Department of Veterans Affairs Office of Research and Development

Instructions for Preparing a Career Development Proposal

General Instructions

Refer to VHA Handbook 1200.4 "Office of Research & Development Career Development Program" for a complete description of awards, eligibility, and other guidance. The answers to Frequently Asked Questions regarding the program are also posted.

A Career Development proposal may be submitted only after the nominee has obtained an approved Letter of Intent (LOI). The proposal should be prepared using Arial 11-point font, printed on 8.5x11 inch white paper with 1-inch margins at each edge. Pages should be numbered consecutively in the lower right corner, starting with VA Form 10-0102, Career Development Application, and should include the nominee's name and page number (e.g., Smith-1 to Smith-22). Applications that exceed specified page limits or fail to comply with font size or margin specifications risk being returned without review.

The work proposed must be approved by the local VAMC R&D Committee and appropriate subcommittees either prior to submission to ORD or under "Just In Time" review. In addition, the ACOS/R&D must obtain all pertinent letters and concurrences from relevant local VA offices. Nominees are encouraged to work with their ACOS/R&D to avoid delays and misunderstandings. No additional or replacement information will be accepted after submission of the proposal unless explicitly requested by program review.

Application deadlines for receipt at VA headquarters are December 15 and June 15, or the first business day thereafter if the 15th falls on a weekend.

Preparation

The CDA proposal consists of the following documents and narratives. Note: Italicized text indicates information specific to an award or service in these instructions. Assemble materials according to the order listed below.

- 1. VA Form 10-0102, Career Development Application (Page 1) http://www.va.gov/vaforms/medical/pdf/vha-10-0102-fill.pdf
 - a. Complete boxes 3 through 9 as indicated on VA Form 10-0102 (Items 1 and 2 are left blank). **Note**: Block 4, social security number **should appear on the original only**. The social security number should be left blank on all copies submitted.
 - b. In box 10a (R&D Service), check the appropriate service (Biomedical Laboratory (BLR&D), Clinical Science (CSR&D), Health Services (HSR&D), or Rehabilitation (RR&D)). In box 10b

(Award Type), enter the type of award being sought (Career Development Award-1 (CDA-1), Career Development Award-2 (CDA-2), Career Development Transition Award (CDTA), or Career Development Enhancement Award (CDEA)).

- c. Complete items 11 through 16 as indicated.
- d. Original signatures are required from the nominee and the Associate Chief of Staff (ACOS) for R&D.
- 2. VA Form 10-0102, Summary Description of Program (Page 2). Provide a lay language summary (1-page limit) of the application. The nominee's name and project title should appear exactly as written on page one. 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 summary description should be written similarly to a scientific abstract, providing information about the nominee'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 should follow VA Form 10-0102. Page 13 is provided as an example. Indicate N/A for not included (or non-applicable) items.
- **4.** Response to prior submission (3-Page Limit). If the proposal has been revised from a previous submission, a letter addressing the committee's concerns should be included, followed by copies of the review summary letter and written critiques. Changes to the narratives should be highlighted for reviewers.
- 5. Budget Pages. Include the following VA Forms:
 - a. VA Form 10-1313-3, Current Funds and First-Year Request. Include an itemized account of first-year funds being requested to support the nomination. Please refer to VHA Handbook 1200.4 "Office of Research & Development Career Development Program" for a detailed description of the appointments supported by each award level and VA Handbook 5007 for appropriate physician and dentist pay administration.
 - (1) <u>CDA-1</u>: Include only estimated salary support (limited to the GS-11 range for non-clinicians and GS-13 equivalent range for clinicians). Physicians and dentists are appointed as "Associate Investigators" under this award and are ineligible for pay under VA Handbook 5007 Part IX. CDA-1 awardees must maintain a minimum 5/8 VA appointment and 75% research effort. No research support may be requested.
 - (2) <u>CDA-2</u>: The budget may include salary (see below) and/or up to \$50,000 in research funds, should local support be unavailable to carry out a specific project proposed in the research plan. Project funds are subject to availability and approval by the relevant ORD service director.

(a) Non-clinicians – This award provides salary limited to GS-13. Non-clinicians must maintain a minimum 5/8 VA appointment and 100% VA research effort.

