SUBJECT: Pharmacotherapies for Alcohol and Substance Use Disorder Alliance (PASA) Announcement of Research Funding Opportunities

3 May 2022

The PASA Consortium is funded by the Alcohol and Substance Use Disorder Research Program (ASUDRP), formally known as the ASADRP, and managed by the Congressionally Directed Medical Research Program (CDMRP). The goal of the PASA Consortium is to fund research projects for developing new medications that can be brought to therapeutic use to improve treatment outcomes for alcohol and substance use disorders (ASUD), especially as related to post-traumatic stress disorder (PTSD) and other psychological disorders.

The PASA Consortium is administered by a Management Core led by RTI International in collaboration with the Baylor College of Medicine. The Management Core is responsible for soliciting and prioritizing applications. Successful applications will be selected by the ASUDRP Programmatic Panel.

The Management Core contains multidisciplinary expertise and experience in support of Alcohol and Substance Use Disorders (ASUD) research and will provide infrastructure and resources to facilitate rapid development of research. PASA Management Core resources include but are not limited to: general coordination and oversight of projects, protocol development and review, regulatory coordination and drug development strategies, statistical expertise, and data management capabilities. Additional information about PASA is available on its website: https://pasa.rti.org/.

This PASA Request for Application (RFA) #6 cycle includes has three aims:

- **Aim 1:** Discover: Test new chemical entities and repurpose existing medications in strictly pre-clinical and non-clinical models of ASUD with comorbid PTSD and other psychological disorders.
- **Aim 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.
- **Aim 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.

- **RFA 6a/Planning Grant:**
  - Small-cost and short-duration planning grant concerning a specific compound or combination of compounds; to determine the clinical development plan and associated clinical trial(s) needed to advance the compound (or combination of compounds) to FDA approval for ASUD treatment.
  - **For this RFA (6a/Planning Grant):**
    - **Soliciting for planning grants under Aims 2 and 3 human participant clinical trials.**
  - **Timeline:**
    - Letter of Intent (LOI)* 27-May-22
    - Full Application Deadline 08-Jul-22

- **RFA 6b/Pre-Clinical:**
  - Full study implementation awards for proof-of-principle pre-clinical animal research to determine which compounds are most appropriate for human research trials. Using animal models, medications will be assessed to determine if they reduce the aberrant behaviors in models of ASUD comorbid with PTSD or other psychological disorders and potential dosages of these medications can then be estimated for human studies.
  - **For this RFA (6b/Pre-Clinical):**
    - **Soliciting for research grants under Aim 1 pre-clinical animal research studies.**

- **Timeline:**
  - Letter of Intent (LOI)* 27-May-22
  - Full Application Deadline 22-Jul-22

- **RFA 6c/Non-Clinical:**
  - Full study implementation awards for proof-of-principle non-clinical research to identify a pool of compounds most appropriate for additional research. The non-clinical research is intended to increase the potential pool of compounds for investigation in subsequent pre-clinical studies and clinical trials. Approaches to identifying promising compounds for development or repurposing studies that leverage large-scale data through computational-based analysis include but are not limited to in silico and augmented intelligence research.
  - **For this RFA (6c/Non-Clinical):**
    - **Soliciting for research grants under Aim 1 non-clinical research studies focused on ASUD comorbid with PTSD and other psychological disorders**
  - **Timeline:**
    - Letter of Intent (LOI)* 27-May-22
    - Full Application Deadline 22-Jul-22

*The LOIs are for planning purposes; no response from PASA is required to proceed with the full application.

The RFAs are available from the PASA Consortium website at:
https://pasa.rti.org/About/Grant-Program