

Department of Veterans Affairs
VA New England Healthcare System

VISN 1

Instructions for Preparing a Career Development Proposal
(Released February, 2016)

General Instructions

A Career Development proposal may be submitted only after the nominee has submitted a Letter of Intent (LOI) and received approval of the LOI (see "Request for Applications" for instructions on submitting a LOI).

If the application is funded and before the work begins, the work proposed must be approved by the appropriate local subcommittees and the R&D Committee. 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.

The application deadline for receipt at the VISN 1 Office is June 6, 2016. Applications must be submitted through the Medical Center's R&D Office. Applicants should consult their R&D Office for the local deadline for submitting the application.

Please note that funding for selected proposals will start October 1, 2016 and deferrals considered only in cases of prolonged leave.

Preparation

The CDA proposal consists of the following documents and narratives. Assemble materials according to the order listed below.

- 1. Summary Description of Program.** Provide a lay language summary (1-page limit) of the application. Include the following: nominee's name and project title; three or more key words; information about the nominee's research background and current research interests; hypotheses to be tested; specific objectives; relevance to veterans' health and health care; 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.
- 2. Table of Contents.**
- 3. Response to prior submission (3-Page Limit).** If the proposal has been revised from a previous submission, a letter addressing the review committee's concerns should be included, followed by copies of the written critiques. Changes to the narratives should be specified for reviewers.
- 4. Budget Page.** Provide the grade and step and the salary and fringe benefit cost expected to be set by the local professional standards board for award years one and two. The award will pay 75% of the salary. Awardees must be full time VA employees and maintain 75% research effort. No research support may be requested.

5. Additional Information. The following items are required from the nominee and each mentor, if applicable. 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.

a. **Applicant and Mentor Biographic Sketches.** Either the VA or the NIH format may be used. Each biosketch is limited to no more than four pages. 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.

b. **Applicant and Mentor 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, NIH grants, private or foundation research grants, cooperative agreements, contracts, and university awards. All currently funded and pending support should be included for each individual.

If there is overlap present, 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. This summary should be listed next to the active grant or award where there is overlap.

- i. If the applicant or mentor has no active or pending support, "None" should appear after the individual's name.
- ii. For each grant or award
Source/Project No. -name of the awarding agency and the project number, if assigned
Project Title -full title (and the sub-project number, if appropriate)

(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.

6. Career Plan [Note: the "Narrative" of the application includes items 6 and 7. Narrative portions are limited to 10 pages.] The career plan should describe:

- a. Research background, including training, experience, prior funding, and other accomplishments.
- b. Research interests.
- c. Percentage efforts planned to be devoted to each of clinical, research, teaching and administrative duties (as applicable) at the VA and the affiliate.
- d. Relationship between the nominee's interests and skills and those of the proposed mentor(s).
- 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.
- 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).

7. Research Plan. [included in Narrative] Page limits include all text, figures, charts, graphs and diagrams. 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.

- 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.
 - i. **Significance.** Explain the potential importance of the proposed work and describe the unique ideas or potential contributions that might result from the career development experience.
 - ii. **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.** Preliminary results are not required. 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. If available, 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.

8. Human Studies Section [not included in Narrative page limit]. If the project involves human subjects, 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.

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 is not required 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.

9. **Animal Subjects [not included in the Narrative page limit].** If the project involves animals, 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.
- 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.

10. **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.

11. Literature Citations for Narrative.

12. Mentor Letters 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.)
- c. 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

13. Endorsements. Note: Updated letters should be provided for all resubmissions.

- a. The appropriate Service Chief must submit a statement describing the nominee's proposed clinical and other non-research duties upon receiving the Career Development award. The nominee's expected percent effort in non-research activities should not exceed 10 hours per week.
- b. The medical center Director's letter should indicate support for the applicant, acknowledgement that 25% of the awardee's salary will be provided by the local facility, and commitment of the medical center to the applicant's career development should be described in detail (including how space needs will be met and an endorsement of the applicant's 75% time commitment to research).
- c. Letter from the Chair of the applicant's university department
- d. Two reference letters should be obtained from professional colleagues, former/current teachers, former mentor, etc. Reference letters need not be limited to the nominee's institution or affiliated university.

14. Appendices. The following items may be appended to the application: Copies of (or web links to) no more than two reprints or manuscripts.

Submission Instructions

Applications must be complete and comprehensive upon submission. 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.

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, and should include the nominee's name and page number (e.g., Smith-1 to Smith-22). Applications that exceed specified page limits, fail to comply with font size or margin specifications risk being returned without review.

Compile all items (1-14) into a single document in PDF format. Submit this document to the Office of Research at the proposed VA facility, which must submit it to the VISN 1 Chief Medical Office **no later than 5pm on June 6, 2016**.

Questions

Please consult the FAQ document for answers to common questions. Further questions may be addressed to Kristin Mattocks, VISN 1 Research Lead, Kristin.Mattocks@va.gov.