

Department of Veterans Affairs

Guidance for Submitting Career Development Enhancement Award Letter of Intent (LOI) to BLR&D Service

Updated February 2018

This guidance document supplements and supports VHA Handbook 1200.4-- Research Career Development Program and, wherein the Handbook describes policy this Guidance provides Biomedical Laboratory Research and Development (BLR&D) and Clinical Science Research and Development (CSR&D) Services implementation in accordance with Paragraph 1 of the Handbook, and does not apply to RRD and HSRD.

I. INTRODUCTION

The process for a Career Development Enhancement Award (CDEA) begins with a Letter of Intent (LOI). Prior to the submission of an LOI to BLR&D or CSR&D, nominees should review VHA Handbook 1200.4--Research Career Development Program and this Guidance for Submitting CDEA LOI to BLR&D or CSR&D, and work closely with their local VA Research and Development office to ensure compliance with eligibility, other BLR&D/CSR&D requirements, and to prepare the LOI. Consistent with the Office of Research & Development's (ORD) overall mission (*i.e., to discover knowledge, develop VA researchers and health care leaders, and create innovations that advance health care for our Veterans and the nation*) nominees should review the scientific purview of BLR&D and CSR&D to ensure that the subject area of the LOI is consistent with the purview outlined below and that the research falls within an appropriate area.

BLR&D Purview

BLR&D funds preclinical, biomedical, and behavioral studies of disorders and diseases of importance to the health of Veterans. The BLR&D purview includes *in vitro* and *in vivo* studies using tissue cultures, animal models, or human biological samples collected using minimally invasive procedures (e.g., blood, urine, buccal swabs) or from tissues acquired without direct contact with subjects (e.g., from tissue banks or pathology material; the VA will not fund studies of human fetal tissue) and analysis of big data such as those collected through the Million Veteran Program (MVP). MVP or other big data studies should significantly advance discoveries related to genetic risk factors of the diseases and/or conditions and the disease-associated molecular pathways, as well as discovery of pharmacogenomic markers, utilizing the large sample sizes for either discovery or replication studies. Studies should be designed to (1) identify and confirm clinically relevant biomarkers as diagnostic, prognostic, and therapeutic indicators in diseases/disorders relevant to Veterans or (2) develop innovative analytical strategies/tools for defining genome-wide association (GWA) of genotypes and phenotypes, gene-gene interactions, gene networks, gene-by-environment interactions and complex molecular pathways. Studies that seek to administer surveys or questionnaires (e.g., new clinical data collection), or perform medical procedures and treatments (including biopsies) or observational studies should be submitted to the Clinical Sciences R&D Service (CSR&D). Priority research areas of specific interest to BLR&D include (but are not limited to):

- Posttraumatic stress disorder
- Traumatic brain injury
- Suicide prevention research (with emphasis on biological markers)
- Opioid addiction and other substance abuse (e.g., smoking, alcohol)
- Service-related illnesses or injuries
- Women Veterans' health
- Genomic and personalized/precision medicine
- Pain
- Parkinson's disease, Epilepsy, Amyotrophic Lateral Sclerosis, and Multiple Sclerosis
- Illnesses of aging Veterans

CSR&D Purview

CSR&D funds clinical, behavioral, and epidemiological research on disorders and diseases of importance to the health of Veterans. Studies supported include experimental and observational studies involving human subjects for research purposes. Studies involving administration of survey instruments or questionnaires, the collection of medical histories from research subjects and/or performing medical procedures (including imaging studies or surgical biopsies), treatment regimens, or interventional trials are supported by CSR&D. CSR&D research priorities for MVP or similar big data should focus on projects that will potentially lead to better effectiveness underlying therapeutic approaches (e.g., studies on validation of pharmacogenomics markers), and clinical epidemiology. Proposals to CSR&D must have a focus on potential application to advancing treatment based upon genetic understanding and must be differentiated from other ongoing MVP studies. Examples of priority research areas of specific interest to CSR&D include focus on:

