MEDICAL RESEARCH SERVICE
CAREER DEVELOPMENT PROGRAM HANDBOOK

1. **REASON FOR ISSUE:** This Veterans Health Administration (VHA) Handbook provides guidelines and application procedures for the Medical Research Service (MRS) Career Development program. The fundamental objectives of the Career Development program remain the same – to build capacity, in a wide geographic distribution, for the Department of Veterans Affairs (VA) to conduct research in areas of high relevance to the veterans healthcare system in fulfillment of its primary mission of patient care, supported by appropriate research and education.

2. SUMMARY OF MAJOR CHANGES: The major changes are as follows:

a. Eligibility requirements and application procedures for all program levels are specified by MRS. (See paragraph 3). This Handbook does not include guidelines for applications to other ORD services.

b. There is a new procedure for selected Research Career Development (RCD) awardees applying for Advanced Research Career Development (ARCD) awards. This procedure is described in the Handbook (see paragraph 3a (4)) and Appendix F, Short Form Application Guidelines.

c. There is increased funding for ARCD awardees who are successful in obtaining Merit Review funding in the third year of the award (see paragraph 3.b.(2)(b)).

d. Progress reports are due annually (twice during the award) for RCD awardees and at the midterm (one time) for ARCD awardees (see Appendix D).

e. There are changes made in due dates for Letters of Intent, application, and review calendar (see Appendix G).

f. There is a requirement for just in time receipt of compliance/assurance documentation (see Appendix B, paragraph 14).

3. RELATED DIRECTIVE: VHA Directive 1202 to be issued.

4. RESPONSIBLE OFFICE: The VHA Office of Research and Development, Medical Research Service (121) is responsible for the contents of this VHA Handbook.

5. RESCISSION: VHA Directive 1201.8.

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

Robert H. Roswell, M.D.
Under Secretary for Health

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MEDICAL RESEARCH SERVICE
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1. PURPOSE: The overall objective of the Career Development CADE program is to build and maintain capacity for Department of Veterans Affairs (VA) clinicians to conduct research in areas of high relevance to the health care of veterans. Within Medical Research Service (MRS), the objective is to promote the professional careers of outstanding clinician scientists committed to conducting biomedical research through a mentored research training program. Implicit in all CADE applications is the understanding that the applicants plan to continue their careers within VA. At the conclusion of the award, it is anticipated that the awardee will continue to work as a VA clinician research scientist and apply for independent funding through mechanisms such as VA Merit Review or other national programs.

2. DESCRIPTION AND GOALS: The (CADE) program supports clinician scientists for a period of concentrated research training with limited non-research responsibilities. Three levels of CADE awards are available through MRS: Research Career Development (RCD), Advanced Research Career Development (ARCD), and Career Development Enhancement Award (CDEA). These awards are open to applicants with clinical doctoral degrees including physicians, dentists, psychologists, social workers, clinical engineers, audiologists, speech pathologist, etc.

a. The RCD and ARCD awards each provide a three-year mentored research training opportunity for junior investigators. The goal for RCD awardees is to acquire sufficient research proficiency to continue in the career development program at the ARCD level, compete for the VA mentored Merit Review Entry Program, or obtain independent, non-mentored funding. Selected RCD awardees who have made satisfactory progress may use a Short Form ARCD application to apply to the next level. This allows a total of six years of support. The goal for ARCD awardees is to acquire sufficient research proficiency to obtain non-mentored, independent funding. Sponsoring VA medical centers are expected to help RCD and ARCD awardees obtain VA clinical staff appointments following the award.

b. The CDEA provides a six-month training opportunity for senior investigators to learn new techniques in a sponsor's laboratory. The goal for CDEA awardees is to acquire new research skills that can be actively incorporated into their research program at the local VA medical center.

3. DESCRIPTION OF THE AWARDS

a. **Research Career Development (RCD) Award**. The RCD award is a 3-year, non-renewable, mentored award that is designed for clinicians just entering a research career. The RCD provides VA clinician researchers support for the nearly full-time pursuit of medical research training together with research support of $20,000 for research. Applicants should propose to develop research skills in areas of importance to the mission of VA. The training program should be developed to promote the progress of the applicant towards independence. Selected RCD awardees who have made satisfactory progress may continue their program at the ARCD level for an additional three years (see Paragraph a. (4) below).

(1) The eligibility requirements for a RCD award are:

(a) Approval to apply for an award is obtained only through a Letter of Intent (LOI).

(b) Physician applicants must have completed clinical training and obtained board-eligibility to practice in a relevant specialty or sub-specialty area. Clinician Ph.D. applicants should meet board certification or licensure requirements for practicing in the relevant healthcare profession.

(c) Applicants should be less than 5 years beyond completion of clinical training (i.e., internship, residency, clinical fellowship, etc.) and should have no more than 2 years of research experience since completion of the doctoral degree. ***Note**: Applicants holding both M.D. and Ph.D. degrees should apply for the ARCD level.* Research fellowships are not considered clinical training, therefore, they count towards the post-training limitation.

(d) Applicants should not have substantial (more than $50,000 per year) independent research funding, but must show evidence of research competence, such as being first- or co-author on a research publication, or being first author on at least one abstract for a research presentation at a national meeting**.** Applicants who show evidence of significant research experience may be administratively advanced to the ARCD level for review.

(e) Applicants with an academic appointment above the Instructor level must submit a "Request for Exception" with the Letter of Intent (LOI).

(f) Applicants are not required to be VA employed clinicians at the time of application; however the award will not begin until an awardee is employed by the VA.

(g) Applicants enrolled in Masters, Ph.D. graduate programs or fellowships (research or clinical) may be eligible to apply if the program is completed prior to the start of the CADE award. Proof of completion must be submitted to MRS prior to funding.

(h) Concurrent funding of a VA CADE award plus another non-VA training award (e.g., NIH "K" series) is not allowed.

(2) RCD Appointments. RCD awardees may be appointed at the Senior Grade (up to GS-14/10 equivalent). Special pay for Title 38 physicians and dentists is authorized. In order to receive special pay, the awardee must devote 25 percent effort to non-clinical activities. The remaining 75 percent of an awardee's effort must be devoted to research. $20,000 per year in research support will also be provided.

(3) Requirements and Conditions

(a) The RCD award must be conducted in the same physical location at the VA (or in VA approved space) as the primary mentor or in close proximity to the primary mentor, except in unusual circumstances as documented in a "Request for Exception" letter submitted with the Letter of Intent (LOI).

(b) Annual reports are required (see Paragraph 4.k. and Appendix D for instructions).

(c) RCD awards are not renewable, but awardees may apply for ARCD awards to start upon completion of the RCD (see ARCD Award and Appendix F for instructions).

