## CONTENTS

## CHAPTER 4. MERIT REVIEW PROGRAM

**PARAGRAPH** **PAGE**

# CHAPTER 4. MERIT REVIEW PROGRAM

## 4.01 GENERAL INFORMATION

The Merit Review Program is the principal mechanism for sustained biomedical and behavioral research funding of VA scientists. Before or after appointment to VA, applications may be submitted to VA Central Office by independent VA investigators for a specifically defined study **f**alling within their area of interests and competence. These are peer reviewed by Merit Review Boards which provide Medical Research Service with a fair and objective evaluation of the quality of investigator-initiated research programs. VA Central Office constituted Merit Review Boards evaluate research proposals for scientific and technical merit, budgetary needs, and duration of funding.

a. All research programs reviewed by Medical Research Service must first be evaluated by VA medical center R&D Committee and approved by the Director of the medical center, before submission to VA Central Office; **first level of review.**

b. Merit Review Boards provide the **second level of review** in VA peer review system. Proposals for merit review are not considered as individual "grant applications" but rather as the total research program of the principal investigator. Investigators must submit their entire research program at one time as a unit proposal—total **program review.** Thus, VA investigators may not have several merit review proposals running concurrently with different termination dates. If an investigator has diverse and unrelated projects, separate budgets must be prepared for each project along with a summary budget. Investigators with an ongoing research program who wish to explore a new area **of** research may submit a supplemental application to the ongoing program. Before submission of a supplement, approval must be obtained in writing from Director, Medical Research Service.

c. Research proposals are reviewed in the context of all of the investigator's VA and non-VA research support. **Other research programs, regardless of their source of funding, must be described briefly in the current proposal.** The research abstract and detailed current or first-year budget for all funded or pending non-VA proposals must be included **so** that reviewers can assess the investigator's total research activity and commitments.

d. **The Medical Research Service research program is intramural** and it funds only biomedical and behavioral research conducted by staff at a VA medical center. Clinician-investigators are eligible for VA Central Office medical research support only if they have established a significant role in VA medical center. (See ch. 3.)

e. To be eligible for merit review support, **newly recruited nonclinician Ph.D. principal investigators** who request 5/8 or more of their salary from Merit Review must receive a fundable priority score in Merit Review before appointment to VA. New nonclinician Ph.D. scientists requesting less than 5/8 of their salary from Merit Review and who receive a fundable priority may, in some cases, be approved for appointment to VA by the RSEC (Research Scientist Evaluation Committee). (See ch. 10.) Approved and funded Ph.D. principal investigators are given term appointments.

f. Each research program usually has one principal investigator who is responsible for all aspects of the program, including the budget. However, two or more investigators may share such responsibility equally and are considered **co-principal investigators.** This

relationship applies to the total VA medical research program of each investigator. The budget will be distributed equally among the investigators. No principal investigator may have more than one Merit Review proposal unless the Medical Research Service solicits a special set of proposals in response to an **RFP** (Request for Proposal).

g. VA makes information regarding VA-supported research generally available to the public or other Federal agencies upon written request. This is required by the **Freedom of Information** Act (5 U.S.C. 552). Release does not depend upon the intended use of the information, but is subject to deletion of material that would affect patent or other valuable rights. Disclosures will be made unless one or more of the nine exemptions contained in the Freedom of Information Act are applied. The Act is implemented by 38 CFR 1.550-1.559. VA medical center, ACOS for R&D, and principal investigator will be notified about any such release. Information in the research proposal file is also subject to the **Privacy Act of 1974** (5 U.S.C. 552a) and VA may not initiate disclosure of such information except in accordance with the provisions of that Act and 38 CFR 1.575-1.584.

h. Clinical studies which include the experimental use of devices or drugs of unproven safety and efficacy are subject to **FDA (Food and Drug Administration)** regulations. For clinical investigations involving significant risk devices or drugs, an Investigations Exemption application must be submitted to the FDA (45 Fed. Reg. 3732 (1980) 21 CFR Part 821.1 et seq.) prior to submission of the study to Merit Review.

i. VA has adopted NIH Guidelines for research involving **Recombinant DNA Molecules.** Investigators requesting VA support for work in this area must follow these guidelines, including review by either VA medical center or the affiliated university's Institutional Review Board for these matters.

j. **VA Form 10-1436, Research and Development Information System Project Data Sheets,** must be submitted to the RDIS (Research and Development Information System) for all intramural and extramural research projects. Additionally, the ACOS for R&D must ensure that all projects are reported on VA **Form 10-5368, RDIS Report** RCS 15-5, part 2, page 20, which is submitted at the end of each fiscal year. VA Form 10-5368, Investigator Data Sheet, page 18, must be submitted to RDIS for each principal investigator.

k. Investigations involving human subjects will not be reviewed until they have been approved by VA medical center or affiliated university **Subcommittee on Human Studies.** A completed and current VA Form 10-1223, Report of Subcommittee on Human Studies, dated no earlier than 1 year before the receipt date for the application, must be submitted with the merit review application and must be accompanied by the consent form, VA Form 10-1086, Agreement to Participate in Research By or Under the Direction of VA, that will be presented to each subject or legally responsible representative prior to the subject's participation in the study.

