

# **I. OVERVIEW OF THE FUNDING OPPORTUNITY**

**Program Announcement for the Department of Defense**

**Defense Health Program**

**Congressionally Directed Medical Research Programs**

**Alcohol and Substance Abuse Disorders Research Program**

**Consortium Award**

**Announcement Type: Initial**

**Funding Opportunity Number: W81XWH-17-ASADRP-CA**

**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 20, 2017
- **Application Submission Deadline:** 11:59 p.m. ET, October 4, 2017
- **End of Application Verification Period:** 5:00 p.m. ET, October 11, 2017
- **Peer Review:** November 2017
- **Programmatic Review:** January 2018

*This Program Announcement must be read in conjunction with the General Application Instructions, version 20170516. The General Applications Instructions document is available for downloading from the Grants.gov funding opportunity announcement by selecting the “Package” tab, clicking “Preview,” and then selecting “Download Instructions.”*

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## **II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY**

### **II.A. Program Description**

Applications to the Fiscal Year 2017 (FY17) Alcohol and Substance Abuse Disorders Research Program (ASADRP) 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 execution management agent for this Program Announcement is the Congressionally Directed Medical Research Programs (CDMRP). The ASADRP was initiated in 2010 to decrease the clinical impact of alcohol and substance abuse disorders. Appropriations for the ASADRP from FY10 through FY16 totaled \$32.075 million (M). The FY17 appropriation is \$4M.

The ASADRP is seeking applications to explore integrated approaches to address alcohol and substance use disorders (ASUD), especially related to traumatic brain injury (TBI) and post-traumatic stress disorder (PTSD), through multidisciplinary, team-based research efforts that translate basic knowledge into enhanced clinical pharmacological treatment protocols.

The program's goal is to organize multidisciplinary, team-based translational research efforts to:

- Identify promising compounds;
- Conduct proof-of-principle basic research to determine which compounds are most appropriate for human research trials;
- Conduct human proof-of-concept trials with promising compounds.

This approach should accelerate the translation of contemporary basic science knowledge into enhanced clinical pharmacological treatment protocols for ASUD, including a regulatory strategy for U.S. Food and Drug Administration (FDA) compliance.

Further information regarding the ASADRP including the annual report and the Alcohol Use Disorder and Comorbid PTSD/TBI Landscape Summary can be found at <http://cdmrp.army.mil/asadrp/default>.

### **II.B. Award Information**

The CDMRP expects to allocate FY17, FY18, and FY19 funding, if appropriated, to fund approximately one ASADRP Consortium Award. The maximum period of performance is 5 years. The ASADRP Consortium year will be funded initially with allocations from the FY17 ASADRP Congressional appropriation (\$3.532M). The maximum allowable total costs (direct and indirect) for the entire period of performance are \$10.596M. The maximum allowable total

costs (direct and indirect) for the entire period of performance are \$10.596M, of which only \$3.532M is currently available. Refer to [Section II.D.5, Funding Restrictions](#), for detailed funding information.

The FY17 ASADRP Consortium Award will support the establishment of a Consortium whose purpose is to identify promising compounds for translation from basic science knowledge to enhanced clinical pharmacological treatment protocols for ASUD, especially related to TBI and PTSD, to include building on research previously supported by the ASADRP. Information about ASADRP Consortia-funded research can be found at <http://cdmrp.army.mil/asadrp/default>. The Consortium will ultimately consist of a single Management Core as well as basic research and clinical trial sites. The Consortium participants will be jointly responsible for prioritizing, proposing, conducting, and analyzing proof-of-principle basic research and proof-of-concept human clinical trials and developing a roadmap to translate promising basic science knowledge into enhanced clinical pharmacological treatment protocols for ASUD, including a regulatory strategy for FDA compliance.

A single organization must apply to this Program Announcement as a Management Core through a single application and may also serve as a future research and/or trial site. The award resulting from this Program Announcement will be issued as a cooperative agreement between the recipient (Management Core) and the Government. Awards to Federal Government organizations (to include intramural DoD organizations) will be executed through the Military Interdepartmental Purchase Request (MIPR) or Funding Authorization Document (FAD) process. The Government will have substantial involvement in the Consortium through a Government Steering Committee (GSC) and U.S. Army Medical Research and Materiel Command (USAMRMC) staff interactions with the Consortium. Award funds will be used to support the Management Core's efforts as well as Consortium-associated studies at the to-be-determined basic research and clinical trial sites. The Management Core will manage and fund the basic research and clinical trial sites through appropriate subawards or other instruments.

***It is expected that within the first year of the award, a solicitation will be released by the awardee and at least two studies will be selected and funded.*** Following the maximum award performance period of 5 years, the Consortium is expected to be an ongoing, self-sustaining entity.

Award selection will depend upon evaluation of the organization of the Consortium, available capabilities, the proposed research strategy for basic research and clinical trials to be implemented, and the feasibility of the collective group to accomplish the overall award objectives. Applications should highlight the ability of the proposed Management Core to establish research collaborations. During the performance period, the Management Core and all basic research and clinical trial sites will be responsible for working collaboratively to identify new basic research projects and clinical trials for implementation by the Consortium. ***Clinical trials that include military and Veteran populations are encouraged.***

## Consortium Organizational Structure

### 1. Management Core

The Management Core Principal Investigator (PI) must be located at the Management Core's institution and will serve as the Director of the Consortium, Chair of the Consortium Executive Committee (CEC), and be the primary liaison with the USAMRMC Grants Officer's Representative (GOR). ***The Management Core PI must have strong collaborative leadership experience and must demonstrate a broad understanding of ASUD research, including knowledge of the current state of ASUD research in the military context.***

The Consortium shall consist of one central Management Core that will be responsible for the planning, prioritizing, and soliciting of proposals, and providing oversight and coordination for future proof-of-principle basic research projects and proof-of-principle human clinical trials to be supported by the Consortium. The Management Core will administratively review the regulatory, statistical, resource, and data management/storage functions necessary to facilitate rapid development and accelerate translation. The Management Core must contain multidisciplinary expertise and extensive experience in support of ASUD research.

The application should identify and describe the core facilities and functions that the Management Core will provide to the Consortium participants (i.e., data management, statistical analysis, scientific communication, etc.).

The Management Core is expected to:

- Ensure that the Consortium adheres to the planned timeline and milestones for overall study execution.
- Manage the Consortium organizational structure.
- Manage a communications plan and real-time communications with the basic research and clinical trial sites.
- Be responsible for establishing procedures for releasing a competitive call for basic research and clinical trial proposals and be responsible for coordinating all aspects of proposal receipt and review including external independent scientific peer review. It is expected that within the first year of the award, a solicitation will be released and at least two studies will be selected and awarded.
- Manage procedures to ensure that all sites maintain compliance with local Institutional Review Boards (IRBs) and the USAMRMC Office of Research Protections (ORP) Human Research Protection Office (HRPO) for the proper conduct of clinical studies and the protection of human subjects; or to the local Institutional Animal Care and Use Committees (IACUCs) and the USAMRMC ORP Animal Care and Use Review Office (ACURO) for animal studies.

- Provide a Consortium Research Project Manager who will oversee and support the efforts of the Research Coordinators at each of the basic research and clinical trial sites. The Consortium Research Project Manager will be responsible for coordinating and facilitating clinical protocol approval, patient accrual, and study activities across all sites. For individual clinical studies, the Management Core should ensure the maintenance of overall patient accrual per year, appropriate for the target population.
- Manage Consortium-developed quality assurance and quality control mechanisms for study monitoring, including, but not limited to:
  - On-site monitoring program (to include safety).
  - Management plan for the handling, distribution, and banking of specimens and imaging products generated from Consortium studies.
  - Registration, tracking, and reporting of participant accrual.
  - Timely medical review, rapid reporting, and communication of adverse events as well as establishment of a safety committee to provide timely analysis of adverse events.
  - Interim evaluation and consideration of measures of outcome.
- To support future studies that involve human subjects research, implement statistical execution plans/support for all Consortium clinical studies that can address the following:
  - Develop statistical model(s) and data analysis plan with respect to the study objectives and endpoints as appropriate for the type of studies required.
  - Establish study variables required and describe how they will be measured, including a description of appropriate controls and the endpoints to be tested, and the reliability and validity of assessment measures, if applicable.
  - Develop methods required that will be used to recruit a sample cohort from the accessible population (e.g., convenience, simple random, stratified random).
  - Develop human subject-to-group assignment process required (e.g., randomization, block randomization, stratified randomization, age-matched controls, alternating group, or other procedures), if applicable.
  - Identify specific actions to accomplish the group assignment (e.g., computer assignment, use of table of random numbers).
- To support future studies that involve human subjects research, implement human subject recruitment and safety procedures for all Consortium clinical studies that address the following:
  - Study Population: Identify 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). The research team's access to the proposed study population and the inclusion and exclusion criteria for the proposed studies should be considered. 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. ***Inclusion of Women and Minorities in Study***. Consistent with the Belmont Report, "Ethical Principles and Guidelines for the Protection of Human Subjects," and Congressional legislation, special attention is given to inclusion of women and/or minorities in studies funded or supported by the USAMRMC. This policy is intended to promote equity both in assuming the burdens and in receiving the benefits of human subjects research. Justification should be requested if women and/or minorities will be excluded from the clinical research/trial.