(d) Research support from other VA programs is not allowed for the duration of the RCD.

(4) RCD Awardees Applying for ARCD Level Awards. To promote the succession of RCD awardees to the ARCD level, selected RCD awardees who receive two "satisfactory" ratings on their annual programs may submit an ARCD Short Form application. (See Appendix F for instructions.) Awardees who are not selected for the Short Form may apply in the same manner as new ARCD applicants and must obtain an approved LOI prior to submitting an application.

b. **Advanced Research Career Development (ARCD) Award**. The ARCD award is a 3-year, non-renewable, mentored award designed for clinician scientists who have some research experience but need additional mentored training to become fully independent investigators. The ARCD provides VA clinician researchers support for the nearly full-time pursuit of medical research training together with $50,000 for research. The ARCD should enrich the overall research program of the sponsoring medical center, especially in areas of high relevance to VA.

(1) The eligibility requirements for an ARCD award are:

(a) Approval to apply for an award is obtained only through a LOI.

(b) Physician applicants must have completed all clinical training and be board eligible to practice in a relevant specialty or sub-specialty area. Clinician Ph.D. applicants should meet Board certification or licensure requirements for practicing in the relevant healthcare profession.

(c) Applicants should have at least 3 years of research experience since completion of the doctoral degree, but no more than 5 years of research experience.

(d) Applicants must show evidence of research competence, such as being first- or co-author on a research publication, or contributing author on multiple papers on a similar research topic.

(e) The ARCD award is not intended for an independent, established investigator; therefore, at the time of submission, the applicant may not be, or have been, principal investigator on a non-mentored national peer-reviewed award such as VA Merit Review, NIH R01, National American Heart Association, National Kidney Foundation, etc.

(f) Applicants must have their primary laboratories located in the VA facility or have plans in place to move to the VA facility before the award begins.

(g) Applicants may not have an academic position above the rank of Assistant Professor. In unusual circumstances, a "Request for Exception" letter submitted with the LOI will be considered.

(h) Applicants may apply for both VA Career Development and MREP funding in the same review cycle, but only one award may be accepted.

(i) Applicants are not required to be VA employed clinicians at the time of application; however, they must be employed by the VA prior to the start of funding.

(2) ARCD Appointments

(a) ARCD awardees may be appointed grades with salaries and special pay determined appropriate by their local Professional Standards Board but not to exceed Chief Grade (GS-15). In order to receive special pay, the awardee must devote 25 percent effort to non-research activities. The remaining 75 percent of an awardee's effort must be devoted to research.

(b) ARCD awardees will receive $50,000 annually in VA research support during the term of the award. This support may be requested in the Career Development application, or may come from a Merit Review funded subsequent to initiation of the ARCD award. Concurrently funded Merit Review proposals may provide up to $75,000 in recurring funds and up to $25,000 for start-up equipment upon request during the last year of the ARCD award. Non-VA funding is not subject to the $50,000 annual limit.

(3) Requirements and Conditions

(a) The ARCD award may be conducted in the same physical location at the VA (or in VA approved space) as the primary mentor or in close proximity to the primary mentor, except in unusual circumstances as documented in a "Request for Exception" letter in the LOI.

(b) A mid-term report is required (see Appendix D for instructions.)

(c) ARCD awards are not renewable, but awardees are encouraged to apply for VA Merit Review awards to begin as the award is completed. During the award period, ARCD awardees may compete for extramural peer-reviewed research funds.

c. **Career Development Enhancement Award (CDEA)**. The CDEA is designed to support established clinician scientists who wish to secure time to enter a new area of research specialization, especially in areas of importance to the VA mission. MRS provides six months support to awardees to enhance their research skills.

(1) The eligibility requirements for a CDEA are:

(a) An applicant must be a principal investigator on an ongoing non-mentored VA peer-reviewed funded research program at the time of application.

(b) An applicant must have a history of VA research funding, including a minimum of six years as a principal investigator.

(c) An applicant must identify a sponsor who will facilitate and train the applicant.

(d) There must be clear benefits resulting from the training award to both the applicant and the VA Medical Center.

(2) Award Requirements

(a) The CDEA provides support, including fringe benefits, for up to six months. This award must be matched with educational leave granted by the applicant's VA medical center. CDEA applicants are required to submit documentation from their local medical center indicating contingent approval of educational leave in time and amount**.**

(b) Awardees must devote 100 percent time to research and may not be involved in administrative roles during the award.

(c) CDEAs are not renewable beyond the award period. MRS will support one CDEA during an investigator's career.

(d) A report detailing the research accomplishments during the award period is due two months after completion of the award.

4. APPLICATION GUIDELINES FOR ALL CADE AWARDS

a. **Procedure**. Each potential applicant must submit a LOI. Only applicants with approved LOIs may submit applications. A CADE LOI can be sent to one service only within ORD. Applicants conducting clinical research may wish to consult the Clinical RCD program information (see VHA Notice 99-03). See Appendix G for calendar of deadlines.

b. **Mentors**. Mentors play a vital role in the CADE program by preparing RCD and ARCD awardees for independent research careers. Applicants for these awards select one to three qualified mentor(s) with expertise and interest in the applicant's research. The RCD application is prepared jointly with the mentor, while the ARCD application is prepared by the applicant in consultation with the mentor. At least one mentor must be a VA-based investigator with current national peer-reviewed funding from an appropriate discipline who is committed to training and developing the applicant as an independent research scientist. Up to two mentors (VA or non-VA) may supplement the expertise of the primary mentor. Participation of VA Research Career Scientists as mentors is strongly encouraged.

c. **Letter Of Intent**. An approved LOI is required before a CADE award proposal can be submitted (see **Appendix A** for instructions*.)* Approved LOIs remain valid for **three** consecutive application cycles. Applicants may not submit a second LOI for the same level award once the three cycles are completed.

(1) For consideration of any exception, a "Request for Exception" letter must be included with the LOI. Request for Exception letters will be reviewed before a LOI is approved. Among the circumstances requiring a Request for Exception:

(a) RCD applicant proposes to conduct research in a non-VA facility;

(b) RCD applicant proposes to conduct research at a site remote from the primary mentor;

(c) ARCD applicant holds an academic rank above Assistant Professor.

