



Discovery



Innovation



Advancement

Guidance for Submitting Career Development Letter of Intent **BLR&D and CSR&D Services**



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Veterans | Health Administration
Research & Development

Improving Veterans' Lives  www.research.va.gov

CDA-2 Goal

Veterans Health
Administration



www.research.va.gov

Overall program goal is to ensure a strong and stable capacity of VA scientists to address the health care needs of America's Veterans



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Key Areas of Review

- Eligibility
- Meets BLR&D or CSR&D purview
- VA mentors with research program (funding, pubs) appropriate expertise, involvement in the proposed research
- Applicant proposed project is distinct from mentor(s) and there is a path to independence (Veteran-centric, innovation, impact)
- Proposed training and career plans

Submission & Deadlines

- LOIs are due by May 1st or November 1st
- An approved LOI allows a maximum of 3 submissions (within 4 cycles)
- An applicant is allowed one approved LOI for their entire career
- Once an LOI is approved, the applicant may NOT renew, extend or submit a new LOI

Eligibility

- All applicants must be U.S. citizens
- An LOI **MUST** include a signed copy of the Citizenship Certification (do not attach other documents)
- For all applicants, a letter from the local VA Human Resources Management must be provided
- VA-appointment is not required to submit an LOI or CDA-2 application, however, a VA-paid appointment must be obtained before funds are released

Eligibility

- **NON-CLINICIANS:** No more than 5 years beyond receipt of terminal degree (e.g. PhD)
- **CLINICIANS:** No more than 5 years past last clinical training (e.g. residency clinical fellowship) **AND** no more than 10 years past receipt of MD (or PhD for clinical psychologists) degree
- Applicants need to have at least one senior-authored publication (e.g. first or last author depending on scientific field)
- **NOTE:** More successful applicants in BLR&D/CSR&D in the peer review have 2-3 senior authored manuscripts, as well as postdoctoral or research fellowship experience

Requirements for VA Research Appointment and Salary

- Salary on awards is shared between research and clinical care

If applying as a Clinician:

- A minimum of 6/8 VA appointment is required
- A letter from the Medical Center Director in the LOI application must also include a commitment to provide a VA-paid clinical appointment at the end of the CDA-2 award

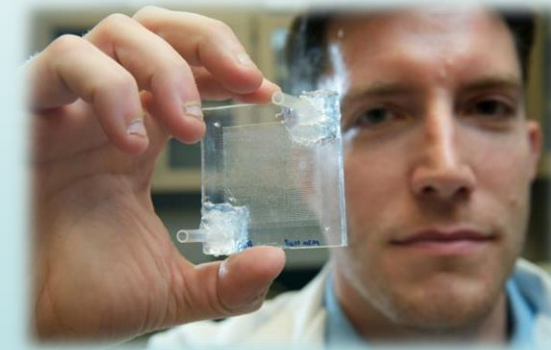
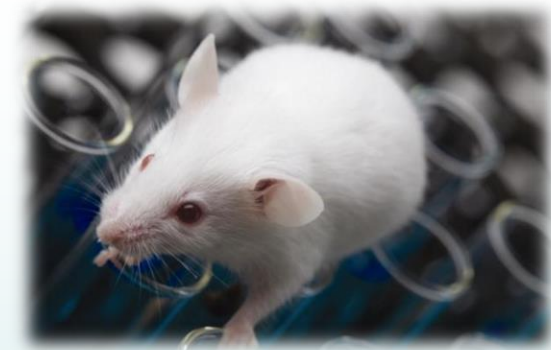
Requirements for VA Research Appointment and Salary

If applying as a Non-clinician:

- Applicant may request an 8/8ths VA appointment for 12 months of salary support devoted to CDA-2
- If the applicant request less than 8/8ths VA appointment, any additional non-VA support requires submission of a Memorandum of Understanding (MoU)

Biomedical Laboratory Research & Development

BLR&D supports pre-clinical research: *in vitro* and *in vivo* studies using tissue cultures, animal models, or human biological samples collected using minimally invasive procedures (blood, urine, buccal swabs) or from tissues acquired without direct contact with subjects (e.g., from tissue banks or pathology material).



Clinical Science Research & Development

Veterans Health
Administration



www.research.va.gov

CSR&D supports clinical, behavioral, and epidemiological research: experimental and observational studies involving human subjects, including applications 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) or treatment regimens.



