Pharmacotherapies for Alcohol and Substance Use Disorder Alliance (PASA)
Study Research Planning Program (SRPP)
Compound Development Planning Award Application
Request for Application (RFA) #7a: [FY23; Round 1]

Release: June 2, 2023

TIMELINE

• Letter of Intent Due	6/30/2023
• Full Application Due	7/14/2023
• Peer Review Process Ends	8/14/2023
• Programmatic Panel Review	Late September 2023
• Notification of Award Recommendations	Early October 2023
• Award Negotiations Begin	Mid-October 2023

Request for Application (RFA) #7a: [FY23; Round 1]
Synopsis

Small-cost and short-duration planning award awarded to investigators concerning a specific compound or combination of compounds. Designed to determine the clinical development plan and associated studies needed to advance the compound 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

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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 Disorder **A**lliance (PASA) is funded by the Congressionally Directed Medical Research Programs (CDMRP) (https://cdmrp.health.mil/) as part of its Alcohol and Substance Use Disorders Research Program (ASUDRP) consortium awards (W81XWH-17-ASADRP-CA and W81XWH-21-ASADRP-CA). The PASA's goal is to fund studies that explore integrated approaches to address ASUD, especially comorbid ASUD with PTSD and other psychological disorders, and reduce the number of opioid and other substance use-related deaths through multidisciplinary, team-based research efforts that translate basic 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 ASUDs and PTSD or other psychological disorders 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) comorbid with PTSD or other psychological disorders 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 development plan needed to advance the compound to FDA approval for ASUD treatment through development of a series of studies, some of which might receive funding through PASA. A productive planning award will yield a clinical development plan, 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. 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 Core led by RTI International in collaboration with the Baylor College of Medicine (BCM). The PASA Leadership team consists of Principal Investigator Tracy Nolen, DrPh, from RTI and co-Principal Investigators Tom Kosten, MD, from BCM and, Nathan Vandergrift, PhD, from RTI. Oversight of PASA is provided by a Programmatic Panel assembled by the CDMRP.

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 psychological disorders. These medications will ideally address the comorbidity between ASUDs and other psychological disorders. Clinical trials that include military service member (SM) and Veteran populations are highly desirable because these comorbidities are common in these populations.

C. PASA Core

The PASA Core is responsible for soliciting and prioritizing applications. Successful applications will be recommended for funding by the Programmatic Panel assembled by the CDMRP. The PASA Core will

provide oversight and coordination for future proof-of-principle human clinical trials supported by PASA. The PASA 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 Core support. The PASA Core contains multidisciplinary expertise and experience in support of ASUD research. The PASA 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. Expert Advisers

In addition to the PASA Core, the National Institute of Alcohol Abuse and Alcoholism (NIAAA) is available to provide consultation, guidance, and expertise on the design, conduct and analysis of relevant clinical studies evaluating potential medications for treatment of PTSD-Alcohol Use Disorders. In addition, depending on the relevance of the proposed studies to the current medication development goals of NIAAA, and on the availability of funds, NIAAA will consider contributing support to responsive, meritorious application(s) if the study is ultimately approved to move forward. For example, NIAAA might consider expanding the populations being studied beyond SMs and Veterans by funding additional civilian sites. Applicants interested in consideration of NIAAA co-funding are encouraged to contact Dr. Daniel Faulk at NIAAA (falkde@mail.nih.gov).

E. 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 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.

F. Pharmaceutical Company Participation

Obtaining FDA approval for a pharmacotherapy is facilitated by partnership with a pharmaceutical company for Phase 3 testing and eventual New Drug Application. Although developing such a commercial partnership may not be possible for 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 Focus

A. Research Aims

The PASA has three broad aims:

1. Discover: Test new chemical entities and repurpose existing medications in pre-clinical and non-clinical models of ASUD with comorbid PTSD and other psychological disorders.
2. Phase 1 First-in-Human Safety: Conduct clinical trials of potential medications that include assessment of medical safety and doses for potential efficacy in subjects with ASUD and comorbid PTSD and other psychological disorders.
3. Phase 2 Efficacy: Conduct multiple-site clinical trials to test preliminary efficacy and safety of potential medications or medication combinations in humans with ASUD and comorbid PTSD

and other psychological disorders, and to also explore precision medicine tools for matching patients to these medications.

B. Research Areas of Emphasis

1. Improved formulations to treat ASUD with comorbid substance use
2. Improved formulations to treat ASUD with comorbid PTSD and other psychological disorders
3. Stronger, longer-duration formulations to counteract opioid (including fentanyl analogs) overdose
4. New formulations and/or combinations of existing medications to improve treatment compliance, prevent relapse, and reduce risk of misuse
5. Novel medications and immunotherapies to treat substance and/or ASUD
6. New medication targets for the treatment of substance and/or ASUD

For this RFA, we are only soliciting for planning awards under Aims 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 basic science non-clinical research studies and pre-clinical, animal research studies (Aim 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 development plan (CDP) needed to advance the compound to FDA approval for ASUD treatment comorbid with PTSD or other psychological disorders through a series of studies, some of which might 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 comorbid with PTSD or other psychological disorders. 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 Letter of Intent

A letter of intent (LOI) must be submitted prior to submission of the full application. The LOI 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
- 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 LOIs must be submitted as a PDF file by e-mail no later than 11:59 PM Eastern Time on **June 30, 2023 14, 2023;** to:
PASA_RFA@rti.org

The LOIs are for planning purposes only and no response from the PASA Core is required to proceed with the full application. If any concerns or questions are identified upon review of the LOI, the PASA Core will contact the listed investigators.

