U.S. Department of Veterans Affairs
Office of Research and Development (VA-ORD)

# SF424 (R&R)
# Application Guide for VA-ORD

**A guide for preparing and submitting VA-ORD applications via Grants.gov using the SF424 (R&R)**

**For use by VA intramural investigators for submissions to:**

- Biomedical Laboratory Research & Development Service (BLR&D)
- Clinical Science Research & Development Service (CSR&D)
- Health Services Research & Development Service (HSR&D)
- Quality Enhancement Research Initiative (QUERI)
- Rehabilitation Research & Development Service (RR&D)

**To be used with Adobe-Forms-B application packages**

**Revised: January 25, 2013**

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# PART I

## Instructions for Preparing and Submitting an Application

# 1. Foreword

### Hyperlink Navigation

This application guide includes hyperlinks that allow you to find additional information and/or instructions. You must have the "Web" toolbar enabled in order to use Microsoft Word's "Back" and "Forward" features to navigate to and from hyperlinks.

Revisions and clarifications to previous instructions (VA-SF424 Application Guide) are marked in green highlight.

### Adobe-B Application Guide — Previously released February 23, 2011

This application guide includes changes to SF424 Research & Related (R&R) instructions necessitated by the June, 2008 OMB renewal of the forms.

Modifications related to changes in the SF424 (R&R) forms include:

- A new "Agency Routing Identifier" field has been added to the Cover Component.
- A document upload field has been added to the Cover Component for attaching the SF-LLL (Disclosure of Lobbying Activities) or other explanatory documents.
- A new field has been added to the Project/Performance Site Location(s) form for the Congressional District of the project. The Areas affected by Project and Congressional Districts of Project fields on the Cover component have been deleted.
- Fields requesting the type and year of degree have been added to the Senior/Key Personnel forms. **Do not use the "Suffix" box to enter degrees.**
- Questions on Human Subjects Research on the Other Project Information form have been re-ordered and a new question, whether the project is exempt from Federal regulations, has been added.
- A Personal Statement requirement has been incorporated into the Biographical Sketch.

Additional details on all the form changes noted above can be found at: http://grants.nih.gov/grants/funding/424/index.htm#inst or http://grants.nih.gov/grants/ElectronicReceipt/files/Adobe_Forms_B_Summary.pdf.

**Some information available at this URL (which belongs to NIH) may not be applicable to applications to VA-ORD**.

### VA-ORD Application Guide

This application guide contains instructions and other useful information for preparing research proposals for submission to the VA Office of Research and Development (VA-ORD).

This application guide is used as a companion document to the SF424 Research and Related (R&R) application forms. A complete application to VA-ORD will include SF424 (R&R) components and all required attachments as indicated in this document.

The use of these forms also involves electronic submission of completed applications through Grants.gov. VA-ORD will use Requests for Applications (RFAs) to solicit scientific proposals for review. **In Grants.gov, RFAs are referred to as Funding Opportunity Announcements (FOAs).** Specific Funding Opportunity Announcements (FOAs) will clearly indicate which forms and submission process an applicant should use. See Section 2.4.2 for definitions.

Applicants must carefully review VA-ORD RFAs for guidance on when to use the SF424 (R&R) forms, instructions, and electronic submission for a specific mechanism. This process will apply to all types of submissions (new, resubmission, and renewal) for the announced mechanism. Each

RFA will include a link to the most current version of these instructions. Applicants are encouraged to check the VA-ORD intranet site frequently for the most current version.

For purposes of this document, any reference to "VA-ORD" includes all Research and Development (R&D) Services within VA-ORD: Biomedical Laboratory R&D (BLR&D), Clinical Science R&D (CSR&D), Health Services R&D (HSR&D), and Rehabilitation R&D (RR&D).

**Be sure to use an application package for the correct RFA and R&D Service within VA-ORD when submitting proposals.**

**This is a checklist item.**

**Application packages are not interchangeable between R&D Services or between RFAs within a specific R&D Service.**

## 1.1 Application Guide Format

This application guide is organized into three distinct parts:

**Part I: Instructions for Preparing and Submitting the Application.** Part I includes specific instructions for completing the application form components as well as information on electronically submitting applications through Grants.gov.

**Part II: Supplemental Instructions for Human Subjects Research.** Part II should be used if your proposed research will involve human subjects. These instructions assist you in completing the Human Subjects component of the Research Plan.

**Part III: Policies, Assurance, Definitions, and Other Information.** Part III includes information on policies, assurances, definitions, and other information relating to submission of applications for traditional, solicited and unsolicited, investigator-initiated research projects to VA-ORD. Applicants should refer to this document as well as the VHA Handbook for each Research and Development Service within VA-ORD. These Handbooks can be accessed on the VA-ORD web site at: http://www.research.va.gov/resources/policies/by_service.cfm#All_ORD.

## 1.2 VA-ORD Intramural Research and Research Training Programs

The VA Office of Research and Development (VA-ORD) homepage on the intranet (http://vaww.research.va.gov/ or internet (http://www.research.va.gov) provides an array of helpful information about VA-ORD research programs. Applicants are encouraged to bookmark this site and visit it often. Request for Application (RFA) documents and Guidance Documents related to electronic submission of applications can only be accessed via the ORD intranet (http://vaww.research.va.gov/).

Information about VA-ORD intramural research and research training programs, funding opportunities, and the application process, can be obtained by contacting the appropriate ORD R&D Service (see Table 1.4.1 below).

## 1.3 Research Funding Mechanisms and Program Guidelines

A list of research funding mechanisms using the SF424 for electronic submission of applications is provided below.

### Research Awards

- Merit Review Award (I01)
- Pilot Project/Small Project Award (I21)

- Program Project Award (IP1)
- Research Enhancement Award Program – REAP (I50)
- Center of Excellence Award (I50)Center_of_Excellence

**Research Career Development Awards**

- Career Development Award – CDA-1 (IK1)
- Career Development Award – CDA-2 (IK2)
- Nursing Research Initiative – NRI (IK3)
- Research Career Scientist Award – RCS (IK6)

## 1.4 Interactions with VA-ORD Staff

The R&D Services within VA-ORD encourage applicants to communicate with staff throughout the entire application, review and award process. Web site addresses and staff phone numbers of relevant R&D Services are listed in the table below.

**All inquiries regarding the assignment, review, or recommendation on funding of applications are to be made only to R&D Service officials.**

**Table 1.4.1 VA–ORD R&D Service Contacts**

| R&D SERVICE | CONTACT INFORMATION |
|---|---|
| Biomedical Laboratory and Clinical Science Research & Development (BLR&D / CSR&D)<br>Alex Chiu, PhD | http://www.research.va.gov/services/blrd/<br>http://www.research.va.gov/services/csrd/<br>vhacoblcsrdrev@va.gov<br>(202) 443-5672 |
| Biomedical Laboratory and Clinical Science Research & Development (BLR&D / CSR&D) Career Development Award<br>Boriana Cavicchia | http://www.research.va.gov/services/blrd/career_dev.cfm<br>http://www.research.va.gov/services/csrd/career_dev.cfm<br>vhacadereview@va.gov<br>(202) 443-5684 |
| Cooperative Studies Program (CSP)<br>Grant Huang, PhD | http://www.research.va.gov/programs/csp/<br>(202) 443-5700 |
| Health Services Research & Development (HSR&D)<br>Kristy Benton-Grover | http://www.hsrd.research.va.gov/funding<br>(202) 443-5728 |
| HSR&D Quality Enhancement Research Initiative (QUERI)<br>Linda McIvor | http://www.queri.research.va.gov/<br>(202) 443-5740 |
| HSR&D Career Development Award<br>Robert Small | http://vaww.research.va.gov/funding/cdp.cfm<br>(202) 443-5743 |
| Rehabilitation Research & Development (RR&D)<br>Tiffany Asqueri | http://www.rehab.research.va.gov/staff/index2.html<br>(202) 443-5757 |

**Before Submission**

You may wish to contact VA-ORD staff with a variety of questions before submitting an application.

See Table 1.4.1 for the appropriate contacts within each R&D Service; do not direct these questions to the Scientific Review Officer (SRO) for individual SRGs.

- To identify an R&D Service and/or a Scientific Review Group (SRG) that might be appropriate for your application. Note: requests for assignment to an R&D Service and/or SRG (previously referred to as a review panel) may be made in a separate cover letter sent directly to the R&D Service.
- To determine whether your proposed application topic would fit into the R&D Service's programmatic area.
- To learn about programmatic areas of interest to the R&D Service.
- To discuss whether you should respond to a particular service-specific Request for Application (RFA) – **This is a checklist item.**
- To learn about available funding mechanisms.

**After Submission**

The VA-ORD web site lists the recurring SRGs (review panels), and you may suggest/request assignment to a specific SRG. Although these suggestions will be taken into consideration, the final determination will be made by the R&D Service(s) issuing each solicitation. If the initial assignment to an R&D Service or SRG seems inappropriate, the local VA Research and Development Office may request reassignment on behalf of the PD/PI; requests submitted directly by applicants will be returned the R&D Office without consideration. Although these requests will be carefully considered, the R&D Service will make the final determination.

**No individual may directly contact reviewers regarding a submitted application.** Any discussion of an application or attempt to influence the review outcome will constitute a conflict of interest in the review process. Reviewers are required to notify the Scientific Review Officer (SRO) if anyone contacts them (or attempts to contact them) concerning a submitted application. **Direct contact with reviewers (regardless of the source of contact) may result in debarment of the applicant from submitting to Research and Development Services within ORD.**

**After Assignment**

Contact your SRO to discuss the review assignment, and/or to discuss any review concerns (e.g., expertise needed to review your application, potential conflicts/reviewers that may have bias); **requests/suggestions for specific reviewers will not be accepted**. *Note: not all R&D Services allow submission of supplemental material, and permission to submit additional material will be granted only in exceptionally rare instances. Recorded media (i.e., video clips, movies, CD's, DVD's, etc.) will not be accepted as part of an application or as supplemental material.*

**After Peer Review**

While ORD recognizes that feedback to applicants is very important, **program officials will not be able to discuss any aspect of an application's review until the Summary Statement has been released (issued) in eRA Commons.** Summary Statements (including final score and percentile when calculated) will **only be made available through the applicant's eRA Common account; paper copies will not be issued. Percentiles may not be calculated for all funding mechanisms or for all SRGs.** Once the PD/PI receives their Summary Statement, s/he may contact the appropriate awarding component program official (noted on the Summary Statement):

- To discuss the review outcome of the application and obtain guidance.
- To get feedback and answers to any questions about the Summary Statement.
- To find out the meaning of a numerical designation pertaining to human subjects or vertebrate animals on the Summary Statement.

## 1.5 Authorization

VA-ORD requests the information described in these instructions pursuant to its statutory authority for funding intramural VA research programs. Therefore, such information must be submitted if an application is to receive due consideration for an award. Lack of sufficient information may hinder the ability of the VA-ORD to review an application and to monitor performance.

## 1.6 Paperwork Burden

VA-ORD estimates that it will take approximately 22 hours to complete this application for a regular research project. This estimate excludes time for development of the scientific plan. Items such as human subjects and vertebrate animals are accounted for separately. Therefore, these items are also not part of the time estimate.

# 2. Process for Application Submission via Grants.gov

Application submission through Grants.gov involves several steps. Some of the steps need only be done one time. Others are ongoing steps that will be necessary for each application submission. Before beginning the application process, you are encouraged to access the Grants.gov Web site and review all the resources available there.

## 2.1 Overview

The following steps must be taken in order to submit a VA research application through Grants.gov and eRA Commons. Please be sure to complete all steps to ensure that VA-ORD receives the application in a timely manner.

1. Your VA medical center/health care system must be **registered as an institution at Grants.gov**. This is a one-time only registration process. If your medical center has already completed this step for any Federal agency submission, skip to step #2. If your medical center has not completed this step, see Section 2.2.1 for more details. Registration of individual investigators at Grants.gov is not required.
2. Your VA medical center/health care system must be **registered as an institution in the eRA Commons**. This is a one-time only registration process. If your organization has already completed this step, skip to step #3. If your organization has not completed this step, see Section 2.2.2 for more details.
3. All Project Directors/Principal Investigators (PD/PI) must be **individually registered** in Commons (i.e. have an eRA Commons ID) as well. See Section 2.2.2.2 for further guidance.
4. Find a Funding Opportunity Announcement (FOA; Request for Application) using the Grants.gov "Apply" feature that reflects use of the SF424 (R&R) forms and electronic submission through Grants.gov. (See Section 2.4.3 for more details.)
5. Download the RFA-specific Application Package from Grants.gov. **This is a checklist item**. Complete the appropriate application components, including all PDF attachments. Upload all attachments into the appropriate application component. (See Section 2.6 for more details on the requirements for text (PDF) attachments.)

6. The completed application should be reviewed through your own organizational review process.
7. Only an Authorized Organizational Representative (AOR) at your VA medical center can submit the application to Grants.gov by the date specified. (**Keep a copy locally at your VA medical center.**)
8. Receive the Grants.gov tracking number.
9. After agency validation, receive the agency tracking number (accession number).
10. PD/PI and Signing Official (SO) complete a verification process in the eRA Commons. (See Section 2.11 for detailed information).

The following sections explain each step in more detail.

## 2.2 Registration Processes

### 2.2.1 Grants.gov Registration

Grants.gov requires a **one-time** registration *by your VA medical center*. PDs/PIs do not need to individually register in Grants.gov unless they also serve as the Authorized Organizational Representative (AOR) for their medical center. If a VA medical center has already completed Grants.gov registration for another Federal agency, they can skip this section and focus on the NIH eRA Commons registration steps noted below. For those VA medical centers still needing to register with Grants.gov, registration information can be found at http://www.grants.gov/applicants/get_registered.jsp. While Grants.gov registration is a one-time only registration process, it does involve several steps and will take some time. VA medical centers needing to complete this process are encouraged to **start early** allowing several weeks to complete all the steps before actually submitting an application through Grants.gov.

The AOR is an individual authorized to act for the medical center and who has the authority to sign research applications and required certifications and/or assurances that are necessary to fulfill the requirements of the VA-ORD application process. Once this individual is registered, the medical center can then apply for any funding opportunity listed in Grants.gov.

Questions regarding Grants.gov registration should be directed to the Grants.gov Contact Center at telephone: 1-800-518-4726. Contact Center hours of operation are Monday–Friday from 7:00 a.m. to 9:00 p.m. Eastern Time.

### 2.2.2 eRA Commons Registration

The VA medical center, all PD/PIs, and all individuals with a postdoctoral role (see definition of postdoctoral scholar in Part III.3) and one month or more of measurable effort must complete a **one-time** registration in the eRA Commons. Access to the Commons is vital for all steps in the process after application submission. The medical center and PDs/PIs must be registered in the Commons before they can take advantage of electronic submission and retrieval of information, such as reviewing research applications, institute/center assignments, review outcomes, and Summary Statements. Institutional/organizational officials are responsible for registering PDs/PIs in the eRA Commons. PDs/PIs should work with their AOR (also known as the Signing Official in the eRA Commons) to determine their institutional/organizational process for registration.

IMPORTANT: The eRA Commons registration process should be started at least **two (2) weeks** prior to the submittal date of a Grants.gov submission. Failure to register in the Commons and to include a valid PD/PI Commons ID in the credential field of the Senior/Key Person Profile Component will prevent the successful submission of an electronic application to VA-ORD.

#### 2.2.2.1 Commons Registration for the Organization

VA medical centers may verify their current registration status by accessing the "List of Grantee Organizations Registered in NIH eRA Commons" (http://era.nih.gov/userreports/ipf_com_org_list.cfm).

To register an Organization in the eRA Commons:

1. Open the eRA Commons homepage (https://commons.era.nih.gov/commons/).
2. Click **Grantee Organization Registration** (found in "About the Commons" links on the right side of the screen).
3. Follow the step-by-step instructions. Remember to fax in the registration signature page to eRA.
4. Click **Submit**. The organization is registered when the NIH confirms the information and sends an email notification of registered Signing Official (SO) account (userid/password).

The eRA Commons registration is independent of Grants.gov and may be done at any time.

Organizational data elements, such as Institutional Profile Number (IPF), Entity Identification Number (e.g., 5555555555A5) and DUNS Number must be accurately identified. **Note the DUNS number must be included in the Institutional Profile for applications to be accepted. In addition, the DUNS number in the Institutional Profile must match that entered in the SF424 (R&R) Cover Component in Section 5, Applicant Information.** This information will be used to generate the electronic application image that the Signing Official and the PD/PI will be asked to verify within the eRA Commons. See Section 2.11 for details on the Commons application verification process.

Since eRA has not previously required a DUNS number during eRA Commons registration, there are many accounts that do not contain valid information in this field. Prior to submission, the AOR/SO should verify that their organization's eRA Commons profile contains the valid DUNS number that will be used for the submission process. The SO has the ability to edit this field in the organization profile in Commons.

To confirm that your organization has a DUNS number or to find out if the DUNS number you have matches the one in eRA Commons, access the List of Grantee Organizations Registered in NIH eRA Commons (http://era.nih.gov/userreports/ipf_com_org_list.cfm). This listing of grantee organizations registered in Commons and their DUNS numbers can be accessed without logging into the Commons.

#### 2.2.2.2 Commons Registration for the Project Director/Principal Investigators (PD/PIs) and Individuals with a Postdoctoral Role

The individual(s) designated as a PD/PI on the application must also be registered in the Commons. A PD/PI must hold a PI account **and** be affiliated with the VA medical center. **An organizational official (or delegate) who is already registered in the Commons must do this registration and/or affiliation.** To register PDs/PIs in the Commons, refer to the NIH eRA Commons System Users Guide (http://era.nih.gov/Docs/COM_UGV2630.pdf). **If a PD/PI already has an eRA Commons ID created through another institution, the VA official only needs to affiliate the VA medical center with the existing account; a new commons ID should not be created.**

Once a PD/PI has received email confirming his/her registration within the Commons, the PD/PI must verify that all Personal Information located within the Personal Profile tab in the eRA Commons System is accurate. Please have the PD/PI review and update, as needed, data elements such as first name, middle initial, last name, prefix and/or suffix to PD/PI name (including all embedded punctuation), email, phone, fax, street address, city, state, country, zip and degrees

earned. These data must contain the most recent information in order for the application to be processed accurately.

Both PD/PI and SO need separate accounts in Commons since both need to verify the application. If you are the SO for your organization as well as a PI of a research project, you will need two separate accounts with different user names – one with SO authority and one with PI authority. When an organization is registered, an SO account is created. Log on to the account with the SO authority role and create another account with PI authority.

Individuals with a postdoctoral role and one month or more of effort must also be registered in the eRA Commons and should verify that all Personal Information located within the Personal Profile tab in the eRA Commons system is accurate.

An **Individual DUNS or CCR registration** (such as those used for some NIH Peer Reviewers), are different than any DUNS number and CCR registration used by a VA medical center and **should not be used on any applications submitted to VA-ORD**.

**An investigator profile (Page 18), including the Commons ID, must be completed in ePromise for all personnel assigned the PD/PI role; This is a checklist item.**

## 2.3 Software Requirements

### 2.3.1 Adobe Reader

In order to access, complete and submit applications, applicants need to download and install the Adobe Reader, version 8.1.1 or later. For minimum system requirements and download instructions, please see the Grants.gov User Guide or visit http://grants.gov/help/download_software.jsp.

**Adobe Reader 8.1.1 or higher is required** to open and work on the SF424 (R&R) application forms; **version 9.1 or higher is strongly recommended**. The use of **earlier versions** of Adobe Reader **may permanently corrupt the application file**. If this occurs, you will need to download a new application package and start over.

A request to local IRMS to install a compatible version of **Adobe Reader** on a workstation may be required. This request should be made through the local VA Research & Development Office. **The electronic application package cannot be completed using any other software.**

Please note that you must set the Adobe Reader's page layout options to "Continuous" instead of "Single Page" to ensure all features function properly. To do this, choose View > Page Layout, and then choose the "Continuous" option.

While the **full version of Adobe Acrobat** may be used**, it is not required**. Information on using Adobe Acrobat (Standard or Professional) with applications submitted to Grants.gov is available at http://www.grants.gov/help/download_software.jsp#adobe811. **Use of Adobe Acrobat, rather than Adobe Reader, to complete an application package is done at the investigator's own risk.**

### 2.3.2 Creating PDFs for Text Attachments

**VA-ORD requires all text attachments to the SF424 (R&R) application forms to be submitted as Portable Document Format (PDF) files**. Some type of PDF-creation software is necessary to create the PDF as the free Adobe Reader *will not create* a PDF. The full version of Adobe Acrobat can perform this function. For those who do not have licensed copies of Adobe Acrobat, VA has licensed copies of ScanSoft PDF Professional (also called Nuance: PDF Converter Professional), available on a first-come-first-serve basis. **You will need to make a specific request through your local IRMS to have access to this software.**

**Do not submit attachments in other formats** such as Microsoft Word, Word Perfect, etc. Other formats may be allowed through Grants.gov but **are not accepted by NIH.**

Save all files with descriptive file names of **50 characters or less** and be sure to **use only standard characters** in file names: **A through Z, a through z, 0 through 9, and underscore (_). Do not use any special characters** (example: "&", "-", "*", "%", "/", and "#") **or spaces** in the file name; **use underscore for word separation** (example: "My_Attached_File.pdf") in naming the attachments.

PDF attachments for applications to VA-ORD have **required file names**. A list of the required file names and corresponding template Word files can be found on the VA-ORD Intranet at: http://vaww.research.va.gov/funding/electronic-submission.cfm.

A 0 byte (empty) attachment is an invalid PDF and will result in the application being rejected by the eRA system.

Note that all PDF attachments must be submitted as individual files. Although some software packages allow bundling of multiple PDFs into a single file, eRA systems cannot support "Bundling" or "Portfolio" features at this time. Use of these features may result in delays in the review of an application or an application not being reviewed.

Applicants should prepare text attachments using any word processing program (following the format requirements in Section 2.6) and then convert those files to PDF before attaching the files to the appropriate component in the application package. (The PDF format is used to preserve document formatting).

Attachments cannot be larger than U.S. standard Letter paper size of 8.5 x 11 inches. Use at least one-half inch margins (top, bottom, left and right) and do not include any information in the margins.

**Do not use headers or footers in Word.** Applicants are encouraged to use Section Headings within the document.

Be sure to "**Accept All Changes in Document**" in Word if you have been using Track Changes, and to **remove all comments** before converting the file to PDF format.

**Hyperlinks (a URL attached to a word or phrase) are not allowed** in the SF424 Research Plan documentation where PDFs are uploaded as part of the application. A complete URL ( e.g. http://www.nih.gov/) must be displayed within the document.

**To avoid problems related to PDF attachments, keep these guidelines in mind:**

Attachments cannot be larger than U.S. standard Letter paper size of 8.5 x 11 inches. **Be sure that the default paper size for printing in your PDF converter is set to this size** (i.e. not A2 or A2).

Disable all security features in the PDF document. Protected documents prevent NIH from opening and processing the document. Security settings vary by PDF tool, but please ensure security settings are not marked. The applicant needs to look at the Document Security tab under Document Properties (directly from the tab) and set the security parameters to ensure open access so NIH can process the content. For instance, do not password-protect the document and do not mark Content Extraction or Copying, Document Assembly, etc as "Not Allowed."

**Do not include any information in the header or footer area of PDF attachments** (i.e., the header and footer areas of the original Word document must be empty). A header will be system-generated that references the name of the PD/PI. Page numbers for the footer will be system-generated in the complete application, with all pages sequentially numbered.

It is important that the submitted PDF attachment be a "flat file", one that is not editable and does not have comments associated with it. If a PDF attachment (not the SF424 application

package itself) is submitted that has editable (fill-able) fields or uses comments, that data will be lost when the application image is created, resulting in errors that will prohibit the application from moving forward for consideration.

Recommendation: When provided an option to download an MS Word version of a form or a PDF version of a form, always select the MS Word version of the form, then convert the form to PDF after the form is completed. This process will "flatten" the file, making it acceptable for submission.

If you are having trouble fixing the PDF settings, simply cut and paste from the PDF document into a Microsoft Word document and then reconvert (in some cases it may be better to use another PDF converter).

**Scanning should only used for combining original signed documents**, such as letters of support, into a single attachment file. Applicants should not scan text documents to produce the other PDF attachments required for an application. Instead, VA-ORD recommends producing the documents electronically using text or word-processing software and then converting documents to PDF.

Scanning paper documents, without the proper Optical Character Recognition (OCR) process, will hamper automated processing of your application for analysis and reporting, and in some cases may cause the application to be rejected by either grants.gov or eRA Commons.

In addition, scanning may produce files with incorrect margins, type fonts that are too small, **incorrect vertical line spacing** and which are otherwise difficult for the reviewers to read. Scanned attachments will also greatly increase the total size of your application package, making it more difficult to share with your AOR for submission.

**Applications that fail to meet content and formatting requirements (font, margins, vertical line spacing, etc) or are incomplete will be administratively withdrawn (not accepted for review).**

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DISCLAIMER: References to software packages neither constitute nor should be inferred to be an endorsement or recommendation of any product, service, or enterprise by VA-ORD, any other agency of the United States Government, or any employee of the United States Government. No warranties are stated or implied.

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### 2.3.3 Special Instructions for Macintosh Users

With the conversion to Adobe Reader, application submissions there are no longer special instructions for Macintosh users.

## 2.4. Funding Opportunities

Health-related research and research training projects or activities make up the largest category of funding provided by VA-ORD R&D Services. Many applications for support are unsolicited and originate with individual investigators who develop proposed plans for research or research training within an area that is relevant to the VA. Research funding is awarded to VA medical centers (VAMCs) on behalf of PDs/PIs to facilitate the pursuit of a scientific objective when the idea for the research is initiated by the investigator. VA-ORD also issues targeted requests for applications (RFAs) for research addressing specific Veterans' health care issues (see Section 2.4.2). VA-ORD funding awards are for terms ranging from one to five years. See Part III: Policies, Assurances, Definitions, and Other Information for a list and brief description of funding mechanisms.

### 2.4.1 NIH Guide for Grants and Contracts

**VA-ORD Funding Opportunity Announcements (RFAs) will not be published in the NIH Guide for Grants and Contracts.** The *NIH Guide for Grants and Contracts*, a weekly electronic publication, contains announcements about funding opportunities, such as Requests for Applications (RFAs) and Program Announcements (PAs) from NIH and other PHS agencies.

### 2.4.2 Solicitations

Request for Applications (RFA)

Each R&D Service will issue a "Parent" Request for Applications (RFA) for investigator-initiated research. These RFAs parallel the Parent RFAs issued by NIH. Although the global purview of each R&D Service will be described in the Parent RFA, there will be no focus on any particular scientific area(s) or Veterans' health care issue(s).

To hasten the development of a program or to stimulate submission of applications in an area of high priority or special concern, one or more R&D Services within VA-ORD may issue additional RFAs inviting applications in well-defined scientific area(s) or Veterans' health care issue(s).

Each RFA will contain a table of **announcement-specific submission dates** (including first and last date to submit). A specially convened Scientific Review Group (SRG) may review applications submitted in response to an RFA issued by an awarding component of VA-ORD.

Read the RFA carefully for any special instructions. **The instructions in the RFA may differ from the general instructions contained in the VA-ORD Application Guide for SF424, and they supersede the general instructions.** Each RFA will contain contact information under *Inquiries* in addition to information specific to the RFA.

Each RFA will be assigned a unique announcement number that must be used to download the application package from Grants.gov. **In Grants.gov, RFAs are referred to as Funding Opportunity Announcements (FOAs).** In reading any VA-ORD FOA:

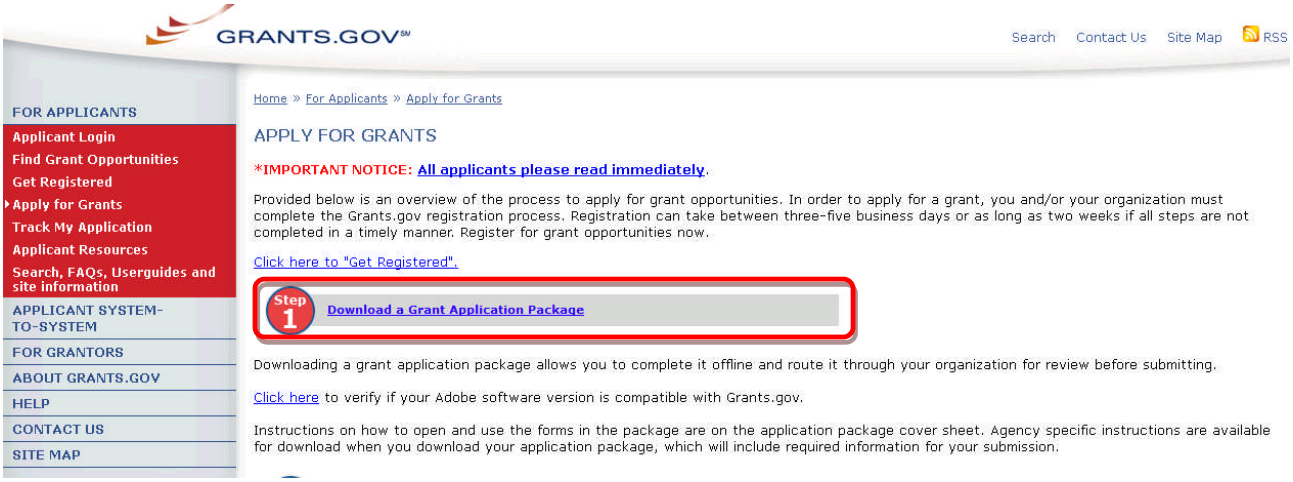
- A "release/posted date" refers to the date the FOA is posted on Grants.gov/Apply. An applicant can download the application package on that date and begin filling it out. However, the applicant must wait until the FOA's "opening date" to have the AOR submit the application.
- When you download an application package from Grants.gov, the RFA number and "expiration date" are pre-populated in the forms management screen. **Be sure you have the correct application package before you begin filling out the forms; there is no mechanism for changing the RFA designation within the package**. **This is a checklist item.**
- An application can be submitted to Grants.gov anytime between the "opening date" and "last possible submission date" noted in **Table 4 (Deadline, Review, and Award Dates) in each FOA/RFA**.

### 2.4.3 Finding an application package in Grants.gov for a VA-ORD Funding Opportunity Announcement (FOA/RFA)

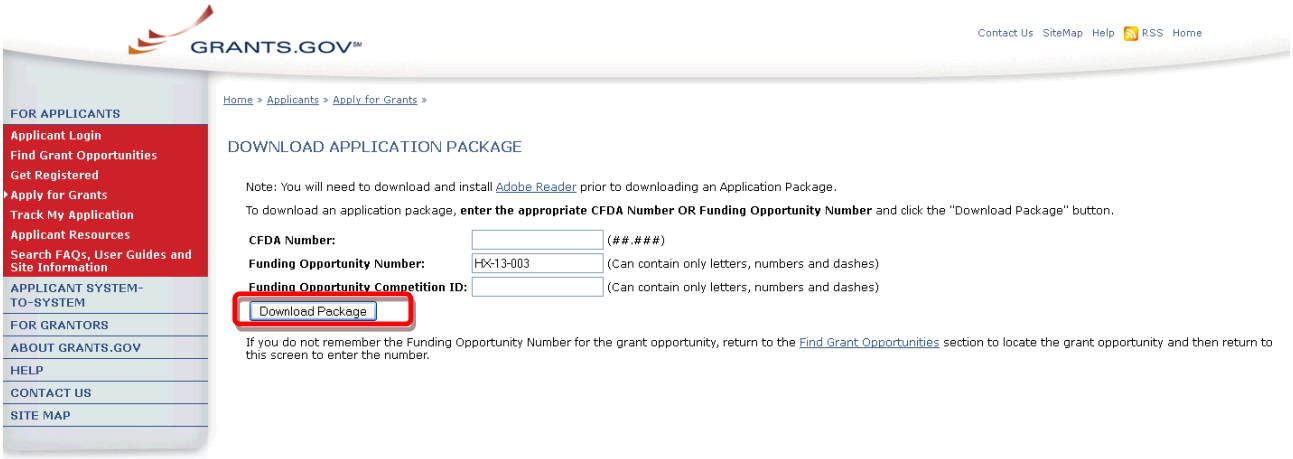
VA-ORD FOAs are **not searchable through the "Find Grant Opportunities"** feature on Grants.gov, nor will they be published in the *NIH Guide for Grants and Contracts* or the *Federal Register*. Instead, the list and full text (and number) for all VA-ORD RFAs for electronic submission of research applications will only be available on the VA-ORD intranet site.

