



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

VA-ORD

Application Guide

SF424 (R&R)

**A guide for preparing and submitting VA-ORD applications
via Grants.gov Workspace or NIH ASSIST**

For use by VA intramural investigators for submissions to VA-ORD:

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

To be used with Adobe-Forms Version-E application packages

Revised: January 5, 2018; Updated: April 24, 2018

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PART I
**Instructions for Preparing and Submitting
an Application**

1. Foreword

VA-ORD Application Guide SF424 (R&R) Forms Version “E”

FORMS-E application packages incorporate the latest versions of the Federal-wide forms managed by Grants.gov (OMB Number: 4040-0001, Expiration Date: 10/31/2019).

Summary of Key Updates for January 5, 2018:

- **The Grants.gov Downloadable Forms legacy option is no longer available for application submissions.** You will need to determine which system is most convenient for your application submission: [Grants.gov Workspace](#) or the NIH [Application Submission System & Interface for Submission Tracking](#) (ASSIST).
- R&R Other Project Information Form: Added exemption numbers 7 and 8 to question 1.a [If YES to [Human Subjects](#)]; however, these exemptions should not be used at this time.
- R&R Budget Forms: Added new “K. [Total Costs and Fee](#)” calculation to budget periods and cumulative budget.
- R&R Senior/Key Person Profile (Expanded) Form: Updated [Biographical Sketch](#) form (Rev. 09/17 Approved Through 03/31/2020) and instructions so that scholastic performance requires only scientific/professional graduate courses to be listed. **Note:** Biographical Sketch form (Rev. 10/15 Approved Through 10/31/2018) may continue to be used through October 31, 2018.

Updates for April 24, 2018 are highlighted in YELLOW.

Do NOT use any PHS Forms. PHS forms are NOT applicable to VA-ORD.

REMINDER: Within VA-ORD, each Service-specific funding opportunity announcement/request for application (FOA/RFA) instructions will ALWAYS supersede these general application instructions. Carefully review both the SF424 (R&R) and Service-specific FOA/RFA when preparing an application for submission to VA-ORD.

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 forms 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 section 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. You should refer to this document as well as the Veterans Health Administration (VHA) Handbook or VA-ORD Program Guides for each Service (see Service-specific web sites). Handbooks can be accessed on the VA web site, VHA Publications, at <http://www.va.gov/vhapublications/>. Additional VA-ORD Policies and Guidance documents can be found at <http://www.research.va.gov/resources/policies/default.cfm> and <https://www.research.va.gov/resources/policies/handbooks.cfm>.

1.2 VA-ORD Intramural Research and Research Training Programs

The VA-ORD homepage on the intranet (<http://vaww.research.va.gov/default.cfm>) or internet (<http://www.research.va.gov/default.cfm>) provides an array of helpful information about VA-ORD research programs. You are encouraged to bookmark these sites and visit often.

Additional information about VA-ORD intramural research and research training programs, FOA/RFAs, and the application process, can be obtained by contacting the appropriate Service (see Service-specific FOA/RFAs for appropriate staff contact(s) for each Service) or sending questions to the VA-ORD eRA Mailbox: vhacordera.vhacordera@va.gov.

1.3 Research Award Activity Codes and Program Guidelines

A list of research award activity codes 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 Award \(I50\)](#)
- [Center of Innovation Award - COIN \(I50\)](#)
- [Cooperative Studies Program – CSP \(IU1\)](#)

Research Career Development Awards

- [Career Development Award – CDA-1 \(IK1\)](#)
- [Career Development Award – CDA-2 \(IK2\)](#)
- [VA-ORD Historically Black College and University Research Scientist Training Program Award \(IK2\)](#)
- [Nursing Research Initiative – NRI \(IK3\)](#)
- [Research Career Scientist Award – RCS \(IK6\)](#)

1.4 Interactions with VA-ORD Staff

You are encouraged to communicate with Service staff throughout the entire application, review and award process. Refer to Scientific/Research Contacts within the Service-specific FOA/RFA.

1.5 Before and After Application Submission

Prepare to Apply

Use this application guide 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) forms and all required attachments as indicated in this document.

Determine which system is most convenient for your application submission: [Grants.gov Workspace](https://grants.gov) or the NIH [Application Submission System & Interface for Submission Tracking \(ASSIST\)](https://grants.nih.gov/grants/how-to-apply-application-guide/prepare-to-apply-and-register/submission-options.htm). For an overview of these submission options see <https://grants.nih.gov/grants/how-to-apply-application-guide/prepare-to-apply-and-register/submission-options.htm>.

Identify the right FOA/RFA for your research. Specific FOAs/RFAs will clearly indicate which forms and submission process you should use. See [Section 2.2.2](#) for solicitations.

You must carefully review VA-ORD FOA/RFAs for guidance on when to use the SF424 (R&R) forms, instructions, and application submission for a specific activity code (i.e., IO1, I21, IP1, I50, IK1, IK2, IK3, IK6). This process applies to all types of submissions for the announced award activity code (new, resubmission, and renewal applications). You should check the VA-ORD intranet site, [RFAs and Program Announcements](http://vaww.research.va.gov/funding/rfa.cfm) (<http://vaww.research.va.gov/funding/rfa.cfm>), under the appropriate VA-ORD Service, for the most current version prior to each submission.

[Proposal Guidance and Templates](#) related to application submissions can also only be accessed via the VA-ORD intranet at <http://vaww.research.va.gov/funding/electronic-submission.cfm>.

Be sure to use an application package for the correct FOA/RFA and Service when submitting applications. Application packages are not interchangeable between Services or between FOA/RFAs within a specific Service.

Before Submission

Your VA Medical Center (VAMC) Research and Development Office (R&D Office) Associate Chief of Staff/Research (ACOS/R) and/or Administrative Officer (AO) can provide you with a wealth information and assistance. You may also have your ACOS/AO contact VA-ORD staff with any additional questions. See Service-specific FOA/RFAs for appropriate staff contact(s) for each Service.

Determine your registration status. Before beginning the application process, you are encouraged to review [Grants.gov For Applicants](#).

All registrations require that the submitting VAMC be issued a [Dun and Bradstreet](#) Universal Numbering System (DUNS) number. After obtaining a DUNS number, you can begin both [System for Award Management \(SAM\)](#) (formerly CCR) and [eRA Commons](#) registrations (VAMC and individual investigators). The same DUNS number must be used for all registrations and on the award application itself.

Grants.gov and eRA Commons are distinct, one-time registrations, which may be completed simultaneously. SAM registration requires renewal at least annually in order to maintain an active entity registration.

After Submission

The VA-ORD web site lists the recurring Scientific Review Groups (SRGs), and your VAMC R&D Office may [suggest/request assignment](#) to a specific SRG on your behalf. Although these suggestions will be taken into consideration, the final determination will be made by the specific Service(s) issuing each solicitation. If the initial assignment to a Service or SRG seems inappropriate, the VAMC R&D Office may [request reassignment](#) on behalf of the PD/PI; requests submitted directly by PD/PIs will be returned to the VAMC R&D Office without consideration. Although these requests will be carefully considered, the Service will make the final determination.

You (as an applicant), PD/PIs, or any other interested party, must never contact reviewers regarding a submitted application. Any discussion of an application or attempt to influence the review outcome will constitute a serious breach of confidentiality and 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 from submitting to any VA-ORD Service.**

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 Services allow submission of supplemental material, and permission to submit additional material will be granted only in exceptionally rare instances.*

After Peer Review

While VA-ORD recognizes that feedback is very important, SROs 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 contact PD/PI's eRA Commons account;** paper copies will not be issued. Percentiles may not be calculated for all award activity

codes or for all SRGs. Once the PD/PI receives his/her Summary Statement, s/he may contact the appropriate awarding Service's SRO (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.

1.6 References

If you are new to VA-ORD: Getting Started

<http://www.research.va.gov/resources/>

<http://www.research.va.gov/resources/policies/default.cfm>

VA-ORD Applying Electronically

<http://vaww.research.va.gov/funding/electronic-submission.cfm>

<http://vaww.research.va.gov/funding/rfa.cfm>

VA-ORD Staff Person Contact Information

See Service-specific FOA/RFAs for appropriate staff contact(s) for each Service.

VA-ORD Award Information and Data

<http://vaww.research.va.gov/funding/>

http://vaww.research.va.gov/resources/funded_studies.cfm

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, and ensuring all VA facilities with Federal-wide Assurance attain Full Accreditation and creating and implementing the VA Central IRB.

VA Office of Research Oversight (ORO)

The [Office of Research Oversight \(ORO\)](#) monitors, reviews, and investigates matters of research compliance that involve VA research and provides oversight of compliance with VA and other Federal requirements for the protection of human research subjects, laboratory animal welfare, research safety, research laboratory security, research information security, and research misconduct.

VA-ORD Technology Transfer Program

The [Technology Transfer Program \(TTP\)](#) mission is to facilitate the commercialization of VA inventions to benefit Veterans and the American public.

VA-ORD Requirements for the Protection of Human Subjects in Research

http://www1.va.gov/vhapublications/ViewPublication.asp?pub_ID=3052

VA-ORD Use of Animals in Research

http://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=2464

Canine Research Protocols:

https://www.research.va.gov/resources/policies/animal_research.cfm

Office of Laboratory Animal Welfare (OLAW)

Animal welfare and related regulations and assurances information is available at

<http://grants.nih.gov/grants/olaw/olaw.htm>

eRA Commons

<https://commons.era.nih.gov/commons/index.jsp>

Institutions and PD/PIs are required to register with eRA Commons. Registered PD/PIs can check assignment/contact information, review outcome, and other important information in eRA Commons.

Telephone: 1-866-504-9552 (toll-free) or 301-402-7469

eRA Service Desk: <http://grants.nih.gov/support>

Business hours: M-F 7am-8pm Eastern Time

Grants.gov Online User Guide

The Grants.gov Online User Guide is a comprehensive reference to information about

Grants.gov: <http://www.grants.gov/help/html/help/index.htm>

NIH Grants and Funding Help Page

This site provides a self-help wizard to guide inquiries to the correct NIH website for additional information on specific topics: <http://grants.nih.gov/support/index.html>

1.7 Authorization

VA-ORD requests the information described in these instructions pursuant to its statutory authority for funding intramural VA-ORD 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.

2. Process for Application Submission

2.1 Software Requirements

In order to access, complete and submit applications, you will need the free Adobe Reader software to view Portable Document Format (PDF) documents (including the application image assembled by eRA systems); a PDF generator to format all documents attached to application forms; and a web browser. For additional information see [Obtain Software](#).

PDF generator software is necessary to create the PDF as the free Adobe Reader *will not create a PDF*. **You will need to make a specific request through your VAMC IRMS to have access to PDF generator software.**

Do NOT submit attachments in other formats such as Microsoft (MS) Word, Word Perfect, etc. Other formats may be allowed through Grants.gov but are not accepted by NIH. You should prepare text attachments using any word processing program (following the creation and format guidance in [Section 2.4](#)) and then convert those files to PDF before attaching the files to the appropriate form in the application package. The PDF format is used to preserve document formatting.

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.

2.2 Funding Opportunities

Health-related research and research training projects or activities make up the largest category of funding by VA-ORD. 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 VAMCs on behalf of PD/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 FOA/RFAs for research addressing specific Veterans' health care issues (see [Section 2.2.2](#)).

VA-ORD funding awards are for terms ranging from one to seven years, as specified in each FOA/RFA. See Part III: Policies, Assurances, Definitions, and Other Information for a list and brief description of [research award activity codes](#).

2.2.1 Solicitations

Each Service will issue a “Parent” FOA/RFA for investigator-initiated research. Although the global purview of each Service will be described in the Parent FOA/RFA, there may be little or no focus on any particular scientific area(s) or Veterans’ health care issue(s). Each FOA/RFA will be assigned a unique announcement number (i.e., RX-18-001).

To stimulate submission of applications in an area of high priority or special concern, one or more Services may issue additional FOA/RFAs inviting applications in well-defined scientific area(s) or Veterans’ health care issue(s).

Each FOA/RFA will contain a table of **announcement-specific due dates** (including first and last date to submit). A specially convened SRG may review applications submitted in response to an FOA/RFA issued by a Service.

Read the FOA/RFA carefully for special instructions. **The instructions in the FOA/RFA may differ from and supersede the general instructions contained in this VA-ORD Application Guide SF424 (R&R).**

In reading any VA-ORD FOA/RFA:

- A “release/posted date” refers to the date the FOA/RFA is posted on [Grants.gov](https://www.grants.gov). You can access the application package (see [Section 2.2.2](#) below) on that date and begin filling it out in Grants.gov Workspace or NIH ASSIST. However, you must wait until the FOA/RFA “opening date” to have the AOR submit the application.
- When you access an application package, the FOA/RFA number and “expiration date” are auto-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 FOA/RFA designation within the package.
- An application can be submitted to Grants.gov anytime between the “opening date” and “last possible submission date” noted in the Deadline, Review, and Award Dates Table in each FOA/RFA.

2.2.2 Finding an application package for VA-ORD FOA/RFAs

VA-ORD FOA/RFAs are **not searchable through the “Search Grants” (a.k.a. “Search”)** feature on Grants.gov. The list and full text (and number) for all VA-ORD FOA/RFAs are only available on the [VA-ORD Intranet, RFAs and Program Announcements](#).

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 processing within the eRA system or to be administratively withdrawn by VA-ORD without review.

2.3 Forms for a SF424 Application to VA-ORD

The SF424 (R&R) form set is comprised of a number of forms, each listed in the table below as a separate “document” in the order they appear in the application package. **Do NOT** cut and paste from any other program (i.e., WORD or ePROMISE) to complete fields on SF424 forms; the font may not transfer correctly and may cause erroneous characters (e.g., “&”, “i” or “□”) to be introduced. **Check the final e-Application carefully for such errors.**

All required and optional forms for submission listed below are available through Grants.gov Workspace, NIH ASSIST, or on the VA-ORD Intranet, [Proposal Guidance and Templates](#). **Do NOT** use any forms or format pages from other sources.

Table 2.3-1 Forms for a VA-ORD Application (in order of appearance)

Document	Required	Optional	Instructions
SF424 (R&R) (Applicant Information, Project Title, etc.)	✓		Section 3.2
Project/Performance Site Locations	✓		Section 3.3
Research and Related Other Project Information (Abstract, Relevance, Introduction to Revised Application, Specific Aims, Research Plan, VA Career Plan, VA Mentoring Plan, Progress Report Publications, Human Subjects, Vertebrate Animals, Multiple PD/PI Leadership Plan, Consortium/Contractual Agreements, Director’s Letter, R&D Committee Letter, Letters of Support, Data Management and Access Plan, Appendices)		Different FOA/RFAs and/or award activity codes may require different attachments	Section 3.4
Research and Related Senior / Key Person Profile (Expanded) (Biosketches and Current & Pending Support)	✓		Section 3.5
Research and Related Budget*	✓		Section 3.7

*Application packages for VA-ORD funding opportunities include only the Research and Related Budget; modular budgets are not accepted. Unless otherwise stated in a FOA/RFA, a budget form must always be submitted. See Section 3.7 for additional details.

2.4 Creating and Formatting Text (PDF) Attachments

All text attachments to the application package must be submitted as PDFs and all final text attachments in the e-Application must conform to specified formatting requirements. Failure to follow these requirements will lead to administrative withdrawal of the application during VA-ORD validation.

2.4.1 Creating Text (PDF) Attachments

Text attachments should be generated using word processing software and then converted to PDF using separate PDF generating software before attaching to the appropriate form in the application. You and your AO or Signing Official (SO) are encouraged to check the e-Application within eRA

Commons during the 2-day application viewing window to ensure that all of the attachments are the correct version, have correct formatting, and that there are no blank pages included.

When an 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. The font, line spacing, and margin requirements 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 all formatting requirements will be not accepted for review.**

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

- **“Accept All Changes in Document” and “Final”** in MS Word if you have been using Track Changes, and **remove all comments** before converting the file to PDF format.
- **Use U.S. standard letter-sized paper (8.5 x 11 inches).** Set the default paper size for printing in your PDF converter to this size.
- **Disable all security features.** Security settings vary by PDF tool, therefore, you must ensure security settings are not marked and prevent NIH from opening and processing the application. Go to the Document Security tab under Document Properties (directly from the tab) and set the security parameters to ensure open access. 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.** The header and footer areas of the original MS Word document must be empty (use Section Headings within the document). In the e-Application, a header will be system-generated that references the name of the PD/PI and a footer will be generated to contain page numbers, with all pages sequentially numbered.
- **PDF attachments must be “flat files”.** A flat file is 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, data will be lost when the application image (e-Application) is created, resulting in errors that will prevent application processing. To save a flattened PDF document: File, Save As Other, Optimized PDF, ‘Check/Mark’ Discard Objects (i.e., make sure it is selected so that objects will be removed), OK. If you do not have the appropriate rights/permissions to edit a file in your PDF creating software, you may print, scan and then re-upload the file in order to flatten it (although this is not recommended as scanning can create other format issues). When selecting a PDF to attach, Save As and select the ‘Restrict Editing’ box.
Recommendation: When provided an option to download a MS Word version of a form or a PDF version of a form, always select the MS Word version and then after the form is completed, convert to PDF. This process will “flatten” the file, making it acceptable for submission. If you have trouble fixing the PDF settings, simply cut and paste from the PDF document into a MS Word document and then reconvert (in some cases it may be better to use another PDF generator).
- **PDF attachments must be text PDFs not images.** To determine if you have a properly created text PDF and not an image, highlight only a section of a PDF document – if the highlight

automatically covers the entire page (not just the section), then this is an image. Images may contain hidden URLs or other codes which can cause validation issues and system errors.

