

**Department of Veterans Affairs
Veterans Health Administration
Washington, DC 20420**

**VHA HANDBOOK 120x.x
Transmittal Sheet
Xx,xx, 2005**

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

1. REASON FOR ISSUE: This Veterans Health Administration (VHA) Handbook clarifies policy and establishes procedures for the Rehabilitation Research and Development Service (RR&D) Merit Review Entry Program (MREP) Award.

2. RELATED DIRECTIVE: VHA Directive 1202.

3. RESPONSIBLE OFFICE: The Office of Research and Development, Rehabilitation Research and Development Service (122) is responsible for the contents of this VHA Handbook.

4. RECERTIFICATION: This document is scheduled for rectification on or before the last working date of June 2007.

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Under Secretary for Health

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

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REHABILITATION RESEARCH AND DEVELOPMENT SERVICE MERIT REVIEW ENTRY PROGRAM

1. PURPOSE: This Veterans Health Administration (VHA) Handbook provides policy and guidelines related to the Rehabilitation Research and Development Service (RR&D) Merit Review Entry Program (MREP) and instructions for submission of MREP proposals.

2. BACKGROUND: The Merit Review Entry Program (MREP) is an intramural program designed to recruit and train junior level Department of Veterans Affairs (VA) investigators with little or no prior research experience. While part of the Merit Review program, the MREP is a mentored award that transitions junior scientists from trainee to independent investigator. The MREP is a 3-year, non-renewable award intended to enhance the probability that junior scientists will successfully compete for independent funding under the Merit Review program. MREP proposals are evaluated for the quality of the science, the applicant's potential, and the quality of the proposed training program and mentor(s).

3. SCOPE:

a. Applicant Requirements and Restrictions

(1) Permission to apply to the program is obtained only through a Letter of Intent (LOI).

(2) MREP applicants must hold a minimum 5/8th VA paid appointment at the time of funding.

(3) The applicant may not have an academic appointment above the level of Assistant Professor, or its equivalent. In unusual circumstances, a "Request for Exception" letter may be included in the LOI package.

(4) Non-clinician scientists must be no more than 5 years beyond receipt of their PhD at the time of application. Clinician scientists must be no more than 5 years beyond completion of clinical training (i.e., residency, internship, clinical fellowship, etc.) at the time of application. Research fellowships are not considered clinical training; therefore, they count toward the five-year post-training limitation. Applicants with more extensive research experience who have recently changed fields of study, may be considered.

(5) Applicants must demonstrate potential for developing an independent VA research career. The applicant must be first-author on at least one research publication or a contributing author on multiple publications.

(6) Current VA Research Career Development (RCD) or mentored NIH K-series awardees may apply for MREP funding to begin with the termination of the Career Development award but may not receive both MREP and Career Development funding simultaneously.

(7) Principal investigators on current or previous independent research projects, peer-reviewed and supported at the national level by public (e.g. NIH, NSF) or private organizations (e.g., National American Heart Association, American Diabetes Association, etc.), may not apply for MREP funding. The MREP is not intended for independent,

established investigators

(8) Applicants may apply for both MREP and VA Career Development funding in the same review cycle, but may not receive simultaneous funding for MREP and VA Career Development. Previous recipients of the VA Advanced Career Development (ARCD) award may not apply for MREP funding. An investigator may receive only one MREP award during the investigator's VA career.

b. Salary, Effort, and Scientific Support

(1) Salary support for non-clinicians is provided at the GS-12 level. Non-clinician scientists must have at least a 75 percent effort on the proposed research and at least a 5/8th VA paid appointment. A clear justification for any effort below 75 percent must be provided.

(2) Clinician scientists must have at least a 25 percent effort on the proposed research and a VA paid appointment of 5/8th. However, a clear justification for any effort below 50 percent must be provided.

(3) MREP awards are non-renewable and are limited to \$50,000 per year for 3 years, exclusive of equipment and non-clinician principal investigator salary. A maximum of \$15,000 may be requested for equipment in the first year's budget.

c. Location of Primary Work Site

MREP awardees may establish an independent laboratory at a VA Medical Center, may work in a mentored VA laboratory or may work in a VA-mentored non-VA laboratory. If work will be done in a VA mentor's off-site laboratory, a copy of the mentor's approved off-site waiver must be provided.

4. APPLICATION GUIDELINES:

a. Procedure

Each potential applicant must submit an LOI. Only applicants with approved LOIs may submit MREP applications. MREP proposal submission deadlines are the same as for Merit Review program applications. *Note: Deadlines and instructions for preparation and submission of the LOI are in Appendix A.*

b. Mentors

Mentors play a vital role by preparing MREP awardees for independent research careers. Applicants for an MREP award must identify a primary scientific mentor (VA or non-VA) with expertise and interest in the applicant's research. Up to 2 additional mentors may supplement the expertise of the primary mentor. At least 1 mentor must be a VA-based investigator with nationally peer-reviewed funding who is committed to training and developing the applicant as an independent VA research scientist. Participation of VA Research Career Scientists as mentors is strongly encouraged.

(1) The MREP application should be written by the applicant in consultation with the mentor(s) and should convincingly demonstrate the potential of the applicant for achieving independent status during the course of the award.

(2) The MREP application must contain a letter of support from each mentor documenting the specific commitment to the applicant and describing the mentorship program to develop research skills and attain independence as a research investigator. Training is a critical component of the MREP and should be explained in detail. *Note: The content of the Mentor's letter is described in Appendix B.*

c. Letter of Intent (LOI)

An approved LOI authorizes the investigator to submit an MREP proposal. The MREP proposal must be submitted in the Merit Review cycle immediately following approval of the LOI. An investigator may obtain one, and only one, MREP LOI approval.