- Recruitment Plan: The methods for identification of potential human subjects for the proposed studies. The recruitment plan should take into consideration a description of the recruitment process (who will identify potential human subjects, who will recruit them, and what methods will be used to recruit them), the compensation plan if the human subjects will be compensated for participation in the study, and the recruitment and advertisement materials.
- Informed Consent Plan: The plan for obtaining informed consent from human subjects for the proposed studies. The informed consent plan for the proposed studies should take into consideration:
  - Who is responsible for explaining the study, answering questions, and obtaining informed consent to ensure that human subjects' questions will be addressed during the consent process and throughout the trial.
  - The timing and location of the consent process.
  - 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.
  - 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.
  - 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.
  - The plan for the consent of the individual's Legally Authorized Representative (LAR) to be obtained prior to the human subject's participation in the study (if applicable). State law defines who may act as the LAR. The local IRB of record should be consulted for guidance regarding who can serve as LAR for research at the study site.

- Screening Procedures: 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: Identification of all study risks. Study risks include any risks that the human subject is subjected to as a result of participation in the clinical study or trial. 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:
    - ❖ Safety measures to minimize and/or eliminate risks to human subjects and study personnel or to manage unpreventable risks. Include safeguards and planned responses such as dose reduction or stopping criteria based on toxicity grading scales or other predetermined alert values.
    - ❖ 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.
    - ❖ Special precautions to be taken by the human subjects before, during, and after the study (e.g., medication washout periods, dietary restrictions, hydration, fasting, and pregnancy prevention).
    - ❖ Special care (e.g., transportation due to side effects of study intervention impairing ability to drive) or equipment (e.g., thermometers, telemedicine equipment) needed for human subjects enrolled in the study.
  - Potential benefits of the studies to the human subject, a specific community, or society.
- Manage the regulatory strategy for FDA compliance leading to potential product development and licensing. Ensure that all investigators are FDA-registered to use Investigational New Drugs (INDs); and manage procedures for ensuring compliance with FDA requirements for investigational agents and devices.
  - Manage standardization and, when appropriate, centralized review of imaging, histopathology, neuropsychological, and other data through committees and scientific core facilities.

- Manage Consortium-developed comprehensive data collection and data management systems that address the needs of all basic research and clinical trial sites in terms of access to data, data security, data integrity measures, and data sharing. Data collection and management should include the components listed below:
  - Unique identifiers or specific code system to be used to identify human subjects, if applicable.
  - Confidentiality:
    - Measures taken to protect the privacy of 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.
    - Access to study records, data, and specimens, including an acknowledgment that representatives of USAMRMC are eligible to review study records.
    - Requirements for reporting sensitive information (if applicable) to state or local authorities.
    - 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.
    - How data will be reported and how it will be assured that the documentation will support a regulatory filing with the FDA, if applicable.
    - Whether or not the results of screening and/or study participation will be shared with human subjects or their primary care provider, to include results from any screening or diagnostic tests performed as part of the study.
    - How information, data, and research resources generated under awards funded by this Program Announcement will be made available to the research community (which includes both scientific and consumer advocacy communities) and to the public at large.
- Manage Consortium-developed laboratory evaluations which should include the components listed below:
  - Specimens to be collected, schedule, and amount.
  - Evaluations that will be made for study purposes. How the results of laboratory evaluations will be used to meet the objectives of the study (or to monitor safety of human subjects).
  - Specimen storage, to include location of storage, how long specimens will be stored, any special conditions required, labeling, and disposition.

- Laboratories performing evaluations and special precautions. If transport of samples is required, provisions for ensuring proper storage during transport.
- Manage costs to support the basic research and clinical trial sites, including provision of personnel, equipment, and materials required to conduct approved basic research and clinical studies.
- Manage Consortium-related intellectual and material property issues among organizations participating in the Consortium.
- Manage Consortium-developed procedures for the timely publication of major findings and other public dissemination of data.
- Coordinate the preparation of briefings to the Interim Progress Review (IPR) Panel, GSC and USAMRMC in person, by teleconference, and/or by video teleconference.
- Develop, organize, and submit quarterly written progress reports, annual reports, and a final written comprehensive report to the GSC and USAMRMC. These reports must outline accrual and retention statistics, any problems with study execution, plans for remediation, and actions to disseminate study results.

Additional competencies of the Management Core may be identified and justified as being essential to the success of the Consortium.

## **2. Consortium Executive Committee**

The Management Core will appoint members to the CEC, which will be comprised of the Management Core PI, the research site PIs, and additional ad hoc subject matter expert representatives. The CEC will be responsible for identifying, prioritizing, and guiding proof-of-principle basic research studies to determine which compounds are most appropriate for human research trials, as well as proof-of-principle clinical trials to test promising compounds. All studies considered for funding will undergo an external independent scientific review and further review by the CEC, which will provide an Order of Merit List of studies recommended for funding to the GSC. In addition to basic research projects and clinical trials as part of the FY17 ASADRP Consortium Award, the Consortium members are encouraged to submit additional applications to the CEC if additional funding opportunities are available. Pursuit of funding by the Consortium from additional sources including industry, private sector, and other Federal organizations is encouraged. The CEC will develop the regulatory strategy for FDA compliance leading to potential product development and licensing. The Management Core staff will be responsible for facilitating and coordinating these processes. The CEC, through the Management Core PI, will be expected to maintain monthly or more frequent contact with a USAMRMC GOR/CDMRP Science Officer.

## **3. Basic Research and Clinical Trial Sites**

The Consortium shall present a plan for incorporating basic research and clinical trial sites necessary to effectively support the Consortium goals. *The plan should include criteria that*

***will be used to evaluate and select studies and sites. Criteria should require all sites to have experience and multidisciplinary expertise in supporting ASUD research.*** The research sites may include military and Department of Veterans Affairs (VA) locations, and it is preferred that the sites have experience working with military and Veteran populations. It is expected that within the first year of the award at least two studies will be selected and funded. The selection of sites and studies is based on factors including:

- Lead site PIs' commitment to and experience in ASUD research. It is expected that each site demonstrate sufficient depth in expertise and leadership to account for any unforeseen change in the lead site PIs.
- Ability to develop proposals in accordance with the Consortium standard operating procedures (SOPs) for consideration for funding by the ASADRP or CEC during the performance period of the award.
- Evidence of multidisciplinary clinical and/or laboratory expertise within the institution that could serve as the basis for the development of clinical protocols by the Consortium.
- Ability to collaborate with other Consortium basic research and clinical trial sites.
- Demonstration of adequate resources for coordinating with the Management Core and other sites.
- Evidence of institutional commitment to using facilities and resources in the conduct of Consortium studies, as required.
- Demonstration of adequate resources and expertise in ASUD patient recruitment and processing, including specimen collection.
- Ability to access a suitable patient population that will support a meaningful outcome for the study.
- Ability to enroll military and Veteran participants in Consortium-sponsored studies.
- Inclusion of a clearly articulated statistical analysis plan, appropriate statistical expertise on the research team, and a power analysis reflecting sample size projections that will clearly answer the objectives of the study.
- Commitment to implement procedures established by the Management Core to meet local IRB and USAMRMC ORP HRPO requirements for the conduct of clinical trials and the protection of human subjects.
- Adherence to Federal data sharing requirements and appropriate utilization of topic-specific common data elements (CDEs), and sharing of data with the Management Core.
- Implement procedures established by the Management Core for data collection methodology and strategies.

- Demonstration of adequate resources and expertise for data management, and maintenance of data security/confidentiality in accordance with the Consortium SOPs/procedures established by the Management Core.
- Designate a lead site PI and develop a succession plan upon request in case of departure of the site PI; the site PI must agree to adhere to the Consortium SOP and participate fully in the CEC.
- As applicable, provide a Research Coordinator, who will interact with the Research Coordinators of other clinical trial sites and the Consortium Research Project Manager at the Management Core to expedite and guide clinical protocols through regulatory approval processes and to coordinate patient accrual and study activities across sites.
- As applicable, provide a Research Coordinator, who will interact with the Research Project Managers of other basic research sites and the Consortium Research Project Manager at the Management Core to expedite and guide animal protocols through regulatory approval processes.
- Comply with Consortium-developed quality assurance and quality control procedures, as appropriate, including:
  - Participation in an on-site monitoring program to be managed by the Management Core.
  - Implementation of the Consortium-developed management plan for acquisition and aggregation of protocol-specified specimens, biological fluids, and relevant data to the appropriate laboratories for testing and/or storage.
  - Submission of appropriate data and materials to allow for verification and review of protocol-related procedures (e.g., pathology, imaging techniques, surgical methods, and therapeutic use).
- Serve as a resource or core laboratory for the conduct of protocol-specified laboratory projects (including correlative studies), as appropriate.
- Implement procedures established by the Management Core for ensuring compliance with FDA requirements for investigational agents and devices, as appropriate.
  - Description of the planned indication for the product label including an outline of the regulatory strategy and development plan required to support that indication.
  - Demonstration of documented availability of and access to the drug/compound, device, and/or other materials needed. The quality of the product should be commensurate with FDA manufacturing standards applicable to the type and phase of product being developed (i.e., Quality System Regulation, Good Manufacturing Practices).