(2) Each LOI will be reviewed to determine if the area of research proposed is of high priority to VA, the background of the applicant is appropriate for the requested award level, and the background of the mentor(s) or sponsor is appropriate to train and develop the applicant.

d. **Application Submission**. All CADE applications must be evaluated by the local VA medical center R&D Committee and approved by the Dean's Committee or its equivalent and the medical center Director prior to submission.

e. **Resubmission.** An application that was not funded may be revised and resubmitted for a total of 3 submissions (original application plus two resubmissions). The revised application must contain a letter, not to exceed three pages, discussing the applicant's response to the reviewers' comments, a copy of the letter notifying the applicant of LOI approval, and copies of the previous summary statement and reviewers' comments. Applications that do not contain this information will be returned without review. All other application requirements remain the same for resubmissions. ***NOTE:*** *Career Development applications are not subject to a formal appeal process.*

f. **Review**. Applications will be reviewed by MRS based on the following criteria:

(1) Applicant's qualifications (i.e., training and research experience) and commitment to a clinical research career;

(2) Qualifications and suitability of the mentor(s) (RCD or ARCD) or sponsor (CDEA);

(3) Suitability of the training program to the development of the applicant;

(4) Scientific merit of the research proposed;

(5) Relevance of the research to MRS;

(6) Evidence that the local VA is committed to the applicant's VA research career.

g. **CADE Program Contract.** All CADE awardees will 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 intellectual property policy, and participate in progress reviews. Failure of an awardee to meet these conditions may result in termination of the award.

h. **RCD and ARCD Appointments**

(1) Appointments for RCD and ARCD awardees are on a full-time temporary basis as time-limited appointments unless the awardee already holds a career appointment, and are subject to applicable qualification requirements.

(2) Awardees in occupations covered by 38 U.S.C. will be appointed under 38 U.S.C. 7405 (a)(1). Title 38, physician and dentist awardees may not exceed Senior grade (GS-14) for RCD and Chief grade (GS-15) for ARCD. Physician and dentist RCD and ARCD awardees are authorized to receive all components of special pay for which they are eligible. Title 5

applicants may be appointed under Title 5 Code of Federal Regulations (CFR) 213.3227(a) (Schedule B). Grade determinations of Title 5 employees will be based on qualification standards in MP-5, Part I, Chapter 338; or the Office of Personnel Management (OPM) Handbook as applicable. Title 38 and Title 5 employees are required to meet the VA and Federal appointment hiring requirements as applicable. The employment application process should be coordinated with the local Human Resource Management (HRM) office to ensure applicants meet the VA appointment regulations. The ACOS for R&D, or responsible VHA facility management official, is responsible for ensuring current employees are converted to the applicable appointment authority cited in this subparagraph upon receiving a CADE Award.

i. **Award Transfers.** The Director, MRS, may, in exceptional circumstances, approve a transfer of a funded award to a VA medical center different from that originally proposed. Such approval will be given only if an appropriate mentor is identified at the new medical center, and if the transfer is in the best interest of the awardee's training program and the VA research program. No RCD transfers will be permitted before at least one year of work has been completed. The transfer request should include approvals from the R&D Committee, Dean's Committee or its equivalent, and Director of the new medical center endorsing the transfer. This request must ensure that sufficient VA space and support will be available for the successful completion of the transferee's award. All relevant biosafety, animal studies, and human studies approvals must be in place at the new facility before funds will be transferred. A letter from the proposed new mentor/s must be included as well as a current curriculum vitae (c.v.). Research funds will not be provided to cover any moving or relocation expenses. If approved, the awardee may complete the remaining portion of the award at the new VA medical center.

j. **Change in Mentor.** If the primary mentor relocates to a different facility, or is unavailable to train the awardee, the ACOS/R&D must immediately request approval of a new mentor by Medical Research Service. The primary mentor may not be replaced without the approval of MRS.

k. **Progress Reports.** RCD and ARCD awardees will be reviewed to ensure that satisfactory progress is being made towards becoming independently funded VA scientists. This is in addition to Annual Proficiency Reviews and Performance Reviews for Title 38 and Title 5 employees, respectively. RCD awardees will be evaluated annually (two times during the three year award); ARCD awardees will be evaluated at the mid-term of the award (one time during the three year award). A report of the accomplishments by CDEA awardees will be evaluated two months following the completion of the award. (See Appendix G for deadlines.) The progress reports will be evaluated to make two ratings: (1) satisfactory or unsatisfactory rating of progress, and (2) selection for RCD awardees to submit a Short Form application to the ARCD level.

(1) If rated unsatisfactory, the awardee will be placed on 6 months probation in order to return performance to a satisfactory level. If review at 6 months determines that progress is still unsatisfactory, the award will be terminated within 60 days. The decision for termination will be final and is not subject to appeal.

(2) If rated satisfactory without contingencies on the two consecutive RCD annual reports, applicants will be approved to submit a Short Form application for an ARCD award. (See Appendix F for instructions.) The intent is to simplify the application process for successful

RCD awardees applying to the next level of Career Development. RCD awardees not selected for the Short Form application may apply for an ARCD award following approval of a LOI and by submitting a full application. (See Appendix B for instructions.)

l. **Contact Information.** The principal investigator may contact a Medical Research Service (MRS) Program Specialist with questions related to the Career Development program, including eligibility, application preparation, LOI, Annual Progress report, post award information, etc. at:

Program Specialist (121E)
Medical Research Service
1400 Eye Street, NW
Suite 400
Washington, DC 20005
(202) 408-3600

Questions specific to the submission and review of proposals should be directed to:

Program Review Division (121F)
Medical Research Service
1400 Eye Street, NW
Suite 700
Washington, DC 20005
(202) 408-3630

LETTERS OF INTENT FOR CAREER DEVELOPMENT AWARDS

1. Use only letter-quality print in preparing a LOI. 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 each.

2. The LOI should contain the following materials in the specified order:

a. Department of Veterans Affairs (VA) Form 10-1313-13, VHA Research and Development Letter of Intent Cover Page. In block 1, check Medical Research Service. In block 3, check Career Development and the level of the award (RCD, ARCD, CDEA).

b. Name(s) and signature(s) of mentor(s) for RCD and ARCD; or sponsor for CDEA.

c. Abstract of work proposed (1 page limit) according to the following format:

(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 Medical Research priority areas, the mission of the Department of Veterans Affairs health care system, and the general research effort of the local VA medical center.

(2) Research Objectives. Outline precisely and clearly the goals of the planned project, including the hypothesis to be tested and the specific objectives of the project.

(3) Project Design and Methods. Briefly define and describe the approach to the research. If applicable, include a description of the subject population to be used in the proposed research.

d. Applicant's and mentor/s' qualifications (2 page limit). Describe the research experience of the applicant. Include a list of any current, pending, previous training awards, or other nationally peer-reviewed funded proposals held by the applicant (if none, so state). Describe the applicant's career objectives. Provide a description of the mentor/s' qualifications relevant to the proposed work and experience in training junior investigators.

e. The applicant and mentor's (RCD and ARCD) or sponsor's (CDEA) curriculum vitae. Curriculum vitaes should be up-to-date when submitted and reference any existing VA appointments.

f. 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 VA medical center. If the applicant is currently employed by the VAMC, this should be stated.

g. Any letter(s) requesting exception, e.g., ARCD applicant with a rank above Assistant Professor, RCD applicant's research space not located at VA medical center, or eligibility.