(1) LOIs must be prepared according to the instructions contained in Appendix A.

(2) LOIs will be reviewed for scientific merit, relevance to RR&D Service priority areas, qualifications of the applicant and mentor(s), and background of the mentor(s) as it pertains to the training and career development of the applicant.

(3) Approval of an MREP LOI does **not** constitute eligibility to apply for, or receive MREP funding.

d. MREP Application Review

(1) MREP applications will not be accepted without documentation of an approved LOI. Applications must follow guidelines noted in Appendix B.

(2) In addition to scientific and relevance review, MREP proposals are evaluated for the qualifications of the mentor(s), suitability of the proposed training program, and suitability of the medical center (or other proposed research site) for the research and/or training program. MREP applications will undergo peer review by a Merit Review subcommittee.

e. MREP Contract

All awardees will contractually agree to acknowledge VA as their primary affiliation on all public reports and presentations, conduct research in a VA medical center (unless specifically exempted), comply with VA policies regarding intellectual property disclosure obligations and ownership rights, and participate in annual MREP progress review. Failure of an MREP awardee to acknowledge VA support or employment may, at the discretion of the Chief Research and Development Officer, result in termination of the award.

f. Award Transfers

The Director of the RR&D Service may, in exceptional circumstances, approve a request to transfer an MREP award from one VAMC to another. Such approval will only be given if an appropriate mentor is identified at the new medical center and if the transfer is in the best interest of both RR&D and the awardee's training program. No MREP transfers will be

permitted before at least 1 year of work has been completed. A letter of support from the new mentor must be included as well as the new mentor's current C.V. All transfer requests must be endorsed by the Medical Director of the new facility and all local assurances are in place. No funds will be released until all approvals have been documented. The request must ensure that sufficient space and support will be available for the successful completion of the transferred award. Research funds will not be provided to cover any moving or relocation expenses.

g. Change in Mentor

If the primary mentor relocates to a different facility, or becomes unavailable to train the awardee, the Associate Chief of Staff (ACOS) for Research must immediately notify the RR&D Service and request approval of a new primary mentor.

h. Annual Progress Review

Each MREP awardee will receive an annual review to ensure satisfactory progress toward independence. (*Note: Instructions for preparation and submission of the Annual Progress Review are described in Appendix C.*) Failure to submit a progress review or to appropriately respond to RR&D Service evaluation of the progress review may result in withdrawal of funding and termination of the award. Annual progress reports must be received by RR&D. RR&D senior staff will determine whether current progress and future plans are satisfactory, conditional (satisfactory with contingencies), or unsatisfactory. If unsatisfactory, the awardee will be placed on 6 months of probation during which time performance must return to a satisfactory level. If a re-review at the end of the probation period determines that progress has not been satisfactory, the award, including non-clinician salary, will be terminated within 60 days. Awardees whose programs have been terminated are not eligible to reapply. The decision for termination is not subject to appeal.

i. Transition to Independent Merit Review Funding

It is expected that all MREP investigators will submit a proposal the Merit Review program on its due date, 9 months prior to termination of the MREP award, to obtain compete for uninterrupted funding.

(1) MREP awardees may submit merit review proposals 1 cycle before the due date, but no earlier. Otherwise, awardees jeopardize their MREP award.

(2) To submit a Merit Review application, all MREP investigators must meet the eligibility requirements as described in VHA Handbook 1200.15, "Eligibility for VA Research Support Handbook".

(3) Permission to perform MREP-funded research in off-site research space does not confer approval to conduct future studies off-site. All investigators who intend to perform any portion of the research proposed in their Merit Review proposal in off-site research space must submit a request for an off-site waiver prior to the Merit Review submission deadline (see VHA Handbook 1200.16, "Off-Site Research Handbook").

5. INQUIRIES:

Information regarding point of contact for issues related to MREP awards is contained in Appendix D.

LETTERS OF INTENT FOR MREP AWARDS

1. The LOI is limited to six 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.

2. The LOI must contain the following materials:

a. VA Form 10-1313-13, “VHA Research and Development Letter of Intent Cover Page”

In block 1, check Rehabilitation Research and Development Service. In block 3, check Merit Review and insert the words “Entry Program”.

b. Supplemental information page (limit 1 page)

List the following 5 items in the order specified:

(1) Letter of Intent - Merit Review Entry Program (MREP) Proposal.

(2) Name, degree, social security number, and percent effort to be devoted to the project. If the applicant is not currently a VA salaried employee, provide the proposed date of VA employment, proposed title, proposed grade and step, and proposed 8th VA employment status.

(3) Indicate whether this project involves an epidemiological or clinical study.

(4) Name, degree, position title, grade, 8th VA employment, academic affiliation and rank, and percent effort for each proposed mentor.

(5) Signature(s) of mentor(s).

c. Abstract of work proposed (limit 1 page)

Use the following headings:

(1) Background.

(a) Indicate the scientific basis (rationale) for the proposed research and its relationship to other major research findings.

(b) Describe the significance of the research and its relevance to the mission of VHA, RR&D priority areas, and ongoing research efforts within the local VAMC.

(2) Research Objectives

Outline precisely and clearly the goals of the planned project, including the individual objectives as well as the overarching hypothesis to be tested.