- (b) Clinicians requesting salary Appointments are made under Title 38 United States Code (U.S.C.) 7405 (a) (1) with salary determined by the local compensation panel. The VAMC must provide a 75% time commitment to VA-approved research. The VAMC must appoint awardees on an 8/8ths temporary, time-limited appointment and must commit to continuing to provide at least a 5/8 clinical appointment upon conclusion of the award. The budget should include an itemized estimate of salary, fringe benefits, and any special pay.
- (c) Clinicians not requesting salary Clinicians with a minimum 5/8ths appointment at the time they are nominated may continue their appointment and request project funds only; however, they must maintain a minimum 25% research effort.
- (3) CDTA: Only clinicians are eligible for the CDTA. Appointments are made under Title 38 United States Code (U.S.C.) 7405 (a) (1) with salary determined by the local compensation panel. The VAMC must provide a 75% time commitment to VA-approved research. The VAMC must appoint awardees on an 8/8ths temporary, time-limited appointment and must commit to continuing to provide at least a 5/8 clinical appointment upon conclusion of the award. The budget must include the pages describing the research support to be obtained from a VA merit review proposal that has been reviewed and approved, even if it did not receive a fundable score. The Merit Review approval notification letter and proposal narrative should be included as an appendix.
- (4) <u>CDEA</u>: ORD will provide a maximum of six months salary support, including fringe benefits for a period of educational leave approved by the VA medical center. The local facility must provide matching funds for clinicians. Include only current salary support, fringe benefits, and special pay (if applicable). 100% of the awardee's effort must be devoted to research during the CDEA, and the awardee must be released from all administrative responsibilities during this award. There is no change in pre-award appointment.
- b. VA Form 10-1313-4, Estimated Per-Year Expenses for Project. Include salary with fringe benefits and/or research support (CDA-2 only).
- 6. VA 10-1313 Forms. The following set of VA forms is required from the nominee and each mentor or sponsor (CDEA). Include these forms also for consultants or content mentors who might not be part of the formal mentoring team, but who would provide expertise in key areas, and whose effort would be 5% or greater. Non-VA scientists may submit the NIH comparable PHS 398 Biographical Sketch.
 - a. <u>VA Form 10-1313-5/6</u>, <u>Investigator's Biographic Sketch</u>. List complete citations of only the most relevant publications and accepted manuscripts in peer-reviewed journals. Do not

include abstracts or manuscripts that are submitted or in preparation, or non-refereed publications. Copies of Form 10-1313-6 may be made and included, as needed.

- b. VA Form 10-1313-7, Investigator's Total VA and Non-VA Research Support (Current and Pending) 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 VA merit review or locally funded awards, private or foundation research grants, cooperative agreements, contracts, and university awards. All currently funded and pending support should be included. If the investigator has no active or pending support, "None" should appear in the first description box.
- c. VA Form 10-1313-8, Investigator's Total VA and Non-VA Research/Development Support If the investigator has no active or pending support, "None" should appear 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. Make as many copies of Form 10-1313-8 as needed.
 - (1) In the box provided for description, use the following format for each active and pending funding listed on Form 10-1313-7:
 - (a) *Role*: State the mentor'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.
- 7. Overlap. On a separate page, in a paragraph headed "Overlap," the nominee should provide a single summary of any potential overlap between the research in the proposal and any active or pending research, including that of the mentor(s), with respect to the science, budget or time commitment. 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.

a. 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.

- b. 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.
- 8. Career Plan (CDA-1 & CDA-2, 5-7 page allocation suggested; CDTA & CDEA 3 pages suggested). [Note: the "narrative" of the application includes items 8 and 9. CDA-1 application narrative portions are limited to 15 pages; CDA-2, to 25 pages.] The career plan should describe:
 - a. Research background, including training, experience, prior funding, and other accomplishments.
 - b. Research interests.
 - vA service and other involvement.
 - d. Relationship between the nominee's interests and skills and those of the proposed mentor/s or sponsor.
 - e. Potential impact of the proposed career development experience on the improvement and/or evaluation of veteran health care and/or health policy.
 - f. Expected results of the experience in terms of the benefit to VA and to the nominee in terms of their research program.
 - g. Commitment to and/or goals for professional advancement within VA. *CDTA nominees note:* be sure to articulate why the specific amount of time is essential, its "added value" in terms of ensuring the nominee's long-term VA role, and the specific position and timing that is planned for the nominee at the end of the requested period.
 - h. Specific formal and informal training activities and objectives, and specific new skills to be attained.
 - i. Future research plans and ambitions (explain how the proposed award enhances these plans).
 - j. Percent of time to be devoted to research, and other concurrent commitments to the local VA medical center.