- **Attaching a PDF document to a form.** When you attach a PDF, you are attaching an actual document, not just pointing to the location of an externally stored document. If the document is revised after it has been attached, you must delete the previous attachment and then reattach the revised document to the form. Use the ‘**View Attachment**’ button to determine if the correct version has been attached.
- **Scanning should only be used for combining original signed documents.** For example, scanning can be used for the Letters of Support attachment in order to combine letters from various individuals and institutions into a single attachment file. You should not scan text documents to produce the other PDF attachments required for an application. Instead, it is recommended that the documents are produced using text or word-processing software and then converted to PDF.

Scanning paper documents, without the proper Optical Character Recognition (OCR) process, will hamper automated processing of your application, 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, fonts that are too small, and incorrect vertical line spacing. Scanned attachments will also greatly increase the total size of the application package.

- **Use only a standard, single-column format for the text.** Since reviewers will be viewing applications electronically, you are strongly encouraged to avoid using a two-column format since it can cause difficulties when viewing the application.

PDF Attachment File Names

- The file names for PDF Attachments 1 - 9 under [Section 3.4](#) Research and Related Other Project Information Form, Item 12. Other Attachments, are mandatory and may not be changed (refer to specific FOA/RFA, Table 1). Altered file names will cause an **error** to be generated. Mandatory file names and corresponding template MS Word files can be found on the VA-ORD Intranet: <http://vaww.research.va.gov/funding/electronic-submission.cfm>.
- Only the descriptor may be changed in the file name for additional Appendices (i.e., 10, 11, 12...). These file names can include descriptors of 50 characters or less using only standard characters: A through Z, a through z, 0 (zero) through 9, and spaces **between words if a multiple word descriptor is used.** NOTE: If using ASSIST, the system will automatically change a space to an **underscore between each word in a multiple word descriptor file name.** Do NOT use any special characters (example: “&”, “*”, “%”, “/”, or “#”) in multiple word descriptors.
- File names are NOT case sensitive.

2.4.2 Formatting PDF (Text) Attachments

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 these formatting requirements or are incomplete will be administratively withdrawn (not accepted for review) by VA-ORD.

Font (size, color, type density) and Line Spacing

- **Typeface:** Arial, Georgia, Helvetica, or Palatino Linotype
- **Font Size:** 11 points or larger
- **Text Color:** Black or other high-contrast text color is recommended
- **Type Density:** Must be no more than 15 characters per horizontal inch, including characters and spaces
- **Line Spacing:** Must be no more than six lines per vertical inch
- A **Symbol font** may be used to insert Greek letters or special characters, but the font size, font typeface, and color requirements still apply. Although Grants.gov limits the characters allowed in application form fields, a broader range of characters may be used in PDF attachments. The system supports the use of the **Unicode character standard** that allows the recognition and storage of Greek and other scientific characters.

Paper Size and Page Margins

- **Paper:** Use standard paper size 8 1/2 x 11 inches, not a European size such as A2.
- **Margins:** Use at least one-half inch margins (top, bottom, left and right) for all pages. No information should appear in the margins (including the PD/PI's name or page numbers), however, a vertical bar drawn in the margin is allowed, provided that:
 - the changes in text are also indicated as instructed in this guidance; and
 - any issues with margins that arise from the use of the vertical bar are the responsibility of the PD/PI and will not be viewed as grounds to accept margin/font problems in the e-Application.

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 inches (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. You and your AO should print a page from each section of the e-Application from an attachment (i.e., Research Plan, Specific Aims, etc.) during the 2-day application viewing window 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).

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

A smaller font point size may be used but it must be in a black font color, clear and readily legible, and follow the font typeface requirement. Color can be used in figures.

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 MS Word table function. **Do NOT** place an Excel table in a MS Word document.

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

Tables may not be used to condense text or to otherwise avoid stated font requirements 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 for tables.

Page Limits

Although many of the sections of this application are separate text (PDF) attachments, page limitations referenced in these instructions and/or FOA/RFA must be followed. Observe the page number limitations given in [Table 2.4-2](#). eRA and VA-ORD validations will include checks for some page limits. Note that while these system validations will help minimize incomplete and/or non-compliant applications, they should not replace a detailed review conducted by you or your AO during the 2-day application viewing window, nor do they replace the validations conducted by VA-ORD staff.

Inclusion of URLs

All applications must be self-contained (i.e., without use of URLs or video clips) within specified page limits. Internet website addresses (URLs) and video clips may not be used to provide information necessary to the review. Reviewers are under no obligation to view supplemental material, moreover, they are cautioned that they should not directly access an Internet site as it could compromise their anonymity. URLs may only be placed in the Biographical Sketch and Bibliography and References Cited attachments. VA-ORD strongly encourages you to take the time necessary to carefully review the application for inclusion of URLs prior to application submission. **Any submission with URLs placed anywhere else except the Biographical Sketch and Bibliography and References Cited will be withdrawn from review. NOTE: URLs within official documents that cannot be altered, such as letterhead (i.e., Letters of Support attachment) or published articles/manuscripts (i.e., Appendix attachments), will be accepted.**

The following steps may be taken to help ensure a successful application submission without inclusion of URLs:

- Use the “Remove Web Links” function in AcrobatPro DC (Edit PDF, Links menu “Remove Web Links” tool).
- Use Ctrl+F (“Search” or “Find” feature) for ‘www’ and ‘http’.
- Use Ctrl+F (“Search” or “Find” feature) for the following: .com, .edu, .gov, and .org - if there is a sentence that starts with a word beginning with these first three letters (such as ‘Communication’), the system picks up the preceding period (.) and the ‘Com’ and returns a false positive hyperlink warning. If this is the case, it will not be considered a fatal error.
- Check all Attachments/Appendices to be sure each is a text PDF flat file and not an image. To determine if you have a text PDF and not an image, highlight only a section of a PDF document – if the highlight automatically covers the entire page (not just the section), then this is an image. Images may contain hidden URLs or other codes which can cause system errors.

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.

Table 2.4-1 Page Limitations and Content Requirements*

* FOA/RFA instructions always supersede SF424 instructions.

Section	Page Limit*	Content
Introduction to Revised Application	See the Service-specific FOA/RFA for number of pages allowed*	See Instructions
Specific Aims	1 page	See Instructions
Research Plan Background and Significance, Preliminary Studies/Progress Report, Research Design and Methods	See the Service-specific FOA/RFA for number of pages allowed*	Includes all text, figures, charts, tables, and diagrams.
Other Components VA Career Plan, Mentoring Plan, Progress Report Publication List, Human Subjects, Vertebrate Animals, Multiple PD/PI Leadership Plan, Consortium/Contractual Agreements, Director’s Letter, R&D Committee Letter, Letters of Support, Data Management and Access Plan (DMAP), Appendices	See the Service-specific FOA/RFA for number of pages allowed*	See instructions for Item 12 on the Other Project Information Form (Section 3.4)

Section	Page Limit*	Content
Bibliography & References Cited	4 pages	See Instructions.
Biographical Sketches	5 pages	No more than five pages for each person listed as Senior/Key Persons.
Appendices	See the Service-specific FOA/RFA for number of pages allowed*	There are restrictions on what is allowed for inclusion in an Appendix. Please read the guidelines carefully.

2.5 “Resubmission” (Revised) Applications

Up to two revised applications (identified as “Resubmission” applications on the SF424 (R&R) Form) are allowed, with the exception of HSR&D Pilot and RR&D SPiRE submissions (I21) for which only one revised application will be accepted.

In general, we would expect the submission timeframe to be three application submissions within six review cycles for mechanisms that allow three submissions, and two application submissions within three review cycles for mechanisms that allow two submissions. BLR&D and CSR&D allows three submissions over four review cycles for Career Development Awards, Clinical Trials, and Epidemiology (EPIDs), as specified in the LOI approval letter.

Resubmission applications are denoted as -01A1 (first submission) and -01A2 (second submission) in the eRA-generated application number. **No further resubmissions will be accepted for review.**

If an application has been “revised” in response to the reviewers and will now be submitted to a different 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.

There are policies for application resubmissions of certain categories. See [Resubmission of Unpaid FOA/RFA Applications and Resubmission of Applications with a Changed Award Activity Code](#) in Part III.

Acceptance of a resubmission application will not automatically withdraw the prior version. eRA Commons keeps all versions (i.e., -01, -01A1, and -01A2) of an application active and provides an internal Multiple Active Applications (MAA) flag for each application in an active cluster. The cluster allows you and program staff 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 taken by you or staff.

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

1. The Summary Statement for the previous application must be available in eRA Commons; the critiques from the previous review are included in the Summary Statement (<http://commons.era.nih.gov/commons>).
2. The PD/PI(s) must make significant changes to the application, compared to the previously submitted application (-O1 or -O1A1) that it follows.
3. An [Introduction to Revised Application](#) (page limited – see the Service-specific FOA/RFA for number of pages allowed) 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; include the issue you are responding to and not just the response.
4. 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 section should incorporate work completed since the prior version of the application was submitted.

After **the allowable number of reviews**, 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 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 administratively withdrawn.

2.6 “Revision” Applications

VA-ORD does not accept submission of competing supplemental applications (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 Service that is funding the project.

2.7 Similar, Essentially Identical, or Identical Applications

Simultaneous submission of identical (or essentially identical) applications to one or more Services are not allowed, and VA-ORD will not accept similar applications with essentially the same research focus from the same VAMC for the same (or other) due date. 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 VAMCs or by different PD/PIs will not be accepted for the same due date. VAMCs should ascertain and assure that the materials they are submitting on behalf of the PD/PI are the original work of the PD/PI 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 PD/PI(s). 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.

2.8 Submitting Your Application

For VA-ORD, there are two options for submitting applications: Grants.gov Workspace and NIH Application Submission System and Interface for Submission Tracking (ASSIST).

Be aware that on-time submission means that an application is submitted error free (of both Grants.gov and eRA Commons errors) **before 6 p.m.** on the due date (Last Possible Submission Date), local time of the VAMC. You are encouraged to submit your application(s) several days early to ensure enough time to correct any errors before the deadline. Changed/Corrected applications submitted after the Last Possible Submission Date will not be accepted for review.

2.8.1 Grants.gov Workspace

Workspace enhances the Grants.gov Apply functionality by providing a shared, online environment to collaboratively complete and submit applications. For step-by-step guidance on using Workspace for application submission, go to [Workspace Process](#). The Grants.gov User Guide is found at: https://www.grants.gov/help/html/help/GetStarted/Get_Started.htm. There is also guidance on tapping the full potential of Workspace on the Grants.gov Community Blog: <https://blog.grants.gov/tag/grants-gov-workspace/>.

Workspace provides for the following:

- Multiple users can concurrently complete the application forms
- Reuse/copy existing Workspace forms
- Upfront validation so you can correct application errors prior to submission
- Seamless integration between online webforms and offline PDF forms

- Collaboration with users external to your organization
- Changes to the FOA/RFA are known immediately (as reflected in Workspace)

2.8.2 NIH ASSIST

ASSIST is a web-based system used to prepare applications using the SF424 (R&R) form set and to submit electronically through Grants.gov to NIH. You will need a FOA/RFA number (i.e., RX-18-001) to initiate an application and active Grants.gov and eRA Commons credentials. For step-by-step guidance on using ASSIST for application submission, go to [ASSIST Login](#). The ASSIST User Guide is found at: https://era.nih.gov/files/ASSIST_user_guide.pdf.

ASSIST provides for the following:

- Leverage current eRA Commons credentials to access
- Delegate application preparation responsibilities to multiple users within and outside your VAMC while maintaining appropriate access control and security
- Populate data from established eRA Commons profiles
- Run validations on Federal-wide and VA-ORD business rules prior to submission
- Generate Table of Contents, headers, footers, page numbers, etc., automatically
- Print/Preview applications prior to submission
- Present to reviewers clear, color PDF images rather than scanned versions of the application
- Allow tracking of an application through Grants.gov to eRA Commons with a single login

2.9 After You Submit Your Application

It is important to a fair review that all applicants competing together for funding have adhered to the same rules. It is also important that your application is submitted in a way that allows Grants.gov and eRA to efficiently process your application and make it available for funding consideration by VA-ORD. Once an application is submitted to Grants.gov, three basic application checks are performed - by Grants.gov, eRA, and by VA-ORD staff – before it is referred for review. These business rule checks are also referred to as “validations”.

The key to a successful submission and passing through this series of validations is simple:

- Follow the VA-ORD Application Guide SF424 (R&R) and Service-specific FOA/RFA instructions; and
- Submit early enough to allow time to address any system identified errors and submit a changed/corrected application prior to the deadline.

If a problem is found, Grants.gov will reject your application with a "Rejected with Errors" status. You must address all errors and submit again. If no problem is found, Grants.gov places your application in a queue for VA-ORD retrieval.

You must check the status of your application in eRA Commons. If problems with your application are identified, a list of errors and warnings is provided. Errors will stop an application from

proceeding in the system and must be addressed. Warnings will not stop your application from moving forward and are addressed at your discretion based on your situation.

Once an error-free application is received, a consolidated document of all your submitted forms and attachments is created and placed in an assembled application image (e-Application) in eRA Commons Status for you and/or your AOR/SO to view.

There is a 2 business day application viewing window to check your assembled e-Application. Your application automatically moves forward to receipt and referral for further processing after the viewing window has closed (third business day) unless the application is explicitly "rejected" by the SO in eRA Commons.

Submit

- Submit early – this provides time to track your application, view your application, and correct any errors and resubmit before the due date.
- The specific actions you take to submit your application will vary by submission method used (ASSIST or Grants.gov Workspace).
- Each application is assigned a Grants.gov tracking number (e.g., GRANT12345678). Save this number as you will need it to track your submission.
- You will also receive a Grants.gov timestamp noting the official submission date/time.
- An error-free application must be submitted by 6 p.m. local time of your VAMC. (Note: Grants.gov displays its timestamp in Eastern time.)
- If there are no validation errors, you, the AOR/SO and the Applicant Contact will receive an email notification with an agency accession number (e.g., AN654321), 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 eRA Commons, however, it is the agency accession number that will be used to refer to the application, not the Grants.gov tracking number.**

Track

- You and your AOR/SO are responsible for tracking your application through Grants.gov to a visible application image in eRA Commons.
- Any errors identified in Grants.gov and eRA Commons must be addressed before the submission deadline. See [Section 2.10 Correcting Errors](#).
- You will receive a series of Grants.gov and eRA Commons email notifications throughout the submission process. However, you should proactively track your application status in Grants.gov, ASSIST or eRA Commons:
 - For Grants.gov Workspace go to [Step 4 Track a Workspace Package](#), select Track a Workspace Package, enter your application’s Grants.gov Tracking Number, select Submit Tracking Number(s). For additional information, select [Learn more about Track My Application](#).
 - For ASSIST go to the [ASSIST User Guide](#), 10 Application Submission.

- [Steps for the PI to Track Submission Status in eRA Commons.](#)
- [Steps for the AOR/SO to Track Submission Status in eRA Commons.](#)

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

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

Failure to provide eRA Commons ID for all PD/PIs in the [Credential](#) field of the Senior/Key Person Profile(s) form will prevent emails from being distributed to either the PD/PI or AOR/SO.

View

- The assembled application image in eRA Commons is the same document used by VA-ORD staff and reviewers. Check it carefully!
- Use the 2 full business day application viewing window (Monday – Friday, excluding weekends and Federal holidays) to view/check your assembled e-Application (electronic “grant image”) before it automatically moves on to receipt and referral for further processing (on the third day). It is critical that you **and** your AOR/SO 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.
 - If additional changes are made within this viewing window, the SO must REJECT the application and then submit a changed/corrected application. See [Section 2.10 Correcting Errors.](#)
 - **Do NOT submit a changed/corrected version of an application without first “rejecting” the previous successfully submitted application. If multiple versions are submitted and become verified, all versions may be returned without review.**
 - If an application is submitted after the “Down to the Wire” submission deadline published in the Deadline, Review and Award Dates Table (found in the FOA/RFA), the 2-day application viewing window may not be used.
- Changes can no longer be made to the application through Grants.gov after the 2-day application viewing window has closed unless you request VA-ORD to officially withdraw your application from the system to allow for a changed/corrected application to be submitted and ONLY if the submission deadline hasn't passed.
- A corrected submission replaces the previous submission – the corrected submission cannot be rejected or withdrawn in order to return to a previous submission.
- Any changed/corrected application must be submitted by 6 p.m. local time of your VAMC on the last possible submission date even if you are addressing identified errors or warnings.
- **Once verified, an application is considered final and no other version will be accepted for review.**

2.10 Correcting Errors

All changed/corrected applications must meet both deadlines (submission and verification; see the Deadline, Review and Award Dates Table found in the Service-specific FOA/RFA to which you are applying).

The application will only be assigned for scientific review once all errors are resolved. Applications that fail Grants.gov, eRA or VA-ORD program staff validations or administrative review will not be accepted. You and your VAMC may be contacted for further corrections/clarifications.

Prior to the specified submission deadline (due date), you may make corrections and submit a “changed/corrected” application, provided that the previous version has not been verified. After the specified submission deadline, if you 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 specific Service; approval will only be provided in highly unusual circumstances. See [Section 2.12](#) for additional information on due dates.

If errors or warnings result from the validation process, you (PD/PI), AOR/SO, and Applicant Contact will be issued an email instructing you to log on to eRA Commons to review the list of warnings/errors that were encountered during the validation process.

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 incorrect formatting that have been identified based on system validations. **Errors must be corrected and a changed/corrected application submitted in order for the application to be accepted.**

Conversely, the word *warning* characterizes any condition that may be acceptable, at least for the time being, but is worthy of bringing to your attention. **Warnings do not require any immediate action** or submission of a changed/corrected application, however, some warnings may, in fact, indicate a problem that will prevent the application from passing the VA-ORD staff administrative review. Do not assume that a warning can be ignored. Correcting a warning is at your and the AOR/SO’s discretion.

