

Part I - Overview Information

Department of Veterans Affairs

Participating Organizations

Veterans Health Administration, Office of Research and Development (VA-ORD)

Components of Participating Organizations

Health Services Research and Development (HSR&D) Service, VA-ORD

Title: HSR&D Career Development Award (CDA-1)

Announcement Type

New

Update: There are no updates relating to this announcement.

NOTICE: Applications submitted in response to this Request for Applications (RFA) must be submitted electronically through Grants.gov (<http://www.grants.gov>) using the Adobe-compatible version of the SF424 Research and Related (R&R) forms. **Applications may not be submitted on Paper or CD. Only Adobe-based application packages may be submitted**

This RFA must be used in conjunction with the VA version of the SF424 (R&R) Application Guide available on the VA-ORD **Intranet** site at <http://vaww.research.va.gov/funding/electronic-submission.cfm>.

Several registration processes must be completed before an electronic application can be submitted (see [Section IV](#)). Applicants must provide their completed application to the appropriate VA institutional signing official for submission to Grants.gov. Applicants are highly encouraged to start the submission process well in advance of the submission deadline to ensure it passes the validations performed at Grants.gov and the National Institutes of Health (NIH).

Request for Applications (RFA) Number: HX-11-020

For Assistance downloading this or any Grants.gov application package, please contact Grants.gov Customer Support at <http://grants.gov/CustomerSupport>.

Catalog of Federal Domestic Assistance Number(s)

Not Applicable

Key Dates

Release/Posted Date: March 31, 2011

Letters of Intent Receipt Date(s): Prior to and including April 15, 2011

Opening (earliest submission) Date(s): Standard dates apply; please see [Table 4](#) in Part II, Section IV.

Application Deadline(s): Standard dates apply (see [Table 4](#) in Part II, Section IV).

All new or changed/corrected applications must meet 2 separate deadlines:

1. **Submission and acceptance in Grants.gov on or before 6 p.m. (local time) of the [Last Possible Submission Date](#) (submission deadline) in [Table 4](#).**

AND

2. **Verification by eRA Commons on or before the [Verification Deadline](#) in [Table 4](#).**

Applications that miss either deadline will not be accepted for review.

NOTE: Applications accepted by eRA Commons with no errors (with or without warnings) are provided a two-business day examination window to check for errors. The application is automatically verified on the third business day if it is not explicitly rejected (withdrawn) by the signing official (SO) during the 2-day examination window.

Once verified, an application is considered final and no other version will be accepted for review.

It is the responsibility of the PD/PI and AOR/SO to check for errors (including font and margins) in the eApplication during the 2-day examination window.

It is strongly recommended that submissions to Grants.gov be completed by the [Down to the Wire Deadline](#) in [Table 4](#) to ensure sufficient time to correct any errors that may be identified by either Grants.gov or eRA Commons.

New or Changed/Corrected applications submitted to Grants.gov and accepted after the "[Last Possible Submission Date](#)" in [Table 4](#) will cause the verification deadline to be missed; late applications will not be accepted for review.

Peer Review Date(s): Standard dates apply; please see [Table 4](#) in Part II, Section IV.

Earliest Anticipated Start Date(s): Standard dates apply; please [Table 4](#) in Part II, Section IV.

Additional Information: Not Applicable

Expiration Date: December 31, 2020

Additional Overview Content

Executive Summary

This Funding Opportunity Announcement (FOA) will use the non-U.S. Department of Health & Human Services (HHS) Career Development Award (IK2) mechanism.

- **Purpose.** The Research Career Development Program is an intramural funding mechanism designed to attract, develop, and retain talented VA-ORD researchers in areas of particular importance to VA. In this Program both clinically and non-clinically trained post-doctoral researchers may gain mentored research time intended to advance awardees toward independence as funded VA-ORD scientists. Implicit in all Career Development applications is the understanding that the applicants plan to continue their careers within VA.
- **CDA-1 Level Award.** The CDA-1 award provides an initial mentored research experience, consisting of up to two years of salary support, to highly qualified scientists with demonstrated abilities in key research areas who have not benefited previously from research fellowship-level training. Nominees must express a clear commitment to a VA career and enlist the support of at least one appropriately qualified VA mentor. The training experience should be closely integrated with the mentor's ongoing funded research. At the conclusion of the CDA-1 award, awardees may compete for advancement to CDA-2. **The CDA-1 award only provides salary for the PD/PI.**
- **HSR&D Purview:** VA's Health Services Research and Development Service (HSR&D) works to identify and evaluate innovative strategies that lead to accessible, high quality, cost-effective care for Veterans and the nation. HSR&D underscores all aspects of VA healthcare: patient care, care delivery, health outcomes, cost, and quality. This includes research that addresses critical issues for Veterans returning home from Iraq and Afghanistan with conditions that may require care over their lifetimes.

Note: Proposals involving procedures for obtaining biological specimens from human subjects or including a clinical trial are not appropriate for HSR&D.

Career Development proposals electronically submitted to HSR&D through Grants.gov will be peer-reviewed by a merit review committee to provide the Director of HSR&D with evaluations of the proposed research and make recommendations on the quality/appropriateness of proposed training and career plans, scientific merit, budgets and funding durations.

- **Mechanism of Support.** This Request for Applications will use the **IK1 mechanism for CDA-1** level Career Development awards.
- **Funds Available and Anticipated Number of Awards.** Availability of funds is dependent on Congressional appropriation.
- **Eligible Institutions/Organizations.** All VA medical centers with an active research program are eligible. Each VA medical center must be registered as an

applicant organization in Grants.gov and eRA Commons before any proposals can be submitted.

- **Eligible Project Directors/Principal Investigators (PD/PIs).** Only individuals who have **an approved letter of intent (LOI) for a CDA-1 level application** that has not expired may respond to this funding announcement. A proposal must be submitted within three consecutive cycles of the approved LOI. Once the initial proposal is submitted, the approved LOI remains valid for up to two proposal revisions.
- **Resubmissions.** For proposals that have been reviewed, but not selected for funding, VA-ORD allows the submission of up to two revised (Resubmission) applications. The LOI remains valid through the resubmission process. All resubmission applications must include a brief “Introduction to the Revised Application” that addresses the concerns raised in the previous review.

Resubmission applications for proposals that were **previously submitted electronically via Grants.gov** must be **marked as “Resubmission” in Box 8** on the SF424 (R&R) Cover Component and the Introduction to the revised Application submitted as an attachment named 01_VA_Intro.pdf. See Section 1 “[Introduction to Application](#)” in Table 2 for further details. **In Box 4a (Federal Identifier) of the Cover Component, enter only the 2-letter R&D Service designation and serial number of the previously assigned application/award number (e.g., CX123456); do not include any other portion (e.g., 1 I01 or -01A1) of the previous number.**

Resubmission applications for **proposals that were previously submitted on paper, CD, or e-mail must be marked as “New” in Box 8** on the SF424 (R&R) Cover Component **and the Introduction to the Revised Application submitted as an appendix named "11_VA_Appendix_2_Response.pdf.** These resubmissions, however, will still be counted by HSR&D as second or third submissions. See “[Appendices](#)” in Table 2 for further details; Attachment 1 (01_VA_Intro.pdf) may not be used.

