Pharmacotherapies for Alcohol and Substance Use Disorders Alliance (PASA)
Study Research Planning Program (SRPP)
Planning Award Application
Request for Application (RFA) #8a

Release: March 18,2026

TIMELINE

• Pre-application Due	04/15/2026
• Go/ No Go Response from PASA Management Core (for submission of full applications)	04/24/2026
• Full Application Due	06/05/2026
• Peer Review Process	July 2026
• Consortium Steering Committee Review	Mid-August 2026
• Notification of Award Recommendations	August 2026
• Award Negotiations Begin	September 2026

Request for Application (RFA) #8a: Planning Award Synopsis

Small-cost and short-duration planning award awarded to investigators concerning a specific compound or combination of compounds. Designed to determine the clinical implementation strategy plan and associated studies needed to advance the compound through regulatory pathways to FDA approval for ASUD treatment. The protocol for the first study will be developed as part of the planning award and may be considered for funding and implementation by the PASA.

Additional details and associated templates for this RFA are available at: https://pasa-research.org/funding-opportunities

Table of Contents

I. Funding Opportunity Description

A. Introduction and Intent of Award Mechanism

The **P**harmacotherapies for **A**lcohol and **S**ubstance Use Disorders **A**lliance (PASA) is funded by the Congressionally Directed Medical Research Programs (CDMRP) (https://cdmrp.health.mil/) through the Alcohol and Substance Use Disorders Research Program (ASUDRP) consortium awards (W81XWH-15-2-0077, W81XWH-18-2-0044, W81XWH-22-2-0081, and HT94252520002). The PASA's goal is to fund studies that explore integrated approaches to address ASUD, especially comorbid ASUD, particularly but not limited to with PTSD and other mental health conditions, and reduce the number of opioid and other substance use-related deaths through multidisciplinary, team-based research efforts that translate knowledge into enhanced clinical pharmacological treatment protocols and enhanced quality of life for Service Members, Veterans, and the American public. Studies of military and Veteran populations are encouraged. These medications will ideally address the comorbidity between PTSD, TBI, or other mental health conditions as these comorbidities are common in the military and veteran populations. Alcohol use disorder (AUD) is the most common ASUD in the military, but opiate use disorder also has developed significant clinical importance because of prolonged pain treatments with opiates. Commercialization linked to FDA approval for these new medications or combinations of medications is critical so early linkages to pharmaceutical companies are considered strengths of any application for PASA funding.

The PASA SRPP is requesting applications for planning award(s) to support early phase, proof of concept clinical trials to develop/evaluate a compound(s) for treatment of any ASUD (meaning AUD, SUD or combined ASUD), particularly but not limited to comorbid with PTSD or other mental health conditions leading to enhanced quality of life for Service Members, Veterans, and the American public. These studies will be conducted as part of PASA in collaboration with the applying investigators. The planning awards will provide support for the extensive efforts required to determine the clinical implementation strategy needed to advance the compound through regulatory pathways to FDA approval for ASUD treatment through development of a series of studies, some of which may receive funding through PASA. A productive planning award will yield a clinical implementation strategy, a protocol for the first study in the plan, and FDA approval or exemption for the plan and protocol. The first study from a planning award will be considered for funding and implementation by PASA, therefore a budget in RR format for the proposed protocol must also be developed. Preference will be given to compounds that have potential value to a pharmaceutical company to gain support for final development by the company. The expected duration of a planning award is 9-12 months.

B. Program Description

PASA is administered by a PASA Management Core led by RTI International in collaboration with the Baylor College of Medicine (BCM). The PASA Leadership team consists of Principal Investigator Ryan Whitworth, PhD from RTI International and co-Principal Investigator Tom Kosten, MD, from Baylor College of Medicine. Oversight of PASA is provided by a Consortium Steering Committee (CSC) assembled by the CDMRP ASUDRP.