(3) Project Design and Methods

Briefly define and describe the research design and corresponding methodology. If applicable, include inclusion and exclusion criteria and any other pertinent human subject information.

d. Applicant and mentor qualifications (limit 3 pages).

(1) Research experience of the applicant

Provide evidence of research experience, such as being first author on a research publication or contributing author on multiple publications. Describe any training in the research area proposed. List any current, pending, or previous training awards or other nationally peer-reviewed funded proposals held by the applicant; if none, so state.

(2) Applicant's career objectives

(a) Describe the applicant's career objectives at both the VA and its affiliate institution.

(b) Describe plans for achieving independent research support by the end of the award period.

(3) Mentor qualifications

(a) At least one mentor must be a VA scientist with nationally peer-reviewed funding, conducting research at a site approved by Office of Research and Development (ORD). Provide a description of the mentor's qualifications and experience relevant to the proposed research. MREP awardees may establish an independent laboratory at a VA Medical Center, may work in a mentored VA laboratory or may work in a VA-mentored non-VA laboratory. If work will be done in a VA mentor's off-site laboratory, a copy of the mentor's approved off-site waiver must be provided

(b) Up to 2 additional VA or non-VA mentors with specialized scientific expertise required for the proposed research may also be identified. Describe each additional mentor's qualifications and experience relevant to the proposed research. Define the roles of each proposed mentor and their associated responsibilities to the proposed study, training of the applicant and the applicant's career development.

e. Attachments:

(1) A copy of the applicant's CV and associated bibliography. The CV should clearly identify the applicant's VA appointment (paid or Without Compensation (WOC)), if one currently exists.

(2) A copy of each mentor's CV. The CV should clearly identify the mentor's VA appointment, if one currently exists.

(3) A statement/letter from the local Human Resource Management (HRM) office indicating that the applicant is eligible for the respective appointment and can be hired by the VAMC. If the applicant is currently employed by the VAMC, this should be stated.

(4) If a VA mentor's off-site laboratory will be used, provide a copy of the approved off-site waiver.

(5) LOIs will be returned if they are not submitted in accordance with established procedures. The responsibility for following instructions and preparing a complete and timely submission lies with the local VAMC R&D Office.

3. SUBMISSION:

RR&D accepts LOIs twice yearly (see <http://www.vard.org/handbook/1203-1appenda.pdf>). Submit the original and 5 exact copies of the LOI to:

If mailed through the U.S. Postal Service or other contract carrier such as Federal Express:

Attn: MREP LOI
Rehabilitation Research and Development Service
Department of Veterans Affairs
810 Vermont Avenue, NW, MC-122P
Washington, DC 20420
202-254-0255

PREPARATION AND SUBMISSION OF A REHABILITATION RESEARCH AND DEVELOPMENT SERVICE MERIT REVIEW ENTRY PROGRAM PROPOSAL

1. GENERAL INSTRUCTIONS FOR PROPOSAL PREPARATION:

The Rehabilitation Research and Development Service (RR&D) Merit Review Entry Program (MREP) proposal is a mentored, 3-year training program for junior investigators. The instructions in this Appendix apply to all new and resubmission proposals. The office of the Associate Chief of Staff for Research (ACOS-R) or its equivalent at the local VAMC provides assistance in proposal preparation and is responsible for submitting proposals to VACO. Before you prepare your application, consult with the ACOS-R. You must have an approved LOI to submit an MREP application.

a. Approvals

Prior to submission to VACO, all proposals require approval by the local VAMC R&D Committee and appropriate subcommittees. The ACOS-R must obtain letters and other supporting documents to facilitate this process. Please refer local assurance questions to the office of the ACOS-R. This office can also provide you with other pertinent information such as local submission deadlines.

(1) Proposals lacking the required local approvals and concurrences will be administratively withdrawn.

(2) No additional or replacement information will be accepted after submission of the proposal unless requested by the RR&D Service.

2. SPECIFIC INSTRUCTIONS FOR PROPOSAL PREPARATION:

The applicant should obtain an MREP from the ACOS-R. 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 www.va.gov/resdev/fr/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 PROMISE system. Staff of the ACOS-R will assist you in printing and submitting these forms.

a. **Page 1; form 10-1313-1.** Staff of the ACOS/R&D, familiar with the use of the PROMISE 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, 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 June 15, 2005, the review date is fall 2005. If the submission deadline is December 15, 2005, the review date is spring, 2006.

(3) **Block 5 (facility number).** The number assigned to the PI's VAMC as listed in PROMISE.

(4) **Block 6.** The location of the VAMC by **city and state**. *Note: The Research and*

Development Information System (RDIS) and Research and Development Computer Center (RDCC) use this information to denote a VAMC rather than the facility name or regional designation.

(5) Block 7. The social security number of the PI. *Note: the social security number should appear on the original form only. It should be removed from all subsequent copies of the proposal.*

(6) Block 8. The last date the principal investigator submitted an MREP or other Merit Review program application, regardless of its outcome. A blank indicates that no MREP or Merit Review proposal on any topic has ever been submitted.

(7) Block 9. The Last Name, First Name, Middle Initial, degree(s) of the PI. Also, include the PI's VA telephone number with extension (if needed), mailing address, and e-mail address.

(8) Block 10. The title of the project, which may not exceed a total of 72 characters including spaces. The title should describe the program activity.

(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 10-1313-3 and 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 forms 10-1313-3 and 10-1313-4).

(10) Block 12. The employment status in VA paid 8ths of the principal investigator 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 research appropriation.

(a) Check with the appropriate service chief or the ACOS-R for the correct appropriation.