## You Must Use The "Apply for Grants" (Apply) Feature

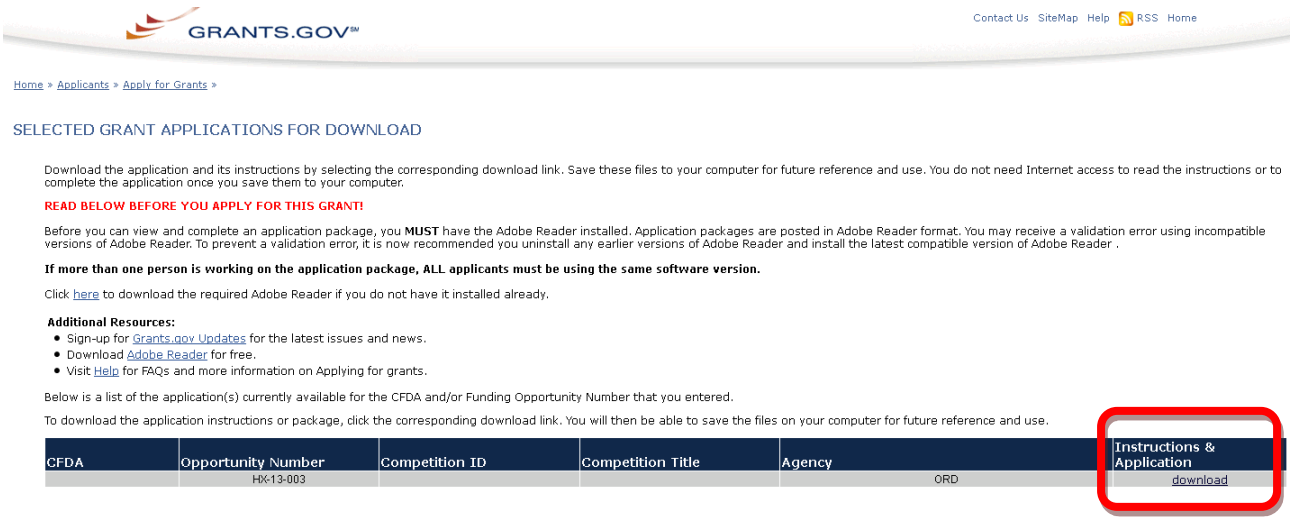
Using the RFA number retrieved from the VA-ORD intranet go to the Grants.gov home page and select "Apply for Grants" in the red box on the left-hand side of the screen. Alternatively, you may go directly to Apply for Grants at http://www.grants.gov/applicants/apply_for_grants.jsp.



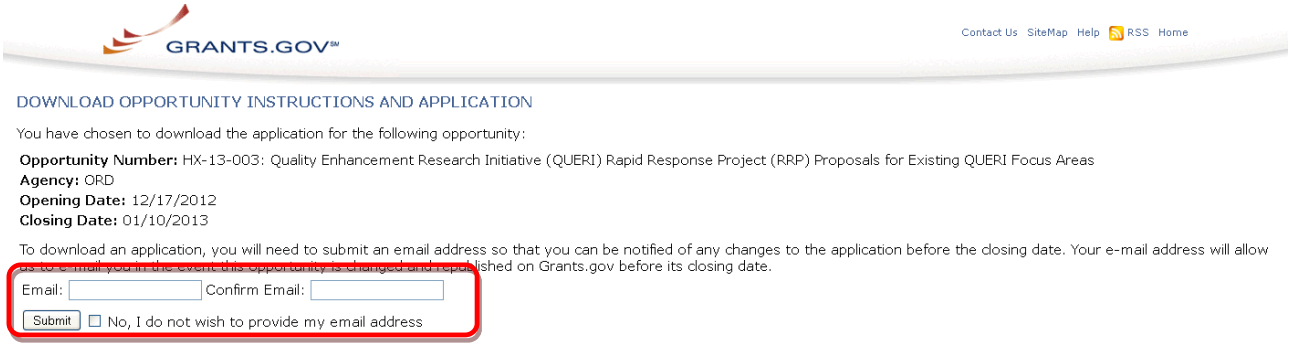

Select "Step 1: Download a Grant Application Package" and the screen below will appear.




An RFA/Funding Opportunity Number is referenced on the first page of each VA-ORD RFA. Enter this number in the Funding Opportunity Number field and click "Download Package." This takes you to the "Selected Grant Applications for Download" screen shown below.




Only the specific FOA requested will be displayed. Click the corresponding "download" link to access the actual application form pages and instruction material. The following screen appears:




**You must either enter your e-mail address or check the box indicating you do not want to provide it and then click "Submit" to get the screen below. If you enter your e-mail address in the box provided, you will be automatically notified if the RFA is modified and re-posted on Grants.gov.**

To download the application package, click "2. Download Application Package". The RFA number will be pre-populated in the forms management screen and the corresponding R&D Service encoded in the header of the application package. **Be sure you have the correct application package from the correct R&D Service and RFA before you begin filling out the**

**forms; there is no mechanism for changing the RFA number or R&D Service in an application package. This is a checklist item.** Section 2.5 provides specific information regarding the components of an Application Package. Section 3 provides additional instructions for properly completing an application package.

To download the instructions, click "1. Download Application Instructions". For VA-ORD opportunities, this action will download a document containing a link to the VA-ORD intranet site where the most current version of the VA SF424 Application Guide (this document) and the full text of the RFAs are available. Alternatively, you may go directly to this URL to obtain the most recent version. Applicants are encouraged to check this site regularly for the most current version.

**Do not "share" completed application packages between investigators. Some data fields may not be editable once completed and "left-over" information may cause your application to have fatal errors that prevent submission or to be returned without review.**

## 2.5 Components of an SF424 Application to VA-ORD

The SF424 (R&R) form set is comprised of a number of components, each listed in the table below as separate "documents" in the order they appear in the application package.

***Table 2.5-1. Components of a VA-ORD Application (in order of appearance)***

| Document | Required | Optional | Instructions |
|---|---|---|---|
| SF424 (R&R) Cover Component<br>(Applicant Information, Project Title, etc) | ✔ | | Section 4.2 |
| SF424 (R&R) Other Project Information<br>(Abstract, Relevance, Introduction to Revised Application, Specific Aims, Research Plan, VA Career Plan, VA Mentoring Plan, Progress Report Publications, Human Subjects, Vertebrate Animals, Director's Letter, Letters of Support, Checklist, Appendices) | Different RFAs and/or funding mechanisms may require different components | | Section 4.3 |
| SF424 (R&R) Project/Performance Site Locations | ✔ | | Section 4.4 |
| SF424 (R&R) Senior / Key Person Profile(s)<br>(Biosketches and Current & Pending Support) | ✔ | | Section 4.5 |
| SF424 (R&R) Budget* | ✔ | | Section 4.6 |
| SF424 (R&R) Subaward Budget Attachment Form** | | ✔ | Section 4.7 |

*Application packages for VA-ORD funding opportunities include only the SF424 (R&R) Budget; modular budgets are not accepted. Unless otherwise stated in a funding announcement, a budget component must always be submitted.

**Subaward Budgets may be required for multi-site projects (see specific RFAs for instructions).

All required and optional forms for electronic submission listed above are available through Grants.gov and should be downloaded from the FOA/RFA being applied to. Do not use any forms or format pages from other sources; these may include extraneous headers/footers or other information that could interfere with the electronic application process.

## 2.6 Format Specifications for Text (PDF) Attachments

Designed to maximize system-conducted validations, multiple separate attachments are required for a complete application. When the application is retrieved from grants.gov by eRA Commons, all

submitted forms and PDF attachments are concatenated into a single document (e-Application) for use during the review process.

**VA-ORD requires all text attachments to the Adobe application package to be submitted as PDFs and that the final text in the resulting sections of the eApplication conform to the formatting requirements noted below.**

**Failure to follow these requirements may lead to rejection of the application during VA-ORD validation or delay in the review process.** (See Section 2.3.2 for more information on creating PDFs.)

Text attachments should be generated using word processing software and then converted to PDF using separate PDF conversion software. Avoid scanning paper documents when possible to create PDF files since that may cause problems for the agency handling the application.

When attaching a PDF document to the actual forms, please note you are attaching an actual document, not just pointing to the location of an externally stored document. Therefore, if you revise the document after it has been attached, you must delete the previous attachment and then reattach the revised document to the application form. Use the **"View Attachment"** button to determine if the correct version has been attached. In addition, check the electronic e-Application within eRA Commons during the 2-day examination period to ensure that the correct version of all attachments were used and do not contain blank pages or have incorrect formatting.

**The font, line spacing, and margin requirements below refer to the e-Application in eRA Commons, not to the source word processing documents or converted PDF attachments.**

**E-Applications (in eRA Commons) that fail to meet the formatting requirements below will be not accepted for review.**

**Font and Type Density**

Word processing documents that will be converted to PDF attachments must use an **Arial, Helvetica, Palatino Linotype, or Georgia typeface,** a black font color, and a font size of 11 points or larger. A Symbol font may be used to insert Greek letters or special characters, but the font size, font typeface, and color requirements still apply.

**Type density, including characters and spaces, must be no more than 15 characters per horizontal inch. There may be no more than six lines per vertical inch on a page**.

Do **NOT** cut and paste from any other program (i.e., WORD or ePROMISe) to complete fields on SF424 components; the font may not transfer correctly and may cause erroneous characters (e.g., "&"or "□") to be introduced. **Check the final eApplication carefully for such errors.**

**Paper Size and Page Margins**

Use *standard paper size (8 ½" x 11).*

Use at least one-half inch margins (top, bottom, left, and right) for all pages. No information should appear in the margins, including the PI's name or page numbers.

**Issues that may cause over-sized margins and/or reduced font size during conversion to PDF files:**

- Margins for the final PDF document set larger than the margins in the original Word document
- Default paper size for printing set smaller than 8.5 x 11 (i.e., A4) in the conversion program

  You may need to change the printer settings in the PDF conversion software to "remove margins" and redo the PDF conversion

**Reduction of font size may not be readily apparent in the converted PDF file. Applicants and Signing Officials should print a page from each section of e-Application derived from a PDF attachment (i.e., Research Plan, Specific Aims, in eRA Commons during the 2-day examination period to ensure that font and margin requirements have been met.**

**The most apparent indications of an error in margins/font size when examining the e-Application are (1) if the margin on the right side of the page is larger than the left side or (2) if all margins appear excessively large (although the same on both sides).**

**Page Formatting**

Since reviewers will be reviewing applications as an electronic document, applicants are strongly encouraged to use only a standard, single-column format for the text. **Avoid using a two-column format since it can cause difficulties when reviewing the document electronically.**

**Do not include any information in the header or footer regions of the attachments**. A header will be system-generated that references the name of the PD/PI. Page numbers for the footer will be system-generated in the complete application, with all pages sequentially numbered.

**Figures, Graphs, Diagrams, Charts, Tables, Figure Legends, and Footnotes**

You may use a smaller type size but it must be in a black font color, readily legible, and follow the font typeface requirement. Color can be used in figures; however, all text must be in a black font color, clear and legible.

**A table must consist of a uniform row/column structure (i.e., a consistent number of rows and columns).** Each piece of data in the table must be contained in its own cell in the table.

Tables should include a title. When creating tables, use the Microsoft Word table function; do not place an Excel table in a Word document.

- **All text in the body of the table must:**
  - **may not exceed 17 characters per horizontal inch**
  - **be single-spaced**
- **All text in table and figure legends must:**
  - **may not exceed 20 characters per horizontal inch.**
  - **be single-spaced**

**Tables may not be used to condense text or to otherwise avoid stated font and page limits; drawing a box around a page of text, or a portion of a page, does not make it a table.**

**Tables may not be reduced in size and presented as graphs, figures, or diagrams to avoid the font restrictions stated above for tables.**

**Grantsmanship**

Use English and avoid jargon.

If terms are not universally known, spell out the term the first time it is used and note the appropriate abbreviation in parentheses. The abbreviation may be used thereafter.

**Page Limits**

Page limitations referenced in these instructions and/or funding opportunity announcement must be followed. Observe the page number limitations given in Table 2.6-1. Agency validations will

include checks for some page limits. **Note that while these computer validations will help minimize incomplete and/or non-compliant applications, they do not replace the validations conducted by VA-ORD staff. Applications found not to comply with the requirements may lead to rejection of the application during agency validation or delay in the review process.**

All applications and proposals for VA-ORD funding must be self-contained within specified page limitations. **Unless otherwise specified in a VA-ORD funding announcement, internet website addresses (URLs) may not be used to provide information necessary to the review; reviewers are under no obligation to view these sites.** Moreover, reviewers are cautioned that they should not directly access an Internet site as it could compromise their anonymity.

***Table 2.6-1. Page Limitations and Content Requirements***

| Section | Page Limit | Content |
|---|---|---|
| Introduction to Resubmission Application | 3 pages | See Instructions |
| Specific Aims | 1 page | See Instructions |
| Research Plan<br>Background and Significance, Preliminary Studies/Progress Report, Research Design and Methods | 24 pages | Includes all text, figures, charts, tables, and diagrams. |
| **Other Components**<br>Progress Report Publication List,<br>Human Subjects,<br>Vertebrate Animals,<br>Multiple PD/PI Leadership Plan,<br>Consortium/Contractual Agreements,<br>Director's Letter,<br>Letters of Support,<br>Checklist<br>Appendices | no limit | See instructions for Item 12 on the Other Project Information Component (Section 4.3) |
| Bibliography & References Cited | 4 pages | See Instructions |
| Biographical Sketches | 4 pages | No more than four pages for each person listed as Senior/Key Persons. |
| Appendices | No limit | Restrictions have been placed on what is allowable to be included in an Appendix. Please read the guidelines carefully. |

## 2.7 "Resubmission" (*Revised*) Applications

VA-ORD allows the submission of **up to two revised applications** (identified as "Resubmission" applications on the SF424 Cover Component) with no restriction on timeframe; these applications will be denoted as 01A1 and 01A2 in the eRA-generated application number). **No further resubmissions will be accepted for review.**

If an application hs been "revised" in response to the reviewers and will now be **submitted to a different R&D Service (i.e. BLR&D vs. CSR&D), it is considered to be a 'New"**

**application** to the new Service; in this case **the response to the previous review should be submitted as an Appendix.**

See the policy on Submission of a Revised (amended) Application to VA-ORD in Part III.

VA-ORD has established new policies for application resubmissions of certain categories. See Resubmission of Unpaid RFA Applications and Resubmission of Applications with a Changed Activity Mechanism in Part III.

Acceptance of a resubmission application will not automatically withdraw the prior version. eRA Commons keeps all versions (i.e., 01, A1, and A2) of an application active and provides an internal Multiple Active Applications (MAA) flag for each application in an active cluster. The cluster allows program staff and applicants to quickly identify all versions of one application. If any version in a cluster is awarded, all other applications within the cluster will be automatically withdrawn without any additional action by applicants or staff.

There are four requirements for a Resubmission (revised) application:

- The Summary Statement for the previous application must be available in the eRA Commons; the critiques from the previous review are included in the Summary Statement.
- The PD/PI(s) must make significant changes to the application.
- An Introduction (3-page limit) must be included that summarizes the substantial additions, deletions, and changes to the application. The Introduction must also include a response to the issues and criticism raised in the Summary Statement; be sure to include the issue you are responding to and not just the response. The 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 Preliminary Studies/Progress Report section should incorporate work completed since the prior version of the application was submitted.

**After three (3) unsuccessful reviews (-01, -01A1, and -01A2), no further resubmissions will be accepted and a "new" application must be submitted (and no response to the previous review will be allowed)**. While it is recognized that investigators are trained in a particular field of science and are not likely to make drastic changes in their overall research interests, **a new application following three unsuccessful reviews is expected to be substantially different in content and scope with more significant differences than are normally encountered in a Resubmission application.** Simply rewording the title and Specific Aims or incorporating minor changes in response to comments in the previous Summary Statement does not constitute a substantial change in scope or content. **Changes to the Research Plan should result in significant changes in direction and approach for the research project, and be reflected in the title of the "new" application**. Thus, a new application would include substantial changes in all sections of the Research Plan, particularly the Specific Aims and the Research Design and Methods sections. A request for review by a different SRG is not sufficient reason to consider an application as new.

In the referral process, VA-ORD staff look at all aspects of the application, not just the title and Project Summary/Abstract. Requesting review by a different SRG (if permitted by the R&D Service) does not affect the implementation of this policy. When necessary, previous applications are analyzed for similarities to the present one. Thus, identical applications or those with only minor changes will not be accepted for review. If identified after assignment or review, identical applications will be withdrawn.

## 2.8 "Revision" Application

**VA-ORD does not accept electronic submission of competing supplemental applications (now known as "Revision" applications)**, which would request additional support for expansion of an existing project's scope or research protocol. All such requests must be submitted directly to the R&D Service funding the project.

## 2.9 Similar, Essentially Identical, or Identical Applications

**Submission of identical (or essentially idential) applications to one or more R&D Services within VA-ORD are not allowed**, and VA-ORD will **not accept similar applications with essentially the same research focus** from the same applicant organization. This includes derivative or multiple applications that propose to develop a single product, process or service that, with non-substantive modifications, can be applied to a variety of purposes. Likewise, identical or essentially identical applications submitted by different applicant organizations or by different principal investigators will not be accepted. Applicant organizations should ascertain and assure that the materials they are submitting on behalf of the principal investigator are the original work of the principal investigator and have not been used elsewhere in the preparation and submission of a similar application by another investigator. Applications to VA-ORD are grouped by scientific discipline for review by individual SRGs and not by disease, disease state, or medical subspecialty of the principal investigator(s). The reviewers can thus easily identify multiple applications for essentially the same project. In these cases, application processing may be delayed or the application(s) may not be reviewed.

## 2.10 Submitting Your Application via Grants.gov

**The Applicant Organizational Representative (AOR) registered in Grants.gov is the only official with the authority to actually submit applications through Grants.gov.** Therefore, PDs/PIs will need to work closely with their AOR to determine that all the necessary steps have been accomplished prior to submitting an application. This includes any internal review process required by the VA medical center.

Before starting the final submission step, **applicants are encouraged to save a copy of the final application locally**. Once you have properly completed all required documents and attached any required or optional documentation, click on the **Check Package for Errors** button to ensure that you have successfully completed all required data fields. If any of the required fields are not completed you will receive an error notice which will indicate where revision is needed within your package. Correct all errors and save the application. Only after the package has been saved with no errors will the **Save & Submit** button become active. The application package must then be saved once more before the submission process begins. Only an AOR will be able to perform the submit action, and they will be taken to the applicant login page to enter the Grants.gov username and password that was established in the Register with Grants.gov process (if not connected to the internet you will be instructed to do so).

Once logged in, the application package will be automatically uploaded to Grants.gov. A confirmation screen will appear once the upload is complete and a Grants.gov Tracking Number will be provided on this screen. The AOR should record this number and provide it to the applicant so that they may refer to it should they need to contact Grants.gov Customer Support. This Tracking Number (e.g., GRANT123456) may be needed to prepare a Changed/Corrected application.

For additional information, access Grants.gov/Submit Application Package (http://grants.gov/SubmitApplication).

## 2.11 After You Submit Your Application via Grants.gov

The Authorized Organizational Representative (AOR) can use Grants.gov to check the status of an application at any time. Note that Grants.gov requires a user login and password. To check the status of an application, go to https://apply07.grants.gov/apply/checkApplStatus.faces

Once an application has been submitted via Grants.gov, several emails are generated by Grants.gov and sent to the AOR (also known as the Signing Official [SO]) named in the application indicating a Grants.gov tracking number that is assigned to the submission:

1) Submission Receipt: An email is sent indicating your application has been received by Grants.gov and is currently being validated.
2) Submission Validation Receipt: An email is sent indicating your application has been received and validated by Grants.gov and is being prepared for VA-ORD retrieval.
3) Agency Retrieval Receipt: An email is sent indicating your application has been retrieved by VA-ORD.
4) Agency Tracking Number Assignment for Application: An email is sent indicating your application has been assigned an Agency Tracking Number.

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If the AOR/SO has not received a confirmation message from Grants.gov within 48 hours of submission, please contact:

Grants.gov Contact Center
Telephone: 1-800-518-4726
Email: support@grants.gov

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At that point, the application will be scheduled for download into the eRA system for agency validation. It is imperative that the email address provided in blocks 15 (for the PD/PI) and 19 (for the AOR/SO) on the SF424 (R&R) Cover component be current and accurate. Once agency validation is completed, an agency notification (not Grants.gov) will be emailed to the PD/PI and AOR/SO named in the application.

This email notification will inform the PD/PI and AOR/SO that the application has been received and processed by the agency and will indicate whether any errors or warnings resulted during the validation process. The PD/PI and AOR/SO will be invited to log on the eRA Commons, to view the assembled application, or review the list of warnings/errors that were encountered during the validation process.

If there were no validation errors, this email notification will also inform the PD/PI and AOR/SO of an agency accession number, which represents the "agency tracking number." This number replaces the Grants.gov tracking number that was assigned when the application was first submitted. The Grants.gov system will indicate that the agency tracking number has been assigned, and will reflect both numbers. **In subsequent interaction with the eRA Commons, however, it is the agency accession number that will be used to refer to the application, not the Grants.gov tracking number.**

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

**However, since email can be unreliable, it is the responsibility of the applicant and AOR/SO to periodically check on the application's status in the Commons.**

**Failure to provide the eRA Commons ID for all PD/PIs in the Credential field of the Senior/Key Person Profile Component will prevent e-mails from being distributed to either the PD/PI or AOR/SO.**

Once an application package has been successfully submitted through Grants.gov and the e-Application has been assembled by the eRA Commons, PDs/PIs and AORs/SOs will have **two full business days (Monday – Friday, excluding Federal holidays) to view the e-Application**. It is critical the PD/PI **and** Signing Official review the e-application to ensure that all the content is complete and formatting requirements have been met. If everything is acceptable, no further action is necessary. **On the third business day**, excluding Federal holidays, **the application will automatically become verified and move forward to VA ORD for processing**.

If, however, it is determined that some part of the application contains errors, was lost or did not transfer correctly during the submission process, the AOR/SO will have the option to "Reject" the application and submit a Changed/Corrected application. Once rejected, applicants should follow the instructions for correcting errors in Section 2.12.

Applications successfully retrieved by eRA commons (processed with no errors) can be viewed as an "e-Application" within eRA Commons.

**To view the assembled e-Application image the AOR/SO and PD/PI should:**

1. Login to the eRA Commons with your account.
2. Click the **Status** tab on the Commons menu bar.
3. Click **Recent/Pending eSubmissions** on the left-hand side of the screen.
4. Search for your application by date received, Grants.gov tracking number, or accession number (AOR/SO only).
5. A hitlist of application numbers will be displayed. If the application was validated with warnings only, or without encountering any problems whatsoever, its accession number (e.g., "AN:2911064") will be used to identify it in the hitlist. This is the same number that Grants.gov displays and refers to as the "agency tracking number."

   If any errors were identified during validation, then the application will be identified by its Grants.gov tracking number (e.g., "GRANT12345678") in the hitlist. This is the number that Grants.gov assigned to your application at the time of submission.
6. When you find the appropriate application, click the accession number in the Application ID column to view the status information screen.
7. Click e-Application from the Other Relevant Documents section to view the assembled application.

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Note: The application can be rejected by clicking on the "**Reject e-Application**" hyperlink from the Action Column of the search hit list.

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1. If errors were identified during validation, the application will be identified by its Grants.gov tracking number (e.g., "GRANT12345678") in the hitlist. This is the number that Grants.gov assigned to your application at the time of submission.
2. When you find the appropriate application, click the accession number in the **Application ID** column to view the status information screen.
3. Click e-Application from the Other Relevant Documents section to view the assembled application.

If an application is submitted after the "Down to the Wire" submission deadline in **Tables 2.15.1 and 2.15.2**, the 2-day viewing/correction window may not be used to identify errors and submit a corrected application as this would cause the corrected application to miss the verification deadline.

The "Reject" feature should also be used if you determine that warnings are applicable to your application and need to be addressed now. Remember, warnings do not stop further application processing. If an application submission results in warnings (but no errors), it will automatically move forward if no action is taken. Some warnings may need to be addressed later in the process.

PDs/PIs should work with their AOR/SO to determine when use of the "Reject" feature is appropriate.

**Do not submit a corrected version of an application without "rejecting" the previous successfully submitted application. If multiple versions are submitted and become verified, all versions may be returned without review.**

**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 in the e-Application during the 2-day examination window.**

## 2.12 Correcting Errors

Prior to the specified submission deadline, applicants may make corrections and submit a "corrected" application through Grants.gov, **provided that the previous version has not been verified**. After the specified submission deadline, if applicants make corrections and resubmit, the application will be considered late. **Late applications will not be accepted for review unless approval to submit late is obtained in advance from the R&D Service; approval will only be provided in highly unusual circumstances.** See Section 2.14 for additional information on submission dates.

If errors or warnings result from the validation process, the PD/PI and AOR/SO will be issued an email instructing them to log on to the eRA Commons to review the list of warnings/errors that were encountered during the validation process. The eRA system will make every effort to send an email to the PD/PI and AOR/SO indicating whether errors or warnings were detected. **E-mail can be unreliable**; applicants are strongly encouraged to check periodically on the status of their application(s) in the eRA Commons, so that any errors or warnings can be resolved in the timeliest manner possible.

Please be aware of the distinction between *errors* and *warnings*. The word *error* is used to characterize any condition that causes the application to be deemed unacceptable for further consideration. Generally, errors will indicate significant inaccuracies, inconsistencies, omissions, or formatting errors that have been identified in the body of the application. Conversely, the word *warning* characterizes any condition that is acceptable, but worthy of bringing to the applicant's attention. It is at the applicant's discretion, whether a warning condition requires any action.

Errors must be corrected, and then the application may be submitted as a changed/corrected application (as outlined below) in order for the application to be accepted. Please note that if

validation has identified *warnings only*, then the PD/PI and SO will be allowed to view the application.

Warnings do not require any action or submission of a changed/corrected application at this time. However, please be aware that some warnings may, in fact indicate a problem that will prevent the application from passing the administrative review process; **do not assume that a warning can be ignored**.

Failure to comply with stated VA-ORD policies can also result in a submitted application being returned to the applicant without review. For this reason, **applicants are strongly encouraged to review all warnings, to ensure that they require no further attention and that they are satisfied with the validation results.** If desired, warnings can be corrected in the same manner as errors.

A changed/corrected application may also be submitted if the e-Application, as viewed in the eRA Commons, is incomplete or inaccurate from that submitted.

**To correct errors and resubmit the application:**

1. Make whatever corrections are necessary, wherever appropriate. Most often, this means that you have to edit the data within the application forms to correct whatever problem or inconsistency that was noted.
2. Check the "Changed/Corrected Application" box in block 1 of the SF424 (R&R) Cover component.
   - When you check the Changed/Corrected Application box, Item 4a. Federal Identifier becomes a required field.
   - When submitting a Changed/Corrected Application for a "New" Type of Application (Item 8 = New), in the Federal Identifier field (Item 4a) enter the Grants.gov tracking number for the previous application that you are correcting. You should obtain this number from your AOR/SO.
   - When submitting a Changed/Corrected Application for a "Resubmission," or "Renewal" Type of Application (Item 8 = Resubmission or Renewal), in the Federal Identifier field (Item 4a) enter only the 2-letter R&D Service designation and serial number of the previously assigned application/award number (e.g., BX123456); **do not include any other portion of the number (e.g., 1 I01- or -01A1)**.
   - Do **not** use the Changed/Corrected Application box to denote a submission of a revised or amended application. That will be indicated in item 8, Type of Application.
3. Have the AOR/SO submit the revised application package to Grants.gov again.

The same email notifications will be issued once VA-ORD has downloaded and validated the re-submitted application and the PD/PI and AOR/SO will once again be required to log on to the Commons either to view/verify the application, or to review the errors that were encountered during validation.

**All Changed/Corrected applications must meet both deadlines (submission and verification; see Tables 2.15.1 and 2.15.2). The 2-day examination window cannot be used if it will result in the application missing either deadline.**

The application will only be assigned for scientific review once all errors are resolved.

In addition to the validations performed by the eRA system, VA-ORD staff will conduct administrative validations. Applications that fail these validations will not be accepted for review. The PD/PI and/or the applicant organization may be contacted for further corrections/clarifications. Such requests will include a deadline for the resubmission and

acceptance of the corrected application in Grants.gov and eRA Commons. Applications received after this deadline may be returned without review.

## 2.13 Submission of Supplementary or Corrective Information

Unless specifically required by instructions in the VA SF424 Application Guide, by a specific RFA, or is solicited by the Scientific Review Officer (SRO) of the SRG, **supplementary or corrective material will not be accepted after an application becomes verified**.

## 2.14 Application Dates (Submission and Verification Deadlines)

For electronic submission through Grants.gov, each FOA/RFA posted in Grants.gov includes an Opportunity Open Date and an Opportunity Close Date, as well as a **Table of Deadline, Review, and Award Dates**. These announcements are posted in Grants.gov showing an Open/Close period that spans the entire active period of the announcement. Applicants should read the Funding Opportunity Announcement (RFA) carefully for specific submission/receipt dates.

Once an application package has been successfully submitted through Grants.gov, it is retrieved by eRA Commons for error checking of the e-Application (electronic "grant image"). If fatal errors are identified by eRA, the application will be rejected; warnings will not prevent the application from being retrieved. Retrieved applications with no errors (with or without warnings) are then provided a two-day window to correct any eRA-identified warnings or errors identified by the SO or PD/PI. The error correction window excludes weekends and Federal holidays. **At 12:01 am on the third (3rd) business day** after retrieval of the application from Grants.gov, the application becomes **"verified"** and the final assembled e-Application is created in the eRA Commons.

**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 in the e-Application during the 2-day examination window.**

**Applications are considered on time only if they meet both deadlines indicated in Table 4 (Deadline, Review, and Award Dates) in each FOA/RFA:**

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

   **AND**

2. **Verification by eRA Commons on or before the verification deadline.**

**Weekend/Holiday Submission Dates.** If a submission or verification deadline falls on a weekend, it will be extended to the following Monday; any time the date falls on a Federal holiday, the deadline will be extended to the following business day.

**Late Applications: Applications that miss either deadline (submission or verification) above will not be accepted for review**.

**Deadlines indicated in an RFA take precedence over the dates contained in this application guide.**

## 2.15 Submission, Review and Award Cycles

The VA-ORD submission, review, and award schedule is provided in **Table 4 (Deadline, Review, and Award Dates) in each FOA/RFA**. For specialized funding opportunities, consult with the appropriate R&D Service prior to the preparation of an application.

Note: Applicants should refer to the VA-ORD intranet site for mechanisms that have transitioned to electronic submission using the SF424 (R&R) application.

Some RFAs issued by an R&D Research Service may allow submission of proposals for multiple review cycles (Spring, Summer, Fall, and/or Winter). Please read all RFAs carefully.

### *Application Assignment Information*

Competing applications that have been successfully submitted through Grants.gov (including correcting all errors and the application assembled by the eRA Commons system) will be processed through VA-ORD unless otherwise stated. The application will be assigned to an appropriate SRG and R&D Service. Assignment is based on the scientific content of the application using established referral guidelines. Business rule validations are conducted by the system as well as by VA-ORD staff.

***Assignment to SRG***: VA-ORD staff will assign appropriately completed applications to an SRG (commonly referred to as a "review panel" or "study section") that will perform the scientific/technical merit review. Applications to VA-ORD are grouped by scientific discipline for review by individual SRGls and not necessarily by disease, disease state, or medical subspecialty of the principal investigator(s).

***Assignment to Relevant Potential R&D Services:*** In addition, VA-ORD will assign each application to the R&D Service that is the potential funding component. When the scientific areas and the research proposed in an application are sufficiently relevant to the program responsibilities of two or more awarding components, the application will be discussed to determine which R&D Service will be responsible for the review and funding decision.

The VA-ORD web site lists the recurring SRGs (review panels), and you may suggest/request assignment to a specific SRG or R&D Service. Although these suggestions will be taken into consideration, the final determination will be made by the R&D Services participating in each solicitation. After the submission date, usually within four (4) weeks, the PD/PI and the VA medical center will be able to access in the eRA Commons the application's assignment number; the name, address, and telephone number of the Scientific Review Officer (SRO) of the SRG to which the application has been assigned; and the assigned R&D Service contact and phone number. Review outcome and other important information are also available in the Commons. If the initial assignment to an R&D Service or SRG seems inappropriate, the local VA Research and Development Office may request reassignment on behalf of the PD/PI.

**If assignment information is not available in the eRA Commons within four weeks of the submission date, contact the appropriate R&D Service (see Table 1.4.1). If there is a change in assignment, you will receive notification.**

Applicant investigators must not communicate directly with any SRG member about an application either before or after the review. Failure to observe this policy will create serious breaches of confidentiality and conflicts of interest in the peer review process. From the time of assignment to the time the review of your application is complete, applicant investigators must direct all questions to the SRO. This individual is in charge of the SRG and is identified in the eRA Commons.

**Assignment/Reassignment Request Letters (if permitted by the R&D Service). The local Research Office (not individual PD/PIs) may submit a separate letter for each application:**

- To request an initial assignment to a particular SRG after a proposal is submitted.

- To request re-assignment to a particular SRG after an initial assignment has been made available in eRA Commons.
- To indicate individuals who should not review the application and explain why (i.e., competitors, conflicts of interest, etc.). **Requests to exclude reviewers that are not fully justified in writing may not be considered**.
- To indicate scientific disciplines or techniques involved in the application that may require special attention during review – **specific reviewers may NOT be suggested**.

**Each R&D Service will determine if and how assignment requests may be submitted (i.e., e-mail, mail, etc). Table 1.4.1 lists the appropriate contacts for each Service.**

## 2.16 Resources for Finding Help

**Do not address questions to the Grants.gov or eRA helpdesks unless you are having a technical problem with registration or logging on to either of these systems.**

**The Grants.gov and eRA helpdesks are not familiar with, nor are they responsible for, the format and/or submission requirements for VA applications.** Grants.gov or eRA Helpdesks can only tell you about NIH requirements. This will not help you and may in fact make your problems worse if you decide to follow their advice.

### 2.16.1 Finding Help for Grants.gov Registration

Contact **Grants.gov customer support** if help is needed with the **Grants.gov registration** process or with **logging on to Grants.gov** to submit an application:

Grants.gov Program Management Office
200 Independence Avenue, SW
HHH Building, Room 739F
Washington, DC 20201

Grants.gov Helpdesk: support@grants.gov

Grants.gov Contact Center Phone Number: 1-800-518-4726

The Contact Center's hours of operation are Monday-Friday from 7:00 a.m. to 9:00 p.m. Eastern Time.