The goal of the PASA is to fund study applications for developing new medications that can be brought to therapeutic use to improve treatment outcomes for ASUD, especially as related to PTSD and ideally address the comorbidity between ASUDs and other mental health conditions. Clinical trials that include military Service Members (SM) and Veteran populations are highly desirable because these comorbidities are common in these populations.

C. PASA Management Core

The PASA Management Core is responsible for soliciting and prioritizing applications. Successful applications will be recommended for funding by the Consortium Steering Committee (CSC) assembled by the CDMRP ASUDRP. The PASA Management Core will provide oversight and coordination for future proof-of-principle human clinical trials supported by PASA. The PASA Management Core will provide the administrative, protocol development and review, regulatory, statistical, resource, and data management/storage functions necessary to facilitate rapid development of research that would perhaps not otherwise be feasible without the PASA Management Core support. The PASA Management Core contains multidisciplinary expertise and experience in support of ASUD research. The PASA Management Core will coordinate the regulatory strategy for FDA compliance, in collaboration with the industry or academic sponsor and collaborators, leading to potential product development and licensing. Additional information about PASA is available on its website (https://pasa-research.org).

D. Study Sites with Military and Veteran Focus

Applications should address relevant topics with a focus on military SMs and Veterans. To this end, the PASA Management Core is available to facilitate collaboration between applicants and military and Veteran medical centers. PASA also has contacts at many VA medical centers and military treatment facilities (MTFs) that can be used to establish collaborators and clinical sites to support clinical studies. Additional information concerning such collaborations can be obtained by contacting PASA_RFA@rti.org.

E. Pharmaceutical Company Participation

Obtaining FDA approval for a pharmacotherapy is facilitated by partnership with a pharmaceutical company for Phase 3 testing and eventual long-term goal of a New Drug Application. Although developing such a commercial partnership may not be possible for all the studies to be funded by the PASA SRPP, it is strongly recommended that such a commercial partner be obtained as early in the medication development process as possible. A demonstrated relationship with a pharmaceutical company with a path to eventual marketing of the pharmacotherapy will be a factor in the award selections.

II. Research Goals and Focus

A. Strategic Goals

The ASUDRP has three strategic goals:

i. Goal 1 (Discover): Identify new chemical entities and repurpose existing medications in **pre-clinical and nonclinical (e.g. drug discovery) research models**, including Investigational New Drug (IND)-enabling studies, for the treatment of ASUD with co-occurring PTSD, and other mental health conditions.

ii. Goal 2 (Phase 1 First-in-Human Safety): Evaluate candidate medications, including the assessment of **safety, pharmacokinetics (PK), and pharmacodynamics (PD),** to determine optimal dosing in individuals with ASUD, or ASUD with co-occurring PTSD and other mental health conditions, or as needed, healthy volunteers.

iii. Goal 3 (Phase 2 Efficacy): Advance potential treatments by testing the **preliminary efficacy and safety** of medications or medication combinations in individuals with ASUD, or ASUD with co-occurring PTSD and other mental health conditions; and by exploring **precision medicine tools** for improved treatment outcomes for individual patients.

B. Focus Areas

1. New medication targets
2. Novel medications
3. Re-purposed medications
4. Vaccines and other immunotherapies
5. Drug-drug combinations
6. More potent, longer-acting formulations to counteract opioid overdose, including fentanyl and its analogs

For this RFA, we are only soliciting for planning awards under Goals 2 and/or 3 for human participant clinical trials. The planning award must address at least one research area of emphasis. Separate RFAs are available for drug discovery research studies and pre-clinical, animal research studies (Goal 1).

C. Planning Award for Developing Promising Compounds

Small-cost and short-duration planning awards may be awarded to an investigator concerning a specific compound or combination of compounds. These awards are designed to determine the clinical implementation strategy (CIS) needed to advance the compound to FDA approval for ASUD treatment, particularly but not limited to comorbid with PTSD or other mental health conditions, through a series of studies, some of which may be funded through the PASA. Preference will be given to compounds that have potential value to a pharmaceutical company to gain support for final development by the company. Participation in the award by a company will be highly valued.

