I. OVERVIEW OF THE FUNDING OPPORTUNITY

Program Announcement for the Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

Joint Program Committee 5
Military Operational Medicine Research Program

Psychological Health and Traumatic Brain Injury Research Program

Prevention Research to Reduce Sexual Assault and/or Understand Adjustment Disorders Investigator-Initiated Focused Research Award

Announcement Type: Initial

Funding Opportunity Number: W81XWH-19-PHTBIRP-PSAAD-IIFRA

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 19, 2019
- **Application Submission Deadline:** 11:59 p.m. ET, October 3, 2019
- **End of Application Verification Period:** 5:00 p.m. ET, October 7, 2019
- **Peer Review:** December 2019
- **Programmatic Review:** February 2020

This Program Announcement must be read in conjunction with the General Application Instructions, version 20190530. The General Application Instructions document is available for downloading from the Grants.gov funding opportunity announcement by selecting the "Package" tab, clicking "Preview," and then selecting "Download Instructions."

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II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY

II.A. Program Description

Applications to the Fiscal Year 2019 (FY19) Psychological Health and Traumatic Brain Injury Research Program (PH/TBIRP) Prevention Research to Reduce Sexual Assault and/or Understand Adjustment Disorders (PSAAD) Investigator-Initiated Focused Research Award (IIFRA) are being solicited for the Defense Health Agency (DHA) J9, Research and Development Directorate, by the U.S. Army Medical Research Acquisition Activity (USAMRAA) using delegated authority provided by United States Code, Title 10, Section 2358 (10 USC 2358). As directed by the Office of the Assistant Secretary of Defense for Health Affairs (OASD[HA]), the DHA manages the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriation. The U.S. Army Medical Research and Development Command (USAMRDC) Congressionally Directed Medical Research Programs (CDMRP) provides execution management support for DHA research program areas, including the Joint Program Committee-5/Military Operational Medicine Research Program (JPC-5/MOMRP). The execution management agent for this Program Announcement is the CDMRP with strategic oversight from JPC-5/MOMRP.

The PH/TBIRP was initiated by Congress in FY07 to provide support for research of exceptional scientific merit in response to the devastating impact of traumatic brain injury (TBI) and psychological health (PH) issues to our deployed Service members (SMs) in Iraq and Afghanistan. The PH/TBIRP mission is to establish, fund, and integrate both individual and multi-agency research efforts that will lead to improved prevention, detection, and treatment of PH issues and TBI. The vision of the PH/TBIRP is to prevent, mitigate, and treat the effects of traumatic stress and TBI on function, wellness, and overall quality of life for SMs as well as their caregivers and families.

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

II.A.1. Background

Area of Emphasis: Sexual Assault/Violence Prevention

Over a decade of advances in the DoD have led to a significant decrease in the number of sexual assaults, from approximately 34,000 in 2006 to approximately 15,000 in 2016 (*DoD Annual Report on Sexual Assault in the Military*, FY17). In addition, reporting of this crime to the

proper authorities has risen from approximately 7% in 2006 to approximately 32% in 2017 (Office of People Analytics, 2017), in large part due to the increased awareness and level of response given to those who have experienced a sexual assault. However, there is limited tangible evidence of the DoD's ability to prevent sexual assault before it occurs in the Armed Forces. Compared to other forms of violence (e.g., youth violence) and other public health problems (e.g., HIV, Human Immunodeficiency Virus), the evidence base for sexual violence prevention programs is less developed. Awareness campaigns and training programs alone are not enough to eliminate sexual assaults in the DoD. The DoD's Sexual Assault Prevention and Response Office is currently taking a strategic and comprehensive approach to preventing sexual assaults in the military, using programs, policies, and practices evaluated by the Centers for Disease Control and Prevention (CDC) and other public health entities. The DoD recently published its strategic approach to preventing sexual assault. This Prevention Plan of Action (PPoA) identifies and prioritizes actions and steps to be taken at the DoD, Service, and/or National Guard (NG)/Reserves to improve sexual assault prevention. The PPoA steps, goals, and objectives should be considered when applying for this award. The PPoA can be found at: https://www.sapr.mil/prevention.

In Section 702 of the FY19 National Defense Authorization Act (NDAA), Congress tasked the DoD to pilot and evaluate an intensive outpatient (IOP) treatment program to provide care to SMs who experience mental health symptoms that can accompany sexual assault. The Psychological Health Center of Excellence (PHCoE) leads the DoD efforts for this pilot study to ensure existing direct-care IOP programs are leveraged to meet the Congressional mandate and minimize duplication of effort. Further information can be found at https://www.pdhealth.mil/clinical-guidance/sexual-assaultsexual-harassment/recent-legislative-updates. ***Applications that duplicate or significantly overlap with this effort will not be considered.***

Defining Sexual Assault

Sexual assault is defined in Department of Defense Directive (DoDD) 6495.01 as any "intentional sexual contact characterized by use of force, threats, intimidation, or abuse of authority or when the victim does not or cannot consent" (DoDD, 2017). Under this definition, sexual assault includes rape, aggravated sexual contact, abusive sexual contact, forcible sodomy (forced oral or anal sex), or attempts to commit these acts. "Consent" shall not be deemed or construed to mean the failure by the victim to offer physical resistance.

In Section 522 of the FY06 NDAA, Congress amended the Uniform Code of Military Justice (UCMJ) to consolidate and reorganize the array of military sex offenses. These revised provisions took effect October 1, 2007. Article 120, UCMJ, was subsequently amended in FY12. As amended, Article 120, UCMJ, "Rape, Sexual Assault, and Other Sexual Misconduct," defines rape as "a situation where any person causes another person of any age to engage in a sexual act by: (1) using unlawful force; (2) causing grievous bodily harm; (3) threatening or placing that other person in fear that any person will be subjected to death, grievous bodily harm, or kidnapping; (4) rendering the person unconscious; or (5) administering a substance, drug, intoxicant, or similar substance that substantially impairs the ability of that person to appraise or control conduct" (Title 10 USC 920, Article 120). Article 120 of the UCMJ defines "consent" as "words or overt acts indicating a freely given agreement to the sexual act at issue by a competent person." The term is further explained as:

- An expression of lack of consent through words or conduct means there is no consent;
- Lack of verbal or physical resistance or submission resulting from the accused's use of force, threat of force, or placing another person in fear does not constitute consent;
- A current or previous dating relationship by itself or the manner of dress of the person involved with the accused in the sexual conduct at issue shall not constitute consent;
- A person cannot consent to sexual activity if he or she is "substantially incapable of appraising the nature of the sexual conduct at issue" due to mental impairment or unconsciousness resulting from consumption of alcohol, drugs, a similar substance, or otherwise, as well as when the person is unable to understand the nature of the sexual conduct at issue due to a mental disease or defect; or
- Similarly, a lack of consent includes situations where a person is "substantially incapable of physically declining participation" or "physically communicating unwillingness" to engage in the sexual conduct at issue.