1. VA is committed to conforming to Federal and State regulations pertaining to Animal Research Facilities. Applications involving the use of animals must contain and conform to a completed checklist as outlined in M-3, part I, chapter 12. The information containing the approval of the **Subcommittee on Animal Studies,** dated no earlier than 1 year before the receipt date for the application, must be signed and dated by VA medical center veterinarian and submitted with the application. Prior to Merit Review, proposals to use animals are mail reviewed by individual VA or non-VA laboratory animal specialists chosen for experience, knowledge, and research in laboratory animal science

and medicine. To the extent, possible proposals are matched with the subspecialty expertise or interests of veterinary medical reviewers. Recommendations from this review are evaluated by the Merit Review Boards, and are then forwarded with the merit review results to the investigator.

m. Proposals containing procedures that constitute a potential biohazard must be accompanied by a current explanation of required safety precautions. A statement from the local VA medical center or university Biohazard Subconuuittee on Safety must be submitted with the proposal.

n. Submission of applications for Merit Review are due in VA Central Office December 21 for October I funding and June 21 for April 1 funding. Receipt dates will be waived only in extreme circumstances. Two or more members of the Medical Research Service, Program Review Division and other professional staff within VA Central Office assign each proposal to the Merit Review Board most qualified to provide a scientific review of the proposal. When a proposal is not appropriate for review by any of the established boards, it is assigned to a specialty Ad Hoc Committee, submitted for a mail review by a select group of four or more ad hoc reviewers, or a program site visit is arranged.

o. Investigators may suggest to the Program Review Division the Merit Review Board to which they would prefer to have their proposal assigned. The recommendation must be submitted in a letter of transmittal mailed separately from the merit review applications, and should include justification for recommending assignment to a specific Board. However, the final decision for assignment is made by the Program Review Division.

p. If a program includes research studies in more than one subject area, the individual projects may be assigned to different Merit Review Boards, in order to obtain the most appropriate expert appraisal. Recommendations for multi-project programs are then synthesized into one overall recommendation. For example, for approved proposals priority scores of two or more Merit Review Boards are averaged in order to obtain a final priority, or, if one Board recommends disapproval and another Board recommends approval with a fundable priority, the proposal will be reviewed by a site visit team.

q. Proposals will not be accepted for Merit Review unless they have been identified 3 weeks before each deadline, via teletype. The teletype must include only Merit Review proposals and not RAG (Research Advisory Group) or Career Development applications. The teletype should include only the first and last name of the principal investigators) in alphabetical order.

r. Principal investigators submitting merit review applications are encouraged to suggest the names of two or more scientists they believe are qualified to review their proposal. This is especially useful when the research does not fall within the area of expertise of any of the standing Merit Review Boards. The potential reviewers' names must show their academic affiliation, complete address, and telephone number. This information must not be a part of the proposal package, but should be sent as a separate letter to the Assistant Director of Scientific Review (151D). The names of those extramural scientists who reviewed the proposal for VA medical center R&D committee should also be included.

s. The guidelines **for** Merit Review must be followed completely. VA Central Office reserves the option of returning, unreviewed, all proposals that are incomplete. Funding of proposals and requests for a change of scheduled receipt dates for their submission are handled by Field Operations and not through Program Review. No additional or replacement information will be accepted after submission of the proposal unless requested by VA Central Office. If proposals are withdrawn, VA Central Office must be

notified promptly by telephone with a written follow-up. When a principal investigator transfers to another VA medical center in the middle of a cycle, the new VA medical center must submit the required VA forms related to animal, human, and other resources because the proposal must be reviewed in the context in which the research takes place.

t. All forms must be signed by a Chairperson except when that person is the principal investigator. In such ‘cases, the Chairperson may not sign the forms for the committee because this is a conflict of interest, so another committee member must be delegated. This responsibility may never be delegated to the Administrative Assistant or ACOS for R&D.

## 4.02 TYPES OF MERIT REVIEW PROGRAMS

a. **Program.** The term “Program” is used to include all of VA supported research activities of a principal investigator. A program may include one or more research projects. A “Project” is a definitive and separate component of a research program.

b. **New Program.** A program is new if it has not received prior approval with funding by a VA Central Office Merit Review Board within the previous 5 fiscal years. RAG, Career Development, and Cooperative Studies funding are not included in this category.

c. **Ongoing Program.** A program is ongoing if it has been approved with funding by a VA Central Office Merit Review Board within the previous 5 fiscal years. A program is considered ongoing even if the title is changed or the principal investigator has a major shift of research emphasis. A program is ongoing even though after an approval with fundings, it was subsequently disapproved or approved without funding within the previous 5 fiscal years.

d. **Supplemental Program.** A program is Supplemental if it is different from the investigator’s ongoing program and requires additional funding. A program is not considered Supplemental if it is a request for funds due to unexpected expenses arising in connection with an ongoing program. A Supplemental program must terminate with the ongoing program and may not request supplemental yearly funds, including equipment costs, in excess of 50 percent of the current annual allocation for the ongoing program. The request must include a detailed report of the progress since the last merit review as well as a justification for the additional funds. Supplemental requests are not for funds to meet increased but routine costs, e.g., inflation, personnel actions, or equipment failure. These requests are not submitted and reviewed by the merit review system but are handled through administrative channels. A Supplemental application may not be submitted until after the original application has been funded. The principal investigators of a Supplemental application must be the same principal investigator(s) as in the ongoing program. Supplemental applications are not subject to the formal appeals process.