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

(c) Non-clinicians appointed on the research appropriation and requesting salary through this proposal should indicate cost center CC103.

(d) Career Development awardees should indicate CC108 as their employment source.

(12) Block 14. Check the "New" and "Merit Review Entry Program" boxes. The box labeled "No. Projects" in Program may be left blank.

(13) Block 15. Under Program enter "822" Rehabilitation Research and Development Service and under Cost Center enter CC103(?), which is the cost center designation for MREP awards.

(14) Block 16. The Primary Research Program Area and Primary Specialty Areas are selected from a list in PROMISE.

(15) Block 17. VA Hospital Service and Section are selected from a list in PROMISE.

(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 should be checked if the research has any relation to human beings, even if the Institution Review Board (IRB) has found the research to be exempt.

1. Check this box if 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. Also check this box if 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. Check the box if human tissue is obtained from surgery or autopsy, tissue banks, other non-profit sources, or commercial sources.

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

5. 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*. Check this box if animals or any tissue derived from animals are used in the proposed project, even if obtained from a tissue bank or commercial sources.

(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 prior to submission of this application.

(e) *Biohazard*. 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, Safety of Personnel Engaged in Research. If your research uses any of the products listed in the appendix, the Biohazards box must be checked.

2. Questions about research safety documentation should be directed to the VACO Research Biosafety Officer.

(18) Block 20. Summarize the principal investigator's research support for the last three fiscal years in chronological order. "Non-VA", include all other sources of research funding other than VA.

(19) Block 21. Enter the date the principal investigator entered or will enter VA duty (all applicants must be VA employees by the time the application is funded).

(20) Signatures and dates in this block shall be within 6 months of the submission due date, and the date the ACOS/R&D signed shall be subsequent to the approval date of the R&D Committee. The signature of the ACOS/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, Summary Description of Project/Program; form 10-1313-2.

(1) The principal investigator's name and project title should be exactly as written on Page 1 (10-1313-1).

(2) Use keywords that describe the disease, system, mechanism being studied, and major methods/techniques used. Because the keywords are used for searches and portfolio related issues, only Medical Subject Headings (MeSH) terms may be used. The ACOS/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 significance of potential new findings. 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.

d. Page 4, Current Funds and First Year Requests for Program/Project (Form 10-1313-3).

At the top of the form check the "Project" box.

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

(2) A recurring budget (i.e., total budget less principal investigator salary and equipment) may

not exceed \$50,000 per year nor may the equipment request exceed \$15,000.

(3) MREP applicants shall limit their project duration to three years.

(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 shall include fringe benefits for all personnel to be paid from RR&D funds.

| | |
|-----------------------------------|---|
| Table 2: Table of Contents | |
| Form 10-1313-1 | front page |
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| Form 10-1313-2 | (abstract) |
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| Form 10-1313-3 | first year budget |
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| Form 10-1313-4 | all years budget and justification |
| 5 | |
| Biographic Information | |
| | Starting with principal investigator (Forms 10-1313-5, 6, 8; front, budget and abstract pages from active research projects). |
| | Follow with complete sets from each mentor. |
| — | |
| 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 |
| | — |
| | Animal Studies |
| | — |
| | Resources |
| | — |
| | Training Program |

Table 2: Table of Contents

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|-------------------------------|--|
| Form 10-1313-1 | front page |
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| Form 10-1313-2 | (abstract) |
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| Form 10-1313-3 | first year budget |
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| 5 | |
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| | 1. Rationale |
| | — |
| | 2. Background and Significance |
| | — |
| | 3. Work Accomplished |
| | — |
| | 4. Work Proposed |
| | — |
| | Human Studies |
| | — |
| | Animal Studies |
| | — |

(a) The salary request should be proportional to the percent effort listed (non-clinician principal investigators' salaries are an exception, see 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. Principal investigators shall not be paid through inter-agency personnel act (IPA) agreements.

(b) If the PI is a non-clinician, salaried by research appropriation CC103, in the “% effort”

column the PI shall 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 person’s 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 principal investigator listing 75 percent effort for the proposed research, 15 percent effort as an uncompensated co-investigator on an NIH grant, 5 percent service to VA research administration, and 5 percent VA teaching and mentoring would request 100 percent of their 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) shall be described fully in the budget justification. Non-Clinician MREP applicants should devote at least 75 percent effort on the project.

(c) All mentors and technical staff, whether paid or not, should be listed in the personnel section. There are restrictions on who can be paid directly by the VA. Check to ensure that no salary is requested for a person who cannot be paid directly by the VA.

(d) If a person is paid through a contract for services or an IPA, put “IPA” in the column for requested funds. List the specific costs of IPAs in the “all other expenses” section of the budget.

(e) *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 RRD to the investigator for the 12 months preceding the first year request.

(6) Consultants. List any mentors who do not have an active role in the research and indicate their role as mentor.

(7) Equipment. Although the form 10-1313-3 states that all equipment in excess of \$3,000 must be listed, RRD requires that each item of equipment, no matter the cost, shall be listed separately and thoroughly justified on form 10-1313-4. Equipment consists of relatively permanent, fixed assets that are essential to the completion of the proposed research.

(a) Equipment shall be purchased in the first year of the project and is limited to \$15,000.

(b) Expendable items shall be requested as supplies.

(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. List all other expenses by major category, including costs for publications, rental and contractual fees. Include the daily (*per diem*) and total charges for Animal Research Facility maintenance of all animal subjects required in the research. Check 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, you may request a proportionate amount of the service contract. Travel costs are permitted for project staff if the travel is directly related to the proposed research, but travel costs for scientific meetings as well as registration fees and expenses for books and journals are not permitted.

e. **Estimated Expenses For Program/Project (Form 10-1313-4)**. At the top of the form, check the Project box.