3. 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 R&D Office at the originating VA medical center.

4. **Submission**. LOIs are accepted continuously for review. LOIs received by the last working day of any month will be reviewed during the following month. LOIs should be submitted as early as possible. Submit the original and 3 copies of each LOI to: See Appendix G for deadlines.

If mailed to Medical Research Service:

Department of Veterans Affairs
Medical Research Service
Career Development Program (121E)
810 Vermont Avenue, NW
Washington, DC 20420
(202) 408-3600

If shipped to Medical Research Service by door-to-door courier:

Department of Veterans Affairs
Medical Research Service
Career Development Program (121E)
1400 Eye Street, NW, Suite 400
Washington, DC 20005
(202) 408-3600

CAREER DEVELOPMENT APPLICATIONS
RCD and ARCD AWARDS INSTRUCTIONS

1. GENERAL INSTRUCTIONS

a. A Career Development application can only be submitted after approval of a Letter of Intent (LOI). Use a clear, black font when completing forms. Font size for all text shall be at least 11 point and printed on 8.5x11 white paper, with each page numbered consecutively in the lower right corner, starting with the face sheet, VA Form 10-0102, and should include the principal investigator's name and page number (e.g., Smith-1 to Smith-22).

b. Prior to submission to VACO, all proposals require approval by the local VAMC R&D Committee and appropriate subcommittees. In addition, the ACOS/R&D obtains letters and concurrences from several offices at the local VAMC. Applicants are encouraged to work with ACOS/R&D in proposal submissions to avoid delays and misunderstandings.
No additional or replacement information will be accepted after submission of the proposal unless requested by the Program Review Division.

c. Proposal submission deadlines are October 1 for Spring review and April 1 for fall review.

2. VA FORM 10-0102, CAREER DEVELOPMENT APPLICATION

a. Complete Items 3 through 9 as indicated on the Form (Items 1 and 2 are left blank). ***Note****: Block 4, social security number should only appear on the original. The social security number should be blank on all copies submitted*. To the right of the text in Item 10 (Program Level) enter "MRS" to indicate the application is being submitted to Medical Research Service. In addition, list the award level (i.e., RCD, ARCD) that is being sought. Item 11 (Proposed Starting Date) should be left blank. Complete items 12 through 16 as indicated on the Form. Original signatures are required from the applicant and the Associate Chief of Staff (ACOS) for R&D.

b. The back of VA Form 10-0102 is to be used for a lay language summary (1 page limit) of the application. The principal investigator's name and project title should be exactly as written on Page 1. Three or more key words should be used which describe the disease, system, and/or mechanism being studied and major methods/techniques used. Because the key words are used for searches and portfolio issues, only Medical Subject Headings (MeSH) terms may be used. (The ACOS/R&D should have MeSH terms book, which is also available at the medical center library.) The summary description (abstract) of the proposal provides information about the applicant's research background and current research interests, hypotheses to be tested, specific objectives, relevance, subject population, procedures to be used and significance of potential new findings. It should include enough information so that the proposal can be referred to appropriate reviewers.

3. Table of Contents. A Table of Contents must follow VA Form 10-0102. Table 1 on page B-8 page shows the format for the Table of Contents. Indicate N/A for not included (or non-applicable) items.

4. Applicant and Mentor Biographic Sketch, Bibliography, and Research Support. A complete set of the following three VA Forms are required for the applicant and each mentor:

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

b. **Investigator's Bibliography (Form 10-1313-6)**. In chronological order (2 page limit), list complete citations of the investigator's most relevant publications and accepted manuscripts in peer-reviewed journals. Do not included abstracts, or manuscripts that are submitted or in preparation. If you need a second page, use another copy of Form 10-1313-6.

c. **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) Health Services Research and Development, (EPIM)Epidemiological Research Program MERIT, (CLIM)Clinical Research Program MERIT, (RR&D) Rehabilitation Research and Development, and (REAP) Research Enhancement Award Programs/Centers. Include all currently funded and pending support. Do not include the financial resources requested in this application.

(1) 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.

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

(a) *Role*: State the applicant's role in the project (principal investigator, co-investigator, principal investigator of sub-project, etc.)

(b) *Dates of Approved/Pending Project*: Indicate the inclusive dates of the project as funded or proposed.

(c) *Annual Direct Costs*: For active awards, provide the current year's direct cost budget and for pending applications provide the initial budget period.

(d) *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.

(e) *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.

(3) 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. 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. Statements such as "there are no budgetary, scientific or administrative overlaps" without any discussion of the science are not acceptable.

1. 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.

2. 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.

5. RESPONSE TO PRIOR SUBMISSION (3 PAGE LIMIT)

For resubmissions only, a letter should address the changes the principal investigator has made in the new application in response to the comments of reviewers from the previous review.

6. Narrative Instructions for RCD and ARCD Application (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 you propose 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. The Narrative must be comprehensive without reference to any other document. 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, MRS recommends the following outline and page restrictions.

a. **Rationale**. (1-2 pages recommended):

(1) Statement of the Problem. Briefly state the problem to be investigated.

(2) Hypotheses or Key Questions. State the hypotheses or key questions to be answered by the proposed research.

(3) 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.

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

(1) 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.

(2) Significance. Explain the potential importance of the proposed work and identify any unique ideas or potential contributions that might result from this study.

(3) Relevance to Veterans Health. Describe the relevance of the proposed work to the VA patient care mission specifically and health issues in general.

c. **Work Accomplished**. (6-8 pages recommended). 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.

d. **Work Proposed**

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

(2) 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.

(3) 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 methodologies.

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

(5) 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).

7. 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.

8. 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.

a. 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.

b. 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.

c. Provide information on the veterinary care of the animals involved.

d. 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.

e. 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

9. RESOURCES (1 PAGE LIMIT)

Describe the facilities where the work will be conducted, including office and research space, by specifying the exact location with room numbers. Specify whether the space is in a VA or non-VA facility. Describe pertinent resources and major pieces of equipment available to the applicant, avoiding facility inventories. If applicable, describe clinical and animal facilities available. Do not describe resources that are available but not used for the proposed research. Prior approval must be included if the research space is not in a VA facility. This approval must be obtained through a Request for Exception submitted with the LOI.

