Part I - Overview Information

Department of Veterans Affairs

Participating Organizations

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

Components of Participating Organizations

Rehabilitation Research and Development (RR&D) Service, VA-ORD

Title: VA-ORD Historically Black College and University Research Scientist Training Program Award

Announcement Type

New

Update: Updates relating to this announcement are highlighted in <mark>Yellow</mark>.

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 Application Guide SF424 (R&R) available on the VA-ORD **Intranet** site at http://vaww.research.va.gov/funding/electronic-submission.cfm. **NOTE: The instructions in this RFA may differ from, and supersede, the general instructions contained in the VA Application Guide SF424 (R&R).**

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).

Funding Opportunity Announcement (FOA)/Request for Applications (RFA) Number: <mark>RX-15-010</mark>

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: <mark>October 2, 2014</mark>

Letters of Intent Receipt Date(s): Standard dates apply; please see Table 4 in Part II, Section IV.

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 application viewing 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 application viewing 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 application viewing window. Do not submit a Changed/Corrected application without "rejecting" (withdrawing) the previous successfully submitted application. If multiple versions are submitted and become verified, all versions may be returned without review.

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.

Any application submitted to Grants.gov 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)/Request for Applications (RFA) will use the non-U.S. Department of Health & Human Services (HHS) Research Project (IK2) award <mark>activity code</mark>.

- **Purpose.** In order to increase the diversity of VA researchers and to increase opportunities for minority-serving institutions to participate in federally funded research, the VA Office of Research and Development (VA-ORD) has established a Historically Black College and University Research Scientist Training Program (HBCU-RSTP), managed by the Rehabilitation Research and Development (RR&D) Service. The HBCU-RSTP qualifies as a Research Career Development Program within VA-ORD and represents 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. The HBCU-RSTP will utilize the IK2 <mark>activity code</mark> for Level 2 Career Development Awards, and is intended to provide a unique and substantial training opportunity for researchers based at HBCUs who are interested in advancing research for the benefit of our nation's Veterans. Implicit in all Career Development applications is the understanding that the applicants plan to continue their careers within VA.

- **Award Level**. This award provides salary and/or project funds to support a three to five year program of research career development and mentoring. Applicants need to demonstrate a high degree of potential in their area of interest and strong VA commitment. By the end of the award, it is anticipated that the awardees will have competed for independent research funding.

  Applications electronically submitted to VA-ORD through Grants.gov will be peer-reviewed by Career Development Program Review Panel (SRG) to provide the Director of VA-ORD with evaluations of the proposed research and make recommendations on scientific merit, budgets, funding durations, and quality/appropriateness of the proposed training and career plans.

- **Mechanism of Support.** This Request for Applications will use the IK2 <mark>activity code</mark> for Level 2 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 applications can be submitted.

- **Eligible Project Directors/Principal Investigators (PD/PIs).** Only individuals who have an **accepted letter of intent (LOI) for the current review cycle** may respond to this funding announcement.

- **Resubmissions.** For applications that have been reviewed, but not selected for funding, VA-ORD allows the submission of up to two revised (Resubmission) applications. **An LOI is valid (permits submission of applications) for only the current review cycle. An LOI must be submitted for each review cycle.** All resubmission applications must include a brief Introduction to the Revised Application that addresses the concerns raised in the previous review.

  Resubmission applications for applications that were **previously submitted electronically** must be **marked as "Resubmission" in Box 8** on the <mark>SF424 (R&R) Form</mark> and the Introduction to Revised Application submitted as an attachment named 01_VA_Intro.pdf. See Section 1 "<u>Introduction to Revised Application</u>" in Table 2 for further details. In Box 4a (Federal Identifier) of the <mark>SF424 (R&R) Form</mark>, enter only the 2-letter R&D Service designation <mark>(RX)</mark> and serial number of the previously assigned application/award number (e.g., RX123456); **do not** include any other portion of the number (e.g., 1 IO1, -A1 or –A2). You should obtain the application number from the previous Summary Statement.

  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. When submitting a "New," or "Resubmission," Type of Application, after checking the "Changed/Corrected Application" box in block 1 of the <mark>SF424 (R&R) Form</mark>, the Previous Grants.gov Tracking ID field (Box 4c) becomes required. Enter the Grants.gov tracking number for the previous application that you are correcting. You should obtain this number from your AOR/SO.

- **Renewals.** HBCU-RSTP 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 <u>Section IV.1</u> for application materials.

- **General Information.** For general information on VA Application Guide SF424 (R&R) and Electronic Submission to VA-ORD, see <u>http://vaww.research.va.gov/funding/electronic-submission.cfm</u>.

Table of Contents

Part II - Full Text of Announcement

Section I. Funding Opportunity Description

1. Research Objectives

In support of Presidential Executive Order 13256, which calls on all federal agencies to help strengthen the capacity of Historically Black Colleges and Universities (HBCUs) to increase opportunities for such minority-serving institutions to participate in and benefit from Federal programs, the VA Office of Research and Development (VA-ORD) has established the HBCU Research Scientist Training Program (HBCU-RSTP). The primary goals of this program are 1) to increase the number of individuals from underrepresented racial and ethnic groups who pursue career paths in biomedical, clinical, rehabilitation and health services research at VA Medical Centers, and 2) to partner with minority serving institutions, such as HBCUs, that are committed to increasing diversity within the scientific workforce through their education and training of clinicians and non-clinician scientists *who represent a wide range of backgrounds and experiences* in order to help advance health care for Veterans. The HBCU-RSTP qualifies as a Research Career Development Program within VA-ORD. The Research Career Development Program is an intramural funding mechanism designed to attract, develop, and retain talented researchers within VA-ORD in areas of particular importance to VA and the Veteran population that VA serves. 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. Areas of emphasis are broad and expansive encompassing basic scientific research that has strong implications for translation into clinical practice, health services research, clinical research, as well as rehabilitation strategies, interventions, and techniques, including prosthetic devices and the reintegration of Veterans into all facets of civilian life.