e. Applications for a program are reviewed by the appropriate Merit Review Board, primarily for their prospective scientific and technical merit. The budget and years requested are determined by the needs of the proposed research. These programs are usually 2 to 5 years in duration.

f. Medical Research Service will not review proposals that request recurring funds of less than $10,000 annually.

the research. The Centers provide biomedical statistical advice and assistance, facilities for data collection and evaluation, administrative management, and supportive services such as those of a Human Studies Subcommittee.

## 4.03 INSTRUCTIONS FOR PREPARATION OF MERIT REVIEW APPLICATIONS

a. Applicants may obtain information concerning forms, instructions, and an acknowledgement postal card from the ACOS for R&D. Each proposal must be accompanied by one acknowledgement postal card and one VA Form 10-1313-A, Merit Review Board Summary Statement. The proposal package is routed through VA medical center office of the ACOS for R&D (or designated equivalent), the R&D Committee, the Director, medical center, and other appropriate channels and addressed to Director, Medical Research Service (151D).

b. Submit the original plus 25 un bound copies of the proposal duplicated on 21.5 x 27.9 centimeter paper. Do not staple copies, and do not insert colored paper between the copies. Black spring clips or rubber bands may be used.. Except for the original, which must be duplicated face only, all forms and narrative material must be duplicated back-to-back. Use a blank sheet of paper as a continuation sheet for the special VA forms where necessary. VA Central Office will use the original as the master file copy. Except for the special forms provided, use blank white paper, and elite or 10.5 to 12 point or equivalent (no more than 15 characters per inch) type, to make an imprint suitable for reproduction. Type material single spaced, leaving a 2.6 centimeter wide binding margin at each edge of each sheet. Do not submit applications prepared from a dot matrix printer, and do not use photoreduction.

(1) Submit 20 extra copies of VA Fon-n 10-1313-1 with VA Form 10-1313-2 duplicated back-to-back. These must be submitted with each proposal, but must be separate from the proposal.

(2) Applications will be considered incomplete and returned unreviewed if they are illegible, fail to follow instructions relating to type size and page limits, or the material presented is insufficient to permit an adequate review.

c. Type the name of the principal investigator in the lower right portion of each page and number each page consecutively, starting with the face sheet, VA Form 10-1313-1 (e.g., Smith-1 to Smith-22). Place the Merit Review Board Summary Statement, VA Form 10-1313-A, and the acknowledgement card in front of page 1 of the original proposal. The R&D Committee statement should be separate from the transmittal letter. No attachment should be placed in front of VA Form 10-1313-1. Do not prepare an index or table of contents.

d. Round off all dollar figures to the nearest hundred dollars.

e. Use the date the proposal is sent from VA medical center as the date of submission.

f. On the address side of the acknowledgement card, enter the name and address of the ACOS for R&D. Complete items 1 and 2 only on the other side of the card. The acknowledgement postal card will be returned to your facility approximately 1 month after the receipt date and after the proposal has been assigned to an appropriate Merit Review Board.

g. Selected publications, reprints, or manuscripts often assist the reviewers in assessing the expertise and experience of investigators and their colleagues as well as progress made toward completing the goals of a new or ongoing program. You may submit no more than six copies of up to five appropriate selected papers, but such copies must be separate from the copies of the proposal. Do not place publications in an appendix with the 25 photocopies of the proposal.

h. Arrange the forms and narrative material in the following order:

(1) **VA Form 10-1313-A, Merit Review Board Summary Statement.** This form must be completed like **VA Form 10-1313-1;** however, only an original should be submitted with the original copy of the proposal. Do not complete items 1 to 4 or any item after number 19. The following items may need clarification:

Item 9. Type the last name of the principal investigators) in capital letters, followed by the first name and initial(s). List telephone number(s), FTS number and/or area code, and commercial number of the principal investigators).

Item 10. Do not use a title that has more than 72 typewritten characters (including spaces). Try to be as specific and descriptive as possible on the choice of title to assist readers in quickly identifying the overall program objectives. The title should not contain references to animals or specific species, e.g., "in the turkey," "in man," "in an animal model," etc. If more than one project is being submitted in this program, do not submit separate titles for individual projects in this item. The title of a Supplemental project does not have to be the same as that of the program previously approved.

Item 11. Insert the 3-digit Program code (821 for Medical Research) representing the R&D service to which the proposal is being submitted for review. Insert Cost Center 103 (research funds) or 106 (centrally directed priority areas).

Item 13. VA employment status refers to current or projected VA salary status. Investigators who are consultants, attendings, or WOC (without compensation) should compute their average hours/week over a year's time, i.e., number of hours/month times number of months worked divided by 52 weeks.

Item 15. A program funded through merit review within the previous 5 fiscal years is ongoing even though it acquires a new title or there is a major shift in programmatic objectives. Investigators who have several projects and choose to describe each as a separate activity must record the total number of projects. All other investigators should record the number one (1).

