

Biomedical Laboratory Research & Development (BLR&D)

Guidance for Submission of a Letter of Intent for a Drug and Therapeutic Development Merit Award

I. Introduction

The application process for a BLR&D Drug Development 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 Drug Development Merit Definition

The goal of this RFA is to accelerate translation of research from demonstration of efficacy *in vivo* to submission of an investigational new drug application (IND) to the FDA. To accomplish this mission, BLR&D will provide resources to support pharmacological and toxicological testing or manufacturing services for a lead agent.

In order to be eligible to submit this RFA, an investigator must have a validated target and at least one lead agent (or no more than 3 optimized lead agents for a target) with at least a pending patent. The lead agent must have the potential for commercial licensing and to be developed further for clinical use.

Lead agents include novel biologics, chemical or molecular therapeutics, imaging agents (i.e. chemotherapeutics, antibodies, contrast imaging agent, specialized nanoparticles etc.).

Applications to this RFA require strong preliminary data demonstrating mechanism of action, reproducibility, reliability, and sensitivity and specificity (effectiveness) of the lead agent for the target. Data should also demonstrate in relevant human tissue the target availability and distribution. Investigator should provide substantive data that supports the efficacy of the lead agent in humans from model systems. Further, applications should demonstrate an awareness of existing FDA guidelines and milestones supporting the conduct of preliminary studies and collection of data in support of an IND application.

Studies focused on target discovery, drug screens, new combinations or formulations of agents already in practice or already being tested (unless being combined with a new agent), prevention, studies on mechanism of action are not appropriate for this RFA.

III. LOI Approval Considerations

The BLR&D Drug Development Merit LOI must:

- a. Fall within the BLR&D purview.
- b. 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 for commercial licensing and to be developed further for clinical use.
- 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.

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 the date specified in the RFA. 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 who are not eligible to receive VA funding.

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

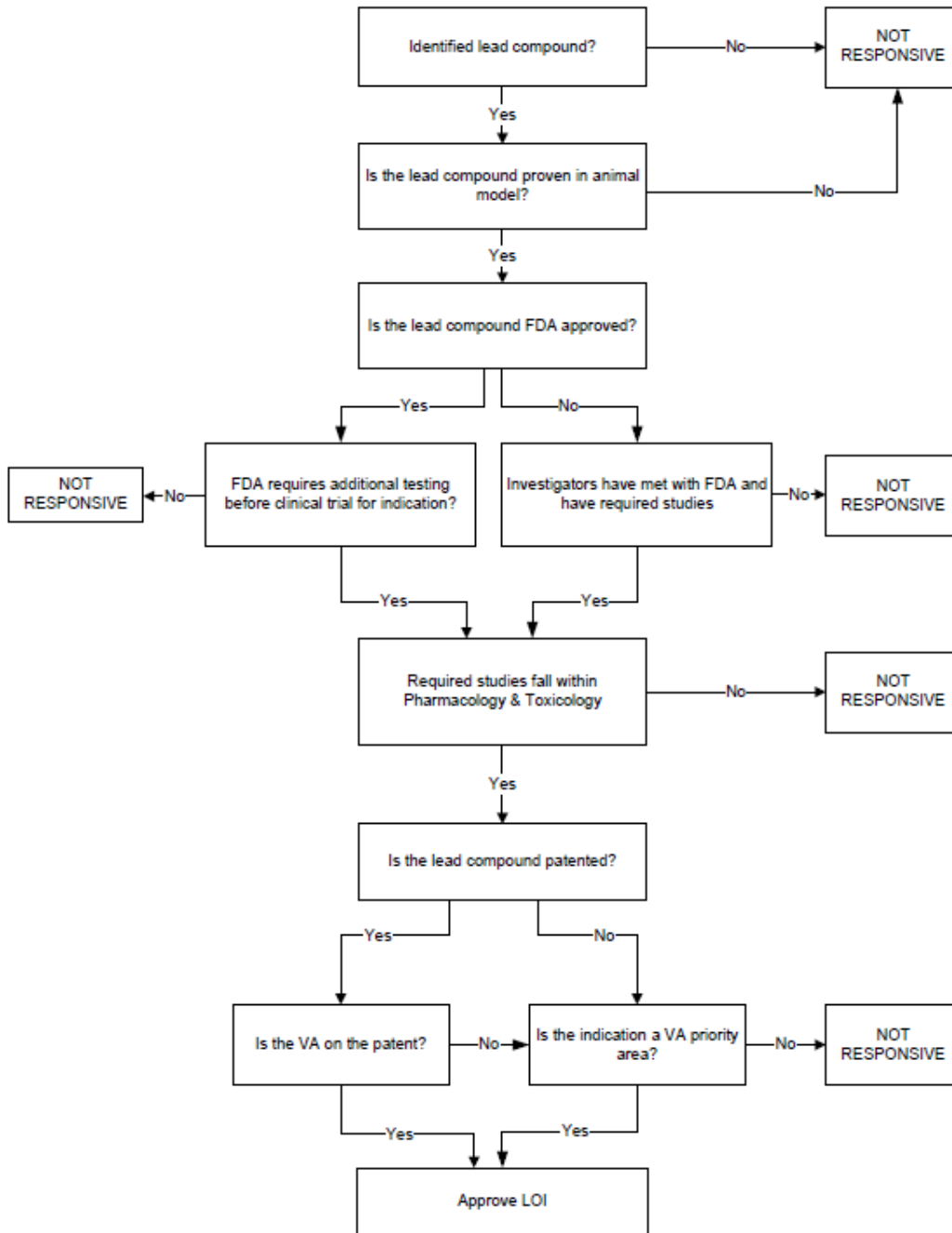
- Lacking in innovation/impact;
- Do not fall within the purview of BLR&D and/or research priority area;
- Are overly represented by ongoing ORD-funded studies;

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 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 drug development 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.

Decision Tree for BLRD Drug Development LOI



Effective: October 2018