I. Introduction

The application process for a BLR&D 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 BLR&D 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 BLR&D purview.

In addition, submission of the LOI allows BLR&D 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. BLR&D Collaborative Merit Definition

The purpose of the RFA is to invite applications for collaborative I01 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 stress disorder, traumatic brain injury, pain, and opioid addiction. For a collaborative set of collaborative I01s, each site has its own Program Director(s)/Principal Investigators(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.

At least 3 applications must be submitted as part of the collaborative research application. A shared Overall Research Strategy is required for the linked applications.

III. LOI Approval Considerations

The BLR&D Drug Development Merit LOI must:

a. Fall within the BLR&D purview.

b. Address, expand, improve, or transform the understanding of the etiology, pathogenesis, and/or genetics of suicidality, suicide prevention, post-traumatic stress disorder, traumatic brain injury, 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. Address Department of Veterans Affairs (VA) investigator eligibility.
e. Provide BLR&D 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 BLR&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. Note: As this is an LOI for a proposed Collaborative Merit Review, the biosketch of all local site investigators must be attached.

V. Submission of the LOI

BLR&D will review and respond to submitted LOIs at any time; however, an LOI must be submitted no later than December 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 VHABL RD-CSRD@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 VHABL RD-CSRD@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 BLR&D and/or research priority area;
b. Lacks in innovation/impact or that do not address suicidality, suicide prevention, post-traumatic stress disorder, traumatic brain injury, 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, 08b_VA_Letters.pdf). A submitted clinical trial application must not deviate significantly in specific aims from the original approved clinical trial LOI. BLR&D 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: November 2017