

Department of Veterans Affairs VHA NOTICE 99-03

Veterans Health Administration

Washington, DC 20420 January 29, 2000

COOPERATIVE STUDIES PROGRAM CLINICAL RESEARCH CAREER DEVELOPMENT PROGRAM

1. **Purpose.** This Veterans Health Administration (VHA) notice announces the Office of Research and Development (R&D) Career Development Program, the Cooperative Studies Program Clinical Research Center Development (CSPCRCD) Program. This career development track has a fundamental objective to build capacity, in a wide geographic distribution, for the Department of Veterans Affairs (VA) to conduct patient-centered clinical research in acute-care hospitals, long term care facilities, or outpatient settings. *NOTE: This will advance the veterans healthcare system in fulfillment of its primary mission of patient care, supported by appropriate research and education.*

2. **Background.** The CSPCRCD awards are designed to foster the research careers of clinician scientists who are not yet fully independent but who seek to become independent clinical researchers. The program will provide salary and limited research funding. *NOTE: Tuition expenses are not provided.*

3. **Description of Award**

a. **Eligibility**

(1) The CSPCRCD Program is open to fully-trained clinicians of all types with doctoral degrees: physicians, dentists, psychologists, social workers, clinical engineers, audiologists, speech pathologists, etc. The CSPCRCD program provides protected time to clinician-investigators for a period of concentrated research activity. Awardees may not function in administrative roles, such as clinical Section Head, Service Chief, or Department Head during the terms of their CSPCRCD appointments. Implicit in all CSPCRCD applications is the understanding that the applicant foresees a career within VA.

(2) The CSPCRCD award is for 3 years and is designed to provide salary and supplemental research support to a fully trained clinician who is entering, or has recently entered, a career in clinical research. The applicant must be nominated by the VA medical center and should propose to develop clinical research skills in areas of importance to the mission of VA. The applicant need not be an independent researcher, but must show evidence of research competence. The goal for awardees at this level is to acquire sufficient proficiency to compete for research funding by the end of the appointment. Physician applicants must have completed clinical training and meet Board certification requirements for practicing in the relevant health care profession or obtain a

waiver of such requirements from Office of Patient Care Services in VHA Headquarters. Non-physician candidates must be licensed as required to conduct the research.

b. **Salary and Requirements.** The CSPCRCD award salaries may not exceed Senior Grade for Title 38 physicians and dentists. Title 5 awardees will be appointed at a maximum level of GS-12 unless currently employed at a higher grade. At least 75 percent of an awarded's time must be devoted to research and/or didactic work. In reference to MP-5, Part II, Chapter 3, Section B, subparagraph 1c(2) (b), as revised, awardees are expected to make a clinical contribution (up to 25 percent time) to their local medical center. Supplemental funding support may be requested up to \$10,000 per year. It is desirable that work under CSPCRCD award be conducted at established VA training sites located at Cooperative Studies and Epidemiological Research and Information Centers (ERIC). Awardees are not required to spend full time at the Center, but may work out an appropriate schedule to work at the Center part time. **Other non-Center sites may be considered with strong justification.** CSPCRCD awards are not renewable.

4. **Application.** Applications will be accepted from candidates with an approved Letter of Intent (LOI). Approved LOIs are valid for three consecutive application cycles. All applicants for CSPCRD program must be evaluated by the VA medical center R&D Committee and approved by the Dean's Committee and the medical center Director prior to submission. Peer review of all applications will be coordinated by CSP.

a. **Evaluation.** Applications will be evaluated on the following criteria:

- (1) Qualification of the applicant (i.e., previous training and accomplishments) and quality of the clinical research program proposed;
- (2) Qualifications of the mentor, including accomplishments and research support;
- (3) Suitability of the training and career development plan to the background and career goals of the applicant (i.e., research vision and growth potential);
- (4) Suitability of proposed coursework;
- (5) Suitability of the medical center for the research and training proposed;
- (6) Suitability of on-site training (i.e., at the CSP centers) for those who will not be in residence at a Center full-time.
- (7) Anticipated effect of the proposed award on the VA research career of the applicant;
- (8) Relevance and feasibility of the work to the needs of the VA; and
- (9) Long-term commitment of the VA medical center to the applicant.

**b. Submission.** The application must be submitted in accordance with instructions contained in Attachment B.

**c. Resubmission.** An application that was disapproved or approved but not funded, may be revised and resubmitted. The revised application must contain a letter not to exceed three pages, discussing the response to the reviewers' comments and a copy of the original LOI approval letter.

