

I. OVERVIEW OF THE FUNDING OPPORTUNITY

Program Announcement for the Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

**Traumatic Brain Injury and Psychological Health
Research Program**

Idea Development Award

Announcement Type: Modified

Funding Opportunity Number: W81XWH-21-TBIPHRP-IDA

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

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application Submission Deadline:** 5:00 p.m. Eastern time (ET), September 22, 2021
- **Application Submission Deadline:** 11:59 p.m. ET, October 7, 2021
- **End of Application Verification Period:** 5:00 p.m. ET, October 13, 2021
- **Peer Review:** December 2021
- **Programmatic Review:** February 2022

This program announcement must be read in conjunction with the General Application Instructions, version 605. The General Application Instructions document is available for downloading from the Grants.gov funding opportunity announcement by selecting the “Package” tab, clicking “Preview,” and then selecting “Download Instructions.”

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II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY

II.A. Program Description

Applications to the Fiscal Year 2021 (FY21) Traumatic Brain Injury and Psychological Health Research Program (TBIPHRP) are being solicited 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). The execution management agent for this program announcement is the Congressionally Directed Medical Research Programs (CDMRP) at the U.S. Army Medical Research and Development Command (USAMRDC).

In Fiscal Year 2007 (FY07), Congress appropriated funding for traumatic brain injury (TBI) and psychological health research in response to the TBIs sustained and psychological health issues experienced by our deployed forces in Iraq and Afghanistan. The current Peer-Reviewed TBIPHRP complements ongoing Department of Defense (DOD) efforts toward promoting a better standard of care for psychological health and TBI in the areas of prevention, detection, diagnosis, treatment, and rehabilitation. Appropriations for the TBIPHRP from FY07 through FY20 totaled \$1.872 billion (B). The FY21 appropriation is \$175 million (M).

The TBIPHRP vision is to optimize psychological health and reduce or eliminate the effects of TBI and traumatic stress. The program seeks to fund research to understand, prevent, and treat TBI and psychological health conditions that accelerates solutions to improve the health, well-being, and healthcare of Service Members, Veterans, military beneficiaries, and the American public.

In April 2021, the TBIPHRP held a Stakeholders Meeting to engage TBI and psychological health academic, clinical, lived experience (consumers), and government subject matter experts in an open dialogue forum to identify critical issues and underfunded areas in TBI and psychological health research and care. This meeting was attended by representatives from non-profit organizations, academia, government agencies, and the public. Outcomes from this meeting were considered by the TBIPHRP Programmatic Panel in developing the FY21 program. The FY21 Stakeholders Booklet and Meeting Summary, including presentation materials, can be found at <https://cdmrp.army.mil/tbiphrp/>.

The proposed research must be relevant to active-duty Service Members, Veterans, military beneficiaries, and/or the American public.

II.A.1. FY21 TBIPHRP IDA Focus Areas

To meet the intent of the FY21 TBIPHRP Idea Development Award (IDA), applications **must address at least one sub-area** within one of the three FY21 TBIPHRP IDA Focus Areas listed below. Selection of the appropriate FY21 TBIPHRP IDA Focus Area and sub-area is the responsibility of the applicant.

1. **Understand:** Research will address knowledge gaps in foundational science, epidemiology, and etiology of TBI and psychological health.
 - a. Understanding of pre-exposure risk, injury, and biological factors contributing to an individual's response, recovery, and long-term outcomes following a brain injury or traumatic event. Studies with a biomarker component are allowed. Research of interest includes, but is not limited to:
 - The role of psychological health conditions, genetics, endophenotypes, health demographics, previous injuries or repetitive exposures, pathophysiology, and environmental factors (e.g., extreme temperatures/pressures).
 - Contribution of pre- and post-injury patient, family, and caregiver education, as well as cultural, demographic, stigma, and bias factors that may relate to treatment seeking and adherence.
 - Computational models from clinical data to forecast the long-term and/or late effects of brain exposures, such as TBI, critical traumatic events, and co-occurring conditions.
 - b. Approaches for preclinical to clinical translation that expedite and advance prevention and treatment. Studies with a biomarker component are allowed. Research of interest includes, but is not limited to:
 - Pairing clinical populations to animal models in order to validate the clinical relevance and development of prevention and treatment solutions. Animal models should be well-justified, supported within the literature, and clearly align with clinical relevance.
 - Communication, tools/technology adoption, and identification of risk factors, educational barriers, social determinates of health, and other factors that may impede clinical translation.
 - c. Understanding sexual harassment and assault prevention, perpetration, victimization, and response. Methodologies that ensure anonymity for participants are encouraged. Research of interest includes, but is not limited to:
 - Understanding processes of shame, stigma, and institutional betrayal among sexual assault victims and their units/teams and evaluation of approaches to mitigate these experiences. Experiences of marginalized groups, male victims, and victims of intimate partner violence are of particular interest.
 - Understanding how organizational-level factors influence interpersonal and individual conditions, choices, and behaviors as they relate to sexual assault and harassment prevention and response. Measurement and analysis of organizational-level factors, such as culture and climate, beyond aggregating individual perceptions are encouraged. Research could include the progression from sexual harassment to sexual assault and factors influencing sexual harassment.

- Understanding barriers to reporting sexual assault and factors that contribute to retaliation within units/teams and evaluation of approaches to mitigate barriers and prevent retaliation. Research could include data from influencers, bystanders, and perpetrators; environmental, structural, and demographic factors (e.g., workplace culture, climate, senior leader diversity, age, gender).
- 2. Prevent:** Research will address the prevention or progression of TBI or psychological health conditions through population, selective, and indicated prevention approaches. Efforts that focus on primary prevention (including protection), screening, diagnosis, and prognosis are within scope.
- a. Identification and validation of biomarkers or other objective markers for diagnosis, prognosis, or monitoring of psychological health conditions/brain injuries, repetitive exposures, and associated sequelae (e.g., chronic migraine, dizziness, neurocognitive symptoms, sleep, post-traumatic headache). When appropriate, the use of U.S. Food and Drug Administration (FDA)-approved devices is encouraged.
 - b. Approaches or tools to prevent or mitigate brain injuries or psychological health conditions and assess health status. Research of interest includes, but is not limited to:
 - Translation of environmental sensor outputs to conditions within the brain.
 - Development of innovative materials and technologies that can prevent or mitigate TBI.
 - Generation of physiological evidence regarding the safety, efficacy, and utility of candidate neuroprotective measures. Animal models, if used, should be validated and well-justified within the literature and should demonstrate clear alignment to clinical populations.
 - Validated, objective methods for assessing psychological health conditions such as posttraumatic stress disorder (PTSD), adjustment disorders (AdjDs), acute stress reactions (ASRs), major depressive disorder, substance use disorders, suicidality, comorbid conditions, or TBI, and real-time health status monitoring.
 - Evidence that existing symptom-based return to activity/duty guidelines protect against risk of persistent symptoms.
 - Development of clinical decision-making frameworks or tools that incorporate objective assessments and long-term outcomes to return to activity/duty decisions.
 - Development of injury thresholds and exposure standard.
 - c. Development, evaluation, and implementation of cross-cutting prevention approaches targeting upstream factors or leveraging communities and peers to address multiple adverse outcomes such as suicide, multiple forms of violence, and alcohol and substance misuse. Examples of upstream factors could include social connectedness, inclusiveness,

culture, problem-solving, emotional regulation, communication, underlying health disparities, and financial stability. Research of interest may include, but is not limited to:

