topic(s) of Interest under which the application will be submitted. Include anticipated study objectives/specific aims. LOIs are used for program planning purposes only (e.g., reviewer recruitment) and will not be reviewed during either the peer or programmatic review sessions.

- **Tab 6 – Submit Pre-Application**

  This tab must be completed for the pre-application to be accepted and processed.

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

Applications will not be accepted unless the PI has submitted a complete pre-application package.

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 (https://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 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.

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Table 1. Full Application Submission Guidelines

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Extramural Submissions	Intramural DoD Submissions
Application Package Location	
Download application package components for W81XWH-19-PHTBIRP-FITBIRA from Grants.gov (https://www.grants.gov) and create a Grants.gov Workspace. 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-19-PHTBIRP-FITBIRA from eBRAP (https://ebrap.org).
Full Application Package Components	
SF424 Research & Related 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 • Research & Related Subaward Budget Attachment(s) Form (if applicable)	**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 **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 Workspace, complete all required forms, and check for errors before submission.	**Submit package components to eBRAP (https://ebrap.org).** **Tab 5 – Submit/Request Approval Full Application:** After all components are uploaded

Extramural Submissions	Intramural DoD Submissions
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.	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 may be modified *with the exception of the Project Narrative and Research & Related Budget Form*.	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 may be modified *with the exception of the Project Narrative and Research & Related Budget Form*. 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.
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.

Both Extramural and Intramural Organizations: Application viewing, modification, and verification in eBRAP are strongly recommended, but not required. ***The Project Narrative and Research & Related Budget Form 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.

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 Research & Related 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 (16-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.

    – **Background:** Describe in detail the rationale for the retrospective study and include a literature review, preliminary studies, and/or preclinical data that led to the development of the proposed project. The background section should clearly support the choice of analysis variables and should explain the basis for the study questions

and/or study hypotheses. Establish the relevance and applicability of the proposed study and findings to the intent of the award mechanism.

– **Objectives/Specific Aims/Hypothesis:** Provide a description of the purpose and objectives of the retrospective study with detailed specific aims and hypotheses.

– **Research Design and Methods:** Describe the overall research design, methods, and analyses. Define the analysis variables, including identifying the FITBIR CDEs to be analyzed. As appropriate, include a description of controls and why they were chosen. Identify and describe the studies within FITBIR necessary to complete the proposed work. Demonstrate understanding of the selected studies' research population(s), data collection methods, and research endpoints. Describe any other non-FITBIR public or private data sources and associated studies contained within (as appropriate) that will be accessed in addition to FITBIR. If a non-FITBIR data source is used, clearly demonstrate how the non-FITBIR data source's research data elements map to the FITBIR CDEs and support the objectives of the research. Provide evidence that sufficient usable data are available within FITBIR and non-FITBIR data source (if applicable) to complete the retrospective study. Identify and describe potential problem areas in the proposed approach and alternative methods and approaches that will be employed to mitigate any risks that are identified.

– **Statistical and Data Analysis Plan:** Describe the statistical and data analysis plan with respect to the retrospective study objectives. Include a complete power analysis to demonstrate that the sample is appropriate to meet the primary objectives of the analysis. If subpopulations will be used, provide a statistical analysis to ensure appropriate power can be achieved. Ensure sufficient information is provided to allow thorough evaluation of all statistical calculations during review of the application.

○ **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 articles 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.

– 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.

– Data and Research Resources Sharing Plan: Describe how data and resources generated during the performance of the project will be shared with the research community. Refer to the General Application Instructions, Appendix 2, Section K, for more information about the CDMRP expectations for making data and research resources publicly available.

– Use of DoD Resources (if applicable): Provide a letter of support signed by the lowest-ranking person with approval authority confirming access to active duty military populations and/or DoD resources or databases.

– Use of VA Resources (if applicable): Provide a letter of support from the VA Facility Director(s) or individual designated by the VA Facility Director(s), such as the

ACOS/R&D or Clinical Service Chief confirming access to VA patients, resources, and/or VA research space. For VA PIs, if the VA NPC is not identified as the applicant institution for administering the funds, include a letter from the VA ACOS/R&D confirming this arrangement and identifying the institution that will administer the funds associated with the proposed research.

- **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.

  The structured technical abstract should be clear and concise and, at a minimum, provide the following information:

  – **Background:** Present the ideas and reasoning behind the proposed work.

