

**Clinical Science Research & Development (CSR&D)
Letter of Intent (LOI) Template for Epidemiology Proposals**

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.

For both Observational and Descriptive studies, please complete questions 1-5.

1. Brief description of the objectives of the proposed study and the hypothesis to be tested
(max 500 characters)
2. Scientific rationale and significance to the Veteran population *(max 1500 characters)*
3. Background Data/Preliminary Studies conducted and supporting the application. Provide references for any published results *(max 1500 characters)*
4. Study design/statistical methods *(max 1500 characters)*

5. Data analysis plan (*max 1500 characters*)

For Observational Studies, please also complete questions 6-9

6. Please address the following:

Study Duration: years

Number of subjects:

Note: Descriptive (retrospective) studies are limited to a maximum of 2 years. Combined retrospective and prospective studies may be funded for a total of 4 years.

7. Sample Details. Include power analysis to justify the number of subjects. Describe the assumptions for sample size including effects size, event rates, or mean differences with standard deviations and expected drop-out rates. Specify the statistical methods used to calculate sample size. (*max 500 characters*)

8. Brief description of subject screening/recruitment methods and inclusion/exclusion criteria
(*max 1500 characters*)

9. 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*)