

**BIOMEDICAL LABORATORY RESEARCH AND DEVELOPMENT (BLR&D) AND
CLINICAL SCIENCE RESEARCH AND DEVELOPMENT (CSR&D) SERVICES**

MERIT REVIEW AWARD PROGRAM

- 1. REASON FOR ISSUE:** This Veterans Health Administration (VHA) Handbook clarifies policy and 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.
- 2. SUMMARY OF MAJOR CHANGES:** This Handbook represents a complete revision of existing policy.
- 3. RELATED DIRECTIVE:** VHA Directive 1202 to be issued.
- 4. RESPONSIBLE OFFICE:** The Office of Research and Development, (BLR&D and CSR&D) is responsible for the contents of this VHA Handbook.
- 5. RESCISSION:** This VHA Handbook rescinds VHA Manual M-3, Part II, Chapter 4, Chapter 5, and Chapter 6.
- 6. RECERTIFICATION:** This document is scheduled for recertification on or before the last working date of November 2010.

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

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MERIT REVIEW AWARD PROGRAM

1. PURPOSE

This Veterans Health Administration (VHA) Handbook provides policy related to the Merit Review Award Program (Merit Review) for the Biomedical Laboratory Research and Development (BLR&D) and Clinical Science Research and Development (CSR&D) services.

2. BACKGROUND

The Merit Review Award Program is an intramural funding mechanism to support investigator-initiated research conducted by eligible VA investigators at VA medical centers or VA-approved sites. This program is BLR&D/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. The BLR&D purview includes laboratory studies, both *in vitro* and *in vivo*, including tissue culture, animal models and studies on human biological samples. The CSR&D purview includes studies on whole human subjects involving interventional or exploratory procedures (with the exception of procedures for obtaining biological samples such as drawing blood, buccal swabs etc.) Proposals submitted to BLR&D and CSR&D are jointly peer-reviewed by Subcommittees of Merit Review Committee. Subcommittees, which are based on scientific disciplines provide the Directors of BLR&D and CSR&D with evaluations of the quality of the research proposed and make recommendations for funding, including budgets and funding durations.

3. SCOPE

Merit Review funding is intended to support research by fully trained independent investigators. The principal investigator (PI) on a Merit Review award must be competent to develop and direct a research project. Evidence of independent research by the PI includes previous training and/or experience in research and research productivity as demonstrated by attaining independent grant support and/or refereed publications, especially first or senior author publications in the field of the proposed research.

Merit Review may include special programs that have specific programmatic requirements and supplemental proposal requirements. Merit Review guidelines may also be applicable to special initiatives and requests for proposals (RFPs). Information on current special Merit Review programs as well as special initiatives and RFPs following Merit Review guidelines can be found in the guidance document, [*Special Merit Review Programs*](#).

4. MERIT REVIEW POLICY

NOTE: Unless specified, the policies described here in Paragraph 4 apply to all Merit Review proposals, including special Merit Review programs.

a. Eligibility to Submit a Merit Review Proposal.

Determinations regarding eligibility are made by individual services within the Office of Research and Development (ORD). The VHA policy for eligibility to receive research support from the Office of Research and Development (ORD) is described in the VHA Handbook 1200.15.

(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 single PI who is eligible to submit a Merit Review proposal. A PI shall hold a M.D., Ph.D., or equivalent doctoral degree in medical, biological, or behavioral sciences. Co-PIs are not allowed.

(2) 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.

(3) To be eligible to submit Merit Review proposals to BLR&D or CSR&D services, the PI (both clinician and non-clinician) must have at least a 5/8ths time VA appointment at the time the Merit Review is funded (refer to VHA Handbook 1200.15). If the clinician PI's appointment is to start at the time of funding, the VA medical center Director's letter must contain a statement indicating that the PI will be employed by the VA at least 5/8ths time.

(4) In addition to meeting eligibility requirements, all **new non-clinician PIs** must be accepted into the BLR&D /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) paid by the clinical care appropriation. It is assumed but not required that s/he treats patients at the VA Medical Center. All others are considered as non-clinicians. Current guidelines for submitting a request and due dates can be found in the guidance document, [Requesting Acceptance into the Intramural Research Program for Non-clinician Scientists](#).

(5) Non-clinician PIs wishing to transfer their ongoing research programs 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.

(6) Non-clinician PIs who are recipients of the former Merit Review Entry Program (MREP) or the current Career Development program are considered as new PIs and will need to obtain 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 controls laboratory space at any other location(s), a waiver to perform the research off-site must be obtained for that investigator (refer to VHA Handbook 1200.16). The use of an off-site core facility or a collaborator's laboratory does not require an off-site waiver, except if the VA investigator is a core director.

(1) Guidelines for submitting an application for an off-site waiver are described in the VHA Handbook 1200.16, VA Off-site Research Handbook.

(http://www1.va.gov/vhapublications/ViewPublication.asp?pub_ID=441).

Deadlines for submitting an application for off-site waiver are in the guidance document, [Current Merit Review Guidelines and Submission Dates](#). Waiver requests received after the deadline will be reviewed for the following round. A copy of the off-site waiver approval letter must be included in the Merit Review proposal. Once a waiver is granted, a new request for a waiver does not have to be submitted for each subsequent renewal Merit Review application, unless the PI is submitting a new proposal.

(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 the leased space. (refer to VHA Handbook 1200.16). A copy of the signed lease should be submitted with the proposal. In the absence of formal oversight agreement, leases for \$1 per year and “no cost” leases may not qualify as VA-leased space.

c. Proposal Restrictions. The Merit Review award is not intended to be the only source of support for investigators. The PI is encouraged to seek additional funding from other ORD services, other agencies of the Federal Government, and other public and private funding sources. Submission of proposals to BLR&D/CSR&D is subject to the **single project rule**, whereby a PI may have only one active Merit Review from each of the two services, BLR&D and CSR&D, and typically, each investigator may submit only one Merit Review proposal to each of the two services, BLR&D and CSR&D, for any review round.

(1) An investigator may have a second BLR&D or CSR&D Merit Review award in response to a special request for proposals (RFP) or a program announcement (PA), if specified in the RFP or PA. However, the total number of Merit Review awards held by an investigator at any point in time, from BLR&D and CSR&D services together, may be limited.

For the current limit on total number of awards, refer to the guidance document, [Current Merit Review Guidelines and Submission Deadlines](#).

For purposes of the single project rule, Centers and Research Enhancement Award Programs (REAP) are not considered Merit Reviews.

(2) A proposal submitted to BLR&D or CSR&D may not be submitted simultaneously to any other component of ORD (RR&D, HSR&D, or CSP).

d. Budget of Merit Awards. A Merit Review proposal requires a budget of at least \$50,000 per year, exclusive of equipment and non-clinician PI salary, and at least 2 years duration to complete the proposed research. Merit Review budgets excluding PI salary and equipment budgets may be capped in any given round due to budgetary constraints, at the discretion of the Directors of BLR&D and CSR&D. For current budget cap guidelines, refer to the guidance document, [Current Merit Review Guidelines and Submission Deadlines](#).

Rare exceptions to the budget cap may be granted for compelling circumstances. Requests for exceeding budget caps must be submitted as a letter of intent (LOI). For instructions on preparing and submitting an LOI and due dates, refer to the guidance document, [Instructions for Preparing and Submitting a Letter of Intent for Exceeding Budget Cap](#).

e. Duration of Merit Awards. Merit Review award durations are based on past award history and experience of the PI as a nationally peer-reviewed PI as well as budget constraints of BLR&D and CSR&D services.

(1) First time applicants who will have less than 3 years of Merit Review funding or other nationally peer-reviewed, non-mentored funding by the proposed start of the award may request funding for a maximum duration of 3 years.

(2) Applicants who will have a minimum of 3 years previous Merit Review or equivalent nationally peer-reviewed, non-mentored funding by the proposed start of the award may request durations greater than 3 years. However the maximum award duration may be capped for any given round at the discretion of the Directors of BLR&D and CSR&D, due to budgetary constraints. For current guidelines on Merit Review award durations, refer to guidance document, [*Current Merit Review Guidelines and Submission Deadlines*](#).

(3) Rare exceptions to the award duration cap may be granted for compelling circumstances. Requests for exceeding duration caps must be submitted as a letter of intent. For instructions on preparing and submitting an LOI and due dates refer to the guidance document, [*Instructions for Preparing and Submitting a Letter of Intent for Budget Cap*](#).

f. Preparing the Proposal. Deadlines and current guidelines for submission of all proposals for new, revised, or renewal Merit Reviews are described in the guidance document, [*Current Merit Review Guidelines and Submission Deadlines*](#). Detailed procedures for preparing the proposal are described in the guidance document, [*Instructions for Preparing and Submitting a Merit Review Proposal*](#).

(1) Proposals that fail to meet BLR&D and CSR&D requirements may be administratively withdrawn without review.

(2) No additional or replacement information will be accepted after submission of the proposal, unless requested by the Program Review staff. The only exceptions are official letters of acceptance for publication of manuscripts submitted by the PI. These may be sent to the Chief of Program Review at any time.

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

(4) The receipt date is waived only in compelling circumstances, and any waiver must be obtained in advance from the Chief of Program Review. If a proposal is withdrawn, the Chief of Program Review must be notified promptly by telephone with a written follow-up.

g. Proposal Review. Subcommittees of the BLR&D and CSR&D Joint Merit Review Committee evaluate Merit Review proposals. Subject matter experts review all Merit Review applications for scientific quality. 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. The review process including review criteria and scoring guidelines is described in the guidance document, [Merit Review Process](#).

h. Funding Merit Review Proposals. The results of the scientific merit review process are forwarded as recommendations to the Directors, BLR&D and CSR&D services. The recommendations, along with programmatic priorities, are used by the Directors, BLR&D and CSR&D, to make the final funding decisions.

If the Merit Review Subcommittee expresses serious concerns about the procedures described for human or animal studies, biosafety, or administrative and/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. This is so, regardless of whether the work is funded or not. If the study is underway, all work must stop until the hold is lifted.

i. Appeals. There is a formal process to appeal the recommendation of a Merit Review Subcommittee. The appeals 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. The basis for an appeal and the procedure for submitting an appeal are detailed in the guidance document, [Merit Review Appeal Process](#). If a PI submits a revised application and an appeal of the previous application is subsequently sustained and funded, the revised application will be administratively withdrawn. If the revised application receives a fundable score and the appeal is sustained and fundable, the single project rule applies, and only one of the two projects will be funded.

Note: Applicants are encouraged to resubmit their Merit Review while an appeal is under review.

j. 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 accepted standards of rational experimental research design, accurate data recording, unbiased reporting of data, respect for the intellectual property of other investigators, adherence to established ethical codes, legal standards for the protection of human and animal subjects, and 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.

k. 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.**

l. 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).

m. Renewal Of Awards. The deadline for receipt of a renewal application in VA Central Office can be found on the monthly Budget Allocation Report in the Office of the ACOS for R&D.

(1) To provide for continuity of funding, BLR&D and CSR&D will accept renewal applications for review one round prior to the deadline. For example, if the renewal application is due in the Spring 2005 round, renewal applications will be accepted for review in the Fall 2004 round. This allows the PI to submit an application and one revision (if the renewal is not funded) without experiencing a funding gap. If the early submission is approved for funding, the PI may opt for one of the following scenarios: delay the new project start date until the conclusion of the currently funded project; or start the new project at the earliest possible start date, terminating the currently funded project before its conclusion.

(2) BLR&D / CSR&D discourage submitting renewal applications more than one round early (in the example above, submitting an application for review in the Spring 2004 round or earlier). **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.

n. Continuation of Non-clinician PI Employment

(1) 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 :

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

Note: Salary for the non-clinician PI of a special Merit Review project may or may not be continued. Refer to the guidance document, [Special Merit Review Programs](#) for specific details.

o. Change in the Location of the PI. If the PI of a funded Merit Review at one VA medical center transfers to another VA medical center, the new medical center may request a transfer of unexpended Merit Review funds. The R&D Committee (and appropriate subcommittees) at the new medical center must evaluate and approve the project. The new medical center must initiate

the request to transfer the project. *Note: the original medical center must submit a page 19 to identify the funds to be withdrawn and transferred to the new medical center.*

(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/or off-site waiver requests must be obtained prior to or along with submitting a transfer request. A non-clinician Ph.D. must request acceptance into the BLR&D and CSR&D intramural programs upon transfer. Acceptance is based upon the PI's proposed activities at the new site (see guidance document, [*Requesting Acceptance into the Intramural Research Program for Non-Clinician Scientists*](#)).

(3) All correspondence regarding change in the PI's location needs to be addressed to the Director of BLR&D or CSR&D service. The Director, BLR&D or CSR&D, must approve the transfer of funds.

p. Change in PI. 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. 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.

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

(2) The request to transfer the PI must include a memorandum from the facility Director and current PI indicating agreement with the request, and a justification for the change. Include the curriculum vitae of the proposed PI. The R&D Committee must approve the request to change the PI. **NOTE:** *The proposed PI must be an eligible, qualified investigator, currently involved in the research as a co-investigator or active collaborator.*

(3) 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.

(4) All correspondence regarding change in the PI should be addressed to the Director, BLR&D or CSR&D service. The Director, BLR&D or CSR&D must approve the request for 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) should make all other contacts with

BLR&D and CSR&D staff at VA central office (VACO), including questions relating to budget modifications noted in the summary statement.