  – **Objective/Hypothesis:** State the objective(s) to be reached/hypothesis to be tested. Provide evidence or rationale that supports the objective/hypothesis.

  – **Specific Aims:** State the specific aims of the retrospective study.

  – **Retrospective Study Design:** Briefly describe the study design including appropriate controls.

  – **Impact:** If applicable, identify the FY19 FITBIR Analysis Award Topic(s) of Interest to be addressed or describe the alignment of the proposed research with the intent of the mechanism. Briefly describe how the proposed research will improve TBI care for the military, Veterans and the general public.

- **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.

  – Describe the objectives and rationale for the retrospective study in a manner that will be readily understood by readers without a science or medical background.

  – As applicable, identify the FY19 FITBIR Analysis Award Topic(s) of Interest to be addressed or alignment with the intent of the mechanism.

  – Describe the potential clinical applications, benefits, and risks.

- – Describe how the proposed project will benefit military Service members and the public.

- ○ **Attachment 5: Statement of Work (four-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 FY19 FITBIR Analysis Award mechanism, use the SOW format example titled "SOW for Advanced Tech Development Research". 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. The SOW should also include the submission of the Award Expiration Transition Plan in the final three months (90 days) of the period of performance.

- ○ **Attachment 6: Impact and Military Benefit (two-page limit):** Upload as "Impact.pdf". Explain the proposed retrospective study's potential impact and military benefit as follows:

  - – **Short-Term Impact:** Describe the anticipated short-term outcome(s) that will be directly attributed to the results of the proposed study. Describe the actionable insights to be identified for the diagnosis, management, and treatment of TBI.

  - – **Long-Term Impact:** Describe the anticipated long-term vision for implementation of the knowledge generated from the proposed study and provide a projected timeline. Compare the anticipated analysis outcomes to currently available clinical guidance/practice, if applicable.

  - – **Military Benefit:** Clearly articulate how the proposed study can improve the diagnosis, management, and treatment of TBI within the military roles of care[1].

  - – **Public Purpose:** Concisely describe how this retrospective study can benefit the general public.

  - – **Challenges:** Describe potential issues or challenges that might limit the impact of the proposed retrospective study. Applications should also identify any possible solutions to these challenges or potential issues.

- ○ **Attachment 7: FITBIR Data Access Approval: Upload as "FITBIR.pdf".** Provide documentation from FITBIR stating that the FITBIR Data Access Committee has

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[1] For a description of the DoD roles of medical care go to:
https://www.cs.amedd.army.mil/FileDownloadpublic.aspx?docid=6f9e0685-1290-4e92-8277-c1e7b0f2fef0

reviewed and approved the request for data access and associated privileges. Proof that the Data Access Request has been submitted does not satisfy this requirement.

- ○ **Attachment 8: Transition Plan (three-page limit): Upload as "Transition.pdf".** Provide information on the methods and strategies to move the anticipated research outcomes to the next phase of development/research or delivery to the military or civilian clinical practice. Include a description and timeline of collaborations and other resources that will be used to provide continuity of development, e.g., proposed development or modification of clinical practice guidelines and recommendations, provider training materials, patient brochures, and other clinical support tools, scientific journal publications, models, simulations, and applications.

- ○ **Attachment 9: Representations, if applicable (extramural submissions only): Upload as "RequiredReps.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 10: 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 & Related Budget Form under subaward costs. Refer to the General Application Instructions, Section III.A.8, 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, and/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.3, 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 NIH Biographical Sketch may also be used. All biographical sketches should be submitted in uneditable PDF format.

- ○ 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.5, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.4, 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.6, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.5, for detailed information.

- **Extramural Applications Only**

  Research & Related Subaward Budget Attachment(s) Form (if applicable): Refer to the General Application Instructions, Section III.A.7, for detailed information.

  - ○ **Extramural Subaward:** Complete the Research & Related Subaward Budget Form through Grants.gov. (Refer to the General Application Instructions, Section III.A.7, 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 10. (Refer to the General Application Instructions, Section IV.A.4, for detailed information.) Each Intramural DoD Collaborator should include costs per year on the Grants.gov Research & 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 sub-recipient 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 organization's Entity registration in SAM well in advance of the application submission deadline. Allow several 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.

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 the application package 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 **18 months**.

