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

Release: March 18,2026

SUBMISSION AND REVIEW DATES

• 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 Ends	July 2026
• Consortium Steering Committee Review	Mid-August 2026
• Notification of Award Recommendations	August 2026
• Award Negotiations Begin	September 2026

Request for Application (RFA) #8d: Expansion Award Synopsis

Expansion award to support the continued research of highly impactful studies that were funded by the Pharmacotherapies for Alcohol and Substance Abuse Use Disorders Alliance (PASA) Study Research Planning Program (SRPP).

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

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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 study applications 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 that early linkages to pharmaceutical companies are considered strengths of any application for PASA funding.

The PASA SRPP is requesting applications for expansion awards to support the continuation or extension of previously funded PASA research to further compound identification, assessment, and/or development. Eligible studies may include the same types of research supported under new RFAs, such as drug discovery, pre-clinical animal studies, and planning awards to support the development of human participant clinical trials. Expansion award applications may also include clinical trial expansion (i.e. a new clinical trial phase) based on a previous planning award's clinical implementation strategy. Separate RFAs are available for investigators seeking support for new research projects in those areas.

B. Program Description

The 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 (BCM). Oversight of PASA is provided by a Consortium Steering Committee 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 other mental health conditions. These medications will ideally address the comorbidity between ASUD and other mental health conditions.

C. PASA Management Core

The PASA Management Core is responsible for soliciting and prioritizing applications. Successful applications will be recommended for funding by Consortium Steering Committee assembled by the CDMRP ASUDRP. The PASA Management Core will provide oversight and coordination for future proof-of-principle drug discovery studies, receive all relevant study data in a timely manner and act as a data repository, and provide analytic support in study design and analyses.

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. Additional information about PASA is available on its website (https://pasa-research.org).

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 soliciting for expansions of current or previously funded PASA studies (all types). Separate RFAs are available for new nonclinical (drug discovery) research studies (Goal 1), pre-clinical studies (Goal 1) and planning awards for human participant clinical trials (Goals 2 and 3). The research expansion award must address at least one strategic goal and focus area.

C. Expansion Award Information

This award is designed to support expansion of current or previously funded research by PASA.

III. Submission Information

This award will support continued research and further development of research projects previously funded by the PASA SRPP. The awards are intended to fund work that is a next step or an expansion on currently funded work. The expansion award may be used to support drug discovery or pre-clinical or

clinical research. The total funded amount and period of performance should align with the proposed work.

A. Types of Studies to be Awarded

Type	Period of Performance	Maximum Total Cost (Direct and Indirect)
Expansion Award	12-24 months	$250,000-$750,000

Note: ***Maximum total cost includes direct and 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.

All applications should include details on the objective and results of the previously funded PASA project. The description should include how these results or accomplishments relate to this application.

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 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;
- List the strategic goal(s) and focus area(s) the proposed research addresses.
- A brief overview of the previous research and accomplishments of the previously funded project by PASA.
- A list of the sites where the study will be conducted.

All pre-application must be submitted as a PDF file by e-mail no later than 11:59 PM Eastern Time **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 PASA aims, screening will be based on the following criteria:

- Alignment with Topic Area: Whether the proposed project relates to the PASA aims.
- 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, particularly but not limited to 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 Expansion 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 full application consists of the following components:

Item	Description
Proposal Cover Sheet	See Appendix A for this template.
Title	Provide the title of the proposed project.
Abstract	Include an abstract for the proposed expansion award.
Personnel (3-page limit)	Demonstrate that the PIs, collaborators, and other researchers are well suited to the project 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.
Background (3-page limit)	Detail the objective and results of the previously funded PASA project. Please include published and/or unpublished data.
Research Rationale (1-page limit)	Detail rationale that the previously funded PASA project is ready for the next phase of development. Include how the proposed project builds upon previous research.
Research Aims & Objectives (1-page limit)	Research aims and objectives should be clearly defined and sensibly tied to a definite research question. A clear endpoint or set of endpoints should be tied to each objective.
Research Strategy and Feasibility (10-page limit)	The overall strategy, methodology, statistical plan, and analyses should be well reasoned and appropriate to accomplish the specific aims of the project. A sample size estimate must be included and supported by a power analysis or other justification that demonstrates the adequacy of the sample size. *For studies proposing non-exempt clinical research:* Sex as a Biological Variable (SABV) Strategy: Describe the strategy for how sex will be considered as a biological variable. This strategy should include a brief discussion of what is currently known regarding sex differences in the applicable research area. Clearly articulate how sex as a biological variable will be factored into the data analysis plan and how data will be collected and disaggregated by sex. If needed, provide a strong rationale for proposing a

