I. OVERVIEW OF THE FUNDING OPPORTUNITY

Program Announcement for the Department of Defense
Defense Health Program
Congressionally Directed Medical Research Programs

Joint Program Committee 5 / Military Operational Medicine
Research Program
Psychological Health and Traumatic Brain Injury
Research Program
Resilience and Readiness Optimization/Enhancement
Translational Research Award

Announcement Type: Initial

Funding Opportunity Number: W81XWH-18-PHTBIRP-R2OE-TRA

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), October 5, 2018
- Application Submission Deadline: 11:59 p.m. ET, November 16, 2018
- End of Application Verification Period: 5:00 p.m. ET, November 19, 2018
- Peer Review: January 2019
- Programmatic Review: March 2019
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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 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) Congressionally Directed Medical Research Programs (CDMRP) provides execution management support for DHA research program areas, including the Joint Program Committee-5/Military Operational Medicine Research Program (JPC-5/MOMRP). The execution management agent for this Program Announcement is the CDMRP with strategic oversight from JPC-5/MOMRP.

The PH/TBIRP was initiated by Congress in FY07 to provide support for research of exceptional scientific merit in response to the devastating impact of traumatic brain injury (TBI) and psychological health (PH) issues to our deployed Service members (SMs) 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 SMs as well as their caregivers and families.

The JPC-5/MOMRP is one of six major research program areas within the DHA. DHP RDT&E funding is administered through JPC-5/MOMRP, which consists of Department of Defense (DoD) and non-DoD medical and military technical experts relevant to the program area. The JPC-5/MOMRP research portfolio is focused on developing effective medical countermeasures against operational stressors and to prevent physical and psychological injuries during training and operations in order to maximize the health, readiness, and performance of SMs and their families, which are critical to force health and readiness. The research in this portfolio is relevant to active duty SMs, Veterans, other military beneficiaries, and the American public. Further information about JPC-5/MOMRP can be found at https://momrp.amedd.army.mil/.

II.A.1. FY18 PH/TBIRP Award History and Topic Area

Service members, first responders, and small teams (e.g., Special Operations Forces) are expected to perform under physically and psychologically arduous conditions. Such conditions
include being exposed to threats ranging from death and danger to sleep deprivation, noise, lack of privacy, and extended separation from units/larger teams. Other threats include the potential for mission uncertainty, rapid changes in mission sets, and situational ambiguity.

Maintaining health and optimal performance in this context is a necessary challenge. Research has documented variation in individual response and reaction to stress and has identified the potential for negative sequelae in response to mission-related stressors; such a negative effect has the potential to impact both health and performance.\(^1\) Few studies have documented evidence-based interventions to maintain or boost performance under such conditions. Optimal execution of these tasks requires ongoing coordination of physical and cognitive resources to meet the common and unique demands presented by both task and setting. These resources are adversely impacted by internal and external threats, such as sleep loss, physical stressors, injury, environmental hazards and stressors, changes in nutritional/hydration status, and social/emotional stress. Impaired ability to perform work or training tasks adequately or optimally has significant consequences for the individual and the unit/larger team.

The Joint Forces have an overarching priority to ensure that SMs are operationally resilient. For example, the U.S. Army Operating Concept (AOC) emphasizes the integration of advanced technologies with skilled and well-trained teams. Such teams are also expected to perform under harsh conditions and such demands require continued development of tailored resilience building techniques and tools to enhance and accelerate performance of the individual, teams, and leaders. As the military restructures and organizes in preparation for creating rapid-deploying small teams, research is needed to deliver evidence-based accelerated training, team building techniques, and tools to maximize and sustain operational efficiency and protect SM and first responder health and functioning.

When addressing resilience-related issues in the Services, the primary challenge is understanding and measuring resilience-related outcomes at the individual and unit/team level. In addition, linking individual resilience to human performance optimization is needed. The Joint Forces current resilience training model is shifting to include tailored strategies designed to meet the needs of units. Such evidence-based training will be included on a menu of possible interventions that units can select depending on their interest and requirements. Currently, the Joint Forces incorporates foundational resilience training techniques and performance psychology techniques. Additional and novel techniques are being sought for inclusion to provide units with alternative and additional methods for building resilience and optimizing performance. Thus, novel techniques are sought that can potentially be rolled out to units through existing training resources or using online methodology proven to be effective.

II.B. Award Information

The intent of this Program Announcement is to evaluate the efficacy of evidence-based methods and strategies for rapidly enhancing leader effectiveness, individual and small team performance, and resilience to stressors. Applications that examine the effectiveness of approaches that translate and integrate content into the everyday routines of SMs, first responders, and small

teams to enhance psychological health readiness are encouraged. While additional intervention techniques are being sought as part of this award, the goal is not to overload individuals, units, and leaders with new training. Instead, the goal is to ensure that any training that is offered is engaging and proven to be effective. In addition, the intervention does not necessarily have to be training-based. Strategies that include non-intrusive methods are of interest if they improve the health and functioning of individuals, teams, and/or leaders.