GUIDANCE DOCUMENTS

CURRENT MERIT REVIEW GUIDELINES AND SUBMISSION DEADLINES

1. Proposal Restrictions

Submission of proposals is subject to the **single project rule**, whereby a PI may have only one active Merit Review from each of the two services, BLR&D and CSR&D, and typically, each investigator may submit only one Merit Review proposal to each of the two services, BLR&D and CSR&D, for any review round. BLR&D/CSR&D will determine the final service assignment. For questions regarding the appropriate service, the PI may contact the appropriate portfolio manager in VACO. If the PI submits a second proposal to the service where s/he has a currently funded Merit Review, which does not terminate before the proposed start date, the proposal will be administratively withdrawn.

a. **Exceptions to this single project rule:** An investigator may have a second BLR&D or CSR&D Merit Review award in response to a request for proposals (RFP) or program announcement (PA), if specified in the RFP or PA.

Note: Proposals submitted to the Clinical Trials program and Epidemiology Research Program are no longer considered as exceptions to the single project rule.

For purposes of the single project rule, Centers and Research Enhancement Award Programs (REAP) are not considered Merit Reviews.

b. **Total Number of Merit Review Awards:** The limit on the total number of Merit Review awards is **two**. At any point in time, an investigator may have **no** more than **two** Merit Review awards from BLR&D and CSR&D services together. *BLR&D/CSR&D may allow more than two funded Merit Review awards in rare cases for exceptionally innovative and scientifically meritorious proposals that are aligned with VA research priorities.*

2. Merit Review Budget and Duration.

a. Recurring budget (total budget less PI salary and equipment) may not exceed \$125,000 for both BLR&D and CSR&D per year and the equipment request may not exceed \$50,000. **Clinical trials are an exception, for which the recurring budget may not exceed \$150,000 per year.**

b. Applicants who will have less than 3 years of Merit Review funding or other nationally peer-reviewed, non-mentored funding by the proposed start of the award may request funding for a maximum duration of 3 years.

c. Applicants who will have a minimum of 3 years previous Merit Review or equivalent nationally peer-reviewed, non-mentored funding by the proposed start of the award may request maximum award duration of 4 years for proposals submitted to either BLR&D or CSR&D. **Clinical trials are an exception, for which the maximum award duration is 5 years.**

3. Letter of Intent (LOI). Exceptions to the budget caps for amount and/or duration may be requested in the form of a letter of intent (LOI). A detailed justification for the additional budget and duration requested must be included. Under no circumstances can more than 5 years of

funding be requested. An LOI is required for requesting a waiver to exceed the Merit Review budget cap, including amount and duration of the award and equipment.

a. For instructions on preparation and submission of an LOI to exceed budget caps, see the guidance document, [Instructions for Preparing and Submitting a Letter of Intent \(LOI\) to Exceed Budget Caps.](#)

b. LOIs will be accepted throughout the year. Early submission of LOIs is encouraged. The last date for submitting an LOI for the Spring Merit Review round is January 15 and for the Fall Merit Review round is July 15. LOIs submitted after these deadlines will be considered for the subsequent round.

4. Deadlines. Avoid delays and misunderstandings by reading and following the instructions carefully. Table 1 contains deadlines for Merit Review applications. Depending on the investigator’s particular circumstance, requests for off-site waiver, eligibility determination, acceptance into the intramural program, or approval to exceed budget limits may be needed. The Office of the ACOS for R&D or BLR&D and CSR&D Portfolio Managers can help determine which approvals may be needed.

TABLE 1 - Receipt, Review, and Award Dates		
	Spring Round	Fall Round
Receipt Dates		
Letters of Intent for Exceeding Budget Caps	January 15	July 15
Requests for Off-site Waivers, Eligibility and Acceptance into the Research Program	January 15	July 15
Intent to Submit (electronic through ePROMISe)	March 1	September 1
Merit Review Applications	March 15	September 15
Suggestions for Subcommittee assignment and Reviewers	March 16	September 16
Review and Award Schedule		
Scientific Merit Review	May-June	Nov-Dec
Earliest Project Start Date	October 1	April 1

a. **Approvals.** Prior to submission to VA Central Office, all proposals require approval by the local facility’s R&D Committee. In addition, the ACOS for R&D has to obtain letters and concurrence from several offices at the local VA medical center. The ACOS for R&D can provide the local submission deadlines.

(1) Proposals submitted prior to receiving approval by any required R&D subcommittees (e.g., Human Studies Subcommittee, Animal Studies Subcommittee, etc), require R&D Committee approval for submission purposes only. The proposed research may not proceed until

approval is received by all required subcommittees and reviewed again by the R&D Committee for approval to conduct the proposed research.

(2) Proposals lacking the required local R&D approvals for submission will be administratively withdrawn.

(3) No additional or replacement information will be accepted after submission of the proposal unless requested by the Program Review Division.

b. **Intent to Submit.** The ACOS for R&D must transmit a list of names of PIs, via the Project Management and Information System (ePROMISE), to the Research and Development Computing Center (RDCC) by March 1 for Spring review and September 1 for Fall review. This step is required in addition to the submission of any required LOI.

c. **Just In Time Submission of Compliance and Assurance Documentation (JIT).** All required forms and approvals of appropriate R&D subcommittees must be submitted to VACO only after the station receives notification of funding. For guidelines on Just-In-Time (JIT) submissions, forms required and instructions on preparation and submission of JIT documents, refer to section 8 in the guidance document, [*Instructions for Preparing and submitting a Merit Review Proposal.*](#)

INSTRUCTIONS FOR PREPARING AND SUBMITTING A MERIT REVIEW PROPOSAL

1. GENERAL INSTRUCTIONS FOR PROPOSAL PREPARATION: *The instructions in this document apply to all new, resubmission and renewal Merit Review proposals and supersede all previous instructions.* The Office of the Associate Chief of Staff (ACOS) for Research and Development (R&D), or equivalent, at the local Department of Veterans Affairs (VA) medical center provides assistance in proposal preparation and is responsible for submitting proposals to VA Central Office. Before preparing an application, consult with the office of the ACOS for R&D. While these instructions are applicable to Merit Review, special programs such as Epidemiology Research Program and Clinical Trials program, and Requests for Proposals (RFP), may have additional submission requirements. If you are unsure of whether your study meets the requirements for a special Merit Review program or an RFP, be sure to discuss submission requirements with the ACOS for R&D or contact the appropriate Program Manager in BLR&D/CSR&D at VA Central Office.

2. SPECIFIC INSTRUCTIONS FOR PROPOSAL PREPARATION. Obtain a Merit Review packet from the local VA research office. The packet should contain all the forms necessary for completing the application and any additional forms required for local review. Official VA research forms in PDF and Word format can be found at <http://www.research.va.gov/funding/process/forms.cfm>. Use a clear, black font when filling out all forms. Font size for all text shall be at least 11 point. Certain forms must be submitted electronically through the ePROMISE system. The Local VA research office staff will assist in printing and submitting these forms.

a. **Page 1; VA Form 10-1313-1, Merit Review Application.** This is the front page for the applications. Local VA research office staff, familiar with the use of the ePROMISE program, will help enter the data for 10-1313-1. The program will generate (from the internal database) default values for a number of the fields, so it is important to check each field for accuracy.

(1) Blocks 1, 2, and 3. Left blank.

(2) Block 4 (review date). The season and the year for the upcoming round of review. For example if the submission deadline is March 15, 2004, the review date is Spring 2004. If the submission deadline is September 15, 2004, the review date is Fall 2004.

(3) Block 5 (facility number). The number assigned to the PI's VA medical center as listed in ePROMISE.

(4) Block 6. The location of the VA medical center by city and state. **NOTE:** *The Research and Development Information System (RDIS) and RDCC use this information to denote a VA medical center rather than the facility name or a regional designation.*

(5) Block 7. The social security number of the PI. **NOTE:** *The social security number will be captured by ePROMISE, but will not print on paper copies.*

(6) Block 8. The last date the PI submitted a Merit Review application regardless of its outcome. A blank indicates that no Merit Review proposal on any topic, including an Epidemiology and Clinical Trial proposal, has ever been submitted.

(7) Block 9. The last name, first name, middle initial, degree(s) of the PI, and VA telephone number of the PI.

(8) Block 10. The title of the project, which may not exceed a total of 72 characters including spaces. The title should reflect the content of the application as accurately as possible.

(9) Block 11. The total budget for each year of requested funding and the total amount for all years of the program. The amounts and duration shall agree exactly with the totals on VA Form 10-1313-3 and VA Form 10-1313-4. Amounts on the paper copy must equal those submitted electronically. All budget totals and subtotals shall be rounded to the nearest \$100 (see instructions for VA Form 10-1313-3 and VA Form 10-1313-4).

(10) Block 12. The employment status in VA paid 8ths of the PI at the time of application.

(11) Block 13. The PI's source of employment at the time of application. All VA employees are employed either through the medical care appropriation or through the medical research and prosthetics appropriation.

(a) Check with the ACOS for R&D for the correct appropriation.

(b) PIs appointed on the medical care appropriation should check "Patient Care." Investigators appointed on the medical care appropriation cannot request salary in the proposal.

(c) Non-clinician PIs appointed on the medical research and prosthetics appropriation and requesting salary through the Merit Review proposal should indicate cost center CC103.

(d) Non-clinicians who are appointed as Research Career Scientists (RCS) should indicate CC110, but may not request salary in the proposal.

(e) Applicants receiving salary from other ORD services (Health Services Research and Development (HSR&D), Rehabilitation Research and Development (RR&D)), must be accepted into the BLR&D and CSR&D intramural program prior to submitting an application (see Appendix G).

(12) Block 14. If the PI, at the time of application, has not had Merit Review funding in the past 5 years, the "NEW" box should be checked; otherwise check the "ONGOING" box. The "No. Projects in Program" may be left blank.

(13) Block 15. For BLR&D, under Program enter 821 and under Cost Center enter CC103. For CSR&D, under Program enter 829 and under Cost Center enter 150.

(14) Block 16. Enter Primary Research Program Area and Primary Specialty Area.

(15) Block 17. Enter VA Hospital Service and Section.

(16) Block 18. Enter PI's current academic rank, primary academic department, and the name of the university affiliation.

(17) Block 19. Program Use; check each block that applies.

(a) Human Subjects. This box must be checked if the research has any relation to human beings, even if the institutional review board (IRB) has found the research to be exempt.

Check box if:

1. Human subjects are exposed to manipulations or interventions, interact with researchers, or can be identified from data collected, even if the data already exists.

2. Human tissues are obtained. Tissues include, but are not limited to, biopsies, blood, cerebrospinal fluid, urine, feces, saliva, nail clippings, hair, sweat, and tears.

3. Human tissue is obtained from surgery or autopsy, tissue banks, other non-profit sources, or commercial sources.

Note: Work on human immortalized cell lines is not considered research on human subjects, but does involve biohazards.

Note: If the research involves banking of human specimens, gene testing, gene transfer, and/or stem cells, it must comply with all VA policies and guidelines regulating the conduct of such activities.

(b) Animal Subjects. The animal subjects boxes should be checked for any proposal using animals or animal tissues using the criteria in items (1) and (2) below. These criteria do not serve as a basis for determining if local Institutional Animal Care and Use Committee (IACUC) approval is required. They should be used only for the purposes of determining if an Animal Component of Research Protocol (ACORP) must be submitted as a prerequisite for receiving VA funding for a Merit Review application.

(1) An ACORP must be submitted when requested as JIT documentation if any of the following conditions apply (the "Yes" box for animal subjects should be checked):

(a) Animals are requested in the application budget for use in proposed experiments.

(b) Animals purchased with other VA funds or with non-VA funds would be used primarily or exclusively for experiments proposed in the application.

(c) Animal tissues or primary cell lines purchased with other VA funds or with non-VA funds would be derived from animals sacrificed primarily or exclusively for use in the experiments proposed in the VA application.

(2) An ACORP is not required for submission if the proposed animal use meets one of the following criteria (the "No" box for animal subjects should be checked):

(a) Immortal animal cell lines or explants would be used in the proposed experiments such that no additional animals would need to be euthanatized to meet application objectives.

(b) Animals on other IACUC-approved projects would be used, but these animals would be utilized for other projects even if the need for the animals by the proposed VA project did not exist.

(c) Animal tissues, blood and other body fluids, or primary cell lines would be obtained from live animals on other IACUC-approved protocols, but samples from these animals would be collected even if the need for the tissues or cell lines by the proposed VA project did not exist.

(d) Animal tissues, blood and other body fluids, or primary cell lines would be obtained from animals euthanatized while on other IACUC-approved protocols, but samples from these animals would be collected even if the need for the tissues or cell lines by the proposed VA project did not exist.

(e) Animal-derived reagents or products such as serum, antibodies and mediators required in the application are limited to those that would be purchased from a USDA-licensed commercial vendor.

(3) If guidance is needed on applying the criteria in paragraphs (1) and (2), the Chief Veterinary Medical Officer (CVMO) should be contacted.

(c) Investigational Drugs or Devices. Check the appropriate box if the use of investigational drugs or devices with human subjects is proposed.

(d) Radioisotopes. If radioisotopes are used, check the “Radioisotopes” box and include appropriate information in the biohazard form. The local Radiation Safety Committee must approve the use of radioisotopes before any studies contained in the application may be conducted.

(e) Biohazard. Almost all research submitted to BLR&D/CSR&D involves biohazards. Blood, however obtained, cerebrospinal fluid, and all body secretions and excretions, e.g., urine, feces, saliva, sweat, and tears, are biohazards. Most chemicals used in laboratories are biohazards.

1. A checklist of biohazards by category is provided on the first page of Appendix G of VHA Handbook 1200.8

(http://www1.va.gov/vhapublications/ViewPublication.asp?pub_ID=401).