Applications electronically submitted to VA-ORD through Grants.gov will be peer-reviewed by the Career Development Scientific Review Group (SRG) to provide the administrator of the HBCU-RSTP 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 Funding Opportunity Announcement (FOA)/Request for Applications (RFA) will use the IK2 activity code for Career Development awards. Only one application may be submitted to

this FOA/RFA in any given review cycle and an investigator may only have one funded project from this VA-ORD FOA/RFA.

This FOA/RFA uses "Just-in-Time" information concepts.

2. Funds Available

Budget Cap: The budget for a HBCU-RSTP award is limited to salary support for the PD/PI and up to $65,000/year of research project funding. Cost of living adjustments (maximum of 3% per year) are permitted for all VA-paid salaries; cost of living adjustments are not permitted for any other budget category or for personnel on an IPA. While the salary of research personnel may increase in the out years, the total project budget cannot exceed the 65K/yr. The PD/PI salary is in addition to the 65K/yr project budget.

- For physician applicants (licensed to practice in the US and has a VA-paid clinical appointment):
  - o A minimum of 6 calendar months effort is required
  - o A maximum of 9 calendar months effort may be requested
  - o Salary commensurate with calendar months effort will be provided for physician applicants up to a maximum of 9 calendar months
  - o Medical Center must, therefore provide at least 1/8th VA-paid salary

- For non-physician applicants:
  - o A minimum of 7.5 calendar months effort is required
  - o A maximum of 12 calendar months effort may be requested
  - o Salary commensurate with calendar months effort will be provided for non-physician applicants

Duration of Award: The maximum duration of a HBCU-RSTP award is 5 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 in partnership with an HBCU.

Documentation of support for the application from the Medical Center Director must be included as a separate attachment in all applications. Applications submitted without such documentation may be administratively withdrawn. See Item 8 "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.**

1.B. Permission to Submit for Individuals

Permission for an individual to submit a HBCU-RSTP award is conveyed solely by the terms of the letter of intent (LOI). The PD/PI must have at least a 5/8ths time VA appointment at the time the HBCU-RSTP Award is funded (refer to VHA Handbook 1200.15). **Contract clinicians cannot be VA employees (i.e., have a direct, VA-paid appointment) and therefore may not seek research funding from VA-ORD, even if the terms of the contract permits or includes research activities.** An investigator profile (page 18), including the Commons ID, must be completed in ePromise for all personnel assigned the PD/PI role.

During the term of their award, non-clinician and clinician HBCU-RSTP awardees are strongly encouraged to submit an initial Merit Review application; if needed, revised applications may be submitted for 2 additional review cycles, which may extend beyond the duration of the HBCU-RSTP award.

2. Cost Sharing or Matching

Not Applicable

3. Other—Special Criteria

Applicants for the HBCU-RSTP are required to identify at least one mentor with a full-time appointment (rank of associate professor and above) at the partner HBCU and at least one mentor with an appointment at the supporting VA Medical Center to serve as their mentors for the duration of the award period.

3. A. Location of Research Space

VA Career Development awardees may perform work in an off-site mentor's laboratory. If the off-site mentor is not a VA investigator, no off-site waiver is required; if the off-site laboratory space is controlled by a VA Mentor, the mentor must have an approved off-site waiver (refer to VHA Handbook 1200.16). VA Career Development awardees may not, however, be assigned control of off-site laboratory space.

All non-VA performance sites must be included in the Project/Performance Site Locations Form of the SF424 (R&R) application package.

3. B. Duplicate Submissions

An application submitted in response to this FOA/RFA may not be concurrently submitted to any other R&D Service within VA-ORD (HSR&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/web/grants/applicants/organization-registration.html). Your VA Medical Center/health care system must be **registered as an institution at Grants.gov**. This is a one-time only registration process for all Federal agencies. However, an annual renewal of information provided to the System for Award Management (SAM) is necessary to retain active Grants.gov credentials; additional information on Registering with SAM is available from Grants.gov.
- eRA Commons (https://public.era.nih.gov/commons/public/registration/registrationInstructions.jsp)

All registrations require that applicants be issued a Dun and Bradstreet Universal Numbering System (DUNS) number. After obtaining a DUNS number, your VA Medical Center can begin both System for Award Management (SAM) (formerly CCR) and eRA Commons registrations. The same DUNS number must be used for all registrations and on the grant application itself.

Note that VA Medical Centers must complete and maintain an active entity registration in SAM **which requires renewal at least annually**. This requires that you review and update the information at least annually after the initial registration, and more frequently if required by changes in your information or another award term. The renewal process may require as much time as the initial registration. SAM registration includes the assignment of a Commercial and Government Entity (CAGE) Code for domestic organizations which have not already been assigned a CAGE Code. Use the SAM.gov "Manage Entity" function to manage your entity registrations. See the Grants Registrations User Guide at http://www.sam.gov and Registering with SAM available from Grants.gov for additional information.
For additional information regarding maintaining an active SAM registration, please see NIH Guide Notice NOT-OD-11-004.

In addition, the PD/PI named in Box 14 on the ==SF424 (R&R) Form== 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 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 FOA/RFA.**

1. Request Application Information

Applicants must download the specific SF424 (R&R) application forms for this FOA/RFA through Grants.gov/Apply. Click on the link to "Download a Grant Application Package" and then enter the FOA/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 FOA/RFA can be used to respond to that FOA/RFA. You will not be able to use any other SF424 (R&R) forms (e.g., sample forms, forms from another FOA/RFA), although some of the "Attachment" files may be useable for more than one FOA/RFA.