The FY18 JPC-5/MOMRP PH/TBIRP Resilience and Readiness Optimization/Enhancement (R2OE) Translational Research Award (TRA) Funding Opportunity seeks to support research with the goal of evaluating evidence-based interventions and techniques to optimize and enhance resilience and readiness designed to:

(1) Accelerate and enhance the development of effective teams (e.g., first responders, small teams, and remote/isolated units).

(2) Efficiently strengthen unit cohesion in the context of isolated, small teams.

(3) Succeed under significant emotional demands using resilience-building techniques, tools, and strategies to enhance emotion regulation.

Applications to this Program Announcement must address one or more of the following topics of interest:

- Performance psychology and approaches to enhance performance
- Emotion regulation strategies
- Emotional intelligence
- Rapid and accelerated team building methods
- Methods to mitigate negative effects of isolation and loneliness
- Approaches to enhance social connection and belongingness
- Cognitive performance enhancement strategies
- Accelerated learning strategies (individual and collective)
- Accelerated performance-enhancement techniques
- Individual, team, and/or leader strategies
- May include but are not limited to technologies (e.g., virtual reality approaches)
- Strategies to support small team culture (e.g., first responders, remote/isolated units)

In addition, methods for accelerating learning strategies are also a focal point given the potential for small teams to have to adapt quickly to changing circumstances and technologies. Given the
importance of leaders at the unit level and above, the goal of the award is also to evaluate evidence-based methods for rapid leader development and for strategies to ameliorate leader effectiveness and individual and small team performance. **This Program Announcement seeks applications that support clinical trials of behavioral health interventions.**

A clinical trial is defined as a prospective accrual of human subjects in whom an intervention (e.g., behavioral intervention, device, drug, biologic, surgical procedure, rehabilitative modality, or other) is tested for a measurable outcome with respect to safety, effectiveness, and/or efficacy. This outcome represents a direct effect on the subject of that intervention or interaction.

Proposed behavioral health interventions should be applicable to all DoD Service branches (Army, Navy, Air Force, Marines) as well as Special Operations and the Reserve Component (Reserves/National Guard). Military collaborations are encouraged. **Veterans are an important population, but this Program Announcement is not focused on Veterans.** The expectation of this research is to demonstrate the utility of evidenced-based interventions and techniques to optimize and enhance resilience and readiness and benefit our SMs, first responders, small teams and the public at large.

**Preclinical (animal) studies are not allowed.**

The JPC-5/MOMRP expects to allot approximately $7.5 million (M) of the FY18 PH/TBIRP appropriation to fund approximately three R2OE TRA 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. **The maximum period of performance is 3 years.** For additional funding information, see Section II.D.5, Funding Restrictions.

This Program Announcement is focused on research that delivers solutions for SM health but should also demonstrate a broader benefit to the public at large.

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.

**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.
DoD FY18 PH/TBIRP Resilience and Readiness Optimization/Enhancement (R2OE) Translational Research Award

Use of DoD or Department of Veterans Affairs (VA) Resources: If the proposed research involves access to active duty military patient populations and/or DoD resources or databases, the application must describe the access at the time of submission and a plan for maintaining access as needed throughout the proposed research. Access to target active duty military population(s) and/or 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 involves access to VA populations, VA study resources and databases, and/or VA research space and equipment, VA Principal Investigators (PIs) must have a plan for obtaining and maintaining access throughout the proposed research. Access to VA population, 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 patient populations, 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.

DoD and other Federal Agencies Collaboration and Alignment Encouraged: Relevance to the health care needs of the Armed Forces, their family members, and their communities is a key feature of this award. Therefore, PIs are strongly encouraged to collaborate, integrate, and/or align their research projects with DoD or other Federal Agencies’ research laboratories and programs. Agencies listed in Appendix 2 are potential resources and do not represent an all-inclusive list of work in the target research area.

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, 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. 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.

Use of Common Data Elements and Data Sharing: The National Research Action Plan recommends the use of common data elements (CDEs) to facilitate sharing of data to promote collaboration, accelerate research, and advance knowledge on characterization, prevention, diagnosis, and treatment of PH disorders and post-traumatic stress disorders. The USAMRMC strongly encourages applicants to incorporate CDEs appropriate to each field of study, such as the PhenX Core and Specialty collections, which are available in the Mental Health Research, Substance Abuse and Addiction, and Research Domains Collections of the PhenX Toolkit, https://www.phenxtoolkit.org/index.php, into all studies involving human subjects as applicable.

For studies that will enroll subjects with psychological health disorders, awardees may be requested to submit data to the National Institute of Mental Health Data Archive https://data-archive.nimh.nih.gov or another data repository to be identified by the Government.

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 to be named as PI.

An eligible Principal Investigator, 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.

Each investigator may be named on only one FY18 PH/TBIRP R2OE TRA application as the PI; however, there are no limitations on the number of applications for which an investigator may be named as a co-investigator.