If the research uses any of the products listed in the appendix, the Biohazards box must be checked.

2. Questions about research safety documentation are to be directed to the VA Central Office Research Biosafety Officer.

(18) Block 20. Summarize the PI’s research support for the last 3 fiscal years in chronological order. “Non-VA” includes all other sources of research funding other than VA.

(19) **Block 21.** Insert the date the PI entered or will enter VA duty (all applicants must be VA employees at the time the application is funded).

(20) Signatures and dates in this block must be within 6 months of the submission due date, and the date the ACOS for R&D signed must be subsequent to the approval date of the R&D Committee. The signature of the ACOS for R&D signifies the completeness and accuracy of the contents of the application. The signature of the PI signifies responsibility for the proposal contents, the scientific responsibility for the proposed projects, and agreement to follow VA policies for acknowledging VA support and intellectual property rights. “Per,” “by,” or “for” signatures are not acceptable.

b. **Page 2, VA Form 10-1313-2, Summary Description of Project/Program.**

(1) The PI’s name and project title must be exactly as written on Page 1 (VA Form 10-1313-1).

(2) Use keywords that describe the disease, system, mechanism being studied, and major methods and/or techniques used. Because the keywords are used for searches and portfolio related issues, only Medical Subject Headings (MeSH) terms may be used. The ACOS for R&D has a MeSH terms book, which is also available at the medical center library or may be obtained online (<http://www.nlm.nih.gov/mesh/meshhome.html>).

(3) **Summary Description.** The summary description (abstract) of the proposal provides information about the hypotheses to be tested, specific objectives, relevance, subject population, procedures to be used, and the significance of potential new findings. It must include enough information so that the proposal can be referred to the appropriate Merit Review Subcommittee and reviewers. Use only the allotted space.

c. **Page 3, Table of Contents.** Use Table 2 as the format for the Table of Contents. Indicate “N/A” for not included or non-applicable items. Consecutively number all pages in the application and place the starting page number for each section in the Table of Contents.

TABLE 2 – Table of Contents

VA Form 10-1313-1 - front page	1_
VA Form 10-1313-2 - (abstract)	<u>2</u>
Table of Contents	<u>3</u>
VA Form 10-1313-3 - first year budget	<u>4</u>
VA Form 10-1313-4 - all years budget and justification	<u>5</u>
Investigators’ Biographic Information	
Starting with PI (VA Form 10-1313-5/6, VA Form 10-1313-8; Description of any funding overlap Follow with complete sets from each co-investigator.	—
Text of Proposal	
Response (resubmitted applications only, not to exceed 3 pages)	—
List of acronyms/abbreviations	—
Narrative: Parts 1-4 (not to exceed 25 pages)	
1. Rationale	—
2. Background and Significance	—
3. Work Accomplished	—
4. Work Proposed	—
Human Studies Section	—
Animal Studies Section	—
Resources (1 page)	—
Publications from last funding period	—
Literature citations (not to exceed 4 pages)	—
Administrative Issues	
R&D Committee approval memorandum	—
VA medical center Director’s memorandum	—
Other Letters of Endorsement	—
VA Central Office Approvals: Exceptions, Waivers or Permissions letters (eligibility, acceptance into program, off-site location, exceeding budget cap)	—
For Resubmissions Only:	
Previous Reviews	—
Previous Summary Statement (VA Form 10-1313A)	—
Previous Summary Statement Text	—

d. Page 4, VA Form 10-1313-3, Current Funds and First Year Request for Program/Project.

(1) All budget subtotals are to be rounded to the nearest \$100.

(2) Recurring budget (i.e., total budget less PI salary and equipment) may not exceed \$125,000 for both BLR&D and CSR&D per year, with the exception of clinical trials. **The**

recurring budget for a clinical trial may not exceed \$150,000 per year. The first year equipment request may not exceed \$50,000 unless prior approval has been obtained through an LOI.

(3) Following are the current guidelines for BLR&D and CSR&D project durations. *Note: If requesting more than a 3-year duration, include all appropriate prior funding history on VA form 10-1313-5/6 (Investigator's Total Research/Development Support).*

(a) Investigators who will have less than 3 years of Merit Review funding or other nationally peer-reviewed, non-mentored funding by the proposed start of the award may request a 2 or 3-year duration on proposals submitted to either BLR&D or CSR&D service.

(b) Investigators who will have a minimum of 3 years previous Merit Review or equivalent nationally peer-reviewed, non-mentored funding by the proposed start of the award may request a maximum award duration of 4 years for proposals submitted to BLR&D and CSR&D service. **Exceptions are clinical trials for which investigators may request funding for a maximum duration of 5 years**

Exceptions to the budget caps for amount and/or duration may be requested in the form of an LOI as described in the guidance document, [Instructions for Preparing and Submitting a Letter of Intent \(LOI\) to Exceed Budget Caps](#). A detailed justification for the additional amount and years requested must be included in the LOI. Under no circumstances can more than 5 years of funding be requested.

(4) **Personnel.** Starting with the PI, list all personnel involved in the project. In the appropriate columns list their names (with Grade and Step in parentheses), role in the research proposed, the percent effort each will devote to the project, and whether or not salaries are requested. Salaries are to include fringe benefits for all personnel to be paid from BLR&D and CSR&D funds. The maximum allowable fringe benefits rate is calculated yearly and may be found in the BLR&D and CSR&D Merit Review program announcement that is sent out to the VA research offices prior to the submission deadlines for each round.

(a) Salary requests are to be proportional to the percent effort listed (non-clinician PI's salaries are an exception, see subpar. 2d(4)(b) below. Secretarial salaries are not allowed. Physicians and dentists, and, in most cases, nurses may not receive salaries from the medical research and prosthetics appropriation. Physicians and dentists who are not licensed to practice in the United States may request salary, but must be clearly identified as such in the Budget justification section. PIs cannot be paid through Inter-agency Personnel Act (IPA) agreements. *Note: Prior to any funding decisions, all proposals under consideration will undergo an administrative review of the budgets by BLR&D/CSR&D staff. This review ensures that VA Research funds are not used for inappropriate purposes including patient care and salaries of Title 38 employees.*

(b) If the PI is a non-clinician, salaried by research appropriation CC103, in the “% effort” column the PI must indicate the actual percent effort that the investigator will expend for the research described in this application only. However, in the “First Year Requested Funds” column, the non-clinician PI may request salary consistent with the total VA effort.

1. Total VA effort includes the work anticipated in this application, participation in other VA and non-VA research, service toward core facilities, teaching, supervision of students, participation in research centers, service on committees, etc. For example, a non-clinician PI listing 40 percent effort for the proposed research, 20 percent effort as an uncompensated co-investigator on a National Institutes of Health (NIH) grant, 15 percent service to research administration, and 10 percent teaching and mentoring would request 85 percent of the investigator's full-time equivalent salary.

2. Salary support may be requested only for activities that are uncompensated from other sources, such as the academic affiliate or other funding agencies. Any differences in the percent effort for the work proposed and total VA effort (salary support) must be described fully in the budget justification.

(c) If the PI is a Research Career Scientist (CC110), list the percent effort the person will devote to the proposed research, but do not include salary in the budget. In the budget justification discuss the investigator's contribution to the proposed research only.

(d) All co-investigators, collaborators, and technical staff, whether paid or not, are to be listed in the personnel section. There are restrictions on who can be paid directly by VA. Check with the local Research Service to ensure that salary is not requested for a person who cannot be paid directly by VA.

(e) If a person is paid through a contract for services or an IPA, list under personnel and put "IPA" in the column for requested funds. List the specific costs of IPAs in the "all other expenses" section of the budget.

(f) Salary compensation may not be requested for an M.D. if the person is licensed to practice medicine in the U.S. A clear statement about license to practice in the U.S. must be included in the justification for any salary for M.D. participants.

(g) Other personnel. Check the list of unauthorized budget items (Table 3) for personnel who may not be included in proposal budgets.

(5) Include in the "Current Year Funds" column all funds allocated by the corresponding service (BLR&D or CSR&D) to the investigator for the 12 months preceding the first year request.

(6) Consultants. A consultant may not receive a fee of more than \$2,500 per year and the consultant's involvement must be fully explained in the budget justification. There are limitations on payment to consultants; contact the office of the ACOS for R&D.

(7) Equipment. Although VA Form 10-1313-3 states that all equipment in excess of \$3,000 must be listed, BLR&D and CSR&D services require that each item of equipment, no matter the cost, be listed separately and thoroughly justified on VA Form 10-1313-4. Equipment consists of relatively permanent, fixed assets that are essential to the completion of the proposed research.

(a) When feasible, equipment is to be purchased in the first year of the project. Under unusual circumstances, and if properly justified, BLR&D and CSR&D services will consider

equipment requests in years 2-5. **NOTE:** Terminology such as ‘miscellaneous small pieces of equipment’ is not be used.

(b) Expendable items are to be requested as supplies.

(c) Approval must be received in advance to request equipment totaling more than \$50,000 (see the guidance document, [Instructions for Preparing and Submitting a Letter of Intent \(LOI\) to Exceed Budget Caps.](#)

(8) **Supplies.** Itemize expendable supplies in separate categories, such as: glassware, chemicals, radioisotopes, etc. Categories totaling less than \$1,000 do not need to be itemized. If animals are to be purchased, state the species, cost per animal, and number to be purchased in the first year.

(9) **All Other Expenses.** List all other expenses by major category, including costs for publications, rental and contractual fees, and travel costs. Travel for accomplishing any part of the proposed specific aims should be clearly justified in the budget justification section. Travel costs for presenting research findings at scientific meetings may **not** exceed \$1000. *Note: Investigators must abide by VA policy for acknowledging VA affiliation and support on scientific presentations as described in the VHA Handbook 1200.19.* Include the daily and total charges for Animal Research Facility maintenance of all animal subjects required in the research. **Refer to Table 3 for a list of unauthorized items.** List service contracts for equipment utilized only for the proposed research. If the equipment is used by multiple research projects, request a proportionate amount of the service contract.

TABLE 3. Unauthorized Budget Items

PERSONNEL

Increases over years to account for inflation or salary increases

Dishwashing aide

Summer students

Graduate Students

EQUIPMENT

Office Furniture

SUPPLIES

Office supplies

OTHER (Usually supplied by local facility)

Books and journals

“charge-back costs”

Medical media and/or slide preparation and/or photography

Photocopying charges

Maintenance costs which are unjustified

Maintenance costs for core or shared equipment

Library computer searches

Word processing

Long distance phone charges

Cylinder demurrage charges

Communication costs

Radioisotope waste disposal
Biohazard waste disposal

e. **VA Form 10-1313-4, Estimated Expenses For the Project.**

(1) Enter the totals for each budget category for all additional years of support requested. The total operating expenses for the first year must be identical to the total indicated on VA Forms 10-1313-1 and 10-1313-3. Cost-of-living adjustments are not allowed.

(2) All differences in the operating expenses between years needs to be fully justified.

(3) Justification. All items in the budget must be clearly justified. Use continuation pages if necessary.

(a) Personnel. Fully explain the role and percent effort of the PI and all personnel listed in the Personnel section of VA form 10-1313-3. If the PI is a non-clinician scientist, paid by the research appropriation CC103, fully describe the basis for any difference in the % effort for the work proposed and total VA effort (salary support). The signature of the ACOS for R&D on VA Form 10-1313-1 signifies agreement to have the non-clinician PI perform the work described to justify salary. Salary compensation may not be requested for a clinician if the person is licensed to practice medicine in the United States. A clear statement to regarding license to practice in the U.S. must be included in the justification section if salary is requested for a clinician investigator.

(b) Consultants. Clearly explain the expertise of each consultant with regard to the proposed research. State the frequency of consultations. M.D. consultants may not receive salary compensation.

(c) Equipment. For each item, justification should include a discussion of why the equipment is needed and why similar existing equipment (if any), whether in the laboratory, common resource equipment, borrowed, or on loan, cannot be used. Describe the equipment used in the generation of the data in the “Work Accomplished” section and its availability for the proposed research. The equipment budget is capped at \$50,000. Requests for exceeding the equipment budget cap must be included in the letter of intent (see Appendix D for instructions).

(d) Supplies. Explain how the costs for each category of supplies were derived (e.g., based on the PI’s expense history in performing similar research).

(e) All Other Expenses. Items in this category should be explained in the same manner as those in the supplies category. Personnel contracts or IPAs should be listed here including the basis for the individual’s salary.

1. Travel costs for accomplishing any part of the proposed specific aims should be clearly justified in the budget justification section. Travel costs for presenting research findings at scientific meetings may not exceed \$1000.

Note: Investigators must abide by VA policy for acknowledging VA affiliation and support on scientific presentations as described in the VHA Handbook 1200.19.

(4) The budget totals on VA Form 10-1313-3 and VA Form 10-1313-4 must match each other as well as the totals in block 11 of VA Form 10-1313-1. The accuracy of these items needs to be checked before sending the proposal.

f. **Investigator Information (VA Form 10-1313-5/6, VA Form 10-1313-8)**. The two forms (VA Form 10-1313-5/6, and VA Form 10-1313-8) must be completed for the PI and for each scientist who will participate in the design, performance or scientific direction of the proposed research. For those investigators devoting 5 percent effort or less, include only biographical information (see VA Form 10-1313-5/6). Do not include any of the above forms for consultants or technical staff. **NOTE:** *VA Form 10-1313-7 is no longer required.*

(1) **Investigator's Biographic Sketch (VA Form 10-1313-5/6)**. Follow the instructions on the form. If requesting more than a 3-year duration, include all appropriate prior funding history.