NOTE: Warnings do not stop further system application processing. If an application submission results in warnings (but not errors), the application will automatically move forward in eRA after the two-day application viewing window closes if no action is taken.

Failure to comply with stated VA-ORD policies can also result in a submitted application that will not be considered for review. For this reason, you are **strongly encouraged to review all warnings to ensure that they require no further attention and that you 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 eRA Commons, is incomplete or inaccurate from that submitted.

Errors and warnings may be reviewed within the system the application was submitted - Grants.gov Workspace, NIH ASSIST, or in eRA Commons:

- **Grants.gov Workspace:** An application can be checked for errors via the *Check Application* button on the *Forms* tab of the *Manage Workspace* page or the *Manage Workspaces for Organization* page (see Grants.gov Online User Guide, https://www.grants.gov/help/html/help/ManageWorkspaces/Check_Application_in_Workspace.htm). When a Workspace participant action triggers an error, an alert message will appear – either at the top of the *Manage Workspace* page, or in a popup window. In most cases, the issue must be addressed before the desired action can be completed (see Grants.gov Online User Guide, https://www.grants.gov/help/html/help/ManageWorkspaces/Resolving_Problems_and_Errors.htm).
- **NIH ASSIST:** Before an application can be submitted, it must pass various system and business validations – validation checks are triggered automatically whenever the status of the application is updated by an ASSIST user, or the checks can be run manually (see ASSIST User Guide, https://era.nih.gov/files/ASSIST_user_guide.pdf, *Validating the Application*). When an application fails validation, any errors and warnings are listed on the Application Errors and Warnings Results page, which opens as a separate window (see ASSIST User Guide https://era.nih.gov/files/ASSIST_user_guide.pdf, *Application Errors and Warnings Results*).
- **eRA Commons:** <https://commons.era.nih.gov/commons/>; log on using your eRA Commons username and password. Click the *Status* tab. Click *Recent/Pending eSubmissions*.
 - SOs: search by date received, Grants.gov tracking number, or accession number.
 - PD/PIs: click *Recent/Pending eSubmissions* to automatically display a hit list.

To correct errors and resubmit an application:

- **Do NOT use the Changed/Corrected Application box to submit changes after the submission deadline in Grants.gov.** Applications submitted after the submission deadline will not be accepted for review.
- **Do NOT** use the Changed/Corrected Application box to denote resubmission of an application submitted in a previous review cycle; this must be indicated in the Type of Application (Item 8).
- Submitting a Changed/Corrected application replaces the previous submission and removes the previous application from consideration. Once an application has moved forward to VA-ORD staff following the two-day application viewing window, subsequent changed/corrected applications will not be accepted unless the application is withdrawn by VA-ORD staff; do not submit another “New” application to circumvent the need to contact VA-ORD staff.
- Make whatever corrections are necessary, wherever appropriate – to your local copy of the application and/or within the system the application was submitted (Grants.gov Workspace or NIH ASSIST).
- When the Changed/Corrected Application box is checked, the Previous Grants.gov Tracking ID (Box 4c) 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 4c Previous Grants.gov Tracking ID. You can obtain this tracking number from your AOR/SO.
- For a “**Resubmission**” or “**Renewal**” **Application** (Item 8 = Resubmission or Renewal) enter only the 2-letter 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 can obtain the application number from the previous Summary Statement. In addition, you must enter the tracking number assigned by Grants.gov (e.g., GRANT123456) to the immediately previous application that you are correcting in Item 4c Previous Grants.gov Tracking ID. Note: 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.
- The AOR/SO will have to submit the changed/corrected application package. A new Grants.gov tracking number will be assigned. It is the PD/PI’s and AOR/SO’s responsibility to track the application. Successful submission may take several rounds of changed/corrected applications, since correcting one error may reveal or create an additional error.

2.11 Post-Submission Application Materials

Unless specifically required by instructions in the VA-ORD Application Guide SF424 (R&R), by a Service-specific FOA/RFA, or is solicited by the SRO of the SRG, post-submission application materials (supplementary or corrective material) will not be accepted by VA-ORD after an application becomes verified.

2.12 Application Due Dates

For specific submission information, review the Service-specific FOA/RFA which includes an Open Date and an Expiration Date, as well as a **Deadline, Review, and Award Dates Table**. These announcements are posted in Grants.gov showing an Open/Close period that spans the entire active period of the announcement.

Once verified, an application is considered final and no other version will be accepted for review. Applications are considered on time only if they meet both deadlines indicated in the Deadline, Review, and Award Dates Table in a FOA/RFA:

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

AND

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

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

Weekend/Federal Holiday Submission Due Dates. When an application submission due date or verification deadline falls on a weekend or Federal holiday, the deadline will be automatically extended to the following business day.

2.13 Submission, Review and Award Cycles

The submission, review, and award schedule is provided in the **Deadline, Review, and Award Dates table** in each Service-specific FOA/RFA. For specialized funding opportunities, consult with the appropriate Service prior to the preparation of an application. Some FOA/RFAs issued by a Service may allow submission of applications for multiple review cycles (Spring, Summer, Fall, and/or Winter).

Application Assignment Information

Applications that have been successfully submitted will be processed through VA-ORD unless otherwise stated. The application will be assigned to an appropriate SRG and Service. Assignment is based on the scientific content of the application using established referral guidelines.

Assignment to SRG: VA-ORD staff will assign applications to a SRG (commonly referred to as a “review panel” or “study section”) that will perform the scientific/technical review. Applications to VA-ORD are grouped by scientific discipline for review by individual SRGs and not necessarily by disease, disease state, or medical subspecialty of the PD/PI(s).

Assignment to Relevant Potential Services: In addition, VA-ORD will assign each application to the 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 Services, the application will be discussed to determine which Service will be responsible for the review and funding decision.

VA-ORD’s web site lists the recurring SRGs and you may [suggest/request assignment](#) to a specific SRG or Service through your VAMC R&D Office (ACOS/R and/or AO). Although these suggestions will be taken into consideration, the final determination will be made by the Service(s) participating in each (FOA/RFA).

After the due date, usually within four weeks, you and your VAMC R&D Office will be able to access and view the following information regarding the application in eRA Commons:

- application’s assignment number;
- name, address, and telephone number of the SRO of the SRG to which the application has been assigned; and
- assigned Service contact and phone number.

Review outcome and other important information are also available in Commons. If the initial assignment to a Service or SRG seems inappropriate, your VAMC R&D Office may [request reassignment](#) on behalf of the PD/PI.

If assignment information is not available in eRA Commons within four weeks of the submission due date, contact the appropriate Service (see Service-specific FOA/RFAs for appropriate staff contact(s) for each Service). If there is a change in assignment, you will receive notification.

Contact with the SRG is NOT Permitted

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

Assignment/Reassignment Request Letters (if permitted by the Service)

The VAMC R&D Office (not individual PD/PIs) may submit a separate letter for each application:

- To request an initial assignment to a particular SRG after an application is submitted.
- To request re-assignment to a particular SRG after an initial assignment has been made and 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 Service will determine if and how assignment requests may be submitted (i.e., email, mail, etc.). See Service-specific FOA/RFAs for appropriate staff contact(s) for each Service.

2.14 Resources for Finding Help

Do NOT address questions to Grants.gov Support or eRA Service Desk unless you are having a technical problem with registration or logging on to either of these systems.

Grants.gov Support and eRA Service Desk staff are not familiar with, nor are they responsible for, the format and/or submission requirements for VA-ORD applications. Grants.gov Support or eRA Service Desk staff can only respond about NIH requirements. This will not help you and may in fact make an issue worse if you decide to follow advice based on NIH requirements.

2.14.1 VA-ORD Help for Application Preparation and Submission

Your VAMC R&D Office must submit all inquiries/problems concerning application submissions to the **VA-ORD eRA Mailbox in Outlook** (vhacordera.vhacordera@va.gov). This is not a communication mechanism for individual investigators to by-pass the VAMC R&D Office and communicate directly with VA-ORD staff.

If you directly contact individuals at VA-ORD (by phone or email) and 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.

2.14.2 Finding Help for Grants.gov Registration

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

Grants.gov Support: <http://www.grants.gov/web/grants/support.html>

Grants.gov Self-Service Web Portal: <https://grants-portal.psc.gov/Welcome.aspx?pt=Grants>

Grants.gov Help Desk: support@grants.gov

Grants.gov Contact Center Phone Number: 1-800-518-4726 (Toll Free); 606/545-5035 (Local or International)

Grants.gov Support is available 24 hours a day, 7 days a week (except Federal holidays).

2.14.3 Finding Help for eRA Commons Registration or eRA Commons Validation Processes

Contact the eRA Service Desk ONLY concerning **problems with eRA Commons registration** process for the VAMC and PD/PIs or with **logging on to eRA Commons**. eRA customer support is also provided by eRA Commons Service Desk:

eRA Website: <http://era.nih.gov>

eRA Commons Website: <https://commons.era.nih.gov/commons/index.jsp>

eRA Commons On-line Resources and Web Ticketing: <http://grants.nih.gov/support>

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

eRA Service Desk hours of operation are Monday-Friday from 7:00 a.m. to 8:00 p.m. Eastern Time (except Federal Holidays).

NOTE: To help expedite your eRA Service Desk request, we recommend that you have the following information readily available (NOTE: Additional details may be required depending upon the type of issue/request):

- Full Name of Affected User
- Full Name of VAMC
- Grants.gov Tracking Number
- Due Date
- FOA/RFA Number and Title
- Principal Investigator's (PD/PI) Username
- Signing Official's (SO) Username

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

3.1 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. Applications that are not consistent with these instructions will be withdrawn from the review process.

As you navigate through SF424 forms, required fields are highlighted in yellow and outlined in red. Optional fields and completed fields are displayed in white. **However, there may be required fields for VA-ORD applications that are not highlighted in yellow and outlined in red.**

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 obtain a new application and start over.

Do NOT cut and paste from any other program (i.e., WORD or ePROMISE) to complete fields on SF424 forms; the font may not transfer correctly and may cause erroneous characters (e.g., “&”, “i” or “□”) to be introduced. Check the final e-Application carefully for such errors.

3.2 SF424 (R&R) Form

<input type="button" value="View Burden Statement"/>		OMB Number: 4040-0001 Expiration Date: 10/31/2019	
APPLICATION FOR FEDERAL ASSISTANCE SF 424 (R&R)		3. DATE RECEIVED BY STATE	State Application Identifier
1. TYPE OF SUBMISSION <input checked="" type="checkbox"/> Pre-application <input type="checkbox"/> Application <input type="checkbox"/> Changed/Corrected Application		4. a. Federal Identifier	
2. DATE SUBMITTED		b. Agency Routing Identifier	
Applicant Identifier		c. Previous Grants.gov Tracking ID	
5. APPLICANT INFORMATION			
Legal Name:		Organizational DUNS:	
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:	
Position/Title:			
Street1:		Street2:	
City:		County / Parish:	
State:		Province:	
Country: USA: UNITED STATES		ZIP / Postal Code:	
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 <input type="checkbox"/> Women Owned <input type="checkbox"/> Socially and Economically Disadvantaged			
8. TYPE OF APPLICATION:		If Revision, mark appropriate box(es).	
<input type="checkbox"/> New <input type="checkbox"/> Resubmission		<input type="checkbox"/> A. Increase Award <input type="checkbox"/> B. Decrease Award <input type="checkbox"/> C. Increase Duration <input type="checkbox"/> D. Decrease Duration	
<input type="checkbox"/> Renewal <input type="checkbox"/> Continuation <input type="checkbox"/> Revision		<input type="checkbox"/> E. Other (specify):	
Is this application being submitted to other agencies?		Yes No What other Agencies?	
9. NAME OF FEDERAL AGENCY:		10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER:	
TITLE:		TITLE:	
11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT:			
12. PROPOSED PROJECT:		13. CONGRESSIONAL DISTRICT OF APPLICANT	
Start Date Ending Date		Start Date Ending Date	

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”, “Resubmission”, “Renewal”, or “Revision” application for the same review cycle, click the **Changed/Corrected Application** box and enter the Grants.gov tracking number in the Previous Grants.gov Tracking ID field. [See Section 2.10 Correcting Errors](#) for guidance.

Note: Not all Services accept Renewal applications or for all types of awards.

Pre-Application: Unless specifically noted in a FOA/RFA, the Pre-Application option is not used.

Application: All initial submissions for a given review cycle, regardless of the type of application marked in Box 8 (i.e., New, Resubmission or Renewal), should be designated an “Application”.

Changed/Corrected Application: **Prior to the application due date**, this box must be used if you need to submit the same application again to correct system validation errors, application assembly problems, or to incorporate other changes identified by the PD/PI or SO during the 2-day application viewing window. [See Section 2.10 Correcting Errors](#) for guidance.

2. Date Submitted and Applicant Identifier

In **Date Submitted** field **will auto-populate upon application submission**. For the **Applicant Identifier** field, enter the control numbers created by your VAMC R&D Office. This identifier should be used to identify which version of an application is being submitted.

3. Date Received by State and State Application Identifier

Leave these fields blank.

4.a. Federal Identifier

For applications marked “New” in Box 8, leave this field blank.

For “Resubmission” or “Renewal” applications, enter only the 2-letter Service designation and serial number from the previously assigned application/award number (e.g., use BX987654 from 1I01BX987654-01A1) even if submitting a Changed/Corrected application. **Do NOT** include any other portion of the previous application number (e.g., 1I01- or -01A1).

You must use the correct previous application number – entering the wrong Federal Identifier will prevent the system from processing your application or will mis-identify it as belonging to another investigator or project. Applications submitted with another investigator’s previous application number will not be accepted for review.

4.b. Agency Routing Identifier

Box 8 Type of Application	Box 1 Type of Submission	Box 4a Federal Identifier	Box 4b Agency Routing Identifier	Box 4c Previous Grants.gov Tracking ID
New	Application	Leave Blank	Enter the VAMC Station number and city (e.g., 673-Tampa). A Center name may also be included.	Leave blank
New	Changed/Corrected Application	Leave Blank	Enter the VAMC Station number and city (e.g., 673-Tampa). A Center name may also be included.	Grants.gov tracking ID (e.g., GRANT123456) from previous submission*
Resubmission or Renewal [^]	(New) Application	Application number assigned to the previous submission (e.g., BX123456) ‡#	Enter the VAMC Station number and city (e.g., 673-Tampa). A Center name may also be included.	Leave Blank
Resubmission or Renewal [^]	Changed/Corrected Application	Application number assigned to the previous submission (e.g., BX123456) ‡#	Enter the VAMC Station number and city (e.g., 673-Tampa). A Center name may also be included.	Grants.gov tracking ID (e.g., GRANT123456) from previous submission*

* Grants.gov Tracking IDs can be obtained from your AOR/SO.

‡ Applicant Numbers can be obtained from the previous Summary Statement.

Include only the 2-letter 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 Services accept renewal applications or for all types of awards.

4.c. Previous Grants.gov Tracking ID

Enter the previous Grants.gov tracking number, if you checked the Changed/Corrected Application box for Type of Submission. Obtain the previous Grants.gov Tracking ID (example, GRANT12345678) from your AOR/SO.

5. Applicant Information

This information is for the VAMC, not a specific individual (PD/PI).

Field Name	Instructions
Organizational DUNS	Enter your VAMC's DUNS or DUNS+4 number. This field is required. This DUNS must match the number entered in eRA Commons Institutional Profile (IPF) for your VAMC . The AO is encouraged to confirm that a DUNS has been entered in eRA Commons IPF prior application submission. In the application, the same DUNS should be used in eRA Commons IPF, Grants.gov and SAM registrations, and in this DUNS field.
Legal Name	Enter the legal name of your VAMC . Enter the complete address of the VAMC (including county and country), and name, telephone number, email, and fax of the person to contact on matters related to this application.

Field Name	Instructions
Department	Enter the name of the primary organizational department, service, laboratory, or equivalent level within your VAMC that will undertake the assistance activity.
Division	Enter the name of the primary organizational division, office, or major subdivision within your VAMC that will undertake the assistance activity.
Street1	Enter the first line of the street address of your VAMC. This field is required.
Street2	Enter the second line of the street address of your VAMC, if applicable. This field is optional.
City	Enter the city for address of your VAMC. This field is required.
County/Parish	Enter the county/parish for address of your VAMC.
State	Enter the state where your VAMC is located.
Province	Leave this blank.
Country	Select United States.
ZIP Code	Enter the ZIP+4 (nine-digit Postal Code) of your VAMC. This field is required.

Person to be contacted on matters involving this application:

This information is for the AO at your VAMC, not the PD/PI or his/her designee. This 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 name of the person to contact on matters related to this application.
First Name	Enter the first (given) name of the person to contact on matters related to this application. This field is required.
Middle Name	Enter the middle name of the person to contact on matters related to this application.
Last Name	Enter the last (family) name of the person to contact on matters related to this application. This field is required.
Suffix	Enter the suffix (e.g., Jr., Sr., Ph.D.) for the person to contact on matters related to this application.

Field Name	Instructions
Position/Title	Enter the Position/Title for the person to contact on matters related to this application.
Street 1	Enter the first line of the street address for the person to contact on matters related to this application in "Street1" field. This field is required.
Street 2	Enter second line of the street address for the person to contact on matters related to this application. This field is optional.
City	Enter the city for the person to contact on matters related to this application. This field is required.
County/Parish	Enter the county/parish for the person to contact on matters related to this application.
State	Enter the State where the person to contact on matters related to this application is located. This field is required.
Province	Leave this blank.
Country	Select United States. This field is required.
ZIP Code	Enter the ZIP+4 (nine-digit Postal Code) for the person to contact on matters related to this application. This field is required.
Phone Number	Enter the daytime phone number for the person to contact on matters related to this application.
Fax Number	Enter the fax number for the person to contact on matters related to this application.
Email	Enter the email address for the person to contact on matters related to this application. This field is required.