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 (https://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.

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](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 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.

**FY18 PH/TBIRP R2OE TRA 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**

**Letter of Intent (LOI) (one-page limit):** Provide a brief description of the research to be conducted. 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

All contributors and administrators to the application must use matching compatible versions of Adobe software when editing and preparing application components. The use of different software versions will result in corruption of the submitted file. Refer to the General Application Instructions, Section III, for details on compatible Adobe software.

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

<table>
<thead>
<tr>
<th>Extramural Submissions</th>
<th>Intramural DoD Submissions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Application Package Location</strong></td>
<td></td>
</tr>
<tr>
<td>Download application package components for W81XWH-18-PHTBIRP-R2OE-TRA from Grants.gov (<a href="http://www.grants.gov">http://www.grants.gov</a>) 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.</td>
<td>Download application package components for W81XWH-18-PHTBIRP-R2OE-TRA from eBRAP (<a href="https://ebrap.org">https://ebrap.org</a>).</td>
</tr>
</tbody>
</table>
### Extramural Submissions

#### Full Application Package Components

<table>
<thead>
<tr>
<th><strong>SF424 (R&amp;R) Application for Federal Assistance Form:</strong></th>
<th><strong>Tab 1 – Summary:</strong> Provide a summary of the application information.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Refer to the General Application Instructions, Section III.A.1, for detailed information.</td>
<td><strong>Tab 2 – Application Contacts:</strong> This tab will be pre-populated by eBRAP; add Authorized Organizational Representative.</td>
</tr>
</tbody>
</table>

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**
- **R&R 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.

### Intramural DoD Submissions

#### 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.
<table>
<thead>
<tr>
<th>Extramural Submissions</th>
<th>Intramural DoD Submissions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Application Verification Period</strong></td>
<td><strong>Application Verification Period</strong></td>
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<tr>
<td>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, <em>with the exception of the Project Narrative and Budget Form</em>, may be modified.</td>
<td>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, <em>with the exception of the Project Narrative and Budget Form</em>, 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.</td>
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<tr>
<th>Further Information</th>
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<tr>
<td><strong>Tracking a Grants.gov Workspace Package.</strong> 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.</td>
<td>Refer to the General Application Instructions, Section IV, for further information regarding eBRAP requirements.</td>
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</tbody>
</table>

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.

The organization’s Business Official or Authorized Organization Representative (or Resource Manager/Comptroller) should approve/verify the full application submission prior to the application verification deadline.

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 (20-page limit): Upload as “ProjectNarrative.pdf”**. The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) 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.

    - **Alignment to Intent of Program Announcement:** State the relevance of the proposed research to the intent of the award mechanism in Section II.B, Award Information, and explain the potential impact of resilience and readiness optimization/enhancement interventions to translate and integrate content into the everyday routines of SMs, first responders and small teams to enhance psychological health readiness.

      - Describe the proposed intervention and how the relevant literature and pilot or preliminary data support the proposed work. Describe previous experience most pertinent to this research.

      - Describe how the resilience-based intervention accelerates and enhances leader effectiveness and the development of effective teams (first responders, small teams, and remote/isolated units).

      - Describe how the resilience-based interventions efficiently strengthen unit cohesion in the context of isolated, small teams.
• Describe how the resilience-based intervention will succeed under significant emotional demands, using resilience-building techniques, tools, and strategies to enhance emotion regulation.

• Describe how the proposed approach addresses the resilience and behavioral health and risk outcomes.

• Explain how the strategies used in the project will enhance resilience in SMs, first responders, and small teams, and address the following topics of interest (not all-inclusive):
  ❖ Performance psychology and approaches to enhance performance
  ❖ Emotion regulation strategies
  ❖ Emotional intelligence
  ❖ Rapid and accelerated team building methods
  ❖ Methods to mitigate negative effects of isolation and loneliness
  ❖ Approaches to enhance social connection and belongingness
  ❖ Cognitive performance enhancement strategies
  ❖ Accelerated learning strategies (individual and collective)
  ❖ Accelerated performance-enhancement techniques
  ❖ Individual, team, and/or leader strategies
  ❖ May include but not limited to technologies (e.g., virtual reality approaches)
  ❖ Strategies to support small team culture (e.g., Security Forces Assistance Brigade model)

• Explain how the proposed resilience-based interventions will accommodate the diverse nature of the targeted population, including gender and occupations. Interventions should be sensitive to the time and contextual constraints associated with occupations and lifestyles of SMs and first responders.

• Describe how the proposed resilience-based interventions will be interactive and engaging to decrease burden and increase buy-in.

• Elucidate the extent to which the proposed approach addresses the potential immediate or long-term PH and well-being of SMs first responders and small teams, and the extent to which the proposed approach may be applicable and beneficial to the general public.
- **Hypothesis:** Provide a description of the hypothesis for the proposed research.

- **Project Milestones:** Identify timelines for critical events that must be accomplished in order for the research to be successful.

