
DEPARTMENT OF VETERANS AFFAIRS

OFFICE OF RESEARCH & DEVELOPMENT

PROGRAM GUIDE 1202.01:

# BIOMEDICAL LABORATORY AND CLINICAL SCIENCE RESEARCH AND DEVELOPMENT SERVICES

MERIT REVIEW AWARD PROGRAM



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## BIOMEDICAL LABORATORY AND CLINICAL SCIENCE RESEARCH AND DEVELOPMENT MERIT REVIEW PROGRAM

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# BIOMEDICAL LABORATORY RESEARCH AND DEVELOPMENT (BLR&D) AND CLINICAL SCIENCE RESEARCH AND DEVELOPMENT (CSR&D) SERVICES MERIT REVIEW AWARD PROGRAM PROCESS

## 1. PURPOSE

This is a revised Veterans Health Administration (VHA) Program Guide, which establishes procedures for the submission, review, and acceptance of Merit Review Award Program for the Biomedical Laboratory Research and Development (BLR&D) and Clinical Science Research and Development (CSR&D) Services of the Office of Research and Development (ORD). This Program Guide describes the program as well as guidance and instructions for applications.

## 2. BACKGROUND

a. The Merit Review Award Program is an intramural funding mechanism to support investigator-initiated research conducted by eligible Department of Veterans Affairs (VA) investigators at VA medical centers or VA-approved sites. This program is BLR&D and CSR&D's principal mechanism for funding basic, preclinical biomedical and behavioral studies, as well as clinical studies of disorders and diseases of importance to the health of Veterans. It is the goal of BLR&D and CSR&D to fund only applications that propose research that is scientifically meritorious and relevant to the health of Veterans.

(1) The BLR&D purview includes laboratory studies, both *in vitro* and *in vivo*, including tissue culture, animal models, and studies on human biological samples. Proposals involving procedures for obtaining biological specimens from human subjects such as drawing blood, collecting urine, and performing a buccal swab are appropriate for BLR&D. Discovery research involving -omic data, including related phenotypic data in studies of genetic risk factors, pathophysiological pathways, treatment target identification, and biomarker discovery are also within BLR&D purview.

(2) The CSR&D purview includes interventional, experimental, and observational studies involving human subjects. Proposals involving collection of prospective medical histories, administering survey instruments or questionnaires, or performing medical procedures (including biopsies) or treatment regimens are appropriate for CSR&D. It is expected that applications will describe the feasibility of enrolling Veterans to meet study goals, and that inclusion of non-Veterans will be rarely considered.

The purview of each funding opportunity is specified in the associated Request for Applications (RFA) document. Applications must fit the purview of the RFA they are responding to.

b. Proposals submitted to BLR&D and CSR&D are peer-reviewed by subcommittees of the Joint Biomedical Laboratory Research and Development and Clinical Science Research and Development Scientific Merit Review Board which provide the Directors of BLR&D and CSR&D with evaluations of the quality of the research proposed and recommendations on scientific merit, budgets, and funding durations.

**3. SCOPE**

a. Merit Review funding is intended to support research by fully trained independent VA investigators, who apply through the VA research office at their local medical center, to specific Requests for Applications (RFAs), and who are:

(1) Fully trained - The principal investigator (PI) on a Merit Review award must be competent to develop and direct a research project; and

(2) Independent - Evidence of independent research includes previous training or experience in research and research productivity as demonstrated by attaining independent research grant support or referred publications, especially first or senior author publications in the field of the proposed research.

b. Merit Review guidelines may also be applicable to special initiatives and requests for applications (RFAs). *Note: Specific information about a special program or initiative is contained in the program announcement or RFA.*

*Note: The Merit Review award is not intended to be the only source of support for VA investigators. The PI is encouraged to seek additional funding from other Office of Research and Development (ORD) Services, other agencies of the Federal Government, and other public and private funding sources.*

(1) All research involving human subjects must comply with all Federal regulations and VA requirements that address the protection of human subjects. The Common Rule is codified by the Department of Veterans Affairs at 38 CFR part 16, and by the Department of Health and Human Services (HHS) at 45 CFR part 46, Subpart A, and VHA Directive 1200.05, Requirements for the Protection of Human Subjects in Research.

(2) All clinical interventional proposals submitted to CSR&D must contain a data and safety monitoring plan which may include:

(a) Use of the CSR&D Data Monitoring Committee (DMC). The DMC is an independent advisory group to the Director, CSR&D. It is primarily responsible for safeguarding the interests of study participants, assessing the safety and efficacy of trial interventions, and monitoring the progress of a study. For each study, the DMC Charter should address the following:

1. Purpose and Responsibilities of the DMC including the timeframe for conducting reviews and monitoring enrollment.

2. DMC Organization including membership and staffing.

3. Communications including documentation for scheduled meetings.

(b) A description of what information and documents will be submitted to the DMC. The information collected should be based on the level of risk and at minimum contain:

1. Conflict of Interest (COI) including procedures for member declaration of existing or new COI.

2. Scheduling, Quorum, and Organization of Meetings including requirements and expectations for members.

3. Materials and Procedures for DMC meetings including recurring data review (Adverse Event, Serious Adverse Event, Unexpected Problems, graphed actual enrollment versus projected, recruitment and retention, and statistical analysis of study progression), and meeting procedures for open and closed sessions.