### 2.16.2 Finding Help for the eRA Commons Registration or eRA Commons Validation Processes

eRA Commons customer support is provided by the eRA Commons Helpdesk. This Helpdesk should be contacted concerning **problems with the eRA Commons registration** process for the applicant organization and PDs/PIs or with **logging on to eRA Commons**:

**eRA Commons Helpdesk (Web): http://ithelpdesk.nih.gov/eRA/**
(preferred method of contact)

**eRA E-Mail: commons@od.nih.gov**

eRA Commons Phone: 301-402-7469
866-504-9552 (Toll Free)
301-451-5939 (TTY)

eRA website: http://era.nih.gov

eRA Commons website: https://commons.era.nih.gov/commons/index.jsp

The eRA Commons Helpdesk hours of operation are Monday-Friday from 7:00 a.m. to 8:00 p.m. Eastern Time.

### 2.16.3 Finding Help for Application Preparation and/or Submission

**The local VA Research & Development Office** must submit all inquiries/problems concerning VA electronic submissions **to the VA eRA Mailbox in Outlook (rd-era@va.gov)**. This is not a communication mechanism for individual investigators to by-pass the R&D Office and communicate directly with VACO personnel.

**Do not directly contact individuals at VACO (phone or e-mail).** If staff is on leave or otherwise unavailable, your questions may go unanswered for several days until they return. This will not be viewed as acceptable grounds for requesting extension of deadlines **or accepting late submissions**.

### 2.16.4 Additional Resources

**eRA Commons**

For electronic submission of applications, organizations/institutions are required to register with the eRA Commons. Registered PDs/PIs can check assignment/contact information, review outcome, and other important information at https://commons.era.nih.gov/commons/index.jsp. For more details on eRA Commons registration, see Section 2.2.2.

Email the Commons Help Desk at commons@od.nih.gov.

You can call the Commons Help Desk at 1-866-504-9552 (toll-free) or 301-402-7469; 301-451-5939 (TTY). Business hours are M-F, 7:00 am-8:00 pm Eastern Time.

**Grants.gov User Guide**

The Grants.gov User Guide is a comprehensive reference to information about Grants.gov. Applicants can download the User Guide as a Microsoft Word document or as a PDF document. The user guide can be accessed at: http://www.grants.gov/applicants/app_help_reso.jsp.

**VA-ORD Program for Research Integrity Development & Education (PRIDE)**

The Program for Research Integrity Development & Education (PRIDE) mission is to protect participants in VA human research. PRIDE is responsible for all policy development and guidance, and all training and education in human research protection throughout the VA.

**VA-ORO Office of Research Oversight**

The Office of Research Oversight (ORO) serves as the primary VHA office in advising the Under Secretary for Health on all matters of compliance and assurance regarding human subjects protections, animal welfare, research safety, and research misconduct.

**Safety and Compliance Issues**

Guidance on Safety and Compliance issues is available at http://www.research.va.gov/resources/policies/by_topic.cfm#Safety_and_Compliance

**Office of Laboratory Animal Welfare (OLAW)**

Animal Welfare and related regulations and assurances information is available at http://olaw.nih.gov
Telephone: (301) 496-7163

# 3. Using the VA-ORD Application Package

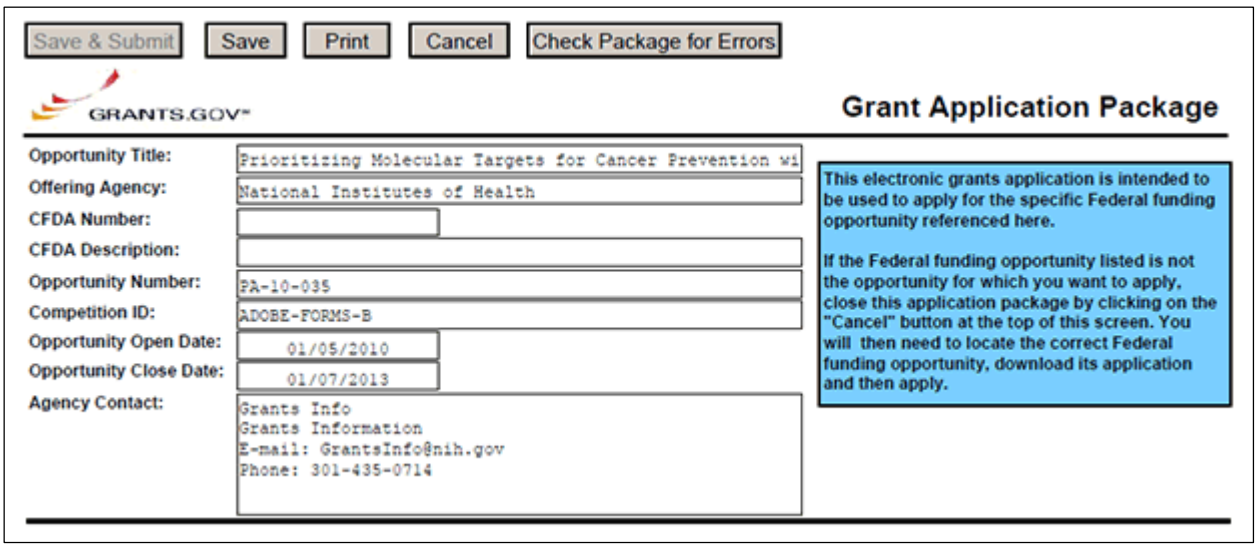
This section describes the steps an applicant takes once the appropriate FOA/RFA (see Section 2.4) has been located and the corresponding application package has been successfully downloaded.

**Note when you save or exit the package, you may receive an error message asking, "Do you want to save changes before closing?" Applicants should always answer "Yes".**

## 3.1 Verify Award Information

When you select a funding opportunity in Grants.gov, verify that the information shown in the Grant Application Package screen corresponds to the funding opportunity for which you wish to apply. Grants.gov auto-populates the following information in the downloaded application:

- Opportunity Title
- Offering Agency
- CFDA Number
- CFDA Description
- Opportunity Number
- Competition ID
- Opportunity Open Date
- Opportunity Close Date
- Agency Contact



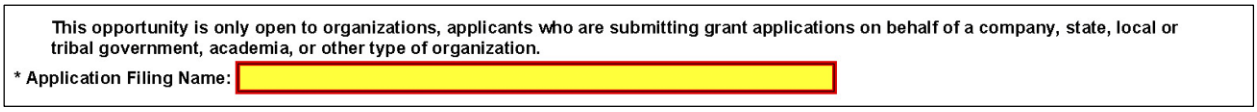

***CFDA Number Field:*** Many FOAs include multiple CFDA (Catalog for Domestic Assistance) numbers. When this is the case, the CFDA Number and CFDA Description fields will appear blank in the Grants.gov Grant Application Package screen shown above. The appropriate CFDA number will be automatically assigned once the application is assigned to the appropriate R&D Service. VA-ORD RFAs may be issued without a CDFA.

***Opportunity Open Date & Close Date Fields:*** Many FOAs posted by VA-ORD include multiple submission/receipt dates and are active for several years. These announcements are posted in Grants.gov showing an Open/Close period that spans the entire active period of the announcement. Applicants should read the funding opportunity announcement carefully for specific submission/receipt dates. **Applications that are submitted or validated after the**

**deadlines specified in Table 4 in the RFA will not be accepted for review**. See also Section 2.14 above for the late application policy.

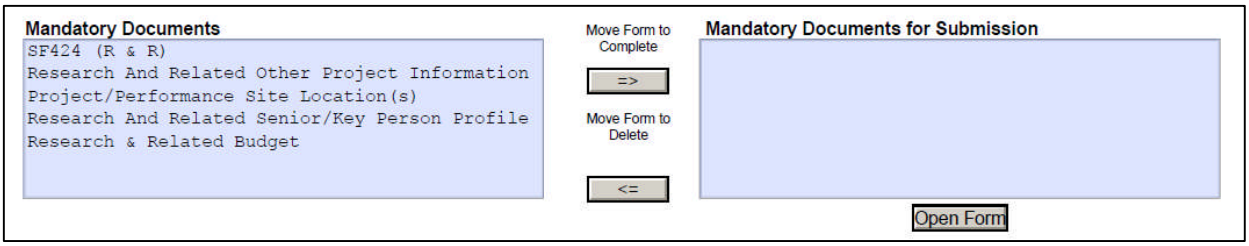
## 3.2 Enter the Name for the Application (Required Field)

Enter a name for the application in the Application Filing Name field. This name is for use solely by the applicant for tracking the application through the Grants.gov submission process; **VA-ORD strongly recommends inclusion of the Facility Number (i.e., 512) and PD/PI's last name**.




## 3.3 Open and Complete Mandatory Documents

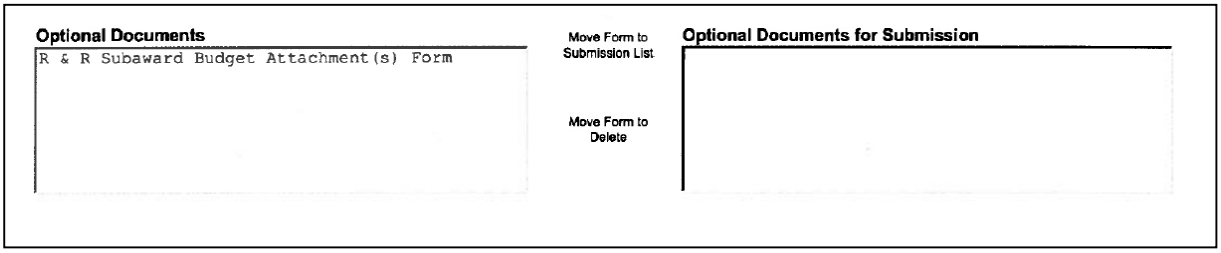
Open and complete all of the documents listed in the Mandatory Documents box. **Complete the component titled SF424 (R&R) first.** Data entered in this component populates fields in other mandatory and optional forms where applicable.




To open an item:

1. Click the document name in the Mandatory Documents box.
2. Click **Move Form to Complete**. This will automatically add the selected document in the correct sequence to the application package that is constructed below the "Documents for Submission" box.
3. Click the document name in the Mandatory Documents for Submission box and click **Open Form**. This will move you to the top of the selected document within the application package
4. To remove a document from the Mandatory Documents for Submission box, click the document name to select it and then click the **Move Form to Delete** box. This returns the document to the Mandatory Documents box.

## 3.4 Open and Complete Optional Documents



Move and "open" these documents as instructed for the Mandatory Documents above.

These documents can be used to provide additional information for the application or may be required for specific types of proposals. At this time, only the R&R Subaward Budget Attachment Form will be accepted as an Optional Document in VA ORD applications. **The PHS Supplemental Forms used by NIH will not be accepted for VA funding announcements.**

Once all required documents have been completed and saved locally, click on the **Check Package for Errors** button to ensure that you have successfully completed all required data fields. If any of the required fields are not completed you will receive an error notice which will indicate where revision is needed within your package. Correct any errors. **Save the application package again after no errors are identified**.

Click **Submit** to submit the application to Grants.gov. **Only an Authorized Organizational Representative (AOR) will be able to perform the submit action**, and will be prompted to enter username and password to verify his/her identity. The Submit button does not become active until all required documents have been properly completed and the application has been saved. If an edit has been made somewhere in the application package, the file must be resaved before attempting to submit. If the Submit button is grayed out, resave the file.

**Reminder: The system will not consider a component form document to be complete until it has been moved to the Completed Documents box.** Once you click the Submit button, a confirmation page appears asking you to verify the desired funding opportunity and Agency to which the application is being submitted.

# 4. Completing the SF424 Research and Related (R&R) Forms

**VA-ORD-specific instructions are denoted by the VA logo displayed to the left of the paragraph, as illustrated here. Additional/revised instructions are indicated in yellow highlight.**

## 4.1 Overview

This section contains all of the instructions you will need to complete the SF424 (R&R) forms.

**Conformance to all instructions is required and strictly enforced. VA-ORD may withdraw applications from the review process that are not consistent with these instructions.**

As you navigate through the forms, required fields are highlighted in yellow, outlined in red, and noted with an asterisk (*). Optional fields and completed fields are displayed in white. Data entered into a specific field is not accepted until you have navigated to the next field. If you enter invalid or incomplete information in a required field, you will receive an error message.

**Caution: Once you have "clicked" on a required field, you may not be able to undo its selection or leave it blank. If this occurs, entering two (2) spaces or "N/A" may satisfy the error check for the required field; if this does not work, you may need to download a new application and start over.**

Note: The highlighted fields required for submissions and the "**Check Package for Errors**" button only refer to requirements and errors in the actual Adobe Reader forms. They do not refer to requirements or data errors against VA-ORD business processes. Those

validations will be performed by the eRA Commons system after the application has been submitted. **There may be required fields for VA-ORD applications that are not highlighted in yellow and outlined in red.**

For those form components that are more than one page, click the **Next** button at the top of the form or scroll down (using the scroll bar on the right hand side of the screen) to navigate to a subsequent page. Once all data have been entered, click the **Close Form** button at the top of the form or scroll up using the scroll bar to return to the Grant Application Package Screen.

**Do NOT cut and paste from any other program** (i.e., WORD or ePROMISe) to complete fields on SF424 components; the font may not transfer correctly and may cause erroneous characters (e.g., "&"or "□") to be introduced. **Check the final eApplication carefully for such errors.**

## 4.2 Cover Component

OMB Number: 4040-0001
Expiration Date: 06/30/2011

APPLICATION FOR FEDERAL ASSISTANCE
**SF 424 (R&R)**

**3. DATE RECEIVED BY STATE** | **State Application Identifier**

**1. * TYPE OF SUBMISSION**
☐ Pre-application ☐ Application ☐ Changed/Corrected Application

**4. a. Federal Identifier**
**b. Agency Routing Identifier**

**2. DATE SUBMITTED** | **Applicant Identifier**

**5. APPLICANT INFORMATION** *** Organizational DUNS:**
* Legal Name:
Department: Division:
* Street1:
Street2:
* City: County / Parish:
* State: Province:
* Country: USA: UNITED STATES * ZIP / Postal Code:

Person to be contacted on matters involving this application
Prefix: * First Name: Middle Name:
* Last Name: Suffix:
* Phone Number: Fax Number:
Email:

**6. * EMPLOYER IDENTIFICATION** *(EIN) or (TIN)*:

**7. * TYPE OF APPLICANT:** Please select one of the following
Other (Specify):
**Small Business Organization Type** ☐ Women Owned ☐ Socially and Economically Disadvantaged

**8. * TYPE OF APPLICATION:**
☐ New ☐ Resubmission
☐ Renewal ☐ Continuation ☐ Revision

If Revision, mark appropriate box(es).
☐ A. Increase Award ☐ B. Decrease Award ☐ C. Increase Duration ☐ D. Decrease Duration
☐ E. Other (specify):

* Is this application being submitted to other agencies? Yes ☐ No ☐ What other Agencies?

**9. * NAME OF FEDERAL AGENCY:** National Institutes of Health Stage

**10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER:**
TITLE:

**11. * DESCRIPTIVE TITLE OF APPLICANT'S PROJECT:**

**12. PROPOSED PROJECT:**
* Start Date * Ending Date

*** 13. CONGRESSIONAL DISTRICT OF APPLICANT**

**14. PROJECT DIRECTOR/PRINCIPAL INVESTIGATOR CONTACT INFORMATION**
Prefix: * First Name: Middle Name:
* Last Name: Suffix:
Position/Title:
* Organization Name:
Department: Division:
* Street1:
Street2:
* City: County / Parish:
* State: Province:
* Country: USA: UNITED STATES * ZIP / Postal Code:
* Phone Number: Fax Number:
* Email:

### 1. Type of Submission (Required Field)

Check one of the Type of Submission boxes. If this submission is to change or correct a previously submitted "New" application, click the **Changed/Corrected Application** box and enter the Grants.gov tracking number in the Federal Identifier field (Item 4a). If this submission is to change or correct a "resubmission" or "renewal" application, leave the Federal identifier field as previously filled with the existing identifier. Do NOT insert the Grants.gov tracking number in these cases. See section 2.12 for additional information on correcting errors.

Note: Not all R&D Services within VA-ORD accept renewal applications or for all types of awards.

**Pre-Application:** Unless specifically noted in a program announcement, the Pre-application option is **not used by VA-ORD**.

**Changed/Corrected Application**: This box must be used if you need to submit the same application again to correct **errors identified by the PD/PI or Signing Official** during the 2-day examination window **or system validation errors/warnings identified by eRA Commons**. When submitting a Changed/Corrected Application:

- **Applicants may not use the Changed/Corrected Application box to submit changes after the submission deadline in Grants.gov**.
- When the Changed/Correct Application box is checked, Item 4a (Federal Identifier) becomes a required field.
- For a **"New" Application** (Item 8 = New), **enter the tracking number assigned by Grants.gov** (e.g., GRANT123456) to the previous application that you are correcting in Item 4a (Federal Identifier). You should obtain this tracking number from your AOR/SO.
- For a **"Resubmission" or "Renewal" Application** (Item 8 = Resubmission or Renewal) **enter only the 2-letter R&D Service designation and serial number of the previously assigned application/award number** (e.g., BX123456) in Item 4a (Federal Identifier); **do not include any other portion of the previous number** (e.g., 1 I01- or -01A1). You should obtain the application number from the previous Summary Statement. **An application may be marked as "Renewal" for only the initial submission; the 2 successive submissions must be marked as "Resubmission".**
- **Applications marked as "Revision" in Item 8 will not be accepted for review.**
- Do not use the Changed/Corrected Application box to denote resubmission of a previously reviewed application; this must be indicated in item 8. Type of Application.

### 2. Date Submitted and Applicant Identifier

In the Date Submitted field, enter the date the application is submitted to the Federal agency (or state, if applicable). In the Applicant Identifier field, enter the applicant's control number (if applicable).

**The Date Submitted should reflect the date the application is submitted to grants.gov (i.e completed by the signing official (SO) just before submission).**

The Applicant Identifier field is a control number **created by the local VA R&D Office**, not VA-ORD. This identifier should be used to identify which version of an application is being submitted.

### 3. Date Received by State and State Application Identifier

Enter the date received by state (if applicable). In the State Application Identifier field, enter the state application identifier, if applicable.

For submissions to VA-ORD, leave these fields blank.

### 4.a. Federal Identifier (This is a checklist item)

New project applications should leave this field blank, unless you are submitting a Changed/Corrected application. When submitting a changed/corrected "New" application, enter the Grants.gov tracking number. If this is a "Resubmission" or "Renewal" application, enter only the 2-letter R&D Service designation and serial number from the previously assigned application/award number (e.g., BX123456) even if submitting a changed/corrected application. **Do not include any other portion of the previous number (e.g., 1 I01- or -01A1).**

Applicants to VA-ORD should complete this field only when submitting a Changed/Corrected version of an application marked as "New" in Item 8 (Type of Application) or when submitting an application marked "Resubmission" or "Renewal" in Item 8. **Use the correct previous application number – using another investigator's application number may cause the system to block the owner of the number from submitting or cause your application to be mis-numbered. Applications with another investigator's previous application number will not be accepted for review.**

### 4.b. Agency Routing Identifier (This is a checklist item)

| Box 8<br>Type of Application | Box 1<br>Type of Submission | Box 4a<br>Federal Identifier | Box 4b<br>Agency Routing Identifier |
|---|---|---|---|
| New | Application | Leave blank | Enter the Station number and city of the VAMC (i.e., 512-Baltmore). A Center of Excellence name may also be included |
| New | Changed/Corrected Application | Grants.gov tracking number (e.g., GRANT123456) from the previous submission) *# | Enter the Station number and city of the VAMC (i.e., 512-Baltmore). A Center of Excellence name may also be included |
| Resubmission or Renewal^ | Application | Application number assigned to the previous submission (e.g., BX123456) ‡# | Enter the Station number and city of the VAMC (i.e., 512-Baltmore). A Center of Excellence name may also be included |
| Resubmission or Renewal^ | Changed/Corrected Application | Application number assigned to the previous submission (e.g., BX123456) ‡# | Enter the Station number and city of the VAMC (i.e., 512-Baltmore). A Center of Excellence name may also be included |

*** Grants.gov tracking numbers can be obtained from your AOR/SO.**

**‡ Applicaton Numbers can be obtained from the previous Summary Satatement.**

**# Include only the 2-letter R&D Service designation and serial number of the previously assigned application/award number (e.g., BX123456); do not include any other portion of the number (e.g., 1 I01- or -01A1).**

**^Not all R&D Services within VA-ORD accept renewal applications or for all types of awards.**

## 5. Applicant Information

**This information is for the VA medical center**, not a specific individual (Principal Investigator).

| Field Name | Instructions |
|---|---|
| Organizational DUNS | Enter your organization's DUNS or DUNS+4 number.<br>For submission to VA-ORD, this DUNS **must** match the number entered in the eRA Commons Institutional Profile for the VA medical center. The applicant AOR is encouraged to confirm that a DUNS has been entered in the eRA Commons Institutional Profile prior to submitting an application. |
| Legal Name | Enter the legal name of the **applicant organization**. Enter the complete address of the **applicant organization** (including county and country), and name, telephone number, e-mail, and fax of the person to contact on matters related to this application. |
| Department | Enter the name of the primary organizational department, service, laboratory, or equivalent level within the **applicant organization** that will undertake the assistance activity. |
| Division | Enter the name of the primary organizational division, office, or major subdivision that will undertake the assistance activity. |
| Street1 | Enter the first line of the street address of the **applicant organization**. This field is required. |
| Street2 | Enter the second line of the street address of the **applicant organization**, if applicable. |
| City | Enter the city for address of the **applicant organization**. |
| County/Parish | Enter the county/parish for address of the **applicant organization**. |
| State | Select the state where the **applicant organization** is located. This field is not active until USA has been selected for the country. This field is required if the applicant is located in the United States. |
| Province | For submissions to VA-ORD, leave this field blank |
| Country | Select the country for the **applicant organization** address. |
| ZIP Code | Enter the postal code (e.g., ZIP code) of the **applicant organization**. This field is required if the applicant is located in the United States. This field is required if a State is selected. |

**Person to be contacted on matters involving this application:**

**This information is for the Administrative or Business Official at the VA medical center, not the PD/PI or their designee.** This person is the individual to be notified if additional information is needed and/or if an award is made. To avoid potential data integrity issues and delays in processing, please ensure that the information provided in this section is identical to the AO profile information contained in eRA Commons.

| Field Name | Instructions |
|---|---|
| Prefix | Enter the prefix (e.g., Mr., Mrs., or Rev.) for the person to contact on matters relating to this application. |
| First Name | Enter the first (given) name of the person to contact on matters relating to this application. This field is required. |
| Middle Name | Enter the middle name of the person to contact on matters relating to this application. |
| Last Name | Enter the last (family) name of the person to contact on matters relating to this application. This field is required. |
| Suffix | Enter the suffix (e.g., Jr., Sr., Ph.D.) for the person to contact on matters relating to this application. |
| Phone Number | Enter the daytime phone number for the person to contact on matters relating to this application. |
| Fax Number | Enter the fax number for the person to contact on matters relating to this application. |
| Email | Enter the email address for the person to contact on matters relating to this application.<br>This is a required field for all applications to VA-ORD. |

### 6. Employer Identification (Required Field)

Enter the TIN or EIN as assigned by the Internal Revenue Service. If your organization is not in the US, type 44-4444444.

If you have a 12-digit EIN, **enter all 12 digits (e.g., 1123456789A1)**.

## 7. Type of Applicant (Required Field)

This information is for the VA medical center, not a specific individual AOR/SO or PD/PI.

| Field Name | Instructions |
|---|---|
| Type of Applicant | Select from the list the appropriate applicant type code.<br>Select *X: Other (specify)*, and then indicate "VA-ORD" in the "Other" space below. |
| Other (Specify) | Complete only if *X: Other* was selected as the Type of Applicant. |
| Woman Owned | Check if you are a woman-owned small business – a small business that is at least 51% owned by a woman or women, who also control and operate it. |
| Socially and Economically Disadvantaged | Check if you are a socially and economically disadvantaged small business, as determined by the US Small Business Administration pursuant to Section 8(a) of the Small Business Act U.S.C. 637(a). |

## 8. Type of Application

| Field Name | Instructions |
|---|---|
| Type of Application | Select the type from the following list. **Check only one**:<br>• **New**: An application that is being submitted to an agency for the first time. Check this option for **first time submissions** through Grants.gov and eRA Commons<br>• **Resubmission**: An application that has been previously submitted (but not funded) and is being resubmitted for new consideration; **this includes resubmission of Renewal applications.** Resubmission applications for proposals that were **previously submitted electronically** must be **marked as "Resubmission"** in Box 8; **all others must be marked as "New"**.<br>• **Renewal:** An application requesting additional funding for a period subsequent to that provided by a current award*. A Renewal application competes with all other applications and must be developed as fully as a New or Resubmission application. Applications for renewal of a **previously funded electronic application** should be **marked as "Renewal"**; applications for renewal of a **previously funded paper or CD application** must be **marked as "New"**. **An application may be marked as "Renewal" for only the initial submission; the 2 successive submissions must be marked as "Resubmission". After 3 unsuccessful submissions (initial + 2 resubmissions), a "New" application must be submitted.**<br>*Note: Not all R&D Services within VA-ORD accept renewal applications or for all types of awards |

| Field Name | Instructions |
|---|---|
| Type of Application (cont) | • **Continuation**: A non-competing application for an additional funding/budget period within a previously approved project period.<br>VA-ORD does not accept electronic Continuation applications**; do not check this box**.<br>• **Revision**: An application that proposes a change in the Federal Government's financial obligations or contingent liability from an existing obligation, or any other change in the terms and conditions of the existing award.<br>**Revision: VA-ORD does not accept electronic"Revision"** applications; **do not check this box**.<br>This field also affects how you complete Item 4a. Federal Identifier. If "Type of Application" is "New", you can leave the Federal Identifier field blank on the first submission attempt. However, the Federal Identifier field becomes a required field when submitting a Changed/Corrected application to address errors/warnings. When submitting a Changed/Corrected "New" application, enter the Grants.gov tracking number of the previous submission attempt (e.g. GRANT87654321). If you are unable to find the tracking number, enter "N/A".<br>If "Type of Application" is "Renewal," or "Resubmission," enter only the 2-letter R&D Service designation and serial number of the previously assigned application/award number (e.g., BX123456). For these types of applications, do not change the Federal Identifier field when submitting Changed/Corrected applications. |
| Is this application being submitted to other agencies? | Check the box, if applicable. **This field is required**.<br>Check the box "yes" if one or more of the specific aims submitted in your application are also contained in a similar, identical, or essentially identical application submitted to another Federal agency. Indicate the agency or agencies to which the application has been submitted. |
| What Other Agencies? | Enter Agency name. Include private foundations, etc. |

### 9. Name of Federal Agency

This is the name of the Federal agency from which assistance is being requested with this application. This field is pre-populated from the funding opportunity package.

### 10. Catalog of Federal Domestic Assistance (CFDA) Number and Title (CFDA)

This is the Catalog of Federal Domestic Assistance number and Title of the program under which assistance is requested. These fields are pre-populated from the opportunity package.

This field may be blank. When this field is blank, leave it blank; the field will not allow any data entry. The appropriate CFDA number will be automatically assigned by the agency once the application is assigned to the appropriate R&D Service.

**11. Descriptive Title of Applicant's Project (Required Field)**

Enter a brief descriptive title of the project.

**VA-ORD limits title character length to 81 characters, including the spaces between words and punctuation.** Titles in excess of 81 characters will be truncated by the system and will not be restored by VA-ORD staff. **This is a checklist item.**

Be sure to only use standard characters in the descriptive title: A through Z, a through z, numbers 0 through 9, and underscore (_).

A "new" application must have a different title from any other VA-ORD project with the same PD/PI. A "Resubmission" or "Renewal" application should normally have the same title as the previous application or award. If the specific aims of the project have significantly changed, however, a new title reflecting these changes should be used.

Do **NOT** cut and paste from any other program (i.e., WORD or ePROMISe) to enter the project title; the font may not transfer correctly and may cause erroneous characters (e.g., "&"or "□") to be introduced. Check your title in the final eApplication carefully for such errors.

**12. Proposed Project Start Date and Ending Date (in MM/DD/YYYY format)**

*Start Date:* Enter the proposed start date of the project. This field is required.

*Ending Date:* Enter the proposed ending date of the project. This field is required.

**Be careful entering these dates. Once entered, the SF424 Cover component may not allow you to change or edit them. This is a checklist item.**

**13. Congressional District of Applicant (Required Field)**

Enter the Congressional District of the "Applicant" (VA Medical Center) named in Box 5 in the format: 2 character State Abbreviation – 3 character District Number. *Examples: CA-005 for California's 5th district, CA-012 for California's 12th district.*

To locate your congressional district, visit the U.S. House of Representatives website to search for your Congressional District by entering your zip code + 4. The screen that pops up will list your representative as well as your congressional district.If you do not know your zip code + 4 you may look it up by visiting: http://zip4.usps.com/zip4/welcome.jsp.

Alternatively, you may use the Congressional Directory using your 5-digit zip code to search; if your zip code is part of multiple districts, you will be asked to enter your address.

Congressional Code format: 2 character State Abbreviation - 3 character District Number.
Examples: CA-005 for California's 5th district, CA-012 for California's 12th district.
Use 00-000 for programs/projects outside the US.

For States and U.S. territories with only a single congressional district enter "001" for the district code. For jurisdictions with no representative, enter "099". For jurisdictions with a nonvoting delegate, enter "098" for the district number. Example: DC-098, PR-098.

**14. Project Director/Principal Investigator (PD/PI) Contact Information**

The Project Director/Principal Investigator (PD/PI) is the individual responsible for the overall scientific and technical direction of the project. If submitting an application reflecting Multiple PDs/PIs, the individual designated as the Contact PI should be entered here. **All PD/PI's must include their respective eRA Commons ID in the Credential field of the Senior/Key Person Profile Component.** See Section 4.5 Senior/Key Person Profile Component for additional instructions for Multiple PDs/PIs. To avoid potential data integrity issues and delays in processing, please ensure that the

information provided in this section is identical to the PD/PI profile information contained in the eRA Commons. All PD/PIs must meet the eligibility requirement(s) of the Research & Development Service being applied to.

| Field Name | Instructions |
|---|---|
| Prefix | Enter the prefix (Mr., Mrs., Dr., or Rev.) of the PD/PI. |
| First Name | Enter the first (given) name of the PD/PI. This field is required. |
| Middle Name | Enter the middle name of the PD/PI. |
| Last Name | Enter the last name of the PD/PI. This field is required. |
| Suffix | Enter the suffix (e.g., Jr., Sr., or III) for the name of the PD/PI. **Do not use this field to indicate degrees (i.e. PhD, MD, etc.)**. |
| Position/Title | **Enter the position and title of the PD/PI at the VA**. This information is used to prepopulate the Senior/Key Person Profile for the PD/PI. |
| Organization Name | Enter the name of the VA medical center or VA Health Care System where the PD/PI is employed. This field is required. |
| Department | Enter the name of the primary organizational department, service, laboratory, or equivalent level within the organization of the PD/PI. |
| Division | Enter the name of the primary organizational division, office, or major subdivision of the PD/PI. |
| Street1 | Enter the first line of the street address for the PD/PI. This field is required. |
| Street2 | Enter the second line of the street address for the PD/PI, if applicable. |
| City | Enter the city where the PD/PI is located. This field is required. |
| County/Parish | Enter the county/parish where the PD/PI is located. |
| State | Select the State where the PD/PI is located in the United States. This field is not active until USA has been selected for the country. This field is required. |
| Province | For submissions to VA-ORD, leave this field blank |
| Country | Select the country for the PD/PI address. |
| ZIP Code | Enter the Postal Code (e.g., ZIP Code) of the PD/PI. This field is required. |
| Phone Number | Enter the daytime telephone number for the PD/PI. This field is required. |

| Field Name | Instructions |
|---|---|
| Fax Number | Enter the fax number for the PD/PI. This field is required. |
| Email | Enter the email address for the PD/PI. This field is required. |

**SF 424 (R&R)** APPLICATION FOR FEDERAL ASSISTANCE **Page 2**

**15. ESTIMATED PROJECT FUNDING**

a. Total Federal Funds Requested

b. Total Non-Federal Funds

c. Total Federal & Non-Federal Funds

d. Estimated Program Income

**16. * IS APPLICATION SUBJECT TO REVIEW BY STATE EXECUTIVE ORDER 12372 PROCESS?**

a. YES ☐ THIS PREAPPLICATION/APPLICATION WAS MADE AVAILABLE TO THE STATE EXECUTIVE ORDER 12372 PROCESS FOR REVIEW ON:

DATE:

b. NO ☐ PROGRAM IS NOT COVERED BY E.O. 12372; OR

☐ PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW

**17. By signing this application, I certify (1) to the statements contained in the list of certifications* and (2) that the statements herein are true, complete and accurate to the best of my knowledge. I also provide the required assurances * and agree to comply with any resulting terms if I accept an award. I am aware that any false, fictitious. or fraudulent statements or claims may subject me to criminal, civil, or administrative penalities. (U.S. Code, Title 18, Section 1001)**

☐ *** I agree**

** The list of certifications and assurances, or an Internet site where you may obtain this list, is contained in the announcement or agency specific instructions.*

**18. SFLLL or other Explanatory Documentation**

Add Attachment | Delete Attachment | View Attachment

**19. Authorized Representative**

Prefix: * First Name: Middle Name:

* Last Name: Suffix:

* Position/Title:

* Organization:

Department: Division:

* Street1:

Street2:

* City: County / Parish:

* State: Province:

* Country: USA: UNITED STATES * ZIP / Postal Code:

* Phone Number: Fax Number:

* Email:

*** Signature of Authorized Representative**: Completed on submission to Grants.gov

*** Date Signed**: Completed on submission to Grants.gov

**20. Pre-application** Add Attachment | Delete Attachment | View Attachment

### 15. Estimated Project Funding (Required Fields)

| Field Name | Instructions |
|---|---|
| a. Total Federal Funds Requested | Enter total Federal funds requested for the entire project period.<br>**This must match the value for Section G, Direct Costs (A thru F) on the Composite Budget.** |
| b. Total Non-Federal Funds | Enter the total non-Federal funds requested for the entire project period.<br>**For VA-ORD applications, enter zero ("0") in this field** |
| c. Total Federal & Non-Federal Funds | Enter the total estimated funds for the entire project period.<br>For VA applicants, this field will be the same as item 15a |
| d. Estimated Program Income | **For VA-ORD applications, this field must be $0.** |

### 16. Is Application Subject to Review by State Executive Order 12372 Process? (Required Field)

If yes, check the "Yes" box. If the announcement indicates that the program is covered under Executive Order 12372, you should contact the State Single Point of Contact (SPOC) for Federal Executive Order 12372. If no, check the "**No**" box.