Item	Description
	single-sex study, based on justification from scientific literature, preliminary data or other relevant considerations. Refer to the CDMRP Directive on Sex as a Biological Variable in Research for additional information: https://cdmrp.health.mil/pubs/pdf/CDMRP%20SABV%20Directive_Revised_MAR2025_signed.pdf *For studies proposing animal clinical research:* Rigor of Experimental Design: All projects should adhere to a core set of standards for rigorous study design and reporting to maximize the reproducibility and translational potential of clinical and pre-clinical research such as those described here: https://arriveguidelines.org/arrive-guidelines
Impact and Innovation (1-page limit)	State how the project 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 to comorbid with PTSD or other mental health conditions and reduce the number of opioid and other substance related deaths. A successful application will also describe how the proposed research: • Meaningfully expands on the previous PASA study without overlapping existing research/current studies. • Uniquely contributes to the understanding of ASUD, particularly but not limited to comorbid with PTSD or other mental health conditions and not replicate current studies but move beyond with an innovative approach or objectives. • Promotes the development of improvements in pharmacotherapies for ASUD, particularly but not limited to comorbid with PTSD or other mental health conditions leading to approval and marketing.
Environment (1-page limit)	Applicants should describe how the project benefits from unique features of the scientific environment, or collaborative arrangements. A description of all locations should also be provided. Also describe how each proposed site contributes to the study and how these sites will be able to complete the study protocol.
Pharmaceutical Company Collaboration/Regulatory Pathway Progression Potential *(clinical research studies only)* (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 to a new label/indication if the study where to be successful.
Laboratory Animals (pre-clinical studies only)	Each animal protocol must include: 1. A justification for using animals, the number of animals to be used, and the species chosen;

Item	Description
	2. The procedures or drugs to be used to eliminate or minimize pain and discomfort; 3. A description of the methods and sources used to search for alternatives to painful procedures; and 4. A description of the search used to ensure that the experiment does not unnecessarily duplicate previous research.
Human Subject Recruitment and Safety Procedures *(clinical research studies only)*	This section should address the following topics: • Study Population: Describe the population at the study sites including the approximate number and pertinent demographic characteristics of the population from which participants will be recruited. • Describe how the application addresses ethnic and sex diversity and access to the appropriate populations. • Inclusion/Exclusion Criteria • Description of the Recruitment Process: Describe the methods for identification of potential human subjects (e.g., medical records review, health care provider identification, etc.) • Description of the Informed Consent Process: (1) Describe who is responsible for explaining the study and answering questions; (2) when and where informed consent will be obtained; (3) address issues of mental capacity • Screening Procedures: List and describe any evaluations (e.g., laboratory procedures, patient histories, or physical examinations) that are required to determine study eligibility. • Risks and Benefit Assessment
Research and Related Budget and Budget Justification	A budget justification which describes the labor and other direct costs necessary to complete the project must be included here. The budget should reflect yearly direct costs for each year over the entire period of performance. Because PASA project funding is available through a CDMRP award, all study subaward funds will be subject to policies and restrictions based on the CDMRP source of this funding. • Budget to be submitted using 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

Item	Description
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 in the Research Methods (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).
	• **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 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 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.
	• **Publications or Patent Abstracts** *(three-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** *(two-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.
	• **Letters of Collaboration (if applicable)** *(two-page limit per letter)***:** Provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed work. 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; not applicable for drug discovery nor pre-clinical research**): If the proposed research plan involves access to active-duty military and/or VA patient populations or resources, include a letter of support, signed by the lowest ranking person with

Item	Description
	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.
	• **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.

B.3 Full Application Format

All 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 by a peer-review committee according to the following scored criteria, which are of equal importance. For multisite studies, feasibility, personnel, and environment will be evaluated across all sites.

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 Rationale

- How the proposed expansion clearly builds on the existing/previous PASA research studies.
- How well the scientific rationale supports research on the proposed compound(s) for treatment of ASUD, particularly but not limited to comorbid with PTSD or other mental health conditions. The feasibility of such research, as demonstrated by previous work and critical review and analysis of the literature, supporting data, and logical reasoning.
- How well the application describes existing drug discovery, pre-clinical and/or clinical trial research of the proposed compound(s) and justifies additional study for treatment of ASUD comorbid, particularly but not limited to with PTSD or mental health conditions.