- **Research Strategy:** Describe objectives, specific aims, experimental design, methods, and analyses.
  
  ▪ Explain how the research will evaluate resilience and readiness optimization/enhancements for the purpose of optimizing and enhancing resilience and readiness.
  
  ▪ Present the ideas and reasoning behind the proposed work.
  
  ▪ Align the methods and procedures with the research aims. State how they will be developed and integrated into the project and their feasibility to address the need(s) described.
  
  ▪ Identify any potential problems and address alternative approaches.
  
  ▪ Define the study variables and describe how they will be measured. Include a description of appropriate controls and the endpoints to be tested.
  
  ▪ Describe the methods that will be used to recruit a sample cohort from the accessible population (e.g., convenience, simple random, stratified random).
  
  ▪ Describe access to the subject population(s) with a viable plan for recruitment, consent, screening, and retention of appropriate subjects, and identify sampling methods to gain a representative sample from the population(s) of interest.
  
  ▪ Describe the human subject-to-group assignment process (e.g., randomization, block randomization, stratified randomization, age-matched controls, alternating group, or other procedures), if applicable. Explain the specific actions to accomplish the group assignment (e.g., computer assignment, use of table of random numbers).
  
  ▪ Describe the reliability and validity of assessment measures, if applicable. Include critical survey questions, if applicable.
  
  ▪ Provide a description of the range of environments in which the resilience and readiness optimization/enhancement could be used in and address the following questions:
    
    ❖ What is the intervention modality (in-person, virtual, both)?
    
    ❖ When can the resilience and readiness optimization/enhancement intervention occur (duty hours, off-duty hours, i.e., during work, after work, or both)?
- Where should the resilience and readiness optimization/enhancement intervention take place (barracks, work site, home, or other locations)?

- Is the same location needed to execute the intervention?

- **Statistical and Data Analysis Plan:** Describe the statistical model(s) and data analysis plan with respect to the study objectives and endpoints as appropriate to the type of study. Specify the number of human subjects that will be enrolled. If multiple study sites are involved, state the approximate number to be enrolled at each site. Include a complete power analysis to demonstrate that the sample size is appropriate to meet the objectives and endpoints of the study.

- **Personnel:** Describe how the background, experience, and expertise of the PI and other key personnel demonstrate their ability to perform the proposed research and the appropriate composition of the research or study team (e.g., study coordinator, statistician).
  - Demonstrate the extent to which the PI has formed a multidisciplinary team of scientists and stakeholders that represent SMs, first responders, and small teams.
  - Describe the levels of effort by the PI and other key personnel.
  - State whether each key investigator’s record of accomplishments demonstrates his/her understanding of working with military populations.

- **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 (one-page limit per letter): Provide a letter (or letters, if applicable) signed by the Department Chair or appropriate organization official, confirming the laboratory space, equipment, and 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) (one-page limit per letter): Provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed work. 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.

- 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 patient 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.

  - 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: Indicate whether CDEs will be incorporated into the study (if applicable) and 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 expectations for making data and research resources publicly available.

- 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 the ideas and reasoning on which the proposed work is based. Describe how the study rationale examines the efficacy and effectiveness of resilience interventions to translate and integrate content into the everyday routines of SMs, first responders and small teams to enhance psychological health readiness.

- **Objective/Hypothesis:** State the objective to be reached and hypothesis to be tested. Provide evidence or rationale that supports the objective/hypothesis.

- **Specific Aims:** State the specific aims of the study and how they support the proposed work.

- **Study/Project Design:** Briefly describe the study/project design, including controls.

- **Impact and Military Benefit:** Briefly explain the potential impact of resilience interventions to translate and integrate content into the everyday routines of SMs, first responders, and small teams to enhance psychological health readiness.

○ 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. Minimize use of acronyms and abbreviations, where appropriate. The lay abstract is an important component of the application review process because it addresses issues of particular interest to the consumer (SMs, first responders, and small teams) community. Do not duplicate the technical abstract.
- Describe the objectives and rationale for the application in a manner that will be readily understood by readers without a background in psychological health or the military.

- Describe the efficacy and effectiveness of resilience interventions to translate and integrate content into the everyday routines of SMs, first responders and small teams to enhance psychological health readiness.

- Briefly describe how the proposed project will benefit SMs, first responders, small teams, and the public at large.

○ **Attachment 5: Statement of Work (SOW) (eight-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 FY18 PH/TBIRP R2OE TRA mechanism, use the SOW format example titled, “SOW for Clinical Research (Including Trials, Special Populations).” 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 required for each task and at each site. Refer to the General Application Instructions, Appendix 1, for additional information regarding regulatory requirements.
  
  - For studies with prospective accrual of human subjects, indicate quarterly enrollment targets.
  
  - Briefly state the methods to be used.


  - Describe how the proposed work enhances the psychological health of SMs, first responders and small teams. Show how the proposed study complements ongoing resilience-based interventions research.
  