Defining Sexual Harassment

The DoD Military Equal Opportunity (MEO) Program policy, DoDD 1350.2, defines sexual harassment as: A form of sex discrimination that involves unwelcome sexual advances, requests for sexual favors, and other verbal or physical conduct of a sexual nature when:

- Submission to such conduct is made either explicitly or implicitly a term or condition of a person's job, pay, or career, or
- Submission to or rejection of such conduct by a person is used as a basis for career or employment decisions affecting that person, or
- Such conduct has the purpose or effect of unreasonably interfering with an individual's work performance or creates an intimidating, hostile, or offensive working environment.
- Workplace conduct, which for the military may include on or off duty conduct 24 hours a day, considered to be actionable as "abusive work environment" harassment, need not result in concrete psychological harm to the victim, but rather need only be so severe or pervasive that a reasonable person would perceive, and the victim does perceive, the work environment as hostile or offensive (DoD, 2015).
- Gender discrimination is defined in DoDD 1350.2 as "unlawful discrimination" where there is discrimination based on "sex that is not otherwise authorized by law or regulation" (DoDD, 2017).

Defining Prevention as It Applies to Sexual Violence

The CDC categorizes sexual assault as sexual violence. They define sexual violence as "sexual activity when consent is not obtained or not freely given."

For the purposes of this funding opportunity, sexual violence and sexual assault can be used interchangeably. Additionally, both sexual assault/violence *and* sexual harassment are of potential interest to this program announcement, as long as sexual assault/violence and sexual harassment are operationally defined as separate behaviors and assessed as such.

In an effort to establish a shared understanding of prevention, the DoD adopted the CDC's definition of prevention as it applies to sexual violence. The CDC identifies three levels of prevention based on when the prevention efforts occur:

- *Primary Prevention.* Approaches that take place before sexual violence has occurred to prevent initial perpetration or victimization. Primary prevention may be delivered to an entire population without regard to risk (universal primary prevention) or to a specific subgroup with heightened risk for sexual violence perpetration and/or victimization (targeted primary prevention). ***The DoD places primary prevention at the core of its focus in developing prevention-related tasks and initiatives that seek to reduce, with the goal to eliminate, the factors leading to, or associated with, sexual violence, thereby stopping the crime before it occurs.***

- *Secondary Prevention.* Immediate responses after sexual violence has occurred to address the early identification of victims and the short-term consequences of violence.

- *Tertiary Prevention.* Long-term responses after sexual violence has occurred to address the lasting consequences of violence, recidivism prevention, and treatment interventions.

Ecological approaches to preventative interventions at multiple levels of the social ecological model (i.e., individual, relationship, community, and society) are critical to having a population-level impact on preventing sexual assaults/harassment (Basile et al., 2016[1]). Social ecological prevention emphasizes the context of human behavior. Of central importance is addressing the opportunities and constraints in the social and community environment (Glass and McAtee, 2006[2]). Therefore, the DoD seeks to emphasize prevention that aims to modify the ecological context to facilitate positive behavior, while eliminating sexual assault.

Social ecological approaches attend not just to the nested ecological levels, but also to the principles of community ecology (cycling of resources, interdependence, adaptation, and succession; Hawe, 2017[3]). For example, prevention programs might consider addressing how interventions add value and resources into the setting (cycling of resources), how interventions in one part of the community have impacts elsewhere (interdependence), maximizing fit of

[1] Basile KC, DeGue S, Jones K, Freire K, Dills J, Smith SG, and Raiford JL. 2016. STOP SV: A technical package to prevent sexual violence. Atlanta, GA: National Center for Injury Prevention and Control, Centers for Disease Control and Prevention. https://www.cdc.gov/violenceprevention/pdf/sv-prevention-technical-package.pdf.

[2] Glass TA and McAtee MJ. 2006. Behavioral science at the crossroads in public health: Extending horizons, envisioning the future. *Social Science & Medicine* 62(7):1650-1671.

[3] Hawe P. 2017. The contribution of social ecological thinking to community psychology: Origins, practice, and research. In: *APA Handbook of Community Psychology* (Bond MA, Serrano-Garcia I, Keys CB, and Shinn M, Eds.). APA Books, Washington DC.

interventions in diverse settings (adaptation), and understanding how programs and services change over time (succession).

In addition, research targeting the prevention of sexual assault among SMs should address prevention efforts that aim to reduce the occurrence of sexual assault in a variety of settings. These settings include, but are not limited to:

- On-duty locations such as in-garrison/at work, while deployed, in quarters, or in field-training exercises.
- Off-duty locations such as off-post housing or civilian establishments.

Primary prevention at all levels and in all settings of the military culture is the ultimate goal. Applications that address SMs should be limited to prevention interventions and approaches that are within the military's legal and operational control, with or without specific attention on the following subpopulations:

- Gender-targeted prevention (men or women).
- High-risk populations (individuals with pre-military sexual trauma, entry-level SMs, female SMs, LGBT [lesbian, gay, bisexual, or transgender] SMs, subgroups with unhealthy climates [e.g., climates where sexual harassment, hazing, bullying, and sexist jokes are allowed or encouraged]).
- Active duty, NG, Reserves, Military Service Academy SMs, and Reserve Officers' Training Corps.