6. Employer Identification (Required Field)

Enter the Taxpayer Identification Number (TIN) or Employer Identification Number (EIN) as assigned by the Internal Revenue Service. 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 **VAMC**, not a specific individual AOR/SO or PD/PI.

Field Name	Instructions
Type of Applicant	Select X: Other (specify).
Other (Specify)	Enter "VA-ORD".

Field Name	Instructions
Woman Owned	Do NOT use.
Socially and Economically Disadvantaged	Do NOT use.

8. Type of Application (Required Field)

		Box 8 for Each Submission			
Type of Application	Initial	Second (-A1)	Third (-A2)	Next	
New	New	Resubmission	Resubmission	New	
Renewal	Renewal	Resubmission	Resubmission	New	

Field Name	Instructions
Type of Application	<p>Select the type from the following list. Check only one:</p> <ul style="list-style-type: none"> • New: An application that is being submitted to VA-ORD for the first time. • 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 of e-Applications must be marked as “Resubmission” in Box 8; all others must be marked as “New”. • 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 e-Application should be marked as “Renewal”; applications for renewal of a previously funded non-e-Application must be marked as “New”. <u>An application may be marked as “Renewal” for only the initial submission;</u> the two (2) successive submissions must be marked as “Resubmission”. After three (3) unsuccessful submissions (initial + 2 resubmissions), a “New” application must be submitted. <p><i>*Note:</i> Not all Services accept renewal applications or for all types of awards.</p> <ul style="list-style-type: none"> • Continuation: VA-ORD does not accept Continuation applications. Do NOT check this box. • Revision: VA-ORD does not accept Revision applications. Do NOT check this box.
Is this application being submitted to other agencies?	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. This field is required.
What Other Agencies?	Enter the other Federal agency name(s). Include private foundations, etc.

9. Name of Federal Agency

This field is auto-populated from the opportunity package (“Office of Research and Development”).

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

This field is auto-populated from the opportunity package with the Catalog of Federal Domestic Assistance (CFDA) number and Title of the program under which assistance is requested.

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 once the application is assigned to the appropriate Service.

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

Enter a descriptive title of the project that matches the content/subject matter of the application.

The title length is limited to 200 characters, including the spaces between words and punctuation. Titles in excess of 200 characters will be truncated by the system. Use only standard characters: A through Z, a through z, numbers 0 (zero) through 9. Dashes, apostrophes, and colons may be used. **Do NOT** cut and paste from any other program (i.e., WORD or ePROMISE) to enter the title; the font may not transfer correctly and may cause erroneous characters (e.g., “&”, “i” or “□”) to be introduced. Carefully check your title in the final e-Application for such errors.

A “new” application must have a different title from any other VA-ORD project submitted for the same application due date 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, a new title reflecting these changes should be used.

Title changes: If an Intent to Submit (ITS) or Letter of Intent (LOI) is a required step in the submission process, you **MUST** check with the appropriate Service (see Service-specific FOA/RFAs for appropriate staff contact(s) for each Service) before changing the title in the application from that submitted for the ITS or LOI.

12. Proposed Project (in MM/DD/YYYY format) (Required Fields)

Start Date: Enter the proposed start date of the project.

Ending Date: Enter the proposed ending date of the project.

Be careful entering these dates. Once entered, the SF424 (R&R) Form may not allow you to change or edit them.

13. Congressional District of Applicant (Required Field)

Enter the Congressional District for your VAMC named in Box 5 Applicant Information in the following 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

SF 424 (R&R) APPLICATION FOR FEDERAL ASSISTANCE

<p>14. PROJECT DIRECTOR/PRINCIPAL INVESTIGATOR CONTACT INFORMATION</p> <p>Prefix: <input type="text"/> First Name: <input type="text"/> Middle Name: <input type="text"/></p> <p>Last Name: <input type="text"/> Suffix: <input type="text"/></p> <p>Position/Title: <input type="text"/></p> <p>Organization Name: <input type="text"/></p> <p>Department: <input type="text"/> Division: <input type="text"/></p> <p>Street1: <input type="text"/></p> <p>Street2: <input type="text"/></p> <p>City: <input type="text"/> County / Parish: <input type="text"/></p> <p>State: <input type="text"/> Province: <input type="text"/></p> <p>Country: <input type="text"/> USA: UNITED STATES ZIP / Postal Code: <input type="text"/></p> <p>Phone Number: <input type="text"/> Fax Number: <input type="text"/></p> <p>Email: <input type="text"/></p>	
<p>15. ESTIMATED PROJECT FUNDING</p> <p>a. Total Federal Funds Requested <input type="text"/></p> <p>b. Total Non-Federal Funds <input type="text"/></p> <p>c. Total Federal & Non-Federal Funds <input type="text"/></p> <p>d. Estimated Program Income <input type="text"/></p>	<p>16. IS APPLICATION SUBJECT TO REVIEW BY STATE EXECUTIVE ORDER 12372 PROCESS?</p> <p>a. YES <input type="checkbox"/> THIS PREAPPLICATION/APPLICATION WAS MADE AVAILABLE TO THE STATE EXECUTIVE ORDER 12372 PROCESS FOR REVIEW ON: DATE: <input type="text"/></p> <p>b. NO <input type="checkbox"/> PROGRAM IS NOT COVERED BY E.O. 12372; OR <input type="checkbox"/> PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW</p>
<p>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 penalties. (U.S. Code, Title 18, Section 1001)</p> <p><input checked="" type="checkbox"/> I agree</p> <p><small>*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.</small></p>	
<p>18. SFLLL (Disclosure of Lobbying Activities) or other Explanatory Documentation</p> <p><input type="text"/></p> <p style="text-align: right;"> <input type="button" value="Add Attachment"/> <input type="button" value="Delete Attachment"/> <input type="button" value="View Attachment"/> </p>	
<p>19. Authorized Representative</p> <p>Prefix: <input type="text"/> First Name: <input type="text"/> Middle Name: <input type="text"/></p> <p>Last Name: <input type="text"/> Suffix: <input type="text"/></p> <p>Position/Title: <input type="text"/></p> <p>Organization: <input type="text"/></p> <p>Department: <input type="text"/> Division: <input type="text"/></p> <p>Street1: <input type="text"/></p> <p>Street2: <input type="text"/></p> <p>City: <input type="text"/> County / Parish: <input type="text"/></p> <p>State: <input type="text"/> Province: <input type="text"/></p> <p>Country: <input type="text"/> USA: UNITED STATES ZIP / Postal Code: <input type="text"/></p> <p>Phone Number: <input type="text"/> Fax Number: <input type="text"/></p> <p>Email: <input type="text"/></p> <p style="text-align: center;"> <input type="text"/> <input type="text"/> Signature of Authorized Representative Date Signed </p>	
<p>20. Pre-application</p> <p><input type="text"/></p>	<input type="button" value="Add Attachment"/> <input type="button" value="Delete Attachment"/> <input type="button" value="View Attachment"/>
<p>21. Cover Letter Attachment</p> <p><input type="text"/></p>	<input type="button" value="Add Attachment"/> <input type="button" value="Delete Attachment"/> <input type="button" value="View Attachment"/>

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 Zip Code+4 to search; if your zip code is part of multiple districts, you will be asked to enter your address. 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 PD/PI is the individual responsible for the overall scientific and technical direction of the project. If submitting an application reflecting Multiple PD/PIs, the individual designated as the Contact PI must be affiliated in eRA Commons with the VAMC (entered in Box 5. Applicant Information) and entered here. **All PD/PIs must include their respective eRA Commons ID in the [Credential](#) field of the Senior/Key Person Profile(s) Form.** See [Section 3.5 Senior/Key Person Profile](#) form for additional instructions for Multiple PD/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 eRA Commons. **All PD/PIs must meet the eligibility requirement(s) of the Service being applied to.**

Field Name	Instructions
Prefix	Enter or select the prefix (Mr., Mrs., Dr., or Rev.) for the name 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 (family) name of the PD/PI. This field is required.
Suffix	Enter or select the suffix (e.g., Jr., Sr., or III) for the name of the PD/PI, if applicable. Do not use this field to record degrees (i.e., Ph.D., M.D., etc.). Degrees for the PD/PI are requested separately in the Senior/Key Person Profile(s) form.
Position/Title	Enter the position and title of the PD/PI at the VAMC. This information is used to auto-populate the Senior/Key Person Profile for the PD/PI.
Organization Name	Enter the name of the VAMC 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 VAMC for the PD/PI.
Division	Enter the name of the primary organizational division, office, or major subdivision within the VAMC for 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 for address of the PD/PI. This field is required.
County/Parish	Enter the county/parish for address of the PD/PI.
State	Enter the State where the PD/PI is located. This field is required.
Province	Leave this blank.
Country	Select United States.

Field Name	Instructions
ZIP Code	Enter the ZIP+4 (nine-digit Postal Code) of the PD/PI. This field is required.
Phone Number	Enter the daytime telephone number for the PD/PI. This field is required.
Fax Number	Enter the fax number for the PD/PI.
Email	Enter the email address for the PD/PI. This field is required.

15. Estimated Project Funding (Required Fields)

Field Name	Instructions
a. Total Federal Funds Requested	Enter total VA-ORD funds requested for the entire project period. This must match the value for Section G, Direct Costs (A thru F) on the Cumulative Budget .
b. Total Non-Federal Funds	Enter \$0 (zero).
c. Total Federal & Non-Federal Funds	This field will be the same value as entered for item 15a.
d. Estimated Program Income	Enter \$0 (zero) unless program income may/has result(ed) from a technology, etc., that was licensed, then enter the anticipated/known dollar amount and provide a description of the income source in the Budget Justification.

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

Check the “No” box for ‘Program is not covered by E.O. 12372’.

17. Certification (Required Field)

Check “I agree” 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. SFLLL (Disclosure of Lobbying Activities) or Other Explanatory Documentation

If applicable, attach SFLLL or other explanatory documents per FOA/RFA instructions.

19. Authorized Representative (Required Field)

This is equivalent to the Authorized Organization Representative (AOR in Grants.gov) or Signing Official (SO in eRA Commons) – the individual in the VAMC with authority to sign for an application.

Field Name	Instructions
Prefix	Enter or select the prefix (e.g., Mr., Mrs., or Rev.) for the AOR/SO.
First Name	Enter the first (given) name of the AOR/SO. This field is required.

Field Name	Instructions
Middle Name	Enter the middle name of the AOR/SO.
Last Name	Enter the last (family) name of the AOR/SO. This field is required.
Suffix	Enter or select the suffix (e.g., Jr., Sr., or III.) for the AOR/SO.
Position/Title	Enter the title of the AOR/SO. This field is required.
Organization	Enter the name of the VAMC or VA Health Care System for the AOR/SO. This field is required.
Department	Enter the name of the primary organizational department, service, laboratory, or equivalent level within the VAMC for the AOR/SO.
Division	Enter the name of the primary organizational division, office, or major subdivision within the VAMC for the AOR/SO.
Street1	Enter the first line of the street address for the AOR/SO. This field is required.
Street2	Enter the second line of the street address for the AOR/SO, if applicable.
City	Enter the city for the address of the AOR/SP. This field is required.
County/parish	Enter the county/parish for the address of the AOR/SO.
State	Enter the state where the AOR/SO is located. This field is required.
Province	Leave this blank.
Country	Select United States.
ZIP Code	Enter the ZIP+4 (nine-digit postal code) of the AOR/SO. This field is required.
Phone Number	Enter the daytime phone number for the AOR/SO. This field is required.
Fax Number	Enter the fax number for the AOR/SO.
Email	Enter the email address for the AOR/SO. This field is required.
Signature of Authorized Representative	Grants.gov will record the electronic signature for the AOR/SO who submits the application. It is the VAMC's responsibility to assure that only properly authorized individuals sign in this capacity and/or submits the application to Grants.gov.
Date Signed	Grants.gov will generate this date upon application submission. Do NOT manually enter anything in this box.

20. Pre-Application

Do NOT add any attachments. Pre-Applications are not a part of VA-ORD's submission process. **NOTE:** HSR&D uses a separate "Intent to Submit (ITS)" process and RR&D uses a

“Letter of Intent (LOI),” both of which must be submitted and approved before an application will be accepted for review. BLR&D and CSR&D do not require LOIs except for Career Development Awards, Clinical Trials and Epidemiology applications. Check the Service-specific FOA/RFA for details on submitting an ITS or LOI for approval.

21. Cover Letter Attachment

Do NOT add any attachments. Cover letters are not a part of VA-ORD’s submission process.

3.3 Project/Performance Site Locations Form

View Burden Statement

OMB Number: 4040-0010
Expiration Date: 10/31/2019

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)

Do NOT cut and paste from any other program (i.e., WORD or ePROMISE) to complete fields on SF424 forms; the font may not transfer correctly and may cause erroneous characters (e.g., “&”, “i” or “□”) to be introduced. Carefully check the final e-Application for such errors.

Project/Performance Site Primary Location (Required Fields)

Unless otherwise instructed in a FOA/RFA, **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.

Indicate the primary site where the work will be performed - the Primary Location is generally the submitting VAMC identified in Box 5. Applicant Information of the SF424 (R&R) Form.

An off-site primary location is only permitted if a full off-site waiver (see [VHA Handbook 1200.16 Off-Site Research](#)) has been approved in advance of the submission; see Deadline, Review, and Award Dates Table in each Service-specific FOA/RFA for waiver request deadlines. A copy of the full off-site waiver approval letter must be included in [Letters of Support](#) in Item.12 [Other Attachments](#) of the [Other Project Information](#) form.

If a portion of the project will be performed at any other site(s), including other VA facilities or academic affiliates, list all performance sites in the fields provided for Location 1 - # below. A secondary or other performance site is a VA facility or academic affiliate where some of the research activity occurs; the site PD/PI must meet eligibility requirements as stated in the Service-specific FOA/RFA. Each performance site must be listed, even if a full or partial off-site waiver has been approved. An explanation of resources available from each Project/Performance Site in [Item 10. Facilities and Resources](#) of the Other Project Information form should be provided.

If a Project/Performance Site is engaged in research involving human subjects, the submitting VAMC 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 requirements for the protection of human subjects in research ([VHA Handbook 1200.05](#), amended June 29, 2017) 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 VAMC must ensure that all Project/Performance Sites comply with [VA policies on the use of animals](#) in research, as described in [Part II. Assurances and Certifications](#).

Field Name	Instructions
Organization Name	Enter the name of the primary performance 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 block(s) provided.
DUNS Number	Enter the DUNS or DUNS+4 number associated with the primary performance site where the project will be performed.
Street1	Enter the first line of the street address of the primary performance site location.
Street2	Enter the 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.
County/Parish	Enter the county or parish of the primary performance site location.

Field Name	Instructions
State	Enter the state where the primary performance site is located. This field is required.
Province	Leave this blank.
Country	Select United States.
ZIP Code	Enter the ZIP+4 (nine-digit postal code) of the primary performance site location. This field is required.
Project/Performance Site Congressional District	<p>Enter the Congressional District in the format: 2 character State Abbreviation – 3 character District Number. <i>Examples: CA-005 for California’s 5th district, CA-012 for California’s 12th district.</i></p> <p>If all districts in a state are affected, enter “all” for the district number. <i>Example: MD-all for all congressional districts in Maryland.</i></p> <p>If nationwide (all districts in all states), enter U.S.-all.</p> <p>If the program/project is outside the U.S., enter 00-0000.</p> <p>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.</p> <p>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”.</p> <p>For jurisdictions with a nonvoting delegate, enter “098” for the district number. <i>Example: DC-098, PR-098.</i></p>

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 or DUNS+4 number associated with the organization where the project will be performed.
Street1	Enter the first line of the street address of the performance site location.
Street2	Enter the second line of the street address of the performance site location, if applicable.
City	Enter the city of the performance site location.
State	Enter the state where the performance site is located. This field is required.
Province	Leave this blank.
Country	Select the name of the country for the performance site location.
ZIP Code	Enter the ZIP+4 (nine-digit postal code) of the performance site location. This field is required.

Field Name	Instructions
Project/Performance Site Congressional District	<p>Enter the Congressional District in the format: 2 character State Abbreviation – 3 character District Number. <i>Examples: CA-005 for California’s 5th district, CA-012 for California’s 12th district.</i></p> <p>If all districts in a state are affected, enter “all” for the district number. <i>Example: MD-all for all congressional districts in Maryland.</i></p> <p>If nationwide (all districts in all states), enter U.S.-all.</p> <p>If the program/project is outside the U.S., enter 00-0000 (all zeros).</p> <p>To locate your congressional district, visit the Grants.gov web site. It is likely this field will be identical to the “Congressional District of Applicant” field.</p> <p>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. <i>Example: DC-098, PR-098.</i></p>

For additional performance site locations, click **Next Site** to display the fields for Project/Performance Site Locations 2 through 300. The **Next Site** button appears once Site Location 1 is completed.

If you need to add more than 300 locations (primary plus 299 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 300 locations is found under “Additional Format Pages” at: <http://vaww.research.va.gov/funding/electronic-submission.cfm>.

3.4 Research and Related Other Project Information Form

RESEARCH & RELATED Other Project Information

OMB Number: 4040-0001
Expiration Date: 10/31/2019

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 7 8

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 - positive or negative - 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

8. Project Narrative

9. Bibliography & References Cited

10. Facilities & Other Resources

11. Equipment

12. Other Attachments

Do NOT cut and paste from any other program (i.e., WORD or ePROMISE) to complete fields on SF424 forms; the font may not transfer correctly and may cause erroneous characters (e.g., “&”, “i” or “□”) to be introduced. Carefully check the final e-Application for such errors.

