

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

- 1. REASON FOR ISSUE.** This Veterans Health Administration (VHA) Handbook establishes procedures for the 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).
- 2. SUMMARY OF MAJOR CHANGES.** This is a new Handbook addressing the process for the BLR&D and CSR&D Service Merit Review Award.
- 3. RELATED DIRECTIVE.** VHA Directive 1202 (to be published).
- 4. RESPONSIBLE OFFICE.** The Office of Research and Development (12), (BLR&D and CSR&D) is responsible for the contents of this VHA Handbook. Questions may be addressed to 202-461-1676
- 5. RESCISSION.** M-3, Part II, Chapter 4 dated October 30, 1989; M-3, Part II, Chapter 5 dated October 30, 1989; and M-3, Part II, Chapter 6 dated October 30, 1989 are rescinded.
- 6. RECERTIFICATION.** This VHA Handbook is scheduled for recertification on or before the last working date of November, 2013.

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CONTENTS

PARAGRAPH	PAGE
1. Purpose	1
2. Background	1
3. Scope	1
4. Merit Review Award Process	2
5. Questions and Inquiries	7

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1. PURPOSE

This is a new Veterans Health Administration (VHA) Handbook, which establishes procedures for the 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).

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.

(2) The CSR&D purview includes interventional, experimental, and observational studies involving human subjects. Proposals involving collection of medical histories, administering survey instruments or questionnaires, or performing medical procedures (including biopsies) or treatment regimens are appropriate for CSR&D.

b. Proposals submitted to BLR&D and CSR&D are peer-reviewed by Merit Review Board Subcommittees, which provide the Directors of BLR&D and CSR&D with evaluations of the quality of the research proposed and who make recommendations on scientific merit, budgets, and funding durations.

3. SCOPE

a. Merit Review funding is intended to support research by fully-trained independent investigators.

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

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

b. Merit Review may include special programs that have specific programmatic requirements.

c. Merit Review guidelines may 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.*

(3) 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 Handbook 1200.05.

(4) All interventional proposals submitted to CSRD must contain a safety monitoring plan that includes:

(a) The use of a Data Monitoring Committee (DMC) designated by CSRD. The charge of the DMC must include:

1. Determining the continued safety of research subjects based on the data submitted to the DMC.

2. Meeting at least once per year. *Note: CSRD or the IRB may determine that the DMC must meet more frequently based on the potential risks to the subjects.*

3. The written report and minutes of the DMC must be forwarded to the PI, the IRB and CSRD within 14 days of each meeting.

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

1. What safety information will be collected including adverse events and serious or unexpected adverse events.

2. How the safety information will be collected (what case report forms, what study visits, etc.).

3. The frequency of data collection (when safety data collection starts and how it will be collected such as at study visits, through telephone calls with participants), and the frequency or periodic review of cumulative safety data.
4. The statistical tests for the safety data to determine if harm is occurring.
5. Provision for the oversight of safety data, such as by the Data Monitoring Committee.
6. Conditions which will trigger an immediate suspension of investigational treatments.

4. MERIT REVIEW PROCESS

a. **Eligibility to Submit a Merit Review Proposal.** Determinations regarding eligibility are made by individual services within ORD. **NOTE:** *VHA policy for eligibility to receive research support from ORD is described in VHA Handbook 1200.15.*

(1) Merit Review is an intramural program that 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 award is funded (see VHA Handbook 1200.15).

(3) In addition, all new non-clinician PIs must be accepted into the BLR&D and CSR&D intramural research program. For purposes of eligibility, a clinician is defined as a licensed practitioner with a doctoral degree (MD, DO, DDS, etc.), who treats patients at a VA Medical Center (VAMC). All others are considered as non-clinicians.

(a) Non-clinician PIs wishing to transfer their ongoing research projects to a new facility must submit an eligibility request through the new facility. An eligibility determination made at the current facility does not automatically transfer to the new facility. BLR&D and CSR&D must be informed of any change in laboratory location, geographic commitment, paid 8ths, or VA employment status.

(b) Non-clinician PIs who are recipients of the former Merit Review Entry Program (MREP) or the current Career Development Program are considered new PIs and must obtain proper eligibility to submit independent Merit Review proposals.

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 Handbook 1200.16).

(1) The use of an off-site core facility or a 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 Handbook 1200.16).

c. **Merit Review Applications.** Instructions for submitting a Merit Review proposal are described in, or referenced in, the applicable program announcement or request for application (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 or CSR&D may not be submitted simultaneously to any other component of ORD (i.e., RR&D, HSR&D, or CSP).