See the VA SF-424 Application Guide for instructions on submitting a Changed/Corrected application. Failure to follow these instructions may result in the application being removed from review.

- **Renewals.** Research Career Development awards may not be renewed.
- **Number of PD/PIs.** Only one PD/PI may be designated in the application for any Research Career Development award.
- **Application Materials.** See [Section IV.1](#) for application materials.
- **General Information.** For general information on SF424 (R&R) Application and Electronic Submission to VA-ORD, see <http://vaww.research.va.gov/funding/electronic-submission.cfm>.

Table of Contents

[Part I Overview Information](#)

[Part II Full Text of Announcement](#)

[Section I. Funding Opportunity Description](#)

1. Research Objectives

[Section II. Award Information](#)

1. Mechanism of Support
2. Funds Available

[Section III. Eligibility Information](#)

1. Eligible Applicants
 - A. Eligible Institutions
 - B. Eligible Individuals
2. Cost Sharing or Matching
3. Other - Special Eligibility Criteria
 - A. Location of Research Space
 - B. Duplicate Submissions

[Section IV. Application and Submission Information](#)

1. Request Application Information
2. Content and Form of Application Submission
3. Submission Dates and Times
 - A. Submission, Review, and Anticipated Start Dates
 1. Letter of Intent
 - B. Submitting an Application Electronically
 - C. Application Processing
4. Intergovernmental Review
5. Funding Restrictions
6. Other Submission Requirements

[Section V. Application Review Information](#)

1. Criteria
2. Review and Selection Process
 - A. Additional Review Criteria
 - B. Additional Review Considerations
 - C. Sharing Research Data
 - D. Sharing Research Resources
3. Anticipated Announcement and Award Dates

[Section VI. Award Administration Information](#)

1. Award Notices
2. Administrative and National Policy Requirements

[Section VII. Agency Contacts](#)

1. Scientific/Research Contact
2. Financial Management Contacts

Part II - Full Text of Announcement

Section I. Funding Opportunity Description

1. Research Objectives

The Research Career Development Program is an intramural funding mechanism designed to attract, develop, and retain talented VA-ORD researchers in areas of particular importance to VA. In this program both clinically and non-clinically trained post-doctoral researchers may gain mentored research time intended to advance awardees toward independence as funded VA-ORD scientists. **Implicit in all Career Development applications is the understanding that the applicants plan to continue their careers within VA.** HSR&D includes research that underscores all aspects of VA healthcare: patient care, care delivery, health outcomes, cost, and quality. HSR&D investigators work to identify and evaluate innovative strategies that lead to accessible, high quality, cost-effective care for Veterans and the nation. This includes research that addresses critical issues for Veterans returning home from Iraq and Afghanistan with conditions that may require care over their lifetimes.

Note: Proposals involving procedures for obtaining biological specimens from human subjects or including a clinical trial are not appropriate for HSR&D.

Career Development proposals submitted to HSR&D through Grants.gov will be peer-reviewed by a merit review committee to provide the Director of HSR&D with evaluations of the proposed research and make recommendations on the quality/appropriateness of proposed training and career plans, scientific merit, budgets and funding durations.

Section II. Award Information

1. Mechanism of Support

This Request for Applications will use the **IK1 mechanism for CDA-1 level Career Development awards**. Only one proposal may be submitted to this RFA in any given review cycle and an investigator may only have one funded project from this HSR&D RFA .

The applicant is considered the “contact” PD/PI identified in Box 14 of the SF424 Cover Component, and will be responsible for planning, directing, and executing the proposed project(s); **multiple PD/PI's are not permitted for CDA-1 applications.**

This RFA uses “Just-in-Time” information concepts.

2. Funds Available

Career Development CDA-1 Budget Cap:

Clinicians: For Physicians and other clinicians, awards provide full salary and fringe benefits to support a 6/8ths (9 calendar months) CDA appointment for contact PD/PIs identified in Box 14 of the SF424 (R&R) Cover Component who maintain a Title 38 clinical appointment at the VAMC. 100% of the CDA effort must be committed to research and CDA activities.

Non-clinicians: Non-clinician applicants may request a minimum 5/8ths CDA appointment (7.5 calendar months), but may request up to 8/8ths (12 calendar months); whether full or part-time, 100% of their CDA commitment must be devoted to research and CDA activities.

Cost of living adjustments (maximum of 3% per year) are permitted.

Duration of Career Development CDA-1 Awards: The maximum duration of a CDA-1 award is 2 years.

Section III. Eligibility Information

1. Eligible Applicants

1.A. Eligible Institutions

Applications may be submitted from any VA medical center with an active research program. **Documentation of support for the application from the Medical Center Director must be included as a separate attachment** in all applications. Proposals submitted without such documentation may be administratively withdrawn. See Item 8a “[Director’s Letter](#)” in Table 2 for details on meeting this requirement. **A separate approval letter from the R&D Committee is no longer required as part of the application, but is required prior to funding as part of the Just in Time (JIT) document approval process.**

1.B. Permission to Submit for Individuals

Permission for an individual to submit a Career Development CDA-1 award is conveyed solely by the terms of the approved letter of intent (LOI). An approved LOI is valid only for the ORD Service and Career Development level specified in the LOI approval letter. The PD/PI must have at the appropriate VA appointment in place at the time the Career Development Award is funded (See Personnel Sections A and B under Budget Guidance).

2. Cost Sharing or Matching

Not Applicable

3. Other—Special Criteria

3. A. Location of Research Space

VA Career Development awardees must perform all work on-site or request a waiver for any part of their work that can not be performed on premises. If the off-site facility is controlled by a VA mentor, the mentor must have an approved off-site waiver (refer to [VHA Handbook 1200.16](#)). Requests for waivers must include strong justification.

All non-VA performance sites must be included in the Project/Performance Site Locations component of the SF424 application package.

3. B. Duplicate Submissions

A proposal submitted to HSR&D may not be concurrently submitted to any other VA-ORD Service (RR&D, CSR&D, or BLR&D).

Section IV. Application and Submission Information

For a completed SF424 (R&R) application package to be submitted, a one-time institutional registration is required for each VA medical center at both:

- Grants.gov (<http://www.grants.gov/GetStarted>) and
- eRA Commons (<http://era.nih.gov/ElectronicReceipt/preparing.htm>)

In addition, the PD/PI named in Box 14 on the SF424 (R&R) Cover Component must be individually registered in the NIH eRA Commons.