Identifying Risk and Protective Factors for Intervention

Subsequent to defining the magnitude of the problem through surveillance, research identifies risk and protective factors that contribute to that problem. Risk factors are not direct causes of sexual violence, but rather contribute to an environment in which sexual violence is more likely. Protective factors decrease the likelihood that sexual violence will occur or buffer someone from becoming a victim or perpetrator of sexual violence. Risk factors and protective factors have been identified in a variety of contexts, including individual, interpersonal, community, and societal. Prevention is not a single program or initiative, but involves addressing multiple levels of interconnected influences. Comprehensive prevention strategies are used to address these factors through multiple lines of effort. This approach was used in the development of the 2014-2016 Sexual Assault Prevention Strategy. The DoD included risk and protective factors for the perpetration of sexual assault derived from the work by the CDC (https://www.cdc.gov/violenceprevention/sexualviolence/riskprotectivefactors.html). Risk factors and protective factors associated with the perpetration of sexual assault include but are not limited to:

- Individual Risk Factors
    - Alcohol and drug use
    - Coercive sexual fantasies

    - Impulsive and antisocial tendencies
    - Preference for impersonal sex
    - Hostility toward women
    - Childhood history of sexual and physical abuse
    - Witnessed family violence as a child
- Relationship Risk Factors
    - Association with sexually aggressive and delinquent peers
    - Family environment characterized by physical violence and few resources
    - Strong patriarchal relationship or familial environment
    - Emotionally unsupportive familial environment
- Community Risk Factors
    - Lack of employment opportunities
    - Lack of institutional support from police and judicial system
    - General tolerance of sexual violence within the community
    - Weak community sanctions against sexual violence perpetrators
- Societal Risk Factors
    - Poverty
    - Societal norms that support sexual violence
    - Societal norms that support male superiority and sexual entitlement
    - Societal norms that maintain women's inferiority and sexual submissiveness
    - Weak laws and policies related to gender equity
    - High tolerance levels of crime and other forms of violence
- Protective Factors
    - Emotional health and connectedness
    - Academic achievement

- "Loss of face"—a concern for how one's actions affect others
- Parents' use of reasoning to resolve family conflicts
- Empathy

Area of Emphasis: Adjustment Disorders

Defining Adjustment Disorders

Adjustment disorders (ADs) are characterized by clinically significant emotional and behavioral symptoms in reaction to a recent and identifiable stressor such that the distress is out of proportion to the stressor or the individual has difficulty functioning in a social, occupational, or other important context (American Psychiatric Association, 2013). The stressor may be a single event or the culmination of multiple events, and it may be recurrent or continuous. The lack of well-defined symptom and stressor criteria makes ADs easy to diagnose when a case conceptualization is incomplete or the patient has not met criteria for another disorder (Anastasia et al., 2016;[4] Baumeister and Kufner, 2009;[5] Casey, 2018[6]). Additionally, an AD diagnosis might be recorded when a clinician is concerned that a diagnosis such as post-traumatic stress disorder (PTSD) or major depressive disorder might have a negative impact on the patient (Wilk et al., 2016[7]).

In 2016, 20.4% of active component Soldiers had a behavioral health disorder, of which ADs, mood disorders, and anxiety disorders were most common (Army Public Health Center, Army Health of the Force Report – Washington, DC: Office of the Surgeon General, 2017). ADs remained the most commonly diagnosed group of disorders in 2017 among active duty SMs in all Services, with a prevalence rate of 7.1%, compared to the lower prevalence of diagnosed PTSD and depression (2.1% and 4.2%, respectively; PHCoE, 2018).

By definition, ADs occur within 3 months after the start of an identifiable stressor (e.g., sexual assault, a combat stressor, family stressor) and resolve within 6 months of the stressor's termination (Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition [DSM-5]); however, there is now longitudinal data (O'Donnell et al., 2016[8]) showing that the majority of

[4] Anastasia A, Colletti C, Cuoco V, Quartini A, Urso S, Rinaldi R, and Bersani G. 2016. Demographic variables, clinical aspects, and medicolegal implications in a population of patients with adjustment disorder. *Neuropsychiatric Disease and Treatment* 12:737-742.

[5] Baumeister H and Kufner K. 2009. It is time to adjust the adjustment disorder category. *Current Opinion in Psychiatry* 22(4):409-412.

[6] Casey P. 2018. History of the concept of adjustment disorders. In: *Adjustment Disorders: From Controversy to Clinical Practice*. Casey P (Ed.). Oxford University Press, Oxford, United Kingdom. 1-18.

[7] Wilk JE, Herrell RK, Carr AL, West JC, Wise J, and Hoge CW. 2016. Diagnosis of PTSD by Army behavioral health clinicians: Are diagnoses recorded in electronic health records? *Psychiatric Services* 67(8):878-882.

[8] O'Donnell ML, Alkemade N, Creamer M, McFarlane AC, Silove D, Bryant RA, Felmingham K, Steel Z, and Forbes D. 2016. A longitudinal study of adjustment disorder after trauma exposure. *American Journal of Psychiatry* 173(12):1231-1238.

individuals with an AD may still have a mental health diagnosis after 12 months, indicating a chronic, not resolving course.

Research applications that propose to explore this landscape of ADs should address prevention efforts that aim to reduce the likelihood of progression to ADs and PTSD or prevent ADs or PTSD immediately post-trauma.

II.A.2. Focus Areas

All applications must specifically address at least one of the Focus Areas below and be of clear scientific merit with direct relevance to military and public health. If the proposed research does not specifically address at least one of the Focus Areas, the Government will administratively withdraw the application.