A.3 Strategy and Feasibility

- To what extent the overall strategy, methodology, statistical plan, and analyses are reasonable and appropriate to accomplish the specific aims of the project. To what degree the sample size is supported by a power analysis or other justification that demonstrates the adequacy of the sample size. Whether the strategy for considering sex as a biological variable as appropriate to the objectives of the study or whether the justification for a single-sex study is sufficiently strong.
- How well the application defines the aims and objectives of the research and the necessary endpoints.
- How well the application assesses the likely next steps needed for continuing the compound along the regulatory pathway (*for clinical research studies*).
- Whether the investigators demonstrate an ability via pharmaceutical collaboration or otherwise for compound to continue to progress long term on regulatory pathway (*for clinical research studies*).
- How well the application acknowledges potential problems or delays and addresses alternative approaches and solutions.
- How well the study (or studies) is designed to achieve reproducible and rigorous results, including controls, sample size estimation, blinding, randomization, and data handling (*for any animal studies proposed*). All projects should adhere to a core set of standards for rigorous study design and reporting to maximize the reproducibility and translational potential of clinical and pre-clinical research such as those described here: https://arriveguidelines.org/arrive-guidelines

A.4 Impact and Innovation

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

A.5 Expansion

- If the current research is not yet completed, how the expansion is justified with the information available and how the expansion operationally aligns with current research timeline
- Whether the next proposed research plan/development is feasible

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 Laboratory Animal Protocol (if applicable)

- How well the animal protocol provides a justification for the animal used, the procedures or drugs used to minimize discomfort and a description of the search used to ensure that the experiment does not unnecessarily duplicate previous research.

A.8 Human Subject Recruitment and Safety Procedures (if applicable)

- How well the application describes the population at the study sites including the approximate number and pertinent demographic characteristics of the population from which participants will be recruited.
- How well the inclusion/exclusion criteria are described.
- How well the recruitment process is described.

- How well the informed consent process is described: who is responsible for explaining the study and answering questions? (2) when and where the informed consent will be obtained and (3) to what degree is the issue of mental capacity addressed?
- How well the screening procedures are described.
- To what degree the risks and benefit are assessed.
- If applicable, how well the application addresses ethnic and sex diversity and provides evidence of availability of and access to the necessary study populations or resources.

A.9 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 also contribute to the overall evaluation of the application:

A.10 Budget

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

A.11 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 PASA, as evidenced by the following:
  - Relative impact
  - Program portfolio composition
  - Programmatic relevance
  - Adherence to the intent of the award mechanism

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

V. Award Negotiation

If your application is recommended for funding by the Consortium Steering Committee, award negotiations will be held between your institution and the PASA Management Core to establish the scope of the final 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, including major modifications of subawards and changes across cost categories, require approval from the Defense Health Agency Contracting Activity Research and Development.

VI. Post-Award Requirements

A. Milestones

Milestone expectations will be included in the SOW and subcontract for each expansion award. The content of those milestones will vary based on the type of expansion award (planning award, pre-clinical, or drug discovery).

B. Protocol

Within 4 months of study award, all studies shall finalize a protocol based on the proposal in conjunction with the PASA Management Core and submit for review and approval by the PASA Leadership and obtain necessary approvals (Intuitional Review Board (IRB), Human Research Protection Office [HRPO], Institutional Animal Care and Use Committee [IACUC)], and/or Animal Care and Use Review Office [ACURO]. The protocol must follow the PASA Protocol Template on the PASA website.

C. Study Manual of Procedures

In addition to the study protocol, a study manual of procedures (MOP) will be developed by the study team in conjunction with the PASA Management Core and submitted to the PASA Leadership for review and approval. The MOP must be approved in writing by the PASA Leadership prior to the initiation of study activities.

Most studies funded by PASA must be conducted in accordance with GCP and/or GLP requirements. Some basic science studies may not require adherence to GLP, and a determination will be made concerning GLP in consultation between the PI and the PASA Management Core.

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.

For clinical trials that are funded, they are required to 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. Additionally, the CDMRP requires all funded clinical trials register and submit study results on ClinicalTrials.gov.

For non-exempt clinical research and clinical trials to submit initial and thereafter annual Public Health Service Inclusion Enrollment Report Forms (details the distribution of planned and actual enrollment)

E. Quality Assurance

During MOP development, a quality assurance plan must be developed in line with PASA's quality assurance guidelines. This plan will include details of records maintenance at the site, timely data recording, verification, and routine reporting/submission of data to the PASA Management Core and planned checks for data consistency.

F. Publications

A PASA priority is the rapid publication and presentation of study results in high quality peer reviewed journals and venues. Investigators should adhere to PASA publication policy which is available on the PASA website. A primary manuscript should be completed in a timely fashion. PASA Leadership will implement corrective action when 3 months have passed between final analysis and submission to a peer-reviewed journal.

G. Other Expectations of Clinical Research Studies

If your proposed clinical study 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.

- Submission of initial and, thereafter, annual Public Health Service Inclusion Enrollment Report forms (details the distribution of planned and actual enrollment).

Appendix A: Proposal 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)