- Participate in Consortium-developed procedures for the timely publication of major findings.
- Participate in Consortium-developed procedures for resolving intellectual and material property issues among organizations participating in the Consortium.
- Participate in the preparation of written and oral briefings to the IPR Panel, GSC and USAMRMC staff at one-day meetings to be held in the Washington DC metropolitan area.
- Assist with the preparation of quarterly written progress reports, annual reports, and a final comprehensive report.
- Prepare for a site visit audit, if requested by the Government.

Additional competencies for the basic research and clinical trial sites may be identified and justified as being essential to the success of the Consortium.

#### **4. Responsibilities of all Consortium Participants**

All Consortium participants must agree to adhere to the Consortium procedures established by the Management Core. A Manual of Operations or SOP must be developed by the Consortium no later than 12 months after the award date and be made available for review by the GSC. The SOP will include a plan for the CEC composition and responsibilities. The CEC responsibilities will include determining appropriate overall minimum and maximum accrual metrics for clinical trial sites per trial as part of the Consortium SOP. The Consortium SOP should also contain a plan to address underperforming sites and a succession plan for any unforeseen change in the lead PI.

#### **5. Strategic Research Plan**

The Management Core PI must provide a strategic research plan that includes the Consortium aims and objectives. The plan should include the scientific rationale behind the Consortium approach to achieve the aims and objectives. ***The plan should include a description of the types of studies that will be solicited and how these will contribute toward accelerating the delivery of effective treatments for ASUD, especially related to TBI and PTSD, to include building on the research previously supported by the ASADRP.*** The plan should project the number, types, and scope of basic research projects and clinical studies the Consortium expects to execute during the performance period of the award. The strategic plan should outline a feasible timeline that aligns milestones and deliverables with the Consortium aims and objectives. ***It is expected that within the first year of the award, a solicitation will be released by the Consortium and at least two studies will be selected and funded.***

#### **6. Government Steering Committee**

The ASADRP Program Manager (PM) will appoint Federal employees to serve as members on a GSC. The role of the GSC will be to provide program recommendations to the

Consortium, to inform the CEC about evolving ASADRP priorities and gaps, and to conduct programmatic review of CEC-recommended study proposals. The GSC will be responsible for recommending studies to be executed and may recommend future studies and/or focus areas to the Consortium. The GSC will advise the CEC on the regulatory strategy for FDA compliance leading to potential product development and licensing. The Consortium must present written reports and oral briefings to the GSC and USAMRMC staff. Based on these reports and presentations, the GSC will advise the ASADRP PM and GOR. USAMRMC staff will evaluate progress, provide feedback, and invoke modifications, as needed, to facilitate the success of the Consortium. The USAMRAA Grants Officer will issue final approvals for the Statement of Work (SOW) and budget, and release of funds for initiation of studies.

**Investigational New Drug (IND)/Investigational Device Exemption (IDE) Applications:** If a clinical trial involves the use of a drug that has not been approved by the FDA for the proposed investigational use, evidence that an IND application that meets all requirements under the Code of Federal Regulations Title 21, Part 312 (21 CFR 312) has been submitted or will be submitted to the FDA within 60 days of subaward(s) is required. If the investigational product is a device, evidence that an IDE application that meets all requirements under 21 CFR 812 has been submitted or will be submitted to the FDA within 60 days of the subaward, or that the device is exempt from an IDE, is required. The Government reserves the right to withdraw funding to the subaward(s) if the IND or IDE application has not been submitted to the FDA within 60 days of the Department of Defense (DoD) award date or if the documented status of the IND or IDE has not been obtained within 6 months of the subaward(s) date. The goal is to inform study design, sample size, and dosing for future clinical trials.

Funded clinical trials are required to file the study in the **National Institutes of Health clinical trials registry**, <http://www.clinicaltrials.gov>. Refer to the General Application Instructions, Appendix 1, Section C, for further details.

**Multi-Institutional Research:** Multi-institutional research that combines the resources of two or more organizations is encouraged. Applicants are encouraged to collaborate with the National Institute of Alcohol Abuse and Alcoholism (NIAAA), National Institute of Drug Abuse (NIDA), and VA for consultation, guidance, and expertise on the design, conduct, and analysis of relevant clinical studies evaluating potential medications for treatment of ASUD. Depending upon the relevance of proposed FY17 ASADRP Consortium Award studies and availability of funds, the NIAAA, NIDA, and VA may consider contributing support to fund additional sites to expand upon the population being studied or adding an additional arm to conduct a comparison study involving behavioral interventions.

Participating institutions must be willing to resolve potential data sharing, intellectual and material property issues and to remove any barriers that may interfere with achieving high levels of cooperation to ensure successful completion of this award.

***Partnerships with industry are also encouraged along with experience working with military and Veteran populations.***

**Use of Military and VA Populations or Resources:** If the proposed research involves access to Active Duty military and/or VA population(s) and/or resource(s), the PI is responsible for establishing access. If possible, access to target Active Duty military and/or VA patient population(s) should be confirmed at the time of application submission. A letter of support, signed by the lowest ranking person with approval authority, should be included for studies involving Service members, Veterans, military and/or VA-controlled study materials, and military and/or VA databases. Use Attachment 2 to provide this documentation (see [Section II.D.2.b.ii, Full Application Submission Components, Attachment 2, Supporting Documentation](#)).

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

**Research Involving Human Anatomical Substances, Human Subjects, or Human Cadavers:** All DoD-funded research involving new and ongoing research with human anatomical substances, human subjects, or human cadavers must be reviewed and approved by the USAMRMC ORP HRPO prior to research implementation. This administrative review requirement is in addition to the local IRB or Ethics Committee (EC) review. Local IRB/EC approval at the time of submission is *not* required. The HRPO is mandated to comply with specific laws and requirements governing all research involving human anatomical substances, human subjects, or human cadavers that is supported by the DoD. These laws and requirements will necessitate information in addition to that supplied to the IRB/EC. ***Allow a minimum of 2 to 3 months for HRPO regulatory review and approval processes.*** 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. Submission to HRPO of protocols covering more than the scope of work in the DoD-funded award will require HRPO review of the entire protocol as DoD-supported research and may include extensive modifications to meet DoD human subjects protection requirements. 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.

Applied research is defined as work that refines concepts and ideas into potential solutions with a view toward evaluating technical feasibility of behavioral and rehabilitation interventions, diagnostic and therapeutic techniques, clinical guidance, emerging approaches and technologies, promising new products, and/or pharmacologic agents. Applied research may involve human subjects.

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

Randomized controlled trials of an adaptive design that may include a comparative treatment group, measure biomarkers, and surrogate endpoints as well as clinical endpoints are encouraged.

**Research Involving Animals:** All DoD-funded research involving new and ongoing research with animals must be reviewed and approved by the USAMRMC ORP ACURO, in addition to the local IACUC of record. IACUC approval at the time of submission is *not* required. Specific documents relating to the use of animals in the proposed research will be requested **if the application is selected for funding**. The ACURO must review and approve all animal use prior to the start of working with animals, including amendments to ongoing projects. PIs must submit the institutional animal use protocol, IACUC approval of that protocol, and a version of the animal use appendix titled “Research Involving Animals.” ***Allow at least 2 to 3 months for ACURO regulatory review and approval processes for animal studies.*** Refer to the General Application Instructions, Appendix 1, for additional information.

**Common Data Elements and Data Sharing:** The ASADRP strongly encourages the applicant to incorporate CDE measures from the Core and Specialty collections, which are available in the Mental Health Research Collection (Psychiatric, Psychosocial, Alcohol, Tobacco, and other substances as well as Substance Abuse and Addiction) of the PhenX Toolkit <https://www.phenxtoolkit.org/index.php> into all studies involving human subjects as applicable. For TBI populations, the ASADRP strongly encourages the applicant to incorporate CDE measures from the National Institute of Neurological Disorders and Stroke (NINDS) <https://www.commondataelements.ninds.nih.gov/>.

If the project includes TBI research, the PI may be required to make TBI data generated via an award available to the research community by depositing de-identified research data and TBI CDE measures into the Federal Interagency TBI Research (FITBIR) Informatics System (<https://fitbir.nih.gov>).

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

Awards will be made no later than September 30, 2018. For additional information refer to [Section II.F.1, Federal Award Notices](#).

## **II.C. Eligibility Information**

### **II.C.1. Eligible Applicants**

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

**Government Agencies within the United States:** Local, state, and Federal Government agencies are eligible to the extent that applications do not overlap with their fully funded internal

programs. Such agencies are required to explain how their applications do not overlap with their internal programs.