- Optimized messaging for successful dissemination and implementation.
 - Inclusion of families and evaluation of impacts thereon. “Family” should be broadly defined to include not just spouses, but also parents, significant others/fiancés/partners, children, caregivers, or close friends.
- d. Solutions to increase readiness and resilience in individuals, small teams, and families to ameliorate the potential negative impacts of specific military and life stressors. Research of interest includes, but is not limited to:
- Effective pharmacologic or non-pharmacologic prevention interventions. Solutions for prevention of ASRs and PTSD may be proposed.
 - Preparation of Service Members and units for missions and to help reset between deployments within the Sustainable Readiness Model¹.
 - Effective solutions to support relationships and parenting, prepare families for potential secondary trauma exposure, and empower families to access tailored support and resources. “Family” should be broadly defined to include not just spouses, but also parents, significant others/fiancés/partners, children, caregivers, or close friends.
- 3. Treat:** Research will address immediate and long-term treatments and improvements in systems of care, including access to and delivery of healthcare services. Treatment topics may include novel treatments and interventions, personalized medicine approaches, length and durability of treatment, rehabilitation, relapse, and relapse prevention.
- a. Interventions that promote sustained functional recovery, including interventions administered acutely, during the post-acute phase, or during the chronic phase of injury. Research of interest includes, but is not limited to:
- Interventions focused on sensory and locomotor dysfunction after brain injury.
 - Interventions that address cognitive functioning and reserve.
 - Personalized medicine approaches to treatment that may include tailoring treatment to the biological and endophenotypic elements present. Studies may consider how TBI, PTSD, depression, or other psychological health conditions are interrelated.
 - Rapid assessments and treatments for psychological health conditions. Interventions addressing AdjDs, ASRs, and PTSD may be proposed.

¹ https://armypubs.army.mil/epubs/DR_pubs/DR_a/pdf/web/ARN9412_AR525_29_FINAL.pdf

- Effective assessments and interventions for delivery in rural or other resource-limited environments (e.g., far-forward military environments), and/or by non-clinicians (e.g., peers, teams, first responders/medics).
 - Considerations for sequencing and optimal combinations of pharmacologic and non-pharmacologic interventions.
- b. Treatments that promote recovery and improve long-term outcomes. Research of interest includes, but is not limited to, one or more of the following:
- Responders versus non-responders to treatment and rehabilitation.
 - Novel therapeutic candidates based on evolving changes of pathophysiology and/or theoretical mechanisms of TBI and psychological health.
 - Focus on long-term outcomes such as dementia/neurodegeneration, psychological health, family, and well-being are encouraged.
 - Interventions emphasizing community-driven participation, inclusion of caregivers/family, and education to facilitate improved functional outcomes are encouraged.
- c. Validated individual-, peer-/unit-/team-, leader-, family-, caregiver-, community-, and enterprise-level methods for reducing barriers to care for TBI or multiple mental health challenges (e.g., PTSD, suicidal ideation or behaviors, alcohol and substance use, anxiety, depression) and understanding mechanisms of change in help-seeking behavior.
- d. Implementation, follow-up, and services research to increase provider adoption and availability of evidence-based treatments, as well as treatment engagement, follow-up care, and understanding of long-term outcomes. Research of interest includes, but is not limited to:
- Clinical effectiveness studies comparing new/novel capabilities to existing evidence-based treatments and/or the standard of care.
 - Optimized messaging for successful dissemination and implementation of interventions.
 - Understanding mechanisms of action for existing evidence-based treatments is also of interest.
- e. Effective community-level postvention strategies to address social connectedness during reintegration of individuals into teams following a sexual assault or suicide event. Proposed research should prevent subsequent suicides or other counterproductive behaviors among individuals and community members.

II.B. Award Information

The intent of the FY21 TBIPHRP IDA is to support *innovative, non-incremental, high-risk/high-reward research* that will provide new insights, paradigms, technologies, or clinical applications. Studies supported by this award are expected to lay the groundwork for future avenues of scientific investigation. The proposed research project should include a well-formulated, testable hypothesis based on a sound scientific rationale and study design. Preliminary data is not required.

Research deemed innovative may represent a new paradigm, challenge current paradigms, look at existing problems from new perspectives, leverage unique study populations, or exhibit other highly creative qualities. Research that is an incremental advance upon published data is not considered innovative. Projects involving multidisciplinary and/or data science approaches are especially encouraged. The following list, although not all-inclusive, provides examples of research that is *not innovative*:

- Using a published series of in vitro assays to further characterize a model system
- Incorporating known biomarkers into in vivo or clinical models of the disease or condition
- Investigating the next logical step or continuation of a previous research project
- Proposing work that is an incremental advancement of published data

Due to this award's emphasis on innovation, inclusion of preliminary data is allowed but not required. The presentation of substantial preliminary data suggests that the proposed research project would be more appropriately submitted to a different award mechanism. Absence of preliminary data will not negatively affect scientific or programmatic review of the application. Any unpublished, preliminary data provided should originate from the laboratory of the Principal Investigator (PI) or members of the research team. Regardless of whether preliminary data are included, applications should be based on a sound scientific rationale that is established through logical reasoning and/or critical review and analysis of the literature. The outcome of research supported by this award should include the generation of robust preliminary data that can be used as a foundation for future research projects.

Organizations are encouraged to support early-career investigators as PIs on FY21 TBIPHRP IDA applications.

Applicants are encouraged to integrate and/or align their research projects with DOD and/or Department of Veterans Affairs (VA) research laboratories and programs. Collaborations between researchers at military or Veterans institutions and non-military institutions are strongly encouraged. These relationships can leverage knowledge, infrastructure, and access to unique data and research resources that the partners bring to the research effort, ultimately advancing TBI and psychological health research of significance to Service Members, Veterans, military beneficiaries, and the American public. A list of websites that may be useful in identifying additional information about ongoing DOD and VA areas of research interest or potential opportunities for collaboration can be found in [Appendix 2](#).

Relevance to Military Health: Relevance to the healthcare needs of Service Members, Veterans, military beneficiaries, and the American public is a key feature of this award. Investigators are encouraged to consider the following characteristics as examples of how a project may demonstrate relevance to military health:

- Explanation of how the project addresses an aspect of TBI and/or psychological health that has direct relevance to the health and/or readiness of Service Members, Veterans, military beneficiaries, and the American public
- Description of how the knowledge, information, products, or technologies gained from the proposed research could be implemented in a dual-use capacity to benefit the civilian population and also address a military need
- Use of military or Veteran populations, samples, or datasets in the proposed research, if appropriate
- Collaboration with DOD or VA investigators or consultants

The types of awards made under the program announcement will be assistance agreements. An assistance 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. 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. 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, but is not limited to, collaboration, participation, or intervention in the research to be performed under the award. The award type, along with the start date, will be determined during the negotiation process.

The anticipated total costs budgeted for the entire period of performance for an FY21 TBIPHRP IDA will not exceed **\$300,000**. Refer to [Section II.D.5, Funding Restrictions](#), for detailed funding information.

Awards will be made no later than September 30, 2022. For additional information refer to [Section II.F.1, Federal Award Notices](#).

The CDMRP expects to allot approximately \$5.4M to fund approximately 18 FY21 TBIPHRP Idea Development Award applications. Funding of applications received is contingent upon the availability of federal funds for this program as well as the number of applications received, the quality and merit of the applications as evaluated by scientific and programmatic review, and the requirements of the government. Funds to be obligated on any award resulting from this funding opportunity will be available for use for a limited time period based on the fiscal year of the funds. It is anticipated that awards made from this FY21 funding opportunity will be funded with FY21 funds, which will expire for use on September 30, 2027.