10. APPLICANT'S RESEARCH CAREER PLAN (2 PAGE LIMIT)

a. Describe any previous research experience as well as any past funding.

b. Describe current research interests and involvement, including research funding.

c. Describe the relationship between the research interests of the applicant and mentor/s.

d. State the potential impact of the research on the improvement and/or evaluation of veteran health care and/or health policy.

e. Discuss how the award will affect the applicant's commitment and/or professional advancement within VA.

f. State the applicant's future research plans and ambitions (explain how the proposed award enhances these plans).

g. State the time commitment to research. Indicate percent of time to be devoted to research, and describe other concurrent commitments to the local VA medical center.

11. LITERATURE CITATIONS FOR NARRATIVE (4 PAGE LIMIT)

Table 2: Table of Contents for RCD and ARCD Applications

Form 10-1313-1	Front page	1
Form 10-1313-2	Abstract	2
Table of Contents		3
Biographic Information		
	Starting with applicant (Forms 10-1313-5, 6, 8; front, budget and abstract pages from active research projects). Follow with complete sets from each mentor.	4
Text of Proposal		
	Response (resubmitted applications only, 3 page limit)	__
	List of acronyms/abbreviations	__
	Narrative: Parts 1-4 (25 page limit)	__
	1. Rationale	__
	2. Background and Significance	__
	3. Work Accomplished	__
	4. Work Proposed	__
	5. Human Studies Section	__
	6. Animal Studies Section	__
	Resources (1 page limit)	__
	Applicant's Research Career Plan (2 page limit)	__
	Literature citations (4 page limit)	__
Mentor's letter of commitment		__
Compliance and Administrative Issues		
	Human subjects	
	Endorsements:	
	R&D Committee approval memorandum	__
	VAMC director's memorandum	__
	Reference letters (3)	
	Approvals, Exceptions, Waivers or Permissions letters:	
	LOI approval	__
	Off-site waiver (if applicable)	__
Previous review (resubmission only)		
	Reviews	__
	10-1313A-front page (Summary statement)	__
	10-1313A-continuation (summary statement text)	__

12. Mentor's Letter of Commitment. Each mentor should submit a letter describing the mentoring plan, including:

a. The mentor's proposed role in training

b. Planned training activities (coursework, seminars, scientific meetings, etc.)

c. Nature of the interactions between mentor and applicant

d. Percentage of the mentor's effort that will be devoted to the applicant

e. The degree and type of interaction that the applicant will have with other researchers in the mentor's program or elsewhere at the medical center

f. Explicit description of the mentor's current obligations including the number of residents, fellows and other trainees that the mentor is currently supervising in research as well as past trainees, with inclusive dates in table form

g. Description of the mentor's time distribution between research, patient care, teaching, and administration

h. Plan for the applicant to achieve independence

13. Compliance and Administrative Issues.

(a) *On Time Submission of Compliance/Assurance Documents.* Each local facility conducts compliance assurance reviews according local policies. Whether the review(s) is done prior to submission of the application or at a later date, MRS requires just in time submission of compliance/approval documentation for human studies, animal studies and biosafety. Do not submit any human subjects, animal subjects or biosafety forms and/or approvals with an application.

(b) 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. If the appropriate compliance/assurance subcommittees have not approved the application, 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 conducted."

14. ENDORSEMENTS

a. The appropriate Service Chief or Section Head must submit a statement describing the applicant's proposed clinical duties upon receiving the Career Development award. An indication of the applicant's expected percent time in non-research activities should be included (not to exceed ten hours per week).

b. The ACOS/R&D is required to submit a letter of support and acknowledge a commitment to review the applicant's progress and development as a VA research scientist at least annually.

c. MRS will accept a single letter from the medical center Director stating that the Dean's Committee (or equivalent) and the Research and Development Committee have approved the submission of the application. Alternatively, applications may contain three individual nominating letters. The Director's letter is expected to include any information pertinent to administrative matters, such as the commitment to offer a staff position to the applicant at the completion of the award or the date of citizenship eligibility for a non-citizen.

d. Three reference letters should be obtained from professional colleagues, former/current teachers, former mentor, etc. Reference letters should not be limited to the applicant's institution or affiliated university. The applicant is encouraged to include letters of support from other institutions willing to provide support and resources to the development of the applicant's research career.

e. Approvals, Exceptions, Waivers or Permissions letters:

(1) LOI approval

(2) Off-site waiver (if applicable)

f. Prior Review (resubmissions only), including:

(1) 10-1313A, Summary Statement including front page and text

(2) Reviews

15. SUBMISSION INSTRUCTIONS

a. Applications must be complete and comprehensive upon arrival in VHA Headquarters. Applications will be returned if they are illegible, fail to follow instructions, or if the material presented is insufficient to permit an adequate review. The responsibility for a complete and timely submission lies with the R&D Office at the originating VA medical center. Submit a typed single-spaced original, copied front side only, and 20 unbound copies, of the proposal duplicated back-to-back on 8.5 x 11 inch paper, leaving a 1 inch margin at each edge of each sheet. Except for the original, which is duplicated face only, all forms and narrative material are duplicated back-to-back. Except for the special VA Forms provided, use blank white paper, 8.5 x 11 inches. Do not submit applications prepared from a dot matrix printer, and do not use photo reduction; any applications using such low quality or small print (smaller than point size 10) will be returned.

b. **Reprints**. CDEA applicants submit 6 copies of reprints of their three most recent publications.

c. **VA Form 10-0102.** Twenty extra copies of VA Form 10-0102 (front and back). Please ensure the Principle Investigator's social security number does not appear on these copies.

d. **Due Dates**. Applications will be reviewed semi-annually. See Appendix G for calendar of deadlines.

e. **Mailing Addresses.** Applications should be mailed to MRS at:

Department of Veterans Affairs
Medical Research Career Development Program (121F)
VHA Headquarters
810 Vermont Avenue, NW
Washington, DC 20420
(202) 408-3630

or shipped to MRS by door-to-door courier:

Department of Veterans Affairs
Medical Research Service
Office of Program Review (121F)
1400 Eye Street, NW, Suite 700
Washington, DC 20005
(202) 408-3630

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

The following discussion is limited to the receipt of compliance and assurance documentation. Whether subcommittee(s) 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, depends upon local facility decisions. ***NOTE****: There maybe a delay in starting funded awards if all subcommittee approvals are not completed before MRS review. See Appendix G for deadline calendar.*

If a proposal is funded, the office of the ACOS/R&D must submit to MRS all required forms and approvals of appropriate Research and Development subcommittees or their equivalents. **MRS will not accept these documents prior to this notification**. Secondary review, by MRS, of human, animal, or biosafety protocols may be conducted and may delay funding the proposal. **No proposal will be funded until these forms/approvals are received and accepted by MRS.**

If the proposal had been submitted prior to review by R&D subcommittees, the R&D Committee must re-review the proposal and all supporting compliance/assurance documentation and approvals. A letter from the R&D Committee Chairman shall accompany these documents and state that the R&D Committee has given full approval to the proposal.