- Post-deployment-related, military service-related, and Veteran-related behavioral, psychiatric, and cognitive disorders
- Posttraumatic stress disorder including commonly occurring co-morbidities
- Suicide prevention research
- Prevention/reduction in health-risk behaviors (e.g., substance abuse, addictive disorders)
- Women Veterans' health
- Pain mechanisms focused on treatment questions that have potential to advance care and to reduce opioid use
- Diseases with a high health care burden in the Veteran population, including precision medicine studies especially focused on individual treatment response

II. CDEA GOALS

The CDEA is an intramural funding mechanism designed to support established funded VA Merit Review researchers to pursue creative, innovative, and impactful research activities and/or to acquire specific skills that will significantly augment the investigator's research program and enhance the scope of VA research.

The CDEA provides funding for one-half the salary plus associated benefits to support a mentored program of research and acquisition of new knowledge and/or skills. The CDEA provides a maximum of six (6) months' salary support for sabbatical time, including fringe benefits, provided the established investigator has secured educational leave from their local VA Medical Center (VAMC). This award may be leveraged with funds from the local VAMC to provide the nominee with the opportunity for up to one (1) year of leave. In such instances where the established VA researcher's salary is supported by medical service the medical center must provide one-half of the total salary, including fringe benefits, for the entire period of the CDEA. Both clinical and non-clinical established VA researchers may gain mentored research time intended to significantly advance the awardee's research program, knowledge, skills, and career. All of the awardee's effort (i.e., VA effort) must be devoted to research during the CDEA. Additionally, the awardee must be released from all administrative responsibilities during the award, and there is no change in the nominee's original appointment with the approval of a CDEA.

Implicit in all Career Development Awards is the understanding that the nominee plans to continue their VA research career and that the new knowledge and/or skills will be used to promote future innovations in VA-sponsored research projects and contribute to the overall research capacity at the local VAMC.

III. SUBMISSION AND DEADLINES

LOIs submitted to BLR&D and CSR&D are due by **May 1** or **November 1**, and must be submitted to the Career Development mailbox: vhacadereview@va.gov.

A. APPLICANTS

Citizenship

All applicants must be US citizens eligible for VA employment; the CDEA LOI **must** include a completed and signed copy of the CDA Citizenship Certification certifying that the nominee is a US citizen.

B. Eligibility

The CDEA award is intended for currently or recently funded Merit Review established clinician and non-clinician investigators who are advanced in their independent research careers with a record of funded, creative, innovative, and scientifically significant work, and who are interested in acquiring new knowledge and/or research skills to further innovate their research programs directed at improving the health of Veterans.

Nominees for the CDEA must (1) have completed at least 8 years of Merit Review funding, (2) have a current Merit Review Award from BLR&D/CSR&D **or** within six (6) months of completing a Merit Review Award in which they were the original principal investigator and currently seeking VA Merit Review funding.

C. Required Documentation

For all nominees, (1) a letter from the local VAMC Human Resource Management (HRM) office must be provided indicating that the nominee is currently employed by the VAMC. The letter must indicate whether the nominee was granted educational leave

by the VAMC and the duration of the leave must be clearly stated; (2) letter of support from the Associate Chief of Staff for Research (ACOS) describing how the knowledge and/or skills to be acquired by the nominee will impact the research program at the local station; whether the nominee's proposed research plan was approved by the R&D Committee; whether adequate plans were developed to cover the nominee's research and research-related responsibilities during their absence, etc.; (3) letter from the Medical Center Director (and Chief of Staff for clinicians) documenting their commitment and approval for the nominee to pursue the objectives of the CDEA (the Chief of Staff must fully assess the impact of the nominee's absence on the respective clinical service and needs of the medical center); (4) letter from the sponsoring mentor(s) and/or co-mentor(s) detailing the available resources that will be devoted to the nominee's project, commitment in helping the nominee to achieve their stated objectives and goals, and evidence of a well-established research program related to the nominee's area of interest.

IV. MENTORING AND TRAINING

A stronger CDEA LOI will contain the following details concerning the training plan and involvement of the sponsoring mentor(s).