(1) Enter the totals for each budget category for all additional years of support requested. The total operating expenses for the first year shall be identical to the total indicated on VA forms 10-1313-1 and 10-1313-3. Do not include inflationary increases in any of the budget categories or cost-of-living increases, within grade increases, or anticipated promotions in the personnel category.

(2) All differences in the operating expenses between years should 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 principal investigator, and all personnel listed in the Personnel section of form 10-1313-3. If the principal investigator is a non-clinician scientist, paid by the research appropriation CC103, fully describe the basis for any difference in the percent effort for the work proposed and total VA effort (salary support). The signature of the ACOS/R&D on form 10-1313-1 signifies agreement to have the non-clinician principal investigator perform the work described to justify salary.

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 (Many of these items are provided by the local research office or VAMC)
Books and journals
“charge-back costs”
registration and travel to scientific meetings
medical media/ slide preparation/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

***If included, item will be administratively removed.**

(b) *Consultants*: Clearly explain the expertise of each mentor/consultant with regard to the proposed research. State the frequency of consultations.

(a) *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.

(a) *Supplies*: Explain how the costs for each category of supplies was derived; for example, is it based on a mentor'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 fully explained including the basis for the individual's salary.

(4) Budget totals on forms 10-1313-3 and 4 must match each other as well as the block 11 total on form 10-1313-1. The accuracy of these items should be checked before sending the proposal.

f. **Investigator and Mentor Information (Forms 10-1313-5, 10-1313-6, 10-1313-8)**. The three forms (VA Form 10-1313-5, 6, and 8) shall be completed for the principal investigator and for each mentor who will participate in the design, performance or scientific direction of the proposed research. For those investigators devoting 5 percent effort or less, you may include only biographical information (VA Form 1313-5 and 6). Do not include any of the above forms for consultants, or technical staff. *Note: form 10-1313-7 is no longer required.*

(1) **Investigator's Biographic Sketch (form 10-1313-5)**. Follow the instructions on the form.

(2) **Investigator's Bibliography (form 10-1313-6)**. In chronological order, list complete citations of the investigator's most relevant publications and accepted manuscripts in peer-reviewed journals. Do not include abstracts, or manuscripts that are submitted or in preparation. The Investigator's Bibliography may not exceed two pages. If a second page is needed, use another copy of form 10-1313-6.

(3) **Investigator's Total Research/Development Support (form 10-1313-8)**. 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 award, research grants, cooperative agreements, contracts, institutional awards, and awards from other VA research programs such as HSR&D, EPIM, CLIM, CSRD, BLRD and REAP/Centers. Include all currently funded and pending support. Do not include the financial resources requested in this application.

(a) *Copy 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 (principal investigator, co-investigator,

principal investigator 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 initial budget period.

4. Percent Effort: For an active project, 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 of the 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 for from another source.

2. Commitment Overlap occurs when any personnel listed on the project has time/effort commitments (whether salaried or unsalaried) that exceed 100 percent. No individual listed on the project budget form may have in excess of 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.

(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 application on standard 8.5" X 11" white paper, single-sided and single-spaced. Except for margin requirements of specific forms, allow a one-inch (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 reproductions. All tables, diagrams, graphs and charts, must be clear and legible.

(3) The height of the letters must be at least 11 point, 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/printer combinations, correct type size should be verified with a standard type-measuring device. At least the minimum type size shall be used throughout the application.

(4) All figures and tables shall 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 will be administratively withdrawn.

(6) Originals of photographs that do not copy well should be included in the appendix. Copies of these photographs also should 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, shall be incorporated into the Narrative and shall not be placed in the appendix. The Narrative shall be comprehensible without references to any other document including the appendix.

h. **Response (resubmitted applications only, 3-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 principal investigator should have received the summary statement and critiques from the previous review.

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

| Section | Page Limit | Content |
|---|-------------------|---|
| Response | | |
| Revised applications | 3 | See instructions on page B-12 |
| List of Abbreviations and Acronyms | — | |
| Research Narrative | | |
| Sections 1-4 | 25 | Text plus all figures, charts, tables and diagrams. |
| Human Studies Section | | See instructions on page B-15 |
| Animal Subjects | | See instructions on page B-16 |
| Resources | 1 | See instructions on page B-17 |
| Training Program | 3 | See instructions on page B-17 |
| Literature Citations | 4 | Complete citations including titles and all authors |
| Appendix | — | No more than 5 publications including accepted or submitted manuscripts Photographs that don't copy well (include copies in the Narrative) Other materials that do not copy well (include copies in the Narrative) Questionnaires Supplemental methodology may <u>not</u> be included |

(2) The changes in the narrative shall 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. Do not use underline or shading. The Work Accomplished section should include any new work accomplished since the prior submission. Acceptance by RRD to review a revised application automatically terminates the prior version.

i. **List of Abbreviations/Acronyms Used.** Provide a list of the abbreviations and acronyms used in the Narrative and define the term the first time it is used in the Narrative text. 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 shall 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, RRD recommends 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 Questions*. 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. Outline an anticipated timetable for achieving short-term objectives, i.e., the objectives to be accomplished if the work proposed is funded.