**Check "No"for VA-ORD submissions using the SF424 (R&R)**

### 17. Complete Certification (Required Field)

Check the "I agree" box to provide the required certifications and assurances.

The list of VA Assurances, Certifications, and other Policies is found in Part III, Policies, Assurances, Definitions, and Other Information.

### 18. SF-LLL or Other Explanatory Documentation

If applicable, attach SF-LLL (Disclosure of Lobbying Activities) or other explanatory documents per agency instructions.

### 19. Authorized Representative (Required Field)

This is equivalent to the individual with the organizational authority to sign for an application; otherwise known as the Authorized Organizational Representative (AOR) or the Signing Official (SO).

| Field Name | Instructions |
|---|---|
| Prefix | Enter the prefix (e.g., Mr., Mrs., or Rev.) for the name of the Authorized Representative. |
| First Name | Enter the first (given) name of the Authorized Representative. This field is required. |
| Middle Name | Enter the middle name of the Authorized Representative. |
| Last Name | Enter the last (family) name of the Authorized Representative. This field is required. |
| Suffix | Enter the suffix (e.g., Jr., Sr., or III.) for the name of the Authorized Representative. |
| Position/Title | Enter the title of the Authorized Representative. This field is required. |
| Organization | Enter the name of the VA medical center or Health Care System for the Authorized Representative. This field is required. |
| Department | Enter the name of the primary organizational department, service, laboratory, or equivalent level within the organization of the Authorized Representative. |
| Division | Enter the name of the primary organizational division, office, or major subdivision of the Authorized Representative. |
| Street1 | Enter the first line of the street address for the Authorized Representative. This field is required. |
| Street2 | Enter the second line of the street address for the Authorized Representative, if applicable. |
| City | Enter the city for the address of the Authorized Representative. This field is required. |
| County/parish | Enter the county/parish for the address of the Authorized Representative. |
| State | Select the state where the Authorized Representative is located. This field is not active until USA has been selected for the country. This field is required. |
| Province | For submissions to VA-ORD, leave this field blank |
| Country | Select USA as the country for the Authorized Representative address. |
| ZIP Code | Enter the postal code (e.g., ZIP code) of the Authorized Representative. This field is required. |

| Field Name | Instructions |
|---|---|
| Phone Number | Enter the daytime phone number for the Authorized Representative. This field is required |
| Fax Number | Enter the fax number for the Authorized Representative. |
| Email | Enter the email address for the Authorized Representative. This field is required. |
| Signature of Authorized Representative | It is the organization's responsibility to assure that only a properly authorized individual signs in this capacity and/or submits the application to Grants.gov. Since the application is submitted electronically through Grants.gov, leave this field blank. |
| Date Signed | The system will automatically generate this date; do not manually enter anything in this box. |

## 20. Pre-Application

**Do not add any attachments in Box 20.VA-ORD does not use *Pre-Applications* as part of its electronic submission process.**

HSR&D uses a separate "Intent to Submit (ITS)" process and RR&D uses a "Letter of Intent (LOI)", both of which must be approved before an application will be accepted for review. Applicants should consult the individual R&D Service for details on submitting an ITS or LOI for approval. BLR&D and CSR&D do not use any form of pre-application.

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Once all data have been entered, click the **Close Form** button at the top of the form or use the scroll bar to scroll up. You will be returned to the Grant Application Package screen. To remove a document from the Submission box, click the document name to select it and then click the "Move Form to Delete" button. This will return the document to the Mandatory Documents Submission List or Optional Documents Submission List.

## 4.3 Other Project Information Component

**RESEARCH & RELATED Other Project Information**

1. * Are Human Subjects Involved? ☐ Yes ☐ No
   1.a If YES to Human Subjects
   Is the Project Exempt from Federal regulations? ☐ Yes ☐ No
   If yes, check appropriate exemption number. ☐1 ☐2 ☐3 ☐4 ☐5 ☐6
   If no, is the IRB review Pending? ☐ Yes ☐ No
   IRB Approval Date:
   Human Subject Assurance Number:
2. * Are Vertebrate Animals Used? ☐ Yes ☐ No
   2.a. If YES to Vertebrate Animals
   Is the IACUC review Pending? ☐ Yes ☐ No
   IACUC Approval Date:
   Animal Welfare Assurance Number
3. * Is proprietary/privileged information included in the application? ☐ Yes ☐ No
4.a. * Does this project have an actual or potential impact on the environment? ☐ Yes ☐ No
4.b. If yes, please explain:
4.c. If this project has an actual or potential impact on the environment, has an exemption been authorized or an environmental assessment (EA) or environmental impact statement (EIS) been performed? ☐ Yes ☐ No
4.d. If yes, please explain:
5. * Is the research performance site designated, or eligible to be designated, as a historic place? ☐ Yes ☐ No
5.a. If yes, please explain:
6. * Does this project involve activities outside of the United States or partnerships with international collaborators? ☐ Yes ☐ No
6.a. If yes, identify countries:
6.b. Optional Explanation:
7. * **Project Summary/Abstract** Add Attachment | Delete Attachment | View Attachment
8. * **Project Narrative** Add Attachment | Delete Attachment | View Attachment
9. **Bibliography & References Cited** Add Attachment | Delete Attachment | View Attachment
10. **Facilities & Other Resources** Add Attachment | Delete Attachment | View Attachment
11. **Equipment** Add Attachment | Delete Attachment | View Attachment
12. **Other Attachments** Add Attachments | Delete Attachments | View Attachments

**Do NOT cut and paste from any other program (i.e., WORD or ePROMISe) to complete fields on SF424 components;** the font may not transfer correctly and may cause erroneous characters (e.g., "&"or "□") to be introduced. **Check the final eApplication carefully for such errors.**

### 1. Are Human Subjects Involved? (Required Field; This is a checklist item)

If activities involving human subjects are planned at any time during the proposed project at any performance site, check "Yes". Check "Yes" even if the proposed project is exempt from Regulations for the Protection of Human Subjects. If no activities involving human subjects are planned, check "No" and skip the rest of block 1.

**If tissues (e.g., biopsies, banked material, or whole organs) or samples (i.e. blood, sputem, etc.) from human subjects will be used, "Yes" must be checked**

and a Human Subjects attachment must be provided in Item 12 below. Refer to Part II, Supplemental Instructions for Human Subjects Research Requirements.

If established or commercial human cell lines will be used, check "No".

**1.a. If yes to Human Subjects**

***Is project exempt from Federal Regulations? Yes/No.***

**Check "No" for all submissions to VA-ORD even if the IRB review is complete and a determination of exemption status has been made by the IRB**

**Do not check any of the exemption number boxes** even if the IRB review is complete and a determination of exemption status has been made by the IRB.

***If No, is the IRB review Pending?***

If the Institutional Review Board (IRB) review is pending, check "Yes". If IRB review is not pending, check "No".

VA Applicants should check "**Yes**" to the question "Is the IRB review Pending?" even if the IRB review/approval process has not yet begun at the time of submission.

**If you answer "Yes" but click your mouse in the box for IRB Approval Date below, it may become activated as a required field. If this occurs, change the check box for Item 1 (Are Human Subjects Used?) to "No" and then to "Yes" to reset 1a.**

**IRB Approval Date**

In the IRB Approval Date field, enter the latest IRB approval date, if available. Leave blank if review is pending.

An IRB Approval Date is not required at the time of submission. This may be requested later in the award cycle as a Just-In-Time compliance requirement.

**Human Subject Assurance Number**

For Human Subject Assurance Number, enter the approved Federal Wide Assurance (FWA) Number that the applicant VA medical center has on file with the Office for Human Research Protections, if available. Enter only the 8-digit number; do not enter the "FWA" before the number.

**If the IRB of record is at the academic affiliate, you may enter the assurance number for the affiliate. Otherwise, do not use the assurance number of another institution.**

**Use of the academic affiliate's assurance number will generate a "warning" in eRA that can be ignored after confirming that you have used the correct number.**

**If the VA ORD Centralized IRB is used, be sure to use the correct assurance number. The generated warning concerning an institutional mismatch between the submitting medical center and ORD may be ignored.**

**2. Are Vertebrate Animals Used? (Required Field; This is a checklist item)**

If activities involving vertebrate animals are planned at any time during the proposed project at any performance site, check "Yes". If No is checked, skip the rest of block 2.

### 2.a. If YES to Vertebrate Animals

If "**Yes**" is checked, a Vertebrate Animals attachment must be provided in number 11 below. Note that the generation of custom antibodies constitutes an activity involving vertebrate animals.

### Is the IACUC review Pending?

Indicate (Yes or No) if the Institutional Animal Care and Use Committee (IACUC) review is pending.

**If the IACUC review has not been completed (or has not yet begun at the time of submission), check "Yes".**

**If the IACUC review has been completed, check "No". The "IACUC Approval Date" and "Animal Welfare Assurance Number" (see below) will then become required fields.**

**If you answer "Yes" but click your mouse in the box for IACUC Approval Date below, it may become activated as a required field. If this occurs, change the check box for Item 2 (Are Vertebrate Animals Used?) to "No" and then to "Yes" to reset 2a.**

### IACUC Approval Date

Enter the latest IACUC approval date if the IACUC review has been completed. **If the IACUC review is pending, this field cannot be completed.**

### Animal Welfare Assurance Number

For Animal Welfare Assurance Number, enter the federally approved assurance number, if available. (To determine if your VA medical center holds an Animal Welfare Assurance, see http://grants.nih.gov/grants/olaw/assurance/300index.htm.)

VHA Handbook 1200.7 requires that VA medical centers proposing to use vertebrate animals file a written Animal Welfare Assurance with the Office of Laboratory Animal Welfare (OLAW). **Do not enter the Animal Welfare Assurance number of any collaborating institution. If the IACUC of record is at the academic affiliate, you should enter the assurance number for the affiliate.** See VA Policy on use of Vertebrate Animals.

### 3. Is proprietary/privileged information included in the application? (Required Fields)

Patentable ideas, copyright, trade secrets, privileged or confidential commercial or financial information, disclosure of which may harm the applicant, should be included in applications only when such information is necessary to convey an understanding of the proposed project. If the application includes such information, check "Yes" and clearly mark each line or paragraph on the pages containing the proprietary/privileged information with a legend (at the top of each page, NOT as a header or footer). The legend should be similar in content to "The following contains proprietary/privileged information that (name of applicant) requests not be released to persons outside the Government, except for purposes of review and evaluation."

### 4.a -4.d. Environmental Questions (4a is a Required Field)

Unless a specific FOA/RFA indicates that the National Environmental Policy Act (NEPA) applies, applicants should check "**No**" in 4.a and leave 4.b-4.d blank.

**5. Is the research performance site designated, or eligible to be designated, as a historic site? (Required Field)**

If any research performance site is designated, or eligible to be designated, as a historic place, check the "Yes" box and then provide an explanation in the box provided in 5.a. Otherwise, check the "No" box.

Check "**No**" for all submissions to VA-ORD

**5.a. If Yes, please explain.**

If you checked the Yes box indicating any performance site is designated, or eligible to be designated as a historic place, provide the explanation here.

**6. Does this project involve activities outside of the United States or partnerships with International Collaborators? (Required Field)**

Check **"Yes"** if any portion of the proposed work will be conducted at international sites (not within the United States, its territories, or Commonwealths) **or if either human biological specimens or human data originating from international sites will be used**. All other applicants to VA-ORD should check **"No"**.

**6.a. If yes, identify countries**

Enter the countries with which cooperative activities are involved.

**6.b. Optional Explanation**

**Applicants to VA-ORD must leave this blank**. If question 6 is checked "Yes", you must describe the special resources or characteristics of the research project (e.g., human subject populations) in the Human Subjects attachment in Item 12 below.

**7. Project Summary/Abstract (Required Field; This is a checklist item)**

The Project Summary must contain a summary of the proposed activity suitable for dissemination to the public. It should be a self-contained description of the project and should contain a statement of objectives and methods to be employed. It should be informative to other persons working in the same or related fields and insofar as possible understandable to a scientifically or technically literate lay reader. This Summary must not include any proprietary/confidential information. Please click the **Add Attachment** button to the right of this field to complete this entry.

The **Project Summary/Abstract** is meant to serve as a succinct and accurate description of the proposed work when separated from the application. Describe concisely the research design and methods for achieving the stated goals. This section should be informative to other persons working in the same or related fields and insofar as possible understandable to a scientifically or technically literate reader. Avoid describing past accomplishments and the use of the first person. Finally, please make every effort to be succinct. This section must be **no longer than 40 lines of text**, and follow the required font and margin specifications.

**Do not begin the Project Summary with the extra words that state: "Project Summary" or "Abstract" – this is not needed as the file is bookmarked internally by eRA.**

**Do not duplicate or include the relevance statement provided in Item 8 (Project Narrative) below.**

Do not include proprietary, confidential information or trade secrets in the Project Summary. If the application is funded, the Project Summary will be made available on the NIH Research Portfolio Online Reporting Tool (RePORT, available at http://report.nih.gov) and will become public information.

**Proposals containing a Project Summary/Abstract that excedes the stated size limit may require correction and resubmission, or may be returned to the applicant without review.**

The attachment must be in PDF format. See Section 2.6 for additional information on preparing attachments.

### 8. Project Narrative (Required Field; This is a checklist item)

Provide a Project Narrative in accordance with the announcement and/or agency-specific instructions. Please click the **Add Attachment** button to the right of this field to complete this entry. Do not begin the Project Narrative with the extra words that state: "Project Narrative" – this is not needed as the file is bookmarked internally.

**For VA-ORD applications, this attachment must describe the relevance of the proposed research to Veterans' health and/or healthcare issues**. It does not refer to the Research Plan. In this section, be succinct and use plain language that can be understood by a general, lay audience. **A maximum of 10 lines of text may be used.**

**Do not begin the Project Narrative with the extra words that state: "Project Narrative" – this is not needed as the file is bookmarked internally by eRA.**

**Do not duplicate or include the narrative text in Item 7 (Project Description) above.**

### 9. Bibliography & References Cited (Required Field; 4-Page Limit)

Provide a bibliography of any references cited in the Project Narrative. Each reference must include the names of all authors (in the same sequence in which they appear in the publication), the article and journal title, book title, volume number, page numbers, and year of publication. Include only bibliographic citations. Applicants should be especially careful to follow scholarly practices in providing citations for source materials relied upon when preparing any section of the application. To attach a document for Bibliography and References Cited, click **Add Attachment**.

Unless otherwise noted in an FOA/RFA, **this section is required for submissions to VA-ORD**. This section should include all references cited in the Research Plan attachment. The reference should be limited to relevant and current literature; it is important to be concise and to select only those literature references pertinent to the proposed research. **Proposals which exceded the 4-page limitation will be returned to the applicant without review.**

### 10. Facilities & Other Resources (Required Field)

This information is used to assess the capability of the organizational resources available to perform the effort proposed. Identify the facilities to be used (Laboratory, Animal, Computer, Office, Clinical and Other). If appropriate, indicate their capacities, pertinent capabilities, relative proximity and extent of availability to the project. Describe only those resources that are directly applicable to the proposed work. Provide any information describing the Other Resources available to the project (e.g., machine shop, electronic shop) and the extent to which they would be available to the project. Please click the **Add Attachment** button to the right of this field to complete this entry.

No special form is required but this section is required for submissions to VA-ORD.

**VA performance sites must be clearly identified as VA (not just a room and building number).** If there are multiple performance sites, then the resources available at **all sites must be described separately**.

Describe how the scientific environment in which the research will be done contributes to the probability of success (e.g., institutional support, physical resources, and intellectual rapport). In describing the scientific environment in which the work will be done, discuss ways in which the proposed studies will benefit from unique features of the scientific environment, or subject populations or employ useful collaborative arrangements. If research involving Select Agents and Toxins will occur at any performance site(s), the biocontainment resources available at each site should be described.

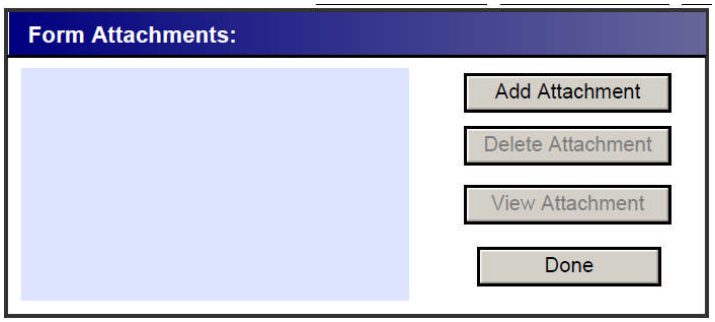
Do not describe off-site resources (equipment or performance sites) that will not be used to carry out the proposed research. Be sure to reference any approved off-site waiver(s) included in the Letters of Support.

### 11. Equipment

List major items of equipment already available for this project and, if appropriate identify location and pertinent capabilities. Please click the **Add Attachment** button to the right of this field to complete this entry.

### 12. Other Attachments

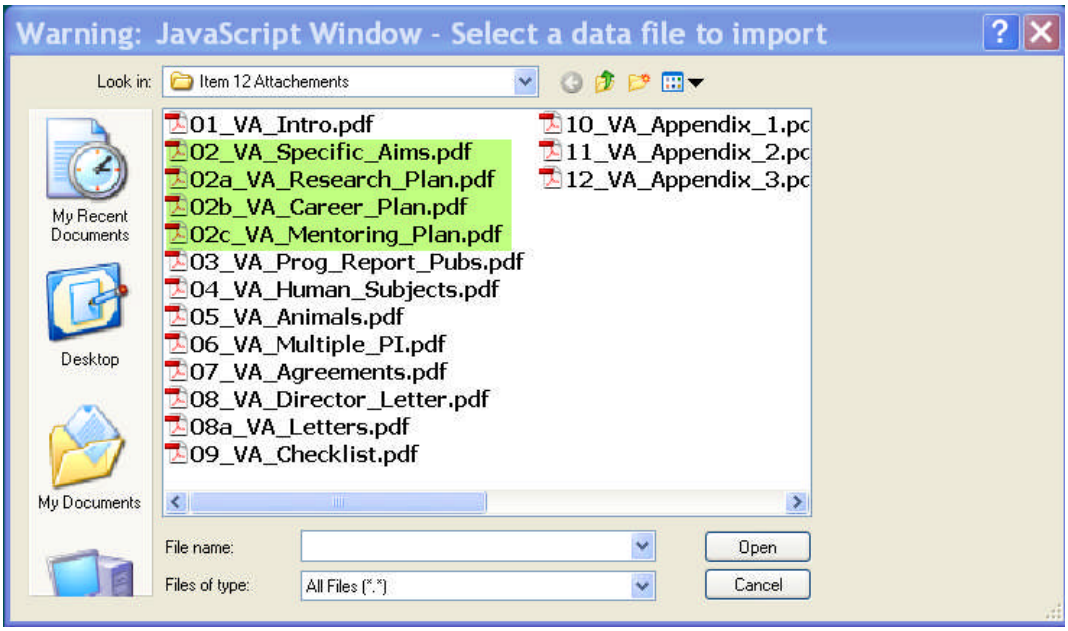
Attach files to provide any other required project information that was not provided above or in accordance with the announcement and/or agency-specific instruction. Clicking on **"Add Attachments"** in item 12 will open the pop-up below:




**A number of separate files must be attached in Item 12 to provide required project information that was not included in Items 1-11 above. The required attachments are described in the Table below.**

Select "Add Attachment" and a second pop-up window will appear to allow you to choose a directory and files to attach.

Attachments can be added one at a time or all at once by holding down the CTRL key and selecting multiple files. Select Open to add the selected attachment(s).




**Attachments for Item 12**

The files names indicated in the table below are mandatory (required) and may not be changed.

**Required file names do not contain any spaces. Inclusion of spaces in file names may result in an eRA error message that a required attachment is missing. Incorrect file names may concurrently generate a warning that a file name may not be correct.**

**A set of templates, with appropriate file names for each section, is available on the VA-ORD intranet site (http://vaww.research.va.gov/funding/electronic-submission.cfm).**

| Attachment and Required File Name | Instructions |
|---|---|
| 1. Introduction to Application (**for Resubmission only**)<br>**01_VA_Intro.pdf** | **Use only if you are submitting a Resubmission application (Cover Component Item 8) for a previously reviewed application that was submitted through Grants.gov.** The Introduction may not exceed three pages for resubmission applications.<br>Save this information in a single PDF file. See instructions for attaching PDF documents in Item 12 above<br>Instructions for attaching the Introduction for Resubmission of previously reviewed applications that were submitted on paper or CD will be provided in service-specific RFAs. |
| 2. Specific Aims<br>***02_VA_Specific_Aims.pdf*** | Concisely state 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.<br>Succinctly list 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.<br>**This attachment is limited to 1 page.** |

| **Attachment and Required File Name** | **Instructions** |
|---|---|
| 2a. Research Plan<br>**02a_VA_Research_Plan.pdf** | The Research Plan should include sufficient information needed for evaluation of the project, independent of any other document (e.g., previous application). Be specific and informative, and avoid redundancies.<br>In general, the Research Plan will contain a description of the Background and Significance, Preliminary Studies and Current Status of the Field, and Research Design and Methods.<br>**Do not repeat the Specific Aims in the research plan.**<br>A Progress Report must be included for renewal applications. Provide the beginning and ending dates for the period covered since the project was last reviewed competitively. Summarize the previous application's specific aims and the importance of the findings. Provide a succinct account of published and unpublished results, indicating progress toward their achievement.<br>Additional and/or alternate sections/headings may be required for certain Funding Announcements. **Each R&D Service will provide specific instructions about the required headings and content for the Research Plan in their posted Funding Announcements (RFAs).**<br>**The Research Plan is limited to 24 pages for all R&D Services.**<br>Save this information in a single PDF file. See instructions for attaching PDF documents in Item 12 above |
| 3. Progress Report Publication List<br>**03_Prog_Report_Pubs.pdf** | For all renewal applications, provide a list of titles and complete citations for all publications, manuscripts accepted for publication, patents, and other printed materials that have resulted from the project since it was last reviewed competitively. Some Service-specific RFAs may indicate that this attachment is not required.<br>For publicly available citations, URLs or PMC submission identification numbers may accompany the full reference. Note: copies of these publications are no longer accepted as appendix material.<br>**Do not include unpublished theses or abstracts/manuscripts submitted, but not accepted for publication.**<br>Save this information in a single PDF file. See instructions for attaching PDF documents in Item 12 above. |

| **Attachment and Required File Name** | **Instructions** |
|---|---|
| 4. Human Subjects | **This attachment is required if you checked the box marked "Yes" for** Question 1 **(Are Human Subjects Involved?) on the Other Project Information Component.** This section covers the information regarding the Protection of Human Subjects. In this attachment, the following headings should be used and fully described. Refer to SF 424 Part II for additional information on Human Subjects Research Requirements.<br><br>**Do not include Informed Consent forms, even if already approved by the IRB**. These documents will be requested as part of the JIT process.<br><br>Fully describe:<br>1. Risk to Subjects.<br>• *Human Subjects Involvement and Characteristics*. Describe the anticipated number, age range, and health status of the subject population. Identify the criteria for inclusion or exclusion of any subpopulation. Explain the rationale for the involvement of special classes of subjects 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 use of non-Veteran subjects in VA-ORD funded research projects.**<br>• *Sources of Materials*. Identify the sources of research material and indicate whether the material or data will be obtained specifically for research purposes or if existing specimens, records, or data will be used.<br>• *Potential Risks*. Describe the potential risks to subjects (physical, psychological, social, legal, or other) and assess their likelihood and seriousness to the subjects. Differentiate therapeutic risk from research risk.<br>2. Adequacy of Protection from Risk<br>• *Recruitment and Informed Consent***.** Describe plans for the recruitment of subjects and the process for obtaining informed consent. **NOTE:** The informed consent document may not be submitted at this time.<br>• *Protection Against Risk*. Describe the planned procedures for preventing or minimizing potential risks (including risks to confidentiality and data security). Specify methods for collecting data on complications of treatment, adverse and severe adverse events for safety monitoring. |

| **Attachment and Required File Name** | **Instructions** |
|---|---|
| 4. Human Subjects (cont) | 3. Potential benefits of research to subjects and others. Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and others.<br>4. Importance of knowledge to be gained. Data and Safety Monitoring Plan. Describe the plans for monitoring the safety of participants and the accuracy and integrity of the data. Describe steps to ensure adequate subject recruitment and enrollment, including if necessary, replacement of study sites.<br>In addition, the inclusion of women, minorities and/or children must be addressed; children cannot 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.<br>Save this information in a single file. See instructions for attaching PDF documents in Item 12 above. |
| 5. Vertebrate Animals<br>**05_VA_Animals.pdf** | **An attachment addressing the following five key points is required if you checked the box marked "Yes" for Question 2 (Are Vertebrate Animals Used?) on the Other Project Information Component.**<br>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.<br>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.<br>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.<br>3. Provide information on the veterinary care of the animals involved.<br>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.<br>5. 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.<br>Save this information in a single file. See instructions for attaching PDF documents in Item 12 above. |

| **Attachment and Required File Name** | **Instructions** |
|---|---|
| 6. Multiple PD/PI Leadership Plan<br>**06_VA_Multiple_PI.pdf** | **A leadership plan is required if more than one individual is assigned the role of PD/PI in Section A of the Budget Component.**<br>**Non-VA investigators may not be assigned the PD/PI role.**<br>A rationale for choosing a multiple PD/PI approach should be described. The governance and organizational structure should be described, including communication plans and procedures for resolving conflicts. The shared administrative, technical, and scientific responsibilities for the project or program should be delineated for the PIs. The use of multiple PD/PI's must not be used to avoid budget caps (restrictions) described in any VA-ORD Funding Announcement. Investigators should discuss the inclusion of multiple PD/PI's with appropriate R&D Service staff prior to submission of their application.<br>Save this information in a single file. See instructions for attaching PDF documents in Item 12 above. |
| 7. Consortium/Contractual Agreements<br>**07_VA_Agreements.pdf** | This attachment should only be used to describe **existing** consortium or contractual agreements that are relevant to the proposed research.<br>It should **not** be used to describe or to justify the required sub-award budgets for multisite projects.<br>Explain the programmatic, fiscal, and administrative arrangements that exist between the applicant VA medical center and any consortium or contractual organization(s).<br>New consortium or contractual agreements will not be considered binding to VA contractually.<br>Save this information in a single file. See instructions for attaching PDF documents in Item 12 above. |
| 8. Director's Letter<br>**08_VA_Director_Letter.pdf**<br>**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:<br>• A statement that the Director understands the impact of the proposed research on the facility's organization and that he/she endorses the project.<br>• 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.<br>If a clinician PD/PI's appointment is to start at the time of funding, the VA medical center Director's memorandum **must** contain a statement indicating that the PD/PI will be given a VA-paid clinical appointment of at least 5/8ths time.<br>**Proposals submitted without this attachment will not be accepted for review. This is a checklist item.** |

| Attachment and Required File Name | Instructions |
|---|---|
| 8a. Letters of Support<br>**08a_VA_Letters.pdf**<br>**The required file name may generate a warning message from eRA Commons concerning the attachment name** | Attach appropriate letters here from all individuals confirming their roles in the project and rate/charge for consulting services. Also, include copies of all approved off-site waivers (if applicable). **This is a checklist item.**<br>Save this information in a single file. See instructions for attaching PDF documents in Item 12 above<br>Note: Biosketches should be included in Senior/Key Person Section, not in Letters of Support. |
| 9. Checklist<br>**09_VA_Checklist.pdf**<br>**The required file name for this attachment may generate a warning message from eRA Commons concerning the attachment name** | Attach a completed copy of the Electronic Merit Review Submission Checklist. **Check only the applicable boxes. Use the checklist to verify that all content and formatting requirements have been met and that the final application is complete.**<br>**Do not check a box until you are sure that the item has been carefully examined and is correct. Proposals with incorrectly checked boxes may not be accepted for review**<br>**Proposals submitted without this attachment will not be accepted for review.** |
| 10,11... Appendices<br>**10_VA_Appendix_1.pdf**<br>**11_VA_Appendix_2.pdf**<br>**12_VA_Appendix_3.pdf**<br>(additional attachments as needed: same file name format) | Only one copy of an appendix is necessary. 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.<br>**Do not include Informed Consent forms as an appendix, even if already approved by the IRB.**<br>**New, resubmission, and renewal applications may include the following materials in the Appendices.**<br>• **Up to 3** of the following types of publications:<br>  o **Manuscripts** and/or abstracts accepted for publication but not yet published.<br>  o **Manuscripts** and/or abstracts published, but a free, online, publicly available journal link is not available.<br>  o **Patents** directly relevant to the project.<br>• Surveys, questionnaires, data collection instruments, clinical protocols, and informed consent documents may be submitted as PDF attachments.<br>• Photographs or color images of gels, micrographs, etc., **are no longer accepted as Appendix material.** These images must be included in the Research Plan and will count toward the 24-page limit. Images embedded in publications are still allowed.<br>Similar appendix material should be combined within an attachment. For example, please place all accepted, but not yet published, manuscripts in one attachment. |

| **Attachment and Required File Name** | **Instructions** |
|---|---|
| 10,11… Appendices (cont)<br>**For Appendix names only:**<br>If descriptive text is included in an attachment name before the ".PDF" (i.e., "_Surveys.PDF"), you will receive a warning message from eRA concerning the attachment name. This warning can be safely ignored. | Do not include unpublished theses or abstracts/manuscripts that have been submitted but not yet accepted for publication.)<br>**Published manuscripts and/or abstracts that have a free, publicly available online journal link should no longer 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 the Biographical Sketch section.<br>For materials that cannot be submitted electronically or materials that cannot be converted to PDF format (e.g., medical devices, prototypes, DVDs, CDs), applicants should contact the SRO for instructions following notification of assignment of the application to an SRG. Applicants are encouraged to be as concise as possible and submit only information essential for the review of the application.<br>**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. |

Once all data have been entered, click the **Close Form** button at the top of the form or use the scroll bar to scroll up. You will be returned to the Grant Application Package screen. To remove a document from the Submission box, click the document name to select it and then click the **Move Form to Delete** button. This will return the document to the Mandatory Documents Submission List or Optional Documents Submission List.

## 4.4 Project/Performance Site Locations Component

OMB Number: 4040-0010
Expiration Date: 08/31/2011

**Project/Performance Site Location(s)**

**Project/Performance Site Primary Location** ☐ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name:
DUNS Number:
* Street1:
Street2:
* City: County:
* State:
Province:
* Country: USA: UNITED STATES
* ZIP / Postal Code: * Project/ Performance Site Congressional District:

**Project/Performance Site Location** 1 ☐ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name:
DUNS Number:
* Street1:
Street2:
* City: County:
* State:
Province:
* Country: USA: UNITED STATES
* ZIP / Postal Code: * Project/ Performance Site Congressional District:

Delete Entry | Next Site

**Additional Location(s)** | Add Attachment | Delete Attachment | View Attachment

**Do NOT cut and paste from any other program** (i.e., WORD or ePROMISe) to complete fields on SF424 components; the font may not transfer correctly and may cause erroneous characters (e.g., "&" or "□") to be introduced. **Check the final eApplication carefully for such errors.**

Indicate the primary site where the work will be performed. If a portion of the project will be performed at any other site(s), identify the site location(s) in the blocks provided.

### Project/Performance Site Primary Location (Required Fields)

The Primary Location is the submitting VA medical center identified in Box 5 of the Cover Component. An off-site primary location is only permitted if a full off-site waiver (see VHA Handbook 1200.16 VA Off-Site Research) has been approved in advance of the submission;

see Table 4 in each RFA for Waiver request deadlines. A copy of the full off-site waiver approval letter must be included in the attachment for Letters of Support in Item.12, Other Attachments, of the Research & Related Other Project Information component.

**If there is more than one performance site, including other VA facilities or academic affiliates, list them all in the fields provided for Location 1 - # below.** This must be completed for all performance sites, even if a full or partial off-site waiver has been approved. Applicants should also provide an explanation of resources available from each Project/Performance Site in Item 10. Facilities and Resources of the Other Project Information form.

Unless otherwise instructed, do not check the "I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization" box.

If a Project/Performance Site is engaged in research involving human subjects, the applicant VA medical center is responsible for ensuring that each Project/Performance Site operates under an appropriate Federal Wide Assurance for the protection of human subjects and complies with VA Policy on the protection of human subjects in research (VHA Handbook 1200.5) and other VA human subject related instructions and policies as described in Part II and Part III of this Application Guide.