## **5. Definitions**

### **a. Appointments**

(1) All appointments are full-time, time-limited appointments and subject to applicable qualification requirements, including credentialing and privileging. The CSPCRCD awards are for 3 years and are non-renewable.

(2) Awardees in occupations covered by Title 38 United States Code (U.S.C.) will be appointed under 38 U.S.C., 7405 (a)(1)(A),(B),(C), or (D), as appropriate. No bonus payments will be authorized. Title 5 applicants may be appointed under Title 5 Code of Federal Regulations (CFR) 213.3227 (a) (Schedule B). Grade determination for Title 38 awardees will be determined locally based on qualification standards in VHA Supplement MP-5, Part II, Chapter 2; MP-5, Part I, Chapter 338, or the Office of Personnel Management (OPM) Handbook as applicable. Awardees covered by Title 5 U.S.C. will be appointed at grades determined appropriate by their local serving Human Resources Management (HRM) office, Title 38 and Title 5 employees are required to meet the VA and Federal appointment hiring requirements as applicable. Documentation of an applicant's eligibility for VA employment must be provided with the LOI (see Att.A). ***NOTE: The employment application process should be coordinated with the local serving HRM office to ensure applicants meet the VA appointment regulations.*** The ACOS for R&D, or a responsible VHA facility management official, is responsible for ensuring that current employees are converted to the applicable appointment authority cited in this subparagraph upon receiving a CSPCRCD award.

### **b. LOI**

(1) Applicants are required to submit an LOI by the November 1 or May 1 deadlines. In addition, a detailed "Request for Exception" letter must be included with the LOI in the following circumstances:

(a) A CSPCRCD applicant proposes to conduct the clinical research at a VA facility other than a Cooperative Studies Center or ERIC.

(b) A CSPCRCD applicant proposes to conduct the clinical research at a site remote from the primary mentor: or

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

(2) Each LOI will be reviewed to determine if the background of the applicant is appropriate for the requested award, and the background of the mentor(s) is appropriate to train and develop the applicant. Approved LOIs will be valid for three consecutive review cycles. LOIs must be prepared in accordance with instructions contained in Attachment A.

c. **Mentors.** Mentors are used in the CSPCRCD Program to prepare the awardee for an independent clinical research career. Applicants may select from one to three highly qualified mentor(s) with expertise and interest in the applicant's research. At least one mentor must be a VA investigator from an appropriate discipline who is committed to the training and development of the applicant. Up to two mentors (VA or non-VA) may supplement the expertise of the primary mentor. The application must contain a letter of support from the mentor(s) documenting their commitment to the applicant and describing the mentorship program.

d. **Didactic Training.** Didactic training may be conducted at the most appropriate established VA training site related to the Cooperative Studies Program (CSP) or the ERIC. Other well-established, well-justified sites will be considered for this portion of the training. ***NOTE: No tuition, travel, or relocation expenses are provided by this program.***

e. **Award Transfers.** The CRADO may, in exceptional circumstances, approve a transfer of award to a different VA medical center. Such approval will only be given if it is in the best interest of the award's training program and VA. The R&D Committee, Dean's Committee and Director of the new medical center are required to endorse the transfer and ensure that sufficient, VA space and support will be available for completion of the award. Research funds will not be provided to cover any moving or relocation expenses. If approved, the awardee may complete the balance of the award at the new VA medical center.

f. **Change in Mentor Status.** If the primary mentor relocates to a different facility, or is unavailable to train the awardee, the ACOS for R&D must immediately notify the CSP. The primary mentor may not be replaced without the approval of the CSP.

g. **CSPCRCD Program Contract.** Awardees will sign a contract agreeing to acknowledge VA as the primary affiliation on all public reports and presentations, and participate in an annual CSPCRCD review. Failure of an awardee to acknowledge VA support or employment may result in termination of the award, at the discretion of the CRADO.

h. **Annual Research Progress and Budget Review for CSPCRCD Awards.** The progress of each awardee will be reviewed annually. This is in addition to Annual Proficiency Reviews and Performance Reviews for Title 38 and Title 5 employees, respectively. The annual review is reviewed after completion of the first 6 months of an award term and annually thereafter. ***NOTE: Instructions for preparation and submission of the Annual Review are described in Attachment C.***

(1) The annual review will be conducted by the ACOS for R&D or by a scientist(s) appointed by the Research Office at the host facility. The review will include the awardee's adherence to the training program, awardee-mentor interactions, research progress and research plans for the coming year. The evaluation and recommendations of the reviewer will be discussed with the awardee and mentor(s). The awardee must respond to the evaluation in writing within 2 weeks. The response should include a plan for correcting any deficiencies identified.