Software requirements for using Grants.gov have changed. Grants.gov recently revised their entire web system and it is now designed for a minimum of 1024 x 768 screen resolution. In addition, you MUST have JavaScript enabled for the system to work properly. A complete list of supported web browsers is available from Grants.gov; this list includes Internet Explorer 9 (IE 9), with "limited" support for IE 8 or IE 10, and Firefox.

Grants.gov maintains a list of software applications that allow you to successfully navigate the Grants.gov pages and complete a downloaded application package. **Adobe Reader** 10 or 11 may be **required**, depending on your operating system, **to open and work on the SF424 (R&R) application package/forms for this FOA/RFA**. The full version of Adobe Acrobat is not required (**see the VA Application Guide SF424 (R&R) for further information on use of Adobe Reader and Acrobat**).
For further assistance downloading the package, contact Grants.gov Customer Support.

2. Content and Form of Application Submission

Prepare all applications using the SF424 (R&R) application forms for this FOA/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 forms. Some forms are required, others are optional. The forms package associated with this FOA/RFA in Grants.gov/Apply includes all applicable forms, required and optional.

Table 1. Forms for a VA-ORD Application

Document	Required	Optional	Instructions*
SF424 (R&R) Form (Applicant Information, Project Title, etc)	✔		Section 4.2
SF424 (R&R) Project/Performance Site Locations Form	✔		Section 4.3
SF424 (R&R) Other Project Information Form (Abstract, Relevance, Introduction to Revised Application, Specific Aims, Research Plan, VA Career Plan, Mentoring Plan, Progress Report Publications, Human Subjects, Vertebrate Animals, Biohazards, Medical Center Director's Letter, Letters of Support, Checklist, Appendices)	✔		Section 4.4
SF424 (R&R) Senior / Key Person Profile(s) Form (Biosketches and Current & Pending Support)	✔		Section 4.5
SF424 (R&R) Budget Form†	✔		Section 4.7
SF424 (R&R) Subaward Budget Attachment Form‡		✔	Section 4.8

*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 form must always be submitted.

‡ Subaward Budgets are currently <u>not</u> being accepted for multi-site Merit Review applications. All requested funds must be listed in the main Budget, with a separate explanation and justification for each site in the Budget Justification.

Guidance specific for this FOA/RFA:

The instructions in this FOA/RFA may differ from, and supersede, the general instructions contained in the VA Application Guide SF424 (R&R).

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

SF424 (R&R) Other Project Information Form

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 (R&R) Other Project Information Form (section 4.4 of the VA Application Guide SF424 (R&R)). Templates are available on the VA-ORD Intranet at http://vaww.research.va.gov/funding/electronic-submission.cfm.

For creation of attachments and format specifications, see VA Application Guide SF424 (R&R), Part I, Section 2.3.2 Creating PDFs for Text Attachments and Section 2.6 Format Specifications for Text (PDF) Attachments.

All applications submitted to VA-ORD funding must be self-contained (i.e., without use of URLs) within specified page limits. Unless otherwise specified in a VA-ORD solicitation, Internet website addresses (URLs) may not be used to provide information necessary to the review because reviewers are under no obligation to view the Internet sites. Moreover, reviewers are cautioned that they should not directly access an Internet site as it could compromise their anonymity. In addition, video clips may not be included in electronically submitted applications.

*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). Altered file names will cause warnings to be generated and may result in parts of your application being excluded from the final electronic image that the reviewers receive or for the sections to appear in the wrong order. **There are no spaces in the required filenames, use only the underscore (_) character for word separation** (example: "My_Attached_File.pdf") **when naming the attachments.** VA-ORD system validations do not allow for the use of a space(s) to separate words and characters in a filename and use of such may cause an error message and the application to be rejected by the system. To ensure that your application package will be successfully submitted, please adhere to the following guidelines for attachment filenames: avoid using special characters (example: &, -, *, %, /, #) including periods (.); avoid attaching documents with same filename; and limit filename to 50 characters or less.*

Table 2: Other Project Information Form Attachments for Item 12

Attachment and *Required File Name*	Instructions	Page Limit
1. Introduction to Revised Application (for Resubmission only) *01_VA_Intro.pdf*	This attachment must be included for "Resubmissions" of applications **previously submitted through Grants.gov.** Information on resubmission applications can be found in the Executive Summary. The substantial scientific changes must be marked in the text of the application by bracketing, indenting, or change of typography. A vertical bar drawn in the margin may be used as long as changes in text are also indicated by bracketing, indenting or change of typography. <u>Do not underline or shade the changes.</u> 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.** **URLs may not be used in the Introduction.**	**3**

Attachment and *Required File Name*	Instructions	Page Limit
2. Specific Aims ***02_VA_Specific_Aims.pdf***	State concisely the goals of the proposed research and summarize the expected outcome(s), including the impact that the results of the proposed research will exert on the research field(s) involved. List succinctly the specific objectives of the research 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 progress in the field, or develop new technology. ==URLs may not be used in the Specific Aims.==	**1**
2a. Research Plan ***02a_VA_Research_Plan.pdf***	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. Do not use appendices or other sections (e.g., human subjects, vertebrate animals, etc.) to circumvent the stated page limit for the Research Plan. An application that utilizes appendices or other sections to circumvent the stated 19-page limit of the Plan will be administratively withdrawn and not reviewed. ==URLs may not be used in the Research Plan.== In general, the Research Plan should include the following sections: **Background and Significance** Briefly sketch the background leading to the present application, critically evaluate existing knowledge, and specifically identify the gaps that the project is intended to fill. State concisely the importance and health relevance of the research described in this application by relating the specific aims to the broad, long-term objectives. 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 application. It should not be exhaustive. **Preliminary Studies** 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 preliminary studies pertinent to this application, including his/her preliminary experience with and outreach to the proposed racial/ethnic	**19** **Total** 2-3 (recommended) 4-6 (recommended)