- Identification of at least one highly successful named sponsoring mentor with a proven track record of research and knowledge in the area, methodology, technology, or skills to be acquired, as it relates to the research proposed and evidenced by funding and publications;
- A clear description of the mentor's and/or co-mentor's expertise, established funded research program, including description of a strong record of publication and mentorship;
- A description of the mentor's commitment to the nominee's training, particularly as it relates to how these new skills will augment the nominee's current or future research projects; how the mentor will support the nominee's training by providing access to the necessary resources (e.g., reagents, equipment, technology, etc.);
- A description of the training activities designed to reach the objectives within the proposed time frame of the award;
- A detailed description of the nature and frequency of the interaction between the mentor and nominee throughout the duration of the award;
- A description of the facilities and resources that will support the nominee's training program; specify whether the space is in a VA or non-VA facility

V. RESEARCH DESIGN

It is the nominee's responsibility to demonstrate the need for protected time. A clear explanation of how the new knowledge and/or skills will enhance/expand the scope of the nominee's current Merit Review program or significantly contribute to advancing the findings from a current award for a future Merit Review application should be included.

Nominees should outline their plan to acquire the new knowledge and/or skills including a timeline for each objective. The objectives, aims, and significance of the research to advance health care for Veterans should be clearly stated. A description of any new knowledge and/or enhanced research-specific skills to be acquired during the award period and how these skills and experiences will enhance/expand the nominee's ability to continue their research program or advance the findings from a current award for a future Merit Review application and contribute to VA overall research capacity should be clearly articulated. A description of the facilities and resources to support the nominee's training should be provided. The nominee should describe (1) the nature of the work to be performed during the award and (2) how the facilities and resources will facilitate completion of the proposed work and/or acquisition of new knowledge and/or skills.

The nominee should provide a plan that clearly details how their current administrative (if applicable), research, and/or other responsibilities (e.g., clinical or other educational responsibilities) will be managed in their absence.

VI. BIOGRAPHICAL SKETCH FOR APPLICANT AND EACH SPONSORING MENTOR

In addition to highlighting only the most recent publications, presentations, and activities relevant to the proposed research activities, all current, previous (awards ending within the past 4 years), and pending research support should be included. Also, include the role in the award, title of the award, supporting agency, performance period, and level of funding for each award (e.g., direct costs only).

VII. RESEARCH PERFORMANCE SITE

The CDEA is intended to provide the nominee protected time to pursue new knowledge and/or skills that are not available at their local VAMC or university affiliate. Therefore, CDEA activities may not be performed in the nominee's laboratory (either at the VAMC or affiliate) during the award period. The proposed work must be performed in the sponsoring mentor's laboratory or institution. The use of other VAMCs with strong research programs and/or their affiliates is encouraged.

If the work proposed will be conducted outside a VA facility prior approval must be obtained from the appropriate Service Director. Requests for exceptions should be requested, in writing, at the time of the LOI submission in the form of a memorandum addressed to the appropriate Service Director.

VIII. LOI REVISIONS, CHANGES, AND PERMISSIONS

Successful nominees of the CDEA are expected to begin their award within six (6) months of the notification letter of approval. If an awardee fails to commence the award within the six (6) months period, the award will be rescinded. If a nominee anticipates that they will not be able to commence their award within six (6) months after notification of approval, a full justification must be provided in the form of a letter to the BLR&D or CSR&D Service Director. Approvals of LOIs, revocation of awards, or waiver of extension are at the discretion of the Service Director.

If the LOI was disapproved a new LOI may not be resubmitted until after 12 months have elapsed.

IX. REQUESTS FOR ADDITIONAL GUIDANCE

If a nominee requires additional guidance in the preparation of a CDEA LOI, the nominee should communicate with their ACOS, who will contact the BLR&D and CSR&D Program Manager for the Career Development Program for additional guidance. While nominees may contact the Program Manager directly to discuss their work, it is preferred they include their ACOS/R in such discussions.

Upon receipt, LOIs will be checked for completeness. LOIs that are incomplete or late will not be reviewed.