  - What are the likely contributions of this study to advancing resilience-based interventions throughout the DoD as well as the potential benefit for the general public?
o Attachment 7: Translation Plan (one-page limit): Upload as “Translation.pdf”.

Clearly state the methods and strategies to move the anticipated research outcomes to the next phase of research or delivery to the military and civilian community after successful completion of the award. The Translation Plan should include the components listed below:

- Describe the funding, schedule, and milestones that will be used to bring the intervention(s) to the next level of development (e.g., specific funding opportunities to be pursued). Detail the timelines toward implementation.
- Describe collaborations and other resources that will be used to facilitate translation of the proposed interventions.
- Describe the management of and access to intellectual property, and/or licensing, if applicable.
- Explain how the proposed effort utilizes designs to develop a knowledge base about “how” interventions are translated to military practice settings that go beyond distribution of information about the intervention.

o Attachment 8: Human Subject Recruitment and Safety Procedures required for all studies recruiting human subjects; no page limit: Upload as “HumSubProc.pdf”.

The Human Subject Recruitment and Safety Procedures attachment should include the components listed below:

- Study Population: Describe the target population (to whom the study findings will be generalized) and the nature, approximate number, and pertinent demographic characteristics of the accessible population at the study site (population from whom the sample will be recruited). Provide evidence that the research team has access to the proposed study population. Discuss past efforts in recruiting human subjects from the target population. Address any potential barriers to accrual and plans for addressing unanticipated delays.

- Inclusion/Exclusion Criteria: List the inclusion and exclusion criteria for the proposed research. Include justification of any age, race, ethnicity, or sex limitations provided. Inclusion/exclusion criteria should take into consideration the specific risk profile of the studies to be conducted and the standard of care for that patient population. Provide detailed justification for exclusions.

  - Inclusion of Women and Minorities in Study: Consistent with the Belmont Report, “Ethical Principles and Guidelines for the Protection of Human Subjects,” and Congressional legislation, special attention is given to inclusion of women and/or minorities in studies funded or supported by the USAMRMC. This policy is intended to promote equity both in assuming the burdens and in receiving the benefits of human subjects research. Include an appropriate justification if women and/or minorities will be excluded.
- **Description of the Recruitment Process:** Explain methods used to identify potential human subjects (e.g., medical record review, obtaining sampling lists, and health care provider identification).

  - Describe the recruitment process in detail. Address who will identify potential human subjects, who will recruit them, and what methods will be used to recruit them.

  - Include a detailed description of and justification for the compensation plan if the human subjects will be compensated for participation in the study. Note that under 24 USC 30, payment to Federal Employees and Active Duty military personnel for participation in research while on duty is limited to blood donation and may not exceed $50 per blood draw. They may not receive any other payment or non-monetary compensation for participation in a research study unless they are off duty or on leave during the time they are participating in the protocol.

  - Describe the recruitment and advertisement materials. The recruitment materials should not be coercive or offer undue inducements and should accurately reflect the study.

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

  *For the proposed study, provide a draft, in English, of the Informed Consent Form.*

  - Identify who is responsible for explaining the study, answering questions, and obtaining informed consent. Include a plan for ensuring that human subjects’ questions will be addressed during the consent process and throughout the trial.

  - Include information regarding the timing and location of the consent process.

  - Address issues relevant to the mental capacity of the potential human subject (e.g., altered capacity due to administration of any mind-altering substances such as tranquilizers, conscious sedation or anesthesia, brain injury, stress/life situations, or human subject age), if applicable.

  - Address how privacy and time for decision-making will be provided and whether or not the potential human subject will be allowed to discuss the study with anyone before making a decision.

  - Address whether research data will be de-identified to minimize risks to privacy when shared with data repositories.

  - Consider the need for obtaining ongoing consent or for re-assessing capacity over the course of a long-term study, and describe any relevant procedures to assure continued consent.
- **Screening Procedures:** List and describe any evaluations (e.g., laboratory procedures, history, or physical examination) that are required to determine eligibility/suitability for study participation and the diagnostic criteria for entry. Note that some screening procedures may require a separate consent or a two-stage consent process. Informed consent must be obtained prior to initiation of any procedures for the purpose of determining eligibility.

- **Risks/Benefits Assessment:**
  
  - Foreseeable risks: Clearly identify all study risks. Study risks include any risks that the human subject is subjected to as a result of participation. Consider psychological, legal, social, and economic risks as well as physical risks. If the risks are unknown, this should be stated. If applicable, any potential risk to the study personnel should be identified.
  
  - Risk management and emergency response:
    
    - Describe all safety measures to minimize and/or eliminate risks to human subjects and study personnel or to manage unpreventable risks.
    
    - Discuss the overall plan for provision of emergency care or treatment for an adverse event for study-related injuries, to include who will be responsible for the cost of such care.
    
    - Address any special precautions to be taken by the human subjects before, during, and after the study.
    
    - Describe any special care or equipment (e.g., monitors, telemedicine equipment) needed for human subjects enrolled in the study.
  