The planning awards considered under this RFA are for promising compound(s) for which a development plan is needed to layout the Phase I or Phase II studies that will be required before pivotal Phase III studies can be conducted. Examples of studies of potential compounds should involve small numbers of subjects and include assessment of medical safety and of potential doses for efficacy in humans with ASUD, particularly but not limited to comorbid with PTSD or other mental health conditions. The studies can range from Phase I through late Phase II including, for example:

- Drug/substance safety interaction studies and pharmaco-kinetic (PK) studies, especially when the compound has not previously been co-administered with the substance of use (such as alcohol)
- Dose finding studies
- Single site or multisite safety and preliminary efficacy trials intended to show sufficient evidence of efficacy for a future Phase III clinical trial

If you have questions about whether you should apply for a planning award, please send a note describing your situation to PASA_RFA@rti.org.

III. Application Submission Information

A. Types of Studies to be Awarded

Type	Period of Performance	Maximum Total Cost (Direct and Indirect)
Planning Award	9-12 months	$150,000

Note: ***Maximum total cost includes direct plus indirect costs***.

B. Application

All applications must include the following elements (as applicable) in the order as listed in this announcement. Page limits are noted where applicable. Failure to include a required element may result in the application not being reviewed. Start each component on a new page with the component title, PI name, and study title at the top of the first page.

Questions about the application process will be received; with answers provided on a rolling basis and posted on a FAQ page of the PASA website.

B.1 Pre-application

A pre-application must be submitted prior to submission of the full application. The pre-application shall not exceed four pages and shall provide:

- The title of the application;
- The name(s) and affiliation(s) of the PI and, if any, co-PIs;
- The address, phone number, and e-mail address of the PI; and
- List the strategic goal(s) and focus area(s) the proposed research addresses.
- A brief overview of the proposed compound including the existing research completed to date with a specific focus on the researcher's experience with the compound.

All Pre-applications must be submitted as a PDF file by e-mail no later than 11:59 PM Eastern Time on **April 15, 2026;** to: PASA_RFA@rti.org

The pre-applications will be given a 'go'/'no go' designation from the PASA Management Core, with those designated as 'go' to proceed with a full application. If any concerns or questions are identified upon review of the pre-application, the PASA Management Core will contact the listed investigators.

Pre-application Screening Criteria: To determine the technical merits and relevance to the ASUDRP research goals and focus, screening will be based on the following criteria:

- Alignment with Topic Area: Whether the proposed project relates to the ASUDRP research goals and focus.
- Research Idea: How well the research hypothesis or objective is presented.
- Impact: To what degree does the proposed work have the potential to inform the needs of future clinical trials of potential medications or medication combinations in patients with ASUD and particularly but not limited comorbid PTSD and other mental health conditions

Following the pre-application screening, PIs will be notified as to whether or not they are a 'go' (aka: invited to submit a full application).

B.2 Compound Development Planning Award Application Submission Requirements

All full applications must be submitted as a PDF file by e-mail no later than **June 5, 2026;** to:
PASA_RFA@rti.org

The application consists of the following components:

Item	Description
Application Cover Sheet	See Appendix A for this template.
Title	Provide the title of the proposed planning award.
Abstract	Include an abstract for the proposed planning award.
Personnel (3-page limit)	Demonstrate that the PIs, collaborators, and other researchers have the background and expertise to perform the proposed work and have an ongoing record of accomplishments. Describe any collaboration between civilian, Department of Defense (Department of War), or VA personnel. Include an organizational chart and briefly describe the roles and responsibilities of the study personnel. For the purposes of the planning award, please focus only on the primary site/investigator being proposed (if that site is an academic institute that traditionally pairs with a VA or MTF to conduct any study, please include details of the associated VA or MTF). No detailed information on other secondary proposed sites is required.
Research Rationale/ Strategy and Feasibility (1-page limit)	Describe the scientific rationale and research strategy of the proposed compound or compounds for the treatment of ASUD, particularly but not limited comorbid with PTSD or other mental health conditions. The proposed compound should address an area of emphasis targeted by the PASA. Describe the feasibility of the research to include a critical review and analysis of the literature and supporting data. All compounds must be in line with ASUDRP research goals and focus areas. The rationale should also clearly describe how the proposed compounds will align with research and clinical goals to maximally benefit Service Members (SMs) and Veterans.
Justification for Human Research (2-page limit)	Provide a summary of research completed by the PI(s) or other investigators that describes existing pre-clinical and clinical trial research of the proposed compound(s) and justifies additional early phase clinical trials including the ability to conduct any IND studies of this compound in this field. Describe how the application addresses ethnic and sex diversity and access to the appropriate populations.