#1: Interventions at the outer levels of the social ecology, such as policy interventions. *Policy interventions can change community-level, environmental, and situational factors to reduce the likelihood of sexual assault and sexual harassment from occurring. Policy interventions in a military setting that can be achieved without increasing SM time in training are preferred.*

#2: Interventions developed, evaluated, and implemented for vulnerable subpopulations. *The content as well as the delivery of such targeted interventions, which require careful development, and testing within a military context are preferred. For example, implementation methods that maintain participant privacy would be needed to avoid inadvertently stigmatizing the at-risk individual.*

#3 Factors that may impede or support the application of evidence-based sexual assault and sexual harassment prevention intervention. *Applying and testing existing implementation science research to military settings to inform the widespread adoption of effective prevention within the military are preferred.*

#4 Limits to integrated, cross-cutting prevention approaches. *Many evidence-based prevention approaches in related areas have not been evaluated for sexual assault and sexual harassment outcomes. Similarly, many evidence-based sexual assault and sexual harassment interventions have not been evaluated for related outcomes, such as alcohol use, sexual risk behaviors, and relationship violence.*

#5 Assessment and screening of those presenting with Adjustment Disorders (ADs) associated with the experience of sexual assault or other stressors that precipitate ADs. *Research that considers military-relevant stressors (such as relocation, deployment, combat, occupational changes, separation, and the cumulative effects of such stressors) is preferred, with the goal of preventing the onset of chronic behavioral health diagnoses (e.g., PTSD, depression, and anxiety disorders), which negatively impact mission readiness. Additional knowledge is needed regarding (a) the validity and reliability of diagnostic criteria for ADs; (b) methods to more accurately distinguish ADs from other behavioral health diagnoses; (c) the defining characteristics of stressor types that precipitate ADs; and (d) the trajectories of ADs, such that treatment guidelines for ADs can be developed.*

II.B. Award Information

Impact: The FY19 PH/TBIRP PSAAD IIFRA is intended to support research focused on: (1) the development or adaptation of prevention efforts to reduce the occurrence of sexual assault and/or harassment and/or (2) understanding the diagnosis, assessment, and screening of adjustment disorders as a consequence of sexual assault and/or stressors that precipitate adjustment disorders.

The application must clearly demonstrate the project's potential immediate and long-range outcome(s) with the potential to yield highly impactful data that are of clear scientific merit and could lead to critical discoveries and/or major advancements and not be limited to a clinical setting such as a behavioral health clinic.

The rationale for a research idea may be derived from population-based studies, a clinician's first-hand knowledge of patients, or anecdotal data. Applications must include relevant data that support the rationale for the proposed study. The data may be unpublished or from published literature.

Research involving human subjects is permitted; however, this award may not be used to conduct clinical trials.

New FY19 definition: A clinical trial is 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.

The proposed research must be relevant to active duty SMs, military beneficiaries, and the American public. Veterans are an important population, but ***this funding opportunity is not focused on Veterans*.**

Research involving the broad category of military sexual trauma (MST) will not be considered. MST is defined by the Department of Veterans Affairs as the "psychological trauma resulting from a physical assault of a sexual nature, battery of a sexual nature, or sexual harassment which occurred while the Veteran *was* serving on active duty, active duty for training, or in active duty training." MST is a category of experience that can only occur after a Service member has left service. Prevention research should be focused on primary or secondary prevention efforts conducted on active duty, NG, or Reserve Service members. The FY19 PH/TBIRP PSAAD IIFRA will only consider applications that target sexual assault and/or harassment as defined in Section II.A.1. These constructs will need to be defined as separate behaviors and assessed as such. Combining them into one category, such as MST that includes behaviors that fall outside the definitions in Section II.A.1., does not fit the intent of this Program Announcement.

***Research involving awareness-based prevention approaches will not be considered*.** Activities aimed at preventing sexual assault have mostly centered on raising awareness about the crime,

but civilian sector research suggests awareness programming does not translate into sustained behavior change required to prevent sexual assault (DeGue et al., 2014[9]).

Research involving IOP treatment for patients who experience mental health symptoms that accompany sexual assault will not be considered.

Preclinical (animal) studies are not allowed.

The anticipated direct costs budgeted for the entire period of performance for the FY19 PH/TBIRP PSAAD IIFRA will not exceed **$750,000**. Refer to Section II.D.5, Funding Restrictions, for detailed funding information.

The JPC-5/MOMRP expects to allot approximately $5.17 million to fund approximately four IIFRA applications. Funding of applications received is contingent upon the availability of Federal funds for this program as well as the number of applications received, the quality and merit of the applications as evaluated by scientific and programmatic review, and the requirements of the Government. Funds to be obligated on any award resulting from this funding opportunity will be available for use for a limited time period based on the fiscal year of the funds. It is anticipated that awards made from this FY19 funding opportunity will be funded with FY19 funds, which will expire for use on September 30, 2025.

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

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

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

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

[9] DeGue S, Valle LA, Holt MK, Massetti GM, Matjasko JL, and Tharp AT. 2014. A systematic review of primary prevention strategies for sexual violence perpetration. *Aggression and Violent Behavior* 19(4):346-362.

(HRPO), prior to research implementation. This administrative review requirement is in addition to the local Institutional Review Board (IRB) or Ethics Committee (EC) review. Local IRB/EC approval at the time of submission is ***not*** required. The HRPO is mandated to comply with specific laws and requirements governing all research involving human anatomical substances, human subjects, or human cadavers that is supported by the DoD. These laws and requirements will necessitate information in addition to that supplied to the IRB/EC. ***Allow a minimum of 2 to 3 months for HRPO regulatory review and approval processes***. Additional time for regulatory reviews may be needed for clinical studies taking place in international settings. When possible, protocols should be written for research with human subjects and/or human anatomical substances that are specific to the DoD-supported effort outlined in the submitted application as a stand-alone study. Submission to HRPO of protocols involving more than the scope of work in the DoD-funded award will require HRPO review of the entire protocol (DoD and non-DoD funded). DoD human subjects protection requirements may be applied to non-DoD funded work and necessitate extensive revisions to the protocol. Applications that involve recruitment of human subjects must indicate the quarterly enrollment targets across all sites in Attachment 5: Statement of Work (SOW). Successful applicants will work with USAMRAA to establish milestones for human subjects recruitment. Continued support for the project will be based upon satisfactory progress in meeting the established milestones. Refer to the General Application Instructions, Appendix 1, and the Human Subject Resource Document available on the electronic Biomedical Research Application Portal (eBRAP) "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) for additional information.

Use of DoD Resources: If the proposed research involves access to active duty military patient populations and/or DoD resources or databases, the application must describe the access at the time of submission and include a plan for maintaining access as needed throughout the proposed research. Access to target active duty military patient population(s) and/or DoD resource(s) or database(s) should be confirmed by including a letter of support, signed by the lowest-ranking person with approval authority.

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

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

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

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

II.C. Eligibility Information

II.C.1. Eligible Applicants

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

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

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

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

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

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

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

II.C.1.b. Principal Investigator

Investigators at all academic levels are eligible to be named by the organization as a 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

Extramural Submission: An application submitted by an organization to Grants.gov.