(2) **Investigator's Total Research/Development Support (VA Form 10-1313-8)**. Read these instructions carefully as they are different from previous instructions for this form. Total research support is defined as all financial resources, whether Federal, non-Federal, commercial or institutional available in direct support of the individual's research. Examples are current Merit Review awards, research grants, cooperative agreements, contracts, institutional awards, and awards from VA research programs such as Epidemiology Research Program, Clinical Trials Program, HSR&D, RR&D, CSP and REAPs or Centers. Include all currently funded and pending support. Do not include the current application as pending support.

(a) **Copy VA Form 10-1313-8 as needed.** If the investigator has no active or pending support, write "None" in the first description box. Otherwise, starting with active awards, follow the instructions on the form for "Status." In the "Grant/Project No" box write the name of the awarding agency and the project number, if assigned. In the Grant/Project Title box, write the full title and the sub-project number, if appropriate.

(b) In the box provided for description, use the following format:

1. Role. State the investigator's role in the project (PI, co-investigator, PI of sub-project, etc.)
2. Dates of Approved/Pending Project. Indicate the inclusive dates of the project as funded or proposed.
3. Annual Direct Costs. For active awards, provide the current year's direct cost budget and for pending applications provide the proposed initial budget period.
4. Percent Effort. For an active award, provide the level of effort (whether salaried or unsalaried) as approved for the current budget period. For pending projects list the level of effort proposed for the initial budget period.
5. Major Goals. Provide a brief statement of the overall objectives of the project. If it is a sub-project on a center grant or contract, provide the objectives for the sub-project only.

(c) Using this format, continue to list all active and pending funding for the investigator.

(d) Overlap. After listing all of an investigator’s support, in a paragraph headed “Overlap,” summarize any potential overlap between the research in the proposal and any active or pending research with respect to the science, budget, or the investigator’s total effort. Statements such as “there are no budgetary, scientific or administrative overlaps” without any discussion of the science are not acceptable.

1. Budget overlap occurs when duplicate or equivalent budget items, such as equipment or salary, requested in the application are already funded, requested in a pending application, or provided from another source.

2. Commitment overlap occurs when any personnel listed on the project has time or effort commitments (whether salaried or unsalaried) that exceed 100 percent. No individual listed on the project budget form may have more than 100 percent effort.

3. Scientific overlap occurs when substantially the same research is proposed in more than one application, is submitted to two or more funding sources, or when the research objectives and the research designs are the same or grossly similar in two or more applications, regardless of funding sources.

g. **General Instructions for Response and Narrative.** Observe the page number limitations specified in Table 4. Proposals exceeding page limitations will not be reviewed.

TABLE 4: Page Limitations and Content Requirements		
Section	Limit	Content
Response (Revised applications)	3	See instructions, paragraph 2h
List of abbreviations and acronyms		
Research Narrative (sections 1-4)	25	All text, figures, charts, tables and diagrams
Human Subjects (as needed)		See instructions, paragraph 2k
Animal Subjects (as needed)		See Instructions, paragraph 2l
Resources	1	See instructions, paragraph 2m
Publications from last funding period		See instructions, paragraph 2o
Literature citations	4	Complete citations including titles and all authors
Appendix (Supplemental methodology may not be included)		No more than five publications including accepted or submitted manuscripts. Photographs that do not copy well (include photocopies in Narrative). Questionnaires Other materials that do not copy well (include photocopies in Narrative)

(1) Avoid delays and misunderstandings by carefully reading and following the instructions. Use proper English and avoid jargon. For terms that are not universally known, spell out the

term for the first time followed by an abbreviation enclosed in parentheses; thereafter the abbreviation may be used. Also, include these terms in the List of Abbreviations and Acronyms.

(2) **Observe type size specifications and margin requirements throughout the application, or it will not be reviewed.** Prepare the original application on standard 8.5" X 11" white paper, single-sided and single-spaced. Except for margin requirements of specific forms, allow a 1" margin at all edges and use a single column. Multiple columns may not be used. Use standard type fonts with black letters that can be clearly copied. Do not use photo reductions. All tables, diagrams, graphs, and charts, must be clear and legible.

(3) The height of the letters must be at least 11 points, the type density must be no more than 15 characters per inch (CPI) and have no more than 6 lines of type within a vertical inch. For proportional spacing, any representative section of text must not exceed a density of 15 CPI. Smaller type sizes are difficult to read and give the applicant an unfair advantage by allowing more text in the proposal. Rather than relying on font selections by word processor or printer combinations, correct type size needs to be verified with a standard type-measuring device. At least the minimum type size must be used throughout the application.

(4) All figures and tables must be included in the text. As long as it is clearly legible, type size for figures, charts, tables, footnotes, and figure legends, may be smaller.

(5) **Proposals that are difficult to read (for example, small font, margin) will be administratively withdrawn.**

(6) Originals of photographs that do not copy well should be included in the appendix. Photocopies of these photographs also are to be placed in the text of the proposal and are included in the 25-page limit. Unpublished questionnaires may also be placed in the appendix. Methods and/or procedures, even if unpublished, are to be incorporated into the Narrative and are not to be placed in the appendix. The Narrative must be comprehensible and complete without references to any other document, including the appendix.

h. **Response (resubmitted applications only, three-page limit).** A revised application will not be reviewed if it fails to comply with all of the requirements for resubmission. Prior to submitting a revised application, the PI should have received the summary statement and critiques from the previous review and these must be included in the resubmission.

(1) The resubmission must contain substantial revision to the content of the proposal. The revised application must start with a response or rebuttal letter of not more than 3 pages, which summarizes the substantial additions, deletions, and changes based on the comments and suggestions in the summary statement. If changes suggested by the reviewers are not made, the reasons need to be explicitly stated. The three-page response does not count toward the 25-page narrative limit.

(2) The changes in the Narrative must be clearly marked by a vertical bar in the margin, bracketing, indenting, or a change in typography, unless the changes are so extensive that it includes the majority of the text. In that case, indicate it in the response letter. Do not use underline or shading. The Work Accomplished section needs to include any new work accomplished since the prior submission. Acceptance by BLR&D/CSR&D Services to review a revised application automatically terminates the previous version.

i. **List of Abbreviations and Acronyms Used.** Provide a list of the abbreviations and acronyms used in the Narrative. Define the term the first time it is used in the Narrative text and abstract. The exception is for those terms that are commonly understood (e.g., known by undergraduate biology students, such as DNA, ATP, etc.).

j. **Narrative (25 page limit including all text, figures, charts, graphs, and diagrams).** The Narrative is organized into four major sections: Rationale, Background and Significance, Work Accomplished, and Work Proposed. Use the Narrative to explain (1) what the P.I. proposes to do; (2) why the proposed work is important; (3) what similar work has been done; and (4) how the proposed work will be done. All tables, graphs, charts, diagrams, and photographs must be included in the 25-page limit; items that do not photocopy well may also be included in an appendix. The 25-page limit for the Narrative will be strictly enforced. Applications that exceed this limit or fail to comply with type size or margin specifications will not be reviewed. Within the Narrative, BLR&D and CSR&D services recommend the following outline and page restrictions.

(1) Rationale (1-2 pages recommended)

- (a) Statement of the Problem. Briefly state the problem to be investigated.
- (b) Hypotheses or Key Question. State the hypotheses or key questions to be answered by the proposed research.
- (c) Specific Objectives. Briefly and concisely list the long-term and more immediate objectives of the proposed research. For long-term objectives, identify expected intermediate goals.

(2) Background and Significance (2-3 pages recommended)

- (a) Background. Briefly describe the current status of research relevant to the present application and how it relates to the hypotheses or key questions. Critically evaluate existing, relevant knowledge and explicitly state the gaps that the proposed research will fill. Cite only relevant and recent literature. The Background section needs to be sufficiently complete to demonstrate that the PI is aware of the critical issues related to the proposal. It need not be exhaustive.
- (b) Significance. Explain the potential importance of the proposed work and identify any unique ideas or potential contributions that might result from this study.
- (c) Relevance to Veterans Health. It is important that the proposed research is relevant to the healthcare of veterans. Describe clearly the relevance of the proposed work to the VA patient care mission specifically and health issues in general.

(3) Work Accomplished (6-8 pages recommended)

(a) New applications (including revisions to new applications). Describe the preliminary or previous studies conducted by the PI that are pertinent to the application. The information should help reviewers evaluate the experience and competence of the investigator to pursue the research. The experience and/or competence of key collaborators may be briefly described. Up to five publications and/or submitted or accepted manuscripts by the PI may be placed in the appendix.

(b) Renewal Applications. In addition to describing relevant preliminary studies, a progress report is required for all renewal applications. Provide the beginning and ending dates for the last period of funding. Summarize the previous program's specific aims and/or objectives, as well as changes to the specific aims due to budget reductions. Discuss the progress made toward achieving the specific aims by providing a succinct account of relevant published and unpublished results of work funded by the previous application. In the section entitled "Publications From Previous Funding Period," provide complete references for all publications, manuscripts submitted or accepted for publication, patents or other printed materials that have resulted from this project during its last funding period. Up to five publications, submitted or accepted manuscripts may be placed in the appendix.

(4) **Work Proposed**

(a) Provide a timetable describing the sequence of the proposed research.

Note: For studies involving enrollment of human subjects, provide a timeline for recruitment, specifying the number of patients to be enrolled per year during the course of the study. Indicate when subjects will start and complete participation in the study.

(b) It is useful to specifically relate each experiment to particular hypotheses and/or key questions. Describe the research design, methods, and procedures to be used to accomplish the specific aims of the application.

(c) Describe the experimental design and/or approach and how the data will be collected, analyzed and interpreted. Describe new methodologies to be used and why they are preferred over existing methods.

(d) Discuss potential problems and limitations of the proposed methods and/or procedures and possible alternative procedures to achieve the specific aims.

(e) If humans or animals are to be studied, power analysis needs to be used to justify the number to be studied. Justify the species of animal to be used. If cell lines or tissue specimens are used, discuss the source of the material.

k. **Human Studies Section (no limit, be succinct - not included in 25-page limit for narrative)**. If form 10-1313-1, Block 19, Human Subjects is checked "Yes," create a section heading titled "Human Subjects." Applicants must address the involvement of human subjects and protections from research risk relating to their participation in the proposed research plan. In this section, provide information to address all of the following four evaluation criteria as they apply to the research proposed. *NOTE: Applications that fail to comply will be withdrawn without review.*

(1) **Risk to Subjects**

(a) **Human Subjects Involvement and Characteristics.** Describe the proposed involvement of human subjects in the work outlined in the Research Design and Methods section. Describe the characteristics of the subject population, including their anticipated number, age range, and health status. Identify the criteria for inclusion or exclusion of any subpopulation. Explain the rationale for the involvement of special classes of subjects, such as pregnant women, prisoners, institutionalized individuals, or others who may be considered vulnerable populations. **Indicate whether all subjects recruited for the study will be veterans or whether non-veterans will also be included. A justification must be provided for use of non-veteran subjects in interventional clinical trials.**

(b) **Sources of Materials.** Identify the sources of research material obtained from individually identifiable living human subjects in the form of specimens, records, or data. Indicate whether the material or data will be obtained specifically for research purposes, or whether use will be made of existing specimens, records, or data.

(c) **Potential Risks.** Describe the potential risks to subjects (physical, psychological, social, legal, or other) and assess their likelihood and seriousness to the subjects. Differentiate the therapeutic risk from research risk.

1. Therapeutic risk is the risk or potential risks associated with an intervention that is required for medical care, but occurs as part of the research. An example is an endoscopy that was required for medical follow-up of a specific illness.

2. Research risk is associated with an intervention that is done only for research purposes regardless if it is an experimental intervention or a commonly used intervention, for example, an extra endoscopy. Where appropriate, describe alternative treatments and procedures, including the risks and benefits of the alternative treatments and procedures to participants in the proposed research.

(2) **Adequacy of Protection from Risks**

(a) **Recruitment and Informed Consent.** Describe plans for the recruitment of subjects and the process for obtaining informed consent. Include a description of the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent. ***NOTE: The informed consent document may not be submitted at this time.***

(b) **Protection Against Risk.** Describe the planned procedures for protecting against or minimizing potential risks, including risks to confidentiality, and assess their likely effectiveness. Where appropriate, discuss plans for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects. In studies that involve interventions, describe the plan for data and safety monitoring of the research to ensure the safety of subjects.

(3) **Potential Benefit of the Proposed Research to the Subject and Others.** Discuss the potential benefits of the research to the subjects and others. Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and others.

(4) **Importance of the Knowledge to be Gained.** Discuss the importance of the knowledge to be gained as a result of the proposed research. Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that reasonably may be expected to result.

1. **Animal Subjects (no page limit, be succinct -- not included in 25-page limit for narrative)**. In this section, provide information to address all of the following five evaluation criteria as they apply to the animal subjects research proposed. *NOTE: Applications that fail to comply or fail to address the following elements will result in the application being withdrawn without review.*

(1) Provide a detailed description of the proposed use of the animals in the work outlined in the Research Design and Methods section. Identify the species, strains, ages, sex, and numbers of animals to be used in the proposed work.

(2) Justify the use of animals, the choice of species, and the numbers to be used. If animals are in short supply, costly, or to be used in large numbers, provide an additional rationale for their selection and numbers.

(3) Provide information on the veterinary care of the animals involved.

(4) Describe the procedures for ensuring that discomfort, distress, pain, and injury will be limited to that which is unavoidable in the conduct of scientifically sound research. Describe the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices, where appropriate, to minimize discomfort, distress, pain, and injury.