  - **Potential benefits:** Describe known and potential benefits of the study to the human subject, a specific community, or society.

- **Attachment 9: Data Management (no page limit):** Upload as “DataManage.pdf”. The Data Management attachment should include the components listed below.

  Describe all methods used for data collection to include the following:

  - **Identifiers:** Describe the unique identifiers or specific code system to be used to identify human subjects, if applicable.

  - **Confidentiality:** Explain measures taken to protect the privacy of study human subjects and maintain confidentiality of study data. Strategies to protect the privacy and confidentiality of study records, particularly those containing identifying information, should be addressed.
• Address who will have access to study records, data, and specimens, including an acknowledgment that representatives of USAMRMC are eligible to review study records.

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

  – **Disposition of data:** Describe where data (both electronic and hard copy) will be stored, who will keep the data, how the data will be stored, and the length of time data will be stored.

  – **Sharing study results:** In cases where the human subject could possibly benefit medically or otherwise from the information, explain whether or not the results of screening and/or study participation will be shared with human subjects or their primary care provider, to include results from any screening tests performed as part of the study.

  ○ **Attachment 10:** 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](https://ebrap.org/eBRAP/public/Program.htm)). For more information, see the General Application Instructions, Appendix 5, Section B, Representations.

  ○ **Attachment 11:** 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](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, and 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 (five-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](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 (five-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 11. (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 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.

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 that the entity’s Administrator is 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 FAQs 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 3 years.

The anticipated **total** costs (direct and indirect) budgeted for the entire period of performance will not exceed **$2.5M**. 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 **$2.5M** 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 3 years.
For this award mechanism, direct costs must be requested for:

- Travel costs for the PI to disseminate project results at one DoD PH/TBIRP in-progress review meeting annually. 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.

May be requested for (not all-inclusive):

- Salary
- Research-related subject costs
- Support for multidisciplinary collaborations
- Equipment
- Clinical trial costs
- Travel between collaborating organizations
- Travel costs for one or two investigators to travel to one scientific/technical meeting per year in addition to the required in-progress review meetings described above. The intent of travel costs to the scientific/technical meeting is to present project information and disseminate project results from the PH/TBIRP R2OE TRA.

May not be requested for:

- Animal studies

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.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-5/MOMRP expects to allot approximately $7.5M of the FY18 PH/TBIRP appropriation to fund approximately three R2OE TRA 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:

- **Alignment to FY18 PH/TBIRP R2OE TRA**
  - To what extent the proposed approach addresses the intent of the award mechanism in Section II.B, Award Information,
  - To what extent the relevant literature and pilot or preliminary data supports the proposed work.
  - To what degree the proposed work has the potential to optimize and enhance PH care for SMs first responders, small teams, and complements ongoing DoD and VA research to optimize and enhance resilience and readiness.
  - To what extent the proposed approach addresses the potential immediate or long-term impact on the PH and well-being of SMs, first responders, small teams, and remote/isolated units and/or communities, and to what extent the proposed approach may be applicable and beneficial to the general public.
  - How well the proposed intervention describes the resilience and behavioral health and risk outcomes that resilience-based interventions are targeting.
  - How well the proposed approach describes the timing and delivery methods of interventions, and how they coincide with important military life cycle stages or transitions.
  - To what extent the interventions studied will be interactive and engaging to decrease burden and increase buy-in.
○ How well the proposed research impacts resilience and readiness optimization/enhancement interventions to translate and integrate content into the everyday routines of SMs, first responders, small teams, and the public at large.

○ How relevant the study population is to the military.

• Hypothesis

○ How well the proposed approach describes the hypothesis for the proposed research.

• Project Milestones

○ To what degree the timelines for the critical events required for the research to be successful align with the hypotheses, aims, methods, and analyses.

• Research Strategy and Feasibility

○ How well the research evaluates resilience and readiness optimization/enhancements for the purpose of optimizing and enhancing resilience and readiness.

○ How well the proposed approach presents the ideas and reasoning behind the proposed work.

○ How well the methods and procedures are described and aligned to the research aims as an integrated project.

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

○ How well the application defines the study variables and describes how they will be measured. Whether the assessment measures are valid and reliable and whether the controls are appropriate and endpoints achievable.

○ The degree to which the methods for sample cohort recruiting are described.

○ How well the human subject-to-group assignment process is described. Whether the specific actions to accomplish the group assignment are realistic/adequate for the proposed study.

○ How viable the plan is for recruitment, consent, screening, and retention of appropriate subjects.

○ To what degree the sampling methods achieve a representative sample from the population(s) of interest.

○ How well the proposed research describes the target population and demonstrates access to the proposed study population.

○ How well the inclusion and exclusion criteria are described for the proposed research.
○ How appropriate the methods are for identifying potential human subjects, recruitment process, informed consent, and compensation plan for the proposed study.

○ How well the research will evaluate the modality of resilience and readiness optimization/enhancement interventions (in-person, virtual, or both).