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, MRS 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 10-0102, box 8). 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 affiliated 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.

c. **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.

d. **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.

e. **Biohazards**. Whether or not the Form 10-0102 Biohazards box is checked, the biohazards Form must be submitted. The form must have the proper signatures and be dated.

f. **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.

g. **Submission of Documents**. Send the original and seven (7) exact copies of all compliance/assurance documentation via regular mail or courier.

(1) If mailed through the U.S. Postal Service, send to:

Medical Research Service
Program Review Division (121F)
810 Vermont Avenue, NW
Washington, DC 20420

(2) If courier or commercial overnight delivery service is used, send to:

Medical Research Service
Program Review Division (121F)
1400 Eye Street, NW
Suite 700
Washington, DC 20005
(202) 408-3630

Career Development Enhancement Award (CDEA) Application Instructions

1. GENERAL INSTRUCTIONS

a. A Career Development application can only be submitted after approval of a Letter of Intent (LOI). Use a clear, black font when completing forms. Font size for all text shall be at least 11 point and printed on 8.5x11 white paper, with each page numbered consecutively in the lower right corner, starting with the face sheet, VA Form 10-0102, and should include the principal investigator's name and page number (e.g., Smith-1 to Smith-22).

b. Prior to submission to VACO, all proposals require approval by the local VAMC R&D Committee and appropriate subcommittees. In addition, the ACOS/R&D obtains letters and concurrences from several offices at the local VAMC. Applicants are encouraged to work with ACOS/R&D in proposal submissions to avoid delays and misunderstandings. No additional or replacement information will be accepted after submission of the proposal unless requested by the Program Review Division.

c. Proposal submission deadlines are October 1 for Spring review and April 1 for fall review.

2. VA FORM 10-0102, CAREER DEVELOPMENT APPLICATION

a. Complete Items 3 through 9 as indicated on Form 10-0102 (Items 1 and 2 are left blank). NOTE: Block 4, social security number should appear only on the original. The social security number should be left blank on all copies. To the right of the text in Item 10 (Program Level) enter "MRS" to indicate the application is being submitted to Medical Research. In addition, list CDEA as award level. Item 11 (Proposed Starting Date) should be left blank. Complete items 12 through 16 as indicated on the Form. Original signatures are required from the applicant and the Associate Chief of Staff (ACOS) for R&D.

b. The back of VA Form 10-0102 is to be used for a one-page lay language summary of the application. The principal investigator's name and project title should be exactly as written on Page 1. Three or more key words should be used which describe the disease, system, and/or mechanism being studied and major methods/techniques used. Because the key words are used for searches and portfolio 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.) The summary description (abstract) of the proposal provides the sponsor's qualifications, site for the proposed training, information about the applicant's research background and current research interests, specific objectives of the training, relevance of the training to applicant's research goals. A statement regarding the benefits of the training to the applicant and VAMC should be included. Enough information should be provided so that the proposal can be referred to appropriate reviewers.

3. Table of Contents. A Table of Contents must follow VA Form 10-0102.

4. Applicant and Sponsor Biographic Sketch, Bibliography, and Research Support. A complete set of the following three VA Forms are required for the applicant and each sponsor.

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

b. **Investigator's Bibliography (Form 10-1313-6)**. (2 page limit) In chronological order, list complete citations of the investigator's most relevant publications and accepted manuscripts in peer-reviewed journals. Do not included abstracts, or manuscripts that are submitted or in preparation. If you need a second page, use another copy of Form 10-1313-6.

c. **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, RR&D and REAPs/Centers. Include all currently funded and pending support. Do not include the financial resources requested in this application. The front page abstract of the research plan, and budget pages for all applications discussed should be placed after the applicant's and mentor's 10-1313-8 forms.

(1) 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.

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

(a) *Role*: State the investigator's role in the project (principal investigator, co-investigator, principal investigator of sub-project, etc.)

(b) *Dates of Approved/Pending Project*: Indicate the inclusive dates of the project as funded or proposed.

(c) *Annual Direct Costs*: For active awards, provide the current year's direct cost budget and for pending applications provide the initial budget period.

(d) *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.

(e) *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.

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

(a) *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. 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. Statements such as "there are no budgetary, scientific or administrative overlaps" without any discussion of the science are not acceptable.

(b) 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.

(c) 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.

5. Narrative (five page limit). The narrative should include the following items, including headings as noted:

a. **Research experience**. Include a brief history of the applicant's research background, including training, experience, and previous funding.

b. **VA service**. Describe service to local VA medical center and national VA research program.

c. **Research Training Plan**. Provide a detailed plan of the research to be conducted. Include a description of the objectives of the training and specific new skills to be attained. Describe the training activities during the award, including formal and informal activities.

d. **Sponsorship**. Describe the relationship between the research interests and skills of the applicant and the sponsor's research interests and skills.

e. **Benefits**. State the expected results of the experience in terms of the benefit to VA, improvement in patient care, increase in productivity, and other beneficial factors as well as the benefits to the applicant in terms of their research program.

6. RESOURCES (1 PAGE LIMIT)

Describe the facilities where the work will be conducted. Specify whether the space is in a VA or non-VA facility. Describe pertinent resources and major pieces of equipment available to the applicant, avoiding facility inventories. If applicable, describe clinical and animal facilities available. Do not describe resources that are available but not used for the proposed research.

7. Letter of Commitment from Sponsor. The sponsor should submit a letter clearly stating their role in the proposed training, including: planned training activities, nature of the interaction between applicant and sponsor, percentage of sponsor's effort that will be devoted to applicant, descriptions of the sponsor's current obligations as well as training history.

8. LOI Approval Letter. A copy of the LOI approval letter from MRS must be included.

9. Nominating Letters. MRS will accept a single letter from the medical center Director stating that the Dean's Committee and the R&D Committee has approved the submission of the application. Alternatively, applications may contain three separate nomination letters.

10. Approved Extended Educational Leave Request. Use VA Form 10-5503, Extended Educational Leave Request Briefing Slip, and VA Form 10-5503a, Extended Educational Leave Checklist.

