Pharmacotherapies for Alcohol and Substance Use Disorder Alliance (PASA) Announcement of Research Funding Opportunities for FY23

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The Pharmacotherapies for Alcohol and Substance Use Disorder Alliance (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 Post-Traumatic Stress Disorder (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. Commercialization linked to U.S. Food and Drug Administration 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.

This PASA Request for Application (RFA) #7 cycle includes the following Research Aims and Areas of Emphasis:

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.

The PASA seeks to address the following research areas:

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

The PASA is offering four Research Mechanisms:

1. RFA 7a/Planning Award - Period of Performance is 9-12 months, with a maximum Total Cost (indirect and direct) of $150,000.
2. RFA 7b/Pre-Clinical Award - Period of Performance is 18 months, with a maximum Total Cost (indirect and direct) of $600,000.
3. RFA 7c/Non-Clinical Award - Period of Performance is 24 months, with a maximum Total Cost (indirect and direct) of $600,000.
4. RFA 7d/Expansion Award - Period of Performance is 12-24 months, with a maximum Total Cost (indirect and direct) of $250,000 to $750,000.

Detailed information regarding application information and submission deadlines can be found at:
https://pasa-research.org/funding-opportunities

Award Synopsis:

1. RFA 7a/Planning Award:

- 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 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.
- PASA is 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.
- The award Period of Performance is 9-12 months, with a maximum Total Cost (indirect and direct) of $150,000.

2. RFA 7b/Pre-Clinical Award:

- Discovery of new medications for ASUD comorbid with PTSD or other psychological disorders can greatly benefit from animal models of these disorders. Medications can 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 be estimated for human studies. More important will be the interaction of substance intoxication or dependence with the PTSD or other psychological disorders models and the effect on the ASUD models after an animal has developed the aberrant behaviors of the PTSD or other psychological disorder models.
- PASA is soliciting for pre-clinical research awards under Aim 1 for pre-clinical animal research studies. The research award must address at least one research area of emphasis
- The award Period of Performance is 18 months, with a maximum Total Cost (indirect and direct) of $600,000.

3. RFA 7c/Non-Clinical Award:

- Non-clinical research expansion 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.
- PASA is soliciting for non-clinical research awards under Aim 1 for non-clinical research studies focused on ASUD comorbid with PTSD and other psychological disorders. The research award must address at least one research area of emphasis.
- The award Period of Performance is 24 months, with a maximum Total Cost (indirect and direct) of $600,000.

4. RFA 7c/Expansion Award:

- PASA is seeking applications for expansions of current or previously funded PASA studies (all Aims). The research expansion award must address at least one research area of emphasis.
- The award Period of Performance is 12-24 months, with a maximum Total Cost (indirect and direct) of $250,000 to $750,000.