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

**Extramural Organization:** An eligible non-DoD organization. Examples of extramural organizations include academia, biotechnology companies, foundations, Government, and research institutes. *Extramural Submission: Application submitted by a non-DoD organization to Grants.gov.*

**Intramural DoD Organization:** A DoD laboratory, DoD military treatment facility, and/or DoD activity embedded within a civilian medical center. *Intramural Submission: Application submitted by a DoD organization for an intramural investigator who is a DoD military or civilian employee working within a DoD laboratory or military treatment facility or in a DoD activity embedded within a civilian medical center. Application submitted by a non-DoD organization to eBRAP.org.*

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

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

#### **II.C.1.b. Principal Investigator:**

- Independent intramural (DoD) and extramural investigators at all academic levels (or equivalent) are eligible to submit applications.
- Cost sharing/matching is not an eligibility requirement.
- Eligible investigators must apply through an organization. Organizations eligible to apply include Federal agencies, national, international, for-profit, nonprofit, public, and private organizations.
- An intramural investigator is defined as a DoD military or civilian employee working within a DoD laboratory or military treatment facility, or working in a DoD activity embedded within a civilian medical center. Submissions from intramural (DoD) organizations are allowed and encouraged for this Program Announcement. Applicants submitting through their intramural organizations are reminded to coordinate receipt and commitment of funds through their respective resource managers. ***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 collaborators involvement.***

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

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

### **II.C.2. Cost Sharing**

Cost sharing/matching is not an eligibility requirement.

### **II.C.3. Other**

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

Each investigator may submit only one FY17 ASADRP Consortium Award application as a PI.

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

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

## **II.D. Application and Submission Information**

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

**Extramural Submission** is defined as an application submitted by a non-DoD organization to Grants.gov.

**Intramural Submission** is defined as an application submission by a DoD organization for an intramural investigator, who is a DoD military or civilian employee working within a DoD laboratory or military treatment facility, or working in a DoD activity embedded within a civilian medical center.

### **II.D.1. Address to Request Application Package**

**Submitting Extramural and Intramural Organizations:** Pre-application content and forms can be accessed at eBRAP (<https://eBRAP.org>).

**Submitting Extramural Organizations:** Full application packages can be accessed at Grants.gov.

**Submitting Intramural DoD Organizations:** Full application packages can be accessed 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/>).

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.

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

**Submitting Extramural Organizations:** Full applications from extramural organizations must be submitted through Grants.gov. 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.

**Submitting Intramural DoD Organizations:** Intramural DoD organizations may submit full applications to either eBRAP or Grants.gov. Intramural DoD organizations that are unable to submit to Grants.gov should submit through eBRAP. Intramural DoD organizations with the capability to submit through Grants.gov may submit following the instructions for extramural submissions through Grants.gov or may submit to eBRAP. Applications from extramural organizations, including non-DoD Federal organizations, received through eBRAP will be withdrawn. See definitions in [Section II.C.1, Eligible Applicants](#).

eBRAP allows intramural organizations to submit full applications following pre-application submission.

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

The application title, eBRAP log number, and all information for the PI, Business Official(s), performing organization, and contracting organization must be consistent throughout the entire pre-application and 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](mailto:help@eBRAP.org) or 301-682-5507 prior to the application deadline.

Application viewing, modification, and verification in eBRAP are strongly recommended, but not required. ***The Project Narrative and Budget cannot be changed after the application submission deadline.*** Prior to the full application deadline, a corrected or modified full application package may be submitted. Other application components may be changed until the end of the [application verification period](#). After the end of the application verification period, the full application cannot be modified.

PIs should ensure that their name and email address are the same as the name and email address that will be provided on the SF-424 Form of the Grants.gov application package submitted to Grants.gov. The organization, Business Officials, PI(s), and eBRAP log number named in the full application submitted to Grants.gov must match those named in the pre-application in eBRAP.

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

**During the pre-application process, each submission is assigned a unique log number by eBRAP. This unique eBRAP log number will be needed 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 may result in delays in 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](mailto:help@eBRAP.org) or 301-682-5507.

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**
- **Tab 2 – Application Contacts**

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

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

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

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

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

FY17 ASADRP 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](mailto:help@eBRAP.org) or 301-682-5507. A list of the FY17 ASDADRP Programmatic Panel members can be found <http://cdmrp.army.mil/asadrp/panels/panels17>.

To preserve the integrity of its peer and programmatic review processes, the CDMRP discourages inclusion of any employee of its review contractors having any role in pre-application or application preparation, research, or other duties for submitted pre-applications or applications. For FY17, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (<http://cdmrp.army.mil/about/2tierRevProcess>). Pre-applications or applications that include names of personnel from either of these companies will be administratively withdrawn unless plans to manage conflicts of interest (COIs) are provided and deemed appropriate by the Grants Officer. Refer to the General Application Instructions, Appendix 3, for detailed information.

- **Tab 4 – Conflicts of Interest (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). Refer to the General Application Instructions, Appendix 3, Section C, for further information regarding COIs.

- **Tab 5 – Pre-Application Files**

**Letter of Intent (LOI) (one-page limit):** Provide a brief description of how the research consortium will address the ASADRP Program Description in section II.A.1. 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 LOI to be accepted and processed.

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

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

*All contributors and administrators to the application must use matching compatible versions of Adobe software when editing and preparing application components. The use of different*

*software versions will result in corruption of the submitted file. Refer to the General Application Instructions, Section III, for details on compatible Adobe software.*

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

Each application submission must include the completed full application package for this Program Announcement. The full application package is submitted by the Authorized Organizational Representative through Grants.gov (<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, including non-DoD Federal agencies, must submit full applications through Grants.gov. Submissions of extramural applications through eBRAP may be withdrawn.

**Table 1. Full Application Submission Guidelines**

Extramural Submissions	Intramural DoD Submissions
<b>Application Package Location</b>	
Download application package components for W81XWH-17-ASADRP-CA from Grants.gov ( <a href="https://www.grants.gov">https://www.grants.gov</a> ).	Download application package components for W81XWH-17-ASADRP-CA from eBRAP ( <a href="https://ebrap.org">https://ebrap.org</a> ).
<b>Full Application Package Components</b>	
<b>SF424 (R&amp;R) Application for Federal Assistance Form:</b> Refer to the General Application Instructions, Section III.A.1, for detailed information.	<b>Tab 1 – Summary:</b> Provide a summary of the application information. <b>Tab 2 – Application Contacts:</b> 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: <ul style="list-style-type: none"> <li>• <a href="#">Attachments</a></li> <li>• <a href="#">Research &amp; Related Senior/Key Person Profile (Expanded)</a></li> <li>• <a href="#">Research &amp; Related Budget</a></li> <li>• <a href="#">Project/Performance Site Location(s) Form</a></li> <li>• <a href="#">R&amp;R Subaward Budget Attachment(s) Form (if applicable)</a></li> </ul>	<b>Tab 3 – Full Application Files:</b> Upload files under each Application Component in eBRAP. Descriptions of each required file can be found under Full Application Submission Components: <ul style="list-style-type: none"> <li>• <a href="#">Attachments</a></li> <li>• <a href="#">Key Personnel</a></li> <li>• <a href="#">Budget</a></li> <li>• <a href="#">Performance Sites</a></li> </ul> <b>Tab 4 – Application and Budget Data:</b> Review and edit proposed project start date, proposed end date, and budget data pre-populated from the Budget Form.

Extramural Submissions	Intramural DoD Submissions
<b>Application Package Submission</b>	
<p><b>Submit package components to Grants.gov (<a href="https://www.grants.gov">https://www.grants.gov</a>).</b>            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.</p>	<p><b>Submit package components to eBRAP (<a href="https://ebrap.org">https://ebrap.org</a>).</b>  <b>Tab 5 – Submit/Request Approval Full Application:</b> After all components are uploaded and prior to the full application submission deadline, enter your password in the space provided “Enter Your Password Here” and press the “Submit Full Application” button. eBRAP will notify your Resource Manager/Comptroller or equivalent Business Official by email to log into eBRAP to review and to approve prior to the application submission deadline.</p>
<b><u>Application Verification Period</u></b>	
<p>The full application package submitted to Grants.gov may be viewed and modified in eBRAP until the end of the application verification period. During the application verification period, the full application package, <b><i>with the exception of the Project Narrative and Budget Form</i></b>, may be modified.</p>	<p>After eBRAP has processed the full application, the organizational Resource Manager/Comptroller or equivalent Business Official and PI will receive an 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, <b><i>with the exception of the Project Narrative and Budget Form</i></b>, may be modified.</p>
<b>Further Information</b>	
<p>Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.</p>	<p>Refer to the General Application Instructions, Section IV, for further information regarding eBRAP requirements.</p>

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

Application viewing, modification, and verification in eBRAP are strongly recommended, but not required. ***The Project Narrative and Budget cannot be changed after the application submission deadline.*** Prior to the full application deadline, a corrected or modified full application package may be submitted. Other application components may be changed until the end of the application verification period. After the end of the application verification period, the full application cannot be modified.