Intramural DoD Submission: An application submitted by a DoD organization to eBRAP.

II.D.1. Address to Request Application Package

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

Extramural Submissions:

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

Intramural DoD Submissions:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The applicant organization and associated 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 PI must contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507.

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

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

- **Tab 1 – Application Information**

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

- **Tab 2 – Application Contacts**

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

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

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

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

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

FY19 PH/TBIRP PSAAD IIFRA 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 (COIs)**

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

- **Tab 5 – Pre-Application Files**

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

- **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

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.

Table 1. Full Application Submission Guidelines

Extramural Submissions	Intramural DoD Submissions
Application Package Location	
Download application package components for W81XWH-19-PHTBIRP-PSAAD-IIFRA from Grants.gov (https://www.grants.gov) and create a Grants.gov Workspace. Workspace allows online completion of the application components and routing of the application package through the applicant organization for review prior to submission.	Download application package components for W81XWH-19-PHTBIRP-PSAAD-IIFRA from eBRAP (https://ebrap.org).
Full Application Package Components	
SF424 Research & Related Application for Federal Assistance Form: Refer to the General Application Instructions, Section III.A.1, for detailed information.	**Tab 1 – Summary:** Provide a summary of the application information. **Tab 2 – Application Contacts:** This tab will be pre-populated by eBRAP; add Authorized Organizational Representative.
Descriptions of each required file can be found under Full Application Submission Components: • Attachments • Research & Related Personal Data • Research & Related Senior/Key Person Profile (Expanded) • Research & Related Budget • Project/Performance Site Location(s) Form • Research & Related Subaward Budget Attachment(s) Form (if applicable)	**Tab 3 – Full Application Files:** Upload files under each Application Component in eBRAP. Descriptions of each required file can be found under Full Application Submission Components: • Attachments • Key Personnel • Budget • Performance Sites **Tab 4 – Application and Budget Data:** Review and edit proposed project start date, proposed end date, and budget data pre-populated from the Budget Form.
Application Package Submission	
Create a Grants.gov Workspace. Add participants (investigators and Business Officials) to Workspace, complete all required forms, and check for errors before submission. **Submit 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	**Submit package components to eBRAP (https://ebrap.org).** **Tab 5 – Submit/Request Approval Full Application:** After all components are uploaded and prior to the full application submission deadline, enter your password in the space provided next to "Enter Your Password Here" and press the "Submit Full Application" button. eBRAP will notify your

Extramural Submissions	Intramural DoD Submissions
submission of the application package **at least 24-48 hours prior to the close date** to allow time to correct any potential technical issues that may disrupt the application submission. **Note:** If either the Project Narrative or the budget fails eBRAP validation or if the Project Narrative or the budget needs to be modified, an updated Grants.gov application package must be submitted via Grants.gov as a "Changed/ Corrected Application" with the previous Grants.gov Tracking ID ***prior to*** the application submission deadline.	Resource Manager/Comptroller/Task Area Manager or equivalent Business Official by email.
Application Verification Period	
The full application package submitted to Grants.gov may be viewed and modified in eBRAP until the end of the application verification period. During the application verification period, the full application package may be modified ***with the exception of the Project Narrative and Research & Related Budget Form***.	After eBRAP has processed the full application, the organizational Resource Manager/Comptroller/Task Area Manager or equivalent Business Official and PI will receive email notification of this status and will be able to view and modify application components in eBRAP. During the application verification period, the full application package may be modified ***with the exception of the Project Narrative and Research & Related Budget Form***. Your Resource Manager/Comptroller/Task Area Manager or equivalent Business Official should log into eBRAP to review and to approve prior to the application verification deadline.
Further Information	
Tracking a Grants.gov Workspace Package. After successfully submitting a Workspace package, a Grants.gov Tracking Number is automatically assigned to the package. The number will be listed on the "Confirmation" page that is generated after submission. Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.	Refer to the General Application Instructions, Section IV, for further information regarding eBRAP requirements.

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

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

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

- **Extramural Applications Only**

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

- **Extramural and Intramural Applications**

  Attachments:

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

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

  - **Attachment 1: Project Narrative (15-page limit): Upload as "ProjectNarrative.pdf".** The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs that provide additional information to expand the Project Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application.

    Describe the proposed project in detail using the outline below.

    - **Background:** Describe how the proposed research project addresses one or more of the FY19 PH/TBIRP PSAAD IIFRA Focus Areas in Section II.A.2. Present the ideas and reasoning behind the proposed work. Cite relevant literature. Describe previous

experience most pertinent to the project. Include relevant preliminary data; these data may be unpublished or from the published literature.

- **Hypothesis:** State the hypothesis to be tested.

- **Specific Aims:** Concisely explain the project's specific aims and the objective(s) to be reached. These aims should agree with the primary aims and associated tasks described in the SOW (Attachment 5). If the proposed work is part of a larger study, present only aims that this DoD award would fund.

- **Research Strategy:** Describe the experimental design, methods, and analyses, including appropriate controls, in sufficient detail for analysis. Address potential problem areas and present alternative methods and approaches. Clearly describe the statistical plan and the rationale for the statistical methodology as well as an appropriate power analysis, if applicable.

  If human subjects or human biological samples will be used, describe the study population and include a detailed plan for the recruitment of human subjects or the acquisition of samples. Describe the availability of the proposed study population and past successes in recruiting similar populations. If active duty military, military families or datasets will be used in the proposed research project, describe the feasibility of accessing the population(s)/dataset(s). Clinical trials are not allowed under the FY19 PH/TBIRP PSAAD IIFRA.

- **Research Team:** Describe how the background and expertise of the PI and other key personnel demonstrate their understanding of working with a military population. Describe whether the composition of the research or study team (e.g., study coordinator, statistician) and/or multidisciplinary team of scientists and stakeholders is appropriate and complementary

- **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 (one-page limit per letter): Provide a letter (or letters, if applicable), signed by the Department Chair or appropriate organization official, confirming the laboratory space, equipment, and other resources available for the project. Letters of support not requested in the Program Announcement, such as those from members of Congress, do not impact application review or funding decisions.