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Criteria for Mentorship

- At least one mentor who is a funded VA investigator with an established research program
- VA-mentor must have a defined role in both the research and training proposed, and committed to supporting the development of the applicant towards independence
- If VA mentor does not have prior mentoring experience, a co-mentor with a successful history should be included with appropriate expertise

Successful applications have a mentoring team that includes a VA-funded investigator with expertise and involvement in the proposed research project

Criteria for Mentorship

- Applicants are strongly advised to seek mentor(s) located within their local VAMC and/or local affiliate
- If mentor outside the local VAMC is proposed and not in compliance with the Federal definition of local travel then a full justification must be provided to the Service Director and attached to the LOI
- The justification should also explain why the mentor outside the local and/or affiliate is critical to the trainees' development and research project

Applicant Training Plan

At the level of the LOI submission we are looking for a very brief preview of the training plan – make it concise, but there should be clarity:

Didactic coursework

Workshops

Seminars

Specialized training



Research Plan

At the level of the LOI:

- Research should be in an area of interest to the applicant with relevance to Veterans (disease or condition focused)
- Proposed research should be distinct from that of the mentor(s); demonstrate clear path to independence
- Does the research fill important gaps; hypothesis driven, logical reasoning; demonstrate access to Veteran population or relevant specimen/samples
- Portfolio/programmatic composition



NEW for 2018: Big data analytics applications

- **Propose to use large datasets like MVP or VINCI etc. (or others outside VA)**
- **Proposed studies should be designed to do one or more of the following:**
 - Facilitate integration of genomic, epigenetic and proteomic data with clinical and other health information to understand disease
 - identify and confirm clinically relevant biomarkers as diagnostic, prognostic and therapeutic indicators in Veteran-relevant disorders /diseases
 - Develop innovative analytical strategies/tools for GWAS; GxG; GxE; gene-gene networks and/or complex molecular pathways

<https://vaww.genisis.med.va.gov/genhub/rfa?>

NEW: Big data analytics applications

- **Big data is interdisciplinary in nature—please ensure your mentorship team reflects the following**
- **Mentor(s) with experience with large cohort data in addition to genomics and/or bioinformatics or other big data analytics**
- **Ex: IF access to CDW is part of the application, a member of the mentoring team should have experience working with CDW.**



Research Plan

- Stronger applications will be those evaluated as opening new directions in the research area (innovation and impact)
- It is expected that results from studies conducted through the CDA-2 will provide scientific rationale for an innovative hypothesis for new investigations in a future Merit Review application



CDA-2 Clinical Trials

- CSR&D supports submission of only Phases II and III clinical trials as part of the CDA-2 program when the proposed trial is the only focus of the application
- If the research proposed is a clinical trial, the applicant must follow the CSR&D CDA Clinical Trial LOI instructions
- Typically involve human subject randomization and appropriate controls designed to assess the potential safety and/or effectiveness of an intervention
- Intervention may involve the use of pharmaceutical compounds or agents, treatments, or devices

CDA-2 Clinical Trials

- Applications require the enrollment of Veteran subjects and use of Veteran samples/tissues
- Must demonstrate access to population, sample size and statistical power
- IND or IDE is required where applicable



CDA-2 Clinical Trials

Considered NOT to be clinical trials:

- Assessment of diagnostics by experiments designed to show equivalence of test results with those of existing diagnostic devices or methods
- Studies focused on mechanisms underlying an intervention that do not contain a primary clinical outcome measure of interest

Questions about CDA-2 clinical trials may be directed to CLIN-Review@va.gov



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Biographical Sketch for Applicant and Mentor(s)

- Highlight only the most recent publications, presentations, and activities relevant to the proposal; all current, previous (awards ending within the past 4 years) and pending research support
- Include the role, title, supporting agency, performance period and level of funding for each award



Biographical Sketch for Applicant and Mentor(s)

MENTORS ONLY:

- Using a table format, list all CDA-2 awardees, if any, for which the mentor previously served or currently serves as mentor, co-mentor, or collaborator
- Indicate whether the awardee transitioned to independence (e.g. obtaining independent research grants and/or advancement in their academic position and highlight any VA CDA-2 awardees

Research Performance Site

- CDA-2 awardees may NOT establish an independent off-site laboratory
- At the minimum, some of the proposed work must be performed in the VA mentor's research space at the VAMC
- If VA mentor's laboratory is not located at the VAMC, the mentor must have an approved Off-site waiver
- Off-site waivers are not required for work performed on a CDA-2 award in an off-site mentor's laboratory

LOI Revisions, Title Changes and Permissions

- Title changes for resubmitted applications do not need prior approval or submission or a revised LOI, provided that the application remains within the scope of work proposed in the approved LOI
- After an LOI is approved and prior to any submissions, if a change in mentor(s) becomes necessary, the applicant must obtain approval for the new mentor(s) from the BLR&D or CSR&D Director

LOI Revisions, Title Changes and Permissions

- An applicant is only allowed one approved LOI
- A copy of the approved LOI letter (including revised) must be included in the application
- If a change in the scope of work will be proposed, a revised LOI must be submitted via the regular LOI submission process; approval of the revised LOI will not change the original expiration date of approval or number of submissions remaining on the original LOI

For more information

- CDA-2 LOI submissions and any other related questions should be sent to the BLR&D and CSR&D Career Development mailbox:
Vhacadereview@va.gov
- Contact a Portfolio Manager
 - http://www.research.va.gov/services/shared_docs/contacts.cfm
- VA ORD Career Development Program
 - <http://www.research.va.gov/funding/cdp.cfm>
- Please see the ORD website for additional information
 - www.research.va.gov/