9. Research Plan (CDTA – required to attach narrative from pending or previously reviewed Merit Review proposal; CDEA – limited to 5 pages). [Note: application narrative includes items 8 and 9. CDA-1 narrative is limited to 15 pages; CDA-2, to 25 pages.] Page limits include all text, figures, charts, graphs and diagrams. Items that do not photocopy well may be included as an appendix and will not be counted against the page limit. The research plan should be organized into four major sections: Objectives, 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 following outline is suggested as a general guideline only; section lengths may vary according to level of award and whether project funds are being requested to carry out the proposed work. Where project funds are being requested, sufficient methodological detail must be provided to be evaluated for scientific merit.

CDTA nominees only, please note that the narrative portion of your Merit Review proposal serves as your research plan - Ignore a-d below.

- a. **Objectives**. Describe the objectives of the proposed career development experience, including a statement of the problem to be investigated, rationale for the proposed research and/or training. Hypotheses or key research questions, if applicable, should be clearly stated, and the long-term and more immediate objectives of the proposed work explained. For long-term objectives, expected intermediate goals should be identified, and an anticipated timetable for achieving short-term objectives (i.e., the objectives to be accomplished if the work proposed is funded) outlined.
- b. Background and Significance. Briefly describe the current status of research relevant to the present application and how it relates to stated hypotheses or research questions. Critically evaluate existing, relevant knowledge and explicitly state the gaps that the proposed research and/or training experience would help fill. Cite only relevant and recent literature. The Background section should reflect awareness of the critical issues related to the proposal. It should not be exhaustive.
 - (1) <u>Significance</u>. Explain the potential importance of the proposed work and describe the unique ideas or potential contributions that might result from the career development experience.
 - (2) 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. Describe any preliminary/previous studies conducted by the nominee that are pertinent to the application. The information should help reviewers evaluate the experience and competence of the nominee to pursue the work described in the proposal. The experience/competence of key collaborators may be briefly described. Up to three publications and/or submitted or accepted manuscripts by the nominee may be placed in the appendix.

d. Work Proposed. Provide a timetable describing the sequence of activities. Specific projects and activities should be directly linked to the stated objectives. Describe the design, methods, and procedures associated with specific projects, including how data would be collected, analyzed and interpreted. New methodologies should be clearly described with a rationale for why they are preferred over existing methodologies. Potential problems and limitations of proposed methods/procedures should be addressed and possible alternative procedures to achieve the specific aims discussed. If humans or animals are to be studied, a power analysis should be used to justify the number to be studied. CDEA nominees should explain and justify the experience proposed and describe how the experience will benefit the local VA and veterans healthcare.

10. Human Studies Section (not included in narrative page limit). If Form 10-1313-1, Block 19, Human Subjects is checked "Yes," create a section heading titled "Human Subjects." Nominees 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) <u>Sources of Materials</u>. 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) <u>Potential Risks</u>. 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. <u>Potential Benefit of the Proposed Research to the Subject and Others</u>. 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. <u>Importance of the Knowledge to be gained</u>. 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.
- 11. Animal Subjects (not included in the narrative page limit). 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. 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.

12. Resources. 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 nominee, 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 work is to be conducted outside of a VA facility. Exceptions should be requested, in writing, at the LOI stage of review.