- A PD/PI who is also an Authorized Organization Representative/Signing Official (AOR/SO) must have separate Commons accounts for each role.
- If the applicant has a PD/PI role and an Internet Assisted Review (IAR) role, however, both roles should exist under one Commons account.
- The eRA Commons account for the PD/PI must be affiliated with the applicant's VA medical center.
- This registration/affiliation must be done by the AOR/SO or their designee who is already registered in the Commons.

Both the PD/PI and AOR/SO need separate accounts in the NIH eRA Commons since both are authorized to view the application image.

Note that if a PD/PI is also an NIH peer-reviewer with an Individual DUNS and CCR (Grants.gov) registration, that particular DUNS number and CCR registration are for the individual reviewer only. **That individual DUNS number should not be used on any SF424 (R&R) application submitted in response to this RFA.**

1. Request Application Information

Applicants must download the specific SF424 (R&R) application forms for this RFA through Grants.gov/Apply. Click on the link to "Download a Grant Application Package" and then enter the RFA number from page 1 of this announcement in the middle box labeled "Funding Opportunity Number." **VA-ORD RFA Numbers cannot be found by using the Grants.gov search engine.**

Note: Only the forms package directly attached to a specific RFA can be used to respond to that RFA. You will not be able to use any other SF424 (R&R) forms (e.g., sample forms, forms from another RFA), although some of the "Attachment" files may be useable for more than one RFA.

Adobe Reader 8.1.1 or higher is required to open and work on the SF424 (R&R) application forms for this RFA; version 9.0 or higher is strongly recommended. The full version of Adobe Acrobat is not required (**see the VA SF-424 Application Guide for further information on use of Adobe Reader and Acrobat**).

For further assistance downloading the package, contact Grants.gov Customer Support at <http://grants.gov/CustomerSupport>.

2. Content and Form of Application Submission

Prepare all applications using the SF424 (R &R) application forms for this RFA in accordance with the VA Application Guide SF424 (R&R) found at <http://vaww.research.va.gov/funding/electronic-submission.cfm>.

The SF424 (R&R) application has several components. Some components are required, others are optional. The forms package associated with this RFA in Grants.gov/Apply includes all applicable components, required and optional. A completed application in response to this RFA includes the data in the following components:

Table 1. Components of a VA-ORD Application

Document	Required	Optional	Instructions*
SF424 (R&R) Cover Component (Applicant Information, Project Title, etc)	✓		Section 4.2
SF424 (R&R) Other Project Information (Abstract, Relevance, Introduction to Revised Application, Research Plan, VA Career Plan, Mentoring Plan, Progress Report Publications, Human Subjects, Vertebrate Animals, Biohazards, Letters of Support, Appendices)	✓		Section 4.3
SF424 (R&R) Project/Performance Site Locations	✓		Section 4.4
SF424 (R&R) Senior / Key Person Profile(s) (Biosketches and Current & Pending Support)	✓		Section 4.5
SF424 (R&R) Budget [†]	✓		Section 4.6
SF424 (R&R) Subaward Budget Attachment Form [‡]		n/a	Section 4.7

*Sections refer to the VA Application Guide SF424 (R&R) found at <http://vaww.research.va.gov/funding/electronic-submission.cfm>

[†] Application packages for VA-ORD funding opportunities include only the SF424 (R&R) Budget; modular budgets are not accepted. A budget component must always be submitted.

[‡] **Subaward Budgets are not used for CDA awards. All requested funds must be listed in the main Budget.**

Guidance specific for this RFA:

The instructions in this RFA may differ from, and supersede, the general instructions contained in the VA-SF424 Application Guide.

Unless otherwise noted, all instructions contained in the VA-SF424 Application Guide must be followed. Failure to follow instructions may cause delays in submission or withdrawal of proposals from review.

SF424 Other Project Information Component

Table 2 below contains descriptions of the required content of the separate files that must be attached to Item 12 “Other Attachments” of the SF424 Other Project Information Component (section 4.3 of the VA-SF424 Application Guide).

Note: The file names indicated in boldface, italic type in the table below are mandatory and may not be changed (unless specifically indicated in the table below). There are no spaces in the required filenames, only the underscore character.

Incorrect file names will cause warnings and/or errors to be generated and may prevent the application from being processed in eRA Commons.

Table 2: Other Project Information Component Attachments for Item 12

Attachment and Required File Name	Instructions	Page Limit
1. Introduction to Application (for Resubmission only) <i>01_VA_Intro.pdf</i>	The Introduction (formerly called Response to Prior Review) is required for all Resubmission applications and may not exceed three pages. Please follow the instructions below depending on whether your previous application was submitted a) through Grants.gov or b) prior to implementation of Grants.gov.	3
	a) Resubmissions of applications previously submitted through Grants.gov: The application must be marked “Resubmission” in Box 8 on the SF424 (R&R) Cover Component and the 2-letter R&D Service designation and serial number of the previously assigned application/award number (e.g., CX123456) must be entered in Box 4a (Federal Identifier); do not include any other portion (e.g., 1 01 or -01A1) of the number.	

Attachment and Required File Name	Instructions	Page Limit
<p>1. Introduction to Application (cont)</p> <p>2. Specific Aims 02_VA_Specific_Aims.pdf</p>	<p>b) Resubmissions of previously reviewed applications that were submitted on paper or CD: The application must be marked as “New” in Box 8 on the SF424 (R&R) Cover Component you must attach your Introduction as an Appendix. See “Appendices” in this table for further details.</p> <p>Additional information on resubmission applications can be found in the Executive Summary.</p> <p>Specific Aims</p> <p>Describe the short-term and long-term objectives of the CDA in terms of both the applicant’s career trajectory and the potential impact of the proposed research on the quality or delivery of veterans health care.</p> <p>List succinctly the specific objectives of each project proposed (e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to clinical practice).</p> <p>State concisely the goals of each proposed project and summarize the expected outcome(s), including the impact that the results of the proposed research will exert on the research areas involved.</p>	<p>1</p>
<p>2a. Research Plan 02a_VA_Research_Plan.pdf</p>	<p>The Research Plan must include sufficient information needed for evaluation of the project, independent of any other document (e.g., previous application). Be specific and informative.</p> <p><u>If the proposal is a resubmission</u>, the revised research plan must address all the concerns outlined in the highlights on the summary statement as well as major issues identified by reviewers of any previous submission. Substantial scientific changes must be marked in the text of the application by bracketing, indenting, or change of typography. Do not underline or shade the changes. Deleted sections should be described but not marked as deletions. If the changes are so extensive that essentially all of the text would be marked, explain this in the Introduction. The Work Accomplished section needs to include any new work accomplished since the previous submission.</p>	<p>9 Total</p>