11. CURRICULUM VITAE OF APPLICANT

12. CURRICULUM VITAE OF SPONSOR

13. SUBMISSION INSTRUCTIONS

a. **Pagination and Number of Copies.** Number each page consecutively, starting with the face sheet, VA Form 10-0102 (e.g., Smith-1 to Smith-22). Do not place any attachments in front of VA Form 10-0102. Applications must be complete and comprehensive upon arrival in VHA Headquarters. Applications will be returned if they are illegible, fail to follow instructions, or if the material presented is insufficient to permit an adequate review. The responsibility for a complete and timely submission lies with the R&D Office at the originating VA medical center. Submit a typed single-spaced original, copied front side only, and 20 unbound copies, of the proposal duplicated back-to-back on 8.5 x 11 inch paper, leaving a 1 inch margin at each edge of each sheet. Except for the original, which is duplicated face only, all forms and narrative material are duplicated back-to-back. Except for the special VA Forms provided, use blank white paper, 8.5 x 11 inches. Do not submit applications prepared from a dot matrix printer, and do not use photo reduction; any applications using such low quality or small print (smaller than point size 10) will be returned.

b. **Reprints**. CDEA applicants submit 6 copies of reprints of their three most recent publications.

c. **VA Form 10-0102.** Twenty extra copies of VA Form 10-0102 (front and back). Box 4, the social security number should be blank.

d. **Due Dates**. Applications will be reviewed semi-annually. Appendix G specifies calendar of deadlines.

e. **Mailing Addresses.** Applications should be mailed to MRS at:

Department of Veterans Affairs
Medical Research Career Development Program (121F)
VHA Headquarters
810 Vermont Avenue, NW
Washington, DC 20420
(202) 408-3630

or shipped to MRS by door-to-door courier:

Department of Veterans Affairs
Medical Research Service
Office of Program Review (121F)
1400 Eye Street, NW, Suite 700
Washington, DC 20005
(202) 408-3630

CAREER DEVELOPMENT PROGRESS REPORT GUIDELINES

1. GENERAL INSTRUCTIONS

The review of all Research Career Development (RCD) and Advanced Research Career Development (ARCD) awardees will be performed by the Associate Chief of Staff for Research and Development (ACOS for R&D) or by a scientist(s) appointed by the Research Office at the host facility. 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. Each performance review should consist of a cover page plus documentation as described below:

a. A cover page listing the following information in the order specified:

(1) Career Development Performance Review.

(2) Department of Veterans Affairs (VA) medical center name and address

(3) Name of awardee; Social Security Number

(4) Level of award (RCD, ARCD), reporting period, and inclusive award dates.

(5) Name, degree, and affiliation of mentor(s).

(6) Percentage of awardee's time devoted to research.

(7) Brief description of non-research activities.

(8) Location of primary work site and/or laboratory (including Building and Room number).

(9) If this is last year of award: please describe awardee's plans to continue as a clinician researcher in the VA. If the awardee does not plan to continue a research career, include a statement describing their career plans.

(10) Name, title, and signature of the awardee; name, title, and signature of the ACOS/R&D.

b. Documentation of the awardee's progress should include the following information:

(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) List the awardee's participation in national or international scientific meetings using the following spreadsheet format:

Date	Meeting	Location	Role	Title of Abstract/Presentation

(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 which could impact on the trainee. Include recommendations for enhancing or improving the mentor-trainee relationship.

(4) Research Progress. Provide a status report of progress made on the proposed research (limit to two pages). Describe any changes from the original research plan, and state the progress the applicant has made toward becoming an independent investigator.

(5) Bibliography. Include a chronological list of publications, submitted manuscripts, and abstracts during the performance period. Highlight awardee's name and indicate percent contribution towards the work. Indicate if the work was related to the CADE award. Attach a copy of each publication, manuscript, and abstract submitted since inception of the award if this is the first progress report, or since the last progress report.

(6) An evaluation of the awardee's performance by the ACOS/R&D or designated reviewer to include a summary of the reviewer's observations about the performance of the awardee and recommendations to enhance the program. Include the name, title, and signature of the reviewer.

(7) Awardee's Response to the Evaluation. The response should include a plan for correcting any deficiencies identified by the reviewer(s). The awardee and mentor(s) must sign the response.

c. **Attachments**

(1) Letter from Mentor(s). Attach a letter from each of the awardee's mentors containing the following information:

(a) Any changes from the application in the distribution of the mentors' time in research, patient care, teaching, and administration. If there are no changes, the letter should so state;

(b) Any changes from the application in the mentor's current obligations, including the number of residents, fellows and other trainees who the mentor is currently supervising as well as projected trainees (if there are no changes, the letter should so state); and

(c) A description of the mentor's interactions with the awardee during the performance period, including 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.

(d) An assessment of the progress the awardee has made in accomplishing the research objectives of the award.

(2) Research Support. Attach VA Form 10-1313-8, Investigator's Total VA and Non-VA Research/Development, to describe all approved and/or anticipated funding during the award period. Include abstract and budget pages for all non-VA support. If there is no other funding, indicate "none". ***NOTE:*** *Research support funds will not be distributed without this documentation.*

2. Submission. Submit the original and 2 copies of the annual performance review package. Only one copy of reprints, manuscripts, and abstracts need be submitted.

3. Due Dates. Reports must be received by Medical Research Service according to the following schedule. Appendix G specifies calendar of deadlines.

4. Mailing Addresses. Reports should be mailed to MRS at:

Department of Veterans Affairs
Medical Research Service
Career Development Program (121E)
810 Vermont Avenue, NW
Washington, DC 20420
(202) 408-3600

or shipped to:

Department of Veterans Affairs
Medical Research Service
Career Development Program (121E)
1400 Eye Street, NW, Suite 400
Washington, DC 20005
(202) 408-3600

CDEA PERFORMANCE REPORT

1. **CDEA Report**. Following completion of a Career Development Enhancement Award (CDEA), each awardee is to report the accomplishments realized during the educational leave.

2. **Content**. Each report should consist of the following materials in the specified order:

a. A cover sheet listing the following information:

(1) Career Development Enhancement Award Report, inclusive dates.

(2) Department of Veterans Affairs (VA) medical center name and address.

(3) Name of awardee and social security number (on original only). Do not provide social security number on copies submitted

(4) Name of sponsor and institution at which the awardee trained.

(5) Name, title, and signature of the awardee; name, title, and signature of the ACOS for R&D.

b. Description of accomplishments during the award period.

c. Benefits of the award to the research career of the awardee.

d. Manuscripts, publications and/or presentations resulting from the award. Enclose a copy of each manuscript, publication, and abstract.

3. **Submission**. Submit the original and 2 copies of the report. Only one copy of reprints, manuscripts, and abstracts need be submitted.

4. **Due Date**. Reports are due at Medical Research Service two months after the completion of the award.

