

Biomedical Laboratory Research and Development (BLRD) Clinical Sciences Research and Development (CSRD)

Guidance for Submission of a Letter of Intent for BLRD and CSRD Collaborative Merit Review Award (BCCMA)

I. Introduction

The application process for a BLRD and CSRD Collaborative Merit Review application begins with the preparation and submission of a Letter of Intent (LOI). **The primary purpose of the LOI is to provide BLRD and CSRD with the opportunity to determine if proposed studies will jointly address a critically important area of concern that is prevalent in the Veteran population; and whether or not the proposed studies fit within the BLRD and CSRD purview.**

In addition, submission of the LOI allows BLRD and CSRD the opportunity to access and provide feedback on the clinical and/or scientific focus and design of the collaborative merit reviews, the proposed innovations, and the overall impact on the veteran population.

II. BLRD and CSRD Collaborative Merit Definition

The purpose of the RFA is to invite applications for collaborative IO1 projects from multi-disciplinary teams to expand, improve, or transform the understanding of the etiology, pathogenesis, and/or genetics of suicidality, suicide prevention, post-traumatic epilepsy, post-traumatic stress disorder, traumatic brain injury, mental health conditions, rare head and neck cancers, pain, and opioid addiction. For a collaborative set of collaborative IO1s, each site has its own Program Director(s)/Principal Investigator(s), and the program provides a mechanism for cross-site coordination and communication. Collaborative studies are appropriate to address research questions beyond the capacity of a single-site investigation, particularly to accommodate collaborations among sites with diverse expertise, perspectives, and contributions.

An important goal of this RFA is to accelerate translational outcomes into clinical trials; however, observational/non-interventional studies that has the potential to develop into clinical trial may be proposed. The collaborative studies may consist of any combination of clinical (including trials) and/or preclinical studies across Biomedical Laboratory or Clinical Science Research Services (i.e. combinations of all Biomedical Laboratory, all Clinical Science, or a combination of the two Research and Development Services applications). One or more of the IO1 applications may be a clinical trial. Applications should be submitted to either the Biomedical Laboratory or Clinical Science Research and Development Services according to purview. The combination of collaborative merits by Service purview should be driven by the projects proposed and is at the discretion of the team of investigators.

At least 3 applications must be submitted as part of the collaborative research project. A shared Overall Research Strategy is required for the collaborative applications. Each research application is presented individually for scientific peer review; however, the BLRD and CSRD Collaborative Merit Review Award will also evaluate the applications for their potential to contribute more than the sum of the individual IO1's.

Only one LOI is required per group of collaborative IO1s. The letter of intent must use the following format BCCMA: Title. Titles may not exceed 200 characters in length, including the tag, BCCMA:, at the beginning of the title.

III. LOI Approval Considerations

The BLRD and CSRD Collaborative Merit Review LOI must:

- a. Fall within the BLRD and CSRD purviews.
- b. Address, expand, improve, or transform the understanding of the etiology, pathogenesis, and/or genetics of suicidality, suicide prevention, post-traumatic epilepsy, post-traumatic stress disorder, traumatic brain injury, mental health conditions, rare head and neck cancers, pain, and opioid addiction. The proposed overall project must have translational potential for the improvement of the healthcare of Veterans, or an individually tailored treatment that will directly improve the healthcare of Veterans.
- c. Have the potential to add to and improve the knowledge base in specific research areas.
- d. Provide BLRD and CSRD an opportunity to plan for appropriate resources that allow for an efficient and effective review process.

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 BLRD and CSRD [webpage \(Section IV, #5\)](#). Please clearly and succinctly address **all** of the requirements.

If one of the proposed projects is a clinical trial, in addition to the LOI template for the collaborative merit RFA, please also attach a completed clinical trial LOI. The template for the clinical trial LOI is also located on the BLRD and CSRD [webpage \(Section IV, #3\)](#).

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. **Note:** As this is an LOI for a proposed Collaborative Merit Review, the biosketch of all local site investigators must be attached. If a multi-site clinical trial is being proposed, all local site investigators' biosketches must be included also.

V. Submission of the LOI

BLRD and CSRD will review and respond to submitted LOIs at any time; however, an LOI must be submitted no later than the date specified in the RFA. LOIs must be e-mailed to VHABLRD-CSRDRD@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-CSRDRD@va.gov. **Applicants are strongly encouraged to submit LOIs as early as possible.**

LOIs with the following issues will be administratively withdrawn:

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

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

- a. Do not fall within the purview of BLRD and CSRD and/or research priority area;
- b. Lacks in innovation/impact or that do not address suicidality, suicide prevention, post-traumatic epilepsy, post-traumatic stress disorder, traumatic brain injury, mental health conditions, rare head and neck cancers, pain, and opioid addiction;
- c. Are overly represented by ongoing ORD-funded studies.

VI. Approval

The LOI approval letter must be submitted with the full application package (in the Letters of Support attachment, o8b_VA_Letters.pdf). **A submitted collaborative merit application must not deviate significantly in specific aims from the original approved clinical trial LOI. BLRD and CSRD may administratively withdraw from review any application that substantially deviates from what was described and approved at the LOI stage.**

An approved Collaborative Merit Review 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: June 2022