1. Are Human Subjects Involved? (Required Field)

Check “Yes” if:

- Activities involving human subjects are planned at any time during the proposed project at any performance site.

- Tissues (e.g., biopsies, banked material, or whole organs) or samples (i.e., blood, sputum, etc.) from human subjects will be used
- The proposed project is exempt from Regulations for the Protection of Human Subjects.

NOTE: If “Yes” is checked, a [Human Subjects attachment](#) must be provided in Item 12. Other Attachments below. Refer to [Part II, Supplemental Instructions for Human Subjects Research Requirements](#).

Check “No” if:

- Established or commercial human cell lines will be used.
- No activities involving human subjects are planned and skip the rest of block 1.

1.a. If YES to Human Subjects

Is project exempt from Federal Regulations? Yes/No

Check “No” even if the Institutional Review Board (IRB) review is complete and a determination of exemption status has been made by the IRB. **Do NOT** check any of the exemption 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?

Check “Yes” even if the IRB review/approval process has not yet begun at the time of submission. If you check “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

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](#) (JIT) compliance requirement.

Human Subject Assurance Number

Enter the approved Federal Wide Assurance (FWA) Number that the VAMC has on file with the Office for Human Research Protections, if available. Enter only the 8-digit number. **Do NOT** enter “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 VAMC and VA-ORD may be ignored.

2. Are Vertebrate Animals Used? (Required Field)

Check “Yes” if activities involving vertebrate animals are planned at any time during the proposed project at any performance site.

If “Yes” is checked, a [Vertebrate Animals attachment](#) must be provided in Item 12. Other Attachments. Note that the generation of custom antibodies constitutes an activity involving vertebrate animals.

Check “No” if no activities involving vertebrate animals are planned and skip the rest of block 2.

2.a. If YES to Vertebrate Animals

Is the IACUC review Pending?

Check “Yes” if an Institutional Animal Care and Use Committee (IACUC) review has not been completed (or has not yet begun at the time of submission).

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.

Check “No” if the IACUC review has been completed. The “[IACUC Approval Date](#)” and “[Animal Welfare Assurance Number](#)” (see below) will then become required fields.

IACUC Approval Date

Enter the latest IACUC approval date if the IACUC review has been completed. If the IACUC review is pending, leave this field blank.

Animal Welfare Assurance Number

Enter the Federally approved assurance number, if available.

To determine if your VAMC holds an Animal Welfare Assurance, see <http://grants.nih.gov/grants/olaw/assurance/300index.htm>. [VHA Handbook 1200.07](#) Use of Animals in Research, requires that VAMCs 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-ORD Policy on use of vertebrate animals](#).

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

Patentable ideas, copyright, trade secrets, privileged or confidential commercial or financial information, disclosure of which may harm you (as 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 as applicable, 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. Environmental Questions (4a and 4c are Required Fields)

Check “No” in 4.a. and 4.c. unless a Service-specific FOA/RFA indicates that the National Environmental Policy Act (NEPA) applies. Leave 4.b and 4.d blank.

4.a. Does the project have an actual or perceived impact—positive or negative—on the environment?

Check “No”.

4.b. If yes, please explain.

Leave blank.

4.c. If this project has an actual or perceived impact on the environment, has an exemption been authorized or an Environmental Assessment (EA) or an Environmental Impact Statement (EIS) been performed?

Check “No”.

4.d. If yes, please explain.

Leave blank.

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

Check “No”.

5.a. If Yes, please explain.

Leave blank.

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. Otherwise, check “No”.

6.a. If yes, identify countries. (Required Field if Question 6 is “Yes”)

Enter the countries with which international cooperative activities are involved.

6.b. Optional Explanation

Leave blank, unless Question 6 is “Yes”, then 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. Other Attachments below.

7. Project Summary/Abstract (Required Field)

The Project Summary/Abstract is meant to serve as a succinct and accurate description of the proposed work and should be able to stand on its own 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. **This section must be no longer than 40 lines of text, and follow required [font](#) and [margin](#) specifications. This is a system validation.**

Do NOT begin the Project Summary with the extra words that state: “Project Summary” or “Abstract” – this is not needed as the file will be bookmarked internally by eRA.

Do NOT duplicate or include the relevance statement provided in Item 8. Project Narrative.

Do NOT include proprietary, confidential information or trade secrets in the Project Summary. If the application is funded, the Project Summary will become public information.

Click the **Add Attachment** button to the right of this field to complete this entry. The attachment must be in PDF format. See [Section 2.4](#) for guidance on creating and formatting PDF attachments.

8. Project Narrative (Required Field)

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. If the application is funded, this public health relevance statement will be combined with the Project Summary (above) and will become public information. **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 will be bookmarked internally by eRA.

Do NOT duplicate or include the narrative text in Item 7. Project Description.

Click the **Add Attachment** button to the right of this field to complete this entry. The attachment must be in PDF format. See [Section 2.4](#) for guidance on creating and formatting PDF attachments.

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

Include all references cited in the [Research Plan](#) attachment. The references 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. **This is a system validation - applications exceeding the 4-page limit will receive an error message in eRA.** If an error message is received it must be corrected before the application will be accepted within eRA. For references with more than three (3) authors, you may use “et al” after the 3rd author has been listed.

Applications that do not include full references (i.e., title, authors, etc., as indicated above) will not be accepted for review.

NOTE: When using a reference software to generate the bibliography and references cited document (i.e., EndNote, etc.), if subsequent changes are made in application documents, references may become misaligned as a result. You are encouraged to carefully review all references cited for accuracy and correct order within the e-Application prior to final submission.

Internet website addresses (URLs), may be included in this attachment. Please note that reviewers are under no obligation to view supplemental material, moreover, reviewers are cautioned that they should not directly access an Internet site as it could compromise their anonymity.

When including links in the Bibliography & References Cited, spell the URL out in full, beginning with ‘http://’ (e.g., <http://grants.nih.gov/grants/oer.htm>). **Do NOT include the link as hyperlinked text (e.g., [NIH Grants Web page](#)) as eRA system processing will not retain the active link in the assembled application image in eRA Commons.**

An example of how one could cite a web-based resource such as CDC without including a URL is provided below:

Centers for Disease Control and Prevention, National Centers for Injury Prevention and Control. Web-based Injury Statistics Query and Reporting System (WISQARS) [online]. (2005) {cited Year Month (abbreviated) Day}.

Click the **Add Attachment** button to the right of this field to complete this entry.

10. Facilities & Other Resources (Required Field)

No special form/format is required for this attachment. VA performance sites must be clearly identified as VA (not just a room and building number). **Leased space must be clearly identified as VA leased space.** 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](#) in 12. Other Attachments below.

Click the **Add Attachment** button to the right of this field to complete this entry.

11. Equipment

List major items of equipment already available for this project and, if appropriate, identify location and pertinent capabilities.

Click the **Add Attachment** button to the right of this field to complete this entry.

12. Other Attachments

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](#).

NOTE: Attachments for Appendices 10, 11, 12... etc., must be uploaded in the order in which you wish each to appear in the final e-Application.

Click on “**Add Attachments**” in Item 12 to open the first pop-up window.

Click “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 file names for Attachments 1 – 9 are **mandatory** and may not be changed. **Altered file names will cause an error to be generated – this is a system validation.** Only the descriptor in the file names for Appendices 10, 11, 12... may be changed. Altering any other part of the file name may result in parts of your application being excluded from the final electronic image that the reviewers receive or for the attachments to appear in the wrong order.

To check for the correct ordering of attachments, review the Bookmarks and Table of Contents (ToC) within the final e-application image - do not view the attachment file names on the Other Project Information form as it may not present a correct final listing of the appendices.

A set of templates, with mandatory file names for each attachment, is available on the VA-ORD intranet site (<http://vaww.research.va.gov/funding/electronic-submission.cfm>). Information for each attachment in Item 12. must be saved in a single PDF file and attached. See [Section 2.4](#) Creating and Formatting (Text) PDF Attachments. VA-ORD general attachment page limits are noted below, however, you should check the Service-specific FOA/RFA for any exceptions.

Attachment and Required File Name	Instructions
<p>1. Introduction to Revised Application (for Resubmissions only) <i>01_VA_Intro.pdf</i></p>	<p>Use only if you are submitting a Resubmission application (SF424 (R&R) Form Item 8) for a previously reviewed e-Application submitted through Grants.gov.</p> <p>Page Limit: See the Service-specific FOA/RFA.</p> <p><u>Do NOT</u> include URLs in the Introduction.</p>
<p>2. Specific Aims <i>02_VA_Specific_Aims.pdf</i></p>	<p>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.</p> <p>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.</p> <p>Page Limit: 1 page.</p> <p><u>Do NOT</u> include URLs in the Specific Aims.</p>
<p>2a. Research Plan <i>02a_VA_Research_Plan.pdf</i></p>	<p>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.</p> <p>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.</p> <p>Additional and/or alternate sections/headings may be required for certain FOA/RFAs. Each Service will provide specific instructions about the required headings and content for the Research Plan in its posted FOA/RFAs.</p> <p>Page Limit: See the Service-specific FOA/RFA.</p> <p><u>Do NOT</u> repeat the Specific Aims in the Research Plan.</p> <p><u>Do NOT</u> include the Progress Report for renewal applications in the Research Plan.</p>

Attachment and Required File Name	Instructions
2a. Research Plan (continued)	Do NOT include URLs in the Research Plan.
2b. VA Career Plan o2b_VA_Career_Plan.pdf	Please see specific Career Development Award FOA/RFAs for guidance on the use of this attachment.
2c. Mentoring Plan o2c_VA_Mentoring_Plan.pdf	Please see specific Career Development Award FOA/RFAs for guidance on the use of this attachment.
3. Progress Report o3_VA_Prog_Report_Pubs.pdf	<p>A Progress Report must be included for all <u>renewal</u> 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.</p> <p>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 FOA/RFAs may indicate that this attachment is not required.</p> <p>Do NOT include URLs or PMC submission identification numbers for publicly available citations; copies of these publications are not accepted as appendix material.</p> <p>Do NOT include unpublished theses or abstracts/ manuscripts submitted, but not accepted for publication.</p> <p>Page Limit: See the Service-specific FOA/RFA.</p>
4. Human Subjects o4_VA_Human_Subjects.pdf	<p>This attachment is required if you checked “Yes” for Question 1 (Are Human Subjects Involved?) on the Other Project Information form. This section covers the information regarding the Protection of Human Subjects. Refer to Part II for additional information on Human Subjects Research Requirements.</p> <p>Do NOT include protocol in this appendix. Address only the requested issues noted below.</p> <p>In this attachment, use the following headings and fully describe:</p> <ol style="list-style-type: none"> 1. Risk to Subjects. <ul style="list-style-type: none"> • <i>Human Subjects Involvement and Characteristics.</i> Describe the anticipated number, age range, and health status of the subject population. Identify the

Attachment and Required File Name	Instructions
<p>4. Human Subjects (continued)</p>	<p>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.</p> <p>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.</p> <ul style="list-style-type: none"> • <i>Sources of Materials.</i> 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. • <i>Potential Risks.</i> Describe the potential risks to subjects (physical, psychological, social, legal, or other) and assess their likelihood and seriousness to the subjects. Differentiate therapeutic risk from research risk. <p>2. Adequacy of Protection from Risk</p> <ul style="list-style-type: none"> • <i>Recruitment and Informed Consent.</i> Describe plans for the recruitment of subjects and the process for obtaining informed consent. NOTE: The informed consent document may not be submitted at this time; if the application is selected for funding, it will be requested as a part of the JIT process. • <i>Protection Against Risk.</i> 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. <p>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.</p> <p>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.</p>

Attachment and Required File Name	Instructions
4. Human Subjects (continued)	<p>The inclusion of women, minorities and/or children must be addressed. Research involving children must be reviewed by the Institutional Review Board (IRB) for its relevance to VA and must not be greater than minimal risk. The VAMC Director must approve participation of children in proposed research. (See VHA Handbook 1200.05)</p>
<p>5. Vertebrate Animals <i>o5_VA_Animals.pdf</i></p>	<p>An attachment addressing the following four key points is required if you checked “Yes” for Question 2 (Are Vertebrate Animals Used?) on the Other Project Information form.</p> <p>When research involving vertebrate animals will take place at other performance site(s), provide this information before discussing the four points. Although there is no specific page limitation, be succinct.</p> <p><u>Do NOT</u> include a copy of the ACORP.</p> <ol style="list-style-type: none"> 1. Provide a concise description of the procedures proposed to be carried out in the animals. Identify the species, strains, ages, sex, and total number of animals to be used in the proposed work. If dogs, cats or primates are proposed, provide the source of the animals. 2. Justify the choice of species for the proposed research, and explain why the research goals cannot be accomplished using an alternative model (e.g., computational, human, invertebrate, <i>in vitro</i>). 3. Describe the interventions to be used, including the use of analgesia, anesthesia, sedation, palliative care and humane endpoints, to minimize discomfort, distress, pain, and injury. 4. State whether the method of euthanasia is consistent with the recommendations of the American Veterinary Medical Association Guidelines for the Euthanasia of Animals. If not, describe the method and provide a scientific justification.
<p>6. Multiple PD/PI Leadership Plan <i>o6_VA_Multiple_PI.pdf</i></p>	<p>A leadership plan is required if more than one individual is assigned the role of PD/PI in the Senior/Key Person Profile. Non-VA investigators may not be assigned the PD/PI role.</p> <p>A rationale for choosing a multiple PD/PI approach should be described. The governance and organizational structure of the PD/PI leadership team should be described, as well as the knowledge, skills and experience of the individual PD/Pis, including communication plans and procedures for resolving conflicts. The shared authority and responsibility for the administrative, technical, and scientific responsibilities for directing the project or program should</p>

Attachment and Required File Name	Instructions
6. Multiple PD/PI Leadership Plan (continued)	<p>be delineated for the PIs. Each PD/PI is responsible and accountable to the VA for the proper conduction of the project or program, including the submission of all required reports. The use of multiple PD/Pis must not be used to avoid budget caps (restrictions) described in any VA-ORD FOA/RFA. Investigators should discuss the inclusion of multiple PD/Pis with appropriate Service staff prior to submission of their application.</p>
7. Consortium/Contractual Agreements 07_VA_Agreements.pdf	<p>This attachment should only be used to describe existing consortium or contractual agreements that are relevant to the proposed research.</p> <p>Do NOT include costs for additional performance sites of multi-site projects here.</p> <p>Do NOT include IPAs here.</p> <p>Explain the programmatic, fiscal, and administrative arrangements that exist between the VAMC and any consortium or contractual organization(s).</p> <p>New consortium or contractual agreements will not be considered binding to VA contractually.</p>
8. Director’s Letter 08_VA_Director_Letter.pdf	<p>A signed (e-signature accepted) and dated (within the last year) copy of a letter of support from the VAMC Director is required must include the following:</p> <ul style="list-style-type: none"> • A statement that the Director understands the impact of the proposed research on the facility’s organization and that he/she endorses the project. • Where the research will be conducted, if any off-site waivers are included with the application, and that the VA space described in the application and necessary support of the VA facility will be available. • If a clinician PD/PI’s appointment is to start at the time of funding, the 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. <p>NOTE: For multiple PD/PI applications where the PIs are at different VAMCs, a letter from <u>each</u> VAMC Director is required.</p> <p><u>Applications submitted without this attachment will not be accepted for review.</u></p>
8a. R&D Committee Letter 08a_VA_R_D_Committee_letter.pdf	<p>See specific FOA/RFAs for guidance on the use of this attachment.</p>

Attachment and Required File Name	Instructions
<p>8b. Letters of Support o8b_VA_Letters_of_Support.pdf</p>	<p>Attach appropriate letters (scanned and submitted as a single PDF document) from all individuals confirming their roles in the project and rate/charge for consulting services. If applicable, include copies of approval letters for LOIs/ITS, eligibility, off-site waivers, and/or exceeding budget caps (per year or total)/duration.</p> <p>All letters of support are expected to be dated within 12 months of the date of submission. Therefore, NEW letters of support may be needed for one or more of the allowable resubmission applications.</p> <p><u>Do NOT include Biosketches in this attachment.</u></p>
<p>9. Data Management and Access Plan o9_VA_DMAP.pdf</p>	<p>All proposals for VA research must include a data management and access plan (DMAP) for research results. For VA-ORD DMAP guidance and REQUIRED template (Version: 7/29/2016): http://www.research.va.gov/funding/default.cfm.</p> <p><u>Applications submitted without this attachment will not be accepted for review.</u></p>
<p>10,11, 12... Appendices 10_VA_Appendix_1_descriptor.pdf 11_VA_Appendix_2_descriptor.pdf 12_VA_Appendix_3_descriptor.pdf (additional attachments as needed: same file name format)</p> <p>For Appendix names only: 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.</p>	<p>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.</p> <p>REQUIRED ATTACHMENTS: See the Service-specific FOA/RFA to which you are applying for guidance.</p> <p><u>Do Not use appendices or other sections (e.g., human subjects, vertebrate animals, etc.) to circumvent any stated page limits. An application that utilizes appendices or other sections to circumvent the stated page limits will be administratively withdrawn and not reviewed.</u></p> <p>These documents must be uploaded in the order in which you wish them to appear in the e-application.</p> <p>Appendices must be named using the following convention in the following order:</p> <ul style="list-style-type: none"> • Appendix number, starting with 10, then 11, 12, etc. • Underscore • The phrase “VA_Appendix” • Underscore

Attachment and Required File Name	Instructions
10,11, 12... Appendices (continued)	<ul style="list-style-type: none"> • Appendix number starting with 1, then 2, 3, etc. • Underscore • Brief description of the contents (e.g., Abbreviations, Accepted Manuscripts, Patents); place a space between words if a multiple word descriptor is used. NOTE: If using ASSIST, the system will automatically change a space to an underscore between each word in a multiple word descriptor file name. • “.pdf” <p>Unless otherwise specified in the FOA/RFA, the first appendix should be an alphabetized list of abbreviations used in the application with the following file name: “10_VA_Appendix_1_Abbreviations.pdf.”</p> <p>Similar appendix material should be combined within an attachment. For example, please place all accepted, but not yet published, manuscripts in one attachment.</p> <ul style="list-style-type: none"> • Up to 3 of the following types of publications: <ul style="list-style-type: none"> ○ Manuscripts accepted for publication but <u>not yet published</u>. ○ Manuscripts published, but a free, online, <u>publicly available journal link is not available</u>. <u>Do Not</u> include published manuscripts that have a free, publicly available online journal. ○ Patents <u>directly relevant to the project</u>. ○ Chapters from review or textbooks. • Surveys, questionnaires, data collection instruments, clinical protocols, and informed consent documents may be submitted. Do NOT include Informed Consent forms even if already approved by the IRB. • Do NOT include photographs or color images of gels, micrographs, etc. These images must be included in the Research Plan (see the Service-specific FOA/RFA for Research Plan page limit). Images embedded in publications are still allowed. • Do NOT include unpublished theses or abstracts/manuscripts that have been submitted but not yet accepted for publication.