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 **July 14, 2023;** 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, DoD, 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 comorbid with PTSD or other psychological disorders. 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 PASA Aims and Areas of Emphasis. These aims and priorities may change based on feedback from the Programmatic Panel. The rationale should also clearly describe how the proposed compounds will align with DoD 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 preclinical 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 gender diversity and access to the appropriate populations. 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).

Item	Description
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 comorbid with PTSD or other psychological 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 comorbid with PTSD or other psychological 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 comorbid with PTSD or other psychological conditions leading to approval and marketing.
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.

Item	Description
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 DoD award, all study subaward funds will be subject to policies and restrictions based on the DoD 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).
	• **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.

Item	Description
	• **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.
	• **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*) 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.

- **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

- **Research Rational, Strategy and Feasibility**
  - How well the scientific rationale supports clinical trial research on the proposed compound for treatment of ASUD comorbid with PTSD or other psychological disorders.
  - How well the feasibility of such research is described by a critical review and analysis of the literature, supporting data, and logical reasoning.

- **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 comorbid with PTSD or other psychological disorders.
  - How well the application acknowledges potential problems or delays and addresses alternative approaches and solutions.
  - If applicable, how well the application addresses ethnic and gender 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.

- **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.

- **Impact and Innovation**

- How the proposed research, if successful, will:
  - Promote greater understanding of the treatment of ASUD comorbid with PTSD or other psychological disorders and/or reduce the number of opioid and other substance use-related deaths.
  - Promote the development of improvements in pharmacotherapies for ASUD comorbid with PTSD or other psychological disorders.
  - Support potential approval and marketing of pharmacotherapies for ASUD comorbid with PTSD or other psychological disorders.
- How the proposed research uniquely contributes to the understanding of ASUD comorbid with PTSD or other psychological conditions using an innovative approach or objectives.

- **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.

- **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:

- **Budget**
  - Whether the budget is appropriate for the proposed planning award and within the funding limitations.
- **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. Programmatic Review

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

- Ratings and evaluations of the 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 Programmatic Panel.

V. Award Negotiation

If your application is recommended for planning award funding, award negotiations will be held between your institution and the PASA Core to establish the scope of the planning award consistent with the recommendations of the Programmatic Panel and subject to final approval of the Programmatic Panel. 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 United States Army Medical Research Acquisition Agency.

VI. Post-Award Requirements

A. Basic Milestones

The table below outlines basic milestone expectations for studies post award. Sites and the PASA Core shall communicate as deliverables are achieved and ensure progress aligns with the outline below. If additional time is needed due to unforeseen obstacles (i.e., COVID-19) this should be expressed immediately in order to address accordingly.

Task	Responsible Party	Timeframe
Subcontract	Site and PASA Core	Within 4 months of study award
Protocol	Site and PASA Core	Within 6 months of study award
Budget	Site and PASA Core	Within 6 months of study award
Clinical Development Plan (CDP)	Site and PASA Core	Within 6 months of study award
IND/FDA Submission	Site and PASA Core	Within 8 months of study award
Draft Case Report Forms	Site and PASA Core	Within 8 months of study award
Data and Safety Monitoring Board Review	Site and PASA Core	Within 9 months of study award
Programmatic Panel Review	Site and PASA 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 basic 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 CDP, draft of first study synopsis and pre-IND meeting packet
4. FDA pre-IND meeting
5. Incorporation of FDA comments into CDP 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 CDP and first study protocol to Programmatic Panel for funding consideration.

VII. Deliverables

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

1. A CDP 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 CDP and approval or exemption for first protocol.
4. Final submission packet to the PASA Leadership and Programmatic Panel to request approval and funding for first study. Materials to include study protocol, budget, and CDP.

VIII. 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 Programmatic Panel.

IX. Other Expectations of Clinical Research Studies

If your proposed clinical study from your clinical development plan 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 basic 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 basic research and clinical trial sites and PASA Clinical Research Manager at the PASA Core to expedite and guide clinical protocols through regulatory approval processes and to coordinate patient accrual and study activities across sites.
- Implement the 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 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 Core for ensuring compliance with FDA requirements, as appropriate.
- Implement procedures established by the PASA Core to meet local Institutional Review Board and United States Army Medical Research and Development Command (USAMRDC) 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 Programmatic Panel as requested, 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.

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 psychological disorders (specify)