Attachment and Required File Name	Instructions	Page Limit
2a. Research Plan (cont)	<p>In general, the Research Plan should include the following sections:</p> <p>Background and Significance</p> <p>Briefly sketch the background leading to the present application. Present the scientific rationale and theoretical framework for the proposed research, and discuss relevant research, completed or underway, inside and outside VA. Critically evaluate existing knowledge, and specifically identify the gaps that the proposed research is intended to fill. State concisely the importance and health relevance of the work described in the research plan by relating the specific aims to the broad, long-term research and career objectives.</p> <p>If the aims of the application are achieved, state how scientific knowledge or clinical practice will be advanced. Describe the effect of these studies on the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field. 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.</p> <p>Preliminary Studies</p> <p>Preliminary data often aid the reviewers in assessing the likelihood of the success of the proposed project. If applicable, use this section to provide an account of the PD/PI's or mentors' preliminary studies pertinent to this application, including his/her preliminary experience with and outreach to the proposed racial/ethnic group members, when relevant. This information will also help to establish the experience and competence of the investigator to pursue the proposed project. For epidemiology research proposals, pilot data demonstrating feasibility of obtaining samples and/or data needed for the project must be included, if applicable. The experience/competence of key collaborators may be briefly described.</p> <p>Research Design and Methods</p> <p>Describe the planned project(s) as fully as possible, including basic study design, sampling plan, control or comparison groups, methods for data collections and analysis, and specific techniques and measures. Specify the kinds or sources of data to be used, how hypotheses will be tested, aggregate and subgroup analyses, and provisions for ensuring data quality and adherence to the study protocol. Although projects earlier in the timeline may be more fully</p>	<p>2-3 (recommended)</p> <p>4-6 (recommended)</p> <p>Although no specific number of pages is recommended, be as succinct as possible.</p>

Attachment and Required File Name	Instructions	Page Limit
2a. Research Plan (cont)	<p>developed than projects later in the timeline, describe how the projects are conceptually linked to each other and to the career plan. Consider:</p> <ol style="list-style-type: none"> 1. How is the study design suited to the specific research question(s) and population? What are the advantages and disadvantages of this approach? Describe new methodologies to be used and why they are preferred over existing methods. Discuss potential problems and limitations to the proposed methods and/or procedures and possible alternative approaches to achieve specific aims. 2. If the study uses “usual care” as either the baseline or as a comparison group, usual care must be defined. 3. Where will the study take place? Why is this setting or geographic location appropriate? Will the results be applicable to other places or populations? 4. What are the characteristics of the study population? How will the sample be selected and what steps will be taken to secure and retain the needed number of subjects (and controls, if applicable)? What steps will be taken to ensure adequate representation of women and minorities? What is the estimated sample size and how was it derived? What assumptions were made regarding the magnitude of the expected treatment effect? At what level of power can inferences be drawn? 5. Identify and define the dependent and independent variables and explain their selection. How will the major variables be measured and how will they be linked in the analysis? Comment on the reliability, validity, and appropriateness of the proposed measures for the study. NOTE: If new or unpublished measures are to be used, the data collection instruments must be submitted as part of the appendix. 6. What is the data collection strategy and timeline? What are the potential problems in collecting data and controlling data quality? How will these problems (e.g., missing data, respondent drop-out, interviewer bias) be addressed? 7. What is the strategy for data analysis? Outline the planned analyses, indicating which variables will be used in which analyses and the order in which analyses will be done (do not merely name proposed statistical tests). What are the strengths 	

Attachment and Required File Name	Instructions	Page Limit
2a. Research Plan (cont)	<p>and limitations of this analytic strategy? Include power calculations as appropriate. Power calculations should be described in terms of clinical significance, if appropriate, as well as statistical significance.</p> <p>8. Describe any novel concepts, approaches, tools, or technologies for the proposed studies. Discuss the potential difficulties and limitations of the proposed procedures and alternative approaches to achieve the aims. Include a timeline.</p>	
<p>2b. VA Career Plan <i>02b_VA_Career_Plan.pdf</i></p>	<p>Candidate's Background</p> <p>Use this section to provide any additional information not described in the Biographical Sketch Format Page such as research and/or clinical training experience or VA Service.</p> <p>Career Goals and Objectives</p> <p>Describe your past scientific history, indicating how the award fits into past and future research career development. It is important to justify the award and how it will enable you to develop or expand your research career. Describe the expected results of the experience in terms of the benefit to VA and to you in terms of your research program. Commitment to and goals for professional advancement within VA should be discussed.</p> <p>Training Activities During Award Period</p> <p>Stress the new enhanced research skills, techniques, and knowledge you will acquire as a result of the proposed award. Describe structured activities, such as course work or technique workshops, which are part of the developmental plan. If course work is included, provide descriptive titles. Briefly discuss each of the activities, except research, in which you expect to participate. Include a percentage of time involvement for each activity by year, and explain how the activity is related to the proposed research and the career development plan.</p>	<p>5 Total</p>
<p>2c. Mentoring Plan <i>02c_VA_Mentoring_Plan.pdf</i></p>	<p>This section should be completed by the applicant to summarize the entire mentoring plan. All mentors, consultants and collaborators involved with the proposed research and career development program should be identified. Briefly describe their roles, anticipated contributions, and interactions with respect to the career development plan. Describe respective areas of expertise and how they will be combined and coordinated to enhance the career development.</p>	<p>3 Total</p>

Attachment and Required File Name	Instructions	Page Limit
3. Progress Report Publication List <i>03_VA_Prog_Report_Pubs.pdf</i>	Do not use. Does not apply.	
4. Human Subjects <i>04_VA_Hum an_Subjects.pdf</i>	<p>This attachment is required if you checked the box marked “Yes” for Question 1 on the Other Project Information Component (Are Human Subjects Involved?) This section covers the information regarding the Protection of Human Subjects. In this attachment, the following four headings should be used and fully described. Refer to Parts II and III of the VA Application Guide SF424 (R&R).</p> <ol style="list-style-type: none"> 1. Risk to Subjects <ul style="list-style-type: none"> • <i>Human Subjects Involvement and Characteristics.</i> Describe the proposed involvement of human subjects in the work outlined. 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. Indicate whether all subjects recruited for the study will be veterans or whether non-veterans will also be included. Justification must be provided for recruitment of non-veteran subjects. • <i>Potential Risks.</i> Describe the potential risks to subjects (physical, psychological, social, legal, or other) and assess their likelihood and seriousness to the subjects. • <i>Sources of Materials.</i> 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. Justification must be provided for use of biological samples from non-veteran subjects. 	None