Item 16. The funds requested each year should be the same as the totals listed on VA Form 10-1313-4, "Estimated Expenses for Each Year." The total is total funding requested for all years. Merit Review funds may be requested for a period up to 5 years.

Item 17. Insert both the primary research program area and primary specialty area that apply to the principal investigators). It should be the same as that reported to the RDIS on VA Form 10-5368, page 18.

i. **VA Form 10-1313-2, Summary Description of Program Project.** Include the research program objectives), hypotheses and procedures, but do not include technical details. List key words that best describe the scientific disciplines encompassed by the studies. Check the appropriate box to indicate whether the description is of a total program or a project. The title of a project may be different from the title of the total program. The principal investigator for a project should be the person(s) responsible for the scientific and technical direction and completion of the work proposed.

j. VA Form 10-1313-3, Current Funds and First Year Request.

(1) Indicate the direct costs of the program. Place the costs of personal services,

equipment, supplies, animals, animal care supplies, and other resources that are attributable to an investigator's program under the appropriate cost center.

(2) Check the appropriate box to indicate whether this form applies to a total program or a project.

(3) List all personnel involved in the program/project, including the principal investigator(s). Give their names, justify their roles, and list the percent of total professional or technical effort devoted to the program/project, whether or not salaries are requested. List salaries, including fringe benefits, for all personnel paid or to be paid from Medical Research funds. Secretarial salaries are not allowed. Physicians, dentists, and nurses may not receive salaries from Medical Research Service funds except with express prior approval of the Director, Medical Research Service, and the Chief Medical Director. Written requests for exception, with justification, must be submitted by the facility Director through Director, Medical Research Service (151).

(4) Identify grade and step for each employee. Salaries listed should be proportional to the time devoted to the program/project.

(5) Include in the first year request column all Medical Research funds that are being requested for the projected first 12 months of the program. This is the 12-month period beginning October or April 1, 9 months after the date of submission of the application. Include in the current year funding column all funds allocated by VA Central Office to the investigator for the 12 months preceding the first year request. For supplemental requests, indicate in the current year funding column the expenditures for the current year of the ongoing program, and in the first year request column give details of the funds needed for the first year of a Supplemental project.

(6) List each consultant and indicate the nature of the service to be performed, the fee for each consultation, the amount of travel and per diem, and the number of consultations to be provided. Append to the proposal a letter from each individual agreeing to consult, along with details of the nature of the consultation. Applicants should be aware that numerous restrictions apply to payment of consultants (non-VA employees). If the services of a consultant are required to conduct a research project, principal investigators should explore current applicable VA rules and regulations before developing their budgets. Any consultant paid $500 or more per consultation, exclusive of expenses, or $2,500 or more per year must be approved by the Secretary, Department of Veterans Affairs, a time-consuming procedure.

(7) List each item of equipment to be purchased and provide justification for any item whose need may not be apparent to reviewers or whose cost is greater than $3,000. As part of the justification, you may use the detailed information or format from R&D circulars (e.g., Research Instrumentation). For major equipment items, indicate how many similar instruments are located at the facility and in nearby laboratories. Do not submit manufacturers' brochures or photocopies as part of the merit review application. All charges for equipment maintenance must be justified.

(8) List supplies by major types such as glassware, chemicals, isotopes, etc.

(9) List all other expenses by major category, including costs for publications, animal subjects (type and number, their unit cost, and unit care cost), and rental and contractual fees. Travel costs are permitted for project staff if the travel is directly related to the research, but travel costs for scientific meetings as well as registration fees and expenses for books and journals are not permitted. Include the daily and total charges for Animal Research Facility maintenance of all animal subjects required in the research. Charge-back costs, as well as costs for manuscript preparation, photocopying, and illustrations are not allowed.

k. **VA Form 10-1313-4, Estimated Expenses for Each Year**

Check the appropriate box to indicate whether this form applies to a total'. program or a project. The total operating expenses for the first year should be identical to the total indicated on VA Form 10-1313-3, for the same program or project. Do not include inflationary increases in any of the budget categories and do not include cost-of-living increases, within grade increase, or anticipated promotions in the personnel category. All differences in the operating expenses between years should be fully justified in the space provided. For Supplemental programs, list only the supplemental funds requested in each year, and do not exceed the duration of support previously recommended for the total program or an amount in excess of 50 percent of the current annual allocation for the ongoing program.

1. **VA Form 10-1313-5, Biographic Sketch**

m. **VA Form 10-1313-6, Bibliography**

Do not exceed two pages in the bibliography for each investigator. Include a chronological list of all of the most important and pertinent publications, but do not include abstracts submitted papers, or papers in preparation. Use the bibliographic format used for the RDIS. Identify those publications that are a result of the most recent period of VA research support and list them after the collaboration section of the narrative. Literature citations must include the full title of the paper being referenced. Do not include curriculum vitae, either in addition to or in place of VA Forms 10-1313-5 and 6.

n. **VA Form 10-1313-7, Total VA and Non-VA Research/Development Support**

Pending requests must also be included even if there is no current support.

o. **VA Form 10-1313-8, Total VA and Non-VA Research/Development Support**

(1) Discuss fully every item listed on VA Form 10-1313-7. Include duration of support and total funding level. Simple statements such as "there are no budgetary, scientific or administrative overlaps" are not acceptable. The abstract of research plan and budget pages for all funded or pending non-VA applications should be placed after VA Form 10-1313-8.