3.5 Research and Related Senior/Key Person Profile(s) Form

OMB Number: 4040-0001
Expiration Date: 10/31/2019

RESEARCH & RELATED Senior/Key Person Profile (Expanded)

PROFILE - Project Director/Principal Investigator	
Prefix: <input type="text"/>	* First Name: <input type="text"/> Middle Name: <input type="text"/>
* Last Name: <input type="text"/>	Suffix: <input type="text"/>
Position/Title: <input type="text"/>	Department: <input type="text"/>
Organization Name: <input type="text"/>	Division: <input type="text"/>
* Street1: <input type="text"/>	
Street2: <input type="text"/>	
* City: <input type="text"/>	County/ Parish: <input type="text"/>
* State: <input type="text"/>	Province: <input type="text"/>
* Country: USA: UNITED STATES	* Zip / Postal Code: <input type="text"/>
* Phone Number: <input type="text"/>	Fax Number: <input type="text"/>
* E-Mail: <input type="text"/>	
Credential, e.g., agency login: <input type="text"/>	
* Project Role: <input type="text"/>	Other Project Role Category: <input type="text"/>
Degree Type: <input type="text"/>	
Degree Year: <input type="text"/>	
* Attach Biographical Sketch <input type="text"/>	<input type="button" value="Add Attachment"/> <input type="button" value="Delete Attachment"/> <input type="button" value="View Attachment"/>
Attach Current & Pending Support <input type="text"/>	<input type="button" value="Add Attachment"/> <input type="button" value="Delete Attachment"/> <input type="button" value="View Attachment"/>

PROFILE - Senior/Key Person 1	
Prefix: <input type="text"/>	* First Name: <input type="text"/> Middle Name: <input type="text"/>
* Last Name: <input type="text"/>	Suffix: <input type="text"/>
Position/Title: <input type="text"/>	Department: <input type="text"/>
Organization Name: <input type="text"/>	Division: <input type="text"/>
* Street1: <input type="text"/>	
Street2: <input type="text"/>	
* City: <input type="text"/>	County/ Parish: <input type="text"/>
* State: <input type="text"/>	Province: <input type="text"/>
* Country: USA: UNITED STATES	* Zip / Postal Code: <input type="text"/>
* Phone Number: <input type="text"/>	Fax Number: <input type="text"/>
* E-Mail: <input type="text"/>	
Credential, e.g., agency login: <input type="text"/>	
* Project Role: <input type="text"/>	Other Project Role Category: <input type="text"/>
Degree Type: <input type="text"/>	
Degree Year: <input type="text"/>	
Attach Biographical Sketch <input type="text"/>	<input type="button" value="Add Attachment"/> <input type="button" value="Delete Attachment"/> <input type="button" value="View Attachment"/>
Attach Current & Pending Support <input type="text"/>	<input type="button" value="Add Attachment"/> <input type="button" value="Delete Attachment"/> <input type="button" value="View Attachment"/>

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 forms; the font may not transfer correctly and may cause erroneous characters (e.g., “&”, “¿” or “□”) to be introduced. Check the final e-Application carefully for such errors.

This form provides the ability to collect structured data for up to 100 Senior/Key Persons. Data must be entered for the first 100 individuals (PD/PI +99 others) before the Additional Senior/Key Person Profile(s) Form Attachments section becomes available. The information for the PD/PI continues to be auto-populated from the SF424 (R&R) Form. See instructions in [Section 3.2](#) SF424 (R&R) if these fields are empty.

Unless otherwise specified in a 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 PD/Pis

Multiple PD/Pis are accepted for most award activity codes. **Check the Service-specific FOA/RFA to which you are applying to make sure that multiple PD/Pis are permitted.** When submitting an application involving Multiple PD/Pis, the Contact PI must be listed as the PD/PI in Box 14 of the SF424 (R&R) Form (see [Section 3.2.14](#)). That information auto-populates the first Senior/Key Person Profile record in this form. For the additional PD/Pis, complete all the requested information. Each PD/PI must be assigned the PD/PI role, even those at other performance sites, when applicable. **The “Co-PD/PI” or “Co-PI” role cannot be used to designate Multiple PD/Pis. Non-VA investigators may not be assigned the PD/PI role.**

If multiple PD/Pis are designated, in SF424 R&R Other Project Information, Item 12. Other Attachments, a [Multiple PD/PI Leadership Plan](#), is required.

Each PD/PI must be registered as an investigator in 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 application records). **Each PD/PI must include their respective eRA Commons ID in the Credential field. This data must be consistent with the Commons ID in the ePROMISE investigator profile (Page 18).**

When completing the Summary Budget Worksheet (SBW) and Budget Justification (see [Section 3.7](#) Summary Budget Worksheet and R&R Budget Form) for either the primary site or other performance sites, the project roles listed in these documents must be consistent with those used in the Senior/Key Person Profile(s) form (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	Auto-populated from the SF424 (R&R). The prefix (e.g., Mr., Mrs., or Rev.) for the name of the PD/PI.
First Name	Auto-populated from the SF424 (R&R). The first (given) name of the PD/PI. This field is required.
Middle Name	Auto-populated from the SF424 (R&R). The middle name of the PD/PI.
Last Name	Auto-populated from the SF424 (R&R). The last (family) name of the PD/PI. This field is required.
Suffix	Auto-populated from the SF424 (R&R). 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. Ph.D., M.D., etc.). This information is included in Degree Type.
Position/Title	Auto-populated from the SF424 (R&R). The title of the PD/PI.
Department	Auto-populated from the SF424 (R&R). The name of primary organizational department, service, laboratory, or equivalent level within the VAMC of the PD/PI.
Organization Name	Auto-populated from the SF424 (R&R). The name of the VAMC or VA Health Care System of the PD/PI.
Division	Auto-populated from the SF424 (R&R). The name of primary organizational division, office, or major subdivision of the PD/PI.
Street1	Auto-populated from the SF424 (R&R). The first line of the street address for the PD/PI in the “Street1” field. This field is required.
Street2	Auto-populated from the SF424 (R&R). The second line of the street address for the PD/PI, if applicable, in the “Street2” field. This field is optional.
City	Auto-populated from the SF424 (R&R). The city for the address of the PD/PI. This field is required.
County/Parish	Auto-populated from the SF424 (R&R). The county/parish for the address of the PD/PI.
State	Auto-populated from the SF424 (R&R). The state where the PD/PI is located. This field is required.
Province	Leave this blank.
Country	Auto-populated from the SF 424 (R&R). Select United States. This field is required.
ZIP Code	Auto-populated from the SF 424 (R&R). The ZIP+4 (nine-digit postal code) of the PD/PI. This field is required.
Phone Number	Auto-populated from the SF 424 (R&R). The daytime phone number for the PD/PI. This field is required.

Field Name	Instructions
Fax Number	Auto-populated from the SF 424 (R&R). The fax number for the PD/PI.
Email	Auto-populated from the SF 424 (R&R). The email address for the PD/PI. This field is required.
Credential, e.g., agency login	Registration in eRA Commons is required for all PD/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. Applications with missing or incorrect Commons IDs will not pass VA-ORD validation requirements. This field is required.
Project Role	PD/PI must be typed in this field. Do Not type “PI” or “PI/PD” or “Principal Investigator” etc., as entering anything other than “PD/PI” will cause an error.
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. This is optional information.
Degree Year	Enter the year the highest degree or other credential was obtained. This is optional information.
Attach Biographical Sketch	Provide a biographical sketch for the PD/PI. The OMB No. 0925-0001 and 0925-0002, Biographical Sketch (Rev. 10/15 Approved Through 10/31/2018) or (Rev. 09/17 Approved Through 03/31/2020) MUST be used (Biographical Sketch Format Page and Biographical Sketch Sample); see additional instructions below . Versions of the form that cannot be verified as the correct format, will NOT be accepted, and if included, the application will be withdrawn from review. Note: Biographical Sketch form (Rev. 10/15 Approved Through 10/31/2018) may continue to be used through October 31, 2018. Save the information in a single file and attach by clicking Add Attachment.
Attach Current & Pending Support	This information is required for the Contact PD/PI listed in Box 14 of the SF424 (R&R) Form at the time of application submission. Refer to Other Support in Part III. Policies, Assurances, Definitions, and Other Information.

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 saved and uploaded. Individuals with a postdoctoral role should be included if they meet the definition of Senior/Key Personnel. All VA personnel (paid and without compensation) with calendar months’ effort greater than zero, even if no salary is requested, must be included in the Senior/Key Person Profile(s) Form, the last row of Section B (Other Personnel) of the R&R Budget Form, and in the SBW totals.

Also use this section to list any [Other Significant Contributors \(OSCs\)](#) after all Senior/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”. Individuals with measurable effort cannot be listed as OSCs.

All individuals serving as consultants or IPAs (non-VA personnel), if they meet the Senior/Key Person or OSC definition, should be included on the Senior/Key Person Profile(s) Form and also included on Line 8, Section F (not under Section B. Other Personnel) of the R&R Budget Form and in the SBW totals. Individuals providing services through a service contract should not be included on the Senior/Key Person Profile(s) Form.

A biosketch, including Research Support information, will be required for all Senior/Key persons and OSCs as this highlights their accomplishments as scientists. Reviewers use these pages to address the “investigator” review criterion.

After providing data for each individual Senior/Key Person (the following instructions also apply to OSCs), 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 100 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 100 Senior/Key Persons, the “Additional Senior/Key Person Profiles” fields will become available once data for the first 100 Senior/Key Persons has been provided. (see [instructions](#) below).

Field Name	Instructions
Prefix	Enter or select the prefix (e.g., Mr., Mrs., or Rev.) for 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	Enter or select the suffix (e.g. Jr., Sr., III.) for the Senior/Key Person. Do Not use this field to indicate degrees (i.e., Ph.D., M.D., etc.).
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. This field is required.
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.

Field Name	Instructions
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	Leave this blank.
Country	Enter the country for the Senior/Key Person address. This field is required.
ZIP Code	Enter the Zip+4 (nine-digit postal 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.
Credential, e.g., agency login	For applications involving Multiple PD/Pis , registration in eRA Commons is required for all PD/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. Commons ID is optional for all other Senior/Key Personnel. Applications with missing or incorrect Commons ID's will not pass VA-ORD validation requirements. This field is required.
Project Role	Select one. 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”. For applications involving Multiple PD/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 PD/Pis. 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. Make sure that the selected role matches the role noted in the SBW and Budget Justification documents. Be sure to include Senior/Key Persons identified in any other performance sites.
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. This is optional information.
Degree Year	Enter the year the highest degree or other credential was obtained. This is optional information.

Field Name	Instructions
Attach Biographical Sketch	<p>Provide a biographical sketch for each Senior/Key Person. The OMB No. 0925-0001 and 0925-0002, Biographical Sketch (Rev. 10/15 Approved Through 10/31/2018) or (Rev. 09/17 Approved Through 03/31/2020) MUST be used (Biographical Sketch Format Page and Biographical Sketch Sample); see additional instructions below. Versions of the form that cannot be verified as the correct format, will NOT be accepted, and if included, the application will be withdrawn from review. NOTE: Biographical Sketch form (Rev. 10/15 Approved Through 10/31/2018) may continue to be used through October 31, 2018.</p> <p>Save the information in a single file and attach by clicking Add Attachment.</p>
Attach Current & Pending Support	<p>This information is required at the time of application submission. Refer to Other Support in Part III. Policies, Assurances, Definitions, and Other Information. A separate Current & Pending Support attachment should be provided for each Senior/Key Person and OSC.</p> <p>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.</p>

Additional Senior/Key Person Profile(s)

If more than 99 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 100 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 ([Biographical Sketch Format Page](#) and [Biographical Sketch Sample](#)) for each Senior/Key Person included in the Additional Senior/Key Person Profile(s) form attachment above. Save the information in a single file and attach. The OMB No. 0925-0001 and 0925-0002, Biographical Sketch (Rev. 10/15 Approved Through 10/31/ 2018 OR Rev. 09/17 Approved Through 3/31/2020), **MUST be used. Other versions of the form will NOT be accepted, and if included, the application will be withdrawn from review. Do NOT alter the Biographical Sketch template by removing the OMB header or other template information** – if VA-ORD staff is unable to verify that the correct template format has been used, the application will be withdrawn from review. **NOTE:** Biographical Sketch form (Rev. 10/15 Approved Through 10/31/2018) may continue to be used through October 31, 2018.

Additional Current and Pending Support

Provide a list of all current and pending support for the PD/PI and each Senior/Key Person (even if they receive no salary support from the project(s) for ongoing projects and pending applications). 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 an application to other organizations will not prejudice its review.

This information is required at the time of application submission for all Senior/Key Persons, including 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 Instructions for a Biographical Sketch (not to exceed five pages per person)

Use the sample *format* ([Biographical Sketch Sample](#)) to prepare this section for **all** applications. **Include biographical sketches for all Senior/Key Personnel and OSCs. The 5-page limit includes the table at the top of the first page.**

If an individual is registered in eRA Commons, include the assigned eRA 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 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, B, C, and D as described below:

- A. Personal Statement.** Briefly describe why you are well-suited for your role in the project described in this application. The relevant factors may include aspects of your training; your previous experimental work on this specific topic or related topics; your technical expertise; your collaborators or scientific environment; and your past performance in this or related fields (you may mention specific contributions to science that are not included in Section C). Also, you may identify up to four peer reviewed publications that specifically highlight your experience and qualifications for this project. If you wish to explain impediments to your past productivity, you may include a description of factors such as family care responsibilities, illness, disability, and active duty military service.
- B. Positions and Honors.** List in chronological order previous positions, concluding with the present position. List any honors. Include present membership on any Federal Government public advisory committee.
- C. Contribution to Science.** Briefly describe up to five of your most significant contributions to science. For each contribution, indicate the historical background that frames the scientific problem; the central finding(s); the influence of the finding(s) on the progress of science or the application of those finding(s) to health or technology; and your specific role in the described work. For each of these contributions, reference up to four peer-reviewed publications or other non-publication research products (can include audio or video products; patents; data and

research materials; databases; educational aids or curricula; instruments or equipment; models; protocols; and software or netware) that are relevant to the described contribution. The description of each contribution should be no longer than one half page including figures and citations.

Complete List of Published Work in MyBibliography:

You may also provide a URL to a full list of your published work as found in a publicly available digital database such as SciENev or My Bibliography, which are maintained by the U.S. National Library of Medicine.

Internet website addresses (URLs), may be included in this attachment. When including links in the Biographical Sketch, spell out the URL in full, beginning with ‘http://’ (e.g., <http://grants.nih.gov/grants/oer.htm>). Do NOT include the link as hyperlinked text (e.g., [NIH Grants Web page](#)) as eRA system processing will not retain the active link in the assembled application image in eRA Commons. Reminder: Internet website addresses (URLs) are only allowed in the Biographical Sketches and the Bibliography & References Cited documents. URLs should not be included in any other areas of the application or the application will be withdrawn from review.

D. Additional Information: Research Support and/or Scholastic Performance. List both selected ongoing and completed research projects for the past three years (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 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.

Scholastic Performance

Predoctoral applicants/candidates (including undergraduates and post-baccalaureates): List by institution and year **all** undergraduate and graduate courses, with

grades. In addition, explain any grading system used if it differs from a 1-100 scale; an A, B, C, D, F system; or a 0-4.0 scale. Also indicate the levels required for a passing grade.

Postdoctoral applicants: List by institution and year **all** graduate scientific and/or professional courses with grades. In addition, explain any grading system used if it differs from a 1-100 scale; an A, B, C, D, F system; or a 0-4.0 scale. Also indicate the levels required for a passing grade.

3.6 Selecting the Appropriate Budget Form

The application forms package associated with VA-ORD funding opportunities are the Research and Related (R&R) Budget Form and the Summary Budget Worksheet (contained within the Budget Justification Section L). The SF424 (R&R) Budget Form must be used for all VA-ORD applications. VA-ORD does not use or accept modular budgets (i.e., PHS 398 Modular Budget Form).

3.7 Summary Budget Worksheet and Research and Related Budget Form

The **Summary Budget Worksheet (SBW; ver. 6.30.17)** is an Excel table designed to maximize the amount of budget information provided in a consolidated worksheet, facilitate budget evaluation by showing the entire budget “at a glance”, and simplify submission of multi-site budgets. Only a few cells highlighted in yellow in the SBW must be transferred to corresponding sections of the R&R Budget Form and most other cells of the R&R Budget Form can be left blank. The SBW includes a section for each site of a multi-site project. Complete only the worksheet tab corresponding to the number of project sites (i.e., single site, up to 5 sites, or up to 20 sites). Leave cells blank or enter “0” (zero) for extra sites or budget periods. It is recommended that the PD/PI fill out the SBW **first** and then the R&R Budget Form.