Attachment and Required File Name	Instructions	Page Limit
4. Human Subjects (cont)	<p>2. Adequacy of Protection from Risk</p> <ul style="list-style-type: none"> • <i>Recruitment and Informed Consent.</i> 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. NOTE: The informed consent document may not be submitted at this time. • <i>Protection Against Risk.</i> Describe the planned procedures for protecting against or minimizing potential risks, including risks to confidentiality and data security, 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. <p>3. Potential benefits of research to subjects 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.</p> <p>4. Importance of knowledge to be gained. Discuss the importance of the knowledge 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.</p> <p>In addition, the inclusion of women, minorities and/or children must be addressed.</p> <p>Children may not be included in VA-approved research conducted by VA investigators while on duty, or conducted at VA facilities or approved off-site locations, unless a waiver has been granted by the Chief Research and Development Officer. Refer to Part II of the VA-ORD Application Guide SF424 (R&R).</p>	
5. Vertebrate Animals <i>o5_VA_Animals.pdf</i>	Do not use. Does not apply to HSR&D.	None
6. Multiple PD/PI Leadership Plan <i>o6_VA_Multiple_PI.pdf</i>	Do not use. Does not apply.	None

Attachment and Required File Name	Instructions	Page Limit
7. Consortium/Contractual Agreements <i>o7_VA_Agreements.pdf</i>	This attachment should only be used to describe existing consortium or contractual agreements that are relevant to the proposed research; new agreements to perform a portion of the proposed research will not be considered binding to VA. Do not include IPAs here.	None
8. Director's Letter <i>o8_VA_Director_Letter.pdf</i> The required file name for this attachment may generate a warning message from eRA Commons	A signed copy of the letter of support from the medical center Director must be submitted as a separate attachment and must include the following: <ul style="list-style-type: none"> • A statement that the Director understands the impact of the proposed research on the facility's organization and that he/she endorses the project. • Where the research will be conducted, if any off-site waivers are included with the application, and that the VA space described in the application and necessary support of the VA facility will be available. • Commitment to provide a VA-paid appointment for a clinician PD/PI for the duration of the CDA-1 award must be addressed. • Commitment to offer a clinician PD/PI a VA staff appointment (at least 5/8ths) at the completion of the Career Development Award must be addressed. <u>Proposals submitted without this attachment will not be accepted for review.</u>	
8a. Letters of Support <i>o8a_VA_Letters.pdf</i> The required file name for this attachment may generate a warning message from eRA Commons	This section is for letters/memoranda from all individuals confirming their roles/participation in the project. Copy of the LOI Approval Letter Letters by the Mentor and Co-mentor(s) Letters from the mentor and co-mentor(s) documenting their role and willingness to participate in the project must be included in this section of the application. As applicable to the mentoring role, each member of the mentoring team must explain how they will contribute and work together in the development of the candidate's research career. The letters should include the following:	None
	1. Describe how the planned activities will be structured to prepare the candidate to submit a	

Attachment and Required File Name	Instructions	Page Limit
8a. Letters of Support (cont)	<p>competitive CDA-2 proposal. This description must include not only research, but also other developmental activities, such as seminars, scientific meetings, training in the responsible conduct of research, and presentations. It should discuss expectations for publications over the entire period of the proposed project and define what aspects of the proposed research project the candidate will be allowed to take with him/her to start their own research program.</p> <ol style="list-style-type: none"> 2. The nature and extent (percent effort) of supervision and mentoring of the candidate, and commitment to the candidate's development that will occur during the award period. 3. Describe the nature of any resources that will be committed to this CDA award. 4. The mentor should describe previous experience as a mentor, including type of mentoring (e.g., graduate students, career development awardees, postdoctoral students), number of persons mentored, dates, VA or non-VA status, and career outcomes. A table is recommended for this information. <p>A single letter signed by <u>all</u> mentors may be submitted in lieu of separate letters, provided that all required information above is included.</p> <p>Consultant Letters</p> <p>The nominee is encouraged to include letters of support from other individuals and other institutions willing to provide support and resources to the development of the nominee's research career. Any rate/charges for consultant services should be specified.</p> <p>ACOS/R&D Letter</p> <p>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.</p>	
	<p>Service Chief or Section Head Letter</p> <p>The appropriate Service Chief or Section Head must submit a statement describing the nominee's proposed clinical duties upon receiving the Career Development award.</p>	

Attachment and Required File Name	Instructions	Page Limit
8a. Letters of Support (cont)	<p>Reference Letters</p> <p>Three reference letters should be obtained from professional colleagues, former/current teachers, former mentor, etc. The reference letters are important and should address the candidate's competence and potential to develop into an independent biomedical or behavioral investigator. Only those individuals who can make the most meaningful comments about the candidate's professional training and qualifications for a research career should be used as references. Where possible, references who are not from the candidate's current department or organization, but are knowledgeable about their qualifications, should be selected.</p> <p>All memoranda/letters in this section should be scanned and submitted as a single PDF document.</p> <p>Note: Biosketches must be included in the Senior/Key Person Profiles(s) component.</p>	
<p>9. Checklist 09_VA_Checklist.pdf The required file name for this attachment may generate a warning message from eRA Commons concerning the attachment name</p>	<p>Attach a completed copy of the Electronic Submission Checklist. Check only those items that have been addressed or are applicable.</p> <p><u>Proposals with incorrectly checked boxes may not be accepted for review</u></p> <p><u>Proposals submitted without this attachment will not be accepted for review.</u></p>	
<p>10, 11,12. Appendices 10_VA_Appendix_1.pdf 11_VA_Appendix_2.pdf 12_VA_Appendix_3.pdf (additional attachments as needed: same file name format)</p>	<p>Do not use Appendices to circumvent the page limitations of the Research Plan. An application that does not observe the stated page limitations will be administratively withdrawn from review.</p> <p>A summary sheet listing all of the items included in the appendix may be included in the first appendix attachment; this is encouraged but not required.</p> <p>Appendices should be named using the following convention in the following order:</p> <ul style="list-style-type: none"> • Attachment number, starting with 10, then 11, 12, etc. • Underscore • The phrase "VA_Appendix" • Underscore • Appendix number starting with 1, then 2, 3, etc. • Underscore • Brief description of the contents (e.g., Abbreviations, Accepted_Manuscripts, Patents) 	

