

Principal Investigator (PI) Name:

Clinical Science Research & Development (CSR&D)

Letter of Intent (LOI) Template for PTSD Psychopharmacology Initiative (PPI)

An LOI is required to submit an application to the PPI. The sections below must be completed and attached to VHA Research & Development Letter of Intent Cover Page (VA Form 10-1313-13) (<http://www.research.va.gov/funding/process/forms.cfm>).
In section 3, check "other" and enter "PPI" in the box under "other".

Please complete each of the fillable boxes below. Your text may not exceed the space provided.

1. Hypothesis to be tested (*max 500 characters*)

2. Brief description of the primary aims of the clinical trial (*max 1500 characters*)

3. Description of intervention and control/s (*max 500 characters*)

4. Description of the primary endpoint. Include measurable clinical outcome(s) for PTSD or explain why it is not the primary outcome, (e.g., sleep measure or other domain of interest related to PTSD symptomology). (*max 1500 characters*)

5. Scientific rationale for the medication (e.g., company donation, purchase). Do you already have an agreement with the company to receive the medication? Do you have a matched placebo?
Note: The quality of the agent/product should be consistent with FDA manufacturing standards.
(*max 1500 characters*)

13. Brief description of subject screening/recruitment methods and projected recruitment rate. As evidence of feasibility, data describing the size of the subject population available at the recruiting site(s) and verification of access to the appropriate Veteran population must be provided. What is your projection of how many subjects will be able to participate? *(max 500 characters)*

14. A list of any local or national competing trials on this topic that would draw subjects from the same Veteran population must be included. If competing trials exist, the distinction from the proposed trial must be accurately described. If no competing trials are underway, indicate NONE. See www.clinicaltrials.gov as one source for this information. *(max 1500 characters)*

15. Attach optional waivers *(see Adobe Acrobat instructions for attaching files)*:

Phase I

Enrollment of non-Veterans

Supplemental funds for planning activities

Over the budget cap (e.g. for multi-site trials)