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

(a) *Background*. Briefly described 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 should be sufficiently complete to demonstrate that the principal investigator is aware of the critical issues related to the proposal. It should 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*. Describe 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). *New applications (including revisions to new applications)*. Describe the preliminary/previous studies conducted by the principal investigator 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/competence of key collaborators may be briefly described. Up to five publications and/or submitted or accepted manuscripts by the principal investigator may be placed in the appendix.

(4) Work Proposed

- (a) Provide a timetable describing the sequence of the proposed research.
- (b) It is useful to specifically relate each experiment to particular hypotheses/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/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/procedures and possible alternative procedures to achieve the specific aims.
- (e) If humans or animals are to be studied, power analysis should be used to justify the number to be studied. Justify the species of animal to be used even if it is contained in the Animal Component of Research Proposal (ACORP).
- (f) The Narrative section must be comprehensible without reference to any other document.

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 four evaluation criteria below** as they apply to the research proposed. **Applications that fail to comply will be withdrawn without review.**

(a). Risk to Subjects

1. 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.

2. 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.

3. Potential Risks: Describe the potential risks to subjects (physical, psychological, social, legal, or other) and assess their likelihood and seriousness to the subjects. Where appropriate, describe alternative treatments and procedures, including the risks and benefits of the alternative treatments and procedures to participants in the proposed research.

(b) Adequacy of Protection From Risks

1. 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. The informed consent document may not be submitted at this time.

2. 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.

(c) 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.

(d) Importance of the Knowledge to be gained. Discuss the importance of the knowledge gained or 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). If form 10-1313-1, Block 19, Animal Subjects is checked “Yes,” create a section heading entitled “Animal Subjects.” In this section, provide information to **address all five evaluation criteria below** as they apply to the research proposed. **Applications that fail to comply will be withdrawn without review.**

Failure 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 reasons 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)**

(1) Describe the facilities to be used to conduct the proposed research. Specifically indicate the performance sites (location with specific room numbers and indicate VA space or off-site).

(2) 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.

(3) Describe laboratory and equipment used to generate the preliminary data and if the equipment is available to the proposed research.

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

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

(6) If the MREP investigator will perform the proposed research in a VA mentor's assigned off-site space, a copy of the mentor's 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 (see VHA Handbook 1200.16, Off-Site Research). No waiver is needed if the MREP investigator will work in a non-VA mentor's off-site laboratory. The MREP investigator may not establish an independent off-site laboratory.

n. **Training Program (6-page limit – not included in 25-page limit for Narrative)**.

Describe the training and mentoring program. Include plans for participation in training activities (formal course work, seminars, laboratory meetings, journal clubs, Grand Rounds, etc.), manuscript preparation, and scientific meetings. Describe the frequency and nature of interactions between the applicant and mentors. Describe the plan for the MREP investigator to achieve independent funding by the end of the training period.

o. **Literature Citations (4-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.

p. **Endorsements**

(1) On Time Submission of Compliance/Assurance Documents. When a local facility conducts compliance assurance reviews is a local decision. Whether the review(s) is done prior to submission of the application or at a later date, RRD requires just in time submission of compliance/approval documentation for human studies, animal studies and biosafety.

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

(3) If the appropriate compliance/assurance subcommittees have not approved the application, following review by compliance/assurance subcommittees, the R&D Committee must review

and approve the proposal again.

(a) The R&D approval letter shall contain the following statement: “This application has been submitted without approval from necessary subcommittees. The PI is admonished that the procedures described in the application may not be run.”

(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 and director endorsements may be combined as long as all requested items are addressed and the R&D Chair and the Director sign the memorandum.

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

(6) Approvals, Exemptions, waivers, permissions.

(a) Include a copy of your MREP LOI approval letter. If you will be working in a VA mentor’s off-site laboratory or VA leased space include a copy of the mentor’s off-site waiver or lease oversight approval letter. A waiver is not needed for MREP trainees to work in a non-VA mentor’s off-site laboratory.

(b) Include a letter of commitment from each mentor describing the mentoring plan for the applicant and the mentor’s training history. The mentoring plan should include the mentors proposed role in the project, proposed time commitment, other ongoing time commitments, frequency and nature of interactions with the applicant. The letter should explain how and why the elements of the training program (described in the application) were selected, and how this program will lead to an independent research career for the applicant. The mentors training history should be provided as a table listing in chronological order the names, degree(s), dates of training, and current position for all current and previous trainees.

q. **Revised Proposals.** Revised proposals shall include the final Summary Statement (including form 10-1313A) and reviews from the most recent review cycle. 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 principal investigator 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).

Updater according to how PROMISE works for RRD

3. TRANSMITTING THE APPLICATION.

a. **Intent to Submit.** By the deadline listed in Table 1, staff of the ACOS/R&D enters the appropriate information in PROMISE and transmits it electronically to the RDCC.

b. **Submitting the application.** Proposal submission involves the electronic transmission of forms 10-1313-1 and 10-1313-2 (including the abstract) and sending hard copies (paper) of the **entire** proposal.

(1) Staff of the ACOS/R&D will complete and electronically transmit forms 10-1313-1 (Face Page) and 10-1313-2 (Summary Description) using the PROMISE system to the RDCC. The paper copies of these forms should be printed from the PROMISE system. The information on the paper copies must be identical to the electronically submitted information. For the paper submission of the entire proposal, the ACOS/R&D and principal investigator sign the printed copy of 10-1313-1. “Per”, “by”, or, “for” signatures are not acceptable. Make any necessary corrections with PROMISE and electronically re-send the corrected information and print a new hard copy. Use of the PROMISE system is confined to staff of the ACOS/R&D.