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

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

#### **II.D.2.b.ii. Full Application Submission Components:**

- **Extramural Applications Only –**

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

- **Extramural and Intramural Applications –**

**Attachments:**

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

For all attachments, ensure that the file names are consistent with the guidance. Attachments will be rejected if the file names are longer than 50 characters or 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 (30-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:** Discuss the unique contribution of the proposed Consortium to the FY17 ASADRP goals as described in the Program Description in Section II.A, and explain how the Consortium will utilize integrated approaches to address ASUD, especially related to PTSD and TBI, through multidisciplinary, team-based research efforts to translate basic knowledge into enhanced clinical pharmacological treatment protocols. Explain how the Consortium will build on the research previously supported by the ASADRP. Describe how a regulatory strategy will be developed for FDA compliance, as applicable. Present the ideas and reasoning behind the proposed plan. Cite relevant literature and preliminary data. Describe previous experience most pertinent to the proposed efforts.

- **Personnel:** State the qualifications of the PI and key personnel to perform management of the Consortium including, but not limited to, the following:
  - Provide an organizational chart identifying key members of the study team including institution/center/department.
  - Describe how well the Management Core PI demonstrates collaborative leadership experience and how he/she has a broad understanding of ASUD research, including knowledge of the current state of ASUD research with respect to the military context. Describe the background and expertise of the PI and other key Consortium personnel and their ability to plan, prioritize, solicit proposals, and provide oversight and coordination of basic research projects and clinical trials that will be supported by the Consortium.
  - Describe to what extent the PI and other key Consortium personnel contain the multidisciplinary subject matter expertise to support ASUD research, manage the regulatory strategy for FDA compliance for all future sites that will be supported by the Consortium and ensure that all sites supported by the Consortium maintain compliance with local IRBs and the USAMRMC ORP HRPO for the proper conduct of clinical studies and the protection of human subjects or to the local IACUCs and the USAMRMC ORP ACURO if there is a potential for animal studies.
  - Describe how the PI's and other key Consortium personnel's records of accomplishment demonstrate their understanding of working with military and Veteran populations.
  
- **Research Strategy:** Describe the strategic research plan that includes the Consortium aims and objectives. The plan should include the scientific rationale behind the Consortium approach to achieve the aims and objectives, including, but not limited to, the following:
  - A description of the types of studies that will be solicited and how these will contribute toward accelerating the delivery of effective treatments for ASUD, especially related to TBI and PTSD, to include building on the research previously supported by the ASADRP. Describe how a regulatory strategy for FDA compliance will be developed, as applicable. The plan should project the number, types, and scope of basic research projects and clinical studies the Consortium expects to execute during the performance period of the award. The strategic plan should outline a feasible timeline that aligns milestones and deliverables with the Consortium aims and objectives. It is expected that within the first year of the award, a solicitation will be released by the Consortium and at least two studies will be selected and awarded.
  - The proposed experimental study designs required to support the studies (including applicable tools and measures), and analyses, and whether they include adaptive design, comparative treatment group, measure biomarkers, surrogate

endpoints and/or clinical endpoints. Include appropriate controls in sufficient detail for analysis.

- How proposed measures, applications, strategies, or technologies decrease the clinical impact of ASUD in military settings. As applicable, provide a description of the intervention(s) that the Management Core will solicit for the basic research and clinical trial sites and include a description of the types of studies that will be solicited and how these will contribute toward accelerating the delivery of effective treatments for ASUD especially related to TBI and PTSD.
  - For research involving human subjects, provide the approximate number of human subjects that are expected to be enrolled in the studies. If multiple study sites are involved, state the approximate number to be enrolled at each site.
  - Provide a description of the FDA regulatory strategy for the proposed studies to ensure compliance with FDA requirements for investigational agents and devices, as appropriate, to include; the planned indication for the product label, the regulatory strategy and development plan required to support that indication; and the availability of and access to the drug/compound, device, and/or other materials needed. As applicable to the proposed studies, describe the regulatory strategy and plan and demonstrate compliance with Good Manufacturing Practices (GMPs), Good Laboratory Practices (GLPs), and Good Clinical Practice (GCP) guidelines, etc.
  - Address the technical maturity of the proposed studies and how the research strategy advances the knowledge base towards fielding a solution.
  - If Active Duty Military and/or Veteran population(s) will be used in the proposed research project, describe the population(s), the appropriateness of the population(s) for the proposed study, and the feasibility of accessing the population. If a non-military population will be used for the proposed research project, explain how the population simulates the targeted population (i.e., Service members or Veterans).
- **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. Any additional material viewed as an extension of the Project Narrative will be removed or may result in administrative withdrawal of the application.

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

- References Cited: List the references cited (including URLs, if available) in the Project Narrative using a standard reference format that includes the full citation (i.e., author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).
- List of Abbreviations, Acronyms, and Symbols: Provide a list of abbreviations, acronyms, and symbols.
- Facilities, Existing Equipment, and Other Resources: Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate whether or not Government-furnished facilities or equipment are proposed for use. If so, reference should be made to the original or present Government award under which the facilities or equipment items are now accountable. There is no form for this information.
- Publications and/or Patents: Include a list of relevant publication URLs and/or patent abstracts. If publications are not publicly available, then copies of up to five published manuscripts may be included in Attachment 2. Extra items will not be reviewed.
- Letters of Organizational Support (if applicable; 1-page limit per letter is recommended): 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.
- Letter(s) of Support for Use of Military and VA Populations or Resources (if applicable; 1-page limit per letter is recommended): If the proposed research plan involves access to active duty military and/or VA patient populations or resources, include a letter(s) of support, signed by the lowest ranking person with approval authority, confirming such access. If access cannot be confirmed at the time of application submission, the Government reserves the right to withhold or revoke funding until the PI has demonstrated support for and access to the relevant population(s) and/or resources.
- Letters of Collaboration (if applicable; 1-page limit per letter is recommended): Provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed work. If an investigator at an intramural organization is named as a collaborator on an application submitted through an extramural organization, the application must include a letter from the collaborator's Commander or Commanding Officer at the intramural organization that authorizes the collaborator's involvement.

- Intellectual Property: Information can be found in Code of Federal Regulations, Title 2, Part 200.315 (2 CFR 200.315), “Intangible Property.”
  - Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations.
- Data and Research Resources Sharing Plan: Describe how data and resources generated during the performance of the project will be shared with the research community.
  - If the project includes TBI research, the PI may be required to make TBI data generated via an award available to the research community by depositing de-identified research data and TBI CDE measures into the Federal Interagency TBI Research (FITBIR) Informatics System (<https://fitbir.nih.gov>). 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.
  - For research involving PTSD populations, the ASADRP strongly encourages the applicant to incorporate CDE measures from the Core and Specialty collections, which are available in the Mental Health Research Collection (Psychiatric, Psychosocial, Alcohol, Tobacco, and other substances as well as Substance Abuse and Addiction) of the PhenX Toolkit (<https://www.phenxtoolkit.org/index.php>) into all studies involving human subjects, as applicable.
  - For research involving TBI populations, the applicant is encouraged to incorporate CDE measures from the National Institute of Neurological Disorders and Stroke NINDS (<https://www.commondataelements.ninds.nih.gov/>).
- Quad Chart: Provide a current Quad Chart Form in pdf format (template available for download in eBRAP) as instructed.
- **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 how the proposed research addresses the FY17 ASADRP Consortium Award goals. Present the ideas and reasoning behind the proposed work.
  - Objective: State the objective/hypothesis to be tested. Provide evidence or rationale that supports the objective/hypothesis.
  - Specific Aims: State the specific aims of the Consortium.

- Research Strategy: Briefly describe the Consortium research strategy including types of studies to be solicited, potential study designs, and how the research strategy advances the knowledge base toward fielding a solution for ASUD treatment.
- Military Benefit: Briefly explain how the Consortium will enhance the development of ASUD clinical pharmacological treatment protocols and be applicable and beneficial to the military and VA populations as well as the general public.
- **Attachment 4: Lay Abstract (one-page limit):** Upload as “LayAbs.pdf.” The lay abstract is used by all reviewers. Abstracts of all funded research projects will be posted publicly. ***Do not include proprietary or confidential information.*** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed. ***Do not duplicate the technical abstract.*** Lay abstracts should be written using the following outline:
  - Describe the objectives and rationale for the application in a manner that will be readily understood by readers without a background in science or medicine.
  - Describe the ultimate applicability of the Consortium.
    - What populations will it help, and how will it help them? (Include currently available statistics for the related population of concern.)
    - What are the potential clinical applications, benefits, and risks?
    - What is the projected timeline it may take to achieve the expected outcome?
    - How will the Consortium enhance the development of ASUD clinical pharmacological treatment protocols and be applicable and beneficial to the military and VA populations as well as the general public?
  - Briefly describe how the Consortium research strategy advances the knowledge base toward fielding a solution for ASUD treatment.
- **Attachment 5: Statement of Work (three-page limit):** Upload as “SOW.pdf.” The suggested SOW format and examples specific to different types of research projects are available on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>). For the ASADRP Consortium Award 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 Consortium operations (initial year plus up to 2 option years) for the entire period of performance (up to 5 years). The SOW should describe only the work for which funding is being requested by this application and should also:

- Include the name(s) of the key personnel and contact information for the Management Core.