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 USAMRDC Office of Research Protections (ORP), Human Research Protection Office (HRPO), prior to research implementation. This administrative review requirement is in addition to the local Institutional Review Board (IRB) or Ethics Committee (EC) review. Local IRB/EC approval at the time of submission is *not* required. ***Allow a minimum of 2 to 3 months for HRPO regulatory review and approval processes.*** Refer to the General Application Instructions, Appendix 1, and the Human Research Protections Office Resources and Overview document available on the electronic Biomedical Research Application Portal (eBRAP) “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) for additional information.

If the proposed research involves more than one institution, a written plan for single IRB review arrangements must be provided at the time of application submission or award negotiation. The lead institution responsible for developing the master protocol and master consent form should be identified and should be the single point of contact for regulatory submissions and requirements.

Research involving animals, human anatomical substances, and human data is permitted; however, this award may not be used to conduct prospectively enrolled human subject clinical trials or clinical research.

Clinical trials are not allowed under this mechanism. A clinical trial is defined as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

Clinical research conducted with prospectively enrolled human subjects is not allowed under this mechanism. A clinical research study is defined as: (1) patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, and (d) development of new technologies; (2) epidemiologic and behavioral studies; and (3) outcomes research and health services research. Note: Studies that meet the requirements for IRB Exemption 4 are not considered CDMRP-defined clinical research. IRB Exemption 4 refers to research involving the collection or study of existing de-identified specimens or data, if these sources are publicly available.

For more information on how to distinguish clinical research from clinical trials, see the Human Subject Resource Document at <https://ebrap.org/eBRAP/public/Program.htm>.

Applicants seeking funding for a clinical trial or prospectively enrolling clinical research should consider applying to other FY21 TBIPHRP funding opportunities:

- Clinical Trial Award (Funding Opportunity Number: W81XWH-21-S-TBIPH1)
- Focused Program Award (Funding Opportunity Number: W81XWH-21-S-TBIPH2)
- Translational Research Award (Funding Opportunity Number: W81XWH-21-TBIPHRP-TRA).

Use of DOD or VA Resources: If the proposed research involves access to military and/or DOD or VA resources or databases, the application must describe the access at the time of submission and include a plan for maintaining access as needed throughout the proposed research. Refer to [Section II.D.2.b.ii, Full Application Submission Components](#), for detailed information. Refer to the General Application Instructions, Appendix 1, for additional information.

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 the application is recommended for funding, 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).

Research Involving Animals: All DOD-funded research involving new and ongoing research with animals must be reviewed and approved by the USAMRDC ORP Animal Care and Use Review Office (ACURO), in addition to the local Institutional Animal Care and Use Committee (IACUC) of record. IACUC approval at the time of submission is *not* required. ***Allow at least 3 to 4 months for ACURO regulatory review and approval processes for animal studies.*** Refer to the General Application Instructions, Appendix 1, for additional information.

Rigor of Experimental Design: All projects should adhere to accepted standards for rigorous study design and reporting to maximize the reproducibility and translational potential of preclinical research. Core standards are described in Landis, S.C., et al., A call for transparent reporting to optimize the predictive value of preclinical research. *Nature* 2012, 490:187-191 (<https://www.nature.com/articles/nature11556>). While these standards are written for preclinical studies, the basic principles of randomization, blinding, sample-size estimation, and data handling derive from well-established best practices in clinical studies. Applicants should consult the ARRIVE 2.0 (Animal Research: Reporting In Vivo Experiments) guidelines to ensure relevant aspects of rigorous animal research are adequately planned for and, ultimately, reported. The ARRIVE 2.0 guidelines can be found at <https://journals.plos.org/plosbiology/article?id=10.1371/journal.pbio.3000410>.

Projects that include research on animal models are required to submit an Animal Research Plan ([Attachment 8](#)) as part of the proposal/application package to describe how these standards will be addressed, and should likewise follow the ARRIVE 2.0 guidelines referenced above.

Optimizing Research Impact Through Community Collaboration: Research funded by the FY21 TBIPHRP should be responsive to the needs of the TBI and psychological health lived experience, family, and care provider communities. Through the establishment and utilization of effective and equitable collaborations and partnerships, the translational and impact potential of the proposed research can be maximized. For the FY21 TBIPHRP IDA, inclusion of Community-Based Participatory Research (CBPR) approaches is encouraged but not required.

CBPR supports collaborative research that involves scientific researchers and community members working together to address diseases and conditions, particularly those that disproportionately affect health disparity populations. Recognizing the strength of each partner, scientific researchers and community members *collaborate and contribute equitably* their expertise on all aspects of the project, which may include a needs assessment, planning, research intervention design, implementation, evaluation, and dissemination. CBPR features shared responsibility and ownership for the research project, and research results are jointly interpreted, disseminated, fed back to affected communities, and may be translated into interventions or policy. CBPR methods are critically important for community-level interventions and for conditions affecting health disparity populations; CBPR methods, such as Lived Experience Consultation (LEC), can also have important impacts on translational research and prototype development to identify and augment the potential impact of a research program on people living with TBI and/or psychological health conditions.

CBPR is characterized by the equitable collaboration between community members and researcher. These collaborative relationships are often established through integrating community members into research teams as co-researchers, advisors, and consultants. Some examples for CBPR collaborations include:

- LEC: The research team includes at least one project advisor with lived TBI and/or psychological health experience who will provide advice and consultation throughout the planning and implementation of the research project. Lived experience consultants may include individuals with a TBI or psychological health condition, their family members, or care partners.
- Partnership with a community-based organization: The research team establishes partnerships with at least one community-based organization that provides advice and consultation throughout planning and implementation of the research project. Community-based organizations may include advocacy groups, service providers, policy makers, or other formal organizational stakeholders.
- Community advisory board (CAB): A CAB is composed of multiple community stakeholders and can take many forms, from a board of lived experience consultants to a coalition of community-based organizations or any combination thereof. As with LEC and organizational partners, the CAB provides advice and consultation throughout planning and implementation of the research project.

Additional information on CBPR can be found here:

- Chung B, Jones L, Dixon EL, et al. 2010. [Using a community partnered participatory research approach to implement a randomized controlled trial: Planning the design of community partners in care](#). *Journal of Health Care for the Poor and Underserved* 21(3):780-795. doi: 10.1353/hpu.0.0345.
- Wallerstein N and Duran B. 2010. [Community-based participatory research contributions to intervention research: The intersection of science and practice to improve health equity](#). *American Journal of Public Health* 100(S1):S40-S46. doi: 10.2105/AJPH.2009.184036.

The CDMRP intends that information, data, and research resources generated under awards funded by this program announcement be made available to the research community (which includes both scientific and consumer advocacy communities) and to the public at large. For additional guidance, refer to the General Application Instructions, Appendix 2, Section K.

II.C. Eligibility Information

II.C.1. Eligible Applicants

II.C.1.a. Organization: All organizations, including foreign organizations, foreign public entities, and 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, federal government organization other than the DOD, and research institutes.

Intramural DOD Organization: A DOD laboratory, DOD military treatment facility, and/or DOD activity embedded within a civilian medical center. ***Intramural Submission: Application submitted by a DOD organization for an intramural investigator working within a DOD laboratory or military treatment facility or in a DOD activity embedded within a civilian medical center.***

USAMRAA makes awards to eligible organizations, not to individuals.

