

Biomedical Research & Development (BLRD)
**Letter of Intent (LOI) Template for Lead Isolation and Optimization and Pre-IND studies of Drugs and
Biologics Merit (I01) Applications**

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. Please submit references cited as separate PDF.

1. Brief description of the objectives of the project (*max 1000 characters*)

2. Scientific rationale for the selection of target/lead and its significance to clinical care of Veterans (*max 1500 characters*)

3. Background Data/Preliminary Studies conducted and supporting the validated target and lead agent(s) and availability of assays and support necessary to conduct the studies. Provide references in a separate document for any published results (*max 1500 characters*)

4. Describe patent, pending patent, discussions with the FDA, or any other information that would support moving the project along a pathway to an IND application or commercialization. If repurposing an already approved drug or therapeutic, justify collection of additional data beyond the drug Masterfile (*max 1500 characters*)

5. Describe the research design conceptual or clinical framework, procedures, and analyses to be used to accomplish the specific aims of the project, and milestones, time-line and Go/No-Go decision points (*max 1500 characters*)