- Include initial year Management Core and Consortium activities for planning, solicitation, execution and support of a minimum of two research projects and clinical trials. These will be funded using allocations from the FY17 ASADRP Congressional appropriation.
- Include activities for up to two option years with corresponding budgets, including additional basic research projects and clinical trials to be solicited and associated Management Core and other Consortium activities. Funding for these option years (if exercised) is contingent upon receipt of future Congressional FY18 and FY19 appropriations and adequate performance.
- Include timelines (if applicable) projected for regulatory approvals relevant to human subjects research (e.g., IND/IDE applications) by the FDA or other Government agency.
- Include the number (and type, if applicable) of research subjects (animal or human) and/or human anatomical samples projected for basic research projects and clinical trials. Refer to the General Application Instructions, Appendix 1, for additional information regarding regulatory requirements.

Exercising the options for additional funding (if available) will be dependent on funding availability, and the Consortium presenting written reports and oral briefings to the GSC and USAMRMC that demonstrate progress and alignment of the Consortium with the goals of the ASADRP. Exercise of an option is at the unilateral discretion of the Government.

○ **Attachment 6: Impact and Military Benefit Statement (one page limit): Upload as “MilBen.pdf.”**

- State explicitly how the proposed work is responsive to addressing ASUD, especially related to TBI and PTSD, through multidisciplinary, team-based translational research efforts to identify promising compounds; conduct proof-of-principle basic research to determine which compounds are most appropriate for human research trials; and conduct human proof-of-concept trials with promising compounds. Briefly explain how the Consortium will enhance clinical pharmacological treatment protocols and be applicable and beneficial to the DoD and general public.
- Provide available information about the current efforts to decrease the clinical impact of ASUD in Service members and/or Veterans, if appropriate and available. Show how the proposed Consortium complements ongoing DoD and VA research, if applicable.

○ **Attachment 7: Transition Plan (one-page limit): Upload as “Transition.pdf.”**

Provide information on the methods and strategies proposed to move the anticipated research outcomes to the next phase of research or delivery to the military practice or civilian market after successful completion of the award. The transition plan should include the components listed below:

- A description of the schedule and milestones for bringing the anticipated research outcomes to the next level of development (e.g., inform study design, sample size, and dosing for future clinical trials, transition to industry, delivery to the military or civilian market, incorporation into clinical practice, or approval by the FDA).
  - A description of collaborations with industry and other institutions (if applicable) that will be used to provide continuity of development, such as proposed development or modification of clinical practice guidelines, dissemination of practitioner and patient educational tools.
  - Details of the funding strategy that will be used to bring the outcomes to the next level of development or commercialization (e.g., specific potential industry partners, specific funding opportunities to be pursued).
  - A description of how the Consortium will manage intellectual property ownership, and address impact of any intellectual property issues on future product development and subsequent Government access to products supported by this Program Announcement. and whether the applicant has demonstrated that he/she has access to all intellectual property rights necessary for development and commercialization and evidence that the Government has the ability to access such products or technologies
- **Attachment 8: DoD Military Budget Form(s), if applicable: Upload as “MFBudget.pdf.”** If a military facility (Military Health System facility, research laboratory, treatment facility, dental treatment facility, or a DoD activity embedded with a civilian medical center) will be a collaborator in performance of the project, complete the DoD Military Budget Form, available for download on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>), including a budget justification, for each military facility as instructed. The costs per year should be included on the Grants.gov Research and Related Budget form under subaward costs. Refer to the General Application Instructions, Section III.A.7, for detailed information.
- **Extramural and Intramural Applications –**
- Research & Related Senior/Key Person Profile (Expanded):** 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.
- PI Biographical Sketch (5-page limit): Upload as “Biosketch\_LastName.pdf.” The suggested biographical sketch format is available on the “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) in eBRAP. The National Institutes of Health Biographical Sketch may also be used. All biographical sketches should be submitted in the portable document format (PDF) that is not editable.
  - PI Previous/Current/Pending Support (no page limit): Upload as “Support\_LastName.pdf.”

- Key Personnel Biographical Sketches (5-page limit each): Upload as “Biosketch\_LastName.pdf.”
- Key Personnel Previous/Current/Pending Support (no page limit): Upload as “Support\_LastName.pdf.”

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

**Budget Justification (no page limit): Upload as “BudgetJustification.pdf.”** The budget justification for the initial and option years (entire period of performance) must be uploaded to the Research & Related Budget.

**Project/Performance Site Location(s) Form):** For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.5, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.4, for detailed information.

- **Extramural Applications Only –**

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

- **Extramural Subaward:** Complete the Research & Related Subaward Budget Form through Grants.gov. (Refer to the General Application Instructions, Section III.A.6, for detailed information.)
- **Intramural DoD Collaborator(s):** Complete the DoD Military Budget Form and upload to Grants.gov as Attachment 8. (Refer to the General Application Instructions, Section III.A.7, for detailed information.) Intramural DoD Collaborator(s) costs per year should be included on the Grants.gov Research and Related Budget form under subaward costs.
- **DoD Military Budget Form:** A military facility collaborating in the performance of the project should be treated as a subaward for budget purposes. However, do not complete the Grants.gov R&R Subaward Budget Attachment Form; instead, complete the DoD Military Budget Form (Attachment 8) to show all direct and indirect costs. 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.7, for detailed information.

- **Extramural and Intramural Applications –**

**Attachments:**

- **Attachment 5: Statement of Work (three-page limit): Upload as “SOW.pdf.”** Refer to the General Application Instructions, Section III.A.2, for detailed information on completing the SOW.
- **Attachment 8: DoD Military Budget Form: Upload as “MFBudget.pdf.”** Refer to the General Application Instructions, Section III.A.7, for detailed information. The costs per year should be included on the Grants.gov Research and Related Budget form under subaward costs.

**Research & Related Budget:** For extramural submissions, refer to the General Application Instructions, Section III.A.4, and for intramural submissions refer to the General Application Instructions, Section IV.A.3, for detailed information.

**Budget Justification (no page limit): Upload as “BudgetJustification.pdf.”**

**Project/Performance Site Location(s) Form:** For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.5, and for intramural submissions (via eBRAP), refer to General Application Instructions, Section IV.A.4, for detailed information.

- **Extramural Applications Only –**

**R&R Subaward Budget Attachment(s) Form.**

- **Extramural Subaward:** Complete the Research & Related Subaward Budget Form through Grants.gov. (Refer to the General Application Instructions, Section III.A.6, for detailed information.)
- **Intramural DoD Collaborator(s):** Complete the DoD Military Budget Form and upload to Grants.gov as Attachment 8. (Refer to the General Application Instructions, Section IV.A.3, for detailed information.)

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

Applicant organizations and all subrecipient organizations must have a DUNS number to submit applications to Grants.gov. The applicant organization must also be registered in the Entity Management functional area of the SAM with an “Active” status to submit applications through the Grants.gov portal. Verify the status of the applicant’s organization’s Entity registration in SAM well in advance of the application submission deadline. Allow 3 to 4 weeks to complete the entire SAM registration process. If an applicant has not fully complied with the requirements by 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**

Prior to the end of the application verification period, PIs and organizational representatives can review and modify in eBRAP certain components of a submitted application. 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.

#### **II.D.5. Funding Restrictions**

A single award to the Management Core applicant will be made to support the FY17 ASADRP Consortium Award. The Management Core will provide funding support for the selected basic research and clinical trial sites as openly competed sub-awards or other appropriate contracting instrument. The Management Core will clearly delineate Consortium infrastructure costs and research costs. Budget out-years should be projected based on the proposed costs of the anticipated studies, with appropriate escalation factors included. Following award, a budget for each study will be negotiated by the awardee once study selections are made.

The maximum period of performance is **5** years.

The maximum allowable total costs (direct and indirect) for the entire period of performance are **\$10.596M** of which only **\$3.532M** is currently available.

**Initial Award Funding:** The applicant may request up to \$3.532M in total costs corresponding to the FY17 ASADRP Congressional appropriation for the period of performance (up to 5 years) to cover Management Core costs and Consortium activities, as well as costs for research projects and clinical trials. This will be funded using allocations from the FY17 ASADRP Congressional appropriation. The budget should include a separate line item for the base funded research project and clinical trial costs. The total for this funding must not exceed \$3.532M in total costs.

**Optional Funding:** In addition to the initial award funding above, the applicant may request two options of up to \$3.532M in total costs, each corresponding to anticipated FY18 and FY19 ASADRP Congressional appropriations, to fund additional basic research projects, clinical trials, associated Management Core costs, and Consortium activities. Funding for these options (if exercised) is contingent upon receipt of future Congressional appropriations and adequate performance. The cooperative agreement will contain options with corresponding budgets. The overall Consortium budget should contain separate items for Management Core and research costs for studies to be funded with the optional funding.

No project shall be initiated until the SOW and budget are approved for each project selected for funding. None of the funds for research projects may be utilized in other budget categories except with the express written approval of the Grants Officer.

Exercising the options for additional funding (if available) will be dependent on funding availability, and the Consortium presenting written reports and oral briefings to the GSC and USAMRMC that demonstrate progress and alignment of the Consortium with the goals of the ASADRP. Exercise of an option is at the unilateral discretion of the Government.