(2) The evaluation and awardee response must be received at VHA Headquarters by CSP by June 15 of each calendar year. The CSP will determine whether the progress and activities planned are satisfactory, satisfactory with contingencies, or unsatisfactory. If unsatisfactory, the awardee will be placed on 3 months probation, during which time the performance must return to a satisfactory level. If a re-review at 3 months determines that progress has not been satisfactory, the contract for the awardee will be terminated within 30 days. The decision for termination will be final. Awardees whose programs have been terminated may not reapply for CSPCRCD awards.

**6. Responsibility.** The Office of Research and Development, Cooperative Studies Program (125) is responsible for the contents of this notice.

**7. Rescission.** This VHA Notice expires the last working day of June 2004.

Thomas Garthwaite, M.D.

Under Secretary for Health

Attachments

DISTRIBUTION: CO: E-mailed 6/29/99

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## ATTACHMENT A

### FORMAT FOR LETTERS OF INTENT FOR CLINICAL RESEARCH CAREER DEVELOPMENT AWARDS

1. A Letter of Intent (LOI) should consist of single-spaced typed pages. Use only letter-quality print; do not use a dot matrix printer. Do not use photo reduction or font size smaller than 11 point.
2. Each LOI should consist of the following materials:
  - a. Department of Veterans Affairs (VA) Form 10,1313-13, VHA Research and Development Letter of Intent Cover Page. In block 1, check "Cooperative Studies Program." In block 3, check "Career Development," **NOTE:** *VA Form 10-1313-13 may be found on the web site: <http://www.va.gov/forms/medical/SearchList.asp>*
  - b. Name(s) and signatures(s) of mentor(s)
  - c. An abstract of the planned research (not to exceed one page).
  - d. Proposed didactic work.
  - e. Letter describing changes from previous application (revised application only).
  - f. Curriculum vitae of the applicant and mentor(s)
  - g. Documentation in the form of a letter or memo from local human resource management (HRM) stating the applicant meets minimum requirements for appointment in the VA.
  - h. Any letter(s) requesting exception, e.g., applicant's training site not located at a Cooperative Studies Centers, or Epidemiological Research and Information Center (ERIC).
3. LOIs will be considered incomplete and 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 Research and Development (R&D) Office at the originating VA medical center.
4. **Due Dates.** LOIs will be reviewed semi-annually. Deadlines for receipt are November 1 and May 1.
5. **Mailing Addresses**

a. LOIs should be mailed to the address listed as follows:

Cooperative Studies Program (125)

VHA Headquarters, Room 775S

810 Vermont Avenue, NW

Washington, DC 20420

(202) 273-8248

## **ATTACHMENT B**

### **FORMAT FOR APPLICATIONS COOPERATIVE STUDIES PROGRAM CLINICAL RESEARCH CAREER DEVELOPMENT AWARDS**

1. A Clinical Research Career Development (CSPCRCD) application may be submitted only after receipt of an approved Letter of Intent (LOI). The full application should be prepared jointly with the mentor. The application must contain:

- a. A history of the applicant's educational and research experience.
- b. The mentor's qualifications, including research accomplishments, funding, training experience, and list of previous trainees.
- c. A detailed description of the training experience to be provided including types of formal courses, seminars, data sessions, and other types of mentoring experience.
- d. A detailed description of the research facilities, including core programs and opportunity for collaborations.
- e. Applicants must include a research proposal which may be a pilot study, with supporting documents (see subpart.2n).

#### **2. Specific Instructions for Career Development Award Applications**

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

(1) Complete items 3 through 9 as indicated on the form. To the right of the text in Item 10 (Program Level) enter "CSP" and list the award (i.e., CRCD) that is being sought. Item 11 (Proposed Starting Date) should be left blank. Item 13 should be completed from the appropriate list in "Codes and Instructions for Investigator Data Sheet" (see page 18 of VA Form 10-5368, VA Medical Research Information System Report). Complete items 13 through 16 as indicated on the form. Original signatures are required from the applicant and the Associate Chief of Staff (ACOS) for Research and Development (R&D).