(2) Investigator biographic information (10-1313-5, -6, -8 should be assembled as complete sets, starting with the principal investigator’s.

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

(1) The original single-sided application with the signatures of the principal investigator and ACOS/R&D on page 1 (form 10-1313-1), assembled in the order specified in the table of contents.

(2) *Note: Prior to making copies, redact the PI’s social security number.* Fifteen (15) exact, clearly legible copies reproduced back to back. Each copy should be bound with a binder (paper) clip. Do not staple copies or use rubber bands or colored paper separators.

(3) Six (6) collated sets of appendix material, such as reprints and manuscripts, may be stapled and each item should be marked with the principal investigator’s name. Videotapes and books are not acceptable as ‘reprints’. A summary sheet listing all the items in the appendix is useful.

d. Carefully check the proposal and copies before submitting them to VACO.

e. **Mailing the proposal.** You may use either U.S. mail or courier service to send the application (original, 15 exact copies, 6 collated copies of the appendix).

(1) If mailed through the U.S. Postal Service or If courier or commercial overnight delivery service is used, send to:

Rehabilitation Research and Development Service
Program Review Division (122P)
810 Vermont Ave, NW
Washington, DC 20420
202-254-0255

f. **Suggested Reviewers.** Under separate cover, the ACOS/R&D may send a list of suggested external reviewers and those reviewers believed to have a bias to Department of Veterans Affairs, RRD (122P), 810 Vermont Ave, Washington DC 20420. Include the address, telephone number and e-mail address, if available, for each suggested reviewer. Final decision on reviewers and referrals are the responsibility of the RRD Service. The deadline for this letter is one day after the deadline for receipt of applications.

4. DEFICIENCIES. Deficiencies may be corrected only at the direction of the RRD Service. No late material (e.g., reprints, approval letters, endorsement letters, proposal corrections, etc) will be accepted unless specifically requested by the RRD Service. The only exception is official letters of acceptance for publication for submitted manuscripts may be sent to the RRD Service.

5. PROPOSAL WITHDRAWAL: A proposal may be withdrawn by the ACOS/R&D by contacting the RRD Service.

6. SITE CHANGE DURING REVIEW CYCLE: All information given to reviewers must reflect the principal investigator's circumstances and research site. If a principal investigator transfers to another VA or the facilities available to the project change, RRD Service must be notified and updated information supplied, if requested.

7. JUST IN TIME RECEIPT OF COMPLIANCE AND ASSURANCE DOCUMENTATION.

The following discussion is limited to the receipt of compliance and assurance documentation. 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, is a local facility decision. Regardless, no proposal will be funded until these forms/approvals are received and accepted by RRD.

(a) *General:* All forms pertaining to human studies, animal subjects or biosafety must be current. Be especially mindful of this requirement when submitting revised applications. The committee Chairperson must sign all 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/R&D sign committee forms.

(b) *Human Subjects:* All proposals involving human subjects or human tissue must be evaluated by the Human Studies Subcommittee or its equivalent (IRB). Send a copy of the "Report of Subcommittee on Human Studies" (form 10-1223). If the research was approved by expedited review, was exempted from review, or was given a waiver from obtaining informed consent, it must be explicitly stated in section 8 "Comments" of the 10-1223 form. The chair of the IRB must sign the form. In lieu of the 10-1223 form, RRD will accept an equivalent IRB form as long as it contains all of the elements of the 10-1223 form.

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, shall be included after form 10-1223.

2. The title on the informed consent form must be the same as the title of the application (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 shall 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 IRB is at the affiliate university.

5. The educational training requirement related to human subjects protection must be met (Office of Research and Development memoranda of August 15, 2000 and March 14, 2001). If the proposed research involves humans or human tissue, the PI and all co-investigators shall document successful completion of the training requirement. Documentation may be in the form of a certificate from the training program or equivalent documentation from the Research and Development Office. One letter detailing the training for multiple investigators is acceptable. Documentation of the training requirement shall follow forms 10-1223 and 10-1086 (if needed).

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 (VHA Handbook 1200.XX).

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 1) 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 2) molecules that result from the replication of those described in the first part of this definition.

(b) *Animal subjects.* An approved, current ACORP must be submitted for any proposal using animals or animal tissues. An ACORP is required even if the animals or animal tissues will be used in a laboratory other than that of the PI's.

(c) *Investigational Drugs and Devices:* FDA approval for use of the investigational drug (IND) or device must be on file at the VAMC. The Research and Development (R&D) concurrence memorandum, signed by the committee chair, certifies that the appropriate approvals are on file. Form 10-9012 "Investigational Drug Information Record" must be used for this purpose, but should not be included in the application.

(d) *Biohazards:* Whether or not the form 10-1313-1 Biohazards box is checked, the biohazards form must be submitted. The form must have the proper signatures and be dated.

(e) *R&D Approval:* Following review and approval by all required subcommittees, the R&D committee must review and give final approval to the application. A letter of approval, signed by the R&D Chair, shall be sent with the other compliance/assurance documentation.

(f) *Submission of Documents:* Send the original and one (1) exact copy of all compliance/assurance documentation via regular mail or courier.

