# PASA Consortium: RFAs 4a and 4b (2019); Frequently Asked Questions (FAQs)

## GENERAL:

1) Where do I submit my LOI?
    a. The email for questions or to send document is: PASA_RFA@rti.org

2) Are opioids of interest to the PASA consortium?
    a. Yes, opioids fall within the spectrum of ASUD (alcohol and substance use disorder) that is of interest to the PASA consortium.

3) Could you please clarify if international researchers are eligible to apply to your grants program?
    a. Yes, international researchers are eligible to apply:
        i. **For applications involving human subjects in a planning grant**:
            1. RFA4a: https://pasa.rti.org/Resources/RFA4/PASA_SRPP_RFA4a_Planning_Grant_FINAL.pdf
            2. You would need to meet the military relevant population requirement for the proposed study (and approval from the PASA Management Core that the proposed study population is relevant to the US military).
        ii. **For proposals on pre-clinical study implementation:**
            1. RFA4b: https://pasa.rti.org/Resources/RFA4/PASA_SRPP_RFA4b_PreclinicalStudy_FINAL.pdf
            2. Applications from institutions outside of the U.S. will be accepted and considered.

4) Where I can find the RFA available for basic science research study?
    a. The link to the preclinical RFA is: https://pasa.rti.org/Resources/RFA4/PASA_SRPP_RFA4b_PreclinicalStudy_FINAL.pdf
    b. Please note that the intention of the RFA is to test for possible treatments of alcohol and substance use disorder comorbid with PTSD and/or TBI in existing animal models.
        i. The funds are not intended to be used for the development of new animal models/paradigms
        ii. The proposal must propose specific therapies of interest.

5) Our plans for various pharmacotherapies involve re-purposing of existing compounds and would likely not require partnering with a pharmacotherapy company. Is this acceptable under this mechanism?
    a. Commercially available medications can be proposed but should be viable for obtaining sponsorship to continue to move the study drug through the new drug application (NDA) FDA approval process for a label change.
    b. A pathway to commercial viability is a topic that you will need to specifically address in your application.
    c. In the RFA, we note the following recommendations and evaluation criteria:
        i. 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. Whether the investigators demonstrate an ability via pharmaceutical collaboration or otherwise for compound to continue to progress on regulatory pathway.

# PASA Consortium: RFAs 4a and 4b (2019); Frequently Asked Questions (FAQs)

## RFA-4A:

1) Please clarify what information is requested for the proposal: is it information how the planning will commence, or is it information about the proposed studies for which the planning will take place?
    a. Personnel should focus on those involved in the planning grants and their relevant expertise.
    b. For research performance site, first cover the site of the relevant personnel in detail but a description of planned sites available of any study funded as well as availability of staff/expertise should be included but at a high level.
    c. Innovation should focus on the innovation/benefit of the proposed compound itself as well as any specific innovation that can be noted for potential studies.

2) If pursuing the unique indication of using [approved drug] in service members and veterans with SUD and PTSD comorbidity; will repurposing of an existing marketed medication be deemed responsive to the RFA?
    a. If your ultimate goal is a new indication (label change) for drug you are investigating, then it would be applicable for a planning grant.

3) Will there be a separate funding opportunity to cover the actual cost of human clinical development, if selected here?
    a. A key deliverable for the planning grant will be the development of a protocol for the first needed Phase I or II study.
    b. At the end of the planning grant, this protocol and associated budget will be submitted to the PASA Government Steering Committee for funding consideration.
    c. While funding approval for the study is not guaranteed, being considered for funding is a built-in aspect of the planning grant.
    d. Section IV.A provides additional details of this process.

## RFA-4B:

1) Please clarify the due date of the PASA Consortium SRPP RFA #4b application. The first page for the RFA and the website says that the deadline for the preclinical study is July 22nd. However, in page 5 of the RFA it says July 15th.
    a. The July 15th date is incorrect, **it is due July 22nd.**

2) Please clarify "All applications should be submitted as a single PDF file, except for the full budget PDF form, which should be a separate file."
    a. The budget justification is not included in the PDF of the main application document (and it is not part of the page limit).

3) Will this grant support research projects which aim to discover novel targets for the treatment of AUDs?
    a. PASA is not only funding drugs available already in the market but is also interested in novel compounds.
    b. However, the drugs for clinical testing are meant to be ready for Phase 1 testing in humans and have completed such hurdles as toxicology, manufacturing, and stability testing in animals with the candidate drugs.
    c. If the drug has failed in Phase 2 human testing for depression, anxiety or some other non-psychiatric indication including cardiology, infectious disease, GI or endocrine diseases, those are potential candidates, if there is a good rationale for their efficacy for SUD or PTSD/TBI.

   d. The PASA consortium does not have a basic science program that is looking for novel treatment targets with no drugs that could engage those targets in humans.
   e. That type of research is for the NIH and NSF (and perhaps large or small pharma companies) since most of those target finding studies yield nothing that could be applied to human studies.

4) Does the 4-page limit include the bibliography of references?
   a. The 4-page limit does not include the bibliography of references.