(5) Describe any method of euthanasia to be used and the reason(s) for its selection. State whether this method is consistent with the recommendations of the Panel on Euthanasia of the American Veterinary Medical Association. If not, present a justification for not following the recommendations.

m. **Resources (1 page limit – not included in 25-page limit for narrative)**

Research Space:

(1) Provide building and specific room numbers and specifically indicate whether the proposed research will be conducted in VA space or off-site, completely or partially. In addition, specify if any portion of the proposed study will be conducted in a collaborator's laboratory or in an off-site common/core facility.

(2) If a VA investigator (PI or VA co-investigator) will perform any portion of the proposed research in assigned off-site space, a copy of an approved off-site waiver must be included in the application. If any of the proposed work will be done in VA leased space, a copy of the approval for the use of the lease must be included. If a non-VA co-investigator (a person neither paid by nor on a without compensation (WOC) appointment with the VA) will complete specific portions of the proposed work in their off-site laboratory, a waiver is not needed.

(3) If clinical space will be used, describe the location, availability, and purpose.

Other Research Resources:

Describe the facilities to be used to conduct the proposed research. Describe the equipment, capabilities and capacities, their relative proximity and the extent of availability to the project. Include a description of common resource space and equipment available to the proposed research.

(1) Do not describe resources that are available, but will not be used for the proposed research.

n. **Publications from Last Funding Period.** List the complete references of all publications, manuscripts that are accepted or submitted, patents, or other printed material from the PI and/or collaborators that are based on work accomplished toward the specific aims of the proposed work and/or objectives completed during the previous funding period.

o. **Literature Citations (four-page limit).** Include a complete citation for all references (all authors, year, title, journal, volume number, and inclusive pages). Start each citation on a new line. List citations by number in the order they first appear in the application. For renewals, the list may include, but does not replace, the citations in “Publications from Last Funding Period.”

p. **Endorsements**

(1) **Just-in-Time Submission of Compliance and/or Assurance Documents.** BLR&D/ CSR&D services require just in time submission of compliance and/or approval documentation for human studies, animal studies, and biosafety. Do not submit any human subjects, animal subjects, or biosafety forms and/or approvals with this application. These documents should be submitted only after funding notices are received by the local VA research offices. However, the local facility may conduct compliance assurance reviews before the funding notice is received, but submit the reviews when requested by VACO.

(2) Include a memorandum signed by the Chair, R&D Committee stating the application was reviewed and approved for submission to VA Central Office (include the date of approval) by the R&D Committee.

(3) If the appropriate compliance and/or assurance subcommittees have not approved the application, following review by compliance and/or assurance subcommittees, the R&D Committee must review and approve the proposal before any studies contained in the application may be conducted.

(a) The R&D approval letter must contain the following statement:

“This application has not yet been reviewed by the necessary subcommittees for approval. The PI has been reminded that only fully approved procedures may be conducted.”

(b) If the research proposes using humans or animals as subjects, the R&D Committee must document discussion of the adequacy of the applications section(s) on “Human Studies” and/or “Animal Subjects.”

(4) Include a memorandum signed by the facility Director stating that the Director understands the impact of the proposed research on the facility's organization, that the Director endorses the project, and that the space described in the application and necessary support of the VA facility will be available. If the PI's appointment is to start at the time of funding, the medical center Director's letter must contain a statement indicating that the Director agrees to employ the PI at least 5/8ths time. The R&D Committee's and facility Director's endorsements may be combined as long as all requested items are addressed and the R&D Chair and the facility Director sign the memorandum.

(5) Provide letters from each collaborator indicating a willingness to fulfill the duties described in the application.

q. **Revised Proposals.** Revised proposals must include the final Summary Statement (including VA Form 10-1313A, Merit Review Board Summary Statement) and reviews from the most recent review round. These materials shall be the very last items in the application with the summary statement placed last.

r. **Page Numbering.** Type the last name of the PI in the lower right corner of each page and number each page consecutively, starting with the VA Form 10-1313-1 (e.g., Smith-1 to Smith-37).

3. TRANSMITTING THE APPLICATION

a. **Intent to Submit.** The local VA research office staff enter the appropriate information in ePROMISE in accordance with deadlines indicated in Table 1.

b. **Submitting the application.** Proposal submission involves completing VA Form 10-1313-1 and VA Form 10-1313-2 (including the abstract) using ePROMISE and sending hard copies (paper) of the entire proposal. The receipt deadlines are March 15 for the spring round and September 15 for the fall round. If the due date is on a weekend, the following Monday is the due date.

(1) ACOS for R&D staff complete VA Form 10-1313-1 (Face Page) and VA Form 10-1313-2 (Summary Description) using the ePROMISE system.

(2) The paper copies of these forms must be printed from the ePROMISE system. The information on the paper copies must be identical to the electronically submitted information.

(3) For the paper submission of the entire proposal, the ACOS for R&D and PI sign the printed copy of VA Form 10-1313-1. "Per," "by," or "for" signatures are not acceptable.

c. **Submit the following in one package**

(1) The original single-sided application with the signatures of the PI and ACOS for R&D on page 1 (VA Form 10-1313-1), assembled in the order specified in the table of contents.

(2) ***NOTE:*** Twenty-five exact, clearly legible copies reproduced back to back. Each copy is to be bound with a binder (paper) clip. Do not staple copies or use rubber bands or colored paper separators.

(3) Seven collated sets of appendix material directly relevant to the proposal, such as reprints and manuscripts, may be stapled and each item is to be marked with the PI's name. Videotapes and books are not acceptable as 'reprints.' **NOTE:** *A summary sheet listing all the items in the appendix is useful.*

(4) Twenty copies of VA Form 10-1313-1 with VA Form 10-1313-2 duplicated back-to-back.

d. Carefully check the proposal and copies before submitting them to VA Central Office.

e. Either United States (U.S.) mail or courier service may be used to send the application (original, twenty-five exact copies, seven collated copies of the appendix). Applications should be mailed to the following address:

Department of Veterans Affairs
BLR&D/CSR&D
Merit Review Application (121F)
810 Vermont Avenue, NW
Washington, DC 20420

Telephone Number for Courier Delivery: (202) 254-0183/84

f. **Under Separate Cover.** The ACOS for R&D may send a list of suggested external reviewers and those reviewers believed to have a bias against the proposed research to Department of Veterans Affairs, 121F, 810 Vermont Avenue, Washington, DC 20420. Include the address, telephone number and e-mail address, if available, for each suggested reviewer. A separate letter may request that the proposal be referred to a specific Merit Review Subcommittee. **NOTE:** *The request must be justified and consistent with the purview of the requested Subcommittee; see guidance document, [Purview of BLR&D and CSR&D Merit Review Subcommittees](#).* Final decision on reviewers and referrals are the responsibility of the Program Review Division. The deadline for these letters is one day after the deadline for receipt of applications.

4. DEFICIENCIES. Deficiencies may be corrected only at the direction of the Program Review Division. No late material (e.g., reprints, approval letters, endorsement letters, proposal corrections, etc.) will be accepted unless specifically requested by the portfolio manager for the Merit Review Subcommittee. The only exception is official letters of acceptance for publication for submitted manuscripts, which may be sent to the Program Review Division at any time.

5. PROPOSAL WITHDRAWAL. A proposal may be withdrawn by the ACOS for R&D by contacting the Chief, Program Review Division.

6. SITE CHANGE DURING REVIEW ROUND. All information given to reviewers must reflect the PI's circumstances and research site. If a PI transfers to another VA, or the facilities available to the project change, the portfolio manager for the Merit Review subcommittee must be notified and updated information supplied, if requested.

7. POST SUBMISSION COMMUNICATION. The originating VA medical center is notified of receipt and tentative acceptance to review the proposal along with the name of the Merit Review subcommittee or other review entity to which the proposal was assigned.

a. Questions or concerns about the Subcommittee assignment may be directed to the Chief, Program Review.

b. Subcommittee review dates are posted on the VA R&D website.

c. Shortly after review by the Merit Review subcommittee, the originating VA medical center will receive an early notification letter and preliminary and/or draft copy of the Summary Statement and individual reviews.

8. JUST-IN-TIME RECEIPT OF COMPLIANCE AND ASSURANCE DOCUMENTATION

a. The following paragraph is limited to the receipt of compliance and assurance documentation. It is a local facility decision whether subcommittee review for human subjects, animal subjects, and/or biosafety is conducted prior to the submission of the application, after the submission, or after notification of possible funding.

(1) Research offices will be notified of proposals that are in consideration for funding and the specific just-in-time documentation needed to complete the review process. If a proposal is being considered for funding, the office of the ACOS for R&D must submit, to BLR&D or CSR&D, all required documents of appropriate R&D subcommittees. These documents will not be accepted prior to this notification. **No proposal will be funded until these forms and approvals are received and accepted by BLR&D and CSR&D.**

(2) If the proposal was submitted prior to review by R&D subcommittees, the R&D Committee must re-review the proposal and all supporting documentation. Documentation, including proposal title and principal investigator name, must exactly correspond to the work proposed in the application. A letter from the R&D Committee Chairman must accompany these documents and state that the R&D Committee has given full approval to the proposal and concurs with the subcommittee recommendations.

b. **Approval Dates.** Approval of all forms pertaining to human studies, animal subjects or biosafety must be current at the time the forms are submitted to VACO. Be especially mindful of this requirement when submitting revised applications. The committee Chairperson must sign all applicable committee forms. If the Chairperson is also the PI, another member of the committee must be delegated the responsibility for signing the forms. Under no circumstance may a member of the Research Service administrative staff or the ACOS for R&D sign committee forms.

c. **Human Subjects.** The Human Studies Subcommittee or its equivalent IRB must approve all proposals involving human subjects or human tissue. Send a copy of the “Report of Subcommittee on Human Studies” (VA Form 10-1223). If the IRB approved the protocol by expedited review, exempted the protocol from IRB review, or granted a waiver from obtaining informed consent, ***it must be explicitly stated in section 8 “Comments” of VA Form 10-1223.*** The chair of the IRB must sign the form. ***NOTE: In lieu of VA Form 10-1223, BLR&D and CSR&D will accept an equivalent IRB form as long as it contains all of the elements of VA Form 10-1223.***

(1) Unless the proposed research was granted a waiver from obtaining informed consent, one or more approved consent forms, filled out using VA form 10-1086, must be included after VA Form 10-1223.

(2) The title on the informed consent form must be the same as the title of the application (VA Form 10-1313-1, box 10). If multiple informed consents are needed, the consent form title may be the application title with a project title appended to it.

(3) Each page of each consent form must be date stamped and the dates on the consent form and Report of the Human Subjects Subcommittee form must be current. Forms from a previous submission of the application may be used, if the dates of approval have not expired and if changes to the proposed research did not necessitate re-review by the IRB.

(4) The VA informed consent form (VA form 10-1086) must be used, even if the affiliated university’s IRB is the IRB of record.

(5) For research involving human subjects or human tissue, all investigators, research coordinators, and research assistants involved in that research must document training in the ethical principals and accepted practices on which human studies research should be conducted. ***Documentation of successful training on both the protection of human research subjects and Good Clinical Practice is required and must be dated within one year of submission of the just-in-time materials.*** Documentation may be in the form of a certificate from a VA-approved training program(s) or equivalent documentation from training programs listed on the VA Research and Development website. One letter detailing the time of completion and training program for multiple investigators is acceptable. Documentation of the training requirement must follow VA Form 10-1223 and VA Form 10-1086.

(6) If the research involves banking of human specimens, gene testing, gene transfer, and/or stem cells, it must comply with all VA policies and guidelines regulating the conduct of such types of research.

(7) Recombinant DNA: Research involving recombinant deoxyribonucleic acid (DNA) must comply with all VA regulations regarding human subject protection in genetic research, biohazards, and other related guidelines. Recombinant DNA is defined according to VA guidelines as:

(a) Molecules that are manufactured outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or

(b) Molecules that result from the replication of those described in the first part of this definition.

d. **Animal subjects.** An approved, current VA ACORP must be submitted for any proposal using animals or animal tissues using the criteria in items (1) and (2) below. Note: These criteria do not serve as a basis for determining if local IACUC approval is required; they should be used only for the purposes of determining if an ACORP must be submitted as a prerequisite for receiving VA funding for a Merit Review application.

(1) An ACORP must be submitted when requested if any of the following conditions apply (the "Yes" box for animal subjects should be checked in item 19 on form 10-1313-1):

(a) Animals are requested in the application budget for use in proposed experiments.

(b) Animals purchased with other VA funds or with non-VA funds would be used primarily or exclusively for experiments proposed in the application.

(c) Animal tissues or primary cell lines purchased with other VA funds or with non-VA funds would be derived from animals sacrificed primarily or exclusively for use in the experiments proposed in the VA application.

(2) An ACORP is not required for submission if none of the criteria in item (1) apply, and the proposed animal use meets one of the following criteria (the "No" box for animal subjects should be checked in item 19 on form 10-1313-1):

(a) Immortal animal cell lines or explants would be used in the proposed experiments such that no additional animals would need to be euthanatized to meet application objectives.

(b) Animals on other IACUC-approved projects would be used, but these animals would be utilized for other projects even if the need for the animals by the proposed VA project did not exist.

(c) Animal tissues, blood and other body fluids, or primary cell lines would be obtained from live animals on other IACUC-approved protocols, but samples from these animals would be collected even if the need for the tissues or cell lines by the proposed VA project did not exist.