Item	Description
	Determine, to the best of existing knowledge, the current location of the proposed compound(s) within the regulatory pathway (e.g., past use in substance using populations, PK studies in presence of substance use, substance use interaction studies, single site studies assessing efficacy and safety for substance use disorder).
Future Clinical Trial Needs (2-page limit)	Describe, to the best of your knowledge, the current trial needs for this compound. This should include but not be limited to the following: • Describe the potential need for an interaction study of the proposed compound and the substance for treatment targeted (i.e., a study where healthy individuals are exposed jointly to compound and ethanol challenge for AUD targeted compounds). • Describe the potential need for a pharmacokinetic (PK) study to assess the effect of substance use on the pharmacokinetics of the compound. • Describe the need for a dose-finding study of the proposed compound. • Describe the potential need for a small, single-site outpatient study assessing the preliminary efficacy and safety of the compound.
Impact and Innovation (1-page limit)	State how the study of the compound has the potential to significantly inform military or VA health care and practice and promote a greater understanding of the treatment of ASUD, particularly but not limited comorbid with PTSD or other mental health conditions and/or reduce the number of opioid and other substance related deaths. A successful application will also describe how the proposed research: o Meaningfully expands on existing research without overlapping with current studies. o Uniquely contributes to the understanding of ASUD, particularly but not limited comorbid with PTSD or other mental health conditions and not replicate current studies but moves beyond with an innovative approach or objectives. o Promotes the development of improvements in pharmacotherapies for ASUD, particularly but not limited comorbid with PTSD or other mental health conditions leading to approval and marketing.

Item	Description
Environment (1-page limit)	Describe how the scientific environment is appropriate for the research proposed to include the availability and accessibility to facilities and resources. Describe your organizational support. Focus only on the primary site/investigator being proposed (if that site is an academic institute that traditionally pairs with a VA or military treatment facility (MTF) to conduct any study, please include details of the associated VA or MTF). No detailed information on other secondary sites is required.
Pharmaceutical Collaboration/ Regulatory Pathway Progression (1-page limit)	Address the proposed collaboration with a pharmaceutical company or other institution that would be used to provide continuity of development to inform study design, sample size and dosing needed to move this compound through the regulatory pathway in support of future clinical trials leading to a new label/indication if the study were to be successful.
Research and Related Budget and Budget Justification	The budget should reflect yearly direct costs for each year over the entire period of performance. A budget justification which describes the labor and other direct costs necessary to complete the project must be included here. Because PASA project funding is available through a CDMRP/ASURP award, all study subaward funds will be subject to policies and restrictions based on the CDMRP/ASURP source of this funding. • Budget to be submitted using Research and Related (R&R) Budget form Forms are available on the PASA website
Quad Chart	All applications must include a quad chart (separate from the application) briefly describing the study including rationale, population to be studied, sample size, study sites, methods, total budget, and a picture or other graphic describing the study. An example of a CDMRP-compliant quad chart can be found at: https://ebrap.org/eBRAP/public/Program.htm
Supporting Documentation	Start each document on a new page with complete header information. Include only those components described below; inclusion of items not requested may result in the removal of those items or administrative withdrawal of the application.
	• **References Cited:** List the references cited (including URLs if available) 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).