4. Reporting Requirements of the DMC including recommendations (unconditional or conditional approval, probation, or termination) and meeting minutes.

5. Reports of DMC meetings including contents of open and closed sessions.

6. Safety plan for the study provided by PI.

## 4. MERIT REVIEW AWARD PROCESS

a. Eligibility to Submit a Merit Review Proposal. Determinations regarding eligibility are made by individual services within ORD.

(1) Merit Review is an intramural program and only funds research conducted by VA investigators at VA medical centers or VA-approved sites. Each proposal must have a PI who holds a M.D., Ph.D., or equivalent doctoral degree in medical, biological, or behavioral sciences. *NOTE: Eligibility to submit proposals to other ORD services, i.e., Health Services Research and Development (HSR&D), Rehabilitation Research and Development (RR&D), does not automatically confer eligibility to submit a Merit Review proposal to BLR&D or CSR&D Services.*

(2) To be eligible to submit Merit Review proposals to BLR&D or CSR&D Services, the PI must have at least a 5/8ths time VA appointment at the time the Merit Review is funded.

(3) In addition, all new non-clinician PIs must be accepted into the BLR&D intramural research program. For purposes of eligibility, a clinician is defined as a licensed practitioner with a doctoral degree (M.D., D.O., D.D.S., etc.) who will treat patients at a VA Medical Center (VAMC) at the time of award. All others are considered non-clinicians. Guidance for requesting acceptance (eligibility) for non-clinician scientists is located on the BLR&D/CSR&D Merit Review Program page at http://www.research.va.gov/services/shared_docs/merit_review.cfm.

General acceptance into the BLR&D non-clinician intramural research program is granted for three years. Additionally, the Principal Investigator of a current BLR&D Merit Award, a BLR&D Research Career Scientist (RCS) or a Senior RCS is considered eligible, and for three years beyond the end date of either the Merit Review Award(s) or RCS term.

b. Location of Laboratory. It is expected that the PI and VA co-investigators will perform all of the funded research in VA space or VA leased space. If a PI or VA co-investigator occupies laboratory space at any other location(s), a waiver to perform the research off-site must be obtained for that investigator (see VHA Program Guide 1200.16).

(1) The use of an off-site core facility or collaborator's laboratory does not require an off-site waiver, unless the VA investigator is a core director.

(2) Although the use of VA-leased space does not require an off-site waiver, ORD must approve a plan for local VA oversight of the research activities performed in VA-leased space (see VHA Program Guide 1200.16).

c. Merit Review Applications. Instructions for submitting a Merit Review proposal are described in the applicable program announcement or RFA.

(1) The proposal submission guidelines for a specific program announcement or RFA include the maximum budget that may be requested each year and the maximum number of years of funding that may be requested.

(2) A proposal submitted to BLR&D and CSR&D may not be submitted simultaneously to any other ORD research service (i.e., RR&D, HSR&D, or CSP).

(3) Proposals that fail to meet BLR&D and CSR&D submission requirements as described in this Program Guide and in the specific RFA may be administratively withdrawn without review.

(4) Unless requested by the Program Review staff, no additional or replacement information will be accepted after submission of the proposal; the only exception is an

official letter(s) of acceptance for publication of a manuscript(s) authored by the PI. *NOTE: This(ese) may be sent to the Merit Review Program Manager at any time.*

d. Proposal Review. Subcommittees of the Joint Biomedical Laboratory Research and Development and Clinical Science Research and Development Scientific Merit Review Board evaluate Merit Review proposals. Subject matter experts review all Merit Review applications for scientific quality. Investigators may request committee assignments, but final committee and reviewer assignments are made by BLR&D and CSR&D staff. If a Merit Review Subcommittee expresses serious concerns about the procedures described for human or animal studies, biosafety, or administrative or budgetary issues, a “hold” is placed on the application. If the hold is placed for human, animal, or biosafety issues, the work described in the application may not be initiated until the hold is lifted, regardless of whether the work is funded or not. If the study is underway, all work must stop until the hold is lifted. The concerns must be appropriately addressed before the hold is lifted.

e. Funding Merit Review Proposals. Recommendations, as the result of the scientific merit review process, are made to the Directors of BLR&D and CSR&D Services. Final funding decisions are made by the Directors based on these recommendations, as well as programmatic priorities.

f. Appeal of Scientific Review. To ensure the fairness of the Merit Review process, BLR&D and CSR&D have a mechanism to formally appeal the recommendation of a Merit Review Subcommittee, if the Principal Investigator (PI) has evidence of serious flaws in the review of a proposal. The appeal process is not intended as a means to resolve differences in scientific opinion between the applicant and the reviewers, to adjust funding decisions, or to circumvent the scientific peer review process.