Attachment and Required File Name	Instructions	Page Limit
<p>10, 11, 12. Appendices (cont)</p> <p>For Appendix names only: If descriptive text is included in an attachment name before the “.PDF” as described in the example in bold, you will receive a warning message from eRA Commons concerning the attachment name. This warning can be safely ignored.</p>	<ul style="list-style-type: none"> • “.pdf” <p>See examples below.</p> <p>The first appendix should be the list of abbreviations used in the application; it should be named: “10_VA_Appendix_1_Abbreviations.pdf.”</p> <p>For resubmissions of applications that have not yet been through the Grants.gov submission mechanism, the next appendix should contain the previous reviews, summary statement, and your response. The file should be named “11_VA_Appendix_2_Response.pdf”</p> <p>New and resubmission applications may include the following materials in the Appendices.</p> <p>Similar appendix material should be combined within an attachment. For example, please place all accepted, but not yet published, manuscripts in one attachment.</p>	
	<ul style="list-style-type: none"> • Applicants may submit up to a total of 3 publications as PDF attachments. They may be of the following types: <ul style="list-style-type: none"> ○ Manuscripts and/or abstracts accepted for publication but not yet published. ○ Manuscripts and/or abstracts published, but a free, online, publicly available journal link is not available. ○ Patents directly relevant to the project. <p>Do not include unpublished theses or abstracts/manuscripts that have been submitted but not yet accepted for publication.)</p> <p>Published manuscripts and/or abstracts that have a free, publicly available online journal link should not be included in the appendix material. The URL or PMC submission identification numbers should be included along with the full reference in the Bibliography and References cited section, the Progress Report Publication List section, and/or</p> 	

Attachment and Required File Name	Instructions	Page Limit
10, 11, 12. Appendices (cont)	<p>the Biographical Sketch section.</p> <ul style="list-style-type: none"> • Surveys, questionnaires, data collection instruments, clinical protocols, and informed consent documents may be submitted as PDF attachments. • Photographs or color images of gels, micrographs, etc., are no longer accepted as Appendix material. These images must be included in the Research Plan PDF and will count toward the 19-page limit. Images embedded in publications are still allowed. 	

R&R Budget Component

Budget Guidance for CDA Appointment

While the dollar fields allow cents to be entered, **all dollar fields should be rounded to the nearest whole number.**

Personnel (sections A and B): Starting with the Contact PD/PI, list all personnel involved in the project. Mentors, consultants, and other supporting personnel must be entered with \$0 salary. In the appropriate columns list their names, role in the research proposed and the calendar months effort each will devote to the project. Salaries for the PD/PI are to include fringe benefits to be paid from HSR&D funds and may include cost-of-living adjustments (maximum of 3% per year) in out years.

No other project funds are provided by the CDA-1.

Only calendar months should be used in section A of a VA Budget. To calculate calendar months for VA-paid employees, or employees with a joint appointment, use the following table (**use only VA hours spent on the project**).

Hours per 40 hour VA work week	Calendar Months
1	0.3
5	1.5
10	3.0
15	4.5
20	6.0
25	7.5
30	9.0

35	10.5
40	12

For Physicians (licensed to practice in US and eligible for a VA-paid appointment):

- 1) 9 calendar months (6/8ths) effort is required on the CDA, for which HSR&D will provide full salary and fringe support**
- 2) The medical center must provide a VA-paid clinical appointment**

For Non-Physicians:

- 1) A minimum of 7.5 calendar months effort is required for non-physician applicants**
- 2) A maximum of 12 calendar months effort may be requested**
- 3) HSR&D will provide salary commensurate with calendar months effort**

Total VA effort includes the work anticipated in this application, participation in other VA and non-VA research, service toward core facilities, teaching, supervision of students/trainees, participation in research centers, service on committees, etc.

Salary support may be requested *only* for activities that are uncompensated from other sources, such as the academic affiliate or other funding agencies. Any differences in the calendar months effort for the work proposed and total VA effort (salary support) must be described fully in the budget justification.

Budget Justification (Section K)

There is a single justification for all budget years, so include all justification information for all years in the same file.

Fully explain the role and calendar months effort of the PD/PI and all listed personnel. Indicate Grade and Step for all VA employees and identify anyone paid through an IPA. If the PD/PI is a non-clinician scientist paid by the research appropriation CC103, fully describe the basis for any difference in the calendar months effort for the work proposed and total VA effort (salary support). Submission of the application signifies facility agreement to have the non-clinician PD/PI perform the work described to justify salary. Physicians and dentists who are not licensed to practice in the United States and are requesting salary must be clearly identified as such and justified in this section. For epidemiology research proposals, the role(s) of an epidemiologist and/or statistician listed in the personnel section of the budget must be clearly delineated here.

SPECIAL INSTRUCTIONS

The Commons ID of the PD/PI identified in Box 14 of the SF424 (R&R) Cover Component must be included in the “Credential” field of the Research & Related Senior/Key Person Profile component. **Failure to include this data will cause the application to be rejected.** Multiple PD/PI’s are not permitted for CDA applications.

An investigator profile (Page 18), including the Commons ID, must be completed in ePromise for the PD/PI.

3. Submission Dates and Times

3.A. Submission, Review, and Anticipated Start Dates

See [Table 4](#) next page.

Deadlines. Avoid delays and misunderstandings by reading and following the instructions carefully. Table 4 contains deadlines for HSR&D Merit Review Award Program and Research Career Development Program applications.

Table 4. Deadline, Review, and Award Dates for 2011

SUBMISSION CYCLES:	Winter 2011 (2011/05 Council)	Summer 2011 (2011/10 Council)
Letter of Intent Deadline	October 15 and unexpired prior approvals	April 15 and unexpired prior approvals
First day to submit electronic applications (to Grants.gov)	November 15	May 16
Down to the Wire Deadline (to Grants.gov) – after this date the 2-day correction window cannot be used. <i>Applicants should target this deadline!</i>	December 8	June 8
Last Possible Submission Date to Grants.gov Assumes no errors (Grants.gov or eRA) will be identified or need to be corrected WARNING: If you submit an application on June 10/ December 10 to Grants.gov and there are errors identified by Grants.gov or eRA there will <u>not</u> be time to fix the errors, resubmit, and have the application received and verified by eRA. <u>You will miss the submission and verification deadlines.</u> If your proposal is accepted by eRA (with no errors), do not withdraw the application during the two business day examination window as <u>you will miss the</u>	December 10 6:00 pm local time	June 10 6:00 pm local time

SUBMISSION CYCLES:	Winter 2011 (2011/05 Council)	Summer 2011 (2011/10 Council)
<u>verification deadline.</u>		
Verification Deadline (in eRA) <u>Once verified, an application is considered final and no other version will be accepted for review.</u>	December 15	June 15
Review and Award Cycles:		
Scientific Merit Review	March	August
Administrative Review	Jan -Feb	September
Earliest Project Start Date	July	January
Note: VA-ORD R&D Services may not always be able to honor the requested start date of an application; therefore, applicants should make no commitments or obligations until confirmation of the start date by the awarding service.		

*If the deadline falls on a weekend or Federal holiday, the due date is the next business day.

‡Verification occurs 2 business days after receipt of an application with no errors or only warnings.

Renewal of Awards. Research Career Development awards may not be renewed.

3.A.1. Letter of Intent

An approved letter of intent is required for this funding opportunity and must be attached (See Table 2.8a.).