The anticipated total costs (direct and indirect) budgeted for the entire period of performance will not exceed **$750,000**. 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 **$750,000** 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 **18 months**.

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

- Travel costs for the PI(s) to disseminate project results at one DoD-related meeting to be determined at the discretion of the Government during the award performance period. Costs associated with travel to this meeting should be included in the budget. For planning purposes, it should be assumed that the 2-day meeting will be held in the National Capital Area. These travel costs are in addition to those allowed for annual scientific/technical meetings.

May be requested for (not all-inclusive):

- Salary

- Support for multidisciplinary collaborations, including travel

- Travel costs for one investigator to travel to one scientific/technical meeting during the period of performance in addition to the required meeting described above. The intent of travel costs to this scientific/technical meeting is to disseminate project results.

Must not be requested for:

- Human subject-enrollment costs

- Animal research costs

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 funds 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.5, 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.5*.

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 FY19 funding opportunity will be funded with FY19 funds, which will expire for use on September 30, 2025.

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 listed in decreasing order of importance:

- **Research Strategy and Feasibility**

  - How relevant and applicable the proposed research and findings are to the intent of the mechanism and, if applicable, at least one of the FY19 FITBIR Analysis Award Topic(s) of Interest.

  - How well the preliminary data and scientific rationale support the proposed study.

  - How well the retrospective study is designed to achieve the proposed objectives, including the chosen individual studies within FITBIR, non-FITBIR data sources, and data elements/CDEs.

  - How well the research team demonstrates access to FITBIR and, as applicable, other non-FITBIR data sources.

  - How well the application acknowledges potential problems and addresses alternative approaches.

  - Whether the study can be completed within the proposed period of performance.

- If applicable, to what degree the intellectual and material property plan is appropriate.

- **Impact**

  - To what extent the anticipated research outcomes or long-term vision of the proposed research may identify actionable insights for the diagnosis, management, and treatment of TBI.

  - To what extent the proposed research can benefit the Service members and the public.

  - To what degree the knowledge generated from the proposed study represents an improvement to currently available clinical guidance/practice.

- **Statistical and Data Analysis Plan**

  - To what degree the statistical plan, including sample size projections and power analysis, and data analysis plan are adequate for the primary analysis and all proposed correlative analyses.

  - If applicable, whether the statistical and data analysis plan compensates for the use of a subpopulation to ensure appropriate power can be achieved.

- **Personnel**

  - Whether the composition of the research team is appropriate.

  - Whether the levels of effort by the PI and other key personnel are appropriate to ensure success of this project.

  - How the study team's background, expertise, and record(s) of accomplishment demonstrate their ability to accomplish the proposed work.

- **Transition Plan**

  - Whether appropriate collaborations and other resources for providing continuity of development are established and/or well described.

  - How the schedule and milestones for bringing the outcome(s) to the next phase of research/development are appropriate.

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

- **Budget**

  - Whether the total 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 research.

- **Environment**

  ○ To what degree the scientific environment and the accessibly of institutional/organizational resources support the proposed research.

- **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 and FY19 JPC-6/CCCRP, as evidenced by the following:

  ○ Adherence to the intent of the award mechanism

  ○ Program portfolio composition

  ○ Programmatic relevance

  ○ Relative impact and military benefit

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**, the evaluation of applications against established criteria to determine technical merit, where each application is assessed for its own merit, independent of other applications. The second tier is **programmatic review**, a comparison-based process in which applications with high scientific and technical merit are further evaluated for programmatic relevance. Final recommendations for funding are made to the Commanding General, USAMRMC, on behalf of the DHA and the OASD(HA) . ***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 https://cdmrp.army.mil/about/2tierRevProcess. A PI Information Paper describing the funding recommendations and review process for the award mechanisms for the FY19 PHTBIRP FITBIR Analysis Award will be provided to the PI and posted on the CDMRP website.

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign a statement declaring 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 supported with FY19 funds are anticipated to be made no later than September 30, 2020. 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 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 Government Organizations: Funding made to Federal Government organizations (to include 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

Unless otherwise restricted, changes in PI will be allowed at the discretion of the Grants Officer, provided the intent of the award mechanism is met. An organizational transfer of an award will not be allowed in the last year of the (original) period of performance or any extension thereof.