○ To what extent the research will evaluate the range of environments in which optimization/enhancement operates in terms of timing (duty hours, off-duty hours, i.e., during work, after work, or both) and location (on-base in barracks, on-base at work site, off-base at home, off-base at other locations).

• Data Sharing Plan

○ How thoroughly the PI has outlined a plan for use of CDEs and sharing of research data as appropriate for the type of study.

○ Whether the application plans to use de-identified data for sharing with data repositories.

• Statistical and Data Analysis Plan

○ To what degree the statistical model and data analysis plan are suitable for the planned study.

○ How the statistical plan, including sample size projections and power analysis, is appropriate to meet the objectives and endpoints of the study.

• Personnel

○ How the background and expertise of the PI and other key personnel demonstrate their understanding of working with a military population.

○ Whether the composition of the research or study team (e.g., study coordinator, statistician) is appropriate and complementary.

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

○ To what extent the research team’s previous experience is pertinent to the proposed work.

○ To what extent the PI has formed a multidisciplinary team of scientists and stakeholders.

• Translation Plan and Intellectual Property

○ Whether the funding strategy, schedule, and milestones described are appropriate to facilitate translation of the proposed interventions.
○ Whether appropriate collaborations needed to facilitate translation of the proposed interventions are established and/or well described.

○ How well the proposed approach utilizes designs that develop a knowledge base about “how” interventions are translated to military practice settings that go beyond distribution of information about the intervention.

○ If applicable, whether the applicant identifies intellectual property ownership, demonstrates access to all intellectual property rights, and describes any appropriate intellectual and material property plan among participating organizations (if applicable). Whether the applicant addresses any impact of intellectual property issues on product or technology development and subsequent Government access and rights to products or technologies supported by this Program Announcement.

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

• **Budget**
  ○ Whether the total costs are equal to or less than the allowable total costs as published in the Program Announcement.
  ○ Whether the budget is appropriate for the proposed research.

• **Application Presentation**
  ○ To what extent the writing, clarity, and presentation of the application components influence the review.

• **Environment**
  ○ How well the research requirements are supported by the availability of and accessibility to facilities and subject populations.
  ○ Whether the quality and extent of institutional support are appropriate for the proposed project.

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-5/MOMRP, and PH/TBIRP, as evidenced by the following:
  ○ Adherence to the intent of the award mechanism
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-5/MOMRP 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 (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 USAMRAA Grants Officer, provided that the intent of the award mechanism is met.

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

In addition to written progress reports, in-person presentations at the in-progress review meetings may be requested. If additional conference travel is proposed, the Grants Officer should be consulted prior to the re-budgeting and in advance of the incurrence of the travel costs, to determine the reasonableness of the expense in accordance with 2 CFR 200.407. For this award mechanism, direct costs must be requested.

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.*

Quarterly, annual, and final technical progress reports and quad charts will be required.

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 applications, the following administrative actions may occur:

II.H.2.a. Rejection

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.

**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 FY18 PH/TBIRP R2OE TRA 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 R2OE TRA Programmatic Panel members can be found at [http://cdmrp.army.mil/phtbi/panels/panels18_r2oe](http://cdmrp.army.mil/phtbi/panels/panels18_r2oe).*

- 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 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](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 does not propose the same research project described in the pre-application.

• An application for which the PI does not meet the eligibility criteria.

• The application proposes preclinical (animal) studies.

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

<table>
<thead>
<tr>
<th>Application Components</th>
<th>Action</th>
<th>Completed</th>
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</thead>
<tbody>
<tr>
<td>SF424 (R&amp;R) Application for Federal Assistance (Extramural submissions only)</td>
<td>Complete form as instructed.</td>
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</tr>
<tr>
<td>Summary (Tab 1) and Application Contacts (Tab 2) (Intramural submissions only)</td>
<td>Complete these tabs as instructed.</td>
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<tr>
<td>SF424 (R&amp;R) Application for Federal Assistance (Extramural submissions only)</td>
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<td>Supporting Documentation: Upload as Attachment 2 with file name “Support.pdf”.</td>
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<td>Technical Abstract: Upload as Attachment 3 with file name “TechAbs.pdf”.</td>
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<td>Lay Abstract: Upload as Attachment 4 with file name “LayAbs.pdf”.</td>
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<td></td>
<td>Statement of Work: Upload as Attachment 5 with file name “SOW.pdf”.</td>
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<td></td>
<td>Impact and Military Benefit Statement: Upload as Attachment 6 with file name “Impact.pdf”.</td>
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<td></td>
<td>Translation Plan: Upload as Attachment 7 with file name “Translation.pdf”.</td>
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<td></td>
<td>Human Subject Recruitment and Safety Procedure: Upload as Attachment 8 with file name “HumSubProc.pdf” if applicable.</td>
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<td></td>
<td>Data Management: Upload as Attachment 9 with file name “DataManage.pdf”.</td>
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<td></td>
<td>Representations (Extramural Submissions only): Upload as Attachment 10 with file name “MandatoryReps.pdf” if applicable.</td>
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<td></td>
<td>DoD Military Budget Form(s): Upload as Attachment 11 with file name “MFBudget.pdf” if applicable.</td>
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<tr>
<td>Research &amp; Related Personal Data</td>
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<tr>
<td>Research &amp; Related Senior/Key Person Profile (Expanded)</td>
<td>Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field.</td>
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<tr>
<td></td>
<td>Attach PI Previous/Current/Pending Support (Support_LastName.pdf) to the appropriate field.</td>
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<tr>
<td>Application Components</td>
<td>Action</td>
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<td>------------------------------------------------------------------------</td>
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<tr>
<td>Attach Biographical Sketch</td>
<td>(Biosketch_LastName.pdf) for each senior/key person to the appropriate field.</td>
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<tr>
<td>Attach Previous/Current/Pending</td>
<td>(Support_LastName.pdf) for each senior/key person to the appropriate field.</td>
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<tr>
<td>Research &amp; Related Budget</td>
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<td><strong>(Extramural submissions only)</strong></td>
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<tr>
<td>Budget (Intramural submissions only)</td>
<td>Complete the DoD Military Budget Form and justification.</td>
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<td>Project/Performance Site Location(s) Form</td>
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<tr>
<td>R&amp;R Subaward Budget Attachment(s) Form, if applicable</td>
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## APPENDIX 1: ACRONYM LIST

