

Clinical Science Research & Development

Guidance for Submission of a Letter of Intent for an Epidemiology Merit Award

I. Introduction

The application process for a CSR&D Merit Review Epidemiology application begins with the preparation and submission of a Letter of Intent (LOI). The primary purpose of the LOI is to provide CSR&D with the opportunity **to determine if a proposed study will address a critically important disease that is prevalent in the Veteran population, and whether or not the proposed study fits within the CSR&D purview.**

Epidemiology applications typically fall within the purview of the Epidemiology Merit Review Panel (EPID). EPID includes traditional population-based epidemiology projects as well as projects in the clinical epidemiology discipline that focus on questions that arise in the clinic or at the hospital “bedside.” The proposed clinical topic would not be restricted by the specialty or subspecialty designation of a disease, but **must** address a health-related problem that is prevalent in the Veteran population.

II. Epidemiology Study Criteria

In CSR&D, an epidemiology application typically satisfies the following criteria:

- The unit of observation for the primary analysis of results is an intact human being (e.g., a Veteran in a health care facility or in the community);
- The research question being addressed involves the etiology, prevention, diagnosis, prognosis, therapy, or related aspects of health and disease;
- The type of epidemiological study is either:
 - observational (e.g., cohort, cross-sectional, or case-control studies) designed to test a specific hypothesis;
 - descriptive (e.g., examines the distribution of disease and possible determinants of disease in the Veteran population, and aims to suggest important risk or protective factors).
- 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.

In CSR&D, an epidemiology application would not include the following:

- Laboratory-based projects that focus on molecular or genetic testing (e.g., molecular epidemiology, with genotypes serving as the unit of analysis);
- Projects that focus on anatomic pathophysiological mechanisms of disease (e.g., at the tissue or organ level);
- Projects that focus on individual patients and not the Veteran population (e.g., clinical medicine);
- Projects that assess the delivery and outcomes of health care (e.g., issues related to quality of care, access, or cost);
- Randomized controlled trials.

If questions arise regarding whether a study meets the EPID criteria, investigators are encouraged to contact the EPID portfolio manager to discuss the proposal and to determine the most appropriate service.

III. LOI Approval Considerations

The following areas must be detailed in your LOI:

A. Focus:

A CSR&D Epidemiology LOI must:

- a.** Address a critically important exposure/disease that is prevalent in the Veteran population and that has translational potential for the improvement of the healthcare of Veterans;
- b.** Clearly define the type of epidemiological study being proposed (e.g., observational or descriptive).

B. Design:

A CSR&D Epidemiology LOI must:

- a.** Include an appropriate study design with a sufficient sample size (n) and statistical power;
- b.** Define the target Veteran population exposed to the factor/disease of interest, as well as a control population (except in a prospective cohort study where a single cohort is studied and analysis is on exposure status);
- c.** Describe in sufficient detail the significance tests to be used;
- d.** Demonstrate with sufficient evidence the feasibility of enrolling the target Veteran population (if a prospective observational study).

IV. Components of the LOI Submission

LOIs must be submitted using the following template. 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](#).

B. Completed LOI Template

The template is available on the CSR&D [webpage](#). 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 cannot access the intranet, please contact your local research office.

V. Submission of the LOI

CSR&D will review and respond to submitted LOIs at any time; however, an LOI must be submitted no later than **November 1** for proposals intended for submission to the Spring Merit Review cycle, and **May 1** for proposals intended for submission to the Fall Merit Review cycle. LOIs must be e-mailed to VHABLRD-CSR@va.gov by the local VA facility research office. Applicants may not upload LOIs directly to the mailbox. Questions relating to the LOI preparation and submission process may also be directed to VHABLRD-CSR@va.gov. **Applicants are strongly encouraged to submit LOIs as early as possible.**

LOIs with the following issues will be administratively withdrawn:

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

LOIs meeting all of the administrative requirements are subject to disapproval if:

- Lacking in innovation/impact or that do not address a clinically relevant disease prevalent in the Veteran population;
- Do not fall within the purview of CSR&D and/or research priority area;
- Are overly represented by ongoing ORD-funded studies.

VI. Approval

If an LOI for an epidemiology study is approved, the LOI approval letter must be submitted with the full application package (in the Letters of Support attachment, o8b_VA_Letters.pdf). **A submitted epidemiology proposal must not deviate significantly in specific aims from the original approved LOI. CSR&D may administratively withdraw from review any application that substantially deviates from what was described and approved at the LOI stage.**

An approved Epidemiology LOI is valid for a maximum of three (3) submissions of an application (initial submission and up to two resubmissions) during a period that encompasses four (4) **consecutive** review cycles following the initial approval of the LOI.

Effective: October 25, 2017