Attachment and *Required File Name*	Instructions	Page Limit
2a. Research Plan (continued)	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 applications, 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. **Research Design and Methods** Describe the research design conceptual or clinical framework, procedures, and analyses to be used to accomplish the specific aims of the project. Include how the data will be collected, analyzed, and interpreted. Describe any new methodology and its advantage over existing methodologies. 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. As part of this section, provide a tentative sequence or timetable for the project. Point out any procedures, situations, or materials that may be hazardous to personnel and the precautions to be exercised. If humans or animals are to be studied, a power analysis should be used to justify the number to be studied. **Be as succinct as possible.** For epidemiology research applications this section must include: • Description of various comparison groups. • Subjects recruitment strategies, if applicable, including control groups. The criteria to be used for subject selection, the criteria for assignments to various study groups, and the number of subjects expected to be recruited each year until the conclusion of the study **should be clearly detailed.** Data describing subject population inclusion/ exclusion criteria at recruiting sites, including number of subjects available, should be provided as evidence of feasibility. • The statistical analysis plan including the statistical approach to the questions being investigated, calculations of sample size, and other comparative measurements should be described. The application also needs to detail how various data measures will be categorized and assessed.	Although no specific number of pages is recommended, be succinct.

Attachment and *Required File Name*	Instructions	Page Limit
2b. VA Career Plan *02b_VA_Career_Plan.pdf*	**Candidate's Background** 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. **Career Goals and Objectives** Describe your past scientific history, indicating how the award fits into past and future research career development. If there are consistent themes or issues that have guided previous work, these should be made clear; if your work has changed direction, the reasons for the change should be indicated. 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. You should include a timeline, including plans to apply for independent funding. **Training Activities During Award Period** Stress the new enhanced research skills and knowledge you will acquire as a result of the proposed award. If you have considerable research experience in the same areas as the proposed research, reviewers may determine that the application lacks potential to enhance your research career. 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.	**5** **Total**
2c. Mentoring Plan *02c_VA_Mentoring_Plan.pdf*	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 to enhance the career development.	**3**
3. Progress Report *03_VA_Prog_Report_Pubs.pdf*	Not applicable for applications in response to this FOA/RFA.	

Attachment and *Required File Name*	Instructions	Page Limit
4. Human Subjects *04_VA_Human_Subjects.pdf*	**This attachment is required if you checked the box marked "Yes" for Question 1 on the Other Project Information Form (Are Human Subjects Involved?) A Human Subjects attachment is required for all use of tissue bank or excess pathology material.** 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). 1. Risk to Subjects *Human Subjects Involvement and Characteristics.* 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.** • *Potential Risks.* Describe the potential risks to subjects (physical, psychological, social, legal, or other) and assess their likelihood and seriousness to the subjects. • *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. **Justification must be provided for use of biological samples from non-Veteran subjects.** 2. Adequacy of Protection from Risk • *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	None

Attachment and _Required File Name_	Instructions	Page Limit
4. Human Subjects (continued)	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; it will be requested as a part of the JIT process, if the application is selected for funding._ • _Protection Against Risk._ 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. 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. 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. In addition, the inclusion of women, minorities and/or children must be addressed. • VA-ORD requires the inclusion of women and minorities, as such any exclusion must be research driven (e.g., prostate-related studies). • 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). This FOA/RFA encourages use of the core measures of the NINDS Common Data Elements appropriate for the outcome measures used in the research plan (see: http://www.commondataelements.ninds.nih.gov.) For studies addressing pain outcomes, please refer to the NIH PROMIS site (http://www.nihpromis.org/) for data elements.	

Attachment and *Required File Name*	Instructions	Page Limit
5. Vertebrate Animals *05_VA_Animals.pdf*	**An attachment addressing the following five key points is required if you checked the box marked "Yes" for Question 2 on the Other Project Form (Are Vertebrate Animals Used?)** When research involving vertebrate animals will take place at other performance site(s), provide this information before discussing the five points. Although there is no specific page limitation, be succinct. 1. Provide a detailed description of the proposed use of the animals. Identify the species, strains, ages, sex, and numbers of animals to be used in the proposed work. 2. 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. 3. Provide information on the veterinary care of the animals involved. 4. 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. 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.	None
6. Multiple PD/PI Leadership Plan *06_VA_Multiple_PI.pdf*	Not applicable for applications in response to this FOA/RFA.	None
7. Consortium/Contractual Agreements *07_VA_Agreements.pdf*	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

Attachment and *Required File Name*	Instructions	Page Limit
8. Director's Letter ***08_VA_Director_Letter.pdf*** **The required file name for this attachment may generate a warning message from eRA Commons**	A letter of support from the Medical Center Director must be submitted as **a separate attachment** and must include the following: • 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 at least a 1/8th VA-paid appointment for a physician applicant for the duration of the 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.** • Director's signature and date (must be within the last year) **Applications submitted without this attachment will not be accepted for review.**	None
8a. R&D Committee Letter ***08a_VA_R_D_Committee_Letter.pdf***	Not applicable for applications in response to this FOA/RFA.	None
8b. Letters of Support ***08b_VA_Letters.pdf*** **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. Letters must be dated within the last year. All memoranda/letters in this section should be scanned and submitted as a single PDF document. You must include: **Copy of the LOI Acceptance 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. **A single letter signed by all mentors may be submitted in lieu of separate letters, provided that all required information below is included.** 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	None

Attachment and *Required File Name*	Instructions	Page Limit
8b. Letters of Support (continued)	the candidate's research career. The letters should include the following: 1. The plan for the candidate's training and research career development. 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. 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. A plan for transitioning the candidate from the mentored stage of his/her career to the independent investigator stage by the end of the project period of the award. 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. **Consultant Letters** 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. **ACOS/R&D Letter** 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.	

