

Guidance for Submission of Letter of Intent to PTSD Psychopharmacology Initiative

I. Introduction

Clinical Science Research and Development Service (CSR&D) is announcing a [PTSD Psychopharmacology Initiative \(PPI\)](#) to focus efforts on testing and confirming the most effective medications for Post-traumatic Stress Disorder (PTSD) in our Veteran population. The medication proposed may be a novel compound provided safety data are already available or a repurposed medication with biological rationale for treating PTSD. We are encouraging submission of Merit Review clinical trial proposals to respond to this initiative. Applications should be submitted to the CSR&D Clinical Trial RFA. Prior to submission, proposals must have an approved Letter of Intent (LOI).

The primary purpose of the LOI is to provide CSR&D with the opportunity to determine if a proposed trial is responsive to the goals of the PPI, if the proposed study will make a unique contribution, and if it appears feasible. CSR&D will evaluate the LOI and provide feedback on the clinical focus and design of the trial, the proposed innovation, overall impact and the apparent feasibility of enrolling the Veteran population.

The LOI submitted to the CSR&D PPI initiative must address the goals of the PPI announcement and constitute the sole objective of the application. A clinical trial must be the only focus and cannot be proposed as one of several specific aims of an application. It is expected that PIs will utilize the Common Data Elements for PTSD per NIH [PhenXToolkit](#) or provide a rationale for not using CDEs.

II. Components of the LOI Submission

LOIs must be submitted using the following template where all text is prepared using at least 11-point font, with no more than 15 characters per inch and no more than 6 lines per inch. Each LOI must contain the following three required components (A-C):

A. VHA Research & Development Letter of Intent Cover Page (VA Form 10-1313-13)

This form is available [on the forms page of the VA Research website](#). In section 3, check “other” and enter “PPI” in the box under “other.”

B. Completed LOI Template

The template is available [on the PPI web page](#). Please clearly and succinctly address **all** of the requirements.

C. PI's Biographical Sketch.

The biographical sketch template is available on the VA Research Intranet. If you can not access the intranet, contact your local research office. Please indicate specific clinical trials experience by highlighting work in the biosketch.

D. The following addenda should be submitted with the LOI (if necessary):

a. Waiver request to approve an early phase trial

In extremely rare circumstances, the CSR&D Director may approve an LOI for an early phase trial (e.g., studies examining first use in humans, safety, or dosing), provided safety data is available in at least two animal species. Early phase (Phase 0 and Phase 1) studies present particular challenges that Phase 2–4 trials do not present in terms of subject safety. Sufficient safety data should be presented as part of the LOI in order to justify approval because these studies are high risk projects that involve an unknown propensity for research-related injuries. Investigators proposing such studies must demonstrate that they and their study teams are experts in the particular subject area. Enrollment of non-Veterans may not be proposed in early phase trials. This waiver request should be described in a memorandum, addressed to the Director, CSR&D, signed by the ACOS/R, and submitted as an addendum to the LOI.

b. Waiver to exceed the Merit Review budget cap or maximum study duration

Rare exceptions to the budget cap and/or maximum study duration may be granted prior to application submission for fully justified and compelling circumstances. A detailed justification must be included in a written request for a waiver. Waiver requests must be submitted as an addendum to the LOI by the local Research & Development Office, and signed by the ACOS/R. For instructions on preparing/submitting a waiver request, refer to the document entitled "[Instructions for Preparing and Submitting a Waiver to Exceed Budget Caps.](#)"

c. Waiver request for enrollment of non-Veteran subjects

Enrollment in CSR&D trials is limited to Veterans, unless a waiver to enroll non-Veterans is approved by the CSR&D Director. The request for a non-Veteran enrollment waiver should be submitted as an addendum to the LOI and should provide sufficient justification for the enrollment of non-Veterans and still support relevance of the trial to the Veteran population. Information regarding this waiver request, including a template, [may be found on the CSR&D website.](#)

d. Waiver to request for supplementary funds in support of a planning meeting

A waiver request for supplementary funds (maximum \$20,000) will be accepted in order to provide support for a planning meeting related to approved study ideas. Attach an additional page detailing the proposal for the planning meeting to be held at the ORD offices in DC, including justification and membership of planning committee.

III. Submission of the LOI

CSR&D will review and respond to submitted LOIs at any time. Applicants are strongly encouraged to submit LOIs as early as possible.

LOIs must be e-mailed to CLIN-Review@va.gov by the local VA facility research office. Applicants may not submit LOIs directly to the mailbox.

LOIs with the following issues will be administratively withdrawn:

- Multiple submissions on behalf of the same PI
- LOIs lacking the requisite information
- LOIs not addressing the PPI initiative
- LOIs submitted by investigators that are not eligible to receive VA funding

IV. Approval

The LOI approval letter must be submitted with the full application package (in the Letters of Support attachment, o8b_VA_Letters.pdf). The LOI approval will allow the submission of up to three applications (“three strikes”), one new plus two resubmissions, unless the application is disapproved in peer review or other trial results suggest the idea has been examined elsewhere.

Effective: December 1, 2016