For research involving live vertebrate animals, the applicant VA medical center must ensure that all Project/Performance Sites comply with VA policies on the use of animals in research, as described in Part III. II. Assurances and Certifications.

| Field Name | Instructions |
|---|---|
| Organization Name | Indicate the primary VA medical center where the work will be performed. This field is required. |
| DUNS Number | Enter the DUNS number associated with the site where the project will be performed. |
| Street1 | Enter first line of the street address of the primary performance site location. This field is required. |
| Street2 | Enter second line of the street address of the primary performance site location, if applicable. |
| City | Enter the city for address of the primary performance site location. This field is required. |
| County/Parish | Enter the county or parish of the primary performance site location. |
| State | Select the state of the primary performance site location. This field is not active until USA has been selected for the country. This field is required. |
| Province | For submissions to VA-ORD, leave this field blank. |
| Country | Select the country of the primary performance site location. This field is required. |

| Field Name | Instructions |
|---|---|
| ZIP Code | Enter the postal code (e.g., ZIP code) of the primary performance site location. This field is required if the project performance site is located in the United States. |
| Project/Performance Site Congressional District | Enter the Congressional District in the format: 2 character State Abbreviation – 3 character District Number. Examples: CA-005 for California's 5th district, CA-012 for California's 12th district.<br>If all districts in a state are affected, enter "all" for the district number. Example: MD-all for all congressional districts in Maryland.<br>If nationwide (all districts in all states), enter US-all.<br>If the program/project is outside the US, enter 00-0000.<br>To locate your congressional district, visit the Grants.gov web site. Note it is likely this field will be identical to the "Congressional District of Applicant" field provided elsewhere in the application.<br>For States and U.S. territories with only a single congressional district, enter "001" for the district code. For jurisdictions with no representative, enter "099". For jurisdictions with a nonvoting delegate, enter "098" for the district number. Example: DC-098, PR-098. |

**Project/Performance Site Location 1 (Required Fields)**

| Field Name | Instructions |
|---|---|
| Organization Name | Enter the name of organization of the first additional performance site location. |
| DUNS Number | Enter the DUNS number associated with the organization where the project will be performed. |
| Street1 | Enter first line of the street address of the performance site location. Complete mailing address (include street, city, state, and country) for the project site. This field is required. |
| Street2 | Enter second line of the street address of the performance site location, if applicable. |
| City | Enter the city of the performance site location. This field is required. |
| County/Parish | Enter the county or parish of the performance site location. |
| State | Select the state where the performance site is located. This field is not active until USA has been selected for the country. This field is required if the performance site location is in the United States. |
| Province | For submissions to VA-ORD, leave this field blank. |
| Country | Select the country for the performance site location. This field is required if the performance site location is in the United States. |

| Field Name | Instructions |
|---|---|
| ZIP Code | Enter the ZIP (Postal) Code of the performance site location. This field is required if the performance site location is in the United States. |
| Project/Performance Site Congressional District | Enter the Congressional District in the format: 2 character State Abbreviation – 3 character District Number. Examples: CA-005 for California's 5th district, CA-012 for California's 12th district.<br>If all districts in a state are affected, enter "all" for the district number. Example: MD-all for all congressional districts in Maryland.<br>If nationwide (all districts in all states), enter US-all.<br>If the program/project is outside the US, enter 00-0000.<br>To locate your congressional district, visit the Grants.gov web site. Note it is likely this field will be identical to the "Congressional District of Applicant" field provided elsewhere in the application.<br>For States and U.S. territories with only a single congressional district, enter "001" for the district code. For jurisdictions with no representative, enter "099". For jurisdictions with a nonvoting delegate, enter "098" for the district number. Example: DC-098, PR-098. |

For additional performance site locations, click **Next Site** to display the fields for Project/Performance Site Locations 3 through 30. The **Next Site** button appears once Site Location 1 is completed.

If you need to describe more than thirty locations (primary plus 29 additional sites), enter the information in a separate file. In the **Additional Locations** section at the bottom of the form, click **Add Attachment**, select the file, and then click **Open**. A sample Additional Performance Sites format page for greater than eight locations is found under "Additional Format Pages" at: http://vaww.research.va.gov/funding/electronic-submission.cfm.

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Once all data have been entered, click the **Close Form** button at the top of the form or use the scroll bar to scroll up. You will be returned to the Grant Application Package screen. To remove a document from the Submission box, click the document name to select it and then click the **Move Form to Delete** button. This will return the document to the Mandatory Documents Submission List or Optional Documents Submission List.

# 4.5 Senior/Key Person Profile(s) Component

OMB Number: 4040-0001
Expiration Date: 06/30/2011

RESEARCH & RELATED Senior/Key Person Profile (Expanded)

**PROFILE - Project Director/Principal Investigator**

Prefix: * First Name: Middle Name:
* Last Name: Suffix:
Position/Title: Department:
Organization Name: Division:
* Street1:
Street2:
* City: County/ Parish:
* State: Province:
* Country: USA: UNITED STATES * Zip / Postal Code:
* Phone Number: Fax Number:
* E-Mail:

Credential, e.g., agency login:

*** Project Role:** PD/PI **Other Project Role Category:**

**Degree Type:**
**Degree Year:**

***Attach Biographical Sketch** Add Attachment Delete Attachment View Attachment
**Attach Current & Pending Support** Add Attachment Delete Attachment View Attachment

**PROFILE - Senior/Key Person 1**

Prefix: * First Name: Middle Name:
* Last Name: Suffix:
Position/Title: Department:
Organization Name: Division:
* Street1:
Street2:
* City: County/ Parish:
* State: Province:
* Country: USA: UNITED STATES * Zip / Postal Code:
* Phone Number: Fax Number:
* E-Mail:

Credential, e.g., agency login:

*** Project Role:** **Other Project Role Category:**

**Degree Type:**
**Degree Year:**

***Attach Biographical Sketch** Add Attachment Delete Attachment View Attachment
**Attach Current & Pending Support** Add Attachment Delete Attachment View Attachment

Delete Entry Next Person

To ensure proper performance of this form; after adding 20 additional Senior/ Key Persons; please save your application, close the Adobe Reader, and reopen it.

**Do NOT cut and paste from any other program** (i.e., WORD or ePROMISe) to complete fields on SF424 components; the font may not transfer correctly and may cause erroneous characters (e.g., "&"or "□") to be introduced. **Check the final eApplication carefully for such errors.**

This component provides the ability to collect structured data for up to 40 Senior/Key Persons. Data must be entered for the first 40 individuals (PD/PI +39 others) before the Additional Senior/Key Person Form Attachments section becomes available. The information for the PD/PI continues to be pre-populated from the SF424 (R&R) Cover component. See instructions in section 4.2 Cover Component if these fields are empty.

Unless otherwise specified in a particular funding opportunity announcement (FOA/RFA), senior/key personnel are defined as all individuals who contribute in a substantive, measurable way to the scientific development or execution of the project, whether or not salaries are requested. Consultants may be included if they meet this definition

**Multiple PDs/PIs**

VA-ORD accepts applications reflecting Multiple PDs/PIs for all funding mechanisms using the SF424 (R&R) application. When submitting an application involving Multiple PDs/PIs, the Contact PI should be listed as the PD/PI in the SF424 R&R Cover Component (see Section 4.2.14). That information automatically pre-populates the first Senior/Key Person Profile record in this component. For the additional PDs/PIs, complete all the requested information. **Each PD/PI must be assigned the PD/PI role, even those at subaward sites when applicable. (The "Co-PD/PI" or "Co-PI" roles cannot be used to designate Multiple PDs/PIs.)**

If multiple PDs/PIs are designated, you must use Item 12, Other Attachments, of the SF424 R&R Other Project Information Component to provide a Multiple PD/PI Leadership Plan. **Non-VA investigators may not be assigned the PD/PI role.**

**Each PD/PI must be registered as an investigator in the eRA Commons** and must be assigned the PI role in that system (Note: other roles such as SO or IAR will not give PDs/PIs the appropriate access to the application records). **Each PD/PI must include their respective eRA Commons ID in the Credential field. This is a checklist item.**

When completing the detailed budget component for either the primary site or a subaward organization, the project roles listed in the budget component must be consistent with those used in the Senior/Key Person component (i.e. an individual must be identified as a PD/PI in both places).

### Profile – Project Director/Principal Investigator (PD/PI)

| Field Name | Instructions |
|---|---|
| Prefix | This field is automatically populated from the SF424 (R&R). It is the prefix (e.g., Mr., Mrs., or Rev.) for the name of the PD/PI. |
| First Name | This field is automatically populated from the SF424 (R&R). It is the first (given) name of the PD/PI. |
| Middle Name | This field is automatically populated from the SF424 (R&R). It is the middle name of the PD/PI. |

| Field Name | Instructions |
|---|---|
| Last Name | This field is automatically populated from the SF424 (R&R). It is the last (family) name of the PD/PI. |
| Suffix | This field is automatically populated from the SF424 (R&R). It is the suffix (e.g., Jr., Sr., or III) for the name of the PD/PI.<br>Do not use this field to indicate degrees (i.e. PhD, MD, etc.). A new data field has been added below for this information |
| Position/Title | This field is automatically populated from Item 14 of the SF424 (R&R) Cover Component**.** It is the title of the PD/PI. |
| Department | This field is automatically populated from the SF424 (R&R). It is the name of primary organizational department, service, laboratory, or equivalent level within the organization of the PD/PI. |
| Organization Name | This field is automatically populated from the SF424 (R&R). It is the name of the organization of the PD/PI. |
| Division | This field is automatically populated from the SF424 (R&R). It is the name of primary organizational division, office, or major subdivision of the PD/PI. |
| Street1 | This field is automatically populated from the SF424 (R&R). It is the first line of the street address of the PD/PI. This field is required. |
| Street2 | This field is automatically populated from the SF424 (R&R). It is the second line of the street address of the PD/PI, if applicable. |
| City | This field is automatically populated from the SF424 (R&R). It is the city for the address of the PD/PI. |
| County/Parish | This field is automatically populated from the SF424 (R&R). It is the county or parish for the address of the PD/PI. |
| State | This field is automatically populated from the SF424 (R&R). It is the state where the PD/PI is located. This field is required if the PD/PI is located in the United States. |
| Province | For submissions to VA-ORD, leave this field blank. |
| Country | This field is automatically populated from the SF424 (R&R). It is the country for the PD/PI address. |
| ZIP Code | This field is automatically populated from the SF424 (R&R). It is the Postal Code (e.g., ZIP Code) of the PD/PI. This field is required if the PD/PI is located in the United States. |
| Phone Number | This field is automatically populated from the SF424 (R&R). It is the daytime phone number for the PD/PI. This field is required. |

| Field Name | Instructions |
|---|---|
| Fax Number | This field is automatically populated from the SF424 (R&R). It is the fax number for the PD/PI. |
| Email | This field is automatically populated from the SF424 (R&R). It is the email address for the PD/PI. This field is required for the PD/PI. |
| Credential, e.g., agency login | If you are submitting to an agency (e.g., NIH and other PHS agencies) where you have an established personal profile, enter the agency ID. If not, leave blank.<br>For VA-ORD applications, registration in eRA Commons is required for all PDs/PIs. **The assigned Commons UserName (the unique name used to log into the system) for anyone assigned the PD/PI role must be entered here. This is a required field.**<br>**Applications with missing or incorrect Commons ID's cannot be processed by eRA. This is a checklist item.** |
| Project Role | Select a project role from the list. Select "Other" if an appropriate project role is not listed.<br>The Contact PD/PI named in Box 14 of the Cover Component is automatically assigned the PD/PI role. Do not change this role. |
| Other Project Role Category | Complete if you selected "Other Professional" or "Other" as a project role; e.g., Engineer, Chemist. |
| Degree Type | Enter the highest academic or professional degree or other credentials (e.g., RN). Degree information in Commons profile is considered official data source. |
| Degree Year | Enter the year the highest degree or other credential was obtained. |
| Attach Biographical Sketch | Provide a biographical sketch for the PD/PI. Recommended information includes: Education and Training, Research and Professional Experience, Collaborators and Affiliations (for conflicts of interest), Publications and Synergistic Activities. Save the information in a single file and attach by clicking Add Attachment.<br>Biographical sketches must use the NIH Biographical Sketch format; see additional instructions below. |
| Attach Current & Pending Support | This information is required at the time of application submission. Refer to Other Support in Part III, Policies, Assurances, Definitions, and Other Information. **This is required for the Contact PD/PI listed in Box 14 of the Cover Component.** |

## Profile – Senior/Key Person [*n*]

The remaining Senior/Key Person Profiles should be listed in alphabetical order. While alphabetical order is preferred, it is not required. However, be aware that these profiles will

appear in the application (and to the reviewers) in the order provided by the applicant. Individuals with a postdoctoral role should be included if they meet the definition of Senior/Key Person.

All personel listed in Section A (Senior/Key Person) of the budget with calander months effort greater than zero, even if no salary is requested, must be included in the Senior/Key Person Profile(s) Component.

**Also use the Senior/Key Person Profile(s) Component to list any Other Significant Contributors (OSCs).** OSCs should be listed after all Key Persons. OSCs are individuals who have committed to contribute to the scientific development or execution of the project, but are not committing any specified measurable effort (in person months) to the project. These individuals are typically presented at "effort of zero person months" or "as needed" and may not be included in Section A of the budget (individuals with measurable effort cannot be listed as Other Significant Contributors). Consultants should be included if they meet this definition.

A biosketch, including Research Support information, will be required for these individuals as this highlights their accomplishments as scientists. Reviewers use these pages to address the "investigator" review criterion. However, if an award is to be made, other support information will not be required or accepted since considerations of overlap do not apply to these individuals.

Should the level of involvement change for an individual listed as an OSC, they should be redesignated as "key personnel." This change should be made before any compensation is charged to the project.

After providing data for each individual Senior/Key Person, click the **Next Person** button at the bottom of the form to enter data for the next Senior/Key Person. Continue in this manner until data has been provided for up to 40 Senior/Key Persons. To ensure proper performance of this form, after adding 20 additional Senior/Key Persons please save your application, close the Adobe reader, and reopen it. For applications involving more than 40 Senior/Key Persons, the "Additional Senior/Key Person Profiles" fields will become available once data for the first 40 Senior/Key Persons has been provided. (see instructions below).

| Field Name | Instructions |
|---|---|
| Prefix | Enter the prefix (e.g., Mr., Mrs., or Rev.) for the name of the Senior/Key Person. |
| First Name | Enter the first (given) name of the Senior/Key Person. This field is required. |
| Middle Name | Enter the middle name of the Senior/Key Person, if applicable. |
| Last Name | Enter the last (family) name of the Senior/Key Person. This field is required. |
| Suffix | This field is automatically populated from the SF424 (R&R). It is the suffix (e.g., Jr., Sr., or III) for the name of the PD/PI.<br>Do not use this field to indicate degrees (i.e. PhD, MD, etc.). A new data field has been added below for this information |

| Field Name | Instructions |
|---|---|
| Position/Title | Enter the title of the Senior/Key Person. |
| Department | Enter the name of primary organizational department, service, laboratory, or equivalent level within the organization of the Senior/Key Person. |
| Organization Name | Enter the name of organization of the Senior/Key Person.<br>This is a required field for applications to VA-ORD. |
| Division | Enter the name of primary organizational division, office, or major subdivision of the Senior/Key Person. |
| Street1 | Enter first line of the street address for the Senior/Key Person. This field is required. |
| Street2 | Enter second line of the street address for the Senior/Key Person, if applicable. |
| City | Enter the city for the address of the Senior/Key Person. This field is required. |
| County/Parish | Enter the county or parish for the address of the Senior/Key Person. |
| State | Enter the State where the Senior/Key Person is located. This field is required if the Senior/Key Person is located in the United States. |
| Province | For submissions to VA-ORD, leave this field blank. |
| Country | Select the country for the Senior/Key Person address. This field is required. |
| ZIP Code | Enter the Postal Code (e.g., ZIP Code) of the Senior/Key Person address. This field is required if the Senior/Key Person is located in the United States. |
| Phone Number | Enter the daytime telephone number for the Senior/Key Person. This field is required. |
| Fax Number | Enter the fax number for the Senior/Key Person. |
| Email | Enter the email address for the Senior/Key Person. **This field is required for the Senior/Key Person**. |

| Field Name | Instructions |
|---|---|
| Credential, e.g., agency login | If you are submitting to an agency (e.g., NIH and other PHS agencies) where you have an established personal profile, enter the agency ID. If not, leave blank.<br>**For VA-ORD applications involving Multiple PDs/PIs, registration in eRA Commons is required for all PDs/PIs.**<br>**The assigned Commons UserName (the unique name used to log into the system) for anyone assigned the PD/PI role must be entered here.** Commons ID is optional for all other Senior/Key Personnel. **This is a required field.**<br>**Applications with missing or incorrect Commons ID's cannot be processed by eRA. This is a checklist item.** |
| Project Role | Select one. Use "Other" if an appropriate category is not listed in the pick list.<br>Investigators other than the PD/PI may be designated roles such as "collaborator" using the "Other – Specify" option in the drop-down list of project roles. The co-investigator role is now included in the drop-down list and does not require the use of "Other-Specify".<br>For applications involving Multiple PDs/PIs, all such individuals **must** be assigned the PD/PI role and a leadership plan must be submitted. Co-PD/PI or Co-PI cannot be used to designate multiple PDs/PIs.<br>If including individuals classified as "Other Significant Contributors (OSCs)," use the "Other" category and indicate "Other Significant Contributor" as the role in the "Other Project Role Category." OSCs should be listed last after all other Senior/Key Persons have been listed.<br>**Make sure that the selected role matches the role selected in Section A of the Budget Component. Be sure to include Senior/Key Persons identified in any submitted subaward budget attachments.** |
| Other Project Role Category | Complete if you selected "Other Professional" or "Other" as a project role. For example, Engineer, Chemist. |
| Degree Type | Enter the highest academic or professional degree or other credentials (e.g., RN). Degree information in Commons profile is considered official data source. |
| Degree Year | Enter the year the highest degree or other credential was obtained. |
| Attach Biographical Sketch | **Provide a biographical sketch for each Senior/Key Person.** Recommended information includes: Education and Training, Research and Professional Experience, Collaborators and Affiliations (for conflicts of interest), Publications and Synergistic Activities. Save the information in a single file and attach by clicking Add Attachment.<br>Biographical sketches must use the NIH Biographical Sketch format; see additional instructions below. |

| Field Name | Instructions |
|---|---|
| Attach Current & Pending Support | This information is required at the time of application submission. Refer to Other Support in Part III, Policies, Assurances, Definitions, and Other Information.<br>**A separate Current & Pending Support attachment should be provided for each Senior/Key Person; this attachment is not needed for OSCs.**<br>**If there is no current "Other Support", use a PDF attachment that has the heading "Other Support" and indicate "None" in the body of the attachment.** |

### Additional Senior/Key Person Profile(s)

If more than forty Senior/Key Person profiles are proposed, enter the information in a separate file and attach it here.

A sample Additional Senior/Key Person Profiles format page for greater than 40 profiles is found under "Additional Format Pages" at: http://vaww.research.va.gov/funding/docs/preson-profiles.doc

### Additional Biographical Sketch(es) (Senior/Key Person)

Provide a biographical sketch for each Senior/Key Person included in the Additional Senior/Key Person Profile(s) attachment above. Recommended information includes: Education and Training, Research and Professional Experience, Collaborators and Affiliations (for conflicts of interest), Publications and Synergistic Activities. Save the information in a single file and attach here.

Biographical sketches must use the NIH Biographical Sketch format; see additional instructions below.

### Additional Current and Pending Support

Provide a list of all current and pending support for each Senior/Key Person (even if they receive no salary support from the projects) for ongoing projects and pending proposals. Show the current year's direct cost (funded project) or proposed first-year's direct cost (pending award) as well as the number of person-months per year to be devoted to the project by the senior/key person, regardless of source of support. Concurrent submission of a proposal to other organizations will not prejudice its review.

**This information is required at the time of application submission for all Senior/Key persons, but not for OSCs,** even if they receive no salary support from the project(s). If the Additional Senior/Key Person Profile(s) attachment is used, provide the combined Current and Pending Support information for the individuals listed in a single document.

### Additional VA-ORD Instructions for a Biographical Sketch (not to exceed four pages per person)

Use the sample *format* on the Biographical Sketch Format Page to prepare this section for **all** VA-ORD applications. Include biographical sketches for all **Senior/Key Personnel and Other Significant Contributors**. The 4-page limit includes the table at the top of the first page.

If the individual is registered in the eRA Commons, include the assigned Commons User Name. This data item is required for the PD/PI but is currently optional for all other Senior/Key Persons.

In other federal forms, this information is referred to as "Credential, e.g., agency login." For information on the eRA Commons, see https://commons.era.nih.gov/commons/index.jsp.

Complete the educational block at the top of the format page beginning with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training when applicable. For each entry provide the name and location of the institution; the degree received (if applicable); the month and year the degree was received, and the field of study. For residency entries, the field of study section should reflect the area of residency.

Following the educational block, complete Sections A – D as described below:

A. **Personal Statement.** Briefly describe why your experience and qualifications make you particularly well-suited for your role (e.g., PD/PI, mentor) and verify that you agree with your role and participation in the project that is the subject of the application.

   Indicate the percentage of time spent on research, clinical, teaching/mentoring, and administration. Dual appointments should be fully explained.

**B. Positions and Honors.** List in chronological order previous positions, concluding with your present position. List any honors. Include present membership on any Federal Government public advisory committee.

**C. Selected Peer-reviewed publications or manuscripts in press (in chronological order)**.

   VA-ORD encourages applicants to limit the list of selected peer-reviewed publications or manuscripts in press. Do not include manuscripts submitted or in preparation. The individual may choose to include selected publications based on recency, importance to the field, and/or relevance to the proposed research.

**D. Research Support.** List both selected ongoing and completed (during the last three years) research projects (Federal or non-Federal support). Begin with the projects that are most relevant to the research proposed in this application. Briefly indicate the overall goals of the projects and responsibilities of the Senior/Key person identified on the Biographical Sketch. *Do not include number of person months or direct costs*

   **Do not confuse "Research Support" with "Other Support."** Although they sound similar, these parts of the application are very different.

   **"Research Support"** (section D of the Biosketch) highlights your accomplishments, and those of your colleagues, as scientists. This information will be used by the reviewers in the assessment of each individual's qualifications for a specific role in the proposed project, as well as to evaluate the overall qualifications of the research team.

   **"Other Support"** information (provided in the Senior/Key Person Profile) is required to check that the proposed research has not already been funded by another Federal agency or private foundation.

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Once all data have been entered, click the **Close Form** button at the top of the form or use the scroll bar to scroll up. You will be returned to the Grant Application Package screen. To remove a document from the Submission box, click the document name to select it and then click the **Move Form to Delete** button. This will return the document to the Mandatory Documents Submission List or Optional Documents Submission List

## 4.6 R&R Budget Component

The SF424 R&R Budget Component must be used for all VA-ORD proposals. **V**A-ORD does not accept modular budgets.

The R&R Budget component includes three separate data entry screens: (1) Sections A and B; (2) Sections C through E; and (3) Sections F through K. To navigate between the various screens, use the "**Previous**" and "**Next**" buttons at the top of the form or use the scroll bar on the side of the screen. Complete the R&R Budget component following the instructions provided. **You must complete a separate detailed budget for each year of support requested. This is a checklist item.** The SF424 form will automatically generate a cumulative budget for the total project period.

**If no funds are requested for a required field, enter "0". All dollar fields should be presented in whole numbers and rounded to the nearest whole dollar.**

If funds are being requested for more than one budget period, click the "**Next Period**" button at the top of the third budget screen (Sections F through K) to navigate to screens for the next budget period.

**You must complete all the required information (i.e., those fields that are highlighted in yellow, outlined in red, and noted with an "*") before the "Next Period" button is activated.**

**Do not click "Next Period" when you have completed the budget pages for the last period being requested. This may cause required fields to be activated that will prevent your application from being submitted if left blank.**

**You must observe the limitations on Merit Review budget caps and durations**. If an application requests a duration or amount that exceeds the caps specified in an RFA, the application may not be accepted for review (see individual RFAs as different RFAs may specify different caps). **This is a checklist item.**

**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 worked and VA time spent on the project)**:

| Hours per 40 hour work week spent on the project | Calendar Months Effort | Percent Effort (based on 40 Hour Work Week) |
|---|---|---|
| 1 | 0.3 | 2.5 |
| 5 | 1.5 | 12.5 |
| 10 | 3.0 | 25.0 |
| 15 | 4.5 | 37.5 |
| 20 | 6.0 | 50.0 |
| 25 | 7.5 | 62.5 |
| 30 | 9.0 | 75.0 |
| 35 | 10.5 | 87.5 |
| 40 | 12.0 | 100.0 |

To calculate the "requested salary" in section A of the Research and Related budget page multiply the "Percent hours worked" from the last column in the Table above by the individual's full VA salary. This should also be done when requesting salary support for an individual who has a joint appointment - only their VA salary (commensurate with the VA appointment) and time spent on the project factor into the request for salary support. It does not matter how many calendar months they work elsewhere.

VA non-clinicians may request all or part of their VA-paid salary, depending upon the VA-ORD Research & Development Service they are applying to (see service-specific RFAs for what is allowed).

Clinician salaries (VA or non-VA) may not be requested in VA-ORD research proposal budgets.

**Salary support for non-VA employees may not be requested in Section A, even though calendar months of effort are identified there. IPA costs must be identified in section F "Other Direct Costs".**

Other Support documentation for individuals with multiple appointments:

If an individual has multiple appointments, it is possible that the combined effort can result in excess of 12 calendar months (not from any one institution, but from the combination of multiple appointments).

In all cases, an individual's combined total professional effort must meet a test of reasonableness.

For individuals with joint appointments, signature by the institutional official on the application certifies that: (1) the individual is applying as part of a joint appointment specified by a formal Memorandum of Understanding between the University and the VA; (2) there is no possibility of dual compensation for the same work; and (3) there is no possibility of an actual or apparent conflict of interest regarding such work.

## 4.6.1 Section A and B

OMB Number: 4040-0001
Expiration Date: 06/30/2011

**RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 1**

* ORGANIZATIONAL DUNS:

* Budget Type: ☐ Project ☐ Subaward/Consortium

Enter name of Organization:

Delete Entry | * Start Date: | * End Date: | Budget Period 1

A. Senior/Key Person

| | Prefix | * First Name | Middle Name | * Last Name | Suffix | * Project Role | Base Salary ($) | Cal. Months | Acad. Months | Sum. Months | * Requested Salary ($) | * Fringe Benefits ($) | * Funds Requested ($) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1. | | | | | | PD/PI | | | | | | | |
| 2. | | | | | | | | | | | | | |
| 3. | | | | | | | | | | | | | |
| 4. | | | | | | | | | | | | | |
| 5. | | | | | | | | | | | | | |
| 6. | | | | | | | | | | | | | |
| 7. | | | | | | | | | | | | | |
| 8. | | | | | | | | | | | | | |

9. Total Funds requested for all Senior Key Persons in the attached file

Total Senior/Key Person

Additional Senior Key Persons: | Add Attachment | Delete Attachment | View Attachment

B. Other Personnel

| * Number of Personnel | * Project Role | Cal. Months | Acad. Months | Sum. Months | * Requested Salary ($) | * Fringe Benefits ($) | * Funds Requested ($) |
|---|---|---|---|---|---|---|---|
| | Post Doctoral Associates | | | | | | |
| | Graduate Students | | | | | | |
| | Undergraduate Students | | | | | | |
| | Secretarial/Clerical | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | Total Number Other Personnel | | | | | Total Other Personnel | |

Total Salary, Wages and Fringe Benefits (A+B)

RESEARCH & RELATED Budget {A-B} (Funds Requested)

**Do NOT cut and paste from any other program** (i.e., WORD or ePROMISe) to complete fields on SF424 components; the font may not transfer correctly and may cause erroneous characters (e.g., "&"or "□") to be introduced. **Carefully check the eApplication in eRA Commons for such errors.**

### Organizational DUNS (Required Field)

Enter the DUNS or DUNS+4 number of your VA medical center. For project budgets, this field is pre-populated from the R&R SF424 Cover Component. For subaward budgets, this field is required. If a subaward/consortium is involved, use the DUNS belonging to the subaward institution, not the DUNS of the applicant organization. **Separate units at the same medical center may not use the subaward component to distinguish themselves; a different DUNS must be used for each Subaward budget.**

### Budget Type (Required Field)

Check the appropriate block:

- **Project**: The budget requested for the primary (submitting) VA medical center.
- **Subaward/Consortium**: The budget requested for subawardee/consortium organization(s). Use the R&R Subaward Budget Attachment and attach as a separate file on the R&R Budget

Attachment(s) form. Note: separate budgets are required only for subawardee/consortium organizations that perform a substantive portion of the project.

Individual R&D Service or RFAs may require separate Subaward/Consortium budgets for multi-site projects (including small clinical trials) if funds are being requested for the additional sites. See Section 4.6.3 and Section 4.7 Special Instructions for Preparing Applications with a Subaward/Consortium Budgets.

**Enter name of Organization**

Pre-populated from the R&R SF424 Cover Component. Enter the name of your VA medical center.

**Delete Entry**

Reset entries on page.

**Start Date (Required Field)**

Pre-populated from the R&R SF424. Enter the requested/proposed start date of each budget period. Use MM/DD/YYYY format.

**End Date (Required Field)**

Enter the requested/proposed end date of each budget period. Use MM/DD/YYYY format.

**Budget Period (Required Field)**

Identify the specific budget period (e.g., 1, 2, 3, 4, or 5). If submitting through Grants.gov, the system will automatically generate a cumulative budget for the total project period.

(If the Delete Entries button is pressed, it will reset entries on page. Please navigate to previous year to enable the submission of the form.)

## A. Senior/Key Person

**This section should include the names of all senior/key persons who are involved on the project in a particular budget year.** Include all collaborating investigators, post-doctoral fellows, or other individuals meeting the senior/key person definition if they are from the submitting VA medical center or academic affiliate.

Salary requests of $0 (e.g., for consultants or Career Development mentors) are allowed, provided that an effort > 0 calendar months is indicated in Section A; do not list individuals with 0 calendar months effort in Sections A or B.

Individuals on an IPA should be identified by including the words "on IPA" following their name in Sections A or B if they meet the senior/key person definition. These individuals must be included in the budget justification. **Costs for IPAs must not be included in Section A or B**. These contractual costs are not salaries and should be identified on lines 8-10 (Other) of Section F. Other Direct Costs.

Personnel listed as **Other Significant Contributors**, who are not committing any specific measurable effort to the project, **should not be included in the Personnel section of the budget (Sections A and B)**.

**Consultants** designated as Senior/Key Persons in the Senior/Key Person Profile Component can be included in Budget Section A with their contribution in calendar months but **no salary ($0) should be entered. All consultant costs must be included on line 3 (Consultant Services)** of Section F. Other Direct Costs.

If more than 8 Senior/Key Personnel need to be identified in Section A, enter the total salary costs for the additional personnel in line 9 and then attach a separate PDF file containing the specific information (Prefix, name, role, calendar months, salary) for all additional personnel using the "**Add Attachment**" button.

| Field Name | Instructions |
|---|---|
| Prefix | Pre-populated from the R&R SF424. Enter the prefix (e.g., Mr., Mrs., or Rev.) for the name of the Senior/Key Person. |
| First Name | Pre-populated from the R&R SF424. Enter the first (given) name of each Senior/Key Person. This field is required. |
| Middle Name | Pre-populated from the R&R SF424. Enter the middle name of each Senior/Key Person, if applicable. |
| Last Name | Pre-populated from the R&R SF424. Enter the last (family) name of each Senior/Key Person. This field is required. |
| Suffix | Pre-populated from the R&R SF424. Select from the list the suffix (for example, Jr., Sr., III) of each Senior/Key Person. |
| Project Role | Enter the project role of the Senior/Key person. This field could also include such roles as Co-Investigator, Collaborator, Postdoctoral Associates or Fellows, and Other Professionals.<br>The role of the PD/PI is auto-populated in the 01 year budget only. Do not change or edit this field for the PD/PI. For future year budgets, use consistent terminology<br>**Co-PD/PI or Co-PI cannot be used to designate multiple PDs/PIs.** For all funding period budgets, use consistent terminology. |
| Base Salary ($) | Enter the annual compensation paid by the employer for each Senior/Key person. This includes all activities such as research, teaching, patient care, or other. You may choose to leave this column blank.<br>A VA medical center may choose to leave this blank; however, VA-ORD may request this information prior to award. |
| Cal. Months | Enter the number of months devoted to the project for each Senior/Key person (for example, calendar, academic, summer).<br>**Use the calendar months column for all Senior/Key personnel.** Calendar months for all investigators with a VA-paid appointment must be based on the VA 40-hr workweek (e.g., 5/8th appointment = 25 hrs/wk = 7.5 months). Effort for non-VA personnel should be calculated by multiplying the percent effort times 12 months (i.e., 10 % effort = 1.2 months). See special instructions below for joint VA-University appointments |
| Acad. Months | **Do not use for VA-ORD applications.** |
| Sum. Months | **Do not use for VA-ORD applications.** |

| Field Name | Instructions |
|---|---|
| Requested Salary ($) | Regardless of the number of months being devoted to the project, indicate the amount of salary being requested for this budget period for each Senior/Key person. This field is required.<br>Non-clinicians may request all or part of their VA-paid salary, depending upon the VA-ORD Research & Development Service they are applying to (see service-specific RFAs for what is allowed). **A maximum 3% cost of living increase is allowed for all VA-paid salaries; COLAs for IPAs are not allowed.**<br>**Clinician salaries (VA or non-VA) may not be requested.** |
| Fringe Benefits ($) | Enter applicable fringe benefits, if any, for each Senior/Key person<br>**For current VA-employees, actual fringe benefits may be requested. For to-be-determined positions, fringe benefits may not exceed 30%.** Total salary costs (salary plus fringe) can be entered under "Requested Salary" above, but $0 must then be entered for the Fringe Benefits. |
| Funds Requested ($) | Enter the requested salary and fringe benefits for each Senior/Key person. This field is required. |
| Total Senior/Key Person | The total funds requested for all Senior/Key persons (auto-calculated). |
| Total Funds requested for all Senior Key Persons in the attached file | Enter the total funds requested for all Senior/Key persons listed in the attached file (see next box).<br>If more than 8 Senior/Key Personnel need to be identified in Section A, enter the total salary costs for the additional personnel on line 9. |
| Additional Senior Key Persons | If funds are requested for more than 8 Senior/Key persons, include all pertinent budget information as identified in this section and attach as a file here. Enter the total funds requested for all additional senior/key persons in line 9 of Section A. This attachment is required if funds are entered in line 9 of Section A.<br>Use the same format as the budget component and include all required information. |

**Special Instructions: Joint University and Department of Veterans Affairs (VA) Appointments.**

**Calendar months for VA investigators must be based on the VA 40-hr workweek** (e.g., a 5/8th VA appointment = 25 hrs/week = 7.5 calendar months). If an individual has multiple appointments their combined effort may exceed 12 calendar months (from the combination of multiple appointments). In all cases, **an individual's combined total professional effort must meet a test of reasonableness.**

VA non-clinicians may request all or part of their VA-paid salary, depending upon the VA-ORD R&D Service they are applying to (see service-specific RFAs for what is allowed). **Clinician salaries (VA or non-VA) may not be requested in VA-ORD research proposal budgets.**

Signature by the institutional official on the application certifies that: (1) the individual is applying as part of a joint appointment specified by a formal Memorandum of Understanding between the University and the VA; (2) there is no possibility of dual compensation for the same work; and (3)

there is no possibility of an actual or apparent conflict of interest regarding such work. Additional information may be requested by VA-ORD.