The **R&R Budget Form** (SF424) includes three separate data entry screens: (1) Sections A and B; (2) Sections C through E; and (3) Sections F through L. Enter data into the R&R Budget Forms following guidance in this SF424 and instructions provided within the submission system being used (Workspace or ASSIST). **You must complete a separate budget for each year of support requested.** The form will automatically generate a cumulative budget for the **total project period**.

If no funds are requested for a required field (as indicated by yellow highlight), **enter “0” (zero)**. For **fields that are not required** and when no funds are being requested, leave the field **BLANK**. All dollar fields should be presented in whole numbers and rounded to the nearest whole dollar.

Follow these instructions to complete Budget Period 1. If funds are being requested for more than one budget period, follow the submission system guidance (Workspace or ASSIST) to navigate to form for the next budget period. Follow same instructions for subsequent budget periods.

You must complete all the required information (i.e., those fields that are highlighted in yellow, outlined in red) and save your data as instructed within the submission system guidance (Workspace or ASSIST). For any new application package, information entered onto the budget forms will auto-populate successively for each budget period (i.e., budget information from Period 1 will auto-populate Period 2, and budget information from Period 2 will auto-populate Period 3, etc.). On the SBW, Budget Period 1 information will auto-populate into Periods 2-4 for all budget categories except Equipment and Travel. Auto populated information, such as dates, must be manually updated for each budget period.

You must observe the limitations on budget caps and durations noted in the Service-specific FOA/RFA. If an application requests a duration or amount that exceeds the caps specified in an FOA/RFA, the application may not be accepted for review.

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

3.7.1 Sections A and B

RESEARCH & RELATED BUDGET - Budget Period 1
Delete Period
OMB Number: 4040-0001
Expiration Date: 10/31/2019

A

ORGANIZATIONAL DUNS: Enter name of Organization:

Budget Type: Project Subaward/Consortium Budget Period: 1 Start Date: End Date:

A. Senior/Key Person

Prefix	First	Middle	Last	Suffix	Base Salary (\$)	Months			Requested Salary (\$)	Fringe Benefits (\$)	Funds Requested (\$)
						Cal.	Acad.	Sum.			
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Project Role: <input type="text"/>											

Additional Senior Key Persons: Total Funds requested for all Senior Key Persons in the attached file:

Total Senior/Key Person:

B. Other Personnel

Number of Personnel	Project Role	Months			Requested Salary (\$)	Fringe Benefits (\$)	Funds Requested (\$)
		Cal.	Acad.	Sum.			
<input type="text"/>	Post Doctoral Associates	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	Graduate Students	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	Undergraduate Students	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	Secretarial/Clerical	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Total Number Other Personnel Total Other Personnel:

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

B

Organizational DUNS (Required Field)

Enter the DUNS or DUNS+4 number of your VAMC. For project budgets, this field is auto-populated from the SF424 (R&R) Form.

Enter name of Organization

This field is auto-populated from the SF424 (R&R) Form, 5. Application Information, Legal Name (NOTE: Changes to the organization’s legal name in this field on the budget form can only be made on the SF424 (R&R) Form). Also enter the name of the VAMC on the SBW.

Budget Type (Required Field)

Check the box labeled Project. VA-ORD does not use Subaward/Consortium budgets using the R&R forms.

Budget Period (Required Field)

Identify the specific budget period (e.g., 1, 2, 3, 4, 5). Follow the submission system guidance for generating a cumulative budget for the total project period.

Start Date (Required Field)

Auto-populated from the SF424 (R&R) Form. Enter the requested/proposed start date of each budget period. Use MM/DD/YYYY format. NOTE: For budget periods 2-5, the project start date is auto-populated from Period 1 and must be manually updated to reflect the correct budget period (year).

End Date (Required Field)

Enter the requested/proposed end date of each budget period. Use MM/DD/YYYY format. NOTE: For budget periods 2-5, the project end date is auto-populated from Period 1 and must be manually updated to reflect the correct project budget period (year).

A. Senior/Key Person

This section should include **only one name of a single PD/PI** for the application. **Do NOT** select the “Add Additional Key Person” or “Add Attachment” buttons. Multiple PD/PIs should be designated under [Section 3.5 Senior/Key Person Profile\(s\) Form](#) and in the roles of the Personnel Section of the Budget Justification. All additional VA personnel effort should be included in Section B. Salary support for non-VA personnel may not be requested in Section A or B. **IPA (Intergovernmental Personnel Act), contract, and consultant effort and costs must be identified under [Section F, Line 8, Other Direct Costs](#)** (not under Section B. Other Personnel).

Non-clinicians may request all or part of their VA-paid salary, depending upon the VA-ORD Service to which they are applying to (see Service-specific FOA/RFAs for what is allowed). Increases in salary over years to account for cost of living (COLA) or salary increases (maximum of 2% per year) may be requested in budget periods 2-5 for all VA personnel, but will be adjusted in accordance with Office of Personnel Management approved salary rates in any given calendar year and

anticipated personnel actions (e.g., within grade increases). PD/PIs cannot be paid through IPA agreements.

Do NOT request clinician salary (VA or non-VA) or salary for Nurses or Licensed Medical Professionals (Hybrid Title 38 occupations with clinical appointments) in VA-ORD research budgets.

To calculate calendar months for VA-paid personnel or personnel with a joint appointment use the following table (**use only VA hours worked and VA time spent on the project**). Enter calendar months effort on the SBW and retype on the SF424 (R&R) Budget Form.

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 Sections A and B of the Research and Related budget page multiply the “Percent effort” 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.

Special Instructions: Joint University and VA Appointments.

Calendar months for VA investigators must be based on the VA 40-hour 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.**

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.

Field Name	Instructions
Prefix / Degree	Summary Budget Worksheet: Enter highest professional degree. R&R Budget Form: Enter or select the prefix (e.g., Mr., Mrs., or Dr.) for the name of the PD/PI.
First Name	Summary Budget Worksheet: Not applicable. R&R Budget Form: Enter the first (given) name of the PD/PI. This field is required.
Middle Name	Summary Budget Worksheet: Not applicable. R&R Budget Form: Enter the middle name of the PD/PI, if applicable.
Last Name	Summary Budget Worksheet: Not applicable. R&R Budget Form: Enter the last (family) name of the PD/PI. This field is required.
Suffix	Summary Budget Worksheet: Not applicable. R&R Budget Form: Enter or select the suffix (for example, Jr., Sr., III) of the PD/PI. Do not use this field to indicate degrees (e.g., M.D. or Ph.D.).
Base Salary (\$)	R&R Budget Form: Leave blank; however, VA-ORD may request this information prior to award.
Cal. Months / Cal. Mo.	Calendar months for all investigators with a VA-paid appointment must be based on the VA 40-hr workweek (e.g., 5/8 th appointment = 25 hrs/wk = 7.5 months). See special instructions above for joint VA-University appointments. Summary Budget Worksheet: Enter the number of calendar months devoted to the project for PD/PI for Year 1. R&R Budget Form: Enter the number of calendar months devoted to the project for PD/PI.
Acad. Months	Do not use.
Sum. Months	Do not use.
Requested Salary (\$) / PI Salary	Summary Budget Worksheet: Indicate the amount of salary being requested for each budget period for the PD/PI. R&R Budget Form: Retype the PD/PI salary from the SBW. This field is required.
Fringe Benefits (\$) / PI Fringe	For current VA personnel, actual fringe benefits may be requested. Summary Budget Worksheet: Enter applicable fringe benefits for the PD/PI each budget period. R&R Budget Form: Retype the PD/PI fringe from the SBW.
Funds Requested (\$)	Summary Budget Worksheet: Not applicable. R&R Budget Form: The requested salary and fringe benefits for the PD/PI. This field is auto-calculated.
Project Role	Summary Budget Worksheet: Not applicable. R&R Budget Form: Identify only the individual serving as the PD/PI. The role of the PD/PI is auto-populated <u>only in Budget Period 1</u> . Do not change or edit this field.

Field Name	Instructions
Project Role continued	<p>VA-ORD does not recognize the term Co-PI, thus Co-PD/PI or Co-PI cannot be used to designate multiple PDs/Pis. If this is a multiple PD/PI application (MPI), list the individual serving as the primary contact for the project in this section. The multiple PD/Pis should be included in Section B, and will be identified by name in the Budget Justification.</p> <p>Budget Justification: List the name, role (PD/PI), associated calendar months, grade, step, eighths, salary and fringe benefits requested. Note variation in effort and costs across budget periods. Describe duties. Do not repeat information about expertise available in the Biosketch.</p>
Additional Senior/Key Persons	<p>Summary Budget Worksheet: Not applicable.</p> <p>R&R Budget Form: Leave blank. Include additional personnel in Section B.</p>
Total Funds requested for all Senior/Key Persons in the attached file	<p>Summary Budget Worksheet: Not applicable.</p> <p>R&R Budget Form: Leave blank. Include additional personnel in Section B.</p>
Total Senior/Key Persons	<p>Summary Budget Worksheet: Not applicable.</p> <p>R&R Budget Form: The total funds requested for the PD/PI will auto-calculate.</p>

B. Other Personnel

The last row of Section B should include all **VA personnel** involved in the project, except the PD/PI named in Section A. Include VA salaried and Without Compensation (WOC) appointments, whether or not salary support is requested on the project.

Do NOT include costs or effort of personnel contributing through IPA agreements, contracts, or as consultants in this section. These individuals cannot be VA-salaried employees. Individuals paid as a consultant, through a contract for services or an IPA **MUST** be included on the SBW under Other Direct Costs and reported in [“Other Direct Costs” Section F, Line 8](#), of the SF424 (R&R) Budget Form.

Field Name	Instructions
Number of Personnel/ # unique staff	<p>Summary Budget Worksheet: List the number of unique VA personnel contributing (current or to-be-hired) during the lifetime of the project in second to last column.</p> <p>R&R Budget Form: In the last row of Section B, retype the number of unique VA personnel proposed. Leave all other rows blank.</p> <p>Budget Justification: Individually list names, roles and duties, associated calendar months, grade, step, eighths, salary and fringe benefits requested. Note variation in effort across budget periods. Do NOT repeat information about personnel expertise available in the Biosketch. Role should correspond to the role on the Senior/Key Person Profile(s) (Expanded) Form.</p>
Project Role	<p>Summary Budget Worksheet: Not applicable.</p> <p>R&R Budget Form: In the last row under project role, enter “unique VA personnel”. Leave all other rows blank.</p>

Field Name	Instructions
Cal. Months / Cal. Mo.	<p>Summary Budget Worksheet: List the total calendar months of effort devoted to the project for VA personnel during year one of the project. Provide separate subtotals for VA personnel already hired and to-be-hired. Do NOT include IPA or contract personnel.</p> <p>R&R Budget Form: In the last row, retype the total calendar months effort of all VA personnel during the budget period.</p>
Acad. Months	Do not use.
Sum. Months	Do not use.
Requested Salary (\$) / Hired Salary or TBH Salary	<p>Non-clinicians may request all or part of their VA-paid salary, depending upon the Service to which they are applying (see Service-specific FOA/RFAs for what is allowed). Increases in salary over years to account for cost of living adjustments or salary increases (maximum of 2% per year) may be requested in years 2-5 for all VA-paid personnel, but will be adjusted in accordance with Office of Personnel Management approved salary rates in any given calendar year and anticipated personnel actions (e.g., within grade increases).</p> <p>Salary support is not authorized for any licensed medical professional with a clinical appointment in VA unless a waiver has been granted by the Chief Research and Development Officer (CRADO). If waived, salary support is allowed only for services beyond usual care. Physicians and dentists and, in most cases, nurses may not receive salaries from the medical research and prosthetics appropriation. Physicians and dentists who are not licensed to practice in the United States may request salary, but they must be clearly identified as such in the Budget Justification section.</p> <p>If any participant in the research is a Research Career Scientist or Career Development Awardee, list the calendar months effort the person will devote to the proposed research, but do NOT include salary in the budget.</p> <p>Clerical support may not be included as study personnel unless the support provided can be justified as necessary to the conduct of the research.</p> <p>Do NOT include costs for tuition remission for graduate students, or graduate student stipends in this section; these costs are not permitted in VA-ORD budgets. Although graduate students may be paid as technicians, they must be listed as such in the budget.</p> <p>Summary Budget Worksheet: List the funds requested for salary for each budget period for all VA personnel regardless of the number of months being devoted for the project. Provide separate subtotals for VA personnel already hired and to-be-hired.</p> <p>R&R Budget Form: In the last row, retype the salary/wages being requested for VA personnel from “Total Other Personnel” on the SBW. Leave all other rows blank.</p>
Fringe Benefits (\$) / Hired Fringe or TBH Fringe	<p>For current VA-employees, actual fringe benefits may be requested. For to-be-hired positions, fringe benefits may not exceed 30%.</p> <p>Summary Budget Worksheet: List funds requested for fringe for each project budget period. Provide separate subtotals for VA personnel already hired and to-be-hired.</p> <p>R&R Budget Form: In the last row, retype the fringe benefits being requested for VA personnel from “Total Other Personnel” on the</p> <p>Summary Budget Worksheet. Leave all other rows blank.</p>

Field Name	Instructions
Funds Requested	Summary Budget Worksheet: Not applicable. R&R Budget Form: This total will auto-calculate.
Total Number of Other Personnel	Summary Budget Worksheet: Not applicable. R&R Budget Form: This total will auto-calculate.
Total Other Personnel	Summary Budget Worksheet: Not applicable. R&R Budget Form: The total funds requested for all other Personnel will auto-calculate.
Total Salary, Wages and Fringe Benefits (A+B) / Total Personnel	Summary Budget Worksheet: The value for "Total Personnel" will auto-calculate. It should match the value automatically calculated for Total Salary, Wages and Fringe Benefits (A+B) on the R&R Budget Form . If these two values do not match, recheck your work.

To navigate to the next page (Sections C through E), click the “**Next**” button at the top of the SF424 (R&R) Budget Form or use the scroll bar on the left-hand side of the screen.

The information for Organizational DUNS, Budget Type, Name of Organization, and Start and End Dates is auto-populated 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.

3.7.2 Sections C through E

C. Equipment Description

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

Equipment item	Funds Requested (\$)
<input type="text"/>	<input type="text"/>
<input type="button" value="Add Additional Equipment"/>	
Additional Equipment: <input type="text"/>	
<input type="button" value="Add Attachment"/>	
<input type="button" value="Delete Attachment"/>	
<input type="button" value="View Attachment"/>	
Total funds requested for all equipment listed in the attached file	<input type="text"/>
Total Equipment	<input type="text"/>

D. Travel

	Funds Requested (\$)
1. Domestic Travel Costs (Incl. Canada, Mexico and U.S. Possessions)	<input type="text"/>
2. Foreign Travel Costs	<input type="text"/>
Total Travel Cost	<input type="text"/>

E. Participant/Trainee Support Costs

	Funds Requested (\$)
1. Tuition/Fees/Health Insurance	<input type="text"/>
2. Stipends	<input type="text"/>
3. Travel	<input type="text"/>
4. Subsistence	<input type="text"/>
5. Other <input type="text"/>	<input type="text"/>
<input type="text"/> Number of Participants/Trainees	
Total Participant/Trainee Support Costs	<input type="text"/>

On the **SBW**, expenses under these categories will be reported and included in the total reported in [Section F, Line 8](#) of the R&R Budget Form.

On the **R&R Budget Form**, Sections C through E should be left blank.

In the **Budget Justification**, the instructions below describe the level of detail required for the costs and associated rationale for each category of expense. While the total dollar amount for all direct costs is reported in Section F, Line 8, within the Budget Justification narrative, costs should be itemized with appropriate detail for each item to justify inclusion in the project budget.

C. Equipment Description

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. Multiple small items may not be combined to meet the \$5,000 minimum cost and may not be included in this category.

Equipment consists of relatively permanent fixed assets that are essential to the completion of the proposed research and should be purchased in the first year of the project. Requests for equipment in Years 2-3 will be considered if well justified, and only under unusual circumstances.

Ordinarily, allowable items will be limited to research equipment and apparatus not already available for the conduct of the work. General-purpose equipment is not eligible for support unless primarily or exclusively used in the actual conduct of scientific research. Patient care equipment must be required for the conduct of the research project and not to be used as part of routine and customary patient care.

Field Name	Instructions
Equipment item / Equipment/Start-up	<p>Summary Budget Worksheet: Enter the total cost of equipment requested for the project on the equipment line on the SBW. For multi-site projects, list the equipment requested at each site on the equipment line for the requesting site.</p> <p>R&R Budget Form: Leave Section C blank. Costs will be included in Section F, Line 8.</p> <p>Budget Justification: All major equipment and costs must be listed and justified individually. For each item, the justification should include a discussion of why the equipment is needed and why similar existing equipment (whether in the laboratory, common resource equipment, borrowed, or on loan) cannot be used. Include the cost of maintenance.</p>
Funds Requested / Equipment/Start-up	<p>Summary Budget Worksheet: List the total cost of all equipment including shipping and any maintenance costs and agreements. Do NOT include IT costs in the list of requested equipment.</p> <p>R&R Budget Form: Leave Section C blank. Costs will be included in Section F, Line 8.</p>

Field Name	Instructions
Additional Equipment	Summary Budget Worksheet: Not applicable. R&R Budget Form: Leave Section C blank. Costs will be included in Section F, Line 8.
Total funds requested for all equipment listed in the attached file	R&R Budget Form: Do NOT attach a file.
Total Equipment	Summary Budget Worksheet: Not applicable. R&R Budget Form: This total will auto-calculate. Should be blank .