(2) The four forms (VA Form 10-1313-5, 6, 7, and 8) should be completed for the principal investigator and for each investigator and collaborator who plans to devote more that 5 percent research effort to the total program. Include only a biographic sketch for those devoting 5 percent effort or less (VA Form 1313-5 and 6). Do not include any of the above forms for consultants, but include all persons who will participate in the design, performance and professional direction of the proposed research.

p. **Investigators resubmitting an application** after a disapproval of approval without funding must include a letter after VA Form 10-1313-8, no longer than three pages, indicating how and where responses to the last review have been addressed. Revised applications with no substantial revisions and no response to previous critiques often receive an unfavorable review. Amended applications that do not include this letter will be returned unreviewed.

q. **Narrative.** Include sufficient information to facilitate an effective review without reference to any previous application. Brevity and clarity are essential components in the presentation of a research plan. There is a 15-page limit on the narrative portion of merit review applications. In complex programs with diverse projects, each of which must have a separate budget, the narrative may extend up to 5 pages for each additional project to a total of not more than 25 pages. An appendix describing new, unusual, or unpublished methodolo " may be added; however, the appendix may not exceed 15 pages and may not be used to expand the narrative. The literature citations, as well as the human consent forms and animal component information forms are not counted toward the 15-page limit of the narrative. Use the following format:

(1) Rationale

(a) Briefly **state the problem** to be investigated.

(b) **State the hypotheses** or key questions to be answered by the study.

(c) **Summarize specific objectives.** Briefly and concisely list the short-term and long-term objectives of this research; for long-term objectives identify expected intermediate goals, Outline an anticipated timetable for achievement of the short-term objectives.

(d) State the **current status of research** in the area. Describe the research that has been done toward solution of the problem(s) and how this knowledge relates to the hypotheses, or questions presented above. This description should be sufficiently complete to demonstrate that the principal investigator is aware of all related work. When pertinent, studies both supportive of and contrary to the hypotheses should be quoted and discussed. This discussion should be concise and relevant to the problem(s), hypotheses, or questions.

(e) State the **significance of this research.** Explain the potential importance of the proposed work, and identify any unique ideas or potential contributions that might result from this study. Significance relates to the likelihood that the research will lead to new knowledge or advances within its field of science, when judged by the "current stat-e of art" **of** that field of science. This is a judgment of the inherent value of the research.

(f) Indicate the **relevance** of the proposed work **to VA patient care mission.**

(2) **Background and Work Accomplished.** Describe briefly any studies you and your co-workers have done that are pertinent to this proposal. If this is an ongoing program or a request for supplemental funds, include a detailed report of the progress made since the program's inception. The Progress Report should describe accomplishments to date and may include charts, graphs, or other materials that succinctly present significant data. If

progress can be best described by some of your publications, submit six copies of each pertinent paper (up to five) to support your Progress Report.

(3) **Work Proposed**

**Methods of procedure.** Give details of your research plan, including descriptive examples of the types of experiments or other work that you propose, the major methods to be used, the specific techniques (e.g., instrumentation, statistical methods) to be employed, the kinds of data that you expect to obtain, and the means by which the data will be analyzed and interpreted. Be as specific as possible. When animals are to be used, list the number and types, including strains and species.

(4) **Resources.** Describe the facilities and personnel required for the projects(s). Indicate which are available and which must be obtained, including office and laboratory space, data processing facilities, clinical research facilities, access to specific patients, access to VA staff, animal rooms, and major equipment and/or supply items.

(5) **Collaboration.** Describe any proposed collaboration with institutions and investigators. Include a description of the role of additional professional personnel and a letter from each agreeing to participate.

(6) **Publications.** List all your major publications resulting from work done during the period on which you are reporting. Do not include clinical case reports, summaries, or verbatim records of lectures, review articles, or abstracts of papers presented at meetings.

(7) **Literature references.** Include full titles of each published paper cited. Limit this information to a maximum of four pages.

r. **VA Form 10-1223, Report of Subconuriittee on Human Studies.** Clinical research proposals and other studies involving human subjects will not be reviewed until they have been approved by VA medical center or affiliated University Subcommittee on Human Studies. A complete and current VA Form 10-1223, Report of Subcommittee on Human Studies, dated no earlier than 1 year before the receipt date for the application, must be submitted with the Merit Review application and must be accompanied **by** VA Form 10-1086 consent form(s) that will be presented to each subject or legally responsible representative prior to the subject's participation in the study. Applications that do not contain this information will be returned unreviewed.

s. **Animal Component of Research Protocol Statement.** All research proposals involving the use of animals must contain and conform to a completed checklist as outlined in M-3, part 1, chapter 12. The information containing the approval of the Subcommittee on Animal Studies, dated no earlier than 1 year before the receipt date for the application, must be signed and dated by the veterinarian. This information must be submitted with the proposal. Applications that do not contain this information will be returned unreviewed.