Attachment and *Required File Name*	Instructions	Page Limit
8b. Letters of Support (continued)	**Service Chief or Section Head Letter** The appropriate Service Chief or Section Head must submit a statement describing the nominee's proposed VA 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). **Reference Letters** 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 that are not from the candidate's current department or organization, but are knowledgeable about their qualifications, should be selected. **Note: Biosketches must be included in the Senior/Key Person Profiles(s) section, <u>not</u> in Letter of Support.**	
9. Checklist **09_VA_Checklist.pdf** **The required file name for this attachment may generate a warning message**	Attach a completed copy of the Electronic Submission Checklist. **Check only those items that have been addressed or are applicable.** <u>**Applications submitted without this attachment or with incorrectly checked boxes may not be accepted for review.**</u>	None
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)	**Do not use appendices or other sections (e.g., human subjects, vertebrate animals, etc.) to circumvent any of the stated page limits. An application that utilizes appendices or other sections to circumvent the stated page limits will be administratively withdrawn and not reviewed.** 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. Appendices should be named using the following convention in the following order:	None

Attachment and *Required File Name*	Instructions	Page Limit

10, 11, 12. Appendices (continued)
 	
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.
	• 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)
	• ".pdf"
	
	See examples below.
	
	The first appendix should be the list of abbreviations used in the application; it should be named:
	
	"10_VA_Appendix_1_Abbreviations.pdf."
	
	New and resubmission applications may include the following materials in the Appendices. Similar appendix material should be combined within an attachment. For example, please place all accepted, but not yet published, manuscripts in one attachment.
	
	• Applicants may submit up to a total of 3 publications as PDF attachments. They may be of the following types:
	   o Manuscripts accepted for publication but not yet published. Do not include unpublished theses or manuscripts that have been submitted but not yet accepted for publication.
	   o Manuscripts published, but a free, online, publicly available journal link is not available.
	   o Patents directly relevant to the project.
	   o Chapters from review or text books.
	• 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 not 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 allowed.	

Attachment and *Required File Name*	Instructions	Page Limit
10, 11, 12. Appendices (continued)	• **Published manuscripts and/or abstracts that have a free, publicly available online journal link should not be included in the appendix material.** The full reference should be included in the Bibliography and References Cited section, the Progress Report Publication List section, and/or the Biographical Sketch section, as appropriate. • For approved supplemental materials, the applicant should contact the SRO after the assignment of the application to a review group is visible in the eRA Commons to discuss logistics for submission. Supplemental materials must be received by the SRO 30 calendar days prior to the peer review meeting. o Only videos for demonstration of devices and experimental data with a temporal element, which refers to the need to show how something functions or occurs over time, or demonstrates movement or change. No devices or other media will be accepted. The video must be embedded in a .pdf file with a maximum file size of 25 MB and it must not exceed 2 minutes. Sufficient descriptive information must be provided within the research plan to understand the information presented in the video, as not all reviewers may be able to access the video, depending on technological constraints. Videos will not be accepted if fewer than 30 calendar days remain before the peer review meeting.	

R&R Budget Form

Budget Guidance

Cost-of-living adjustments are only allowed for VA-paid salaries (no IPAs); these adjustments **(other than for the contact PD/PI salary)** may not cause the budget to exceed the stated cap. **Differences in the operating expenses between years need to be fully justified. All dollar fields must be rounded to the nearest whole dollar**. For any new application package that is downloaded from Grants.gov, the budget forms will automatically transfer budget information from Period One to the remaining budget periods. Check the list of unauthorized items in the table below for items that may not be included in VA-ORD application budgets.

Table 3. Unauthorized Budget Items

Personnel	
Physicians (Title 38)	Except for the Career Development PD/PI, salary support is not authorized for any VA physician.
Title 38 Nurses or any Clinician (Hybrid Title 38 occupations with clinical responsibilities)	Salary support is not authorized for any Title 38 nurse or any clinician (Hybrid 38 occupations with clinical responsibilities) in VA unless a waiver has been granted by the CRADO. If waived, salary support is allowed only for services beyond usual care.
Clerical support	Clerical support may not be included as study personnel unless the support provided can be justified as necessary to the conduct of the research.
Summer/Graduate students	Not authorized
IPAs	IPAs provide for salary and fringe benefit reimbursements; they do not allow for "overhead" costs. IPAs may not be used for physicians. Under no circumstances should IPA agreements be used as a mechanism for hiring clinical staff or as a substitute for scarce medical specialist, sharing, commercial item, or other clinical services contracts. Nor is it appropriate to use IPA agreements for administrative and support positions. In general, IPA agreements should not be used to circumvent restrictions on hiring due to budgetary constraints, reductions-in-force, freezes on grade levels, or ceiling allocations. IPAs are to be used for unique skills that are not available in VA. IPAs may not be used for any individual assigned the PD/PI role. IPAs must be listed under personnel without a requested salary; list the cost of the IPA in the "Other" section of the budget.
Consultants	Services may be obtained by contract or appointment under an appropriate appointing authority and be in a pay or, when appropriate, a non-pay basis (without compensation [WOC]). Consultant fees will be set in accordance with VHA Handbook 5007. Limit of $500 per consultation and $2,500 per annum. Physicians may not be paid as consultants.
Contract for Services	Service contracts are used to obtain a deliverable/product from a company or an institution, e.g. service contract with the University of California for statistical analysis of data. You may not contract for clinical services or identify the individual(s) who will provide the service. A non-VA physician may only perform non-clinical work. A detailed description of the services being contracted for, along with the name and credentials of the person(s) who may be providing the services, should be part of the budget justification.
Equipment	
Computers	Computers (and IT expenditures) should not be listed in the budget. However, do itemize these expenditures in the budget justification.