II.C.1.b. Principal Investigator

Independent investigators at all academic levels (or equivalent) may be named by the organization as the PI on the application.

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

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

II.C.2. Cost Sharing

Cost sharing/matching is not an eligibility requirement.

II.C.3. Other

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

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

Submission of applications that are essentially identical or propose essentially the same research project to different funding opportunities within the same program and fiscal year is prohibited and will result in administrative withdrawal of the duplicative application(s).

Extramural Submission:

- 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 Submission:

- Pre-application content and forms must be accessed and submitted at eBRAP.org.
- Full application packages must be accessed and submitted at eBRAP.org.

Note: Applications from an intramural DOD organization or from an extramural federal government organization may be submitted to Grants.gov through a research foundation.

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.

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* (eBRAP.org) and *full application* (eBRAP.org or Grants.gov) as indicated below. The submission process should be started early to avoid missing deadlines. There are no grace periods. Full application submission guidelines differ for extramural (Grants.gov) and intramural (eBRAP.org) organizations (refer to [Table 1, Full Application Guidelines](#)).

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

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

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

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

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

All pre-application components must be submitted by the Initiating PI through eBRAP (<https://eBRAP.org/>).

The applicant organization and associated PI 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 applicant 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>. Applicants are strongly encouraged to review and confirm the codes prior to making their selection.

- **Tab 2 – Application Contacts**

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

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

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

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

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

[FY21 TBIPHRP 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.

- **Tab 4 – Conflicts of Interest**

List all individuals other than collaborators and key personnel who may have a conflict of interest in the review of the application (including those with whom the PI has a personal or professional relationship).

- **Tab 5 – Pre-Application Files**

Letter of Intent (LOI) (one-page limit): Provide a brief description of the research to be conducted. Identify the [FY21 TBIPHRP IDA Focus Area\(s\)](#) under which the application will be submitted. 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. An invitation to submit is *not* required.

- **Tab 6 – Submit Pre-Application**

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

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

Applications will not be accepted unless a complete pre-application package (LOI) has been received and processed.

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

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

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

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

Do not password protect any files of the application package, including the Project Narrative.

Table 1. Full Application Submission Guidelines

Extramural Submissions	Intramural DOD Submissions
Application Package Location	
Download application package components for W81XWH-21-TBIPHRP-IDA from Grants.gov (https://www.grants.gov) and create a Grants.gov Workspace. Workspace allows online completion of the application	Download application package components for W81XWH-21-TBIPHRP-IDA from eBRAP (https://ebrap.org).

Extramural Submissions	Intramural DOD Submissions
components and routing of the application package through the applicant organization for review prior to submission.	
Full Application Package Components	
SF424 Research & Related Application for Federal Assistance Form: Refer to the General Application Instructions, Section III.A.1, for detailed information.	<p>Tab 1 – Summary: Provide a summary of the application information.</p> <p>Tab 2 – Application Contacts: This tab will be pre-populated by eBRAP; add Authorized Organizational Representative.</p>
<p>Descriptions of each required file can be found under Full Application Submission Components:</p> <ul style="list-style-type: none"> • Attachments • Research & Related Personal Data • Research & Related Senior/Key Person Profile (Expanded) • Research & Related Budget • Project/Performance Site Location(s) Form • Research & Related Subaward Budget Attachment(s) Form 	<p>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:</p> <ul style="list-style-type: none"> • Attachments • Key Personnel • Budget • Performance Sites <p>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.</p>
Application Package Submission	
<p>Create a Grants.gov Workspace. Add participants (investigators and Business Officials) to Workspace, complete all required forms, and check for errors before submission.</p> <p>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.</p> <p><i>Note:</i> If either the Project Narrative or the budget fails eBRAP validation or if the Project Narrative or the budget needs to be modified,</p>	<p>Submit package components to eBRAP (https://ebrap.org).</p> <p>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. <i>Do not password protect any files of the application package, including the Project Narrative.</i></p>

Extramural Submissions	Intramural DOD Submissions
<p>an updated Grants.gov application package must be submitted via Grants.gov as a “Changed/Corrected Application” with the previous Grants.gov Tracking ID <i>prior to</i> the application submission deadline. <i>Do not password protect any files of the application package, including the Project Narrative.</i></p>	
<u>Application Verification Period</u>	
<p>The full application package submitted to Grants.gov may be viewed and modified in eBRAP until the end of the application verification period. During the application verification period, the full application package may be modified <i>with the exception of the Project Narrative and Research & Related Budget Form.</i></p>	<p>After eBRAP has processed the full application, the organizational Resource Manager/Comptroller/Task Area Manager or equivalent Business Official and PI will receive email notification of this status and will be able to view and modify application components in eBRAP. During the application verification period, the full application package may be modified <i>with the exception of the Project Narrative and Research & Related Budget Form.</i> 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.</p>
Further Information	
<p>Tracking a Grants.gov Workspace Package. After successfully submitting a Workspace package, a Grants.gov Tracking Number is automatically assigned to the package. The number will be listed on the “Confirmation” page that is generated after submission.</p> <p>Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.</p>	<p>Refer to the General Application Instructions, Section IV, for further information regarding eBRAP requirements.</p>

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

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

- **Extramural Applications Only**

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

- **Extramural and Intramural Applications**

Attachments:

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

For all attachments, ensure that the file names are consistent with the guidance. Attachments will be rejected if the file names are longer than 50 characters or have incorrect file names that contain characters other than the following: A-Z, a-z, 0-9, underscore, hyphen, space, and period. In addition, there are file size limits that may apply in some circumstances. Individual attachments may not exceed 20 MB, and the file size for the entire full application package may not exceed 200 MB.

- **Attachment 1: Project Narrative (five-page limit): Upload as “ProjectNarrative.pdf”.** The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs that provide additional information to expand the Project Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application.

Describe the proposed project in detail using the outline below.

- **Background/Rationale:** Describe in detail the scientific rationale for the study and include a literature review, unpublished data, preliminary studies, and/or preclinical data that support the development of the proposed project. The background section should clearly support the choice of study variables and should explain the basis for the study questions and/or hypotheses. *The presentation of preliminary and/or unpublished data is allowed but not required.* Any unpublished, preliminary data provided should originate from the laboratory of the PI or members of the research team.
- **Objectives/Specific Aims/Hypothesis:** Provide a description of the purpose and objectives of the study with detailed specific aims and hypotheses. The aims should align with the primary aims and associated tasks described in the Statement of Work (SOW) ([Attachment 5](#)). If the proposed research project is part of a larger study, present only tasks that this FY21 TBIPHRP IDA would fund.
- **Research Strategy and Feasibility:** Explain how the research strategy will meet the project’s research objectives and milestones. Describe the experimental design, methods, and analyses including appropriate controls in sufficient detail for evaluation and how they support completion of the proposed aims. Identify and describe potential problem areas/risks in the proposed approach. Provide alternative methods and approaches that will be employed to mitigate any problem areas/risks that are identified. If cell lines or animals are to be used, justify why the proposed cell line(s) or animal model(s) were chosen and the model’s relevance to human disease; *full details will be required in the Animal Research Plan ([Attachment 8](#)).*

Describe how the proposed project is feasible and will be completed within the proposed performance period.