- Letters of Collaboration (if applicable) (one-page limit per letter): Provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed work. If an investigator at an intramural organization is named as a collaborator on an application submitted through an extramural organization, the application must include a letter from the collaborator's Commander or Commanding Officer at the intramural organization that authorizes the collaborator's involvement.

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

- 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.

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

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

  - **Background:** State the ideas and reasoning on which the proposed work is based. Describe how the proposed research project addresses one or more of the FY19 PH/TBIRP PSAAD IIFRA Focus Areas in Section II.A.2.

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

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

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

  - **Impact and Military Benefit:** Briefly explain the potential impact of the proposed project on the development or adaptation of prevention efforts to reduce the occurrence of sexual assault and/or harassment, and/or understanding the diagnosis, assessment, and screening of ADs immediately post-trauma exposure by addressing at least one of the Focus Areas identified in Section II.A.2.

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

  Lay abstracts should be written using the outline below. Minimize use of acronyms and abbreviations, where appropriate. The lay abstract is an important component of the application review process because it addresses issues of particular interest to the consumer community. ***Do not duplicate the technical abstract.***

  - Describe the objectives and rationale for the proposed research in a manner that will be readily understood by ***readers without a background in PH or the military.***

  - Describe the anticipated short-term and long-term outcomes of the proposed research.

  - As applicable, describe how the proposed research will address prevention efforts to reduce the occurrence of sexual assault and/or harassment for SMs, and the public at large.

- As applicable, describe how the proposed research will enhance the understanding of the diagnosis, assessment, and screening of ADs immediately post-trauma exposure for SMs, and the public at large.

- **Attachment 5: Statement of Work (five-page limit): Upload as "SOW.pdf".** The suggested SOW format and examples specific to different types of research projects are available on the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm). For the FY19 PH/TBIRP PSAAD IIFRA mechanism, use the SOW format example titled "SOW Generic Format." The SOW must be in PDF format prior to attaching.

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

  - Include the name(s) of the key personnel and contact information for each study site/ subaward site.

  - Indicate the number (and type, if applicable) of research subjects required for each task and at each site. Refer to the General Application Instructions, Appendix 1, for additional information regarding regulatory requirements.

  - For studies with prospective accrual of human subjects, indicate quarterly enrollment targets.

- **Attachment 6: Impact and Military Benefit Statement (one-page limit): Upload as "Impact.pdf".**

  - Describe how the proposed work enhances the development or adaptation of prevention efforts to reduce the occurrence of sexual assault and/or harassment, and/or understanding the diagnosis, assessment, and screening of ADs immediately post-trauma exposure by addressing at least one of the Focus Areas identified in Section II.A.2 and of clear scientific merit throughout the DoD as well as the potential benefit for the general public.

  - Describe how the proposed research project will (a) reduce, with the goal to eliminate the factors leading to, or associated with, sexual violence, thereby stopping the crime before it occurs and/or (b) improve diagnosis, assessment, and/or screening of ADs.

  - Describe how the proposed research project will demonstrate potential immediate and long-range outcome(s) that are of clear scientific merit and could yield highly impactful data that could lead to critical discoveries and/or major advancements and not be limited to a clinical setting such as a behavioral health clinic.

- **Attachment 7: Human Subject Recruitment and Safety Procedures (required for all studies recruiting human subjects; no page limit): Upload as "HumSubProc.pdf".** The Human Subject Recruitment and Safety Procedures attachment should include the components listed below:

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

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

    - ***Inclusion of Women and Minorities in Study:*** Consistent with the Belmont Report, "Ethical Principles and Guidelines for the Protection of Human Subjects," and Congressional legislation, special attention is given to inclusion of women and/or minorities in studies funded or supported by the USAMRDC. This policy is intended to promote equity both in assuming the burdens and in receiving the benefits of human subjects research. Include an appropriate justification if women and/or minorities will be excluded.

  - **Description of the Recruitment Process:** Address who will identify potential human subjects, who will recruit them, and what methods will be used to recruit them.

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

    - ***For clinical studies proposing to recruit military personnel, refer to the General Application Instructions, Appendix 1, for more information.***

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

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

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

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

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

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

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

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

  - Consider the need for obtaining ongoing consent or for re-assessing capacity over the course of a long-term study, and describe any relevant procedures to assure continued consent.

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

- **Risks/Benefits Assessment:**

  - **Foreseeable risks:** Clearly identify all potential study risks. Study risks include any risks that the human subject is subjected to as a result of participation. Consider psychological, legal, social, and economic risks as well as physical risks. If the risks are unknown, this should be stated. If applicable, any potential risk to the study personnel should be identified.

  - **Risk management and emergency response:**

    - Describe all safety measures to minimize and/or eliminate risks to human subjects and study personnel or to manage unpreventable risks.

- ❖ Discuss the overall plan for provision of emergency care or treatment for an adverse event for study-related injuries, to include who will be responsible for the cost of such care.

- ❖ Address any special precautions to be taken by the human subjects before, during, and after the study.

- **Potential benefits:** Describe known and potential benefits of the study to the human subject or community at large.

- **Attachment 8: Data Management (no page limit): Upload as "DataManage.pdf".** The Data Management attachment should include the components listed below.

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

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

    - **Confidentiality:** Explain measures taken to protect the privacy of study human subjects and maintain confidentiality of study data. Strategies to protect the privacy and confidentiality of study records, particularly those containing identifying information, should be addressed.

      - ❖ Address who will have access to study records, data, and specimens, including an acknowledgment that representatives of USAMRDC are eligible to review study records.

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

    - **Common Data Elements:** Use of common data elements (CDEs) and sharing of research data as appropriate for this type of study is highly encouraged. Address any instances where use of CDEs and sharing of research data will not occur.

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

- **Attachment 9: Representations, if applicable (extramural submissions only): Upload as "RequiredReps.pdf".** All extramural applicants must complete and submit the Required Representations template available on eBRAP (https://ebrap.org/eBRAP/public/Program.htm). For more information, see the General Application Instructions, Appendix 5, Section B, Representations.

