Biomedical Laboratory Research & Development (BLRD)

Guidance for Submission of a Letter of Intent for a BLRD Data Science Merit Review Award

I. Introduction

The application process for a BLRD Data Science 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 with the opportunity to determine if proposed studies fit within the BLRD purview and meet the objective of the RFA to build a robust data science workforce in the VA intramural research program.

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

II. BLRD Data Science Merit Definition

The goal of this RFA is to support data science approaches to advance Veterans' health. To accomplish this goal, BLRD seeks to build a robust data science workforce in the VA intramural research program. This RFA will accept proposals to leverage VA data (including data from the Million Veteran Porgram [MVP]), apply Big Data science approaches, and develop cutting-edge big data analyses including but not limited to machine learning and/or deep learning algorithms developed for existing biomedical data, to advance knowledge of biological sciences and to promote Veterans' health.

This RFA is open to data scientists who do not have BLRD eligibility conferred based on BLRD eligibility committee review or clinician status. For the purposes of this RFA a data scientist is an individual with expertise in analysis and management of large datasets. Such individuals typically have the following qualifications:

- Having a Ph.D. or equivalent degree in Mathematics, Statistics, Computer Science, Informatics, Physics, or Engineering Disciplines, or
- Having experience and accomplishments demonstrating mastery of computational analytics
 of big data science and informatics approaches including modeling and artificial intelligence,
 as evidenced by post-graduate or post-doctoral training, and/or first-authored peer-reviewed
 publications.
- A PhD, MD or other terminal degree is required by ORD to serve as a principal investigator.

Applicants are encouraged to submit innovative projects that address fundamental research questions to help elucidate the biological underpinnings of diseases relevant to the health of Veterans, develop computational tools to facilitate analyses of research and clinical data, or to analyze existing research and clinical datasets to inform clinical practice and improve treatment outcomes. Research topics of specific interest to BLRD include (but are not limited to):

Harmonization or integration of existing clinical and biological data for future analyses.

- Meta-analysis of biological (e.g., -omics, genetic, physiological, molecular data, etc), phenotypical, or functional/behavioral data.
- Development of algorithms for data visualization or application of big data analytics (e.g., artificial intelligence and machine learning techniques)
 - o to understand fundamental questions in biology and human disease.
 - o to develop biomarkers or therapeutics.
 - o to analyze and classify digital health data (e.g., pathology slices, imaging data, electrophysiologic recordings, EHR data, etc..) and functional/behavioral data.
 - to create predictive models to support clinical decision making, identify risk factors, or design clinical trials

Applications that are not responsive to this RFA will not be reviewed. Applications that are not responsive include:

- Development of mathematical or engineering approaches, models, or algorithms that do not have a clear clinical focus or do not include a clear applicable plan to solving problems with clinical or biological datasets or addressing specific problems of Veterans.
- Applications focused solely on the creation of digital images, development of infrastructure, curating, and cataloging of data.
- Applications that involve wet lab data generation or human subject recruitment.
- Applications that involve studies of human fetal tissue.

Applications that seek to administer surveys or questionnaires (e.g. new clinical data collection) or perform medical procedures and treatments (including biopsies) or observational studies are outside of BLRD purview and should be submitted to other R&D Services as appropriate.

III. LOI Approval Considerations

The BLRD Data Science Merit Review LOI must:

- a. Fall within the BLRD purview.
- b. Apply big data science approaches to advance Veterans' health. The proposed overall project should have translational potential for the improvement of the healthcare of Veterans.
- c. Have the potential to add to and improve the knowledge base in specific research areas.
- d. Provide information that the PI has the qualifications to conduct big data science research.

IV. Components of the LOI Submission

Only one LOI is required for the project. The 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 <u>forms page of the VA Research website</u>.

B. Completed LOI Template

The template is available on the BLRD <u>webpage</u>. Please clearly and succinctly address all of the requirements.

C. Pl's Biographical Sketch

The biographical sketch template is available on the <u>VA Research Intranet</u>. If you cannot access the intranet, please contact your local research office.

V. Submission of the LOI

BLRD 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-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 VHABLRD-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 BLRD and/or the scope of the RFA;
- b. Lacks innovation/impact or that do not address topics of interest for BLRD;
- c. Are overly represented by ongoing ORD-funded studies;
- d. PI has current BLRD funding or is eligible to apply to other BLRD RFAs.

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 Data Science merit application must not deviate significantly in specific aims from the original approved LOI. BLRD may administratively withdraw from review any application that substantially deviates from what was described and approved at the LOI stage.

An approved Data Science 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: March 2021