Department of Veterans Affairs
Medical Research Service
Career Development Program (121E)
810 Vermont Avenue, NW
Washington, DC 20420
(202) 408-3600

or shipped to:

Department of Veterans Affairs
Medical Research Service
Career Development Program (121E)
1400 Eye Street, NW, Suite 400
Washington, DC 20005
(202) 408-3600

SHORT FORM APPLICATION GUIDELINES FOR RCD AWARDEES APPLYING FOR AN ARCD AWARD

1. GENERAL INSTRUCTIONS

Medical Research Service (MRS) provides a continuous training opportunity for Career Development awardees as they transition from the RCD award to the ARCD award level. This transition will be for RCD awardees who show evidence of clear research productivity during the first two years of their RCD. RCD awardees who have received two satisfactory progress reports (Year 1 and Year 2 of their award) may submit a Short Form application for the ARCD level; no approved LOI is required unless there is a major change in the direction of research. The permission to submit a Short Form application will be given by MRS with the second progress report evaluation. RCD awardees who have not been given permission to submit a short form application must follow the guidelines for new ARCD applicants, including LOI approval.

The following describes the ARCD application process for the RCD awardees approved for a short form application. The following documentation must be submitted in the order specified.

a. **VA Form 10-0102, Career Development Application**

(1) Complete Items 3 through 9 as indicated on Form 10-0102 (Items 1 and 2 are left blank). NOTE: Box 4, social security number should be complete on original only. Submitted copies should leave box 4 blank. To the right of the text in Item 10 (Program Level) enter "MRS" to indicate the Research Service to which the application is being submitted. In addition, list ARCD as award level, with the words: SHORT FORM. Item 11 (Proposed Starting Date) should be left blank. Complete items 12 through 16 as indicated on the form. Original signatures are required from the applicant and the Associate Chief of Staff (ACOS) for R&D.

(2) The back of VA Form 10-0102 is to be used for a one-page lay language summary of the application. The principal investigator's name and project title should be exactly as written on Page 1. Three or more key words should be used which describe the disease, system, and/or mechanism being studied and major methods/techniques used. Because the key words are used for searches and portfolio issues, only Medical Subject headings (MeSH) terms may be used. (The ACOS/R&D should have MeSH terms book, which is also available at the medical center library.) The summary description (abstract) of the proposal provides the applicant's research background and current research interests, hypotheses to be tested, specific research objectives, relevance, subject population, procedures to be used and significance of potential new findings. Enough information should be provided so that the proposal can be referred to appropriate reviewers.

b. **Narrative (5 page limit)**

Describe the research to be undertaken during the proposed ARCD award period. Include a statement of the problem, hypotheses or key questions, and specific objectives. Describe work completed by the applicant that is pertinent to this application. Describe the experimental design and approach. State whether and how the direction of the research project will be different from the RCD work, and whether and how the mentoring will be different.

c. **Resources (Limit to 1 page)**

Describe the facilities where the work will be conducted, including office and research space, by specifying the exact location with room numbers. Specify whether the space is in a VA or non-VA facility. Describe pertinent resources and major pieces of equipment available to the applicant. If applicable, describe clinical and animal facilities available. Do not describe resources that are available but not be used for the proposed research.

Prior approval must be included if the research space is not in a VA facility. This approval must be obtained through a Letter of Exception submitted with the second progress report.

d. **Applicant's Research Career Plan (2 page limit)**

(1) Describe current research interests and involvement, including research funding.

(2) Describe the relationship between the research interests of the applicant and mentor/s.

(3) State the potential impact of the research on the improvement and/or evaluation of veteran health care and/or health policy.

(4) Discuss how the award will affect the applicant's commitment and/or professional advancement within the VA.

(5) State the future research plans and ambitions and explain how the ARCD award fits into these plans.

(6) State the time commitment to research. Indicate percent of time to be devoted to research and describe other concurrent commitments to the local VA medical center.

e. **Mentor/s Letter of Commitment**

Each mentor should submit a letter describing the mentoring plan, including:

(1) Statement regarding the applicant's progress during the RCD award (prior three years).

(2) The mentor's proposed role in training during the ARCD award.

(3) Planned training activities (coursework, seminars, scientific meetings, etc.).

(4) Nature of the interactions between mentor and applicant.

(5) Percentage of the mentor's effort that will be devoted to the applicant.

(6) The degree and type of interaction that the applicant will have with other researchers in the mentor's program or elsewhere at the medical center.

(7) Explicit description of the mentor's current obligations including the number of residents, fellows and other trainees that the mentor is currently supervising in research as well as past trainees, with inclusive dates

(8) Description of the mentor's time distribution between research, patient care, teaching, and administration

(9) Plan for the applicant to achieve independence

f. **Compliance and Administrative Documents**

As the protocols are fully developed for the ARCD award, the awardee must obtain Research and Development Committee approval plus any other subcommittee approval necessary for the conduct of research.

2. ENDORSEMENTS AND ATTACHMENTS

(a) The appropriate Service Chief or Section Head must submit a statement describing the proposed clinical duties of the applicant upon receiving the Career Development award. An indication of the applicant's expected percent time in non-research activities should be included (not to exceed ten hours per week).

(b) The ACOS/R&D is required to submit a letter of support and acknowledge a commitment to review the applicant's progress and development as a VA research scientist at least annually.

(c) MRS will accept a single letter from the medical center Director stating that the Dean's Committee (or equivalent) and the Research and Development Committee have approved the submission of the application. Alternatively, applications may contain all three nominating letters. The Director's letter is expected to include any information pertinent to administrative matters, such as the commitment to offer a staff position to the applicant at the completion of the award.

(d) Copies of the two performance reports submitted during the first two years of RCD award, together with the evaluations from MRS.

(e) Copy of the approval from MRS to submit a short form ARCD application.

3. Submission. Deadlines for Short Form ARCD applications are detailed in Appendix G. Submit the original plus 20 copies. Include 20 copies of Form 10-0102. Send all application material to:

Department of Veterans Affairs
Medical Research Service
Career Development Program (121F)
810 Vermont Avenue, NW
Washington, DC 20420
(202) 408-3600

or shipped to:

Department of Veterans Affairs
Medical Research Service
Career Development Program (121F)
1400 Eye Street, NW, Suite 400
Washington, DC 20005
(202) 408-3600

Career Development Program Deadlines

1. Letters of Intent (LOI). LOIs may be submitted at any time for review. LOIs received by the last working day of any month will be reviewed during the following month. LOIs should be submitted as early as possible. The dates on the table below indicate the last date for submitting an LOI by round.

2. Table of Deadlines for Career Development Applications.

	Spring Review	Fall Review
Letters of Intent	August 21	February 21
Applications	November 1	May 1
Review Meetings	March	September
Funding Start*	April 1 (earliest) *or* July 1	October 1 (earliest) *or* January 1

*Funding will not begin until all just in time compliance issues have been reviewed by MRS.

3. Table of Deadlines for Progress Reports on Funded Awards.

RCD funded in spring review round	Annually on April 1
RCD funded in fall review round	Annually on October 1
ARCD funded in spring review round	18 months after funding (April 1)
ARCD funded in fall review round	18 months after funding (October 1)
CDEA	Two months after completion of award