Costs for a clinical trial study must be included within a single funding option and cannot depend on future appropriations.

Regardless of the period of performance proposed, the applicant may not exceed the maximum allowable total costs. Indirect costs shall be proposed in accordance with the organization's negotiated rate agreement.

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

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

- Travel costs for the PI(s) to disseminate project results at one day DoD IPR meeting per year. For planning purposes, it should be assumed that the meeting will be held in the National Capital Area. These travel costs are in addition to those allowed for annual scientific/technical meetings.

May be requested for (not all-inclusive):

- Salary
- Research-related subject costs
- Clinical research costs
- Equipment
- Research supplies
- Support for multidisciplinary collaborations, including travel

- Travel costs for up to 2 investigators to travel to 1 scientific/technical meeting per year in addition to the required IPR meeting described above.

Extramural (non-Federal) awards will consist solely of assistance agreements (Cooperative Agreements and Grants). For extramural awards with an intra-governmental component, direct transfer of funds from an extramural award recipient to a DoD or other Federal agency is not allowed except under very limited circumstances. Funding to intramural DoD and other Federal agencies will be managed through a direct fund transfer. Intra-governmental only funding to intramural DoD and other Federal agencies will be managed through a direct fund transfer. Intramural applicants are responsible for coordinating through their agency's procedures the use of contractual or assistance funding awards or other appropriate agreements to support extramural collaborators.

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

*The CDMRP expects to allocate FY17, FY18 and FY19 funding, if appropriated, to fund approximately one ASADRP Consortium Award. The maximum period of performance is 5 years. The ASADRP Consortium will be funded initially with allocations from the FY17 ASADRP Congressional appropriation (\$3.532M). The maximum allowable total costs (direct and indirect) for the entire period of performance are \$10.596M (initial year plus 2 option years of \$3.532M each). Option year funding is subject to GSC review, approval of the USAMRAA Grants Officer, and receipt of future congressional appropriations. Funding of applications received in response to this Program Announcement is contingent upon the availability of Federal funds for this program.*

#### **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:

- **Research Strategy and Feasibility**
  - How well the unique contribution of the proposed Consortium supports the FY17 ASADRP goals as described in the Program Description in Section II.A, and how well the Consortium will utilize integrated approaches to address ASUD, especially related to

PTSD and TBI, through multidisciplinary, team-based research efforts that translate basic knowledge into enhanced clinical pharmacological treatment protocols.

- To what extent the scientific rationale behind the Consortium will achieve the aims and objectives and how well the experimental design, methods, and analyses are developed and integrated into the overall Consortium research strategy.
- To what extent the proposed interventions and types of basic research projects and clinical studies solicited will contribute towards accelerating the delivery of effective treatments for ASUD especially related to TBI and PTSD during the performance period of the award.
- To what extent the strategic plan outlines a feasible timeline that aligns milestones and deliverables with the Consortium aims and objectives.
- The feasibility of the Consortium to initiate at least two studies within the first year of the award and subsequent studies in the 2 option years.
- Whether the Consortium research studies can be completed within the proposed period of performance.
- Whether the study populations (military, non-military, or Veteran) used in the proposed research project(s) are appropriate and whether the plan to access the population is feasible; this includes women and minorities in the study, if applicable.
- How well the proposed experimental study designs required to support the studies (including applicable tools and measures) and analyses include adaptive design, comparative treatment groups, measures of biomarkers, surrogate endpoints and/or clinical endpoints.
- Whether the technical maturity of the proposed studies and research strategy advances the knowledge base towards fielding a solution, and to what extent the outcomes of the studies and strategy decrease the clinical impact of ASUD in military and veteran populations.
- How well FDA regulatory strategy for the proposed studies ensures compliance with FDA requirements leading to potential product development and licensing to include; the planned indication for the product label, the regulatory strategy and development plan required to support that indication leading to potential licensing; and the availability of and access to the drug/compound, device, and/or other materials needed.
- How well the proposed measures, tools, or strategies requested of the proposed studies are appropriate for the target population.
- To what extent the proposed Consortium research studies are supported by sound scientific rationale as well as previous research data and literature.

- To what extent the proposed Management Core PI is experienced in consortium management and whether they have the appropriate subject matter experts to address the FY17 ASADRP goal.
- How well the Consortium acknowledges potential problems and addresses alternative approaches.
- How well the Consortium has outlined a plan to manage clinical research to include quality assurance and quality control mechanisms for study monitoring.
- How well the Consortium has outlined a plan to ensure that all sites maintain compliance with local IRBs and the USAMRMC ORP HRPO for the proper conduct of clinical studies and the protection of human subjects; or to the local IACUC and the USAMRMC ORP ACURO for animal studies.
- How well the Consortium has outlined a plan to manage data standardization and, when appropriate, centralized review of imaging, histopathology, neuropsychological, and other data through committees and scientific core facilities.
- How well the Consortium has outlined a plan for management and sharing of research data.
- How well the Consortium research strategy supports the transition of the anticipated outcomes to the next level of development (i.e., inform study design, sample size, and dosing for future clinical trials, transition to industry/commercialization, delivery to the military or civilian market, incorporation into clinical practice, or approval by the FDA).
- **Personnel**
  - How well the proposed Management Core PI demonstrates collaborative leadership experience and a broad understanding of ASUD research, including knowledge of the current state of ASUD research with respect to the military context.
  - How well the background and expertise of the Management Core PI and other key Consortium personnel demonstrate their ability to plan, prioritize, solicit proposals, and provide oversight and coordination of basic research projects and clinical trials to be supported by the Consortium.
  - To what extent the proposed Management Core PI and other key Consortium personnel demonstrate their multidisciplinary subject matter expertise to support ASUD research.
  - To what extent the proposed Management Core PI and other key Consortium personnel demonstrate their subject matter expertise to manage the regulatory strategy for FDA compliance for all sites to be supported by the Consortium.
  - To what extent the proposed Management Core PI and other key Consortium personnel demonstrate their subject matter expertise to ensure that all sites to be supported by the Consortium maintain compliance with local IRBs and the USAMRMC ORP HRPO for

the proper conduct of clinical studies and the protection of human subjects or to the local IACUCs and the USAMRMC ORP ACURO if there is a potential for animal studies.

- Whether the composition and levels of effort of the Management Core PI and other key Consortium personnel are appropriate to ensure success of this project.
- Whether the proposed Management Core PI and other key Consortium personnel's records of accomplishment demonstrate their understanding of working with military and Veteran populations.

- **Impact**

- How well the proposed Consortium is responsive to the goal of decreasing the clinical impact of ASUD, especially related to TBI and PTSD, in military populations as well as the potential benefit for the general public.
- How well the proposed Consortium research studies will complement ongoing DoD and VA research, if applicable.
- How well the proposed Consortium research studies will address multidisciplinary, team-based translational research efforts to identify promising compounds; conduct proof-of-principle basic research to determine which compounds are most appropriate for human research trials; and conduct human proof-of-concept trials with promising compounds.
- To what extent the proposed Consortium research studies will enhance clinical pharmacological treatment protocols and be applicable and beneficial to the DoD leadership and general public.

- **Transition Plan and Intellectual Property**

- How the schedule and milestones for bringing the anticipated research outcomes to the next level of development (e.g., inform study design, sample size, and dosing for future clinical trials, transition to industry, delivery to the military or civilian market, incorporation into clinical practice, or approval by the FDA) are achievable.
- Whether collaborations with industry and other institutions exist that will be used to provide continuity of development, such as proposed development or modification of clinical practice guidelines and dissemination of practitioner and patient educational tools and/or inform study design, sample size and dosing for future clinical trials.
- Whether the funding strategy described to bring the anticipated research outcomes to the next level of development (e.g., specific potential industry partners, specific funding opportunities to be applied for) and/or commercialization is reasonable and realistic.
- How the Consortium identifies intellectual property ownership (if applicable), describes an appropriate intellectual and material property plan among participating organizations, and addresses any impact of intellectual property issues for the proposed Consortium research studies to include access to all intellectual property rights necessary for

development and commercialization, and subsequent Government access to products or technologies supported by this Program Announcement.

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

- **Budget**
  - Whether the maximum total costs are equal to or less than the allowable maximum total costs as published in the Program Announcement.
  - Whether the budget is appropriate for the proposed effort.
- **Environment**
  - How the scientific environment is appropriate for the proposed effort.
  - How well the research requirements are supported by the availability of and accessibility to facilities and resources (including military Service members, military-controlled study materials, and military databases, if applicable).
- **Application Presentation**
  - To what extent the writing, clarity, and presentation of the application components influence the review.