Item	Description
	• **List of Abbreviations, Acronyms, and Symbols:** Provide a list of all abbreviations, acronyms, and symbols used in the application.
	• **Facilities, Existing Equipment, and Other Resources:** Describe the primary site/investigator being proposed (if that site is an academic institute that traditionally pairs with a VA to conduct any study, please include details of the associated VA). No detailed information on other secondary sites is required.
	• **Publications or Patent Abstracts** *(3-document limit)*: Include relevant publication URLs or patent abstracts. If publications are not publicly available, then a copy/copies of the published manuscript(s) must be included here. Extra items will not be reviewed.
	• **Letters of Organizational Support** *(2-page limit per letter)***:** Provide a letter (or letters, if applicable), signed by the Department Chair or appropriate organization official, reflecting the institution's commitment to the completion of the trial, including laboratory space, equipment, and other resources available for the project. Please focus only on the primary site/investigator being proposed (if that site is an academic institute that traditionally pairs with a VA to conduct any study, please include details of the associated VA). No detailed information on other secondary sites is required.
	• **Letters of Collaboration (if applicable)** *(2-page limit per letter)***:** Provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed work. Letters of support from a collaborating pharmaceutical company are welcomed and desired.
	• **Letters Confirming Access to Military or VA Patient Populations or Resources (if applicable**): If the proposed research plan involves access to active duty military or VA patient populations or resources, a letter of support, signed by the lowest ranking person with approval authority, confirming such access is desired but not required as part of the planning award application. If access cannot be confirmed at the time of the planning award application submission, it will need to be obtained during the planning award funding period.

Item	Description
	• **Research & Related Senior/Key Person Profile: All applications must include:** o PI Biographical Sketch (4-*page limit*) o PI Current/Pending Support (*no page limit*) o Key Personnel Biographical Sketches (4-*page limit each*) o Key Personnel Current/Pending Support (*no page limit*) In accordance with National Security Presidential Memorandum-33 and all associated laws, all fundamental research funded by the Department of Defense (Department of War) must be evaluated for affiliations with foreign entities. All applicant organizations must disclose foreign affiliations of all key personnel named on applications. Failure to disclose foreign affiliations of key personnel shall lead to withdrawal of recommendations to fund applications. Applicant organizations may be presented with an opportunity to mitigate identified risks, particularly those pertaining to influence from foreign entities specified in law. Implementation of mitigation discussions and utilization of the Department of Defense (Department of War) Component Decision Matrix must decrease risk of foreign influence in accordance with the above-mentioned laws and guidance prior to award. Forms available on the PASA website. No detailed information on secondary sites (if applicable) is required.

B.3 Full Application Format

All full applications should be submitted as a single PDF file except for the full budget PDF form, which should be a separate file. All text should be in Calibri with a font size of no less than 11. All margins should be at least one inch. Inclusion of URLs to provide additional information is prohibited in all sections.

IV. Full Application Review and Selection Process

A. Peer Review

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

A.1 Personnel

- How the background and expertise of the PI(s) and other key personnel demonstrate their abilities to perform the proposed work.
- How the levels of effort by the PI(s) and other co-investigators are appropriate to ensure the successful conduct of the project.
- How the PI(s)'s and co-investigators' record(s) of accomplishment demonstrate their abilities to accomplish the proposed work

A.2 Research Rational, Strategy and Feasibility

- How well the scientific rationale supports clinical trial research on the proposed compound for treatment of ASUD, particularly but not limited comorbid with PTSD or other mental health conditions.
- How well the feasibility of such research is described by a critical review and analysis of the literature, supporting data, and logical reasoning.

A.3 Justification for Human Research

- How well the application describes existing preclinical and clinical trial research of the proposed compound(s) and justifies additional early phase clinical trials for treatment of ASUD, particularly but not limited comorbid with PTSD or other mental health conditions.
- How well the application acknowledges potential problems or delays and addresses alternative approaches and solutions.
- If applicable, how well the application address ethnic and sex diversity and provides evidence of availability of and access to the necessary study populations or resources.
- If applicable, how well the PI addresses the availability of and access to SMs or Veterans for any subsequently funded clinical trials and the prospect of their participation.