- **Attachment 10: DoD Military Budget Form(s), if applicable: Upload as "MFBudget.pdf".** If a military facility (Military Health System facility, research laboratory, medical treatment facility, dental treatment facility, or a DoD activity embedded with a civilian medical center) will be a collaborator in performance of the

project, complete the DoD Military Budget Form, available for download on the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm), including a budget justification, for each military facility as instructed. The costs per year should be included on the Grants.gov Research & Related Budget form under subaward costs. Refer to the General Application Instructions, Section III.A.8, for detailed information.

- **Extramural and Intramural Applications**

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

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

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

  - PI Biographical Sketch (five-page limit): Upload as "Biosketch_LastName.pdf". The suggested biographical sketch format is available on the "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) in eBRAP. The National Institutes of Health (NIH) Biographical Sketch may also be used. All biographical sketches should be submitted in uneditable PDF format.

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

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

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

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

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

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

- **Extramural Applications Only**

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

  - **Extramural Subaward:** Complete the Research & Related Subaward Budget Form through Grants.gov. (Refer to the General Application Instructions, Section III.A.7, for detailed information.) Verify subaward budget(s) and budget justification forms are present in eBRAP during the application verification period. If these components are missing, upload them to eBRAP before the end of the application verification period.

  - **Intramural DoD Collaborator(s):** Complete the DoD Military Budget Form and upload to Grants.gov attachment form as Attachment 10. (Refer to the General Application Instructions, Section IV.A.4, for detailed information.) Each Intramural DoD Collaborator should include costs per year on the Grants.gov Research & Related Budget Form under subaward costs.

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

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

II.D.4. Submission Dates and Times

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

Applicant Verification of Full Application Submission in eBRAP

Following retrieval and processing of the full application, eBRAP will notify the organizational representatives and PI by email to log into eBRAP to review, modify, and verify the full application submission. eBRAP will validate retrieved files against the specific Program

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

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

Intramural DoD Submission: After eBRAP has processed the full application, the organizational Resource Manager/Comptroller/Task Area Manager or equivalent Business Official and PI 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 **3** years.

The anticipated direct costs budgeted for the entire period of performance will not exceed **$750,000**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the Government exceeding **$750,000** direct costs or using an indirect cost rate exceeding the organization's negotiated rate.

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

The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum **3** years.

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

- Travel costs for the PI to disseminate project results at one DoD PH/TBIRP In-Progress Review meeting annually. For planning purposes, it should be assumed that the meetings will be held in the National Capital Area. These travel costs are in addition to those allowed for annual scientific/technical meetings.

May be requested for (not all-inclusive):

- Salary
- Research supplies
- Research-related subject costs
- Clinical research costs
- Support for multidisciplinary collaborations, including travel
- Travel costs for the PI to travel to one scientific/technical meeting per year in addition to the required In-Progress Review meetings described above to present project information and disseminate project results from the FY19 PH/TBIRP PSAAD IIFRA

Must not be requested for:

- Clinical trial costs
- Animal studies

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

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

Funds to be obligated on any award resulting from this funding opportunity will be available for use for a limited time period based on the fiscal year of the funds. The time is considered when establishing the award's period of performance. It is anticipated that awards made from this FY19 funding opportunity will be funded with FY19 funds, which will expire for use on September 30, 2025.

II.D.6. Other Submission Requirements

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

II.E. Application Review Information

II.E.1. Criteria

II.E.1.a. Peer Review

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

- **Hypothesis**
    - How well the proposed approach describes the hypothesis for the proposed research.
- **Research Strategy and Feasibility**
    - How well the scientific rationale supports the project and its feasibility, as demonstrated by a critical review and analysis of the data (unpublished or from published literature), supporting data, and logical reasoning.
    - How well the hypothesis, specific aims, and objective(s) are developed.
    - How well the experimental design, methods, data collection procedures, and analyses are developed and support completion of the aims.
    - If applicable, how well the application provides evidence of availability of, and access to, the necessary study populations and/or resources.
    - How well potential problems are identified and alternative approaches are addressed.
    - Whether the research can reasonably be completed within the proposed period of performance.
- **Ethical Considerations**
    - Whether the level of risk to human subjects is minimized and communicated through informed consent.
    - How well the safeguards are described and in place for vulnerable populations.
    - How well the safety monitoring and reporting plan is appropriate for the level of work proposed.
    - To what degree privacy issues are appropriately considered.
- **Impact**
    - To what extent the project addresses at least one of the Focus Areas in Section II.A.2 and is of clear scientific merit.

- To what extent the project addresses the development or adaptation of prevention efforts to reduce the occurrence of sexual assault and/or harassment and/or understanding the diagnosis, assessment, and screening of ADs immediately post-trauma exposure.

- To what extent the project's potential immediate and long-range outcome(s) will yield highly impactful data that could lead to critical discoveries or major advancements.

- To what extent the proposed research project will (a) reduce, with the goal to eliminate the factors leading to, or associated with, sexual violence, thereby stopping the crime before it occurs and/or (b) improve diagnosis, assessment, and/or screening of ADs.

- **Personnel**

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

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

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

  - To what extent the research team's previous experience is pertinent to the proposed work.

  - To what extent the PI has formed a multidisciplinary team of scientists and stakeholders that is appropriate and complementary.

- **Data Sharing Plan**

  - How thoroughly the application outlines a plan for use of CDEs and sharing of research data as appropriate for the type of study.

  - How thoroughly the application address any instances where CDEs will not be used and sharing of research data will not occur.

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

- **Statistical and Data Analysis Plan**

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

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

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

- **Environment**
    - How well the research requirements are supported by the availability of, and accessibility to, facilities and subject populations.
    - Whether the quality and extent of institutional support are appropriate for the proposed project.
- **Budget**
    - Whether the direct maximum costs are equal to or less than the allowable direct maximum costs as published in the Program Announcement.
    - Whether the budget is appropriate for the proposed research.
- **Application Presentation**
    - To what extent the writing, clarity, and presentation of the application components influence the review.

II.E.1.b. Programmatic Review

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

- Ratings and evaluations of the peer reviewers
- Relevance to the mission of the DHP, JPC-5/MOMRP, and FY19 PH/TBIRP, as evidenced by the following:
    - Adherence to the intent of the award mechanism
    - Program portfolio composition
    - Relative impact and innovation

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, on behalf of the DHA and the OASD(HA). ***The highest-scoring applications from the first tier of review are not automatically recommended for funding. Funding recommendations depend on various factors as described in Section II.E.1.b, Programmatic Review.*** Additional information about the two-tier process used by the CDMRP

can be found at https://cdmrp.army.mil/about/2tierRevProcess. A PI Information Paper describing the funding recommendations and review process for the award mechanisms for the FY19 PH/TBIRP PSAAD IIFRA will be provided to the PI and posted on the CDMRP website.