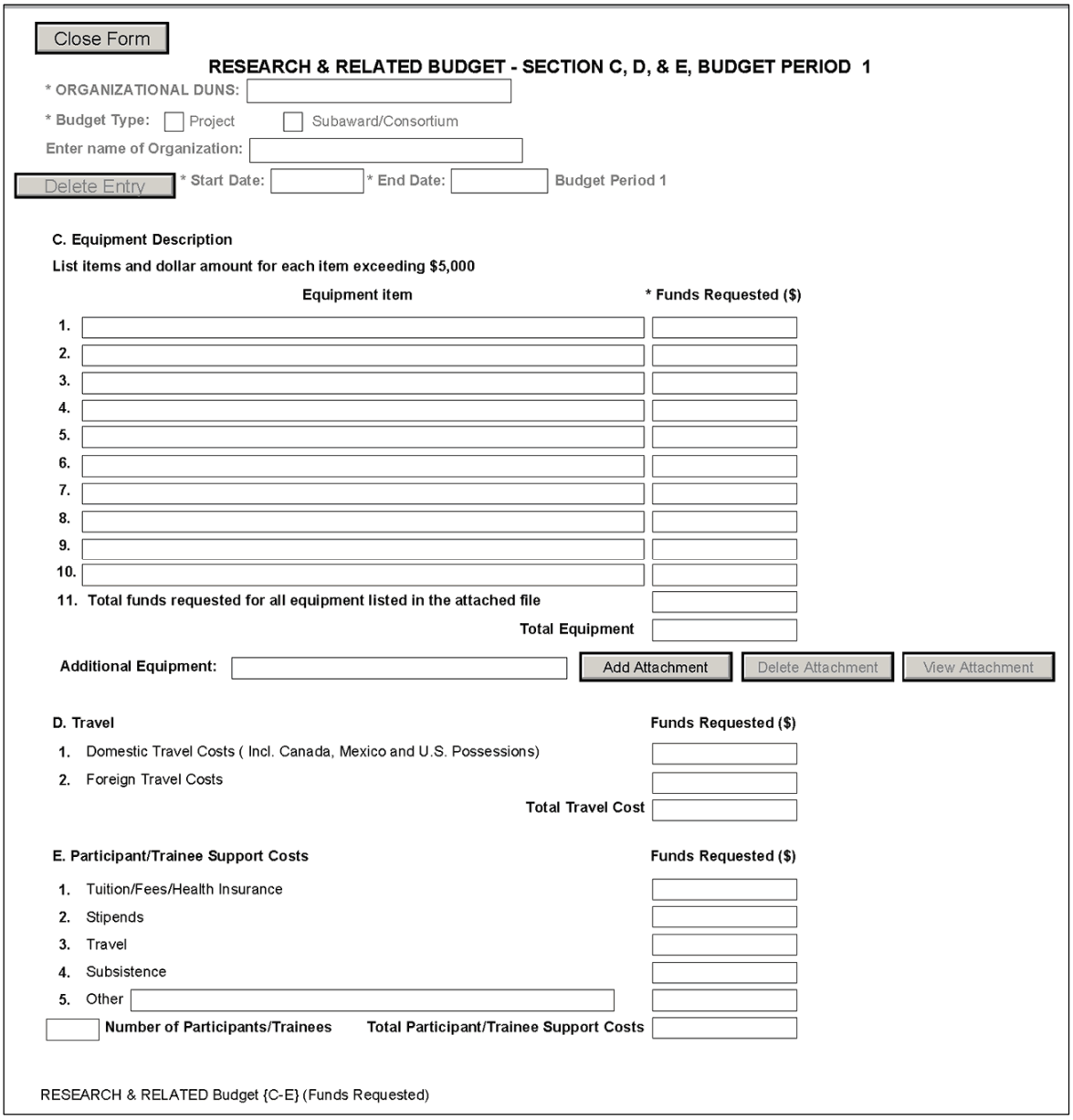
## B. Other Personnel

| Field Name | Instructions |
|---|---|
| Number of Personnel | For each project role category, identify the number of personnel proposed.<br>List any additional project role(s) in the blank(s) provided, e.g., Engineer, Technician, etc.<br>For all individuals not already named in Section A. Senior/Key Person, individually list names, roles and duties, associated Calendar, Academic, or Summer Months, and salary & fringe benefits requested in the Budget Justification.<br>**Administrative support staff must be included in key personnel** and their role in supporting the project included in the budget justification. |
| Project Role | If Project Role is other than Post Doctoral Associates, Graduate Students, Undergraduate Students, or Secretarial/Clerical, enter the appropriate project role (for example, Engineer, Technician, etc.) in the blanks.<br>**Do not include costs for tuition remission for graduate students, or graduate student stipends in this section; these costs are not permitted in VA budgets. Although graduate students may be paid as technicians, they must be listed as such in the budget.** Consultant costs must be listed below in Section F. Other Direct Costs. |
| Cal. Months | Identify the number of months devoted to the project in the applicable box for each project role category. |
| Acad. Months | **Do not use for VA-ORD applications.** |
| Sum. Months | **Do not use for VA-ORD applications.** |
| Requested Salary ($) | Regardless of the number of months being devoted to the project, indicate only the amount of salary/wages being requested for each project role.<br>VA non-clinicians may request all or part of their VA-paid salary, depending upon the VA-ORD Research & Development Service the applicant is applying to (see service-specific RFAs for what is allowed). **Clinician salaries (VA or non-VA) may not be requested. A maximum 3% cost of living increase is allowed for all VA-paid salaries; COLAs for IPAs are not allowed** |
| Fringe Benefits ($) | Enter applicable fringe benefits, if any, for this project role category<br>**For current VA-employees, actual fringe benefits may be requested. For to-be-determined positions, fringe benefits may not exceed 30%.**<br>If total salary costs (salary plus fringe) is entered under "Requested Salary" above, $0 must then be entered for the Fringe Benefits. |

| Field Name | Instructions |
|---|---|
| Funds Requested | Enter requested salary/wages & fringe benefits for each project role. |
| Total Number of Other Personnel | This total will auto-calculate. |
| Total Other Personnel | The total funds requested for all other Personnel. |
| Total Salary, Wages and Fringe Benefits (A+B) | Total Funds requested for all Senior Key Persons and all Other Personnel. This total will auto-calculate. |

To navigate to the next page (Sections C through E), click the "**Next**" button at the top of the form or use the scroll bar on the left-hand side of the screen.

### 4.6.2 Sections C through E


Close Form

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 1

* ORGANIZATIONAL DUNS:

* Budget Type: Project Subaward/Consortium

Enter name of Organization:

Delete Entry * Start Date: * End Date: Budget Period 1

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

| Equipment item | * Funds Requested ($) |
|---|---|
| 1. | |
| 2. | |
| 3. | |
| 4. | |
| 5. | |
| 6. | |
| 7. | |
| 8. | |
| 9. | |
| 10. | |
| 11. Total funds requested for all equipment listed in the attached file | |
| Total Equipment | |

Additional Equipment: Add Attachment Delete Attachment View Attachment

| D. Travel | Funds Requested ($) |
|---|---|
| 1. Domestic Travel Costs ( Incl. Canada, Mexico and U.S. Possessions) | |
| 2. Foreign Travel Costs | |
| Total Travel Cost | |

| E. Participant/Trainee Support Costs | Funds Requested ($) |
|---|---|
| 1. Tuition/Fees/Health Insurance | |
| 2. Stipends | |
| 3. Travel | |
| 4. Subsistence | |
| 5. Other | |
| Number of Participants/Trainees — Total Participant/Trainee Support Costs | |

RESEARCH & RELATED Budget {C-E} (Funds Requested)

The information for Organizational DUNS, Budget Type, Name of Organization, and Start and End Dates is automatically filled in based on the information entered on the first budget screen. To edit this information, return to the initial budget screen (Sections A and B) by clicking the "**Previous**" button.

## C. Equipment Description

List of items and dollar amount for each item exceeding $5,000

| Field Name | Instructions |
|---|---|
| Equipment item | Equipment is defined as an item of property that has an acquisition cost of $5,000 or more (unless the organization has established lower levels) and an expected service life of more than one year. List each item of equipment separately and justify each in the budget justification section. Ordinarily, allowable items will be limited to research equipment and apparatus not already available for the conduct of the work. General-purpose equipment, such as a personal computer, is not eligible for support unless primarily or exclusively used in the actual conduct of scientific research.<br>**Multiple small items may not be combined to meet the $5,000 minimum cost and may not be included in this section. Do not include IT needs in the list of requested equipment.** |
| Funds Requested | List the estimated cost of each item of equipment including shipping and any maintenance costs and agreements. This is required information**.** |
| Total funds requested for all equipment listed in the attached file | Total funds requested for all equipment listed in the attached file.<br>Dollar limits on equipment, if applicable, will be identified in individual funding opportunity announcements. |
| Total Equipment | Total Funds requested for all equipment. |
| Additional Equipment | If the space provided cannot accommodate all the equipment proposed, attach a file by clicking Add Attachment. List each additional item and the funds requested. For all additional items in the attached file, list the total funds requested on line 11 of this section. |

## D. Travel

| Field Name | Instructions |
|---|---|
| Domestic Travel Costs (Incl. Canada, Mexico, and US Possessions) | Identify the total funds requested for domestic travel. Domestic travel includes Canada, Mexico, and US possessions. In the budget justification section, include the purpose, destination, dates of travel (if known), and number of individuals for each trip. If the dates of travel are not known, specify estimated length of trip (for example, 3 days).<br>Expenses for domestic travel that is integral to carrying out the proposed research may be requested, if justified. Limits on funds for domestic travel to attend/present at scientific meetings will be identified in individual funding opportunity announcements. |
| Foreign Travel Costs | Funds for foreign travel may not be requested as part of a VA-ORD research application budget. |
| Total Travel Cost | The total funds requested for all travel. |

## E. Participant/Trainee Support Costs

Unless specifically stated otherwise in a funding opportunity announcement, **VA-ORD applicants should leave Section E blank**.

Note: Tuition remission and/or stipends for graduate students may not be included in Section B. Other Personnel or Section F. Other Direct Costs.

| Field Name | Instructions |
|---|---|
| Tuition/Fees/Health Insurance | Enter the total amount of funds requested for Participant/Trainee tuition, fees, and/or health insurance. |
| Stipends | Enter the total funds requested for Participant/Trainee stipends. |
| Travel | Enter the total funds requested for Participant/Trainee travel. |
| Subsistence | Enter the total funds requested for Participant/Trainee subsistence. |
| Other | Describe any other participant trainee funds requested. Enter the total funds requested for any other Participant/Trainee costs described. |
| Number of Participants/Trainees | Enter the total number of proposed Participants/Trainees. **Do not include subject recruitment in section E.** |
| Total Participant/Trainee Support Costs | The total funds requested for all trainee costs. **Do not include subject recruitment or reimbursement costs in section E.** |

## 4.6.3 Sections F through K

Close Form

**RESEARCH & RELATED BUDGET - SECTION F-K, BUDGET PERIOD 1**

Next Period

* ORGANIZATIONAL DUNS:

* Budget Type: ☐ Project ☐ Subaward/Consortium

Enter name of Organization:

Delete Entry * Start Date: * End Date: Budget Period 1

| F. Other Direct Costs | Funds Requested ($) |
|---|---|
| 1. Materials and Supplies | |
| 2. Publication Costs | |
| 3. Consultant Services | |
| 4. ADP/Computer Services | |
| 5. Subawards/Consortium/Contractual Costs | |
| 6. Equipment or Facility Rental/User Fees | |
| 7. Alterations and Renovations | |
| 8. | |
| 9. | |
| 10. | |
| **Total Other Direct Costs** | |

| G. Direct Costs | Funds Requested ($) |
|---|---|
| **Total Direct Costs (A thru F)** | |

H. Indirect Costs

| | Indirect Cost Type | Indirect Cost Rate (%) | Indirect Cost Base ($) | * Funds Requested ($) |
|---|---|---|---|---|
| 1. | | | | |
| 2. | | | | |
| 3. | | | | |
| 4. | | | | |
| | | | **Total Indirect Costs** | |

Cognizant Federal Agency

(Agency Name, POC Name, and POC Phone Number)

| I. Total Direct and Indirect Costs | Funds Requested ($) |
|---|---|
| Total Direct and Indirect Institutional Costs (G + H) | |

| J. Fee | Funds Requested ($) |
|---|---|
| | |

K. * Budget Justification Add Attachment Delete Attachment View Attachment

(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

The information for Organizational DUNS, Budget Type, Name of Organization, and Start and End Dates is automatically filled in based on the information entered on the first budget screen. To edit this information, return to the initial budget screen (Sections A and B) by clicking the "**Previous**" button.

## F. Other Direct Costs

| Field Name | Instructions |
|---|---|
| 1. Materials and Supplies | List total funds requested for materials and supplies. In the budget justification, indicate general categories such as glassware, chemicals, animal costs, including an amount for each category. Categories less than $1,000 do not have to be itemized.<br>**Multiple small items may not be combined to meet the $5,000 minimum cost for "equipment." Items costing less than $5,000 per item must be requested as supplies.** |
| 2. Publication Costs | Enter the total publication funds requested. The proposal budget may request funds for the costs of documenting, preparing, publishing, or otherwise making available to others the findings and products of the work conducted under the award. In the budget justification include supporting information. |
| 3. Consultant Services | List the total costs for all consultant services. In the budget justification, identify each consultant, the services he/she will perform, total number of days, travel costs, and the total estimated costs.<br>In the budget justification, also provide the names and organizational affiliations of all consultants other than those involved in consortium/contractual arrangements. Include consultant physicians in connection with patient care and persons who are confirmed to serve on external monitoring boards or advisory committees to the project. Describe the services to be performed. **Annual cost for consultant services may not exceed $2,500 per consultant.** |
| 4. ADP/Computer Services | Enter total funds requested for ADP/computer services. The cost of computer services, including computer-based retrieval of scientific, technical and education information may be requested. In the budget justification, include the established computer service rates at the proposing organization if applicable.<br>**Do not include IT Costs in the budget.**<br>**All anticipated IT needs must be provided, however, in a separate table in the budget justification.** |

| Field Name | Instructions |
|---|---|
| 5. Subawards/Consortium/ Contractual Costs | Enter the total funds requested for 1) all subaward/consortium organization(s) proposed for the project and 2) any other contractual costs proposed for the project.<br>Separate **Subaward budgets may be required for multi-site projects** (including small clinical trials) if funds are being requested for the additional sites. All activities at a single site (VAMC) must be included on the same budget component. **See individual RFAs for details**.<br>Subaward budgets cannot be used to justify or create contracts with non-VA institutions; **do not submit a subaward budget for a non-VA site**.<br>Existing contractual costs for support services, such as the laboratory testing of biological materials, clinical services, or data processing, are occasionally sufficiently high to warrant a categorical breakdown of costs. When this is the case, provide detailed information as part of the budget justification.<br>**The total cost of all Subawards must be listed on line 5, Section F, of the Budget Component (This is a checklist item). If subaward costs are not included on line 5, they will not be part of the award if the application is selected for funding.** |
| 6. Equipment or Facility Rental/User Fees | Enter the total funds requested for equipment or facility rental/use fees. In the budget justification, identify each rental user fee and justify. An example of acceptable fees would be for time on a University core instrument such as a mass spectrometer; rental costs for laboratory space, office space, or IT equipment/facilities would not be considered appropriate. Limits on funds for such fees will be identified in individual funding opportunity announcements. |
| 7. Alterations and Renovations | VA-ORD applicants may not request funds for facility alterations or renovations. |
| 8-10 Other | Add text to describe any "other" direct costs not requested above. Use the budget justification to further itemize and justify.<br>**Use lines 8-10 for such costs as clinical trial subject payments or IPAs. IPAs may be listed individually or combined on one line.**<br>If line space is an issue, combine all remaining "other direct costs" together on the last line and include details in the budget justification (description and funds requested). |
| Total Other Direct Costs | The total funds requested for all other direct costs. |

## Special Instructions for Patient Care Costs

## G. Total Direct Costs (A through F)

The total funds requested for all direct costs.

### H. Indirect Costs

VA-ORD applicants may not request indirect costs; do not enter any data on lines 1-4.

### I. Total Direct and Indirect Institutional Costs (G + H)

The total funds requested for direct and indirect costs will be automatically calculated by the forms.

### J. Fee

Fees are not allowed on applications to VA-ORD.

### K. Budget Justification

All items in the budget (budget categories, budget years, and performance sites) must be clearly justified in a single narrative and attached to Section K of the Research and Related Budget. Use the budget justification to provide the additional information requested in each budget category identified above and any other information you wish to submit to support your budget request. Insufficiently justified categories (i.e., equipment) are likely to be deleted from the requested budget.

Note: There is a single justification for all budget years so include information for all years in the same file. Only one file may be attached (except for Subaward Budget justifications).

Click **Add Attachment** to attach the file.

Use this section to also list the names, role (e.g., PostDoc), associated months, salary and fringe benefits for all Postdoctoral Associates included in Budget Section B. Other Personnel.

Include a justification for any significant increases or decreases between budget years.

**IT needs (equipment, software, and/or computer services) must be itemized in a separate table, with annual totals clearly indicated. A separate justification for these requests must immediately follow the table.**

If the application includes a subaward budget, a separate budget justification is required for the subaward budget; do not include or duplicate that justification in Section K. See Section 4.7 Special Instructions for Preparing Applications with a Subaward/Consortium.

#### Completing Budget Periods 2-5

If funds are being requested for more than one budget period, you must complete a separate detailed budget for each year of support requested. To navigate to screens for the next budget period, click the **Next Period** button at the top of the 3rd budget screen (Sections F through K). You must complete all the required information (i.e., those fields that are highlighted in yellow, outlined in red, and noted with an "*") before the **Next Period** button is activated. If no funds are requested for a required field, enter "0."

Note: The Budget Justification above is a required item and must be attached before the **Next Period** button is activated.

## 4.6.4 Cumulative Budget

**All values on this form are calculated automatically.** They present the summations of the amounts that you have entered previously, under Sections A through K, for each of the individual budget periods. Therefore, no data entry is allowed or required, in order to complete this "Cumulative Budget" section.

If any of the amounts displayed on this form appears to be incorrect, you may correct it by adjusting one or more of the values that contribute to that total. To make any such adjustments, you will need to revisit the appropriate budget period form(s), to enter corrected values.

**RESEARCH & RELATED BUDGET - Cumulative Budget**

| | | Totals ($) |
|---|---|---|
| **Section A, Senior/Key Person** | | |
| **Section B, Other Personnel** | | |
| Total Number Other Personnel | | |
| **Total Salary, Wages and Fringe Benefits (A+B)** | | |
| **Section C, Equipment** | | |
| **Section D, Travel** | | |
| 1. Domestic | | |
| 2. Foreign | | |
| **Section E, Participant/Trainee Support Costs** | | |
| 1. Tuition/Fees/Health Insurance | | |
| 2. Stipends | | |
| 3. Travel | | |
| 4. Subsistence | | |
| 5. Other | | |
| 6. Number of Participants/Trainees | | |
| **Section F, Other Direct Costs** | | |
| 1. Materials and Supplies | | |
| 2. Publication Costs | | |
| 3. Consultant Services | | |
| 4. ADP/Computer Services | | |
| 5. Subawards/Consortium/Contractual Costs | | |
| 6. Equipment or Facility Rental/User Fees | | |
| 7. Alterations and Renovations | | |
| 8. Other 1 | | |
| 9. Other 2 | | |
| 10. Other 3 | | |
| **Section G, Direct Costs (A thru F)** | | |
| **Section H, Indirect Costs** | | |
| **Section I, Total Direct and Indirect Costs (G + H)** | | |
| **Section J, Fee** | | |

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Once all data have been entered, click the **Close Form** button at the top of the form or use the scroll bar to scroll up. You will be returned to the Grant Application Package screen. To remove a document from the Submission box, click the document name to select it and then click the **Move Form to Delete** button. This will return the document to the Mandatory Documents Submission List or Optional Documents Submission List.

## 4.7 Special Instructions for Preparing Applications with a Subaward/Consortium

OMB Number: 4040-0001
Expiration Date: 06/30/2011

**R&R SUBAWARD BUDGET ATTACHMENT(S) FORM**

Instructions: On this form, you will attach the R&R Subaward Budget files for your grant application. Complete the subawardee budget(s) in accordance with the R&R budget instructions. Please remember that any files you attach must be a PDF document.

Click here to extract the R&R Subaward Budget Attachment

Important: Please attach your subawardee budget file(s) with the file name of the subawardee organization. Each file name must be unique.

| | | | | |
|---|---|---|---|---|
| 1) Please attach Attachment 1 | | Add Attachment | Delete Attachment | View Attachment |
| 2) Please attach Attachment 2 | | Add Attachment | Delete Attachment | View Attachment |
| 3) Please attach Attachment 3 | | Add Attachment | Delete Attachment | View Attachment |
| 4) Please attach Attachment 4 | | Add Attachment | Delete Attachment | View Attachment |
| 5) Please attach Attachment 5 | | Add Attachment | Delete Attachment | View Attachment |
| 6) Please attach Attachment 6 | | Add Attachment | Delete Attachment | View Attachment |
| 7) Please attach Attachment 7 | | Add Attachment | Delete Attachment | View Attachment |
| 8) Please attach Attachment 8 | | Add Attachment | Delete Attachment | View Attachment |
| 9) Please attach Attachment 9 | | Add Attachment | Delete Attachment | View Attachment |
| 10) Please attach Attachment 10 | | Add Attachment | Delete Attachment | View Attachment |

**For each subaward/consortium organization, extract and complete a subaward/consortium budget attachment.** The Budget Attachment contains sections A-K, similar to those found in the main Budget Component. Multiple "budget periods" may be requested for each subaward organization using a single Budget Attachment (i.e., 1 Attachment per subaward). The "Start Date" and "End Date" for each requested budget period must identify a single budget period (i.e., each budget period must have a unique start and end date). A budget justification for the subaward (all periods) is a required attachment for the first budget period requested. **This is a checklist item.**

Separate budgets are required only for subawardee/consortium organizations that perform a substantive portion of the project. **Do not attach or include the primary site budget justification to a subaward budget.**

Subaward budgets may be required for multi-site projects if funds are being requested for the additional sites (**see individual RFAs for details**).

When multiple VA medical centers are involved, the submitting VA is considered the primary performance site. Separate budget(s) for the additional VA medical centers may be submitted on separate budget pages using the SF424 (R&R) Subaward Budget Attachment(s) Form.

Subaward budgets cannot be used to justify or create contracts with non-VA institutions; **do not submit a subaward budget for a non-VA site.**

When completing the Project Role for the investigator leading the portion of the project at the consortium site, the project role of "PD/PI" should only be used if the entire application is being submitted under the Multiple PD/PI Policy. Also, the role of the Co-PD/PI is not currently used by VA-ORD. Do not assign any individuals this role. If applicants wish to use role of "Consortium PI," select "Other" for the Project Role field and then insert the appropriate role descriptor in the Other Project Role Category field; the "co-investigator" role is now included in the list of available roles.

**All "Senior/Key Persons" identified in a subaward budget attachment must be included in the Senior/Key Persons Component in the main application.**

This component currently accommodates up to 10 separate subaward budgets. For an application with >10 subaward budgets, budgets 11 and above should be converted to PDF and included as part of Section K. Budget Justification **of the parent budget (R&R Budget Component)**.

Reminder, the sum of all subaward budgets (those attached separately and those provided as part of the budget justification) must be included on Line 5 (Subawards/Consortium/Contractual Costs) of Section F. Other Direct Costs in the parent budget.

To start the process, the applicant organization should:

- Select the Subaward Budget Attachment Form from the Optional Documents in the Application Package.
- Open the form, and click the "**Click here to extract the R&R Subaward Budget Attachment**" button in the middle of the form. A "**SAVE**" dialog box appears.
- Save the file locally using the first ten letters of the consortium organization's name and use ".pdf" as the file extension. (The extracted file is an Adobe PDF file.) Once you save the file, there is no need to extract another budget attachment. Doing so may cause you to lose any data already stored in the saved file.
- Email the extracted, saved form to the subaward organization (VA medical center). Note: subaward organizations must have installed a compatible version of Adobe Reader before they can complete the form. The subaward organization should complete all the budget information as instructed in the R&R Budget component instructions in Section 4.6. Note: The Organizational DUNS and Name of Organization fields must reflect that of the subaward organization.
- The subaward organization must complete the budget component and email it back to the applicant organization.
- Return to the Subaward Budget Attachment Form and attach the subaward budget to one of the blocks provided on the form.

### Submitting Subaward Budgets That Are Not Active for all Periods of the Application

When submitting subaward budgets that are not active for all periods of the application, fill out the subaward R&R Budget form and include only the number of periods for which the subaward is active. The budget period start/end dates reflected in each period should reflect the corresponding main budget period start/end dates. This approach is the most workable solution to the limitations in existing forms that do not allow an "empty" budget period and do not allow submission of a subaward budget with zero effort to skip a budget period.

For example, suppose the primary site has filled out a budget form with the following periods:

- period 1 Jan 1 2008 – Dec 31 2008
- period 2 Jan 1 2009 – Dec 31 2009
- period 3 Jan 1 2010 – Dec 31 2010
- period 4 Jan 1 2011 – Dec 31 2011
- period 5 Jan 1 2012 – Dec 31 2012

Now, suppose there is a subaward that performs in support year 1 and does not become active again until support year 4. The subaward can fill out the first two periods of their budget form as follows:

- period 1 Jan 1 2008 – Dec 31 2008 (dates correspond to main period 1)
- period 2 Jan 1 2011 – Dec 31 2011 (dates correspond to main period 4)

It is not necessary that the budget period numbers between the main and subaward match; the correlation is reflected in the dates. Do be careful, however, that the dates exactly match what is listed for the period in the main budget. **Be sure to include the requested budget on Section F, line 5, of the correct budget periods of the main budget.**

**Note this approach may cause a validation warning regarding the NIH $500,000 per year limit on direct costs. You should ignore this warning if it is received.** You must notify appropriate staff in the OVA-ORD Research & Development Service you are applying to that the subaward is only active for specific periods of the overall project to avoid having the proposal identified as exceeding stated budget caps. This information will make the date correlation immediately apparent and will help avoid any confusion.

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Once all data have been entered, click the **Close Form** button at the top of the form or use the scroll bar to scroll up. You will be returned to the Grant Application Package screen. To remove a document from the Submission box, click the document name to select it and then click the **Move Form to Delete** button. This will return the document to the Mandatory Documents Submission List or Optional Documents Submission List.

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# 5. Completing PHS398 Components

**VA-ORD applications do not use PHS398 components.**

# 6. Peer Review Process

**Overview**

Most research applications submitted to VA-ORD will be reviewed through a two-tier system.

The first level of review will be performed by a 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. The SRG does not make funding decisions.

> **Individual reviewers or review panel chairs may not be directly contacted by the applicant <u>or any other interested party</u> concerning a submitted application, either before or following review. SRG members are required to notify the SRO for the panel of any such contact.**
>
> **Report of such contact will result in administrative withdrawal of the application, and may result in denial of eligibility to submit further applications.**

The second level of review will usually be performed by the appropriate Research & Development Service, based not only on considerations of scientific merit (as judged by the SRG), but also on the relevance of the proposed study to the mission, programs, and priorities of VA-ORD and that Service. Funding decisions are made at the discretion, and approval, of the Director of the appropriate R&D Service.

**Discussed and Nondiscussed Applications**

Before the review meeting, three reviewers who have confirmed that they have no conflict of interest with any PD/PI or other key personnel on the project are assigned to provide a preliminary evaluation and score for that application based on the review criteria described below.

The initial scientific peer review of research applications may include a process in which only those applications deemed by the SRG to have the highest scientific merit will be discussed and be assigned a priority score during the review meeting; the decision to "not discuss" a proposal must be unanimous. Up to 50 percent of applications assigned to an SRG may not be discussed or scored at the review meeting. This process allows the reviewers to focus their time and effort during the meeting on the most meritorious applications.

**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 (1.0 – 5.0) will be given by each eligible SRG member (without conflict of interest) following the panel's 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. The final priority score (100-500) for each discussed application will be calculated by multiplying the arithmetic average of all the eligible members' scores 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.

For proposals discussed during the review meeting, the Summary Statement will also include a summary of the SRG's' discussion during the review meeting, the final priority score and percentile (if calculated), recommendations of the SRG (including budget recommendations), and

administrative notes of special considerations. Percentiles may not be calculated for some funding mechanisms and/or SRGs.

Information about SRG membership may also be obtained from the appropriate R&D Service.

**Research Project Evaluation Criteria**

***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?

***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? Does the investigative team bring complementary and integrated expertise to the project (if applicable)? If a Multiple PD/PI Leadership plan is included in the application, is it justified or necessary for completion of the proposed work?

***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.?

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

***Protection of Human Subjects***: SRGs 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.**

***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*:** Did the applicant respond to the previous review? Are the responses to comments from the previous scientific review group adequate? Are the changes in the resubmission application appropriate? Did the revision(s) improve the quality of the application?

# 7. Supplemental Instructions to the SF 424(R&R) for Preparing a VA Career Development Award (CDA1, CDA2, or NRI) Application

## 7.1 Introduction

All VA Career Development Award applicants must use the SF 424 R&R Application for Federal Assistance, following the instructional information in this Application Guide. The supplemental instructions found in this section (I.7) are for Individual Career Development Award (CDA1, CDA2, or NRI) applications and include guidance and instructional information only when there is a difference in the required information to be submitted or there is a need for more specificity for the individual Career Development Award. Therefore, these supplemental instructions must be used along with the information found in Parts I.1 – I.6 of this document.

It is imperative that applicants become familiar with the VA Career Development activity codes and award types for which support may be requested. Before applying for a Career Development award, applicants should carefully review the applicable Funding Opportunity Announcement (FOA) for the Career Development award of interest, noting especially the eligibility requirements, review criteria, award provisions, and any special application instructions. Each FOA (also referred to as a Request for Applications, or RFA; See Section 2.4.2 for definitions) contains more specific information associated with the award mechanism and includes names of individuals that may be contacted prior to submission of an application for additional or clarifying information.

The eligibility criteria, support levels, and other important aspects of specific VA Career Development awards, including availability, may vary among the R&D Services within the Office of Research & Development (ORD). For this reason, it is strongly recommended that applicants consult with the Scientific/Research contact of the appropriate awarding component prior to submitting an application. FOAs and other guidelines are available on the ORD intranet at http://vaww.research.va.gov/funding/electronic-submission.cfm.

## 7.2 VA Career Development Awards

The following chart provides a summary of the IMPACII/eRA activity codes and corresponding award types within the VA Career Development Program.

### Summary of VA Research Career Development Awards

| ACTIVITY CODE | AWARD TYPE | AWARD DESCRIPTION | REFERENCE LETTERS (3) |
|---|---|---|---|
| IK1 | CDA1 | Career Development Award (CDA1) | Yes |
| IK2 | CDA2 | Mentored Research Scientist Development Award (CDA2) | Yes |
| IK3 | NRI | Mentored Nursing Research Initiative (NRI) (HSR&D only) | Yes |

## 7.3 Letters of Reference must be submitted as part of the electronic application

Three (3) Letters of Reference are required for all applications defined as New and Resubmissions (see Note below) for mentored support as indicated in the table above. The letters should be from individuals not directly involved in the application, but who are familiar with the applicant's qualifications, training, and interests. The mentor/co-mentor(s) of the application cannot be counted toward the three required references. The three (3) letters must be included in the Letters of Support attachment of the Other Project Information Component.

The reference letters are critically 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 referees. Where possible, some referees who are not from the candidate's current department or organization, but are knowledgeable about their qualifications, should be selected.

Applications that are missing the required letters of reference will not be accepted for review.

Note: Letters of Reference must be dated within 12 months of the date of submission. NEW Letters of Reference may, therefore, be needed for 1 or more of the allowable resubmission applications to provide up-to-date evaluation of the applicant's potential to become an independent researcher, and the continued need for additional supervised research experience.

## 7.4 Specific Instructions for VA Career Development Applications using the SF424 (R&R) Application

Standard Instructions found in Sections 1 –6 should be followed with the exceptions detailed below. Section numbers referenced below (e.g. 4.2 – 5.6) reflect those found in Part I.