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<thead>
<tr>
<th>Acronym</th>
<th>Definition</th>
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<tbody>
<tr>
<td>ACOS/R&amp;D</td>
<td>Associate Chief of Staff for Research and Development</td>
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<tr>
<td>CDEs</td>
<td>Common Data Elements</td>
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<td>CDMRP</td>
<td>Congressionally Directed Medical Research Programs</td>
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<td>CFR</td>
<td>Code of Federal Regulations</td>
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<tr>
<td>COI</td>
<td>Conflict of Interest</td>
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<td>Defense Health Agency</td>
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<td>DHP</td>
<td>Defense Health Program</td>
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<td>DoD</td>
<td>Department of Defense</td>
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<td>DoDGARs</td>
<td>Department of Defense Grant and Agreement Regulations</td>
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<td>DUNS</td>
<td>Data Universal Numbering System</td>
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<td>eBRAP</td>
<td>Electronic Biomedical Research Application Portal</td>
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<td>EC</td>
<td>Ethics Committee</td>
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<td>ET</td>
<td>Eastern Time</td>
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<td>FAD</td>
<td>Funding Authorization Document</td>
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<td>FAPIIS</td>
<td>Federal Awardee Performance and Integrity Information System</td>
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<td>FAQs</td>
<td>Frequently Asked Questions</td>
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<td>Federal Service Desk</td>
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<td>Fiscal Year</td>
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<td>GSA</td>
<td>General Services Administration</td>
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<td>HRPO</td>
<td>Human Research Protection Office</td>
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<td>IRB</td>
<td>Institutional Review Board</td>
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<td>LOI</td>
<td>Letter of Intent</td>
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<td>M</td>
<td>Million</td>
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<td>MIPR</td>
<td>Military Interdepartmental Purchase Request</td>
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<td>NPC</td>
<td>Non-Profit Corporation</td>
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<td>OASD(HA)</td>
<td>Office of the Assistant Secretary of Defense for Health Affairs</td>
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<td>ORCID</td>
<td>Open Researcher and Contributor ID, Inc.</td>
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<td>PH/TBIRP</td>
<td>Psychological Health/Traumatic Brain Injury Research Program</td>
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<tr>
<td>PI</td>
<td>Principal Investigator</td>
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<tr>
<td>R2OE</td>
<td>Resilience and Readiness Optimization/Enhancement</td>
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<tr>
<td>RDT&amp;E</td>
<td>Research, Development, Test, and Evaluation</td>
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<tr>
<td>SAM</td>
<td>System for Award Management</td>
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<td>Service Member</td>
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<td>SOW</td>
<td>Statement of Work</td>
</tr>
<tr>
<td>TRA</td>
<td>Translational Research Award</td>
</tr>
<tr>
<td>Abbreviation</td>
<td>Full Form</td>
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<tr>
<td>USAMRAA</td>
<td>U.S. Army Medical Research Acquisition Activity</td>
</tr>
<tr>
<td>USAMRMC</td>
<td>U.S. Army Medical Research and Materiel Command</td>
</tr>
<tr>
<td>USC</td>
<td>United States Code</td>
</tr>
<tr>
<td>VA</td>
<td>Department of Veterans Affairs</td>
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APPENDIX 2: DOD, VA, AND OTHER FEDERAL AGENCY WEBSITES

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

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

Army Medicine
https://www.army.mil/armymedicine

Army Resilient Directorate
http://www.army.mil/readyandresilient/

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

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

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

Department of Veterans Affairs
http://www.va.gov/

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

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

National Institutes of Health
https://www.nih.gov/

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

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

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

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

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

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

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

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

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

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

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