Clinical Science Research & Development (CSR&D)
Letter of Intent (LOI) Template for Clinical Trials

Principal Investigator (PI) Name:

Project Title:

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).

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 *(max 1500 characters)*

5. Scientific rationale and significance to the Veteran population *(max 1500 characters)*

6. If a proposed medication trial, do you already have an agreement with a company to receive the medication? Do you have a matched placebo? Describe how the medication will be obtained. Note: The quality of the agent/product should be consistent with FDA manufacturing standards. *(max 1500 characters)*

7. Background Data/Preliminary Studies conducted and supporting the application. Provide references for any published results. *(max 1500 characters)*

8. Sample Details. Describe the assumptions for sample size *(max 500 characters)*

9. Description of how the results will impact clinical practice and/or plans for further studies. Specifically, what will this trial lead to? *(max 1500 characters)*

10. Description of any anticipated problems or challenges regarding timely start up and execution (including whether the study will be FDA regulated and/or will require agreements with industry or other non-VA entity, patents/licensing, etc.) *(max 500 characters)*

11. Please address the following (**ALL** fill out Clinical Trial Study, Proof of Concept/Trial, fill out **both** sections):

Proof of Concept *(if applicable)*
Study Duration: _____ years
Number of subjects: _____

Clinical Trial Study Duration: _____ years
Number of subjects: _____
Number of VA sites: _____

Site City, State	Site PI
Site City, State	Site PI
Site City, State	Site PI
Site City, State	Site PI
Site City, State	Site PI

If proposing more than 5 VAMCs, please attach separate PDF with list of VA and Site PI. Biosketches for all site PIs required.

12. Description of the study category using FDA Phase Definitions (e.g., Phase 0, 1, 2, 3, or 4; http://clinicaltrials.gov/ct2/help/glossary/phase) *(max 500 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) that would satisfy the planned inclusion/exclusion criteria, 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?

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. Check if any of the following apply (and attach required waivers):

☐ Over the budget cap (e.g., for multi-site)
☐ Enrollment of non-Veterans

See Adobe Acrobat instructions for attaching files