- If human biological samples or datasets will be used, describe the study population and include a detailed plan for the acquisition of samples or datasets. ***This award may not be used to conduct clinical trials or prospectively enrolling clinical research.***
- If applicable, describe the strategy for the inclusion of women and minorities in the research appropriate to the objectives of the study, including a description of the composition of the proposed study population in terms of sex/gender, race, and/or ethnicity, and an accompanying rationale for the selection of subjects. ***This award may not be used to conduct clinical trials or prospectively enrolling clinical research.*** It is not expected that every study will include all genders and racial and ethnic groups. Studies utilizing human biospecimens or datasets that cannot be linked to a specific individual, gender, ethnicity, or race are exempt from this requirement. The Policy on Inclusion of Women and Minorities, and Frequently Asked Questions for the policy may be downloaded from eBRAP under “Resources and Reference Material” at <https://ebrap.org/eBRAP/public/Program.htm>.
- **Innovation:** Describe how the proposed research is innovative, including how it will provide new insights, paradigms, technologies, or clinical applications to the research field and/or patient care. Investigating the next logical step of an existing line of research or providing an incremental advance on published data is not considered innovative.
- **Statistical Plan and Data Analysis:** Describe the statistical model and data analysis plan with respect to the study objectives. Include a complete power analysis to demonstrate that the sample size is appropriate to meet the objectives of the study and all proposed correlative studies.
- **Attachment 2: Supporting Documentation: Combine and upload as a single file named “Support.pdf”.** Start each document on a new page. If documents are scanned to PDF, the lowest resolution (100 to 150 dpi) should be used. The Supporting Documentation attachment should not include additional information such as figures, tables, graphs, photographs, diagrams, chemical structures, or drawings. These items should be included in the Project Narrative.

There are no page limits for any of these components unless otherwise noted. Include only those components described below; inclusion of items not requested or viewed as an extension of the Project Narrative will result in the removal of those items or may result in administrative withdrawal of the application.

- **References Cited:** List the references cited (including URLs, if available) in the Project Narrative using a standard reference format that includes the full citation (i.e.,

author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).

- **List of Abbreviations, Acronyms, and Symbols:** Provide a list of abbreviations, acronyms, and symbols.
- **Facilities, Existing Equipment, and Other Resources:** Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate whether or not government-furnished facilities or equipment are proposed for use. If so, reference should be made to the original or present government award under which the facilities or equipment items are now accountable. There is no form for this information.
- **Publications and/or Patents:** Include a list of relevant publication URLs and/or patent abstracts. If articles are not publicly available, then copies of up to five published manuscripts may be included in Attachment 2. Extra items will not be reviewed.
- **Letters of Organizational Support (two-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 (two-page limit per letter):** Provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed work. 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.
- **CBPR Letters of Commitment, if applicable (two-page limit per letter):** Provide a letter signed by each lived experience consultant or community-based partner(s) confirming their role and commitment to participate on the research team. The letter should include the qualifications and background of the lived experience consultant(s) or community-based partner(s) and their relevance to the proposed research project.
- **CBPR Statement, if applicable (three-page limit):** Describe the CBPR approach that will be used (e.g., LEC, partner organization, CAB, co-researcher model) and at what points CBPR will be employed in the study. Provide a statement that includes:
 - Description of the CBPR approach that will be used (e.g., LEC, partner organization, CAB, co-researcher model) and at what points in the research project.

- Description of the input that will be captured and how this input will be meaningfully integrated and incorporated into the needs assessment, planning, design, execution, analysis, and dissemination of the research.
 - Description of training that will be provided to both scientific researchers and community members on CBPR approaches, decision making, and equitable participation.
 - Description of co-learning and capacity building activities among all partners.
 - Description of resource allocation, decision making processes, and authorship between scientific researchers and community partners (whether individuals or organizations).
 - Description of process measures to assess the effectiveness of the chosen CBPR approach
 - Description of dissemination activities with particular focus on feeding back the data to affected communities
- **Intellectual Property:** Information can be found in Code of Federal Regulations, Title 2, Part 200.315 (2 CFR 200.315), “Intangible Property.”
 - **Intellectual and Material Property Plan (if applicable):** Provide a plan for resolving intellectual and material property issues among participating organizations.
 - **Data and Research Resources Sharing Plan:** Describe how data and resources generated during the performance of the project will be shared with the research community. Refer to the General Application Instructions, Appendix 2, Section K, for more information about the CDMRP expectations for making data and research resources publicly available.
 - **Use of DOD Resources (if applicable):** Provide a letter of support signed by the lowest-ranking person with approval authority confirming access to military populations and/or DOD resources or databases.
 - **Use of VA Resources (if applicable):** If the proposed research involves access to VA patient populations, VA study resources and databases, and/or VA research space and equipment, VA PIs must have a plan for obtaining and maintaining access throughout the proposed research. Access to VA patients, 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.

- **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. Describe the proposed research project, including the following elements:

- **Background:** Describe the idea and rationale behind the proposed work. State the [FY21 TBIPHRP IDA Focus Area\(s\)](#) addressed by the proposed research project.
- **Objective/Hypothesis:** State the objective to be reached/hypothesis to be tested. Provide evidence or rationale that supports the hypothesis(es)/objective(s).
- **Specific Aims:** State concisely the specific aims of the study.
- **Study Design:** Briefly describe the study design.
- **Impact and Innovation:** Describe the innovative qualities of the proposed work. Indicate how the proposed work will lay a foundation for future research projects. Describe how the proposed project will benefit Service Members, Veterans, military beneficiaries, and/or the American public.

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

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 lived experience subject matter experts (consumers).

- Clearly describe the critical problem or question to be addressed, the innovation of the idea, and the ultimate applicability and impact of the research.
- Describe how the proposed research project addresses at least one *sub-area within one of the three* [FY21 TBIPHRP IDA Focus Areas](#).
- Include an overview of the proposed research project that can be **readily understood by readers without a background in science or medicine.**

- Describe how the proposed project will benefit Service Members, Veterans, military beneficiaries, and/or the American public.
- **Attachment 5: Statement of Work (three-page limit): Upload as “SOW.pdf”.** The suggested SOW format and examples specific to different types of research projects are available on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>). Recommended strategies for assembling the SOW can be found at <https://ebrap.org/eBRAP/public/Program.htm>.

For the FY21 TBIPRHP IDA mechanism refer to the “***Suggested SOW Strategy Generic Research***”, and use the blank SOW format titled “Suggested SOW Format”. The SOW must be in PDF format prior to attaching.

- **Attachment 6: Impact Statement (one-page limit): Upload as “Impact.pdf”.** This attachment should be written in a manner that will be *readily understood by readers without a background in science or medicine*.
 - Explain why the proposed research project addresses an important scientific question and is relevant to at least one sub-area within one of the three [FY21 TBIPHRP IDA Focus Area\(s\)](#) addressed.
 - Describe how the research has the potential to generate preliminary data that can be used as a foundation for future research projects.
 - Outline the potential impact, either near-term or long-term, of the proposed research on the field of study and/or patient care.
- **Attachment 7: Relevance to Military Health Statement (one-page limit): Upload as “MilRel.pdf”.**
 - Describe how the proposed effort is responsive to the healthcare needs of Service Members, Veterans, and/or military beneficiaries.
 - If active-duty military, military families, and/or Veteran population(s) or dataset(s) will be used in the proposed research project, describe the population(s)/dataset(s) and the appropriateness of the population(s)/dataset(s) for the proposed study. If a non-military population will be used for the proposed research project, explain how the population simulates the targeted population (i.e., Service Members, Veterans, and/or military beneficiaries).
 - If applicable, show how the proposed research project aligns with DOD and/or VA areas of research interest and/or patient care for TBI and/or psychological health.
 - Provide a description of how the knowledge, information, products, or technologies gained from the research could be implemented in a dual-use capacity to benefit the civilian population and address a military need, as appropriate.