t. **Biohazard Statement.** Proposals containing procedures that constitute a potential **or** possible biohazard must be accompanied by a current explanation of safety precautions to be taken. A signed and dated statement of the local VA or University Biohazard Committee on Safety must be submitted with the proposal. Applications that do not contain this information will be returned unreviewed.

u. **Privacy of Information Statement.** Due regard for Public Law 93-579, The Privacy Act of 1974, must be apparent and evidence of intent to comply must be explicitly presented in this section. The facility Privacy Act Officer (usually the Chief, Medical Administration Service) should be contacted for guidance on Privacy Act requirements.

v. **R&D Committee Review of Proposal**. This must be signed and dated.

w. **GRECC (Geriatric Research, Education, and Clinical Center) Advisory Committee Statement** (Cost Center 106 programs only).

x. **Letters of Endorsement.** Formal letters are required from the following:

(1) The Director of the principal investigator's VA medical center letter must contain statements that the Director understands the potential impact of the proposed research on the facility's organization and endorses the proposed project.

(2) Indicate concurrence from each participating or affected organizational element.

(3) Indicate the specific role of each individual named as a consultant or collaborator in the program.

## 4.04 MERIT REVIEW RELATED ISSUES

a. **Proposals with more than one project.** All projects carried out by a principal investigator must be included in a single program proposal. For each project, the investigator must provide a summary description (VA Form 10-1313-2), budget information for the project (VA Forms 10-1313-3 and 4), and complete narrative. A total budget, summing items for the individual projects, must be included. On assembling the total program, all budget information, all biographical and funding information, and all of the narrative should be grouped together. Only one copy of the bibliographic information and funding information should be included for each investigator.

b. **Proposals with more than one Principal Investigator.** If a proposal has two or more co-principal investigators, all of their names must appear in Item 9 of VA Forms 10-1313-A and 10-1313-1. They may be labeled as A, B, C, etc., for purposes of identification for Items **7,** 12, 13, 16-18, and 20, 21. All co-principal investigators must sign the application. Do not submit a separate VA Forms 10-1313-A and 10-1313-1 for each co-principal investigator. An investigator may not be a principal investigator on one application and a co-principal investigator on another application.

c. **Renewal of proposals**

(1**)** All approved programs will be assigned a deadline date, at which time a renewal proposal to continue the program is due to VA Central Office.

(2) If an investigator chooses to submit an ongoing proposal before the designated renewal date and after review receives a fundable priority, the program renewal will replace the ongoing program and it will be funded the following October or April, 9 months after its receipt date. If disapproved or approved but unfunded, the ongoing program will terminate at the end of September or March, 9 months after the receipt date of the early submission of the ongoing program.

(3) If a principal investigator submits a revised second merit review application while a decision on funding of the first application is pending, the first merit review application will be withdrawn once the next cycle of Merit Review Board meetings begin.

d. **Special Programs renewals.** There may be some cases where an investigator has funds through Merit Review and Special Programs; i.e., GRECCS. Renewal of the Special Program must be supplemental to an ongoing merit review proposal and co-terminate with it.

e. **Proposals in a GRECC.** Proposals identified for Cost Center 106 funding in a GRECC must include a statement signed by the Chairperson of the GRECC Advisory Committee indicating that the Committee has reviewed the proposal and identified it as being within the GRECC I s research focus.

f. **Career Development applicants.** Career Development applicants and eligible Career Development awardees, except Associate Investigators and Senior Medical Investigators, may apply for research support through the merit review process. Both the Career Development Committee and the Merit Review Boards are interested in the principal investigator's total program. Consequently, in the process of submitting to merit review, these investigators must describe any differences between their Career Development application or program and the merit review proposal. The merit review budget represents the principal investigator's total VA research needs, excluding the salary of the principal investigator. VA Form 10-1313-3 should indicate dispersal of all the investigator's current institutional research support, including any Career Development funding received. The First Year Request Column of VA Form 10-1313-3 should indicate the investigator's total research support needs. The Merit Review Board's Summary Statement will indicate the recommended total level of support for the investigator's program. Investigators who are recipients of ongoing merit review funding and who receive a Career Development award may request additional funding through submission of a Supplement to their current merit review proposal.

g. **Nonclinician Ph.D. Salaries.** Cost Center 103 salary may be provided for a nonclinician Ph.D. as a co-principal investigator or co-investigator on a physician's or other scientist's research program. Salary for these Ph.D. investigators should be commensurate with their percentage effort in the research. However, if principal investigators have other funded research, VA or non-VA, that accounts for all of their professional responsibilities they may request their full salary from their merit review. The investigator should include a statement regarding ultimate salary support, dependent upon the result of merit review (VA Form 10-1313-4).