An appeal may be made if the PI believes it can be demonstrated that the Merit Review Subcommittee showed any of the following:

(1) Clear bias in the review process

(2) Conflict of interest

(3) Lack of expertise, or

(4) Significant factual errors

A PI is only allowed to have one active version of an application submitted; if a PI files an appeal, the PI may not submit a revised application.

g. Integrity of Review. BLR&D and CSR&D are committed to supporting the highest ethical standards for the review process. This includes maintaining the confidentiality of

review, preventing improper influences on reviewers and identifying and managing potential conflicts of influence during the review process. All proposal documents are entered into the eRA COMMONS system and ORD staff and reviewers are required to maintain the confidentiality of the documents throughout the process. Reviewers may not share proposals with others (students, post-doctoral fellows, or other colleagues) without written permission from the Scientific Review Officer involved. Reviewers are not to communicate with applicants regarding their proposals or the review process and should report any inquiries about an application to the Scientific Review Officer involved. Inappropriate contact with applicants as well as the failure to report such contact may lead to sanctions including the notification of other Federal agencies. Applicants who contact reviewers about their proposals or about the review process or otherwise attempt to influence the review process will be subject to sanctioning up to and including permanent loss of eligibility to submit for VA research funding and the notification of other Federal agencies. Reviewers should notify Scientific Review Officer of any potential conflicts of interest related to the proposals under consideration including those in which there could be an appearance of a conflict of interest even if they believe that no actual conflict exists.

h. Research Integrity. BLR&D and CSR&D are committed to the highest standards for the ethical conduct of research. Maintenance of high ethical standards requires that VA medical centers and investigators applying for, and receiving, Merit Review awards have appropriate procedures to preclude the occurrence of unethical research practices. This includes maintaining the integrity of the study data associated with the research. All investigator research records must be retained for 6 years after the end of the fiscal year in which the study closed unless there is another regulation that requires the research records to be retained longer (e.g., applicable FDA regulated studies) as described in the VHA Record Control Schedule 10-1. After the required retention period has passed, the records must be destroyed unless the study data are placed in a data repository.

(1) The PI and others associated with the research must subscribe to:

(a) Accepted standards of rational experimental research design,

(b) Accurate data recording,

(c) Unbiased reporting of data,

(d) Respect for the intellectual property of other investigators,

(e) Adherence to established ethical codes,

(f) Legal standards for the protection of human and animal subjects, and

(g) Proper management of research funds.

(2) Deliberate falsification or misrepresentation of research data will result in withdrawal of an application, possible suspension or termination of an award, and potentially, suspension of the investigator's eligibility to submit proposals to BLR&D and CSR&D.

h. Acknowledging VA Research Support. By accepting a Merit Review award, the PI agrees to properly acknowledge VA affiliation and support in all public reports and presentations (see VHA Directive 1200.19). Failure to acknowledge VA affiliation and support may result in termination of the award.

i. Intellectual Property Rights, By accepting a Merit Review award the PI agrees to comply with VA policies regarding intellectual property disclosure obligations and Federal Government ownership rights resulting from the proposed work (see VHA Directive 1200.18).

j. Renewal of Awards. If the applicable RFA is still active, a renewal application may be submitted up to 1 year prior to the end date of the ongoing Merit Review award.

To provide for continuity of funding, BLR&D and CSR&D will accept renewal applications for review 1 year prior to the end date.

(1) For example, if the award ends September 30th, the renewal application is normally due for the Spring round; however, renewal applications are accepted for review the Fall round of the previous year. This allows the PI to submit an application and one revision (if the renewal is not funded) without experiencing a funding gap.

(2) If the early submission is approved for funding, the PI may opt for one of the following scenarios:

(a) Delay the new project start date until the conclusion of the currently funded project; or

(b) Start the new project at the earliest possible start date, terminating the currently funded project before its conclusion.

k. Continuation of Non-clinician PI Employment. A non-clinician PI's BLR&D or CSR&D Merit Award salary may be continued for 1 year beyond the original end date of the investigator's funded Merit Review provided the investigator

(1) Remains employed by the VA,

(2) Continues to resubmit for Merit Review funding, and

(3) Continues to participate in the overall research effort at the facility.

l. Request for Administrative Project Modification. BLR&D and CSR&D utilize the ORD form entitled “Request for Administrative Project Modification” to request approval for changes in funded projects. Please refer to the this link http://www.research.va.gov/services/shared_docs/modifications.cfm

**5. QUESTIONS AND INQUIRIES**

Inquiries related to merit review submission or review should be directed to the Merit Review Program Manager. The PI may contact the BLR&D and CSR&D portfolio managers with questions specifically related to scientific issues raised in the summary statement for a reviewed proposal or the scientific content of a proposal to be submitted. The Associate Chief of Staff (ACOS) for Research and Development (R&D) should make all other contacts with BLR&D and CSR&D staff at VA Central Office, including questions relating to budget modifications noted in the summary statement. The list of contacts is available at http://www.research.va.gov/services/shared_docs/contacts.cfm