#### **II.E.1.b. Programmatic Review**

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

- Ratings and evaluations of the peer reviewers
- Relevance to the mission of the DHP and FY17 ASADRP, as evidenced by the following:
  - Adherence to the intent of the award mechanism
  - Relative fit into the overall ASADRP portfolio composition
  - Relative impact and innovation
  - Relative feasibility of the transition plan

#### **II.E.2. Application Review and Selection Process**

All applications are evaluated by scientists, clinicians, and consumers in a two-tier review process. The first tier is peer review of applications against established criteria for determining technical merit. Each application is evaluated for its own merit, independent of other

applications. The second tier is a programmatic review that makes recommendations for funding to the Commanding General, USAMRMC, on behalf of the DHA and the OASD(HA), based on technical merit, the relevance to the mission of the DHP and ASADRP, the specific intent of the award mechanism, and to other specified evaluation criteria in the Program Announcement. Programmatic review is a comparison-based process in which applications with scientific and technical merit compete in a common pool. *The highest-scoring applications from the first tier of review are not automatically recommended for funding. Funding recommendations depend on various factors as described in [Section II.E.1.b, Programmatic Review](#).* Additional information about the two-tier process used by the CDMRP can be found at <http://cdmrp.army.mil/about/fundingprocess>.

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign a statement that application and evaluation information will not be disclosed outside the panel. Violations of confidentiality can result in the dissolving of a panel(s) and other corrective actions. In addition, personnel at the applicant or collaborating organizations are prohibited from contacting persons involved in the review 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 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 (currently \$150,000) 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 (FAPIS).

An applicant, at its option, may review FAPIS, accessible through SAM, and submit comments to FAPIS on any information about itself that a Federal awarding agency previously entered and is currently available in FAPIS.

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 (DoDGAR), Section 22.415.

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

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

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

## **II.F. Federal Award Administration Information**

### **II.F.1. Federal Award Notices**

Awards will be made no later than September 30, 2018. Refer to the General Application Instructions, Appendix 2, for additional award administration information.

Awards are made to organizations, not to individual PIs. The types of award made under the Program Announcement will be a cooperative agreement. The level of involvement on the part of DoD during project performance is the key factor in determining whether to award a cooperative agreement.

***Extramural Organizations:*** An assistance agreement (grant or cooperative agreement) is appropriate when the Federal Government transfers a “thing of value,” to a “state, local government,” or “other recipient,” to carry out a public purpose of support or stimulation authorized by a law of the United States, instead of acquiring property or service for the direct benefit and use of the U.S. Government. An assistance agreement can take the form of a grant or cooperative agreement. If “no substantial involvement” on the part of the funding agency is anticipated, a grant award will be made (31 USC 6304). Conversely, if substantial involvement on the part of the funding agency is anticipated, a cooperative agreement will be made (31 USC 6305). Substantial involvement may include collaboration, participation, or intervention in the research to be performed under the award. The U.S. Government may exercise other Substantial Involvement authorities in keeping with the Federal Grant and Cooperative Agreement Act of 1977. For this award a cooperative agreement will be used and the start date will be determined during the negotiation process.

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

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

***Intramural Organizations:*** Awards to Federal Government organizations (to include intramural DoD organizations) will be executed through the Military Interdepartmental Purchase Request (MIPR) or Funding Authorization Document (FAD) process. Transfer of funds is contingent upon appropriate safety and administrative approvals. Intramural applicants and collaborators are reminded to coordinate receipt and commitment of funds through their respective resource managers (RM).

After email notification of application review results through the 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. Award Transfers**

Unless otherwise restricted, changes in PI will be allowed at the discretion of the USAMRAA Grants Officer, provided that the intent of the award mechanism is met. The organization transfer of an award supporting a clinical trial is strongly discouraged and in most cases will not be allowed. Approval of a transfer request will be on a case-by-case basis at the discretion of the Grants Officer. An organizational transfer of an award will not be allowed in the last year of the (original or option) 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 DoDGAR found in 32 CFR, Chapter 1, Subchapter C, and 2 CFR, Chapter XI, apply to grants and cooperative agreements resulting from this Program Announcement.

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

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

Refer to full text of the [USAMRAA General Research Terms and Conditions for Institutions of Higher Education, Hospitals, and Non-Profit Organizations](#) 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.

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

In addition to written progress reports, in-person presentations at annual IPRs 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 Terms and Conditions. The applicable Terms and Conditions for institutions of higher education, hospitals, and nonprofit organizations are available in OAR Article I, Section B, in the [July 2016 R&D General Terms and Conditions](#). The applicable Terms and Conditions for for-profit organizations are available in Section 34 of

the [February 2017 USAMRAA General Research Terms and Conditions with For-Profit Organizations](#).

## **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](mailto: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](mailto: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 20170516c. The Program Announcement numeric version code will match the General Applications Instructions version code 20170516.

### **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:

- 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 FY17 ASADRP 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 FY17 ASADRP Programmatic Panel members can be found at <http://cdmrp.army.mil/asadrp/panels/panels17>.*
- The application fails to conform to this Program Announcement description to the extent that appropriate review cannot be conducted.
- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- To preserve the integrity of its peer and programmatic review processes, the CDMRP discourages inclusion of any employee of its review contractors having any role in the preparation, research or other duties for submitted applications. For FY17, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (<http://cdmrp.army.mil/about/2tierRevProcess>). Applications that include names of personnel from either of these companies will be administratively withdrawn unless plans to manage COIs are provided and deemed appropriate by the Grants Officer. Refer to the General Application Instructions, Appendix 3, for detailed information.
- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review 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.
- Applications may be administratively withdrawn from further consideration if the applicant cannot demonstrate access to the relevant study population or resources.

#### **II.H.2.d. Withhold**

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

### II.H.3. Application Submission Checklist

Application Components	Action	Completed
SF424 (R&R) Application for Federal Assistance ( <b>Extramural submissions only</b> )	Complete form as instructed.	
Summary (Tab 1) and Application Contacts (Tab 2) ( <b>Intramural submissions only</b> )	Complete these tabs as instructed.	
Attachments	Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf."	
	Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf."	
	Technical Abstract: Upload as Attachment 3 with file name "TechAbs.pdf."	
	Lay Abstract: Upload as Attachment 4 with file name "LayAbs.pdf."	
	Statement of Work: Upload as Attachment 5 with file name "SOW.pdf."	
	Impact and Military Benefit Statement: Upload as Attachment 6 with the file name "MilBen.pdf."	
	Transition Plan: Upload as Attachment 7 with the file name "Transition.pdf."	
	DoD Military Budget Form(s): Upload as Attachment 8 with file name "MFBudget.pdf," if applicable.	
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 ( <b>Extramural submissions only</b> )	Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field.	
Budget ( <b>Intramural submissions only</b> )	Complete the DoD Military Budget Form and Justification.	
Project/Performance Site Location(s) Form	Complete form as instructed.	
R&R Subaward Budget Attachment(s) Form, if applicable	Complete form as instructed.	

## **APPENDIX 1: ACRONYM LIST**

ACURO	Animal Care and Use Review Office
ASADRP	Alcohol and Substance Abuse Disorders Research Program
ASUD	Alcohol and Substance Use Disorders
CDE	Common Data Element
CDMRP	Congressionally Directed Medical Research Programs
CEC	Consortium Executive Committee
CFR	Code of Federal Regulations
DHA	Defense Health Agency
DHP	Defense Health Program
DoD	Department of Defense
DoDGAR	Department of Defense Grant and Agreement Regulations
DUNS	Data Universal Numbering System
eBRAP	Electronic Biomedical Research Application Portal
EC	Ethics Committee
ET	Eastern Time
FAPIIS	Federal Awardee Performance and Integrity Information System
FDA	U.S. Food and Drug Administration
FITBIR	Federal Interagency TBI Research Informatics System
FY	Fiscal Year
GCP	Good Clinical Practice
GLPs	Good Laboratory Practices
GMPs	Good Manufacturing Practices
GOR	Grants Officer's Representative
GSC	Government Steering Committee
HRPO	Human Research Protection Office
IACUC	Institutional Animal Care and Use Committee
IDE	Investigational Device Exemption
IND	Investigational New Drug
IPR	Interim Progress Review
IRB	Institutional Review Board
LOI	Letter of Intent

M	Million
OASD(HA)	Office of the Assistant Secretary of Defense for Health Affairs
OMB	Office of Management and Budget
ORP	Office of Research Protections
PI	Principal Investigator
PTSD	Post-Traumatic Stress Disorder
RDT&E	Research, Development, Test, and Evaluation
RM	Resource Manager
SAM	System for Award Management
SOP	Standard Operating Procedure
SOW	Statement of Work
TBI	Traumatic Brain Injury
USAMRAA	U.S. Army Medical Research Acquisition Activity
USAMRMC	U.S. Army Medical Research and Materiel Command
USC	United States Code
VA	Department of Veterans Affairs

## APPENDIX 2: POTENTIAL RESOURCES

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

U.S. Army Research Institute  
<https://sslweb.hqda.pentagon.mil/ari/>

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

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

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

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

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

Naval Health Research Center  
[www.med.navy.mil/sites/nhrc](http://www.med.navy.mil/sites/nhrc)

Naval Medical Research Center  
[www.med.navy.mil/sites/nmrc](http://www.med.navy.mil/sites/nmrc)

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

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

U.S. Army Aeromedical Research Laboratory  
[www.usaarl.army.mil](http://www.usaarl.army.mil)

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

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

U.S. Army Research, Development and  
Engineering Command  
[www.army.mil/rdecom](http://www.army.mil/rdecom)

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

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

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

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

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

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