h. **Project site visits.** Site visits may be performed to evaluate research proposals: (1) from a VA scientist applicant who is a member of a Merit Review Board that might ordinarily be expected to review the application; (2) consisting of multiple projects with large budgets when the Board members are unable to reach a conclusion on the basis of the information available to them at the meeting; (3) where there are multiple questions regarding an established investigator's facilities, technical personnel, and budgetary requirements that cannot be resolved by mail or telephone; or (4) that raise other technical or administrative issues. Site visits that are recommended by Merit Review Boards may be arranged before or after Board meetings. The site visit team usually consists of the Executive Secretary of the Board, as well as a member of the appropriate Board and two or more ad hoc consultants who are experts in the field of the proposed

studies. If the site visit was recommended by the Board, the site visit report is the basis for evaluation of the application at the next Board meeting. For site visits initiated by Medical Research Service, the recommendations of the site visit team are the basis for administrative approval or disapproval of a proposal. Site visit team recommendations are the basis for funding decisions of applications of Board members.

i. **Deferred review.** Merit Review Boards may defer a proposal for additional information and rereview the proposal at the next cycle of review. If an ongoing program, the investigator will receive two quarters of full support at the previous ongoing funding level (carry-over funds) until the results of the second review are completed.

j. **Early warning.** Investigators who submit proposals that are disapproved or approved with an unfundable priority are promptly notified of the Merit Review Board recommendations so that they may revise their applications and resubmit them for the next cycle of review; "early warning." As soon as possible after the Board meeting, these investigators with unfundable proposals will be sent copies of the individual edited reviews and the Summary Statement representing the opinion and recommendation reached by the Board.

k. **Continuation of funding.** Medical Research Service will continue to fund ongoing Merit Review programs that are unfunded in one review cycle (but not two successive cycles), and after revision and resubmission are approved with funding in the next review cycle. These programs will receive two quarters of full support (starting October 1 or April 1) at the previous ongoing funding level. Ongoing Merit Review programs with a priority score of 29.9 or better that are revised and resubmitted and are unfunded in a second review cycle will receive continued (phase out) funding at the previous ongoing level for one quarter only. Salaries for nonclinician Ph.D. principal investigators are continued for I year beyond the termination date of the investigator's ongoing Merit Review program providing the investigator remains employed by VA medical center.

1. **Priority score reduction of funds.** The budget for Merit Review approved research proposals, except for equipment funds and the principal investigator's salary, is subject to a priority score reduction of the recommended funds. Proposals approved with a numerical priority score of 10 to 15 are fully funded. For each point above 15 funding of the recommended budget is decreased by 1.6 percent.

m. **Assignment of applications.**

(1) Assignment of an applicant's proposal to an appropriate Board is an important element in peer review. VA has several mechanisms to avoid inappropriate assignments. First, the identity of the Board members is made available to all investigators and they may request that their proposals be assigned to a particular Board. Second, investigators may informally appeal a Board assignment to appropriate staff in VA Central Office. Third, the Board chairperson reviews the appropriateness of the assignment of all applications assigned to the Board. For unfunded proposals, a formal appeal of the assignment is a final option.

(2) It is the policy of the Medical Research Service that merit review applications be reviewed by Merit Review Boards that can furnish the best quality review of the science of the proposed research that falls within the program area expertise of a particular Board, irrespective of the specialty area (clinical discipline) or academic degree of the applicant. It is important to distinguish between peer review by specialty peers; e,g.,

medicine, surgery, psychiatry, anesthesiology, etc., from review by research program area peers; e.g., biochemistry, genetics, immunology, oncology, etc. Peer review based on research program areas assures that a single standard of review is used for the evaluation of the scientific merit of all research applications. It would be a disservice to investigators if their applications were to be reviewed by scientists who were not experts in the research program area encompassed by the proposed study.

n. **Merit Review Board Membership**

(1) Merit Review Board members are selected by their peers. This is achieved by soliciting the names of new Board members from the current members of the Board, and from other specialists within the areas of expertise served by the Board. The final list of experts is then reviewed by the Board Chairperson, personnel in the Program Review Division at Central Office, and the Director of Medical Research Service. This nomination and selection procedure for Board members assures that the Boards have the appropriate expertise to review the types of proposals that the Board will be asked to review. The Board membership must reflect the review needs of a particular set of applications.

(2) Merit Review Boards must have an appropriate balance of reviewers who are close to the latest information in their specialized fields. They must contain members who are experts in the basic sciences, as well as experts in the clinical disciplines served by the Boards. In order to achieve this balance, the Boards' membership has been broadened in recent years, sometimes adding ad hoc members to the Boards to obtain the best cross-disciplinary advice. In addition, each research proposal is reviewed by two mail reviewers, selected by Board members or recommended by the applicants. These ad hoc reviewers are identified as having special expertise in one or more areas embraced by the applicant's research. Thus, many scientists participate in a group judgement of the Board's final recommendation of the scientific merit of each proposal reviewed. This lends credibility to award decisions.

o. **Criteria of Scientific Merit.** Merit Review Boards are expected to review applications solely for scientific merit. Scientific merit is judged by the following criteria:

(1) The theoretical and experimental basis for the study (a reasonable hypothesis);

(2) The importance or significance of the study to a specific field of science;

(3) The novelty and originality of the study;

(4) The soundness and feasibility of the experimental design;

(5) The adequacy of the methodology;

(6) The appropriateness of the methods for data analysis;

(7) The sufficiency of institutional resources and staff;

(8) The competence and level of productivity (referred publications) of the principal investigators) and their commitment of time to the study; and

(9) An evaluation of human and animal ethical concerns and biohazards.