3.B. Submitting an Application Electronically

To submit an application in response to this RFA, applicants should access this RFA via http://www.grants.gov/applicants/apply_for_grants.jsp and follow steps 1–4. Note: Applications must be submitted electronically. **PAPER APPLICATIONS WILL NOT BE ACCEPTED.**

3.C. Application Processing

All new or changed/corrected applications must meet 2 separate deadlines:

- .1 **Submission and acceptance in Grants.gov on or before 6:00 pm (local time) of the Last Possible Submission Date (submission deadline) in Table 4**

AND

2. **Verification by eRA Commons on or before the Verification Deadline in Table 4**

All proposals should be proofread carefully prior to submission.

Applications that miss either deadline will not be accepted for review.

NOTE: Applications accepted by eRA Commons with no errors (with or without warnings) are provided a two-business day examination window to check for errors. The application is automatically verified on the third business day if it is not explicitly rejected (withdrawn) by the signing official (SO) during the 2-day examination window.

Once verified, an application is considered final and no other version will be accepted for review. It is the responsibility of the PD/PI and AOR/SO to check for errors during the 2-day examination window.

Applications which fail to follow formatting and content requirements or are incomplete will be administratively withdrawn and not reviewed.

It is strongly recommended that submissions to Grants.gov be completed by the Down to the Wire Deadline in Table 4 to ensure sufficient time to correct any errors that may be identified by either Grants.gov or eRA Commons.

New or Changed/Corrected applications submitted to Grants.gov and accepted after the “Last Possible Submission Date” in Table 4 will cause the verification deadline to be missed; late applications will not be accepted for review.

Once an application package has been successfully submitted through Grants.gov, any errors have been addressed, and the assembled application has been created in the eRA Commons, the PD/PI and the Authorized Organization Representative/Signing Official (AOR/SO) have 2 business days to view the application image.

Please remember that some warnings may not be applicable or may only need to be addressed after application submission (i.e., JIT). Reminder: warnings do not stop further application processing. If an application submission results in warnings (but no errors), it will automatically move forward after two business days if no action is taken.

During the 2 business day examination period, the electronic image of submitted proposals (e-application in eRA Commons) must be reviewed to ensure that there are no transmission errors. PIs are responsible for printing out and reviewing the electronic image of the e-application during the 2 business day period in order to check the submission for format, transmission or content errors.

E-applications which do not meet formatting and content requirements or are incomplete will be administratively withdrawn and not reviewed. No exceptions will be made. It is the responsibility of the PI to check that each and every page is correct and that all elements of the proposal have been included. After an application has been submitted, the e-application should be checked for problems with font type, font size, margins, characters per inch and lines per inch. It is advised that PIs print out a page of the Research Plan during the 2 business day examination period and MANUALLY check for these types of errors as eRA does

not generate an error message for them. However, such errors WILL cause the proposal to be administratively withdrawn.

A previously submitted application must be rejected/withdrawn before a changed/corrected application can be submitted. **Duplicate applications will be administratively withdrawn and will not be reviewed.**

If an application is accepted by eRA with no errors, do not reject/withdraw an application during the 2 business day examination window unless there is sufficient time to resubmit a changed/corrected application by the submission deadline.

If everything is acceptable, no further action is necessary. The application will automatically move forward for processing after 2 business days.

Both the AOR/SO and PD/PI will receive e-mail notifications when the application is rejected or the application automatically moves forward in the process after 2 days.

Once an application becomes verified it is considered final and no changed/corrected application will be accepted for review.

VA-ORD will not penalize the applicant for an eRA Commons or Grants.gov system issue. However, unless there is documentation of a processing error at either Grants.gov or eRA Commons, applications that fail to meet either the submission or verification deadline will not be accepted for review.

Once an application becomes verified, it will be evaluated for completeness by the HSR&D Program Review staff. **Applications which fail to meet content and formatting requirements or are incomplete will be administratively withdrawn by HSR&D Program Review staff and will not be reviewed.**

No additional or replacement information will be accepted after submission of the proposal, unless requested by the Program Review staff. The only exceptions are official letters of acceptance for publication of manuscripts submitted by the PD/PI. These may be sent by e-mail to the Scientific Merit Review Program Manager (vhacoscirev@va.gov) at any time.

All Merit Review proposals must include a separate attachment containing a signed copy of the letter of [support from the Director](#) of the Medical Center documenting that sufficient resources (i.e., space, equipment, time, appointment, etc.) are available to the investigator. Review of applications submitted to VA-ORD without this attachment will not be accepted for review (see [Table 2](#), Section 8).

There will be an acknowledgement of receipt of applications from Grants.gov and eRA Commons. The submitting AOR receives the Grants.gov acknowledgments. The AOR and the

PD/PI receive eRA Commons acknowledgments. Information related to the assignment of an application to a Merit Review Panel is also in eRA Commons.

The eRA system will make every effort to send an email to the PD/PI and AOR/SO summarizing the download and validation results.

NOTE: Since email can be unreliable, it is the responsibility of the applicant and AOR/ Signing Official(s) to periodically check on the application's status in eRA Commons.

4. Intergovernmental Review

Not Applicable

5. Funding Restrictions

Not Applicable

6. Other Submission Requirements

PD/PI Credential (e.g., Agency Login)

VA-ORD requires the PD/PI to fill in his/her Commons User ID in the "PROFILE – Project Director/Principal Investigator" section, "Credential" log-in field of the "Research & Related Senior/Key Person Profile" component.

In addition, the investigator profile (Page 18) in ePromise must be completed (including the Commons ID) for the PD/PI.

Organizational DUNS

The applicant organization must include its DUNS number in its Organization Profile in the eRA Commons. This DUNS number must match the DUNS number provided at CCR registration with Grants.gov.

Appendix Materials

Applicants **must** follow the specific instructions on Appendix materials as described in the VA-ORD Application Guide SF424 (R&R).

Plan for Sharing Research Data

Not Applicable

Sharing Research Resources

Not Applicable

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process.

2. Review Process

Overview

Applications submitted in response to this RFA will be reviewed by a merit review committee composed of mid-to-senior level HSR&D investigators who are accomplished principal investigators and experienced mentors with expertise in relevant scientific disciplines and current HSR&D research areas. The purpose of the committee is to evaluate the scientific and technical merit of applications as well as applicant potential, mentor qualifications, and the training program. The review committee does not make funding decisions.

All applicants will receive a written “**Summary Statement**” which contains the major points of criticism and all of the reviewers’ pre-meeting written critiques.

Information about review committee membership may also be obtained from the HSR&D web site at <http://www.hsr.d.research.va.gov/funding/cdp/>.

Scoring

Committee members are instructed to evaluate research applications by addressing the review criteria described below. For each application that is discussed, a final global priority score will be given by each eligible committee member (without conflicts of interest) following the panel discussion. Each member’s global score will reflect his/her evaluation of the overall impact of the project in its entirety, rather than an arithmetic formula applied to the reviewer’s evaluation of each criterion. VA-ORD uses a scoring scale of 1.0 to 5.0; the final priority score for each discussed application will be determined by calculating the arithmetic average of all the eligible members’ scores, and multiplying the average by 100. RFAs for different types of funding opportunities may have different and/or additional review criteria.