### 7.4.1 Special Instructions for 4.2 Cover Component

**Item 8. Type of Application:** Career Development applicants **must check either "New" or "Resubmission."** VA Career development awards may not be renewed and "Revision" applications to request additional support for an existing project's scope or research protocol will not be accepted by VA-ORD.

**Item 14. Project Director/Principal Investigator (PD/PI) Contact Information:** Provide the name of the individual candidate (considered the PD/PI for VA Career Development awards). If the candidate is not located at the applicant VA medical center at the time the application is submitted, the information in Item 14 should reflect where the candidate can be reached prior to the requested award start date in item 12. If the PD/PI is not located at the applicant VA medical center at the time of submission, the Commons account for the PD/PI must be affiliated with the applicant VA medical center. For additional information on creating affiliations for users in the eRA Commons, see: http://era.nih.gov/commons/commons-help/175.htm.

### 7.4.2 Special Instructions for 4.3 Other Project Information Component

**Item 7. Project Summary/Abstract** (Do not exceed **40 lines of text**): Provide an abstract of the entire application (candidate, environment, and research). In a addition to a description of the research project as indicated in Section 4.3.7, **include the candidate's immediate and long-term career goals, and key elements of the research career development plan**.

**Item 10. Facilities & Other Resources:** Provide in the Attachment a detailed description of the institutional facilities and resources available to the candidate, following the instructions in Section 4.3.10. The information provided is of major importance in establishing the feasibility of the goals of the career development plan.

**Item 12. Other Attachments:** Standard Instructions for attachments found in the table starting on pg I-57 should be followed, with the following additions:

**2b.Career Plan**–

**Candidate's Background**: Use this section to provide any **additional information not described in the Career Development Candidate's Biographical Sketch Instructions** 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, including 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. Applicants are strongly encouraged to delay applying for independent funding until the last 2 years of a CDA2 award; plans to apply earlier may indicate that the requested mentoring and training is not needed.

**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.

**2c. Mentoring/Training Plan** – to be completed by the applicant

This section should 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 the mentors' respective areas of expertise and how they will be combined to enhance the career development.

**3. Progress Report Publication List –**

Do not use. Career Development Awards may not be renewed.

**8. Director's Letter –**

The Director's Letter must include a commitment to offer a physician PD/PI a VA-paid staff appointment (at least 5/8ths) at the completion of the Career Development Award and to provide at least 1/8th salary support during the award.

**8a. Letters of Support –**

All memoranda/letters in this section should be scanned and submitted as a single PDF document. The Letters of Support attachment must include:

**A copy of the Career Development Award LOI acceptance letter** from the appropriate R&D Service within VA-ORD.

**Copies of the letters from each mentor/co-mentor** or a single letter signed by all mentors. As applicable to the mentoring role, each member of the mentoring team must document their role and willingness to participate in the project, and explain how they will contribute and work together in the development of the candidate's research career. The letter(s) should include the following:

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.

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.

Describe the nature of any resources that will be committed to this CDA award.

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, and postdoctoral students), number of persons mentored, dates, VA or non-VA status, and career outcomes. A table is recommended for this information.

**A letter from the ACOS/R&D** supporting and acknowledging a commitment to review the nominee's progress and development as a VA research scientist at least annually.

**A letter from the appropriate Service Chief or Section Head** describing the nominee's proposed clinical duties upon receiving the Career Development award. An indication of the nominee's expected percent time in non-research activities should be included (not to exceed ten hours per week).

**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.

### 7.4.3 Special Instructions for 4.4 Research & Related Project/Performance Site Locations Component

Indicate where the work described in the Research Plan will be conducted. **All performance sites (VA and non-VA) where the proposed work will be performed must be included**.

### 7.4.4 Special Instructions for 4.5 Senior/Key Person Profile(s) Component

#### 7.4.4.1 The Candidate

For all Career Development Award applications, the candidate is considered the Project Director/Principal Investigator (PD/PI). Therefore, the candidate must be registered in the eRA Commons and be assigned the PI role within the Commons. Follow the instructions in Section 2.2.2 which provides information regarding required registration in the eRA Commons.

Note that VA-ORD policies concerning "Multiple PIs" are not applicable to Career Development Award applications; **do not use the PD/PI role for any other Senior/Key Personnel**.

#### Career Development Candidate's Biographical Sketch Instructions

A biographical sketch attachment (**limited to 4 pages**) is required for the Career Development Award candidate. **Do not use** the **Additional Instructions for Biographical Sketches** in Part I, Section 4.5.

**The candidate's biographical sketch must follow the instructions below: (template at http://vaww.research.va.gov/funding/electronic-submission.cfm)**

**Position Title:** If the candidate is not currently located at the applicant organization, include both "current" and "projected" position titles, labeling each accordingly.

**Education:** Complete the educational block at the top of the format page beginning with the baccalaureate or other initial professional education, such as nursing, and include postdoctoral training; separately referencing residency training when applicable. For each entry provide the name and location of the institution, the degree received (if applicable), the month and year the degree was received, and the field of study. For residency entries, the Field of Study section should reflect the area of residency. For non-degree education, indicate the period covered. List professional certifications received within the last 10 years.

**A. Personal Statement:** Briefly describe why your experience and qualifications make you particularly well-suited to receive the Career Development Award for which you are applying.

#### B. Research and/or Professional Experience:

Use the headings given below instead of the instructions on the Biographical Sketch Format Page. Identify each heading.

#### Employment

Start with the first position held following the baccalaureate and give a consecutive record to date. Indicate the department and organization, department head or supervisor, rank, tenured or non-

tenured, status (full- or part-time), and inclusive dates (month and year). When applicable, include information on military service, and, if not referenced under Education above, internships, residencies, research assistantships, fellowships, etc. If the candidate is not currently located at the applicant organization, include the projected employment position in this section as well.

### Honors

List academic and professional honors chronologically, including research grants and competitive fellowships awarded to the candidate.

### Professional Societies and Public Advisory Committees

Identify professional societies and related organizations in which membership has been held within the last 10 years, giving dates. Include present membership on any Federal Government public advisory committee.

## C. Publications

VA-ORD encourages applicants to limit the list of selected peer-reviewed publications or manuscripts in press. The individual may choose to include selected publications based on recency, importance to the field, and/or relevance to the candidate's proposed research.

**Career Development Award candidates may substitute the following in lieu of publications**:

- **Original research and theoretical treatises;**
- **Non-experimental articles, e.g., review of literature in field, book chapters, etc.;**
- **Books, pamphlets, etc.**

For each publication, list the authors in published sequence, full title of article, journal, volume number, page numbers, and year of publication. Indicate if you previously used another name that is reflected in any of the citations. The URL or PMC submission identification numbers for published manuscripts and/or abstracts that have a free, publicly available online journal link should be included along with the full reference.

**Do not include manuscripts submitted or in preparation.**

## D. Research Support

List both selected ongoing and completed (during the last three years) research projects (Federal or non-Federal support). Begin with the projects that are most relevant to the research proposed in this application. Briefly indicate the overall goals of the projects and responsibilities of the Senior/Key Person identified on the Biographical Sketch. *Do not include number of person months or direct costs*.

Do not confuse "Research Support" with "Other Support." Though they sound similar, these parts of the application are very different. As part of the biosketch section:

> **"Research Support"** highlights your accomplishments, and those of your colleagues, as scientists. This information will be used by the reviewers in the assessment of each individual's qualifications for a specific role in the proposed project, as well as to evaluate the overall qualifications of the research team. In contrast,
>
> **"Other Support"** information is required to check that the proposed research has not already been funded by another Federal agency or private foundation. VA-ORD staff will request

**updated** "other support" information as part of the Just-In-Time process for applications selected for funding.

#### 7.4.4.2 Mentor, Co-mentor(s), and Other Senior/Key Persons

The mentored Career Development Award **requires a primary mentor**, and there **may be co-mentor(s)**, consultants and contributors. All individuals who have committed to contribute to the scientific development and execution of the project, including mentors and co-mentors, **should be identified as Senior/Key Personnel, even if they are not committing any specified measurable effort to the proposed project. Mentors and co-mentors should be assigned the Project Role of "Other Professional" and then enter "Mentor" or "Co-mentor" in the Other Project Role Category field.**

Consultants should also be assigned the "Other Professional" role even if they are not committing any specified measurable effort. Then, enter the specific project role under "Other Project Role Category."

Any individuals identified as Senior/Key Personnel who are committing specified measurable effort should be appropriately assigned under Project Role in Section A of the Budget component (and Other Project Role Category in the Senior/Key Person Profile component).

**Biographical Sketch for Mentor/Co-mentor(s) and Other Senior/Key Person:** For the biographical sketch for all individuals other than the candidate, **follow the Additional Instructions for Biographical Sketches** in Part I, Section 4.5.

**Current and Pending Support for Mentors/Co-mentors:** For Mentored Career Development Awards, as part of the application submission modified **Current and Pending Support pages must be submitted for the mentor , co-mentor(s), and candidate, on the R&R Senior/Key Person Profile (Expanded)** page. Provide information on the following selected items for the mentor's (and co-mentor's) current and pending research support relevant to the candidate's research plan. Each attachment is limited to 4 pages. VA-ORD staff will request **updated** "other support" information as part of the Just-In-Time process for applications selected for funding.

### 7.4.5 Special Instructions for 4.6 Selecting the Appropriate Budget Component

Career Development Award mechanisms are not modular; therefore, only the R&R budget component is applicable and only a few budget categories are actually used. Information regarding allowable costs for the candidate and any allowable research development or other costs is included in each Career Dev elopement Award FOA. Candidates are advised to contact the targeted awarding component if uncertain about allowable amounts for the applicable Career Development Award mechanism, keeping in mind that amounts vary with awarding components. The application forms package associated with Career Development Award funding opportunities includes the appropriate R&R Budget Component.

Instructions for completing the R&R Budget Component are provided below. Additional guidance may also be provided in the specific funding opportunity announcement.

### 7.4.6 Special Instructions for 4.6 R&R Budget Component

Follow the instructions provided in Section.4.6.1 with the following exceptions:

**Changes to 4.6.1. A. Senior/Key Person:** In general, this section should include the name of the candidate and other Senior/Key Persons (e.g., Post Doctoral Associates or collaborators) who

are requesting salary and committing a specific measurable effort to the project. **Mentor(s) should be listed in Section A of the Budget Component with an appropriate calendar month effort indicated, but salary compensation may not be requested.**

**If salary will be requested for the candidate (physician or non- physician PD/PI), it must be included in the submitted budget and the calendar months entered that reflect the actual effor**t the investigator will expend on the Career Development 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. It is expected that candidates will request 100% salary and expend 75% effort (9 calendar months) on the Career Development Award; exceptions must be requested and approved during the LOI process.

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.

For the candidate, provide the base salary, person months, and requested salary and fringe benefits. For person months, be reminded that Career Development programs include a minimum effort requirement, usually 75% or 9 academic person months. Applicants should include information on actual institutional base salary and the actual amount of salary and fringe being requested. An R&D Service within VA-ORD may request updated salary information prior to award. Any adjustments based on policy limitations will be made at the time of the award.

**Changes to 4.6.1. B. Other Personnel:** In the blank lines provided, individually list the name, project role (e.g., technician), associated Calendar Months, and salary & fringe benefits requested for individuals not named in Section A (Senior/Key Person). **Do not use the fill-in box for the number of Post Doctoral Associates; these individuals should be individually listed in Section A.**

# Part II
# Supplemental Instructions for Human Subjects Research

# Human Subjects Research Requirements

## Human Subjects Research

Question 1 and 1.a on the Other Project Information Component of the SF424 requires that you determine whether or not your research involves human subjects, either at the applicant organization or at any other performance site or collaborating institution (e.g., subcontractors, consultants).

The research described in your application may include more than one research project; therefore, the application may include individual projects that meet the requirements for non-exempt or exempt human subjects research, or are not defined as human subjects research. Only an IRB can determine whether a project is exempt.

If research activities involving human subjects are planned at any time during the proposed project period, either at the applicant organization or at any other performance site or collaborating institution, then your **answer to Question 1 is "Yes" even if an IRB has already determined that the research is exempt from regulations for the protection of human subjects. If tissues (e.g., biopsies or whole organs) or samples (i.e. blood, sputem, etc.) from human subjects will be used, "Yes" must be checked.**

**If established or commercial human cell lines will be used, the answer to Question 1 is "No."**

A human subject is a living individual about whom an investigator conducting research obtains:

- data through *intervention* or *interaction* with the individual or identifiable *private information*

***Intervention*** includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. (38 CFR 16.102(f))

***Interaction*** includes communication or interpersonal contact between investigator and subject (for example, questionnaires or surveys). (38 CFR 16.102(f))

What is not human subjects research?

- Research that does not involve intervention or interaction with living individuals, or identifiable private information is not human subjects research (under 38 CFR Part 16).

Research that only proposes the use of cadaver specimens is not human subjects research, because human subjects are defined as "living individuals." The use of cadaver specimens is not regulated by38 CFR Part 16, but is governed by other Federal, state and local laws.

The VA-ORD website contains up-to-date information on human subjects research policies. The Program for Research Integrity Development & Education (PRIDE) is a VA office whose mission is to protect participants in VA human research. PRIDE is responsible for all policy development and guidance, and all training and education in human research protection throughout the VA. The link for PRIDE is http://www.research.va.gov/programs/pride/default.cfm

Requirements for describing proposed human subjects research are detailed in the two specific sections of an RFA, (a) the Research Plan component, and (b) the Human Subjects attachment.

(a) Research Plan attachment

Specific RFAs will describe the requirements related to human subjects research as appropriate for the type of research being conducted. The Research Plan may include descriptions of subject populations, selection criteria, sample size estimates and power analyses, recruitment and enrollment procedures. If a clinical intervention is proposed, additional requirements will be specified regarding assignment to treatment group, interventions and assessments, randomization, blinding procedures, follow up, etc.

(b) Human Subjects attachment

The Human Subjects attachment is required if "Yes" is checked for Question 1 on the Other Project Information Component (Are Human Subjects involved?). This attachment describes the protection of human subjects. Related policies and definitions are described in Part III. The following descriptions must be provided:

1. Risks to Subjects including human subject involvement and characteristics, sources of materials and potential risks

2. Adequacy of Protection from Risks; including recruitment and informed consent and protections against risks including data security and sharing

3. Potential Benefits of Research to Subjects and Others

4. Importance of Knowledge to be Gained

5. Data and Safety Monitoring Plans

Sufficient information must be provided to determine that the proposed research meets (1) the requirements of the federal regulations and VA policies on the protection of human subjects from research risks (38 CFR Part 16), (2) the requirements for data and safety monitoring, and (3) describes inclusion of women, minorities, and children.

**Applications must comply with the requirements for specific information related to human subjects detailed in the RFA; if not provided completely, application processing may be delayed or the application may be returned to the applicant without review.**

### Exempt Human Subjects Research

Some human subjects research is exempt from IRB approval (see also 38 CFR Part 16). Determination of exemption from VA policy can only be made by an IRB. Since VA-ORD does not require IRB approval at time of application, no exemption categories should be marked in Question 1a on the Other Project Information Component of the SF424 at the time of application unless a determination has already been made by an IRB of record. To understand the relevant VA policies and/or considerations taken into account in any final determination of whether an exemption applies, refer to (VHA Handbook 1200.5, para 8b) Written justifications for these exemptions would be submitted to your IRB after you receive a notification of award

VA policy states that "The IRB Chair or an IRB member designated by the Chair, must review all requests for exemption in a timely manner, make a decision based on 38 CFR 16.101, and record the decision". (VHA Handbook 1200.5, para 8b) Although an investigator can request exemption and provide justification, only an IRB can make the exemption determination.

**Do not check any of the exemption number boxes in Question 1.a, even if the IRB review is complete and a determination of exemption status has been made by the IRB.**

### Annual Progress Reports and Competing Renewal Applications

In addition to annual Progress Reports, investigators conducting clinical research are required to provide the cumulative total enrollment of subjects to-date, showing the distribution by ethnic/racial categories and sex/gender on the Inclusion Enrollment Report.

## Human Subjects Research Definitions

As you read the definitions below, note that for the purposes of VA research, data are "identifiable" unless they have been de-identified by both HIPAA and Common Rule criteria.

***Clinical Trial*** is a prospective biomedical or behavioral research study of human subjects that is designed to answer specific questions about biomedical or behavioral interventions (drugs, treatments, devices, or new ways of using known drugs, treatments, or devices). VA-ORD uses a formal definition that is similar to that used by the International Committee of Medical Journal Editors and the World Health Organization. This definition is "any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes."

Clinical trials are used to determine whether new biomedical or behavioral interventions are safe, efficacious, and effective.

Human subjects research involving an intervention to modify behavior (diet, physical activity, psychotherapy, etc.) fits these criteria of a clinical trial.

Human subjects research to develop or evaluate clinical laboratory tests (e.g. imaging or molecular diagnostic tests) might be considered to be a clinical trial if the test will be used for medical decision-making for the subject or the test itself imposes more than minimal risk for subjects.

Clinical trials of experimental drug, treatment, device or behavioral intervention may proceed through four phases:

***Phase I*** clinical trials test a new biomedical intervention in a small group of people (e.g., 20-80) for the first time to evaluate safety (e.g., to determine a safe dosage range, and to identify side effects).

***Phase II*** clinical trials study the biomedical or behavioral intervention in a larger group of people (several hundred) to determine efficacy and to further evaluate its safety.

***Phase III*** studies investigate the efficacy of the biomedical or behavioral intervention in large groups of human subjects (from several hundred to several thousand) by comparing the intervention to other standard or experimental interventions as well as to monitor adverse effects, and to collect information that will allow the intervention to be used safely.

***Phase IV*** studies are conducted after the intervention has been marketed. These studies are designed to monitor effectiveness of the approved intervention in the general population and to collect information about any adverse effects associated with widespread use.

***Coded:*** With respect to private information or human biological specimens, *coded* means that:

- Identifying information (such as name or social security number) that would enable the investigator to readily ascertain the identity of the individual to whom the private information or specimens pertain has been replaced with a number, letter, symbol or combination thereof (i.e., the code)
- A key to decipher the code exists, enabling linkage of the identifying information with the private information or specimens.

*Data and Safety Monitoring Plan* is required for each clinical trial that will provide oversight and monitoring to ensure the safety of participants and the validity and integrity of the data. The level of monitoring should be commensurate with the risks and the size and complexity of the clinical trial. A detailed data and safety monitoring plan must be submitted to the applicant's IRB and subsequently to the R&D Service for approval prior to the accrual of human subjects. The reporting of Adverse Events must be reported to the IRB, the R&D Service, and other required entities. This policy requirement is in addition to any monitoring requirements imposed by 45 CFR Part 46.

***Data Monitoring Committee (DMC).*** VA ORD requires the establishment of a Data Monitoring Committee for multi-site clinical trials involving interventions that entail potential risk to the participants, *and generally for Phase III clinical trials*.

***Gender***. Refers to the classification of research subjects into either or both of two categories: women and men. In some cases, representation is unknown, because gender composition cannot be accurately determined (e.g., pooled blood samples or stored specimens without gender designation).

***Human Subjects***. The VA policy "Requirements for the Protection of Human Subjects in Research" (VHA Handbook 1200.5) and 38 CFR 16.102(f) define a human subject is a living individual about whom an investigator conducting research *obtains*:

- data through *intervention* or *interaction* with the individual or
- *identifiable private information*

***Individually Identifiable Private Information:*** According to its guidance for use of coded specimens, VA generally considers private information or specimens to be *individually identifiable* as defined at 38 CFR 16.102(f) when they can be linked to specific individuals by the investigator(s) either directly or indirectly through *coding* systems. Conversely, VA considers private information or specimens not to be individually identifiable when they cannot be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems.

***Intervention*** includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. (38 CFR 16.102(f))

***Interaction*** includes communication or interpersonal contact between investigator and subject (for example, questionnaires or surveys). (38 CFR 16.102(f))

***Investigator:*** VA considers the term investigator to include anyone involved in conducting the research. VA does not consider the act of solely providing coded private information or specimens (for example, by a tissue repository) to constitute involvement in the conduct of the research. However, if the individuals who provide *coded* information or specimens also collaborate on other activities related to the conduct of the research with the investigators who receive such information or specimens, they will be considered to be involved in the conduct of the research. [OHRP's Coded Specimen Guidance]

***Private information*** includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (for example, a medical record). Private information must be *individually identifiable* (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects. (38 CFR 16.102(f))

***Research Using Human Specimens or Data:*** Regulatory requirements (Federal and state) to protect human subjects apply to a much broader range of research than many investigators realize, and researchers using *human specimens and/or data* are often unsure about how regulations apply to their research. Regulatory obligations to protect human subjects would apply, for example, to research that uses –

Human material, such as cells, blood or urine, tissues, organs, hair or nail clippings, obtained from living individuals who are individually identifiable to the investigator(s), even if these materials were collected by others;

Residual diagnostic specimens from living individuals that are individually identifiable to the investigator(s), including specimens obtained for routine patient care that would have been discarded if not used for research;

Private information, such as medical information, about living individuals that is individually identifiable to the investigator(s), even if the information was not specifically collected for the study in question. This includes research on genetic information that can be readily associated by the investigator(s) with identifiable living individuals.

Research that involves only *coded* private information/data or coded human biological specimens may not constitute human subjects research under the VA human subjects regulations (38 CFR Part 16) if:

- the specimens and/or private information were not collected specifically for the currently proposed research project through an interaction/intervention with living individuals

AND

- the investigator(s) (including collaborators) on the proposed research cannot readily ascertain the identity of the individual(s) to whom the coded private information or specimens pertain (e.g., the researcher's access to subject identities is prohibited by written repository procedures and policies and/or through an agreement signed between the recipient researcher and the repository providing the specimens and/or data).

***Obtains.*** Under the definition of human subject at 38 CFR 16.102(f), *obtaining* identifiable private information or identifiable specimens for research purposes constitutes human subjects research. *Obtaining* means receiving or accessing identifiable private information or identifiable specimens for research purposes. VA-ORD interprets *obtaining* to include an investigator's use, study, or analysis for research purposes of *identifiable private information* or identifiable specimens already in the possession of the investigator.

***Research.*** VA Policy defines *research* as the testing of concepts by the scientific method of formulating a hypothesis or research question, systematically collecting and recording relevant data, and interpreting the results in terms of the hypothesis or question. The Common Rule (38 CFR 16) defines research as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalized knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

# PART III

# Policies, Assurances, Definitions, and Other Information

# I. Policy

## A. Resubmission of Unpaid RFA Applications and Resubmission of Applications with a Changed Funding Mechanism

The majority of research applications submitted to The Office of Research and Development (ORD) each year are investigator-initiated submitted through the Parent Request for Applications (RFA). However, ORD Research and Development Services also solicit applications on specific topics through the use of additional RFAs. Resubmissions of applications fall into the following categories:

1. Applications that were originally submitted using one funding mechanism (e.g., a Merit Review Award using theI01 mechanism) and subsequently resubmitted using a different funding mechanism (e.g., a Pilot Project using theI21 mechanism).

   Since a change of funding mechanism usually involves a change of application characteristics, dollar limits, time limits, eligibility criteria, or review criteria, most unfunded applications should be resubmitted as a **"New"** application for the new funding mechanism.

   Because the application will be new, it will be easier to conform to the new application requirements, which should be an advantage to the applicant in the review process.

   Additionally, submission of a new application will allow the applicant to benefit fully from the VA-ORD policy that allows an applicant to submit two resubmissions.

2. Applications that were originally submitted in response to a topic-specific RFA that has not been re-issued or extended and then resubmitted to the Parent RFA.

3. Applications that were originally submitted as investigator-initiated applications and subsequently resubmitted in response to a topic-specific RFA.

   If the two RFAs are from the same R&D Service and do not differ in terms of funding mechanism, application characteristics, scientific scope, and review criteria, the application **may** be submitted as a **"Resubmission";** otherwise it should be submitted as a **"New"** application.

NEW APPLICATIONS: The new application must be submitted on the scheduled due dates as indicated in the appropriate RFA. It must not include an Introduction describing the changes and improvements made and the text must not be marked to indicate the changes. Although the investigator may still benefit from the previous review, the applicant should not explicitly address reviewers' comments. The reviewers will not be provided with the previous Summary Statement. The investigator will be allowed to submit the new application and up to two revised versions of this application, should that be necessary.

POLICY: This general policy on application resubmission, stated below, applies to all funding mechanisms that might be solicited via an RFA and to instances where there is a change in mechanism. There may, however, be exceptions to this policy, which will be clearly identified in the original RFA or in a follow-up RFA.

1. When an unfunded application that was reviewed for a particular research funding mechanism is to be submitted for a different funding mechanism, it **must** be prepared as a **new** application.

2. When an application that was submitted in response to an RFA is not funded and the investigator wishes to submit a revised application to a different RFA from the same R&D Service it **may** be submitted as a **revision** application, provided the subject matter is within the scope of the new RFA.
3. When an application that was submitted in response to an RFA is not funded and the investigator wishes to submit a revised application to an RFA from a different R&D Service it **must** be submitted as a **new** application
4. , In all cases, submitted applications must conform to the instructions in the RFA being responded to.

## B. Submission of a Revised (Amended) Application to VA-ORD

VA-ORD will not consider a third resubmission (A3) to an application for intramural support. There is no longer a time limit for the submission of the first and second resubmissions (-01A1 and -01A2). This policy applies to all VA-ORD funding mechanisms.

In submitting a resubmission application, it is worth noting that a lengthy hiatus after the initial submission may be marked by significant advances in the scientific field and the comments of the reviewers may no longer be relevant. PDs/PIs and their institutions need to exercise their best judgment in determining the advisability of submitting a resubmission application after several years have elapsed.

The policy limiting the number of resubmissions was established following analysis of data indicating that investigators who receive initial funding for a resubmission application have a lower success rate in obtaining support for a follow-on renewal application. The likelihood of subsequent success decreased with an increasing number of resubmissions. After three reviews, investigators are strongly encouraged to incorporate a fresh approach to their research proposal.

Investigators who have submitted three versions of an application and have not been successful often ask VA-ORD staff how different the next application submitted has to be to be considered a new application. It is recognized that investigators are trained in a particular field of science and are not likely to make drastic changes in their research interests; however, **a new application following three cycles of review is expected to be substantially different in content and scope, with more significant differences than are normally encountered in a resubmission application.** Simply re-wording the title and/or Specific Aims or incorporating minor changes in response to comments in the previous Summary Statement does not constitute a substantial change in scope or content. Changes to the Research Plan should produce a significant change in direction and approach for the research project. **Thus, a new application would include substantial changes in all sections of the Research Plan, particularly the Specific Aims and the Research Design and Methods sections.**

**If changes are made that result in the application needing to be submitted to a different R&D Service (i.e., BLR&D vs. CSR&D), the application must be submitted as a "New" application to the new Service; a response to the previous review may be included as an appendix, but the reviewers will not be provided the previous Summary Statement(s).**

In the referral process, VA-ORD staff look at all aspects of the application, not just the title and Description (abstract). Requesting review by a different review committee does not affect the

implementation of this policy. When necessary, previous applications are analyzed for similarities to the present one. Thus, identical applications or those with only minor changes will not be accepted for review.

## C. Acceptance for Review of Unsolicited Applications Exceeding Published Budget Caps

**Applicants must seek approval from the appropriate VA-ORD R&D Service at least six weeks prior to the anticipated submission of any application requesting a budget that exceeds the budget cap (annual or total award) for that service.**

VA-ORD supports research projects with large budgets but needs to consider such awards as early as possible in the budget and program planning process. Regardless of the merit of the application or the budget justification, unanticipated requests for unusually high amounts of direct costs are difficult for VA-ORD to manage. It is in the best interest of all parties if applicants anticipating large direct costs contact the appropriate ORD program staff as early as possible to ensure that a VA-ORD R&D Service would be willing to accept the application.

This prior acceptance policy does not apply to applications submitted in response to RFAs or in response to other Announcements that include specific budgetary limits. Such applications must be responsive to any budgetary limits specified.

***PROCEDURES***

- An investigator planning to submit an application requesting direct costs in excess of the cap (annual or total award) for a particular VA-ORD R&D Service is required to submit a request for a waiver to that Service. This contact should be made during the development process of the application. If the R&D Service is willing to accept assignment of the application for consideration of funding, a letter of approval to exceed the budget cap will be sent to the Director of the applicant's VA medical center before the application is submitted.
- An application received without indication of prior staff concurrence and identification of program staff contacted may be returned to the applicant without review; inclusion of the approval letter to exceed the cap in the Letters of Support component of the application will avoid this problem. Therefore, VA-ORD strongly encourages applicants to contact appropriate R&D Service staff at the earliest possible time.

For additional information about this policy or to discuss which Service may have the greatest interest in the proposed research, contact the program staff at any VA-ORD R&D Service.

## D. Inventions and Patents

According to VA Policy and Federal law, recipient organizations must promptly report all inventions that are either conceived or first actually reduced to practice using VA resources. Invention reporting compliance is described in VHA Handbook 1200.18 (Intellectual Property Handbook). Information from these reports is retained by the VA as confidential, and submission does not constitute any public disclosure. Failure to report is a violation of 35 USC 202 and may result in loss of the rights of the recipient organization.

Further information and contact information for the VA Technology Transfer Program can be found at http://www.research.va.gov/programs/tech_transfer/default.cfm.

# E. Just-In-Time Policy

Several elements of an application are no longer required at the time the application is submitted. Instead, this information will be requested later in the review cycle (i.e., "just-in-time") to ensure that it is current. The information eligible for just-in-time submission includes:

### IRB Approval

VA-ORD does not require certification of IRB approval of the proposed research prior to VA-ORD peer review of an application.

An institution is automatically considered to be engaged in human subjects research when it receives a VA-ORD award to support nonexempt human subjects research. All institutions engaged in human subjects research must obtain a Federal Wide Assurance (FWA) from OHRP. Instructions for applying for a Federal Wide Assurance (FWA) are available from the OHRP website at http://www.hhs.gov/ohrp/assurances/assurances_index.html.

Any modifications in the Research Plan section of the application, required by either VA or by the IRB must be submitted with the follow-up certification of IRB approval to the VA before the competing award is made. It is the responsibility of the PD/PI and the applicant organization to submit the follow-up certification.

If more than a year will have elapsed between the initial IRB review date and the anticipated award date, the awarding unit staff shall require re-review by the IRB prior to award.

- Human Studies Subcommittee Form (VA Form 10-1223)or Affiliated IRB Approval Letter: The Human Studies Subcommittee or its equivalent IRB must evaluate all proposals involving human subjects or use of human tissue.

  If the IRB approves the protocol by expedited review, exempts the protocol from IRB review, or grants a waiver for obtaining informed consent, it must be explicitly stated in section 8 "Comments." The chair of the IRB must sign the form and the date must be current.

  In lieu of VA Form 10-1223, an equivalent IRB form will be accepted as long as it contains all of the elements of VA Form 10 1223. Pending or out-of-date approvals are not acceptable.

  If not previously provided on the Face Page, provide the Human Subjects Assurance type and number.

- **Informed Consent Form:** Unless the proposed research was granted a waiver, one or more approved consent forms using VA Form 10-1086 are required
- The title on the 10-1086 must be the same as the title of the proposal. If multiple informed consents are needed, the consent form title may be the proposal title with a sub-project title appended to it.
- Each page of each consent form must be dated and the date on the consent form must be current. Forms from a previous submission of the application may be used if the dates of approval have not expired and if the proposed research has not changed.
- The VA informed consent form (VA Form 10-1086) must be used even if the IRB is at the affiliate university.
- If informed consent is not required, indicate the reason(s) on the Human Studies Subcommittee Form.

- **Documentation of Current Training:** For research involving human subjects or human tissue, all investigators, research coordinators, and research assistants involved in the research must document training in the ethical principles and accepted practices by which human studies research should be conducted. For further information refer to the separate section on Required Education in the Protection of Human Research Participants.
- Documentation of successful training in The Protection of Human Research Subjects and Good Clinical Practice is required and must be dated within one year of submission of the just-in-time materials.
- Documentation may be in the form of a certificate from an approved training program such as the VA Learning Center's online web site. One letter detailing the training (time/date/certificate) for multiple investigators, research coordinators, and research assistants involved in the research is acceptable. Documentation of the training requirement should accompany VA Forms 10-1223 and 10-1086.
- Animal Component of Research Protocol (ACORP; VHA Handbook 1200.7, Appendix D): If vertebrate animals are involved a copy of the ACORP, with all appropriate signatures, must be provided upon request to ORD for review by the Chief Veterinary Medical Officer.
- Pending or out-of-date approvals are not acceptable.
- If this information was not previously provided on the Face Page of the application, provide the Animal Welfare Assurance number.
- **Research Protocol Safety Survey:** VA Form 10-0398 is required with all pertinent signatures. The safety officer's signature on designated pages must be current. Alternate forms are not acceptable. It is not necessary to include the chemical inventory of the laboratory. Certain proposals involve no safety issues. If this is the case, a signed form or letter is needed from the safety committee chair.
- **Final R&D Committee Letter of Approval for the Proposal:** Following review and approval by all required subcommittees, the R&D committee must review and give final approval to the application. The letter should be signed by the R&D chair. The minutes of the R&D meeting should not be included. The following text may be used in the approval letter.
- "The R&D committee gave full approval of the Merit Review proposal (project title) of Dr. PI, and confirms (where applicable) approval of the appropriate Subcommittees on: Human Research; Animal Research (ACORP); and Research Safety."
- **VA Research Support Agreement**: This is a single-page document requiring three signatures regarding the PI's acknowledgment of the VA's intellectual property rights.
- **Current Other Support:** See Other Support section for policy information. Use the sample format provided in the Other Support Information section below. For all Key Personnel, provide details on how you would adjust any budgetary, scientific, or effort overlap if this application is funded.