(2) The back of VA Form 10-0102 is to be used for a one-page summary of the application. Key Words from the National Library of Medicine, Permuted Medical Subject Headings should be included. The summary should include a brief description of the research background, current research interests, future plans of the applicant, and a summary of the proposed research.

b. **Table Of Contents**. A Table of Contents must follow VA Form 10-0102. Headings should include items 1 through 15 of this instruction section, with subheadings as necessary for clarity. Add the page numbers for the material in the application corresponding to the headings in the

Table of Contents.

c. **LOI Approval Letter**. Append a copy of the LOI approval notification letter.

d. **Nominating Letters**. The CRCD Committee will accept a single letter from the medical center Director stating that the Dean's Committee 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 or the date of citizenship eligibility for a non-citizen.

e. **Applicant's Biographical Sketch, Bibliography, and Research Support**. VA Form 10-1313-5, Investigator's Biographical Sketch and VA Form 10-1313-6, Investigator's Bibliography, must be included. Applicants must indicate current positions and any positions they expect to have between the time of submission of the application and the projected starting date of the CRCD award. The bibliography should not exceed two pages and should include a chronological list of all of the most important and pertinent publications and submitted papers. Literature citations must include the full title of the paper referenced. Following the bibliography, insert VA Form 10-1313-7, Investigator's Total VA and Non-VA Research Support (Current and Pending), VA Form 10-1313-8, Investigator's Total VA and Non-VA Research/Development Support, and abstract and budget pages for all non-VA support.

f. **Facilities Available**. In a paragraph or two, describe the office and research space and its location, specifying that the space is in a VA facility. Describe clinical resources and equipment available to the applicant, avoiding facility inventories. If the research space is not in a VA facility, prior approval of the Chief Research and Development Officer (CRADO) must be obtained through a Letter of Exception submitted with the LOI.

g. **Mentor's Support Letter and Description of the Training Program**. A letter from each proposed mentor must be included with the application. This letter is critical for the application because it describes the content of the applicant's proposed research-training experience from the mentor's point of view. This letter should contain:

(1) A brief description of the distribution of the mentor's time in research, patient care, teaching and administration;

(2) An 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 and projected trainees, with inclusive dates; and

(3) A description of the plan for mentoring, including the role of the applicant in the mentor's clinical research program, role of the mentor in the applicant's clinical research, formal coursework and training experiences planned by the mentor for the applicant, nature of the mentor's interaction with the applicant, percentage of the mentor's effort that will be devoted to

the applicant, and the degree and type of interaction that the applicant will gain from other researchers in the mentor's program or elsewhere at the medical center.

h. **Delineation of Clinical Role.** The appropriate Service Chief or Section Head must submit a statement describing the proposed patient care role of the applicant upon receiving the CRCDC award. An indication of the applicant's expected percent time in non-research activities should be included (not to exceed 10 hours per week).

i. **ACOS for R&D Support Letter.** The ACOS for R&D is required to submit a letter of support and acknowledge commitment to review the applicant's progress and development at least annually.

j. **Reference Letters.** Include 5 reference letters from professional colleagues. 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 that are willing to provide support and resources to the development of the applicant's clinical research career.

k. **Mentor's Curriculum Vitae with Bibliography and Research Support.** VA Form 10-1313-5 and VA Form 10-1313-6, must be included for each mentor. The bibliography may not exceed three pages and should include a chronological list of the most important and pertinent publications and submitted papers. Literature citations need to include the full title of the paper referenced. Following the bibliography, insert VA Form 10-1313-7 and VA Form 10-1313-8, and abstract and budget pages for all non-VA support.

l. **Response Letter (revised applications only).** A letter, not to exceed three pages, should address changes made in the application in response to the comments of reviewers.

m. **Career Plan.** Submit a detailed description of the Career Plan (no more than seven pages). In the plan, include:

- (1) Previous research experience and funding.
- (2) Current research interests and involvement, include funding.
- (3) Relationship between the research interests of the applicant and mentor.
- (4) Potential impact of the clinical research on the improvement and/or evaluation of veteran health care and/or health policy.
- (5) Potential benefit of coursework to the career of the applicant.
- (6) Discussion of how the award will affect the applicant's VA leadership, commitment and/or professional advancement within VA.

(7) Future clinical research plans and ambitions (explain how the proposed CRCD award fits into these plans).

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

n. **Planned Research.** Submit a research proposal narrative up to 10 pages in length in Merit Review format (see M-3, Pt. II, Ch. 4). All abbreviations and acronyms must be defined.

o. **Budget.** If research support is requested, include VA Form 10-1313-3, Current Funds and First Year Request for Program, and VA Form 10-1313-4, Estimated Expenses of Program. Do not include the applicant's salary in the budget. Total research support is limited to \$10,000 per year. If the applicant has other research support, the difference between the funding limit and the available funds may be requested. *NOTE: No tuition, relocation, or travel expenses will be provided.*

### **3. 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 will be returned if they are illegible, fail to follow instructions, or if the material presented is insufficient to permit an adequate review. Submit a typed single-spaced original, copied front side only, and 10 unbound copies of the proposal duplicated front-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 front-to-back. Except for the special VA Forms provided, use blank white paper, 8.5 x 11 inch. The minimum size for computer-generated print is 11 point. Use clips to separate proposal copies.

b. **Reprints.** The six reprint copies should be collated into sets, separate from the proposal.

c. **Due Dates.** Application deadlines are February 15 and August 15.