(3) Proposals that fail to meet BLR&D and CSR&D requirements 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 Chief of Program Review at any time.*

(5) All proposals must be evaluated and approved by the facility Director and the facility R&D Committee prior to submission to VA Central Office. Proposals submitted to VA Central Office without documentation of proper local review will be withdrawn without review.

d. **Proposal Review.** Subcommittees of the Joint BLR&D and CSR&D Services Merit Review Board evaluate Merit Review proposals. Subject matter experts review all Merit Review applications for scientific quality. 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, BLR&D and CSR&D Services. Final funding

decisions are made by the Directors, BLR&D and CSR&D based on these recommendations, as well as programmatic priorities.

f. **Request for Reconsideration.** A PI may initiate a request for reconsideration of the recommendations of a Merit Review Subcommittee. The reconsideration process is intended to ensure that the scientific review of all proposals is fair and equitable. It 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 peer review process.

(1) If a PI submits a revised application and a request for reconsideration of the previous application is subsequently accepted and funded, the revised application is administratively withdrawn.

(2) If the revised application receives a fundable score and the request for reconsideration is accepted and fundable, only one of the two projects will be funded.

g. **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. All research data must be retained for 5 years after completion of a research project.

(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 Handbook 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 Handbook 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.

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

(a) 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 for 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.

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

1. Delay the new project start date until the conclusion of the currently funded project; or
2. Start the new project at the earliest possible start date, terminating the currently-funded project before its conclusion.

(2) BLR&D and CSR&D discourage submitting renewal applications more than one round early. Submitting more than one round early may jeopardize continued funding and the investigator needs to carefully consider the consequences. If the new submission is approved for funding, it will replace the ongoing project and there will be no funding gap. However, if the early submission is not approved for funding, the currently funded project will terminate prematurely at the end of September for proposals reviewed in the Spring round or at the end of March for proposals reviewed in the Fall round.

k. **Continuation of Non-clinician PI Employment.** A non-clinician PI's salary may be continued for 1 year beyond the termination date of the investigator's funded Merit Review provided the investigator:

- (1) Remains employed by VA,
- (2) Continues to resubmit for Merit Review funding, and
- (3) Continues to participate in the overall research effort at the facility.

l. **Change in the Location of the PI.**

(1) If the PI of a funded Merit Review at one VAMC transfers to another VAMC, the new medical center may request a transfer of the project.

(a) The R&D Committee (and appropriate subcommittees) at the new medical center must evaluate and approve the project.

(b) The new medical center must initiate the request to transfer the project.

1. The request should cite the committee approval dates, the PI's employment status (to ensure eligibility), and the location of the PI's laboratory at the new VA medical center.

2. If needed, eligibility and off-site waiver requests must be obtained prior to, or along with, submitting a transfer request. A non-clinician Ph.D. must request an eligibility determination from the BLR&D and CSR&D intramural programs upon transfer. Eligibility is based upon the PI's proposed activities at the new site.

(c) The original medical center must identify the funds to be withdrawn and transferred to the new medical center.

(d) The original medical center must address any requirements concerning the retention of the original research records rather than copies of the research records at the original medical center.

(2) All correspondence regarding change in the PI's location is to be addressed to the Director of BLR&D or CSR&D Service, who must approve the transfer of the project.

m. Change in PI.

(1) Requests to change the PI of a funded Merit Review are discouraged. In rare cases, a request to transfer an ongoing Merit Review award from the current PI to a new PI at the same VA medical center for a period not to exceed 1 year may be considered.

(a) The Merit Review project of a PI who is newly approved (funded for less than 1 year) may only be transferred to a co-investigator currently assigned to the project.

(b) It is expected that during the 1-year transfer period, the new PI will submit a renewal application for merit review.

(c) The proposed PI must be an eligible, qualified investigator, currently involved in the research as a co-investigator or active collaborator.

(d) The request to transfer the PI must include:

1. A memorandum from the facility Director and current PI indicating agreement with the request.

2. Justification for the change.

3. Curriculum vitae of the proposed PI.

4. The facility R&D Committee must approve the request to change the PI.

(e) If the proposed new PI has an active Merit Review project, the transferred project will be considered supplemental and it will end on or before the termination date of the new PI's active project.

(2) All correspondence regarding change in the PI is to be addressed to the Director, BLR&D or CSR&D service. The Director, BLR&D or CSR&D must approve the request for PI transfer.

5. QUESTIONS AND INQUIRIES

Inquiries related to merit review submission or review should be directed to the Chief of Program Review (121F). The PI may contact the BLR&D and CSR&D portfolio managers (121E) 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) is to 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/>.