All applicants will receive a written “**Summary Statement**” which contains the Program Description/Abstract and Project Narrative (Relevance) sections from the submitted application, all of the reviewers’ pre-meeting written critiques, and a roster of the review meeting participants.

The Summary Statement will also include a summary of the members’ discussion during the review meeting, the final priority score, recommendations of the committee, and administrative notes of special considerations.

CDA-1 Evaluation Criteria

Career and Mentoring Plans: Is the training program comprehensive with didactic courses planned, mentor-applicant interactions described, and research monitoring detailed? Is the proposed program clearly designed to lead to the individual’s growth and development as a VA health services researcher? Does the applicant have clear potential

evidenced by training, research experience, and letters of support? Do the mentor(s) have excellent research and teaching credentials, well-documented history of successful training, and adequate time available to train the applicant? If there will be more than one mentor, is there a plan for coordination of mentoring efforts?

Significance: Does this study address an important Veterans' health problem? If the aims of the application are achieved, how will this advance scientific knowledge or clinical practice? What will be the effect of these studies on the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Approach: Are the conceptual or clinical framework, design, methods, and analyses adequately developed, well integrated, well reasoned, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?

Innovation: Is the project original and innovative? Does the project challenge existing paradigms or clinical practice; address an innovative hypothesis or critical barrier to progress in the field? Does the project develop or employ novel concepts, approaches or methodologies, tools, or technologies for this area?

Investigator: Are the investigators appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the PD/PI and other researchers on the project? Does the investigative team bring complementary and integrated expertise to the project (if applicable)?

Environment: Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed studies benefit from unique features of the scientific environment or subject populations, or employ useful collaborative arrangements? Is there evidence of institutional support?

Feasibility: Is there sufficient evidence to determine that the proposed studies can be successfully completed? Is there sufficient evidence for successful recruitment and enrollment of subjects, if applicable, availability of animal models, attainment of samples and/or data, etc.?

Adequacy of Response to Previous Feedback: If the proposal is a re-submission, the applicant will have received detailed comments on the previously submitted proposal. Any subsequent proposal is expected to highlight changes made in response to such feedback or to defend the earlier plan.

2.A. Additional Review Criteria

In addition to the above criteria, the following issues may be considered in the determination of scientific merit.

Protection of Human Subjects: Reviewers will also evaluate the proposed use of human subjects and protections from research risk relating to their participation according to the following criteria: (1) Risk to subjects; (2) Adequacy of protection against risks; (3) Potential benefits of the proposed research to the subjects and others; (4) Importance of the knowledge to be gained; and (5) Data and safety monitoring for clinical trials.

Inclusion of Women, Minorities, and Children: When human subjects are involved in the proposed clinical research, reviewers will also evaluate the proposed plans for inclusion of minorities and members of both sexes/genders, as well as the inclusion of

children in clinical research. **Research involving children is restricted and must not be conducted by VA investigators while on official duty or at VA or approved off-site facilities unless a waiver has been granted by the Chief, Research and Development Officer.**

If such a waiver is approved, the involvement of children as subjects in research must be in compliance with all applicable Federal regulations pertaining to children as research subjects (see [VHA Handbook 1200.5](#), Appendix D).

NOTE: Congressionally-mandated research programs that involve children are exempt from this policy

Resubmission Applications (formerly “revised/amended” applications): Are the responses to comments from the previous scientific review group adequate? Are the improvements in the resubmission application appropriate?

2.B. Additional Review Considerations

Budget and Period of Support: The appropriateness of the proposed budget and the requested period of support in relation to the proposed research may be assessed by the reviewers. The priority score should not be affected by the evaluation of the budget.

2.C. Sharing Research Data

Not Applicable

2.D. Sharing Research Resources

Not Applicable

2.E. Disapproved Proposals

A proposal may be disapproved if the committee determines that the proposed studies are unethical or are unlikely to yield useful information.

- Proposals that are disapproved are not given a numerical score and may not be resubmitted.
- Studies disapproved for ethical considerations may not be carried out in VA space, with VA resources, even if the project is funded by another agency

3. Anticipated Announcement and Award Dates

The earliest possible start date is June 1 for proposals submitted for the winter round (due December 15th) and January 1 for proposals submitted for the summer round (due June 15th).

Section VI. Award Administration Information

1. Award Notices

After the peer review of the application is completed, the PD/PI (only) will be able to access his or her Final Score and Summary Statement (written critique) via the NIH eRA Commons after this information has been released by HSR&D Staff. A separate notification of the review meeting outcome will be sent to the medical center director, ACOS/R&D, AO/R&D and if there is a HSR&D Center at the PI's location, to the Center (COE, REAP) Director.

If the application is under consideration for funding, VA-ORD will request "Just-in-Time" information from the applicant.

The summary statement will be accessed through eRA Commons.

2. Administrative and National Policy Requirements

Research Integrity. HSR&D is committed to the highest standards for the ethical conduct of research. Maintenance of high ethical standards requires that VA medical centers and investigators applying for, and receiving, Career Development Awards have appropriate procedures to preclude the occurrence of unethical research practices. All research data must be retained for 5 years after completion of a research project.

The PD/PI and others associated with the research must subscribe to accepted standards of rational experimental research design, accurate data recording, unbiased reporting of data, respect for the intellectual property of other investigators, adherence to established ethical codes, legal standards for the protection of human and animal subjects, and proper management of research funds.

Deliberate falsification or misrepresentation of research data will result in withdrawal of an application, possible suspension or termination of an award, and potentially, suspension of the investigator's eligibility to submit proposals to HSR&D.

Acknowledging VA Research Support. By accepting a Career Development Award, the PD/PI agrees to properly acknowledge VA affiliation and support in all public reports and presentations (see [VHA Handbook 1200.19](#)). **Failure to acknowledge VA affiliation and support may result in termination of the award.**

Intellectual Property Rights. By accepting a Career Development Award, the PD/PI agrees to comply with VA policies regarding intellectual property disclosure obligations and Federal Government ownership rights resulting from the proposed work (see [VHA Handbook 1200.18](#)).

Section VII. Agency Contacts

We encourage scientific/programmatic inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants.

1. Scientific/Research Contacts:

Inquiries related to the submission and review process should be directed to the HSR&D Career development program manager, Robert Small, at Robert.small@va.gov or 202-443-5743.

2. Financial Management Contact(s):

Mary Jones at mary.jones@va.gov

Reminder: To ensure a timely response, all questions concerning electronic submission should be directed to the eRA mailbox in Outlook at: rd-era@va.gov. Telephone calls and/or emails sent to individuals may go unanswered if he/she is out of the office.