- **Attachment 8: Animal Research Plan (if applicable; required for all studies utilizing animals; five-page limit per animal study): Upload as “AnimRschPln.pdf”.** When the proposed study involves animals, the applicant is required to submit a plan describing the animal research that will be conducted. Applicants should not submit a verbatim replica of the protocol(s) to be submitted to the IACUC as the Animal Research Plan. The Animal Research Plan should address the following points for each proposed animal study:
 - Briefly describe the research objective(s) of the animal study. Provide evidence that the chosen animal model(s) is validated and well-justified in the literature. Explain how and why the animal species, strain, and model(s) being used can address the scientific objectives and the relevance to human biology.
 - Describe approaches that will be undertaken to validate or corroborate findings from animal studies to relevant human data sources/populations. This could include, but is not limited to, validation of animal transcriptomic data using publicly available human transcriptomic datasets, confirmation of histological findings in a human post mortem case series, and validation against fluid-based or imaging biomarkers.
 - Describe how the proposed validation approaches or corroborative studies “de-risk” the possibility that the findings from the animal study cannot be translated into human populations.
 - Summarize the procedures to be conducted. Describe how the study will be controlled.
 - Describe the randomization and blinding procedures for the study, and any other measures to be taken to minimize the effects of subjective bias during animal treatment and assessment of results. If randomization and/or blinding will not be utilized, provide justification.
 - Describe how data will be handled, including rules for stopping data collection, criteria for inclusion and exclusion of data, how outliers will be defined and handled, statistical methods for data analysis, and identification of the primary endpoint(s).
 - Describe how data will be reported and how it will be assured that the documentation will support a regulatory filing with the FDA or next stage of development, if applicable.
- **Attachment 9: Representations, if applicable (extramural submissions only): Upload as “RequiredReps.pdf”.** All extramural applicants must complete and submit the Required Representations template available on eBRAP (<https://ebrap.org/eBRAP/public/Program.htm>). For more information, see the General Application Instructions, Appendix 5, Section B, Representations.
- **Attachment 10: Suggested Collaborating DOD Military Facility Budget Format, 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 a separate budget, using “Suggested Collaborating DOD Military Facility Budget Format”, available for download on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>), including a budget justification, for each military facility as instructed. The costs per year should be included on the Grants.gov Research & Related Budget Form under subaward costs. Refer to the General Application Instructions, Section III.A.8, for detailed information.

- **Extramural and Intramural Applications**

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

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

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

- PI Biographical Sketch (six-page limit): Upload as “Biosketch_LastName.pdf”. The suggested biographical sketch format is available on the “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) in eBRAP. The National Institutes of Health Biographical Sketch may also be used. All biographical sketches should be submitted in uneditable PDF format.
- PI Previous/Current/Pending Support (no page limit): Upload as “Support_LastName.pdf”.
 - For extramural submissions, refer to the General Application Instructions, Section III.A.4 for detailed information.
 - For intramural submissions, refer to the General Application Instructions, Section IV.A.3, for detailed information.
- Key Personnel Biographical Sketches (six-page limit each): Upload as “Biosketch_LastName.pdf”.
- Key Personnel Previous/Current/Pending Support (no page limit): Upload as “Support_LastName.pdf”.

Research & Related Budget: For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.5, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.4, for detailed information.

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

Project/Performance Site Location(s) Form: For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.6, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.5, for detailed information.

- **Extramural Applications Only**

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

- **Extramural Subaward:** Complete the Research & Related Subaward Budget Form through Grants.gov. (Refer to the General Application Instructions, Section III.A.7, for detailed information.) Verify subaward budget(s) and budget justification forms are present in eBRAP during the application verification period. If these components are missing, upload them to eBRAP before the end of the application verification period.
- **Intramural DOD Collaborator(s):** Complete the “Suggested Collaborating DOD Military Facility Budget Format” and upload to Grants.gov attachment form as [Attachment 10](#). (Refer to the General Application Instructions, Section IV.A.4, for detailed information.) Each Intramural DOD Collaborator should include costs per year on the Grants.gov Research & Related Budget Form under subaward costs.

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

Applicant organizations and all sub-recipient organizations must have a DUNS number to submit applications to Grants.gov. The applicant organization must also be registered in the Entity Management functional area of the SAM with an “Active” status to submit applications through the Grants.gov portal. Verify the status of the applicant organization’s Entity registration in SAM well in advance of the application submission deadline. Allow several weeks to complete the entire SAM registration process. If an applicant has not fully complied with the requirements at the time the federal awarding agency is ready to make a federal award, the federal awarding agency may determine that the applicant is not qualified to receive a federal award and use that determination as a basis for making a federal award to another applicant. Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.

Announcement of Transition to SAM-Generated Unique Entity Identifier (UEI): Through April 2022, a transition from DUNS to the SAM-generated UEI will occur. Refer to the General

Application Instructions, Section III.1, DUNS Number, for more information on the transition and timing.

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

For Both Extramural and Intramural Applicants: eBRAP allows an organization’s representatives and PIs to view and modify the full application submissions associated with them. 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 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. eBRAP does not confirm the accuracy of file content. Application viewing, modification, and verification in eBRAP are strongly recommended, but not required. 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 Research & Related Budget Form cannot be changed after the application submission deadline.*** 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.

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

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

II.D.5. Funding Restrictions

The maximum period of performance is **2** years.

The anticipated total costs budgeted for the entire period of performance will not exceed **\$300,000**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the government exceeding **\$300,000** total costs or using an indirect cost rate exceeding the organization's negotiated rate.

All direct and indirect costs of any subaward or contract must be included in the total direct costs of the primary award.

The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum **2** years.

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

- Travel costs for the PI to present project information or disseminate project results at a DOD-sponsored meeting (e.g., progress review meeting, Military Health System Research Symposium) in year 2 of the award. For planning purposes, it should be assumed that the meeting will be held in the Central Florida Area. These travel costs are in addition to those allowed for annual scientific/technical meetings.

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

- Costs for one investigator to travel to one scientific/technical meeting per year in addition to the required meeting described above. The intent of travel costs to scientific/technical meeting(s) is to present project information or disseminate project results of the FY21 TBIPHRP IDA.

Must not be requested for:

- Clinical trial costs
- Prospective human subject enrollment costs
- Mentor salary

For extramural awards with an intragovernmental component, direct transfer of funds from an extramural award recipient to a DOD or other federal agency is not allowed except under very limited circumstances. Funding to intramural DOD and other federal agencies will be managed through a direct funds transfer. Intramural applicants are responsible for coordinating through

their agency's procedures the use of contractual or assistance funding awards or other appropriate agreements to support extramural collaborators.

Refer to the General Application Instructions, Section III.A.5, for budget regulations and instructions for the Research & Related Budget. *For federal agencies or organizations collaborating with federal agencies, budget restrictions apply as are noted in the General Application Instructions, Section III.A.5.*

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 all of equal importance:

- **Innovation**
 - To what extent the proposed research is innovative and will provide new insights, paradigms, technologies, or applications with the potential to impact the research field and/or patient care.
 - To what extent the proposed research represents more than the next logical step in an existing line of research or an incremental advance upon published data.
- **Research Strategy and Feasibility**
 - How well the scientific rationale, literature review, unpublished data and preliminary studies (if applicable), and/or preclinical data support the development of the proposed research project and provide the basis for the study questions and/or hypotheses.
 - How well the purpose and objectives of the study, with detailed specific aims and hypotheses, are described and aligned with the tasks in the SOW.
 - How likely the research strategy is to achieve the research objectives and milestones.
 - How well the proposal identifies potential problem areas/risks in the proposed approach and provides methods and alternative approaches.
 - Whether the research can be completed within the proposed period of performance.