Applicants are advised to submit this information (countersigned by an authorized business official) only when requested by the awarding component. Guidance for submitting this information will be provided at the time of the request.

# F. Other Support

**Information on Current and Other Support should be submitted at the time of application. Use the format provided below and attach the information in the space marked "Attach Current and Pending Support"on the Research and Related Senior/Key Person Profile component.**

Information on Other Support is required for all applications that are to receive VA-ORD funding. The applicant is expected to update the information provided at the time of application in a timely manner. The awarding R&D Service may request complete and up to date information from applicants as part of the Just-in-Time process.

Don't confuse "Research Support" with "Other Support." Although they sound similar, these parts of the application are very different. As part of the biosketch section of the application, "Research Support" highlights your accomplishments, and those of your colleagues, as scientists. It is used by reviewers for the "investigator" review criterion. In contrast, "Other Support" information is required for all applications that are selected to receive awards. This information will be used to check that the proposed research has not already been Federally-funded.

## Other Support Policy

*Other Support* includes all financial resources, whether Federal, non-Federal, commercial or institutional, available in direct support of an individual's research endeavors, including but not limited to research grants, cooperative agreements, contracts, and/or institutional awards. Training awards, prizes, or gifts are not included.

*Information on Other Support* assists awarding agency staff in the identification and resolution of potential overlap of support. Overlap, whether scientific, budgetary, or commitment of an individual's effort greater than 100 percent, is not permitted. The goals in identifying and eliminating overlap are to ensure that sufficient and appropriate levels of effort are committed to the project; that there is no duplication of funding for scientific aims, specific budgetary items, or an individual's level of effort; and that only funds necessary to the conduct of the approved project are included in the award.

*Budgetary overlap* occurs when duplicate or equivalent budgetary items (e.g., equipment, salary) are requested in an application but are already provided for by another source.

*Commitment overlap* occurs when a person's time commitment exceeds 100 percent, whether or not salary support is requested in the application. While information on other support is only requested for Key Personnel (excluding consultants), no individuals on the project may have commitments in excess of 100 percent.

*Scientific overlap* occurs when: (1) substantially the same research is proposed in more than one application or is submitted to two or more different funding sources for review and funding consideration, or (2) a specific research objective and the research design for accomplishing that objective are the same or closely related in two or more applications or awards, regardless of the funding source.

**Resolution of Overlap.** Resolution of overlap occurs at the time of award.

## Other Support Information

There is no form page for Other Support. Follow the sample format provided below. The sample is intended to provide guidance regarding the type and extent of information requested.

The following instructions should be followed in completing the information:

- Information on active and pending Other Support is required for Key Personnel, excluding consultants. For individuals with no active or pending support, indicate "None." Neither the application under consideration nor the current VA-ORD award for this project should be listed as Other Support. Do not include Other Support for individuals listed as "Other Significant Contributors" unless their involvement has changed so that they now meet the definition of "key personnel."
- If the support is provided under a consortium/subcontract arrangement or is part of a multiproject award, indicate the project number, PD/PI, and source for the overall project, and provide all other information for the subproject only.

### Instructions for Selected Items

*Project Number:* If applicable, include a code or identifier for the project.

*Source:* Identify the agency, institute, foundation, or other organization that is providing the support.

*Major Goals:* Provide a brief statement of the overall objectives of the project, subproject, or subcontract.

*Dates of Approved/Proposed Project:* Indicate the inclusive dates of the project as approved/proposed. For example, in the case of VA or NIH support, provide the dates of the approved/proposed competitive segment.

*Annual Direct Costs:* In the case of an active project, provide the current year's direct cost budget. For a pending project, provide the proposed direct cost budget for the initial budget period.

*Percent Effort/Person Months:* For an active project, provide the level of actual effort in person months (even if unsalaried) for the current budget period. Person months should be classified as academic, calendar and/or summer. For a pending project, indicate the level of effort in person months as proposed for the initial budget period. In cases where an individual's appointment is divided into academic and summer segments, indicate the proportion of each devoted to the project.

*Overlap:* After listing all support, summarize for each individual any potential overlap with the active or pending projects and this application in terms of the science, budget, or an individual's committed effort. This must be provided for each project separately.

## Sample Format for Other Support

| OTHER SUPPORT | | |
|---|---|---|
| **NAME OF INDIVIDUAL**<br>ACTIVE/PENDING | | |
| Project Number (PD/PI)<br>Source<br>Title of Project *(or Subproject)*<br><br>The major goals of this project are… | Dates of Approved/Proposed Project<br>Annual Direct Costs | Person Months (Cal/Acad/ Summer) |
| OVERLAP *(summarized for all listed projects with a separate section for each project)* | | |

**Sample**

| OTHER SUPPORT |
|---|
| **ANDERSON, R.R.**<br>ACTIVE<br>2 R01 HL 00000-13 (Anderson) 3/1/1997 – 2/28/2002 3.60 calendar<br>NIH/NHLBI $186,529<br>Chloride and Sodium Transport in Airway Epithelial Cells<br>The major goals of this project are to define the biochemistry of chloride and sodium transport in airway epithelial cells and clone the gene(s) involved in transport.<br><br>5 R01 HL 00000-07 (Baker) 4/1/1994 – 3/31/2002 1.20 calendar<br>NIH/NHLBI $122,717<br>Ion Transport in Lungs<br>The major goal of this project is to study chloride and sodium transport in normal and diseased lungs.<br><br>R000 (Anderson) 9/1/1996 – 8/31/2002 1.20 calendar<br>Cystic Fibrosis Foundation $43,123<br>Gene Transfer of CFTR to the Airway Epithelium<br>The major goals of this project are to identify and isolate airway epithelium progenitor cells and express human CFTR in airway epithelial cells.<br><br>PENDING<br>DCB 950000 (Anderson) 12/01/2002 – 11/30/2004 2.40 calendar<br>National Science Foundation $82,163<br>Liposome Membrane Composition and Function<br>The major goals of this project are to define biochemical properties of liposome membrane components and maximize liposome uptake into cells. |
| OVERLAP<br>There is scientific overlap between aim 2 of NSF DCB 950000 and aim 4 of the application under consideration. If both are funded, the budgets will be adjusted appropriately in conjunction with agency staff. |

### Special Instructions for Individuals with Multiple Research Appointments (e.g., dual university/Department of Veterans Affairs appointments)

When an individual holds multiple appointments involving support for research activities, information from each appointment must be included separately in the Other Support documentation. The support from each funding source should be clearly and separately delineated so that the separate appointments can be considered independently when determining any potential overlap.

List each appointment separately and include enough information on the type of appointment; (e.g., full time academic or 6/8 VA) and corresponding calendar months so that an assessment of an individual's commitment can be made. Within each appointment, include appropriate sources of research support providing the standard detailed information cited above.

**Note that when an individual has multiple appointments it is possible that the combined effort can result in excess of 12 calendar months (not from any one institution, but a combination of multiple appointments). In all cases, an individual's combined total professional effort must meet a test of reasonableness.**

## G. Graduate Student Compensation

Graduate students may be supported as salaried technicians. However, graduate student stipends (teaching or research assistants) and tuition remission may **not** be paid for using VA research-appropriated funds.

# II. Assurances and Certifications

Each application to VA-ORD requires that the following assurances and certifications be verified by the Authorized Organizational Representative (a.k.a. Signing Official) for the Applicant Organization on the SF424 (R&R) cover component (Item 18) of the application.

### PI and SO Verification

After the PI and SO successfully submit an application, they will receive an automatically generated email requesting them to view and verify (or reject) the application on-line in the Commons. To do this, the PI and SO need to:

1. Make sure they can log onto the NIH eRA Commons. Before they receive the email, they should be sure to know their Commons account names and passwords.
2. Verify the electronic grant application via the NIH eRA Commons. Complete instructions on the verification process are in the Applicant Package.

## A. Human Subjects Research

(Also see Supplemental Instructions for Human Subjects Research Requirements.)

VA Policy on the protection of human subjects in research (VHA Handbook 1200.5) is guided by the ethical principles regarding all research involving humans as subjects, as set forth in the Belmont report "Ethical Principles and Guidelines for the Protection of Human Subjects of Research," regardless of who conducts the research or the source of support. VA is one of the seventeen Federal departments and agencies that have agreed to follow the Federal Policy for the Protection of Human Subjects (Common Rule), effective June 18, 1991, (see 56 Federal Register (FR) 28001).

NOTE: This policy is incorporated in *38 CFR Part 16*.

The regulations require that applicant organizations proposing to involve human subjects in nonexempt research, provide an Assurance of Compliance, or a Federal-wide Assurance (FWA), a written commitment by an institution to protect human subjects participating in research. Assurances are filed through the VA Office of Research Oversight (ORO) with the Department of Health and Human Services (DHHS) Office for Human Research Protections (OHRP). The FWA replaces previous types of OHRP and VA assurances.

Under VA regulations to protect human subjects from research risks, certain research areas are exempt. However, if an applicant makes inappropriate designations of the noninvolvement of human subjects or of exempt categories of research, this may result in delays in the review of an application or the return of the application without review. ORD will make a final determination as to whether the proposed activities are covered by the regulations or are in an exempt category, based on the information provided in the Research Plan.

No non-exempt research involving human subjects can be conducted under an ORD award unless that organization is operating in accord with an approved FWA and provides verification that an Institutional Review Board (IRB) that is registered under the specific Assurance has reviewed and approved the proposed activity in accordance with VA regulations.

In addition to the VA human subjects regulations, FDA regulations (21 CFR part 50; 21 CFR part 56) may also apply to your research. FDA regulations generally apply to biomedical research involving an unapproved drug, device or biologic and may apply to certain studies of approved

products. Researchers proposing such research should consult with their IRB and the FDA to determine whether and how the FDA regulations may apply. Additional information on FDA regulations is available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm.

The Center of Biologics Evaluation and Research (CBER) at FDA regulates the use of biological products in humans, at the investigational and marketing phases, including somatic cell therapies and gene therapies. If your work involves these areas or preclinical research that will support later work in these areas, please see the Office of Recombinant DNA Activities Web site at http://www4.od.nih.gov/oba/.

Note: Under VA regulations to protect human subjects from research risks, certain research areas are exempt. **Only an IRB can make this determination.** Nonetheless, with the exception of research projects that meet the criteria for Exemption 4, studies that are exempt from the human subjects regulations must still address the inclusion of women and minorities and children in the study design. Therefore, applications will be evaluated for compliance with this policy. Research involving the collection or study of existing data, documents, records, pathological specimens, diagnostic specimens, or tissues that can be linked by the investigator(s) to living individuals is considered human subjects research.

Federal requirements to protect human subjects apply to research on human specimens (such as cells, blood, and urine), residual diagnostic specimens and/or medical information, when these specimens and/or medical information are from living individuals who are individually identifiable to the investigator(s).

### Vulnerable Populations

Investigators who conduct research involving pregnant women, human fetuses and neonates, prisoners, or children must follow the provisions of VA policies and regulations (38 CFR Part 16, VHA Handbook 1200.5, 45 CFR Part 46 Subparts C and D) , which describe the additional protections required for these populations.

### Data and Safety Monitoring for Clinical Trials

For each proposed clinical trial, VA requires a data and safety monitoring plan that describes oversight and monitoring to ensure the safety of participants and the validity and integrity of the data. The level of monitoring should be commensurate with the risks and the size and complexity of the clinical trial. A detailed data and safety monitoring plan must be submitted to the applicant's IRB and subsequently to the funding R&D Service for approval prior to the accrual of human subjects. The reporting of Adverse Events must be reported to the IRB, VA, and other required entities. This policy requirement is in addition to any monitoring requirements imposed by 45 CFR Part 46. VA ORD requires the establishment of a Data Monitoring Committee (DMC) for multi-site clinical trials involving interventions that entail potential risk to the participants, and generally for Phase III clinical trials.

### Required Education in the Protection of Human Research Participants

For research involving human subjects or human tissue, all research team members (exclusive of secretarial support) are required to have training in Good Clinical Practices (GCP) and the ethical principles of human research protection before they participate in human research. Documentation from the VA facility must be provided that training is up-to-date in the following areas: Good clinical Practices; the ethical principles of human research protection; Privacy; Cybersecurity; and VA Research Data Security and Privacy. Documentation may be in the form of a certificate from a VA-approved training program(s) or equivalent documentation from

training programs listed on the VA Research and Development website at http://www.research.va.gov/programs/pride/training/default.cfm. One letter detailing the time of completion and training program for multiple investigators is acceptable.

## B. Research on Transplantation of Human Fetal Tissue

VA policy (VHA Handbook 1200.5) states that research in which the subject is a fetus, in-utero or ex-utero (including human fetal tissue) must not be conducted by VA investigators while on official duty, or at VA facilities, or at approved off-site facilities. In addition, research related to in vitro fertilization must not be conducted by VA investigators while on official duty, or at VA facilities, or at approved off-site facilities. When verifying the submitted application in the eRA Commons, the duly authorized representative of the applicant organization certifies that no such research is proposed in the application.

## C. Research Using Human Embryonic Stem Cells

See http://grants.nih.gov/stem_cells/registry/current.htm for the current list of approved human embryonic stem cell lines.

When verifying the submitted application in the eRA Commons, the duly authorized representative of the applicant organization certifies that if research using human embryonic stem cells is proposed, the applicant organization will be in compliance with the NIH Guide Notices "Clarification of Terms and Conditions of Awards using Human Embryonic Stem Cells" (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-029.html) and "First Human Embryonic Stem Cells Approved for use under the NIH Guidelines for Human Stem Cell Research" (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-020.html).

## D. VA-ORD Policy on the Inclusion of Women and Minorities as Subjects in Clinical Research

It is VA-ORD policy that women and members of minority groups and their subpopulations must be included in all VA-ORD-supported biomedical and behavioral research projects unless a clear and compelling rationale and justification establishes to the satisfaction of the relevant ORD R&D Service Director that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. Exclusion under other circumstances may be made by the ORD Chief Research and Development Officer, upon the recommendation of an R&D Service Director based on a compelling rationale and justification. Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources. Women of childbearing potential should not be routinely excluded from participation in clinical research. All VA-ORD-supported biomedical and behavioral research involving human subjects is defined as clinical research. This policy applies to research subjects of all ages.

The inclusion of women and members of minority groups and their subpopulations must be addressed in developing a research design appropriate to the scientific objectives of the study. The Research Plan should describe the composition of the proposed study population in terms of sex/gender and racial/ethnic group, and provide a rationale for selection of such subjects. Such a plan should contain a description of the proposed outreach programs for recruiting women and minorities as participants.

## VA-ORD Policy On Reporting Race And Ethnicity Data: Subjects In Clinical Research

The Office of Management and Budget (OMB) defines minimum standards for maintaining, collecting and presenting data on race and ethnicity for all Federal reporting agencies. The categories in this classification are social-political constructs and should not be interpreted as being anthropological in nature. The standards were revised in 1997 and now include two ethnic categories, "Hispanic or Latino" and "Not Hispanic or Latino." There are five racial categories: American Indian or Alaska Native; Asian; Black or African American; Native Hawaiian or Other Pacific Islander; and White. Reports of data on race and ethnicity shall use these categories. VA-ORD is required to use these definitions to allow comparisons to other Federal databases, especially the census and national health databases.

**Revised Minimum Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity**

The following are the ethnic and racial definitions for the minimum standard categories (1997 OMB Directive 15):

### Ethnic Categories:

***Hispanic or Latino***: A person of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin, regardless of race. The term "Spanish origin" can also be used in addition to "Hispanic or Latino."

***Not Hispanic or Latino***

### Racial Categories:

***American Indian or Alaska Native*:** A person having origins in any of the original peoples of North, Central, or South America, and who maintains tribal affiliations or community attachment.

***Asian*:** A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam. (Note: Individuals from the Philippine Islands have been recorded as Pacific Islanders in previous data collection strategies.)

***Black or African American*:** A person having origins in any of the black racial groups of Africa. Terms such as "Haitian" or "Negro" can be used in addition to "Black or African American."

***Native Hawaiian or Other Pacific Islander*:** A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.

***White*:** A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.

Using respondent self-report or self-identification to collect an individual's data on ethnicity and race, investigators should use two separate questions with ethnicity information collected first followed by the option to select more than one racial designation.

When reporting these data in the aggregate, investigators should report: (a) the number of respondents in each ethnic category; (b) the number of respondents who selected only one category for each of the five racial categories; (c) the total number of respondents who selected multiple racial categories reported as the "number selecting more than one race"; and (d) the

number of respondents in each racial category who are Hispanic or Latino. Investigators may provide the detailed distributions, including all possible combinations, of multiple responses to the racial designations as additional information. However, more detailed items should be designed in a way that they can be aggregated into the required categories for reporting purposes. VA-ORD is required to use these definitions to allow comparisons to other Federal databases, especially the census and national health databases. Federal agencies will not present data on detailed categories if doing so would compromise data quality or confidentiality standards.

## E. VA-ORD Policy on Inclusion of Children

Research involving children must comply with VA Policy on Research Involving Children (VA Policy on Research Involving Children ).

Children cannot 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 (CRADO).

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

If such a waiver is approved, the involvement of children as subjects in research must be in compliance with all applicable subparts of 45 CFR Part 46 as well as with other pertinent Federal laws and regulations.

Additionally, IRBs have special review requirements to protect the well-being of children who participate in research. These requirements relate to risk, benefit, parental/guardian consent, and assent by children, and to research involving children who are wards of the state or of another institution. The local IRB approves research that satisfies the conditions set forth in the regulations.

## F. Vertebrate Animals

VA policy defines "animal" as "any live, vertebrate animal used or intended for use in research, research training, experimentation, or biological testing or for related purposes."

VA Policy on Use of Animals in Research (VHA Handbook 1200.7) requires that applicant organizations proposing to use vertebrate animals file a written Animal Welfare Assurance with the Office of Laboratory Animal Welfare (OLAW), establishing appropriate policies and procedures to ensure the humane care and use of live vertebrate animals involved in research activities supported by VA-ORD. VA policy stipulates that an applicant organization bears responsibility for the humane care and use of animals in VA-supported research activities. This policy implements and supplements the *U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training* and requires that institutions use the *Guide for the Care and Use of Laboratory Animals* as a basis for developing and implementing an institutional animal care and use program. This policy does not affect applicable state or local laws or regulations that impose more stringent standards for the care and use of laboratory animals.

All institutions are required to comply, as applicable, with the Animal Welfare Act (7 USC 2131-2159), USDA Animal Welfare Act Regulations and Standards, Possession, Use, and Transfer of Select Agents and Toxins (42 CFR Part 73), and other Federal statutes and regulations relating to animals. See http://www.research.va.gov/programs/animal_research/ for additional information.

Annual training is mandated for all personnel who work with laboratory animals (VHA Handbook 1200.7, section 8.m). This mandate extends to investigators, research technicians, and all others that perform procedures or manipulations on laboratory animals.

The following guidance is provided on who must document annual training:

Personnel who perform research on animals purchased with VA funds

Personnel who perform animal research at a VA institution

All VA animal facilities and affiliates, or other animal facilities that house animals purchased with VA funds, or used for VA or VA Research and Education Corporation projects must be accredited by the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) International. Under exceptional circumstances, a waiver may be requested in writing from the CRADO, or his/her designee, through the Chief Veterinary Medical Officer's office.

VA-ORD no longer requires Institutional Animal Care and Use Committee (IACUC) approval of the proposed research before peer review of an application. The VA-ORD policy requirement that no award may be made without an approved Assurance and without verification of IACUC approval remains in effect, however.

This policy gives institutions flexibility in the timing of IACUC review relative to the submission of an application and the verification of IACUC review. **The policy does not require that IACUC approval be deferred.** Institutional officials retain the discretion to require IACUC approval prior to VA-ORD peer review in circumstances of their choosing if deemed necessary. As part of the VA-ORD peer review process, the SRG will continue to address the adequacy of animal usage and protections in the review of an application and will continue to raise any concerns about animal welfare issues. Verification of IACUC approval will be required in a "just-in-time" fashion prior to award.

No VA award for research involving vertebrate animals will be made to an applicant organization unless that organization is operating in accordance with an approved Animal Welfare Assurance and provides verification that the IACUC has reviewed and approved the proposed activity in accordance with VA-ORD policy. Applications may be referred by VA-ORD back to the IACUC for further review in the case of apparent or potential violations of the VA policy.

## G. Research Misconduct

Research Misconduct is defined by VA-ORD as fabrication, falsification or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

(a) Fabrication is making up data or results and recording or reporting them.

(b) Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.

(c) Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

(d) Research misconduct does not include honest error or differences of opinion.

The signature of the official signing for the applicant organization on the Face Page of the application serves as certification that the institution will comply with VHA Handbook 1058.02,

which establishes the procedures and other requirements for handling allegations of misconduct in Department of Veterans Affairs (VA) research performed by VA investigators while on duty, or conducted at VA facilities or approved off-site locations.

For further information, please contact the VA Office of Research Oversight (ORO).

## H. Select Agents and Toxins Research

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107-188) is designed to provide protection against misuse of select agents and toxins whether inadvertent or the result of terrorist acts against the United States homeland or other criminal acts.

A select agent is one of a group of agents (viruses, bacteria, rickettsiae, fungi, toxins, and recombinant deoxyribonucleic acid (DNA)) designated by CDC as requiring registration with the CDC Laboratory Registration Program. The regulation of select agents and toxins is codified in 42 CFR Part 73, Possession, Use and Transfer of Select Agents and Toxins; Final Rule. For purposes of this Handbook, select agents and hazardous agents are synonymous, and are to be handled at the same level of security. The terms select agents and toxins also refer to biologic agents and toxins that the Secretary of Agriculture has determined to have the potential to be a severe threat to animal and plant health (7 CFR Part 331, and 9 CFR Part 121). NOTE: Refer to Appendix A of VHA Handbook 1200.06, Control of Hazardous Agents in VA Research Laboratories, for a list of hazardous agents, to CDC's website at http://www.cdc.gov/od/sap for select agents and toxins, and to the APHIS website (www.aphis.usda.gov) for a list of regulated biological agents and toxins.

As a term of award, investigators who conduct research involving Select Agents and Toxins (see 42 CFR 73 for the list; and 7 CRF 331 and 9 CFR 121 for the relevant animal and plant pathogens) are reminded that they must complete registration with the National Select Agent Registry before using VA-ORD funds. No funds can be used for research involving Select Agents and Toxins if the final registration certificate is denied.

For additional information regarding Select Agent and Toxin research, see the following websites maintained by CDC and USDA:

Center for Disease Control Select Agent Program Public Laws and Regulations:
http://www.cdc.gov/od/sap/regulations.htm

Center for Disease Control Select Agent Program:
http://www.cdc.gov/od/sap/index.htm

CDC-NIH
Biosafety in Microbiological and Biomedical Laboratories

NIH Guidelines on Recombinant DNA and Gene Transfer
http://oba.od.nih.gov/rdna/nih_guidelines_oba.html

Center for Disease Control Select Agent Program Guidelines:
http://www.cdc.gov/od/sap/guidelines.htm

Center for Disease Control Select Agent Program Related Links:
http://www.cdc.gov/od/sap/regulations.htm

Animal and Plant Health Inspection Service (APHIS) Select Agent Program:
http://www.aphis.usda.gov/programs/ag_selectagent/

# III. Definitions

(See also Human Subjects Research Definitions.)

**Animal.** Any live, vertebrate animal used or intended for use in research, research training, experimentation, or biological testing or for related purposes at the applicant organization or any collaborating site or other performance site.

**Award.** A financial assistance mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity. An award is used whenever a VA-ORD Research and Development Service anticipates no substantial programmatic involvement with the recipient during performance of the financially assisted activities.

**Co-investigator.** An individual involved with the Project Director/Principal Investigator (PD/PI) in the scientific development or execution of the project. The co-investigator (collaborator) may be employed by, or be affiliated with, the applicant/grantee organization or another organization participating in the project under a consortium agreement. This individual would typically devote a specific percent of effort to the project and would be identified as Key Personnel. The designation of a co-investigator, if applicable, does not affect the PD/PI's roles and responsibilities.

**Commercialization.** The process of developing markets and producing and delivering products for sale (whether by the originating party or by others). As used here, commercialization includes both government and private sector markets.

**Consortium Agreement.** A formalized agreement whereby a research project is carried out by the awardee and one or more other organizations that are separate legal entities. Under the agreement, the awardee must perform a substantive role in the conduct of the planned research and not merely serve as a conduit of funds to another party or parties. These agreements typically involve a specific percent of effort from the consortium organization's PD/PI and a categorical breakdown of costs, such as personnel, supplies, and other allowable expenses. New consortium agreements may not be included as part of a VA-ORD application; awarding of a Merit Review Award does not provide authority to enter in contractual agreements that are binding on VA.

**Consultant.** An individual who provides professional advice or services for a fee, but normally not as an employee of the engaging party. To prevent apparent or actual conflicts of interest, awardees and consultants must establish written guidelines indicating the conditions of payment of consulting fees. Consultants may also include firms that provide paid professional advice or services.

**Equipment.** An article of tangible nonexpendable personal property that has a useful life of more than one year and an acquisition cost per unit that equals or exceeds the lesser of the capitalization threshold established by the awarding ORD Research Service or $5,000.

**Essentially Equivalent Work.** This term is meant to identify "scientific overlap," which occurs when (1) substantially the same research is proposed for funding in more than one contract proposal or grant application submitted to the same Federal agency; **or** (2) substantially the same research is submitted to two or more different Federal agencies for review and funding consideration; **or** (3) a specific research objective and the research design for accomplishing that objective are the same or closely related in two or more proposals or awards, regardless of the funding source.

**Feasibility.** The extent to which a study or project may be done practically and successfully.

**Foreign Component.** The performance of any significant scientific element or segment of a project outside of the United States, either by the PD/PI or by a researcher employed by a foreign organization, whether or not VA research appropriation funds are expended. Activities that would meet this definition include, but are not limited to: (1) the involvement of human subjects or animals; (2) extensive foreign travel by project staff for the purpose of data collection, surveying, sampling, and similar activities; or (3) any activity of the PD/PI that may have an impact on U.S. foreign policy through involvement in the affairs or environment of a foreign country. Applicants to VA-ORD must follow VHA Directive 2005-050, Requirements for Conducting VA-Approved International Research Involving Human Subjects, Human Biological Specimens, or Human Data**.**

**Innovation.** Something new or improved, including research for (1) development of new technologies, (2) refinement of existing technologies, or (3) development of new applications for existing technologies. For the purposes of VA-ORD programs, an example of "innovation" would be new medical or biological products for improved value, efficiency, or costs.

**Key Personnel.** In addition to the PD/PI, Key Personnel are defined as individuals who contribute to the scientific development or execution of the project in a substantive, measurable way, whether or not salaries are requested.

Typically, these individuals have doctoral or other professional degrees, although individuals at the masters or baccalaureate level should be included if their involvement meets the definition of Key Personnel. Consultants should also be included if they meet the definition of Key Personnel. Key Personnel must devote measurable effort to the project whether or not salaries are requested—"zero percent" effort or "as needed" are not acceptable levels for those designated as Key Personnel.

**Other Significant Contributors.** This category identifies individuals who have committed to contribute to the scientific development or execution of the project, but are not committing any specified measurable effort to the projects. These individuals are typically presented at "zero percent" effort or "as needed" (individuals with measurable effort cannot be listed as Other Significant Contributors). Consultants should be included if they meet this definition.

**Person Months.** A metric for expressing the effort (amount of time) that PIs, faculty and other senior/key personnel devote to a specific project. Effort is expressed as a percentage of the total employment (VA + non-VA) and is based on the organization's regular academic-year, summer or calendar-year.

**Postdoctoral Scholar.** An individual who has received a doctoral degree (or equivalent) and is engaged in a temporary and defined period of mentored advanced training to enhance the professional skills and research independence needed to pursue his or her chosen career path.

**Principal Investigator, Program Director, or Project Director (PD/PI).** The individual designated by the applicant organization to have the appropriate level of authority and responsibility to direct the project or program to be supported by the award. The applicant organization may designate multiple individuals as principal investigators who share the authority and responsibility for leading and directing the project, intellectually and logistically. When multiple principal investigators are named, each is responsible and accountable to the grantee organization, or as appropriate, to a collaborating organization for the proper conduct of the project or program including the submission of all required reports.

**Senior/Key Personnel.** The PD/PI *and other individuals* who contribute to the scientific development or execution of the project in a substantive, measurable way, whether or not salaries or compensation are requested under the grant.

Typically these individuals have doctoral or other professional degrees, although individuals at the masters or baccalaureate level should be included if their involvement meets the definition of Senior/Key Personnel. Consultants and those with a postdoctoral role should also be included if the meet the definition of Senior/Key Personnel. Senior/Key Personnel must devote measurable effort to the project whether or not salaries or compensation are requested – "zero percent" effort or "as needed" are not acceptable levels for those designated as Senior/Key Personnel.

**United States.** The 50 states, territories and possessions of the U.S., Commonwealth of Puerto Rico, Trust Territory of the Pacific Islands, and District of Columbia.

# IV. General Information

## A. Research Funding Mechanisms

The following table summarizes the major mechanisms VA-ORD uses to fund intramural research.

VA-ORD is in the process of transitioning the mechanisms listed below to electronic submission through Grants.gov. Specific funding opportunity announcements will be posted on the VA-ORD intranet site when a particular mechanism is transitioned. An RFA for a particular funding mechanism may not be issued by every R&D Service or for every review cycle.

| Type (Mechanism) | Description |
|---|---|
| **Research Awards** | |
| **Merit Review Award (I01 funding mechanism)** | **Merit Review Awards** are made to eligible institutions on behalf of a PD/PI to support a discrete investigator-initiated project related to the investigator's area(s) of interest and competence. Funding durations may vary, up to 5 years. Budget caps vary among the individual VA-ORD Research & Development Services. These awards make up the largest category of VA-ORD funding. |
| **Pilot Project/Small Project Awards (I21 funding mechanism)** | **Pilot Project/Small Project Awards** are specifically directed at establishing project feasibility, or developing data, techniques, concepts or procedures as a preliminary step to undertaking a full Merit Review project. Complete but brief information is needed. A justification must be provided as to why this type of study is needed in lieu of a full-scale project. Proposals are prepared using the same format for submitting a Merit Review proposal; page limits may differ. Funding for Pilot Projects may be limited to 2-years. |
| **Program Project Awards (IP1 funding mechanism)** | **Program Project Awards** are an intramural funding mechanism to support investigator-initiated research conducted by groups of eligible VA-ORD investigators at a single VAMC or VA-approved site. Program Project Awards will support broadly based but focused, multidisciplinary or multifaceted research effort directed at elucidating well-defined biomedical and clinical problems of direct concern to the health care of Veterans. An additional objective of a Program Project is to build long-term biomedical research capacity at the submitting VA medical center. |

| Type (Mechanism) | Description |
|---|---|
| **Research Awards (cont)** | |
| **Research Enhancement Award Program (REAP)**<br>**(I50 funding mechanism)** | **REAP awards** are an intramural funding mechanism to promote and support groups of VA investigators that are not affiliated under the domain of a currently funded **RR&D** Center of Excellence or REAP award. The goal of this program is to increase **RR&D** capacity by assisting VA sites that already show promise, as demonstrated by a history of VA peer-reviewed research and career development funding. |
| **Center of Excellence (Center) Award**<br>**(I50 funding mechanism)** | **Center awards** are an intramural funding mechanism for **RR&D** to establish and cultivate a community of VA clinical scientists and scholars within the VA health care system for the purpose of pursuing specific research objectives in accordance with well-reasoned five-year plans. Centers provide relatively stable core funding, enabling a critical mass of investigators to leverage that support and develop long-term programs of research and mentoring of new investigators. |
| **Center of Innovation (COIN) Award**<br>**(I50 funding mechanism)** | **COIN Awards** are an intramural funding mechanism to support investigator-initiated research conducted by groups of eligible **HSR&D** investigators at VA MCs or VA-approved sites. The award duration is up to 5 years. COIN Awards are designed to promote innovative research and scientific discovery, facilitate effective collaboration across multidisciplinary research teams, train and mentor scientists at various stages of their career, engage clinical and operations partners, and increase the impact of health services research on specific areas of central importance to the health and health care of Veterans. |
| **Research Career Development Awards** | |
| **Career Development Award (CDA-1)**<br>**(IK1 funding mechanism)** | **CDA-1 Awards** are made to eligible institutions on behalf of a PD/PI to provide an initial mentored research experience, consisting of up to 2 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. |

| Type (Mechanism) | Description |
|---|---|
| **Career Development Award (CDA-2) (IK2 funding mechanism)** | **CDA-2 Awards** are made to eligible institutions on behalf of a PD/PI to provide salary and/or project funds to support a 3-5 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 CDA-2, it is anticipated that the awardees will have competed for independent VA research funding. |
| **Nursing Research Initiative (NRI) Award (IK3 funding mechanism)** | The Nursing Research Initiative (**NRI**) is a mentored research and capacity-building program managed by HSR&D for the Office of Research and Development (ORD). Program goals include developing nurses' research skills, encouraging nursing research career opportunities, and developing a cadre of independent nurse investigators within VA. NRI is an award to support a discrete, specified, circumscribed project to be performed by the named investigator(s) in areas focused on high priority, VA mission-oriented areas of investigation. |
| **Research Career Scientist (RCS) Program (IK6 funding mechanism)** | **RCS Awards** (including Senior RCS) are eligible institutions on behalf of a PD/PI to provide salary support to cover their research and mentoring time commitments. Applicants must be established senior VA scientists with an active VA research program and history of mentoring and research service-related activities to VA. Awards are renewable and provide 5 to 7 years of funding, and undergo an interim review by ORD. |