(d) Animal tissues, blood and other body fluids, or primary cell lines would be obtained from animals euthanatized while on other IACUC-approved protocols, but samples from these animals would be collected even if the need for the tissues or cell lines by the proposed VA project did not exist.

(e) Animal-derived reagents or products such as serum, antibodies and mediators required in the application are limited to those that would be purchased from a USDA-licensed commercial vendor.

(3) If guidance is needed on applying the criteria in paragraphs (1) and (2), the CVMO should be contacted.

e. **Investigational Drugs and Devices.** Food and Drug Administration (FDA) approval for use of an investigational drug (IND) or device must be on file at the VA medical center. The R&D concurrence memorandum, signed by the Chair, R&D Committee, certifies that the appropriate approvals are on file. VA Form 10-9012, Investigational Drug Information Record, must be used for this purpose, but need not be submitted.

f. **Biohazards.** Whether or not the Biohazards box in VA Form 10-1313-1 is checked, the biohazards form, VA Form 10-0398, must be submitted, have the proper signatures, and be dated.

g. **R&D Approval.** Following review and approval by all required subcommittees, the R&D committee must review and give final approval to the application and confirm the approval of all applicable subcommittees. A letter of approval, signed by the Chair, R&D Committee, must be sent through the medical center Director with all applicable documentation.

h. **Submission of Documents.** Send the original and four exact copies of all applicable documentation via regular mail or courier to:

Department of Veterans Affairs
BLR&D/CSR&D
JIT Documents (121E)
810 Vermont Avenue, NW
Washington, DC 20420

Telephone Number for Courier Delivery: (202) 254-0183/84

9. QUESTIONS AND INQUIRIES: Inquiries related to Merit Review submission or review should be directed to the Chief of Program Review, BLR&D and CSR&D services. 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, including questions relating to Summary Statements and budgets.

For a current Merit Review calendar and portfolio managers for the various Merit Review Subcommittees, please refer to the website at the following address:

<http://www1.va.gov/resdev/programs/blrd-csrd/merit-rev-calendar.cfm>

SPECIAL MERIT REVIEW PROGRAMS

1. EPIDEMIOLOGY RESEARCH PROGRAM

The Epidemiology Research Program is a special Merit Review Program of BLR&D and CSR&D. This section provides guidelines regarding the Epidemiology Research Program.

a. **Background.** The previous ORD program announcement entitled “Epidemiology Research” described the opportunity for VA investigators to submit investigator-initiated epidemiology research proposals to ORD. *NOTE: This section supersedes all previous announcements related to epidemiology research proposals.* The primary objective of this program is to foster epidemiological studies in areas of high relevance to the VA research mission.

b. **Scope.** For the purpose of the Epidemiology Research Program, epidemiological research is defined as investigator-initiated studies that employ a population based approach in design and methodology and investigate the prevalence, etiology, and risk factors of diseases and disorders affecting veterans. Epidemiological studies may also assess the efficacy of modern diagnostic, treatment, and preventive strategies. Epidemiology research proposals may be reviewed in a special Merit Review Subcommittee (EPID) or in an appropriate disease/organ based Subcommittee. For details regarding purview of the EPID Subcommittee, refer to the guidance document, [Purview of Merit Review Subcommittees](#).

It is recommended that applicants with no previous experience in conducting epidemiology research consult one of the Epidemiology Research and Information Centers (ERICs) prior to submitting a proposal.

c. **Application Requirements.**

The Epidemiology Research Program is open to all BLR&D and CSR&D investigators who are eligible to submit Merit Review proposals to BLR&D or CSR&D services.

d. **Submission of Applications.** Epidemiology research proposals must comply with the instructions for submitting a Merit Review proposal as well as supplemental instructions described in the guidance document, [Supplemental Instructions for Submitting an Epidemiology Research Proposal](#).

e. **Non-clinician PI Salary.** The salary of the non-clinician PI of an Epidemiology Research proposal may be continued for up to one year beyond the termination date of the investigator’s funded Merit Review provided the PI:

- (a) Remains employed by VA,
- (b) Continues to meet all deadlines for applying for Merit Review funding, and
- (c) Continues to participate in the overall research effort at the facility.

f. **Questions and Inquiries.** Discussion of possible epidemiology research proposals with the Program Manager for the Epidemiology Research Program prior to proposal submission is encouraged.

2. CLINICAL TRIALS PROGRAM

The Clinical Trials Program is a special Merit Review program of CSR&D. This paragraph provides guidelines regarding the program and instructions for submission of a clinical trial proposal.

a. **Scope.** The Clinical Trials Program includes randomized clinical trials involving veterans as research participants, designed to assess the effects of potential biomedical or bio-behavioral therapeutic interventions. Studies need to compare groups receiving different treatments, or a treatment(s) versus a control condition. Endpoints of the potential therapeutic interventions are to be clearly defined and can be either definitive clinical outcomes or intermediate physiological measures. A clinical trial proposal is typically a single-site or a small multi-site study. Unless noted in the following, all Merit Review guidelines, requirements and restrictions apply to the Clinical Trials Program.

(1) Studies that are not appropriate for the Clinical Trials Program include: observational studies, correlative studies, device development, development of diagnostic markers, gene expression profiling and studies designed to understand mechanisms of resistance to therapeutic interventions.

(a) Biphasic studies that determine the role of a factor in a disease (cause and effect) followed by an interventional approach are considered premature for the Clinical Trials Program. The cause and effect component must be submitted as a regular Merit Review proposal.

(b) Studies designed to assess the best practice method or cost-efficacy of interventions, are not appropriate for submission to CSR&D.

b. **Application Requirements.** The Clinical Trials Program is open to all BLR&D and CSR&D investigators eligible to submit proposals to Merit Review. A typical clinical trial proposal should describe a single-site or small multi-site study. It is anticipated that funded studies will produce a definite answer to an intermediate endpoint related to potential therapeutic intervention, produce a definite answer to a clinical question, or lead to a larger clinical trial. Therefore, Clinical Trials Program Merit Review awards are not renewable.

(1) Clinical trials with participation of more than one research site are required to submit just-in-time documents pertaining to human subjects from all participating sites.

c. **Submission of Proposals.** Clinical trial proposals must follow the Merit Review instructions as well as supplemental instructions described in the guidance document, [Supplemental Instructions for Submitting a Clinical Trial Proposal.](#)

d. **Non-clinician PI Salary.** The salary of the non-clinician PI of a clinical trial project terminates on the funding termination date.

e. **Questions And Inquiries.** Discussion of possible clinical research proposals with the CSR&D Program Manager for the Clinical Trials Program prior to proposal submission is encouraged.

3. SPECIAL INITIATIVES FOLLOWING MERIT REVIEW GUIDELINES

Submission of proposals in response to the following request for proposals (RFPs) and program announcements (PA) follow Merit Review guidelines:

- a. Parkinsons and Related Neurodegenerative Disorders
(<http://www.research.va.gov/funding/solicitations/docs/parkinsons.pdf>)
- b. Combat Casualty Neurotrauma Research Initiative
(<http://www.research.va.gov/funding/solicitations/docs/neurotrauma.pdf>)
- c. Clinical Trial Development Awards for Evaluating Effectiveness of Treatment-Diagnostic Combinations
(<http://www.research.va.gov/funding/solicitations/docs/CSR-D-Treatment-Diagnosis-RFA.pdf>)
- d. Deployment Health Research: OEF/OIF Veteran Research Issues
(http://www.research.va.gov/funding/solicitations/docs/Deployment_Health_2006.pdf)

SUPPLEMENTAL INSTRUCTIONS FOR SUBMITTING AN EPIDEMIOLOGY RESEARCH (EPID) PROPOSAL

1. Applications must be complete at the time of submission and must comply with all the guidelines for submitting BLR&D and CSR&D Merit Review Award Program (Merit Review) proposals with the following modifications:

a. If an Epidemiologist and/or a Statistician are required for the project, they should be identified in the personnel section of the budget, and their role clearly delineated in the budget justification section.

b. The budget section should detail the cost of enrolling subject groups for the project.

c. The Narrative section of the proposal should address the following issues:

(1) In the Background section, the significance of the problem investigated to veterans' health and the Department of Veterans Affairs (VA) research priority areas should be clearly described.

(2) In the Work Accomplished section, the proposal should provide:

(a) Pilot data demonstrating cooperation between investigators in attaining various samples needed for the project, if applicable. This is particularly important if more than one investigator is involved in the project.

(b) Data demonstrating the feasibility of interaction between investigators at the various study sites, if applicable.

(3) In the Work Proposed section, the narrative should describe:

(a) The experimental design of the project including various comparison groups.

(b) Subjects recruitment strategies, if applicable, including control groups. The criteria to be used for subject selection; the criteria for assignments to various study groups; and the number of subjects expected to be recruited each year until the conclusion of the study should be clearly detailed.

(c) The statistical analysis including the statistical approach to the questions being investigated, calculations of sample size and other comparative measurements should be described. The proposal also needs to detail how various data measures will be categorized and assessed.

SUPPLEMENTAL INSTRUCTIONS FOR SUBMITTING A CLINICAL TRIALS PROPOSAL

Applications must be complete at the time of submission and shall comply with all of the guidelines for submitting Merit Review Award Program (Merit Review) proposals with the following modifications:

1. In the personnel section, a statistician to be associated with the project is to be identified and the statistician's role needs to be clearly delineated. A letter from the statistician, describing the statistician's role in the study design and analysis is to be included in the Administrative Issues section, following the letters of endorsement.
2. The budget must contain a line item for costs of study safety monitoring.
3. The Narrative must address the following issues:
 - a. In the Background section, include references to meta-analysis studies, if appropriate. If the study involves the use of drugs, pertinent pharmacological and toxicological data needs to be summarized with appropriate documentation.
 - b. As appropriate, the following items must be included in the Work Proposed section:
 - (1) An experimental design of the study, including descriptions of comparison groups and control measures;
 - (2) A flowchart of basic study design.
 - (3) Subject (patient) recruitment, selection criteria, and method of assignment to comparison groups.
 - (4) Intervention and/or methods of treatment including, if appropriate, the method of randomization, provision for double-blinding, and breaking the blind.
 - (5) Methods of follow-up and methods of ensuring uniformity of the intervention.
 - (6) Outcome measurements including any specialized rating scales.
 - (7) A schedule of observations and laboratory tests.
 - (8) Sample size issues including the assumptions used to determine number of subjects required, expected drop out rates and procedures for analyzing the data with respect to the drop outs, duration of subject intake period, number of participating medical centers, and description of other studies that could compete for subjects; and
 - (9) A statistical analysis section describing how the major hypothesis or research questions will be tested, including the specification of major endpoints. Studies need to be powered to achieve clinically meaningful outcomes, not just statistically significant outcomes.

(10) Immediately following the Narrative, in a section titled “Safety and Monitoring,” the plans for monitoring the safety of participants and the accuracy and integrity of the data must be detailed.

(a) For multi-site projects, describe any quality assurance procedures including plans for auditing or monitoring clinical site practices at all sites involved.

(b) An appropriate data and safety monitoring plan, including a description of risks and safety measures must be included in the proposal at the time of submission. For single site studies with a high risk intervention and all multiple site studies, a Data and Safety Monitoring Board (DSMB) or its equivalent (which may consist of one individual) must be proposed. The responsibility of the DSMB is to review the progress of the study for safety and efficacy at least every 6 months with a recommendation to the local IRB to continue, amend or terminate the trial. Consideration for use of a DSMB should be given if the study involves vulnerable populations, is blinded or involves placebo controls. For information on requirements for the protection of human subjects in research, refer to VHA Handbook 1200.5. *NOTE: Personnel involved in any aspect of the study may not serve on the DSMB.*

INSTRUCTIONS FOR PREPARING AND SUBMITTING A LETTER OF INTENT TO EXCEED BUDGET CAPS

Preparation. A letter of intent to exceed the Merit Review budget and/or award duration cap consists of the VHA Research and Development Letter of Intent (LOI) cover page (VA Form 10-1313-13) plus a standard LOI. The LOI should consist of single-spaced typed pages. Use only letter-quality print. All text must be prepared with at least 11-point font, with no more than 15 characters per inch and no more than 6 lines per inch. Page margins must be a minimum of 1 inch at each edge.

1. VHA Research and Development Letter of Intent (LOI) Cover Page (VA Form 10-1313-13)
2. Standard LOI
3. LOI Submission

1. VHA Research & Development Letter Of Intent Cover Page

(VA Form [10-1313-13](#)). *Note that the VA Form 10-1313-13 has been revised. Please use the current version available on the VA R&D website*

Instructions for VA Form 10-1313-13 (Boxes 1-5):

Box 1. Select the appropriate service (BLR&D or CSR&D) based on the nature of your proposed study. Use the following guidelines for service purviews:

BLR&D supports laboratory studies, both *in vitro* and *in vivo*, including tissue culture and animal models; and studies on human biological samples. CSR&D supports studies on whole human subjects involving interventional or exploratory procedures (with the exception of procedures for obtaining biological samples such as drawing blood, buccal swabs etc.).

Box 2. Select “New”, if the LOI is for the first submission of the proposed research or the first LOI submission for a competitive renewal of an ongoing project. *Note: This definition of “new” is valid only for an LOI submission and may differ for a full proposal submission.* If this is not a new LOI, you should select either “Revision” or “Resubmission.” Select “Revision” if there are any substantive changes in the scientific component of the study (e.g., number and scope of specific aims or methodology proposed) since the previous LOI submission. Select “Resubmission” if there are no substantive changes in the scientific component of the study since the previous LOI submission.