Furniture	Usually provided by the local facility. Must be justified as necessary for the conduct of this research. Justification must account for disposition of previously funded furniture purchases for projects that are terminated.
Medical Equipment	Usually provided by the local facility. Must be required for the conduct of the research project and not be used as part of routine and customary patient care.
Supplies	
Postage	Not authorized, unless special circumstances require other than ordinary mail
Copying	Not authorized
Books, journals, or reprints	Not authorized
Other	
General Administrative costs	Not authorized
Phone costs	Usually provided by the local facility. Special 800 lines may be approved with strong justification.
Construction	Contact VA-ORD for guidance on construction requests
Professional memberships	Not authorized
Patient Incentives	Small amounts of money can be offered as a reimbursement for time and/or travel to participate in a study. The incentive must not, in and of itself, constitute an incentive and must be consistent with IRB and ethics policies.

Personnel (Section A and B): Starting with the Contact PD/PI, list all personnel involved in the project. In the appropriate columns list their names, role in the research proposed, the calendar months effort each will devote to the project, and whether or not salaries are requested. Salaries are to include fringe benefits (use actual rate for "hired" employees; up to 30% for estimated salaries) for all VA-salaried personnel to be paid from VA-ORD funds. Secretarial salaries are not allowed. Except for the Career Development PD/PI, physicians and dentists and, in most cases, nurses may not receive salaries from the medical research and prosthetics appropriation. Physicians and dentists who are not licensed to practice in the United States may request salary, but they must be clearly identified as such in the budget justification section. PD/PIs cannot be paid through Inter-agency Personnel Act (IPA) agreements.

Only calendar months should be used in sections A and B 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 physician applicants (licensed to practice in the US and has a VA-paid clinical appointment):
    - A minimum of 6 calendar months effort is required
    - A maximum of 9 calendar months effort may be requested
    - Salary commensurate with calendar months effort will be provided for physician applicants up to a maximum of 9 calendar months
    - Medical Center must, therefore provide at least 1/8th VA-paid salary

- For non-physician applicants:
    - A minimum of 7.5 calendar months effort is required
    - A maximum of 12 calendar months effort may be requested
    - Salary commensurate with calendar months effort will be provided for non-physician applicants

It is expected that HBCU-RSTP applicants will request 100% salary and expend a minimum of 75% effort on the award; exceptions must be requested and approved during the LOI process. **If salary will be requested for the PD/PI (clinician and non-clinician), it must be included in the submitted budget and** the calendar months entered that reflect the **actual effort** the investigator will expend on the award; salary consistent with their total VA effort may be requested. Describe the investigator's contribution to the proposed research, as well as the other activities comprising their total VA effort, in the budget justification.

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 <u>uncompensated from other sources</u>, 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.

All co-investigators, collaborators, and technical staff, whether paid or not, are to be listed in the personnel section.

Individuals paid through a contract for services or an IPA must be listed with their calendar months effort in the personnel section, but no salary may be requested; all costs for such contracts or IPAs should be listed in lines 8-10 of Section F "Other Direct Costs" of the budget.

Equipment Description (Section C): Only major equipment is included in this section. Major equipment is defined as an item of property that has an acquisition cost of $5,000 or more. Such equipment consists of relatively permanent, fixed assets that are essential to the completion of the proposed research. When feasible, equipment is to be purchased in the first year of the project. RR&D will consider equipment requests in years 2–4 only under unusual circumstances, and if properly justified.

Travel (Section D): Travel costs for accomplishing any part of the proposed specific aims should be included in the project budget and clearly justified in the budget justification section. RR&D does not provide funds to support travel to scientific meetings.

Other Direct Costs (Section F):
   Materials and Supplies (item 1): Expendable items and small equipment (<&5,000 per item) should be requested as Materials and Supplies.

   Publication Costs (item 2): Cost for publications should be a direct result of the project.

   Consultant Services (item 3): A consultant may not receive a fee of more than $2,500 per year. MD consultants may not receive salary compensation.

   ADP/Computer Services (item 4): Do not include IT costs in the application.

   Subawards/Consortium/Contractual Costs (item 5): Do not use a subaward form to delineate the budget for another performance site; all costs must be included in the main budget and a site-by-site breakout provided in the Budget Justification. The costs for all existing consortia or contracts must be totaled and included here.

   Other Costs (items 8, 9 and 10): List **service contracts for equipment** utilized only for the proposed research. If the equipment is used by multiple research projects, request a proportionate amount of the service contract. List costs for any **personnel to be paid through an IPA**.

Budget Justification (Section K)
All items in the budget must be clearly justified. This is a single justification for all budget years, so include all justification information for all years and all sites in the same file.

Personnel: Fully explain the role and calendar months effort of the PD/PI and all personnel listed under personnel. Indicate Grade and Step for all VA employees and identify anyone paid through an IPA. 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. If the project has more than one performance site, identify the personnel by site.

Equipment: For each item, justification should include a discussion of why the equipment is needed and why similar existing equipment (if any)—whether in the laboratory, common resource equipment, borrowed, or on loan—cannot be used. Include the cost of maintenance. Patient care equipment purchased for use in the research study must be equipment that is not provided in the customary care of patients. If the project has more than one performance site, identify and justify the equipment needed by site.