(1) If mailed through the U.S. Postal Service or If courier or commercial overnight delivery service is used, send to:

Rehabilitation Research and Development Service (122P)
810 Vermont Avenue, NW
Washington, DC 20420

202-254-0255

INSTRUCTIONS FOR SUBMISSION OF ANNUAL PROGRESS REVIEW

1. ANNUAL PROGRESS REVIEW. Annual progress reviews must be received at 12-months and 24-months after the start of the award.

a. **The Associate Chief of Staff for Research and Development (ACOS/R&D) will perform an annual review of all Merit Review Entry Program (MREP) awardees.** A scientist at the host facility may be appointed by the ACOS/R&D to perform these reviews. The review will be based on information provided by the awardee, input received from the awardee's mentor(s) and observations made by the reviewer. The evaluation and recommendations of the reviewer(s) must be discussed with the awardee and mentor(s).

b. **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.

2. CONTENT. The annual progress report must contain the following material:

a. **A cover sheet (limit 1 page) listing the following items in the order specified**

- (1) Merit Review Entry Program Annual Performance Review. – (add month and year)
- (2) VA medical center name and address.
- (3) Name, degree, social security number (on original only), position title, grade, 8ths VA employment, academic affiliation and rank of awardee.
- (4) Start and end dates of the MREP award.
- (5) Name, degree, and affiliation(s) of each mentor.
- (6) Percentage of awardee's time devoted to the MREP award.
- (7) Brief description of the awardee's non-MREP research activities, including collaborations and other research. Indicate the percentage of the awardee's time devoted to these other duties.
- (8) Location of MREP awardee's primary work site and/or laboratory (including Building and Room number). Clearly identify whether this is VA or non-VA research space.
- (9) Name, title, and signature of the ACOS/R&D.

b. **Description of progress**

(1) **Training.** Provide a description of the awardee's participation in training activities during the evaluation period, including formal courses, seminars, data sessions, laboratory meetings, journal clubs, lecture series, etc. Describe the basic content as well as frequency of training activities. Identify any variation from that proposed in the awardee's application; explain the

reason for the change. Include recommendations for enhancing or improving the training program, if applicable.

(2) Professional Meeting Participation. List the awardee's participation in regional, national or international scientific meetings using the following spreadsheet format:

| <u>Date</u> | <u>Meeting</u> | <u>Location</u> | <u>Role</u> | <u>Title of Abstract/Presentation</u> |
|-------------|----------------|-----------------|-------------|---------------------------------------|
|-------------|----------------|-----------------|-------------|---------------------------------------|

(3) Mentor(s). Provide a description of the awardee's interaction with mentors, to include frequency, duration, and nature of interaction. Identify any variation from the mentor/trainee relationship proposed in the awardee's application, and, if applicable, any changes in the mentor's obligations that could impact the trainee. Include recommendations for enhancing or improving the mentor-awardee relationship.

(4) Research Progress (limit 1 page). Provide a status report of progress made on the proposed research. Describe any changes from the original research plan.

(5) Bibliography. Include a chronological list of publications/accomplishments produced **during the performance period**. Highlight the awardee's name and indicate if the work was related to the MREP award. Separate the publications/accomplishments into the following categories:

- (a) Published and in-press peer-reviewed journal articles.
- (b) Published and in-press book chapters and reviews.
- (c) Non-peer-reviewed articles.
- (d) Submitted manuscripts (indicate journal name and date submitted). Do not include manuscripts "in preparation".
- (e) Published abstracts.
- (f) Inventions and Patents

c. **An evaluation of the MREP awardee's performance by the ACOS/R&D or designated reviewer to include the following:**

1. Summary of the reviewer's observations about the performance of the awardee.
2. Recommendations to enhance the program or bring it into compliance with the Merit Review Entry Program, if applicable.
3. Name, title, and signature of the reviewer.

d. **Awardee's Response to the Evaluation**

(1) The response should include a plan for correcting any deficiencies identified by the reviewer(s).

(2) The awardee and mentor(s) must sign the response.

e. **Attachments**

(1) **Letter from each mentor.** Each letter should contain the following information:

(a) Briefly evaluate the progress the awardee has made in accomplishing the research objectives of the award.

(b) Describe the mentor's interactions with the awardee during the performance period. Include the awardee's role in the mentor's research program, the mentor's role in the awardee's research program, formal training experiences completed, the percentage of the mentor's time devoted to the awardee, and the nature and quality of the interactions with the awardee.

(c) Identify any changes in the distribution of the mentor's time to research, patient care, teaching, and administration, or the number of residents, fellows and other trainees who the mentor is currently supervising. If there are no changes, the letter should so state.

(2) **Awardee's Research Support.** Attach VA Form 10-1313-8. List and describe, using VA Form 10-1313-8, all approved and/or anticipated funding during the performance period. If there is no other funding, indicate "none" (Form 10-1313-8 must still be submitted).

(3) **Reprints.** Reprints or copies of the following items must be submitted with the progress report:

(a) Manuscripts published during the reporting period.

(b) Galley proofs of "in press" manuscripts. If galley proofs are not available, provide a copy of the manuscript and letter of acceptance from the journal.

(c) Copies of manuscripts "submitted" for review, including the journal name.

(d) Abstracts submitted for presentation at scientific meetings.

3. SUBMISSION: Submit the original and 2 copies of the annual review package, including attachments (only one copy of reprints) to:

a. **If mailed through the U.S. Postal Service or If shipped by door-to-door courier such as Federal Express, send to:**

MREP Annual Progress Review
Rehabilitation Research and Development Service (122P)
810 Vermont Avenue, NW
Washington, DC 20420
202-254-0255

4. **MERIT REVIEW ENTRY PROGRAM CONTACT INFORMATION:** Questions related to the MREP program, including eligibility, application preparation, LOI, Annual Progress report, post award information, etc. should be directed to Terri Carlton at 202-254-0265.