The Board examines the appropriateness of the budget and duration of funding; however, this is not a component of scientific merit. Reviewers are expected to judge the scientific merit of a proposal as if the applicant had no other current or pending support.

p. **Applicants as independent investigators**

(1) Medical Research Service funds are for the support of independent biomedical investigators. Independence means that the investigator is competent to develop and direct a research project without the supervision of a preceptor. The qualifications of an independent principal investigator to conduct research are based upon evidence of previous training and/or experience in research and proof of productivity as attested to by independent grants support and by referred publications, especially first author publications in the field of the proposed research.

(2) Merit Review Boards are not expected to review applications of designated principal investigators who lack the proven competence to design and direct the studies. Ini their evaluation of scientific merit (see par. o.), Boards give more weight to the principal investigator's experience and track record than to any other single factor. They assign a low priority or disapproval to an applicant who has few or no qualifications to perform a study. Most rejected proposals are for reasons that are emendable, except when the applicant is inexperienced and/or unproductive.

(3) The merit review program is not a training program. Because of the limited availability of funds for support of the merit review program, these funds must be used to support only independent investigators who can compete successfully for research funds. Proposals submitted by an applicant who is not an independent investigator will not be reviewed. The use of such a procedure is a misrepresentation, and not an appropriate use of peer review resources.

q. **Priority score numbers and level of enthusiasm**. All Board members are expected to use a similar set of criteria for numerically rating approved proposals, and to use the full-range of priority ratings on a scale of 10 to 50. To improve uniformity in priority scoring Board members are furnished with the following scale of priority score numbers and descriptive adjectives:

| | |
|---|---|
| Excellent | 10-15, approximately 10 percent of approved proposals |
| Very good | 16-22, approximately 25 percent of approved proposals |
| Good | 23-28, approximately 25 percent of approved proposals |
| Fair | 29-34, approximately 15 percent of approved proposals |
| Marginal | 35-40, approximately 15 percent of approved proposals |
| Poor | 41-50, approximately 5 percent of approved proposals |

r. **Priority scores as basis of funding decisions.** The Medical Research Service does not fund a defined percentage of proposals from a specific discipline. Priority scores of all proposals reviewed from a single review cycle are pooled, and those with the best priority

scores are funded until available funds are depleted. Priority scores among the different categorical Merit Review Boards are expected to reflect differences in scientific merit of the applications reviewed by the Boards rather than differences in the voting behavior (inflation of the priority scores) among the members of the different Boards. Thus, funding decisions are based entirely on the scientific merit of a proposal as determined by the priority score.

s. **Change of principal investigator.** Medical Research Service will consider requests to transfer a merit review award from a currently designated principal investigator to a new principal investigator at that VA medical center. The request must be accompanied by letters from the facility Director and current principal investigator, indicating agreement with the request, as well as a letter of justification and curriculum vitae of the proposed principal investigator. Requests for transfer must be approved by Director, Medical Research Service. The Medical Research Service supports only peer reviewed research, and therefore, only qualified investigators who functioned in an active role in the research of the designated principal investigator will be considered eligible for status of principal investigator, e.g., M.D. or Ph.D. co-principal investigator, co-investigatoi or other active collaborator. If the proposed new principal investigator has an active merit review proposal, the additional proposal will be considered a Supplement and it will end on the termination date of the ongoing proposal. The merit review program of a principal investigator who is newly approved (less than 1 year duration) may only be transf erred to a co-principal investigator assigned to the program.

t. **Review of applications of Board members.** VA scientists must inform the Executive Secretary if they are a member of an advisory group that might ordinarily be expected to review their application. They should indicate if they believe that another committee is qualified to review their proposal. If no other group is considered qualified to review their proposal, a site visit will be arranged.

u. **Confidentiality of review, conflict of interest.** Members of scientific peer review groups may not discuss any matters relating to the review of specific applications with the applicant. Under no circumstances may investigators contact, orally or in writing, any member of a scientific review group in reference to their research application. The interests of the investigator and of the peer review process are harmed when an investigator attempts to personally intervene in the process. This creates a situation which has the appearance of a conflict of interest. Communications from investigators must be directed to the Assistant Director for Scientific Review.

v. **Ensuring integrity of research.** Maintenance of high ethical standards in the conduct of research requires that VA medical centers and investigators applying for and receiving awards have in effect sufficient controls to preclude the occurrence of unethical research practices. All research data shall be retained for 5 years after completion of a research project. The principal investigator and others associated with the research must subscribe to accepted standards of rational experimental research design, accurate data recording, unbiased reporting of data, respect for the intellectual property of other investigators, adherence to established ethical codes and legal standards for the protection of human and animal subjects, and proper management of research funds. Deliberate falsification or misrepresentation of research data will result in withdrawal of an application or suspension or termination of an award.

w. **Acknowledgement of VA support.** Any publication based on research supported by VA must contain an acknowledgement of VA support and identification of VA medical center where the research took place (M-3, pt. 1, ch. 8). Failure to do so will jeopardize an investigator's prospect of receiving future Medical Research Service support.