For research involving animals:

- To what extent the choice of animal model is validated and well-justified in the literature.
- How well the study explains how and why the animal species, strain, and model(s) being used can address the scientific objectives and the relevance to human biology.
- How relevant the approaches are to validate or corroborate findings from animal studies to human data sources/populations.
- To what extent the proposed validation approaches or corroborative studies “de-risk” the possibility that the findings from the animal study cannot be translated into human populations.
- To what extent the data and documentation support a regulatory filing with the FDA or next stage of development, if applicable.
- **Statistical Plan and Data Analysis**
 - As applicable, describe how the randomization and blinding procedures for the study are appropriate, and specify any other measures to be taken to minimize the effects of subjective bias during animal treatment and assessment of results.
 - If applicable, describe how the justification for not utilizing randomization and/or blinding is appropriate.
 - To what degree the statistical model and data analysis plan are suitable with respect to the study objectives.
 - How the statistical plan, including sample size projections and power analysis, is appropriate to meet the objectives of the study and all proposed correlative studies.
- **Impact**
 - To what extent the proposed research project addresses an important scientific question and relevance to at least one sub-area within one of the **three** [FY21 TBIPHRP IDA Focus Areas](#).
 - To what extent the research has the potential to generate preliminary data that can be used as a foundation for future research projects.
 - To what extent the proposed research has potential for impact, either near-term or long-term, on the field of study and/or patient care.
 - If applicable, to what extent the CBPR Letter(s) of Commitment describe the role and commitment of the lived experience or community-based partners on the research team.

- If applicable, how well the CBPR approach that will be used (e.g., LEC, partner organization, CAB, co-researcher model) and at what points CBPR will be employed in planning the study are described.

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

- **Personnel**
 - How appropriate the levels of effort are for successful conduct of the proposed work.
- **Budget**
 - Whether the **total** costs exceed the allowable total costs as published in the program announcement.
 - Whether the budget is appropriate for the proposed research.
- **Environment**
 - If applicable, to what degree the intellectual and material property plan is appropriate.
- **Application Presentation**
 - To what extent the writing, clarity, and presentation of the application components influence the review

II.E.1.b. Programmatic Review

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

- Ratings and evaluations of the peer reviewers
- Relevance to the mission of the Defense Health Program and FY21 TBIPHRP, as evidenced by the following:
 - Adherence to the intent of the award mechanism
 - Program portfolio composition
 - Relative innovation
 - Relative impact and relevance to military health

II.E.2. Application Review and Selection Process

All applications are evaluated by scientists, clinicians, and consumers in a two-tier review process. The first tier is **peer review**, the evaluation of applications against established criteria to determine technical merit, where each application is assessed for its own merit, independent of other applications. The second tier is **programmatic review**, a comparison-based process in which applications with high scientific and technical merit are further evaluated for programmatic relevance. Final recommendations for funding are made to the Commanding General, USAMRDC. *The highest-scoring applications from the first tier of review are not automatically recommended for funding. Funding recommendations depend on various factors as described in [Section II.E.1.b, Programmatic Review](#).* Additional information about the two-tier process used by the CDMRP can be found at <https://cdmrp.army.mil/about/2tierRevProcess>. An information paper describing the funding recommendations and review process for the award mechanisms for the FY21 TBIPHRP will be provided to the PI and posted on the CDMRP website.

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign a statement declaring that application and evaluation information will not be disclosed outside the panel. Violations of confidentiality can result in the dissolving of a panel(s) and other corrective actions. In addition, personnel at the applicant or collaborating organizations are prohibited from contacting persons involved in the review and approval process to gain protected evaluation information or to influence the evaluation process. Violations of these prohibitions will result in the administrative withdrawal of the organization's application. Violations by panel members or applicants that compromise the confidentiality of the review and approval process may also result in suspension or debarment from federal awards. Furthermore, the unauthorized disclosure of confidential information of one party to another third party is a crime in accordance with 18 USC 1905.

II.E.3. Integrity and Performance Information

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

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

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

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

All application review dates and times are indicated in [Section I, Overview of the Funding Opportunity](#).

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

II.F. Federal Award Administration Information

II.F.1. Federal Award Notices

Awards supported with FY21 funds are anticipated to be made no later than September 30, 2022. Refer to the General Application Instructions, Appendix 2, for additional award administration information.

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

Pre-Award Costs: An institution of higher education, hospital, or other non-profit organization may, at its own risk and without the government's prior approval, incur obligations and expenditures to cover costs up to 90 days before the beginning date of the initial budget period of a new award. Refer to the General Application Instructions, Section III.A.5.

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

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

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

Unless otherwise restricted, changes in PI or organization will be allowed at the discretion of the USAMRAA Grants Officer, provided the intent of the award mechanism is met.

An organizational transfer of an award will not be allowed in the last year of the (original) period of performance or any extension thereof.

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

II.F.2. Administrative and National Policy Requirements

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

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

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

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

II.F.3. Reporting

Refer to the General Application Instructions, Appendix 2, Section A, for general information on reporting requirements. ***If there are technical reporting requirement delinquencies for any existing USAMRAA-sponsored awards at the applicant organization, no new awards will be issued to the applicant organization until all delinquent reports have been submitted.***

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

The Award Terms and Conditions will specify if more frequent reporting is required.

Annual quad charts will be required.

Award Expiration Transition Plan: An Award Expiration Transition Plan must be submitted with the final progress report. Use the one-page template “Award Expiration Transition Plan,” available on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) under the “Progress Report Formats” section. The Award Expiration Transition Plan must outline if and how the research supported by this award will progress and must include source(s) of funding, either known or pending.

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

II.G. Federal Awarding Agency Contacts

II.G.1. CDMRP Help Desk

Questions related to program announcement content or submission requirements as well as questions related to the pre-application or intramural application submission through eBRAP should be directed to the CDMRP Help Desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. ET. Response times may vary depending upon the volume of inquiries.

Phone: 301-682-5507

Email: help@eBRAP.org

II.G.2. Grants.gov Contact Center

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

Phone: 800-518-4726; International 1-606-545-5035

Email: support@grants.gov

Sign up on Grants.gov for “send me change notification emails” by following the link on the “Synopsis” page for the program announcement or by responding to the prompt provided by Grants.gov when first downloading the Grants.gov application package. If the Grants.gov application package is updated or changed, the original version of the application package may not be accepted by Grants.gov.

II.H. Other Information

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

Questions related to this program announcement should refer to the program name, the program announcement name, and the program announcement version code 605a. The program announcement numeric version code will match the General Application Instructions version code 605.

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 (LOI) 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 application:

- An FY21 TBIPHRP 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 FY21 TBIPHRP Programmatic Panel members can be found at <https://cdmrp.army.mil/tbiphrp/panels/panels21>.*
- 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 FY21, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (<https://cdmrp.army.mil/about/2tierRevProcess>). Applications that include names of personnel from either of these companies may be administratively withdrawn.
- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review or approval process to gain protected evaluation information or to influence the evaluation process.
- Applications from extramural organizations, including non-DOD federal agencies, received through eBRAP may be withdrawn.
- Applications submitted by an intramural DOD organization may be withdrawn if the intramural organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to extramural collaborators.

- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- A clinical trial or prospective human subject enrollment is proposed.
- The PI does not meet the eligibility criteria.
- Application failed to address at least one sub-area within one of the three [FY21 TBIPHRP IDA Focus Areas](#).

II.H.2.d. Withhold

Applications that appear to involve research misconduct will be administratively withheld from further consideration pending organizational investigation. The organization will be required to provide the findings of the investigation to the USAMRAA Grants Officer for a determination of the final disposition of the application.

II.H.3. Application Submission Checklist

Application Components	Action	Completed
SF424 Research & Related Application for Federal Assistance (extramural submissions only)	Complete form as instructed	
Summary (Tab 1) and Application Contacts (Tab 2) (intramural submissions only)	Complete tabs as instructed	
Attachments	Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf"	
	Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf"	
	Technical Abstract: Upload as Attachment 3 with file name "TechAbs.pdf"	
	Lay Abstract: Upload as Attachment 4 with file name "LayAbs.pdf"	
	Statement of Work: Upload as Attachment 5 with file name "SOW.pdf"	
	Impact Statement: Upload as Attachment 6 with file name "Impact.pdf"	
	Relevance to Military Health Statement: Upload as Attachment 7 with file name "MilRel.pdf"	
	Animal Research Plan: Upload as Attachment 8 with file name "AnimRschPln.pdf", if applicable	
	Representations (extramural submissions only): Upload as Attachment 9 with file name "RequiredReps.pdf" if applicable	
	Suggested Collaborating DOD Military Facility Budget Format: Upload as Attachment 10 with file name "MFBudget.pdf" if applicable	
Research & Related Personal Data	Complete form as instructed	

Application Components	Action	Completed
Research & Related Senior/Key Person Profile (Expanded)	Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field	
	Attach PI Previous/Current/Pending Support (Support_LastName.pdf) to the appropriate field	
	Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field	
	Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person to the appropriate field	
Research & Related Budget (extramural submissions only)	Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field	
Budget (intramural submissions only)	Suggested DOD Military Budget Format, including justification	
Project/Performance Site Location(s) Form	Complete form as instructed	
Research & Related Subaward Budget Attachment(s) Form, if applicable	Complete form as instructed	

APPENDIX 1: ACRONYM LIST

ACOS/R&D	Associate Chief of Staff for Research and Development
ACURO	Animal Care and Use Review Office
AdjDs	Adjustment Disorders
ASRs	Acute Stress Reactions
ARRIVE	Animal Research: Reporting In Vivo Experiments
B	Billion
CAB	Community Advisory Board
CBPR	Community-Based Participatory Research
CDE	Common Data Elements
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
DHP	Defense Health Program
DOD	Department of Defense
DoDGARs	Department of Defense Grant and Agreement Regulations
DUNS	Data Universal Numbering System
eBRAP	Electronic Biomedical Research Application Portal
EC	Ethics Committee
ET	Eastern Time
FAD	Funding Authorization Document
FAPIIS	Federal Awardee Performance and Integrity Information System
FDA	U.S. Food and Drug Administration
FITBR	Federal Interagency Traumatic Brain Injury Research
FY	Fiscal Year
HRPO	Human Research Protection Office
IACUC	Institutional Animal Care and Use Committee
IRB	Institutional Review Board
LEC	Lived Experience Consultation
LOI	Letter of Intent
M	Million
MIPR	Military Interdepartmental Purchase Request
NINDS	National Institute of Neurological Disorders and Stroke
NPC	Non-Profit Corporation
NRAP	National Research Action Plan
ORCID	Open Researcher and Contributor ID, Inc.
ORP	Office of Research Protections

PH/TBIRP	Psychological Health and Traumatic Brain Injury Research Program
PI	Principal Investigator
PTSD	Posttraumatic Stress Disorder
SAM	System for Award Management
SOW	Statement of Work
STEM	Science, Technology, Engineering, and/or Mathematics
TBI	Traumatic Brain Injury
TBIPHRP	Traumatic Brain Injury and Psychological Health Research Program
UDE	Unique Data Element
UEI	Unique Entity Identifier
URL	Uniform Resource Locator
USAMRAA	U.S. Army Medical Research Acquisition Activity
USAMRDC	U.S. Army Medical Research and Development Command
USC	United States Code
VA	Department of Veterans Affairs

APPENDIX 2: DOD AND VA WEBSITES

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

Air Force Office of Scientific Research

<https://www.wpafb.af.mil/afrl/afosr/>

Air Force Research Laboratory

<https://www.wpafb.af.mil/afrl>

Armed Forces Radiobiology Research Institute

<https://afri.usuhs.edu/home>

Combat Casualty Care Research Program

<https://ccc.amedd.army.mil>

Congressionally Directed Medical Research Programs

<https://cdmrip.army.mil>

Defense Advanced Research Projects Agency

<https://www.darpa.mil/>

Defense Health Agency

<https://health.mil/dha>

Defense Suicide Prevention Office

<https://www.dsppo.mil/>

Defense Technical Information Center

<https://www.dtic.mil>

Defense Threat Reduction Agency

<https://www.dtra.mil/>

Military Health System Research Symposium

<https://mhsrs.amedd.army.mil/SitePages/Home.aspx>

Military Infectious Diseases Research Program

<https://midrp.amedd.army.mil>

Military Operational Medicine Research Program

<https://momrp.amedd.army.mil>

Naval Health Research Center

<https://www.med.navy.mil/Naval-Medical-Research-Center/Naval-Health-Research-Center/>

Navy Bureau of Medicine and Surgery

<https://www.med.navy.mil/>

Navy and Marine Corps Public Health Center

<https://www.med.navy.mil/Navy-Marine-Corps-Public-Health-Center>

Naval Medical Research Center

<https://www.med.navy.mil/Naval-Medical-Research-Center/>

Office of Naval Research

<https://www.onr.navy.mil/>

Office of the Under Secretary of Defense for Acquisition, Technology and Logistics

<https://www.acq.osd.mil/>

Psychological Health Center of Excellence

<https://health.mil/Military-Health-Topics/Centers-of-Excellence/Psychological-Health-Center-of-Excellence>

Telemedicine and Advanced Technology Research Center

<https://www.tatrc.org/>

Traumatic Brain Injury Center of Excellence

<https://www.health.mil/About-MHS/OASDHA/Defense-Health-Agency/Research-and-Development/Traumatic-Brain-Injury-Center-of-Excellence/Research>

Uniformed Services University of the Health Sciences

<https://www.usuhs.edu/research>

U.S. Air Force 59th Medical Wing

<https://www.59mdw.af.mil/>

U.S. Army Aeromedical Research Laboratory

<https://www.usaarl.army.mil/>

U.S. Army Combat Capabilities
Development Command
<https://www.army.mil/ccdc>

U.S. Army Institute of Surgical Research
<https://usaisr.amedd.army.mil>

U.S. Army Medical Materiel Development
Activity
<https://www.usammda.army.mil/>

U.S. Army Medical Research and
Development Command
<https://mrdc.amedd.army.mil/>

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

U.S. Army Research Institute of
Environmental Medicine
<https://www.usariem.army.mil/>

U.S. Army Research Laboratory
<https://www.arl.army.mil>

U.S. Army Sharp, Ready and Resilient
Directorate
<https://www.armyresilience.army.mil/sharp/index.html>

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

U.S. Department of Defense Sexual Assault
Prevention and Response Office
<https://www.sapr.mil>

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

U.S. Naval Research Laboratory
<https://www.nrl.navy.mil>

Walter Reed Army Institute of Research
<https://www.wrair.army.mil>