

**REHABILITATION RESEARCH AND DEVELOPMENT SERVICE MERIT REVIEW
PROGRAM**

1. REASON FOR ISSUE. This Veterans Health Administration (VHA) Handbook announces programmatic changes to the Merit Review Program in the Rehabilitation Research and Development (RR&D) Service.

2. SUMMARY OF MAJOR CHANGES. This Handbook has minor revisions to incorporate new research policies pertaining to all research involving human subjects compliance with Federal regulations and Department of Veterans Affairs (VA) requirements that address the protection of human subjects, the use of the Data Safety Monitoring Board and the Data Monitoring Committee. It revises the current award program. It deletes all proposal deadlines and instructions. *NOTE: Deadlines and updated instructions are updated as necessary, and available electronically at www.rehab.research.va.gov.*

3. RELATED DOCUMENTS. VHA Directive 1203, VHA Handbook 1200.5, VHA Handbook 1200.16, and VHA Handbook 1200.16.

4. RESPONSIBLE OFFICE. The RR&D is responsible for the contents of this Handbook. Questions may be addressed to 202-461-1740.

5. RESCISSION. VHA Directive 2001-071, dated November 23, 2001, and VHA Handbook 1203.1, dated August 22, 2008, are rescinded.

6. RECERTIFICATION. This VHA Handbook is scheduled for re-certification on or before the last working date of April 2014.

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REHABILITATION RESEARCH AND DEVELOPMENT SERVICE MERIT REVIEW PROGRAM

1. PURPOSE

This Veterans Health Administration (VHA) Handbook provides policy and guidance related to the Rehabilitation Research and Development (RR&D) Merit Review program and submission of Investigator Initiated Research (IIR) Merit Review proposals.

2. BACKGROUND

a. Rehabilitation is assuming a role of importance as a scientific discipline. As the population of Veterans with chronic disease increase in part, due to improved survival following catastrophic events, the need for research increases. The fundamental goal of rehabilitation is to maximize functional recovery. Additional goals include integrating the Veteran back into the family, work environment, and society. This often means teaching compensatory techniques, providing innovative therapy interventions and providing adaptive equipment, advanced prosthetic equipment, and neural prosthetic devices. The long-term effects on the outcomes of many traditional approaches remain unproven, and as rehabilitation moves forward, researchers must examine efficacy to allow its medical practice to be truly evidence-based.

b. Optimal care also requires that VHA seize the opportunity to devise therapies that lead to regeneration and restoration of function. Therefore, it is necessary to re-examine conventional rehabilitation methods in order to promote better rehabilitation. Research needs to translate bench findings into the clinical arena. Rehabilitation techniques based on findings in animal models, and intended to enhance neural activity in fully or partially-impaired pathways, have unique promise, especially in stroke and spinal cord injury (SCI) patients. A crucial issue is the extent to which external experience influences general health, quality of life, and genuine recovery. The Department of Veterans Affairs (VA) RR&D is committed to advancing and expanding the field of rehabilitation and increasing research capacity within VA.

3. SCOPE

VA's RR&D program supports research relevant to the rehabilitative needs of Veterans. Areas of emphasis are broad and expansive encompassing basic scientific research that has strong implications for translation into clinical practice, as well as rehabilitation strategies, interventions, and techniques, including prosthetic devices and the reintegration of Veterans into all facets of civilian life. Specific research areas include, but are not limited to: prosthetics, orthotics, orthopedics, musculoskeletal disorders, rehabilitation engineering, chronic disease, dementias and psychiatric disorders, sensory systems, communication disorders, SCI and dysfunction regeneration and restoration, neurological dysfunction, brain injury, vocational rehabilitation, disabilities as a consequence of aging, and rehabilitation outcomes.

4. DEFINITIONS

a. **Letter of Intent (LOI).** An approved LOI is required before submitting new or resubmitted proposals for a full-research project or a pilot-study proposal. Investigators are advised as to the appropriateness of the planned project for RR&D Merit Review. **NOTE:** *LOI deadlines can be found under the Frequently Asked Questions (FAQ) section at www.rehab.research.va.gov.*

b. **Proposal Deadlines.** RR&D deadlines for Merit Review proposals can be found under the FAQ section at www.rehab.research.va.gov. The RR&D Scientific Review and Evaluation Board meets throughout the year to review proposals. **NOTE:** *Meeting dates can be found under the FAQ section at www.rehab.research.va.gov.*

c. **IIR Program.** The RR&D IIR Merit Review process includes two types of proposals for submission to RR&D Service; they are:

(1) **Full Research Proposals.** Full Research Proposals are funded for up to \$925,000 for no more than 4 years, with a maximum of \$300,000 in any year, regardless of how many years of support are requested (for more information see FAQ section on RR&D's Website, www.rehab.research.va.gov).

(2) **Pilot Study Proposals.** Pilot Study Proposals are funded up to \$75,000 per year and may be funded for up to 2 years. A pilot proposal is a new study to establish feasibility or to develop data, a technique, concept, or procedure, which is preliminary to undertaking a full Merit Review project. Complete but brief information is needed. An explanation must be given as to why this type of study is needed in lieu of a full-scale project. Pilot proposals are prepared using the same format for submitting a Merit Review proposal (for more information see FAQ section on RR&D's Web site, www.rehab.research.va.gov).

d. **Merit Review Appeal Procedures.** Information regarding the Merit Review Appeal process can be found on RR&D's Website under FAQ's at www.rehab.research.va.gov.

e. **Investigator Eligibility.** RR&D Service is an intramural research program. All applicants (i.e., the Principal Investigator (PI) and any Co-PI(s)) for VA research funds must hold a minimum 5/8 VA salaried position before a research project can be funded. Individuals with less than a 5/8 VA appointment are encouraged to seek at least a 5/8 VA appointment (see VHA Handbook 1200.15).

f. **Human Subjects.** All research involving human subjects must comply with Federal regulations and VA requirements that address the protection of human subjects. The Common Rule is codified by VA at Title 38 Code of Federal Regulations (CFR) Part 16; by the Department of Health and Human Services (HHS) at 45 CFR Part 46, Subpart A; and in VHA Handbook 1200.5. All proposals, which are interventional in nature, dealing with human subject must be submitted to RR&D. These proposals must contain a safety monitoring plan that includes a:

(1) **Data Safety Monitoring Board (DSMB).** The DSMB must be composed of members who do not have a conflict of interest with the research project. DSMB membership must include some individuals who are not affiliated with the PI's VA medical center.