Box 3. Select the appropriate program. Check the box for Standard Merit Review if it for a regular Merit Review, including a clinical trial proposal and epidemiology research proposal. If you are responding to a specific announcement, check the box for Response to a Specific Announcement or Other and type the title of the announcement and number, if applicable, in the box below.

Box 4. Enter the project title (Limit the title to a total of 72 characters, including spaces).

Box 5. Enter the principal investigator’s (PI’s) complete VA direct contact information. If the PI is not a current VA employee, enter the contact information for your local VA

Research Office. *Note: A proposal may have only one principal investigator (PI). As per current policy, BLR&D and CSR&D Services do not allow co-PIs.*

2. Standard Letter of Intent (LOI): Limit to a total of 3 pages

- a) Hypothesis(es)/Research Questions
- b) Discrete Study Objectives
- c) Description of Relevance to VA
- d) Overview of Design/Methods

Note: This section should include a clear statement of the model(s) of choice for the study, i.e., human, animal, cell culture etc.

- e) Description of Intervention(s)/Treatment(s) - *if applicable*
- f) Total Budget and Study Duration: *If you are submitting an LOI to request waiver of budget cap(s) (annual budget and/or equipment budget) and/or the study duration for a Merit Review proposal, the following should be addressed in this section.*

- Provide a budget for the proposed project. Include annual and total costs and specify major elements of the personnel, equipment, consultants, supplies, and all other expenses categories.
- Justify each category.
- For the equipment category, the justification needs to include a discussion of why the equipment is needed and why existing equipment cannot be used. Describe the equipment used or to be used in the generation of pilot data for the research proposal.
- Explain why the project requires special funding consideration based on the topic, the nature of the study, unusual resource requirements, or other factors.
- Describe how the proposed study could be completed or modified if the request to exceed the budget limit is denied.

g) Statement of Disclosure - 1-2 sentence statement from the PI indicating that no financial or contractual relationship exists between any organization involved in the proposed study that could constitute a real or apparent conflict of interest (including all investigators and collaborators who plan to devote 5 percent or more effort to the proposed project). If such a relationship or contract does exist, full disclosure must be provided.

h) Acknowledgment of the VA policy to include women and minorities in research (if applicable).

i) References: Up to five reference citations relevant to the proposed study.

3. LOI Submission

The deadline for LOI submission to BLR&D/CSR&D is January 15 for the Spring round and July 15 for the Fall round. Early submission of LOIs is encouraged.

Submit the original and 3 copies, reproduced back-to-back, to the following address via courier:

Department of Veterans Affairs
BLR&D/CSR&D Letter Of Intent for
Merit Review Budget cap
Program Management Division (121E)
810 Vermont Avenue NW
Washington DC 20420

Telephone Number for Courier Delivery: 202-254-0183/84

REQUESTING ACCEPTANCE INTO THE INTRAMURAL RESEARCH PROGRAM FOR NON-CLINICIAN SCIENTISTS

1. New Non-clinician. All new non-clinician Principal Investigators (PIs) to be paid by the medical research and prosthetics appropriation must be accepted into the (BLR&D or CSR&D) intramural research program prior to submitting a regular Merit Review proposal, special Merit Review proposals such as a clinical trial proposal or an epidemiology research proposal, or responding to a request for proposals.

a. A “new” PI is one who has not been an independent PI on a BLR&D and/or CSR&D-funded Merit Review project within the last 5 years. Acceptance into the BLR&D and CSR&D program is in addition to meeting the eligibility requirement (refer to Veterans Health Administration (VHA) Handbook 1200.15) and the requirement to conduct research at a Department of Veterans Affairs (VA) medical center or VA-approved site (refer to VHA Handbook 1200.16). **NOTE:** *Career Development awardees are not considered to be independent PIs and must request acceptance into the BLR&D and CSR&D intramural research program.*

b. A scientist whose application for acceptance is denied or revoked may not be a PI on any BLR&D and CSR&D-funded project.

2. Changes. BLR&D and CSR&D must be informed of any change in laboratory location, geographic commitment, paid 8ths, or VA employment status. Non-clinician PIs wishing to transfer their research projects to a new VA facility must submit an acceptance request through the new facility.

3. Commitment. Acceptance into the BLR&D and CSR&D intramural research program is based upon the applicant’s record of prior commitment and service to the VA medical center and local intramural research program. Commitment and service may include working in another VA investigator’s laboratory, collaborating or interacting with other VA investigators, helping train and/or mentor VA junior scientists, functioning as a resource for the research community, and serving on local VA research committees.

4. Information to be Submitted. The following information must be submitted:

a. **Letter Requesting Acceptance.** The letter requesting acceptance into the BLR&D and CSR&D program must be endorsed by Associate Chief of Staff (ACOS) for Research and Development (R&D), Chief of Staff, and medical center Director. Requests for more than one investigator at a medical center may not be combined in a single request. A separate request must be submitted for every investigator. Requests for acceptance into the program or waiver from the requirement for a 5/8th clinical appointment may NOT be combined with a request for an off-site waiver. (refer to VHA Handbook 1200.15 for VA requirements for clinical appointments, and VHA Handbook 1200.16 for off-site waivers). Requests for acceptance into the program may be submitted throughout the year but must be received at least two months prior to the proposal receipt deadlines. Requests may not be appended to proposals. **NOTE:** *Be sure to include the applicant’s social security number only on the original; the social security number should be redacted from all submitted copies.*

b. **Employment Status.** Description of current VA and/or affiliated university employment status including title, source of salary support, and current number of VA eighths employed. Include a statement of how an applicant's appointment will change if the proposal is funded. *NOTE: A PI may not be placed on an Intergovernmental Personnel Act (IPA) assignment.*

c. **Location.** Specific location of office and laboratory.

d. **Activities.** Description of applicant's activities at the VA medical center, including research, teaching, mentoring, administration, and any clinical care activities.

e. **Funding History.** Applicant's research funding history.

f. **Ratio.** Number of BLR&D- and CSR&D-funded (i.e., programs 821, 825 and 829) clinicians (licensed to practice, clinical duties) to number of BLR&D- and CSR&D-funded non-clinicians at the Medical Center. Provide actual numbers without arithmetic reduction.

g. **Curriculum Vitae (C.V.).** Must include current VA appointment (VA-Paid or WOC) and previous service to a VA medical center.

h. **Statement of Citizenship.** Provide statement of citizenship status for anyone not born in the United States. Birthplace should be included in the C.V.

5. Evaluation. Applicants will be evaluated to determine if they meet the intent of the intramural program by contributing to the research service over and above the requirements of their personal research program. Over the course of their VA careers, non-clinician PIs are re-evaluated for their VA career track advancement in the intramural program (e.g., Merit Review resubmissions and the Research Career Scientist Program (refer to VHA Handbook 1202.4).

6. Due Dates. BLR&D and CSR&D accepts requests throughout the year. Submission of the request as early as possible is encouraged. The deadline for submitting a request is January 15 for the March 15 application receipt deadline and July 15 for the September 15 application receipt deadline respectively. Requests received after these deadlines will be reviewed for the subsequent round.

7. Submission. Submit the original application package plus three exact copies, reproduced back-to-back to the following address:

Department of Veterans Affairs
BLR&D/CSR&D
Permission to Submit (121E)
VA Central Office
810 Vermont Avenue, NW
Washington DC 20420

Telephone Number for Courier Delivery: (202) 254-0183/84

MERIT REVIEW PROCESS

1. **Scope.** The BLR&D and CSR&D joint Merit Review Committee is the Federal Advisory Committee responsible for the scientific review of Merit Review proposals. The Committee is comprised of Subcommittees that serve as the review groups. Subcommittees may be further divided into panels depending on the number and scope of applications received. The Portfolio Manager of the Subcommittee is the designated Federal Official in charge of the Subcommittee meetings and is responsible for conducting the meeting in accordance with the policies of VHA BLR&D and CSR&D services and the Federal Advisory Committee Act.

2. **Description of Merit Review Subcommittees.** The scientific purview of the Subcommittees is provided in the guidance document, [*Purview of Merit Review Subcommittees*](#).

(1) The Committee members are recruited from VA medical centers, universities, industry, public and private research foundations, and other Federal and state government agencies.

(2) Committee members are expected to:

(a) Have broad knowledge in their areas of expertise,

(b) Have a history of peer reviewed funding or the equivalent scientific experience, and

(c) Be leaders in their fields.

(3) Members of the Committee serve 3 or 4-year terms that may be extended.

(4) Ad hoc members may be recruited as needed.

(5) The Secretary for Veterans Affairs appoints committee members based on nominations from the Directors, BLR&D and CSR&D services.

(6) The proceedings of the Subcommittee meetings are confidential.

3. The Merit Review Subcommittees review all Merit Review proposals including clinical trials and epidemiology proposals. Merit Review Subcommittees consist of core members and ad hoc consultants. Each application is reviewed by three subject matter experts: one primary and two secondary reviewers. All Subcommittee members are present at the meeting. However, in certain circumstances, a member may participate by teleconference or contribute a review by mail.

4. During a convened meeting, reviewers present the research proposed and their individual evaluations. The Chair opens the discussion to the entire Subcommittee. Following discussion and assignment of a priority score, Subcommittee members comment on any ethical, biosafety, animal studies, or human studies concerns. If it appears that the proposal will fall within a possible fundable range, the budget and duration of the award are discussed and recommendations are made. A preliminary draft Summary Statement reflecting the discussion and the recommendations of the Subcommittee is prepared at the meeting. A final Summary Statement is prepared after administrative review, and may contain additional administrative notes.

a. **Criteria for Review and Scoring of the Proposal**

(1) The following criteria are considered during scientific merit review:

(a) Significance of the research.

(b) Scientific approach, including preliminary data and appropriateness of experimental design.

(c) Feasibility of the proposed studies including the expertise of the PI and collaborators and the environment available for conducting the studies.

(d) Innovation

(e) Relevance to the healthcare of veterans

(2) All Subcommittee members, including ad hoc members, present during the review and discussion of the proposal assign a priority score from 10-50 with 10 being the most meritorious score. Following the conclusion of the meeting, the priority scores are averaged. The Subcommittee is not apprised of the mean priority score voted for the proposal at the meeting.

b. **Conflict Of Interest.** Subcommittee members do not participate in review of proposals from their own institutions or those proposals from investigators with whom they have a scientific or personal relationship. Subcommittee members who have a conflict of interest based on academic and/or research affiliations, collaboration, or personal relationships are not present during discussion of a proposal, do not assign a score, and are not made aware of the scoring for that proposal.

c **Disapproved Proposals.** A proposal may be disapproved if the Subcommittee determines that the proposed studies are unethical or are unlikely to yield useful information.

(1) Proposals that are disapproved are not given a numerical score and may not be resubmitted.

(2) Studies disapproved for ethical considerations may not be carried out in VA space, or with VA resources, even if the project is funded by another agency.

PURVIEW OF BLR&D AND CSR&D MERIT REVIEW SUBCOMMITTEES

1. ACRONYMS

- a. AGCG = Aging and Clinical Geriatrics
- b. CARD = Cardiovascular Studies
- c. CAMM = Cellular and Molecular Medicine
- d. CLIN = Clinical Trials
- d. ENDO = Endocrinology
- f. EPID = Epidemiology
- g. GAST = Gastroenterology
- h. HEMA = Hematology
- i. IMMU = Immunology and Dermatology
- j. INDI = Infectious Diseases
- k. MHBS = Mental Health and Behavioral Sciences
- l. NEUA = Neurobiology A
- m. NEUB = Neurobiology B
- n. NEUC = Neurobiology C
- o. NEUD/E = Neurobiology D/E
- p. NEPH = Nephrology
- q. ONCO = Oncology
- r. RESP = Respiration
- s. SURG = Surgery

2. SUBCOMMITTEES

Subcommittees of the joint BLR&D and CSR&D Merit Review Committee review proposals on basic biomedical and behavioral research as well as clinical research including epidemiology and single-site or small multi-site clinical trials. The following purview provides the general

guidelines used for assignment of proposals. While the Principal Investigator may suggest a specific Subcommittee for review, the final assignment is made by Program Review and is based on where the most appropriate subject and scientific expertise is available. In any given review round, a Subcommittee may be further divided, depending upon the total number and scope of proposals received.

a. **Aging and Clinical Geriatrics (AGCG)**. The AGCG Subcommittee may review proposals focused on geriatric syndromes (e.g., frailty, delirium, falls), disease prevention in the elderly (e.g., exercise physiology, nutrition and weight control), aspects of geriatric pharmacology (e.g., polypharmacy), physiologic aging, and aspects of cellular senescence. Proposals that focus on a specific disease/organ system may be referred to the appropriate organ system Subcommittee.

b. **Cardiovascular Studies (CARD)**. The CARD Subcommittee reviews proposals on the etiology, pathogenesis, diagnosis, and treatment of diseases and disorders of the heart and vascular system. This includes studies on the etiology and pathogenesis of idiopathic hypertension. The NEPH Subcommittee reviews nephrogenic hypertension and ENDO reviews endocrine hypertension. Neurobiology Subcommittees review studies of innervation and neural control of the heart. The MHBS Subcommittee reviews behavioral control of hemodynamics and cardiac performance.

c. **Cellular and Molecular Medicine (CAMM)**. The CAMM Subcommittee reviews proposals on cellular or molecular biology, biochemistry, biophysics, or genetics that are not restricted to a particular disease process or organ system. In addition, the CAMM Subcommittee also reviews translational research proposals aimed at the development of new medical laboratory diagnostic systems. Basic science approaches that relate to a particular organ system may be reviewed by the appropriate organ system Subcommittee.