#### **e. Mailing Addresses**

(1) Applications should be mailed to the mailing address listed as follows:

CSP Clinical Research Career Development Program (125)  
VHA Headquarters, Room 775S  
810 Vermont Avenue, NW  
Washington, DC 20420  
(202) 273-8248

## **ATTACHMENT C**

### **CLINICAL RESEARCH CAREER DEVELOPMENT (CRCDD) APPLICATION CHECKLIST**

1. VA Form 10-0102, Career Development Application (front and back completed).
2. Table of Contents.
3. Career Development Letter of Intent (LOI) Approval Notification Letter.
4. Nominating Letters (Medical Center Director, Research and Development (R&D) Committee, and Dean's Committee).
5. VA Form 10-1313-5 Investigator's Biographical Sketch and VA Form 10-1313-6, Investigator's Bibliography.
6. Applicant's Research Support (VA Form 10-1313-7, Investigator's Total VA and Non-VA Research Support (Current and Pending), VA Form 10-1313-8, Investigator's Total VA and Non-VA Research/Development), and abstract and budget pages.
7. Facilities available statement.
8. Mentor's Support letter(s) describing Training Program.
9. Delineation of clinical role.
10. List of proposed courses.
11. Associate Chief of Staff for Research (ACOS for R&D) Support Letter.
12. Reference Letters (Five).
13. Mentor's Curriculum Vitae with VA Form 10-1313-5 and VA Form 10-1313-6.
14. Mentor's Research Support (VA Form 10-1313-7, VA Form 10-1313-8, and abstract and budget pages).
15. Response to Prior Concerns (*resubmissions only*).
16. Career Plan Statement.
17. Research Proposal.
18. Budget (Use VA Form 10-1313-3, Current Funds and First Year Request for Program, and

VA Form 10-1313-4, Estimated Expenses of Program).

19. The original application package and 10 unbound copies.

20. Reprints (six sets).

## ATTACHMENT D

### INSTRUCTIONS FOR CAREER DEVELOPMENT ANNUAL REVIEW

**1. Annual Performance Review.** The annual review of all Clinical Research Career Development (CRCDD) 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.

**2. Content.** Each annual performance review should consist of the following materials:

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

(1) CRCDD Annual Performance Review.

(2) Department of Veterans Affairs (VA) medical center.

(3) Name of awardee.

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

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

(6) Percentage of awardee's time devoted to non-research activities; brief description of non-research activities.

(7) Location of primary work site and/or laboratory.

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

b. **Training.** Provide a description of the awardee's participation in training activities during the evaluation period, to include 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 the training program proposed in the awardee's application; explain the reason for the change. Include recommendations for enhancing or improving the training program, if applicable.

c. **Participation.** Describe the awardee's participation in national or international scientific meetings.

d. **Mentor(s).** Provide a description of the awardee's interaction with mentors (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.

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

(1) Identification of any changes from the awardee's application to the distribution of the mentor's time in research, patient care, teaching, and administration (if there are no changes, the letter should so state).

(2) Identification of any changes from the awardee's application to 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).

(3) 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.

f. **Career Plan**. Describe any changes to the awardee's career plan identified during the performance period.

g. **Research Support**. For approved and/or anticipated funding during the subsequent performance period, attach VA Form 10-1313-7, Investigator's Total VA and Non-VA Research Support (Current and Pending), VA Form 10-1313-8, Investigator's Total VA and Non-VA Research/Development, and abstract and budget pages from all non-VA support.

*NOTE: VA research support funds will not be distributed without this documentation.*

h. **Research Progress**. Provide a status report of progress made on the proposed research. Describe any changes from the original research plan.

i. **Bibliography**. Include a chronological list of publications during the performance period, beginning with the most recent publication. Attach a copy of each publication.

j. **Summary assessment by ACOS**. Progress satisfactory or not?

**3. Awardee Response to the Evaluation**. The evaluation and recommendations of the reviewer(s) will be discussed with the awardee and mentor(s). The awardee must provide a written response to the evaluation within 2 weeks. The response should include a plan for correcting any deficiencies identified.

**4. Due Date**. Annual performance reviews must be received at 6 months, 18 months and 24 months.