Travel: Travel costs for accomplishing any part of the proposed specific aims should be clearly justified.

Other Direct Costs: Justify the costs of any items listed under this budget category.

   Materials and Supplies: Itemize expendable supplies in separate categories. Explain how the costs for each category of supplies were derived (e.g., based on the PD/PI's expense history in performing similar research). Small (<$5,000) equipment must be justified. If animals are to be purchased, state the species, cost per animal, and number to be purchased in each year. Include the daily and total charges for Animal Research Facility maintenance of all animal subjects required in the research. If the project has more than one performance site, identify the materials and supplies needed by site.

   Consultant Services: clearly explain the involvement of each consultant with the proposed research and state the frequency of consultations.

   ADP/Computer Services: <u>Do not include IT costs in the Budget</u>. However, planned IT expenditures must be itemized in the Budget Justification attachment in "Section F. Other Direct Costs" of the SF424 (R&R) Budget Form using the Planned IT Expenditures Table format below. Unusual requests should be accompanied by a vendor quote and a strong justification. Shared network charges are not authorized. If the project has more than one performance site, identify planned IT expenditures by site.

Planned IT Expenditures Table				
Category	Type	Amount Year 1	Amount Year 2	Amount Year 3
Hardware	Purchased			
	Leased			
	Services			
Software	Purchased			
	Leased			
	Services			
Telecommunications	Purchased			
	Leased			
	Services			
IT Supplies and Materials	Purchased			
	Leased			
	Services			
IT Personnel (personnel on a 2210 Position Description)				
	TOTAL			

SPECIAL INSTRUCTIONS

The Commons ID of the PD/PI must be included in the "Credential" field of the Research & Related Senior/Key Person Profile(s) Form. Failure to include this data field will cause the application to be rejected.

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

Applications Involving Multiple Institutions: When multiple VA Medical Centers are involved, the submitting VA is considered to be the primary performance site. Budget requests for all sites must be "rolled up" into the main budget, and a detailed budget and justification for each site provided in separate sections of the Budget Justification. **Do not use the Subaward Form to submit a separate budget for each site**.

3. Submission Dates and Times

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

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

Table 4. Deadline, Review, and Award Dates

SUBMISSION CYCLES:	CYCLE I (WINTER)	CYCLE III (SUMMER)
Deadline for submitting Letter of Intent and Waiver requests (eligibility, off-site research, or exceeding duration/budget caps). Applicants are strongly encouraged to submit waiver requests early to allow sufficient time for processing. Applications submitted without the necessary approvals will be returned without review.	**November 1**	**May 1**
First day to submit Merit Review Award and Research Career Development Program applications (to Grants.gov)	**November 15**	**May 15**
Down to the Wire Deadline (to Grants.gov) – **after this date the 2-day application viewing window cannot be used**	**5 business days prior to the Verification Deadline**	
Last Possible Submission Date (Submission Deadline 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 the Submission Deadline above and errors identified are by either Grants.gov or eRA Commons there may not be enough time to fix the errors, resubmit, and have the application received and verified by eRA. If your application is accepted by eRA with no errors, **do not withdraw** the application during the 2 business day application viewing window unless there is sufficient time to resubmit a changed/corrected application by this submission deadline. **Changed/Corrected application submitted after this deadline will not be accepted for review.**	**3 business days prior to the Verification Deadline**	
Verification‡ Deadline (in eRA) **Once verified, an application is considered final and no other version will be accepted for review.**	**December 15**	**June 15**
REVIEW AND AWARD CYCLES:	CYCLE I (WINTER)	CYCLE III (SUMMER)
Scientific Merit Review	March	August
Administrative Review	March - April	August - September
Earliest Project Start Date Note: R&D Services within VA-ORD 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.	June	November

*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.

3.A.1. Letter of Intent

A letter of intent is required for each review round, including resubmissions and revisions. See Table 3 above. Instructions for Submitting a Letter of Intent are available on the VA-ORD website at http://www.rehab.research.va.gov/.

3.B. Submitting an Application Electronically

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

3.C. Application Processing

Applications must meet <u>2 separate deadlines</u>:

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

   AND

2. **Verification by eRA Commons on or before the <u>Verification Deadline</u> in Table 4.**

Applications that miss either deadline 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.

- During the 2-day application viewing window the PD/PI and AOR/SO should determine whether any warnings should be addressed or any other corrections need to be made. 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 eRA Commons identifies errors in an application submitted to Grants.gov, it will be rejected.
- If warnings or other problems identified during the 2-day application viewing window need to be addressed, **the SO must reject (withdraw) the application before a Changed/Corrected application can be submitted to Grants.gov. All Changed/Corrected applications must be submitted to Grants.gov by the stated submission deadline**.
- **If an application is accepted by eRA with no errors, do not reject/withdraw an application during the 2 business day application viewing 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 become verified on the 3rd business day. **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. **In such cases, prior approval will be required for late submissions. Tiffany Asqueri (tiffany.asqueri@va.gov), Program Analysis and Review Section Administrator, must be notified of any system errors prior to the submission deadline (for Grants.gov issues) or validation deadline (for eRA issues).**
- There will be an acknowledgement of receipt/acceptance of applications from Grants.gov and eRA Commons. The submitting AOR receives the Grants.gov acknowledgment. The AOR/SO and the PD/PI receive Commons acknowledgments. Information related to the assignment of an application to the Review Panel is also in the Commons. **Note: Since email can be unreliable, it is the responsibility of the applicant and Signing Official(s) to check periodically on the application status in Grants.gov and eRA Commons to confirm receipt and/or acceptance of the application.**

Upon receipt, applications will be evaluated for completeness by the VA-ORD Program Review staff. **Incomplete applications will not be reviewed.**

No additional or replacement information will be accepted after submission of the application, 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 Program Analysis and Review Section Administrator (Tiffany Asqueri; **tiffany.asqueri@va.gov**) at any time. Please use the following subject header: **"HBCU-RSTP supporting documents"** in the email in order to facilitate proper receipt of these materials.