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

Applicable requirements in the DoDGARs found in 32 CFR, Chapter I, 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 latest DoD R&D General Terms and Conditions, the USAMRAA General Research Terms and Conditions with Institutions of Higher Education, Hospitals, and Non-Profit Organizations: Addendum to the DoD R&D General 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.*

Annual progress reports as well as a final progress report will be required.

Quarterly technical progress reports and quad charts will be required.

Quad Chart: Upload as "QuadChart.pdf". Complete the Quad Chart template, a one-page PowerPoint file that must be downloaded from the CDMRP eBRAP System at https://ebrap.org/eBRAP/public/Program.htm, save, using Adobe Acrobat Reader, as a PDF file, and submit at the time of award

In addition to written progress reports, in-person presentations may be requested.

Award Expiration Transition Plan: An Award Expiration Transition Plan must be submitted three months (90 days) prior to the end of the period of performance. Use the one-page template "Award Expiration Transition Plan," available on the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) under the "Progress Report Formats" section. The Award Expiration Transition Plan must outline if and how the research supported by this award will progress and must include source(s) of funding, either known or pending.

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 Representations (see General Application Instructions, Appendix 5, Section B).

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 20190218e. The Program Announcement numeric version code will match the General Application Instructions version code 20190218.

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:

* Letter of Intent is missing.

The following will result in administrative rejection of the application:

* Pre-application was not submitted.

* Project Narrative exceeds page limit.

* Project Narrative is missing.

* Budget is missing.

* Attachment 7, FITBIR Data Access Approval, is missing.

II.H.2.b. Modification

- Pages exceeding the specific limits will be removed prior to review for all documents other than the 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 FY19 PH/TBIRP FITBIR Analysis Award 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 FY19 PH/TBIRP FITBIR Analysis Award Programmatic Panel members can be found at https://cdmrp.army.mil/phtbi/panels/panels19_fitbir*.

- The application fails to conform to this Program Announcement description.

- 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 FY19, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (https://cdmrp.army.mil/about/2tierRevProcess). Applications that include names of personnel from either of these companies may be administratively withdrawn.

- 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.

- Proposed research includes animal studies or prospective enrollment of human subjects.

- The applicant fails to demonstrate FITBIR data access approval for the proposed work.

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 Research & Related Application for Federal Assistance **(Extramural submissions only)**	Complete form as instructed	
Summary (Tab 1) and Application Contacts (Tab 2) **(Intramural submissions only)**	Complete 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 the file name "Impact.pdf"	
	FITBIR Data Access Approval: Upload as Attachment 7 with the file name "FITBIR.pdf"	
	Transition Plan: Upload as Attachment 8 with the file name "Transition.pdf"	
	Representations (Extramural submissions only): Upload as Attachment 9 with file name "RequiredReps.pdf" if applicable	
	DoD Military Budget Form(s): Upload as Attachment 10 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	
Research & Related 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
BRICS	Biomedical Research Informatics Computing System
CCCRP	Combat Casualty Care Research Program
CDMRP	Congressionally Directed Medical Research Programs
CDE	Common Data Element
CFR	Code of Federal Regulations
COI	Conflict of Interest
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
GUID	Global Unique Identifier
eBRAP	Electronic Biomedical Research Application Portal
EC	Ethics Committee
ET	Eastern Time
FAD	Funding Authorization Document
FAPIIS	Federal Awardee Performance and Integrity Information System
FITBIR	Federal Interagency Traumatic Brain Injury Research (FITBIR)
FY	Fiscal Year
HRPO	Human Research Protection Office
IRB	Institutional Review Board
JPC-6	Joint Program Committee-6
LOI	Letter of Intent
K	Thousand
M	Million
MIPR	Military Interdepartmental Purchase Request
NINDS	National Institute of Neurological Disorders and Stroke
NPC	Non-Profit Corporation
NRAP	National Research Action Plan
OASD(HA)	Office of the Assistant Secretary of Defense for Health Affairs
ORCID	Open Researcher and Contributor ID, Inc.
PH/TBIRP	Psychological Health and Traumatic Brain Injury Research Program
PI	Principal Investigator
PII	Personally Identifiable Information
RDT&E	Research, Development, Test, and Evaluation
SAM	System for Award Management

SOW	Statement of Work
STEM	Science, Technology, Engineering, and/or Mathematics
TBI	Traumatic Brain Injury
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