

List of Major Changes to Draft Handbook 1202.1

The main body of draft Handbook 1202.1 contains the policy for the BLR&D/CSR&D Merit Review Award program. Detailed guidelines and instructions may be found in the guidance documents that follow the Handbook on the website. Links to the specific guidance documents are provided in the Handbook.

Guidance Document: Current Merit Review Guidelines And Submission Deadlines

[Page 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.

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. However, there is a limit on the total number of active awards a PI may have (see paragraph 2b below).

*Note: CLIN and EPID are **no longer** considered as exceptions to the single project rule.*

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.*

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.**

Guidance Document: Instructions For Preparing And Submitting A Merit Review Proposal

[Page 9] Travel costs for presenting research findings at scientific meetings are allowed but 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.

[Page 15] **Work Proposed** *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.*

[Page 16] **Risk to Subjects**

Human Subjects Involvement and Characteristics.

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.

Guidance Document: Supplemental Instructions For Submitting A Clinical Trial Proposal

[Page 2] For multi-site clinical trials, describe any quality assurance procedures including plans for auditing or monitoring clinical site practices at all sites involved.

Guidance Document: Instructions for Preparing and Submitting A Letter Of Intent (LOI) To Exceed Budget Caps

[Page 1] Use the revised 10-1313-13 on the website at <http://www.va.gov/vaforms/medical/pdf/vha-10-1313-13-fill.pdf>

Guidance Document: Requesting Acceptance Into The Intramural Research Program For Non-Clinician Scientists

[Page 5] Provide statement of citizenship status for anyone not born in the United States. Birthplace should be included in the C.V.

Guidance Document: Purview of BLR&D and CSR&D Merit Review Subcommittees

[Pages 2 and 3] 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.