(2) **Data Monitoring Committee (DMC).** The charge of the DMC must include:

(a) Determining the continued safety of research subjects based on the data submitted to the DMC.

(b) Meeting at least once per year. *NOTE: RR&D or the Institutional Review Board (IRB) may determine that the DMC must meet more frequently based on the potential risks to the subjects.*

(c) Forwarding the written report and minutes of the DMC to the PI, the IRB, and RR&D within 14 days of the each meeting.

(3) **Process for Information Collection.** A process must be established for collection of information and sending it to the DMC. It must be based on the level of risk and, at a minimum, contain:

(a) What safety information will be collected, including serious adverse events;

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

(c) The frequency of data collection (when safety data collections starts and how it will be collected, such as at study visits, through telephone calls with participants, etc.) and the frequency or periodic review of the cumulative safety data;

(d) The statistical tests for the safety data to determine if harm is occurring;

(e) Provision for the oversight of safety data, as by the DMC; and

(f) Conditions which will trigger an immediate suspension of investigational treatments.

g. **Consultants.** Applicants need to be aware that numerous restrictions apply to payment of consultants (non-VA employees). Should the services of a consultant be required to conduct a research project, the PI is advised to explore current applicable VA rules and regulations before developing the proposal budget. Consultants (individuals or firms) who are paid for advisory and assistance services under a letter of agreement (48 CFR § 837.270) cannot receive more than \$500 per procurement action, or more than \$2,500 per year in consulting fees.

h. **Just-in-time Policy.** RR&D operates under the just-in-time policy, and as a result, does not require Animal Studies and Biohazard forms to be submitted with the proposal. Drafts of VA Form 10-1086, Research Consent Form, need to be included. All just-in-time documents must be received prior to any project receiving funding. *NOTE: Prior to Merit Review, all PI's*

and other investigators on a research proposal involving human subjects, including biological specimens, must be certified as having met all current educational requirements for the protection of human subjects as mandated by the Office of Research and Development (ORD) (see VHA Handbook 1200.5). Additionally, if applicable, the proposal must include proof of training in Human Subjects Research for PIs and Co-PIs.

i. **Off-Site Research.** An investigator who seeks permission to perform research outside of a VA medical center, or VA-owned or VA-leased space, must request a waiver to perform the research off-site (see VHA Handbook 1200.16 and VA Directive 6500).

j. **Intellectual Property.** For inventions and transfer of new scientific discoveries see VHA Handbook 1200.18.

k. **Inclusion of Women and Minorities in Clinical Research.** A statement acknowledging VA's policy on the inclusion of women and minorities in clinical research must be included.

5. MERIT REVIEW PROCESS

The RR&D Service IIR Merit Review process is the principal mechanism for competitive funding of VA rehabilitation research; it:

- a. Provides RR&D Service with a critique of the scientific quality and clinical relevance of the entire research, development, and evaluation effort; and
- b. Indicates a recommended level of budgetary support.

6. FUNDING

A Scientific Review and Evaluation Board reviews all proposal applications for merit. Upon completion of this process, the Director of RR&D recommends to the Chief Research and Development Officer (CRADO) funding of projects on the basis of the:

- a. Scientific merit and feasibility of the proposed research; and
- b. Significance and importance of the proposed research to the mission of RR&D, and whether it significantly adds to state-of-the-art in the field of rehabilitation.

7. ACKNOWLEDGEMENT OF VA SUPPORT

Publication or commercialization of a product that is based on research supported by VA must cite an acknowledgement of VA, and the VA health care facility must be identified. This acknowledgement must reference support provided by RR&D Service and identify the investigator's VA employment title. Commercial literature must reference VA, RR&D Service (see VHA Handbook 1200.19).

8. APPLICATION REQUIREMENTS

Specific requirements and guidelines for LOIs and research proposals, as well as other aspects of the RR&D Merit Review program, can be found under the FAQ section at RR&D's Website at www.rehab.research.va.gov .

9. INSTRUCTIONS FOR SUBMITTING A LETTER OF INTENT TO RR&D SERVICE FOR A MERIT REVIEW PROPOSAL

Visit the FAQ section at www.rehab.research.va.gov to obtain current information.

10. INSTRUCTIONS FOR SUBMITTING AN APPEAL TO REHABILITATION RESEARCH AND DEVELOPMENT SERVICE REGARDING A DISAPPROVED MERIT REVIEW PROPOSAL

Visit the FAQ section at www.rehab.research.va.gov to obtain current information.

11. PUBLICATION POLICY

Visit the FAQ section at www.rehab.research.va.gov to obtain current information.

12. GUIDELINES FOR SUBMISSION OF PROGRESS REPORTS AND NARRATIVE SUMMARIES

Visit the FAQ section at www.rehab.research.va.gov to obtain current information.

13. GUIDELINES FOR SUBMITTING FINAL REPORTS

Visit the FAQ section at www.rehab.research.va.gov to obtain current information.

14. MERIT REVIEW TRAVEL

Visit the FAQ section at www.rehab.research.va.gov to obtain current information.