A.4 Future Clinical Trial Needs

- How well the application assesses the likely next steps needed for continuing the compound along the regulatory pathway.
- Whether the investigators demonstrate an ability via pharmaceutical collaboration or otherwise for compound to continue to progress long term on regulatory pathway.

A.5 Impact and Innovation

- How the proposed research, if successful, will:
  - Promote greater understanding of the treatment of ASUD, particularly but not limited comorbid with PTSD or other mental health conditions and/or reduce the number of opioid and other substance use-related deaths.
  - Promote the development of improvements in pharmacotherapies for ASUD, particularly but not limited comorbid with PTSD or other mental health conditions.
  - Support potential approval and marketing of pharmacotherapies for ASUD, particularly but not limited comorbid with PTSD or other mental health conditions.
- How the proposed research uniquely contributes to the understanding of ASUD, particularly but not limited comorbid with PTSD or other mental health conditions using an innovative approach or objectives.

A.6 Environment

- How the scientific environment is appropriate for the proposed research.

- How the research requirements are supported by the availability of and accessibility to facilities and resources.
- How the quality and extent of organizational support are appropriate for the proposed research.

A.7 Pharmaceutical Collaboration/ Regulatory Pathway Progression

- Whether collaborations with industry or other institutions exist that will be used to provide continuity of development to inform study design, sample size, and dosing for future clinical trials.

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

A.8 Budget

- Whether the budget is appropriate for the proposed planning award and within the funding limitations.

A.9 Application Presentation

- To what extent the writing, clarity, and presentation of the application components influence the ease of review and the understanding of the reviewers.

B. Consortium Steering Committee Review

Following the Peer Review, the PASA Management Core leaders will present the applications to the Consortium Steering Committee for their review. The Consortium Steering Committee will make funding recommendations using the following criteria:

- Ratings and evaluations from peer reviewers
- Relevance to the goal of the PASA, as evidenced by the following:
  - Relative impact
  - Program portfolio composition
  - Programmatic relevance
  - Adherence to the intent of the award mechanism

Final recommendation of planning awards to be funded will be made by the Consortium Steering Committee.

V. Award Negotiation

If your application is recommended for planning award funding, award negotiations will be held between your institution and the PASA Management Core to establish the scope of the planning award consistent with the recommendations of the Consortium Steering Committee and subject to final approval of the ASUDRP. All official negotiations of the budget, terms, and conditions of any resulting award will be conducted between the Business Official of your institution and the RTI Subcontracts Specialist. All subawards, and changes to all subawards that result in substantive changes to the budget or Scope of Work, require approval from the Defense Health Agency Contracting Activity Research and Development.

VI. Post-Award Requirements

A. Milestones

The table below outlines milestone expectations for studies post award. Sites and the PASA Management Core shall communicate as deliverables are achieved and ensure progress aligns with the outline below. If additional time is needed due to unforeseen obstacles this should be expressed immediately in order to address accordingly.

Task	Responsible Party	Timeframe
Subcontract	Site and PASA Management Core	Within 4 months of study award
Protocol	Site and PASA Management Core	Within 6 months of study award
Budget	Site and PASA Management Core	Within 6 months of study award
Clinical implementation strategy (CIS)	Site and PASA Management Core	Within 6 months of study award
IND/FDA Submission	Site and PASA Management Core	Within 8 months of study award
Draft Case Report Forms	Site and PASA Management Core	Within 8 months of study award
Data and Safety Monitoring Board Review	Site and PASA Management Core	Within 9 months of study award
Consortium Steering Committee Review	Site and PASA Management Core	Within 12 months of study award

B. Activities

Within 9-12 months of planning award, the following activities will be completed by the investigators in collaboration with the PASA:

1. Compilation of existing supporting science and clinical trial work done to date on compound.
2. Meetings with potential pharmaceutical collaborators to identify interest and potential role.
3. Creation of CIS, draft of first study synopsis and pre-IND meeting packet
4. FDA pre-IND meeting.
5. Incorporation of FDA comments into CIS and development of study protocol .
6. Identification of unique case report forms.
7. FDA submission of first protocol (or exemption).
8. Development of draft case report forms.
9. Address any clinical hold issues (if applicable) and finalized study protocol.
10. Identify sites and develop budget for proposed study.
11. Peer Review of first study protocol by Data and Safety Monitoring Board.
12. Submit CIS and first study protocol to Consortium Steering Committee for funding consideration, pending availability of funds.

C. Deliverables

Within 9-12 months of planning award four deliverables are expected:

1. A CIS for the compound that identifies firmly what next study(ies) are required for

moving the compound along the regulatory pathway.

2. A protocol and associated budget for the immediate next step study. The content of the protocol shall follow the template provided on the PASA website.
3. FDA input on the CIS and approval or exemption for first protocol.
4. Final submission packet to the PASA Leadership and Consortium Steering Committee to request approval and funding consideration for first study. Materials to include study protocol, budget, and CIS.

D. Reporting

Quarterly and annual progress reports will be required in the format shown on the PASA website. In addition to written progress reports, oral presentations may be requested, particularly to the Consortium Steering Committee.

A. Other Expectations of Clinical Research Studies

If your proposed clinical study from your clinical implementation strategy is selected for funding and implementation, then you will be expected to:

- 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 PASA SOP.
- Collaborate with other PASA research and clinical trial sites.
- Maintain a minimum combined participant accrual
- As applicable, provide a Clinical Research Coordinator who will interact with the Clinical Research Coordinators of other research and clinical trial sites and PASA Clinical Research Manager at the PASA Management Core to expedite and guide clinical protocols through regulatory approval processes and to coordinate patient accrual and study activities across sites.
- Implement PASA's core data collection methodology and strategies.
- Comply with PASA quality assurance and quality control procedures, as appropriate, including:
    - Participation in on-site and remote monitoring managed by the PASA Management Core.
    - Implementation of the PASA management plan for acquisition and aggregation of protocol-specified specimens, biological fluids, and relevant data to the appropriate laboratories for testing 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).
- Implement procedures established by the PASA Management Core for ensuring compliance with FDA requirements, as appropriate.
- Implement procedures established by the PASA Management Core to meet local Institutional Review Board and Defense Health Agency Research and Development (DHA R&D) Medical Research and Development Command (MRDC) Office of Human Research Oversight (OHRO) requirements for the conduct of clinical trials and the protection of human subjects.
- Participate in PASA procedures for the timely publication of major findings.
- Participate in PASA procedures for resolving intellectual and material property issues among organizations participating in the PASA.

- Participate in the preparation of written and oral briefings to the Consortium Steering Committee as requested, virtually or at 1-day meetings to be held in the Baltimore, MD/Washington, DC, area.
- Assist with the preparation of quarterly written progress reports, annual reports, and a final comprehensive report.
- Post a copy of the informed consent form used to enroll subjects on a publicly available federal website in accordance with federal requirements described in 32 CFR 219.
- Register the clinical trial, and submit study results, on ClinicalTrials.gov
- Submission of initial and, thereafter, annual Public Health Service Inclusion Enrollment Report forms (details the distribution of planned and actual enrollment).

Appendix A: Application Cover Sheet

Project Title:

Principal Investigator's Name:
Position/Title:
Department:
Organization Name:
Street:
City:
State:
Zip:
E-mail:
Phone:

Direct costs:
Indirects:
Total costs:

Proposed Start Date:

Proposed End Date:

PASA target disorders: (please list all that apply)

Alcohol
Opiates
Marijuana
Stimulants
Other substance (specify)
PTSD
TBI
Other mental health conditions (specify)