d. **Clinical Trials (CLIN)**. The CLIN Subcommittee reviews single-site or small multi-site clinical trials designed to assess the potential effects of therapeutic interventions on intermediate physiological measures or studies aimed at definitive clinical outcomes. Proposals reviewed in CLIN are focused on clinical outcomes in human subjects and require special attention to human studies concerns including safety issues, appropriate populations, and adequate statistical power to obtain meaningful results. Clinical trials may be reviewed in disease-specific Subcommittees when appropriate, depending on the composition and expertise of the Subcommittee.

e. **Endocrinology (ENDO)**. The ENDO Subcommittee reviews applications on the biology, physiology, molecular biology, and genetics of regulation of all endocrine organs and their products (e.g., insulin, glucagon, corticosteroids, and sex hormones). The etiology, pathogenesis, diagnosis, and treatment of diseases associated with endocrine abnormalities (e.g., diabetes, Cushing's syndrome, hyperthyroidism, and obesity) and bone and mineral metabolism (cell biology of bone formation and resorption, osteoporosis, vitamin D and calcium studies) are also reviewed.

f. **Epidemiology (EPID)**. The EPID Subcommittee reviews epidemiological research studies that satisfy the following criteria: the unit of observation for the primary analysis of results is an intact human being; the research question being addressed involves etiology, prevention, diagnosis, prognosis, therapy, or related aspects of health and disease; and the study design is observational (e.g., cohort or case-control studies), rather than experimental (i.e., randomized

controlled trials). Accordingly, EPID projects include traditional population-based epidemiology projects and projects in the discipline known as clinical epidemiology (focusing on questions that arise in clinic or at the hospital “bedside”). Laboratory-based projects focusing on molecular or genetic testing (e.g., molecular epidemiology with genotypes serving as the unit of analysis) or projects focusing on pathophysiological mechanisms of disease are reviewed by the appropriate disease/organ system Subcommittee. *Note: Projects assessing the delivery and outcomes of health care (e.g., issues related to quality of care, access, cost) should be submitted through HSR&D.*

g. **Gastroenterology (GAST)**. The GAST Subcommittee reviews applications on the biology and physiology of the gastrointestinal (GI) system and associated organs such as liver, spleen, gallbladder, and pancreas. Studies on GI motility, regulation of GI secretion, digestion, nutrition, and absorption are examples. This Subcommittee also reviews studies focusing on the etiology, pathophysiology, diagnosis, and treatment of diseases of the GI system and on target organ damage. Studies assessing the effects on GI function produced by immunologic, infectious, toxic, or carcinogenic agents are also reviewed by the GAST Subcommittee.

h. **Hematology (HEMA)**. The HEMA Subcommittee reviews proposals on the physiology of the cellular and non-cellular constituents of blood. The processes of hemostasis, thrombosis, blood coagulation, cell adhesion, hemocompatibility, hematopoiesis, and fibrinolysis are examples. Studies on the etiology, pathogenesis, diagnosis, and treatment of blood diseases such as leukemia, lymphoma, anemia, and thrombocytopenia are reviewed. Studies on normal and abnormal macrophage, platelet, and neutrophil functions are also reviewed by the HEMA Subcommittee.

i. **Immunology and Dermatology (IMMU)**. The IMMU Subcommittee reviews proposals on the basic immunologic mechanisms involved in functions of the immune system. Studies on the etiology, pathogenesis, diagnosis, and treatment of autoimmune disease, immunodeficiency, immune-complex disorders, and diseases related to allergic or delayed hypersensitivity reactions are also reviewed. This Subcommittee reviews proposals on immunopharmacology, immunogenetics, and dermatological disorders of immunologic or unknown etiology, and immunology of organ transplantation. The ONCO Subcommittee reviews immunotherapy of cancer and tumor immunology. The INDI Subcommittee reviews the immune response to specific infectious agents and vaccine development.

j. **Infectious Diseases (INDI)**. The INDI Subcommittee reviews proposals on the etiology, pathogenesis, diagnosis, and treatment of infectious diseases of man and relevant animal infection models. Areas of investigation include pathogenic mechanisms, host-defense mechanisms, immune responses to specific infectious agents, life cycles of the infectious agent, anti-microbial drug therapies, and vaccine development. The IMMU Subcommittee reviews studies on basic immunologic mechanisms that relate to all classes of infectious agents. The appropriate organ or system Subcommittee reviews studies on organ pathology associated with an infectious agent.

k. **Mental Health and Behavioral Sciences (MHBS)**. The MHBS Subcommittee reviews studies of the etiology, pathobiology, diagnosis and treatment of psychiatric and behavioral disorders including psychoses, mood and anxiety disorders, post-traumatic stress disorder and neurocognitive aspects of brain disorders. Sleep disorders as they relate to mood or cognitive function are also reviewed by this Subcommittee, while respiratory aspects of sleep are reviewed

by the RESP Subcommittee. The AGCG Subcommittee may review studies on management of dementia.

Neurobiology. The Neurobiology Subcommittee reviews proposals on the etiology, pathogenesis, diagnosis, and treatment of diseases of the central and peripheral nervous systems. This Subcommittee may be subdivided into Neurobiology A (NEUA), Neurobiology B (NEUB), Neurobiology C (NEUC), Neurobiology D (NEUD) and/or Neurobiology E (NEUE), depending on the number and scope of proposals received in any given review round.

Topics reviewed by the Neurobiology Subcommittees **may** be divided as follows:

l. **NEUA** reviews proposals on the neurotoxicological and behavioral concomitants of substance exposure, substance use, substance abuse, and addictive disorders. Alcoholism and drug dependence, addiction, tolerance, sensitization, craving and withdrawal, pain management and analgesia are topics reviewed by this Subcommittee. The behavioral and genetic etiology, pathobiology and treatment are reviewed by this panel.

Other subcommittees will review proposals dealing with the effects of agents on specific peripheral organs. For example, the RESP Subcommittee reviews pulmonary effects of smoke inhalation. The GAST Subcommittee reviews alcoholic liver disease and cirrhosis. Another neurobiology subcommittee may review pain anatomy proposals. The CLIN Subcommittee may review clinical trials of treatments for pain or addiction. Alcohol or drug use secondary to PTSD, anxiety, depression or schizophrenia may be reviewed by a mental health subcommittee.

m. **NEUB** reviews studies involving sleep, epilepsy, and/or neuronal plasticity.

n. **NEUC** reviews studies of injury and trauma to the central nervous system, including spinal cord injury, traumatic brain injury, stroke, intracerebral and subarachnoid hemorrhage, and the effects of ablation or pressure on neuronal function caused by CNS tumors. This Subcommittee also reviews studies of injury and trauma to the peripheral nervous system, such as peripheral or diabetic neuropathies. NEUC reviews studies on demyelinating disorders such as multiple sclerosis, as well as neuromuscular disorders that are primarily neurologic or muscular, or involve the neuromuscular junction. Studies on the anatomical, biochemical, and/or molecular basis of pain may also be reviewed. NEUC may also review studies involving sensory disorders of vision, taste, hearing, and smell.

o. **NEUD** and **NEUE** review studies of neurodegeneration. If separate, NEUD reviews Alzheimer's Disease, while NEUE reviews Parkinson's Disease, upper and lower motor neuron disease, amyotrophic lateral sclerosis (ALS) and Huntington's Disease.

Neuroendocrinological studies focusing on hypothalamic releasing factors, anterior or posterior pituitary hormones, or peripheral hormones such as cortisol will be reviewed by ENDO. Studies on neoplasms occurring in the nervous system will be reviewed by ONCO; whereas, studies on surgical approaches to resecting CNS tumors will be reviewed by SURG. Functional imaging will be reviewed by MHBS.

p. **Nephrology (NEPH)**. The NEPH Subcommittee reviews proposals on the etiology, pathogenesis, diagnosis, and treatment of diseases and disorders of the kidney. This Subcommittee reviews studies on end-stage renal disease including peritoneal dialysis and renal function following transplantation. The ONCO Subcommittee reviews studies on carcinomas in the kidney. The SURG Subcommittee reviews studies on the surgical approaches to disorders of the kidney and genitourinary tract.

q. **Oncology (ONCO)**. The ONCO Subcommittee reviews proposals on the etiology, pathogenesis, diagnosis, and treatment of various malignant conditions. Studies focusing on aspects of the oncologic process including cancer initiation, promotion, progression, and metastasis are reviewed, as are aspects of therapy including chemotherapy, radiation therapy, immunotherapy, and gene therapy. The Subcommittee also reviews proposals focusing on premalignant conditions. The effects of solid tumors on specific organ or system function are reviewed by the appropriate organ Subcommittee. The SURG Subcommittee reviews surgical management of solid tumors

r. **Respiration (RESP)**. The RESP Subcommittee reviews proposals on the etiology, pathogenesis, diagnosis, and treatment of diseases and disorders of the lung. Respiratory aspects of sleep disorders (sleep apnea), the effects of immunologic, infectious, carcinogenic, or toxic insults on the lung, and the effects of transplantation on pulmonary function are also reviewed.

s. **Surgery (SURG)**. The SURG Subcommittee reviews proposals on the surgical aspects of cardiac, thoracic, orthopedic, vascular, pulmonary, gastrointestinal, renal, and genitourinary tract disorders. Complications of major surgery such as hemostasis, altered immunity, secondary infection, sepsis, multi-organ failure, and reperfusion injury are reviewed. The SURG Subcommittee reviews all aspects of physical trauma, wound healing, surgical nutrition, and burn treatment. This Subcommittee also reviews studies on surgical aspects of organ transplantation, organ transplant survival, and immuno-suppressive therapy. Surgical approaches to peripheral and central nervous system lesions, and reconstructive surgery, ophthalmological, head and neck, ear, nose, and throat disorders are reviewed. This Subcommittee also reviews studies of impotence, dental studies including dental trauma and prostheses, and structural and neoplastic disorders of the oral cavity. The INDI Subcommittee reviews microbiological aspects of dental and periodontal disease. The IMMU Subcommittee reviews immunologic aspects of organ transplantation.

MERIT REVIEW APPEAL PROCESS

1. PURPOSE OF THE APPEAL PROCESS. 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 Merit Review proposal. The appeal process is designed to uncover factual errors through reexamination by individuals not involved in the initial decision. The appeal process is entirely separate from the MERIT review process. The appeal must be regarding a decision that precluded funding. It is not intended as a means to resolve differences of scientific opinion between the applicant and the original reviewers, to adjust funding decisions, or to circumvent the peer review process.

2. BASIS FOR APPEAL. The Merit Review Subcommittee consensus as presented in the final Summary Statement is the only basis for an appeal.

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

(1) Clear bias in the review process, or

(2) That it missed relevant points, or

(3) That it seriously misunderstood or misinterpreted critical elements of the research proposal.

b. Issue(s) upon which the appeal is based must appear in the Summary Statement. If the same issue is raised in individual reviews, the individual review may also be included in the appeal.

c. Issues raised only in individual reviews may not form the basis of, or be part of, an appeal.

d. All information forming the basis of the appeal must have been part of the original proposal. Data obtained since the original submission of the proposal, additional information not included in the original proposal, explanations of material not clearly presented in the original proposal, and letters of support may not be included. If the investigator believes that the Subcommittee consensus was biased, such claim may be corroborated by evidence other than the Summary Statement.

e. The appeal process is completely separate from the Merit Review application process. The investigator's decision to submit a revised application needs to be made separately from the decision to appeal.

3. REVIEW OF AN APPEAL. The appeal letter, Summary Statement, and original proposal are considered in the review of an appeal. The individual critiques of the proposal will only be considered if pertinent to the appeal.

a. The review of an appeal will focus on the validity of the issues in the appeal letter. Reviewers, who were not part of the original scientific review, will be instructed to consider only the appeal issues. The PI receives copies of the written reviews.

b. In considering the appeal review, BLR&D and CSR&D Services have the following options:

(1) **Sustain the investigator's appeal.** The proposed Merit Review program will then be administratively reviewed for funding based on scientific merit and programmatic priorities. A sustained appeal may or may not be funded.

(2) **Deny the appeal.**

4. APPEAL DOCUMENTATION

a. The appeal must be reviewed and approved by the local Research and Development (R&D) Committee, the Associate Chief of staff (ACOS) for R&D, and the medical center Director.

b. Appeal documentation must include:

(1) A letter of approval from the medical center Director.

(2) A letter of approval from the R&D Committee. The Director's and R&D's letters may be combined as long as the Director and Chair, R&D sign the letter.

(3) The appeal letter signed by the PI and the ACOS for R&D. The appeal letter can be no longer than five single-spaced pages, using only letter-quality print. All text must be prepared with at least 11-point font, with no more than 15 characters per inch and no more than six lines per inch. Page margins must be a minimum of one inch at each edge. Submissions failing to comply with these instructions will be withdrawn without review.

(4) The proposal Summary Statement.

(5) The individual reviews of the proposal.

(6) The complete proposal as originally submitted.

(7) If necessary, documentation to support a claim of bias, e.g., reprints of published work, if referenced.

5. SUBMISSION OF AN APPEAL

a. Deadlines for receipt of appeals in BLR&D/CSR&D are September 15 following the spring round of Merit Review and March 15 following the fall round.

b. Submit the original and ten copies of the appeal package, reproduced back-to-back, to the following address:

Department of Veterans Affairs
BLR&D/CSR&D
Merit Review Appeal (121E)
810 Vermont Ave, NW
Washington, DC 20420

Telephone Number for Courier Delivery: (202) 254-0183/84