13. Literature Citations for Narrative.

- **14. Mentor's Letter of Commitment.** Each mentor should submit a letter describing the mentoring plan, including the following. Mentors are expected to provide updated letters for resubmissions.
 - a. The mentor's proposed role in training
 - b. Planned training activities (coursework, seminars, scientific meetings, etc.)
 - Nature of the interactions between mentor and nominee
 - d. Percentage of the mentor's effort that would be devoted to the nominee
 - e. The degree and type of interaction that the nominee would 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 nominee to achieve independence
- **15.Approved Extended Educational Leave Request (CDEA nominee's only).** Use VA Form 10-5503, Extended Educational Leave Request Briefing Slip, and VA Form 10-5503a, Extended Educational Leave Checklist.
- 16. Compliance and Administrative Issues. Please refer to ORD's guidance for Just in Time Receipt for Compliance and Assurance Documentation posted on the VA R&D Website at www.research.va.gov. For CDTAs, VA Merit Review may cover compliance and administrative issues. Similarly, for CDEA, a sponsoring facility may cover these issues. If applicable for CDTA/CDEA, the R&D approval letter should so indicate.

a. On Time Submission of Compliance/Assurance Documents. Each local facility conducts compliance assurance reviews according to local policies. Whether the review(s) is done prior to submission of the application or at a later date, ORD <u>requires</u> just in time submission of compliance/approval documentation for human studies, animal studies and biosafety. Do <u>not</u> 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 cautioned that the procedures described in the application may not be conducted."
- **17. Endorsements.** Note: Updated letters should be provided for all resubmissions.
 - a. Copy of the LOI acceptance letter.
 - b. The appropriate Service Chief or Section Head must submit a statement describing the nominee's proposed clinical duties upon receiving the Career Development award. An indication of the nominee's expected percent time in non-research activities should be included (not to exceed ten hours per week).
 - c. The ACOS/R&D is required to submit a letter of support and acknowledge a commitment to review the nominee's progress and development as a VA research scientist at least annually.
 - d. ORD 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 nominee at the completion of the award.
 - e. Three reference letters should be obtained from professional colleagues, former/current teachers, former mentor, etc. Reference letters should not be limited to the nominee's institution or affiliated university. The nominee is encouraged to include letters of support from other institutions willing to provide support and resources to the development of the nominee's research career.
- **18. Appendices.** The following items may be appended to the application: Notification letter, summary statement, reviewer critiques (resubmissions only); copies of 3 reprints or manuscripts (if not photocopied as part of application); tables or charts that can not be reproduced clearly and inserted into narratives; proposal narrative from application submitted to VA merit review (CDTA candidates only).

19. Submission Instructions. Applications must be complete and comprehensive upon receipt at 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. Additional guidance for resubmitting a revised proposal is included throughout these instructions where relevant.

- a. Submit a typed single-spaced original, copied front side only, and 20 copies duplicated front to back. The only acceptable means of securing pages is with binder clips. Do not use photo reduction; any applications using such low quality or small print (smaller than Arial 11-point font) will be returned. The nominee's social security number should not appear on copies.
- b. <u>Reprints</u>. Nominees may submit 6 copies of reprints of their three most representative publications, if not already copied as appendices. Reprints submitted separately will only be provided to the principal reviewers.
- c. <u>VA Form 10-0102</u>, <u>Career Development Application</u>. Twenty extra copies of VA Form 10-0102 (front and back). Please ensure the nominee's social security number does not appear on these copies.
- d. <u>Due Dates</u>. Applications will be reviewed semi-annually, 12-15 weeks from the deadline of receipt.
- e. <u>Mailing Addresses</u>. Applications should be mailed to the appropriate service at the address listed below:
 - (1) Biomedical Laboratory Research & Development Service

Department of Veterans Affairs BLR&D/CSR&D Letter Of Intent Career Development Program (121F) 810 Vermont Ave., NW Washington DC 20420 (202) 461-1689

(2) Clinical Science Research & Development Service

Department of Veterans Affairs BLR&D/CSR&D Letter Of Intent Career Development Program (121F) 810 Vermont Ave., NW Washington DC 20420 (202) 461-1689

(3) Rehabilitation Research & Development Service

Career Development Program (122P) 810 Vermont Ave., NW Washington, DC 20420 (202) 461-1699

(4) Health Services Research and Development Service

Career Development Program Manager (124D) 810 Vermont Ave., NW Washington, DC 20420 (202) 461-1515

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