All HBCU-RSTP applications must contain a 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. The R&D Committee may need to review the 19-page Research Plan to provide the Director with information on some of these issues. Review of applications submitted to VA-ORD without this documentation may be delayed, preventing their inclusion in the review cycle.

VA-ORD will not accept any application in response to this FOA/RFA that is essentially the same as one currently pending review, unless the applicant withdraws the pending application. VA-ORD will not accept any application that is essentially the same as one

already reviewed. This does not preclude the submission of an application already reviewed with substantial changes, but such application must include an "Introduction" (3 pages maximum) addressing the previous critique. Note: such an application is considered a "resubmission" for the SF424 (R&R).

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(s)" Form.

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 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 FOA/RFA will be reviewed through a two-tier system. The first level of review will be performed by the Career Development Scientific Review Group (SRG) composed of scientists who have expertise in relevant scientific disciplines and current research areas. The purpose of the SRG is to evaluate the scientific and technical merit of applications as well as applicant potential, mentor qualifications, and the training program. The SRG does not make funding decisions.

The second level of review will be performed by the appropriate R&D Service within VA-ORD, based not only on considerations of scientific merit (as judged by the SRG) and considerations of the applicant, mentor, and training program, but also on the relevance of the proposed study to the mission, programs, and priorities of VA-ORD and that Service. Final funding decisions are made at the discretion, and approval, of the VA-ORD Chief Research and Development Officer (CRADO).

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 comments, and a roster of the review meeting participants.

For applications discussed during the review meeting, the Summary Statement will also include a summary of the members' discussion during the review meeting, the final priority score, recommendations of the SRG (including budget recommendations), and administrative notes of special considerations.

Discussed and Non-discussed Applications
The initial scientific peer review of research applications may include a process in which only those applications deemed by the reviewers to have the highest scientific merit, potentially the better half of the applications under review, will be discussed and assigned a priority score at the SRG meeting. Applications in the lower half are reviewed by SRG members but they are not discussed or scored at the SRG meeting. This process allows the reviewers to focus their discussion on the most meritorious applications.

Before the SRG meeting, each review assigned to an application will provide a preliminary score for that application based on the review criteria described below. The preliminary scores will be used to determine which applications will be discussed.

Scoring

SRG 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 (with 1.0 being the best possible score); 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. FOA/RFAs for different types of funding opportunities may have different and/or additional review criteria.

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 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 scientific knowledge or clinical practice be advanced? 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?

Investigators: 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? 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.?

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: The SRG 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, the SRG 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, 48. Research Involving Children).
NOTE: Congressionally-mandated research programs that involve children are exempt from this policy

Vertebrate Animals: The SRG will evaluate any proposed involvement and protection of vertebrate animals for the following: (1) detailed description of the proposed use of the animals; (2) justification for the use of animals and for the appropriateness of the species and numbers proposed; (3) adequacy of proposed veterinary care; (4) appropriate procedures for limiting pain and distress to that which is unavoidable; and (5) appropriate of methods of euthanasia.

***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?

***Biohazards*:** If materials or procedures are proposed that are potentially hazardous to research personnel and/or the environment, determine if the proposed protection is adequate.

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 Applications

An application may be disapproved if the SRG determines that the proposed studies are unethical or are unlikely to yield useful information.

- Applications 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

2.F. Appeals

The appeals process is intended to ensure that the scientific review of all applications is fair and equitable. It is not intended as a means to resolve differences in scientific opinion between the applicant and the reviewers, to adjust funding decisions, or to circumvent the peer review process. The basis for an appeal and the procedure for submitting an appeal are detailed in the guidance document, Merit Review Appeal Process, found at www.rehab.research.va.gov/guid/handbook/1203-1appendc.doc.

If a PD/PI submits a revised application and an appeal of the previous application is subsequently sustained and funded before the revised application is reviewed, the revised application will be administratively withdrawn. If the revised application receives a fundable score and the appeal is sustained and fundable, the single project rule applies, and only one of the two projects will be funded.

Note: Applicants are encouraged to resubmit their application while an appeal is under review.

3. Anticipated Announcement and Award Dates

Standard dates apply; please see Table 4 in Part II, Section IV.

Section VI. Award Administration Information

1. Award Notices

After the peer review of the application is completed, the PD/PI will be able to access his or her Summary Statement (summary of discussion and written critiques) via the NIH eRA Commons.

If the application is under consideration for funding, VA-ORD will issue a notice of intent to award to the PD/PI and the research office. All required "Just-in-Time" (JIT) information will be listed in the VA JIT Document Manager. It is VA-ORD's expectation, and the PD/PI's and research office's responsibility to move forward with the completion of JIT documents to bring the study into compliance. For a project to remain under consideration for funding, VA-ORD must receive all JIT items via the VA JIT Document Manager within 180 days of the notice of intent to award.

2. Administrative and National Policy Requirements

Research Integrity. VA-ORD 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, 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 applications to RR&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 VA 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 HBCU-RSTP submission or review should be directed to the Program Manager, Tshaka Cunningham, Ph.D., at **tshaka.cunningham@va.gov**.

2. Financial Management Contact(s):
Deborah Allen at deborah.allen8@va.gov.

Reminder: To ensure a timely response, all programmatic questions related to the Merit Review process should be directed to Program Analysis and Review Staff (PARS) at: rrdreviews@va.gov. 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.