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

II.E.3. Integrity and Performance Information

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

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

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

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

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

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

II.F. Federal Award Administration Information

II.F.1. Federal Award Notices

Awards supported with FY19 funds are anticipated to be made no later than September 30, 2020. Refer to the General Application Instructions, Appendix 2, for additional award administration information.

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

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

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

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

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

Unless otherwise restricted, changes in PI 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.***

Quarterly, annual, and final technical progress reports and quad charts will be required. Attendance at annual Interim Progress Reviews may be requested.

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

II.G. Federal Awarding Agency Contacts

II.G.1. CDMRP Help Desk

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

Phone: 301-682-5507

Email: help@eBRAP.org

II.G.2. Grants.gov Contact Center

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

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

Email: support@grants.gov

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

II.H. Other Information

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

Questions related to this Program Announcement should refer to the Program name, the Program Announcement name, and the Program Announcement version code 20190530a. The Program Announcement numeric version code will match the General Application Instructions version code 20190530.

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 FY19 PH/TBIRP PSAAD IIFRA Programmatic Panel member is named as being involved in the research proposed or is found to have assisted in the pre-application or application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting documentation. ***A list of the FY19 PH/TBIRP PSAAD IIFRA Programmatic Panel members can be found at https://cdmrp.army.mil/phtbirp/panels/panels19.***
- The application fails to conform to this Program Announcement description.
- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- To preserve the integrity of its peer and programmatic review processes, the CDMRP discourages inclusion of any employee of its review contractors having any role in the preparation, research or other duties for submitted applications. For FY19, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (https://cdmrp.army.mil/about/2tierRevProcess). Applications that include names of personnel from either of these companies may be administratively withdrawn.
- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review or approval process to gain protected evaluation information or to influence the evaluation process.
- Applications from extramural organizations, including non-DoD Federal agencies, received through eBRAP may be withdrawn.
- Applications submitted by an intramural DoD organization may be withdrawn if the intramural organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to extramural collaborators.
- The PI does not meet the eligibility criteria.
- The application does not address one of the Focus Areas in Section II.A.2.
- The application proposes preclinical (animal) studies.
- The application proposes clinical trials as defined in Section II.B.
- The application proposes to study MST as defined in Section II.B.
- The application proposes to study awareness-based prevention approaches as defined in Section II.B.

- The application proposes to study IOP treatment as defined in Section II.A.1.
- The application proposes to study Veteran populations.

II.H.2.d. Withhold

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

II.H.3. Application Submission Checklist

Application Components	Action	Completed
SF424 Research & Related Application for Federal Assistance **(Extramural submissions only)**	Complete form as instructed	
Summary (Tab 1) and Application Contacts (Tab 2) **(Intramural submissions only)**	Complete tabs as instructed	
Attachments	Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf"	
	Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf"	
	Technical Abstract: Upload as Attachment 3 with file name "TechAbs.pdf"	
	Lay Abstract: Upload as Attachment 4 with file name "LayAbs.pdf"	
	Statement of Work: Upload as Attachment 5 with file name "SOW.pdf"	
	Impact and Military Benefit Statement: Upload as Attachment 6 with file name "Impact.pdf"	
	Human Subject Recruitment and Safety Procedures: Upload as Attachment 7 with file name "HumSubProc.pdf" if applicable	
	Data Management: Upload as Attachment 8 with file name "DataManage.pdf"	
	Representations (extramural submissions only): Upload as Attachment 9 with file name "RequiredReps.pdf" if applicable	
	DoD Military Budget Form(s): Upload as Attachment 10 with file name "MFBudget.pdf" if applicable	
Research & Related Personal Data	Complete form as instructed	

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)**	Complete the DoD Military Budget Form and justification	
Project/Performance Site Location(s) Form	Complete form as instructed	
Research & Related Subaward Budget Attachment(s) Form, if applicable	Complete form as instructed	

APPENDIX 1: ACRONYM LIST

AD	Adjustment Disorder
CDC	Centers for Disease Control and Prevention
CDE	Common Data Element
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
COI	Conflict of Interest
DHA	Defense Health Agency
DHP	Defense Health Program
DoD	Department of Defense
DoDD	Department of Defense Directive
DoDGARs	Department of Defense Grant and Agreement Regulations
DSM	Diagnostic and Statistical Manual of Mental Disorders
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
FY	Fiscal Year
HIV	Human Immunodeficiency Virus
HRPO	Human Research Protection Office
IIFRA	Investigator-Initiated Focused Research Award
IOP	Intensive Outpatient
IRB	Institutional Review Board
JPC-5	Joint Program Committee-5
LGBT	Lesbian, Gay, Bisexual, Transgender
LOI	Letter of Intent
MIPR	Military Interdepartmental Purchase Request
MOMRP	Military Operational Medicine Research Program
MST	Military Sexual Trauma
NDAA	National Defense Authorization Act
NG	National Guard
NIH	National Institutes of Health
OASD(HA)	Office of the Assistant Secretary of Defense for Health Affairs
ORCID	Open Researcher and Contributor ID, Inc.
ORP	Office of Research Protections
PH	Psychological Health

PHCoE	Psychological Health Center of Excellence
PH/TBIRP	Psychological Health and Traumatic Brain Injury Research Program
PI	Principal Investigator
PPoA	Prevention Plan of Action
PSAAD	Prevention Research to Reduce Sexual Assault and/or Understand Adjustment Disorders
PTSD	Post-Traumatic Stress Disorder
RDT&E	Research, Development, Test, and Evaluation
SAM	System for Award Management
SM	Service Member
SOW	Statement of Work
STEM	Science, Technology, Engineering, and/or Mathematics
TBI	Traumatic Brain Injury
UCMJ	Uniform Code of Military Justice
USAMRAA	U.S. Army Medical Research Acquisition Activity
USAMRDC	U.S. Army Medical Research and Development Command
USC	United States Code