D. Travel

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 or facilitate the adoption of the research into practice will be identified in individual FOA/RFAs. Travel requests should include VA personnel and others paid through an IPA. Travel for personnel paid through a contract should be included under contract costs in Section F. **Do NOT** include professional development travel in the project budget unless specifically allowed in the Service-specific FOA/RFA.

Field Name	Instructions																		
Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions) / Travel	<p>Summary Budget Worksheet: Identify the total funds requested for travel. R&R Budget Form: Leave Section D blank. Costs will be included in Section F, Line 8. Budget Justification: If funds are requested for travel, the table below IS REQUIRED in this document. The table must be included with purpose, destination, dates of travel (if known), number of individuals for each trip, VA/IPA/consultant status, and estimated costs. If the dates of travel are not known, specify estimated length of trip (e.g., 3 days). Project related travel expenses must be fully explained and a compelling justification provided. Traveler</p> <table border="1"> <thead> <tr> <th></th> <th>Status (VA, IPA, or consultant)</th> <th>Purpose</th> <th>Destination</th> <th>Date</th> <th>Estimated Cost</th> </tr> </thead> <tbody> <tr> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Total</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </tbody> </table>		Status (VA, IPA, or consultant)	Purpose	Destination	Date	Estimated Cost							Total					
	Status (VA, IPA, or consultant)	Purpose	Destination	Date	Estimated Cost														
Total																			
Foreign Travel Costs / Travel	<p>Funds for foreign travel may be requested as part of a budget if adequately justified. Summary Budget Worksheet: Identify the total funds requested for travel. R&R Budget Form: Leave Section D blank. Costs will be included in Section F, Line 8. Budget Justification: Include foreign travel in same table with domestic travel costs.</p>																		
Total Travel Cost	Summary Budget Worksheet: Not applicable. R&R Budget Form: This total will auto-calculate. Should be blank .																		

E. Participant/Trainee Support Costs

Unless specifically stated otherwise in a FOA/RFA, **leave Section E. blank**. NOTE: Tuition remission and/or stipends for graduate students may not be included in the project budget.

Field Name	Instructions
Tuition/Fees/Health Insurance	R&R Budget Form: Leave Section E blank.
Stipends	R&R Budget Form: Leave Section E blank.
Travel	R&R Budget Form: Leave Section E blank.
Subsistence	R&R Budget Form: Leave Section E blank.
Other	R&R Budget Form: Leave Section E blank.
Number of Participants/Trainees	R&R Budget Form: Leave Section E blank. Do NOT include subject recruitment in Section E.
Total Participant/Trainee Support Costs	R&R Budget Form: This total will auto-calculate. Should be blank .

3.7.3 Sections F through L

Investigators are encouraged to review the list of Unauthorized Budget Items to ensure compliance with VA-ORD budget policy.

Table 3.7.3-1 Unauthorized Budget Items

Personnel	
Clerical support	Clerical support may not be included as study personnel unless the support provided can be justified as necessary to the conduct of the research.
Dishwashing aide	Not authorized.
Nurses or Licensed Medical Professionals (Hybrid Title 38 occupations with clinical appointments)	Salary support is not authorized for any Title 38 nurse or licensed medical professional with <u>clinical appointments</u> in VA (Hybrid 38 occupations with clinical responsibilities) unless a waiver has been granted by the CRADO. If waived, salary support is provided for percent effort on the research project (services beyond usual clinical care).
Physicians (Title 38)	Salary support is not authorized for any physician (VA or other salaried).
Summer/Graduate students	Tuition or stipend not authorized. Students may be hired as study personnel necessary to the conduct of research.
Equipment	
Access to Austin or PBM database	Not authorized.
Computers	Computers (and IT expenditures) should not be listed in the budget. However, do itemize these expenditures in the Budget Justification.
Furniture	Provided by the local facility.
Medical Equipment	Usually provided by the local facility. Must be required for the conduct of the research project and not be used as part of routine and customary patient care.

Supplies	
Books or journals	Not authorized. See instructions regarding publications under other direct costs (item 2).
Photocopying charges	Not authorized.
Postage	Not authorized, unless special circumstances require other than ordinary mail.
Other	
Biohazard waste disposal	Not authorized.
“Charge-back costs”	Not authorized.
Communication costs	Not authorized.
Construction	Not authorized. Contact VA-ORD for guidance on construction requests.
Cylinder demurrage charges	Not authorized.
General Administrative costs	Not authorized.
Institutional Review Board (IRB) costs	Not authorized. IRB is an indirect cost and is provided with VERA and CC101 funds.
Library computer searches	Not authorized.
Maintenance costs which are unjustified	Not authorized.
Other Costs continued	
Maintenance costs for core or shared equipment	Not authorized.
Medical media and/or slide preparation and/or photography	Not authorized.
Participant payments to physicians	Payments to physicians for serving as research participants are not authorized.
Phone costs	Usually provided by the local facility. Special 800 lines may be approved with strong justification.
Professional memberships	Not authorized.
Radioisotope waste disposal	Not authorized.
Rental costs for laboratory or office space	Not authorized.
Word processing	Not authorized.

F. Other Direct Costs

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 (\$)
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Add Additional Indirect Cost			
Total Indirect Costs			
Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number)			
<input type="text"/>			

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

J. Fee		Funds Requested (\$)

K. Total Costs and Fee		Funds Requested (\$)
Total Costs and Fee (I + J)		

L. Budget Justification			
(Only attach one file.)			
<input type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/>	<input type="button" value="View Attachment"/>

Section F, Line 8 includes all remaining project costs, including costs from Sections C-E.

On the **SBW**, any category of expenses with costs of \$5,000 per year or more should be entered in a **separate row** under Other Direct Costs (e.g., IPAs \$20,000 or Consultants \$5,000). All remaining costs should be combined and entered under “Other Direct Costs”.

On the **R&R Budget Form**, retype the subtotal costs for equipment, travel, other direct costs, and other sites for multi-site projects on Line 8. All other lines should be left blank.

In the **Budget Justification**, the instructions below describe the level of detail required for the costs and associated rationale for each category of expenses. **Differences in costs between years need to be fully justified.**

Field Name	Instructions
1. Materials and Supplies	<p>Consumables, recurring items, and small equipment, costing less than \$5,000 per item, must be requested as Materials and Supplies. Multiple small items may not be combined to meet the \$5,000 minimum cost for “equipment.”</p> <p>Summary Budget Worksheet: In a new row under Other Direct Costs, enter the costs and the expense category if costs are \$5,000 per year or more. Otherwise include all costs under single line item of “other direct costs”.</p> <p>R&R Budget Form: Leave this item blank.</p> <p>Budget Justification: Itemize expendable supplies in separate categories, such as glassware, chemicals, etc., including an amount for each category. If animals are to be purchased, state the species, cost per animal, and number to be purchased in each budget period. Include the daily and total charges for Animal Research Facility maintenance of all vertebrate animals required in the research. Categories less than \$1,000 do not have to be itemized.</p>
2. Publication Costs	<p>Include the costs of documenting, preparing, publishing, or otherwise making available to others the findings and products of the work conducted under the award.</p> <p>Summary Budget Worksheet: Include publication costs under single line item of “other direct costs”.</p> <p>R&R Budget Form: Leave this item blank.</p> <p>Budget Justification: List the costs and justify how the publication will be a direct result of the project. Include supporting information.</p>
3. Consultant Services	<p>Consultant services may be obtained by contract (see 8-10 Other, Service Contracts) or appointment under an appropriate appointing authority (e.g., VA Handbook 5007 Pay Administration). Consultants who provide advisory and assistance support and are engaged via a Letter of Agreement are limited to \$2,500 per year. Consultants who provide other support and are engaged through Human Resources according to Handbook 5007, are limited to \$7,500 per year. Physician consultants may not receive salary compensation, regardless of whether they are VA or non-VA employees. Travel for appointed consultants is an additional expense that should be included in the VA travel costs on the SBW.</p> <p>Summary Budget Worksheet: In a new row under Other Direct Costs labeled “Consultants”, enter the total costs for all consultant services and the total number of consultants in the far left column.</p> <p>R&R Budget Form: Leave this item blank.</p> <p>Budget Justification: Identify each consultant by name, organizational affiliation, professional status (e.g., Ph.D.), total number of consultations, and the total estimated costs. Include consultant travel costs in the table required for the travel budget justification. Clearly explain the expertise of each consultant with regard to the proposed research and the nature of the service to be provided. Include persons who are confirmed to serve on external monitoring boards or advisory committees to the project.</p>

Field Name	Instructions																																																																								
4. ADP/Computer Services	<p>Do NOT include IT costs in the budget. Only computer hardware and software that meet the definition of scientific computing may be purchased with research funds.</p> <p>For more information, refer to “FY18 IT Funds to Support Field Research Activities Memo and FAQs” at http://vaww.research.va.gov/funding/electronic-submission.cfm .</p> <p>Summary Budget Worksheet: In a new row under Other Direct Costs, enter the costs and the expense category if costs are \$5,000 per year or more for all items that meet the definition of scientific computing. Otherwise include scientific computing costs under single line item of “other direct costs”.</p> <p>R&R Budget Form: Leave this blank.</p> <p>Budget Justification: For items that meet the definition of scientific computing, list items and costs and justify individually.</p> <p>For items that Do NOT meet the definition of scientific computing (i.e., items to be provided by IT), include in the Planned IT Expenditures Table in the Budget Justification under Other Direct Costs, but Do NOT include the costs in the Budget. You will be asked during the JIT phase to provide an assurance memo from your local IT that these items are available for the conduct of your study.</p> <p>The Planned IT Expenditures should include the total cost per item and the established computer service rates at the proposing organization if applicable. Unusual requests should be accompanied by a vendor quote and a strong justification. Shared network charges are not authorized.</p> <table border="1" data-bbox="542 936 1406 1472"> <thead> <tr> <th colspan="5">Planned IT Expenditures Table</th> </tr> <tr> <th>Category</th> <th>Type</th> <th>Amount Year 1</th> <th>Amount Year 2</th> <th>Amount Year 3</th> </tr> </thead> <tbody> <tr> <td rowspan="3">Hardware</td> <td>Purchased</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Leased</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Services</td> <td></td> <td></td> <td></td> </tr> <tr> <td rowspan="3">Software</td> <td>Purchased</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Leased</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Services</td> <td></td> <td></td> <td></td> </tr> <tr> <td rowspan="3">Telecommunications</td> <td>Purchased</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Leased</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Services</td> <td></td> <td></td> <td></td> </tr> <tr> <td rowspan="3">IT Supplies and Materials</td> <td>Purchased</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Leased</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Services</td> <td></td> <td></td> <td></td> </tr> <tr> <td colspan="2">IT Personnel (personnel on a 2210 Position Description)</td> <td></td> <td></td> <td></td> </tr> <tr> <td colspan="5">TOTAL</td> </tr> </tbody> </table>	Planned IT Expenditures Table					Category	Type	Amount Year 1	Amount Year 2	Amount Year 3	Hardware	Purchased				Leased				Services				Software	Purchased				Leased				Services				Telecommunications	Purchased				Leased				Services				IT Supplies and Materials	Purchased				Leased				Services				IT Personnel (personnel on a 2210 Position Description)					TOTAL				
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5. Subawards/Consortium/ Contractual Costs	<p>See Section 3.8 Special Instructions for Preparing Applications with a Subaward/Consortium for further guidance on how to submit a budget for a project with additional performance sites.</p> <p>Summary Budget Worksheet: Costs for additional performance sites will be auto-calculated and displayed under “Subtotal Other Sites” and included in “Subtotal Costs (Equipment, Travel, Other Direct, Other Sites)” and entered in Section F, Line 8.</p> <p>R&R Budget Form: Leave this item blank.</p> <p>Budget Justification: Complete a budget justification for each site sequentially and include in the single attachment in Section L.</p>																																																																								

Field Name	Instructions
6. Equipment or Facility Rental/User Fees	<p>Limits on funds for such fees will be identified in individual FOA/RFAs.</p> <p>Summary Budget Worksheet: In a new row under Other Direct Costs, enter the costs and the expense category if costs are \$5,000 per year or more. Otherwise include all costs under single line item of “other direct costs”.</p> <p>R&R Budget Form: Leave this item blank.</p> <p>Budget Justification: List 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; an example of unacceptable fees would be for rental costs for laboratory space, office space, or IT equipment/facilities.</p>
7. Alterations and Renovations	<p>Requests for funds for facility alterations or renovations are not allowed.</p>
8-10 Other	<p>Combine all remaining costs (except PD/PI and VA personnel at primary performance site) together on Line 8 and include details in the Budget Justification (description and funds requested). Leave lines 9 and 10 blank.</p> <ul style="list-style-type: none"> • IPAs. VA Research is an intramural research program. IPAs are to be used only to obtain unique skills (scientific and/or technical) that are not available in VA. Under no circumstances should IPA agreements be used as a mechanism for hiring clinical staff (e.g., MDs, RNP, PA, etc.), administrative or support staff, or as a substitute for scarce medical specialist, or other clinical service contracts. IPA agreements should not be used to circumvent restrictions on hiring due to budgetary constraints, reductions-in-force, freezes on grade levels, or ceiling allocations. IPAs may not be used for any individual assigned the PD/PI role. IPAs provide for salary and fringe benefit reimbursements; “overhead” costs are not allowed. Effort for non-VA personnel should be calculated by multiplying the percent effort times 12 months (i.e., 10 % effort = 1.2 months). Cost of living adjustments (COLAs) for IPAs are not allowed. Travel for personnel paid through an IPA should be included in the VA travel costs in the SBW. Do NOT include IPAs in Section B. Other Personnel. • Service contracts. Service contracts are used to obtain a deliverable/product from a company or an institution, e.g., service contract with the University of California for statistical analysis of data. You may not contract for clinical services or identify the individual(s) who will provide the service(s). A non-VA physician may only perform non-clinical work on a service contract. List service contracts for equipment utilized only for the proposed research. If the equipment is used by multiple research projects, request a proportionate amount of the service contract. Maintenance contract costs may not be requested for core or shared equipment. Travel for personnel paid through a contract should be included as a separate line item under contract costs and not included under VA travel costs in the SBW. • Study Participant Payments. Small amounts of money can be offered as a reimbursement for time, travel, and inconvenience that results from participating in a study. Payments must not be at a level that would be considered coercive and must be consistent with institutional review board and ethics policies. <p>Non-physician VA employees may receive reimbursement for participating in research studies in accordance with VHA Handbook 1200.05. Payments to physicians for serving as research subjects/participants are not authorized.</p> <p>Summary Budget Worksheet: In a new row under Other Direct Costs, enter the costs and the expense category if costs are \$5,000 per year or more (e.g., service contracts). In a new row labeled “IPAs”, enter total IPA costs, calendar months effort, and total number of IPA personnel. Include all other costs under single line item of “other direct costs”.</p>

Field Name	Instructions
8-10 Other continued	<ul style="list-style-type: none"> • Multi-Site Projects. The total of all site budgets from the worksheet is auto-calculated and displayed in “Subtotal Other Sites” and included under “Subtotal Costs”. <p>R&R Budget Form: Retype “Subtotal Costs” from the SBW in Section F, Line 8.</p> <p>Budget Justification:</p> <ul style="list-style-type: none"> • IPAs. List the name, degree, effort, costs, and description of activities on the project. Justify use of IPA mechanism instead of using VA personnel. Include IPA travel costs in the table required for the travel budget justification. • Service Contracts. Provide a detailed description of the services being contracted for, along with the desired credentials of the service provider, but not the name of the individual providing the services. Include contractual costs for support services, such as laboratory testing of biological materials, clinical services, or data processing. • Study Participant Payments. Provide total costs itemized per participant per study activity or contact (e.g., visit, survey, completing all study activities, etc.). • Other Direct Costs. List any other study costs and provide justification.
Total Other Direct Costs / Subtotal Costs	<p>Summary Budget Worksheet: Subtotal Costs include equipment, travel, other direct costs, and all funds requested from all sites except the primary performance site.</p> <p>R&R Budget Form: Total funds requested for all other direct costs. This total will auto-calculate.</p>

G. Direct Costs (A through F)

SBW: Total project.

R&R Budget Form: Automatically populated for the total funds requested.

H. Indirect Costs

R&R Budget Form: Indirect costs are not allowed. **Do NOT** enter any data in this section.

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

R&R Budget Form: Automatically populated for the total funds requested.

J. Fee

R&R Budget Form: Fees are not allowed. **Do NOT** enter any data in this section.

K. Total Costs and Fee (I +J)

R&R Budget Form: Automatically populated for the total funds requested.

L. Budget Justification (Required Attachment)

All items in the budget (budget categories, budget years, and performance sites) must be listed on the SBW, justified in a narrative, and both attached in a single document to Section L of the SF424 (R&R) Budget. **This is a required attachment.** 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 document for all budget years, therefore, you must include information for ALL years in the same file. **Only one file may be attached.**

An example of a properly completed set of budget documents can be viewed at ([Proposal Guidance and Templates](#), under Additional Format Pages).

Completing Budget Periods 2-5

If funds are being requested for more than one budget period, you must complete a separate detailed R&R budget form for each year of support requested. You must complete all the required information (i.e., those fields that are highlighted in yellow and outlined in red) and confirm/update any auto-populated information (i.e., **start and end** dates from budget period 1 will auto populate for budget periods 2-X, therefore, you must manually enter the correct **start and end** dates for each budget period). If no funds are requested for a required field, enter “0” (zero).

NOTE: The [Budget Justification](#) is a required document and must be attached before the **Add Period** button is activated.

3.7.4 Cumulative Budget

All values on this form are auto-calculated. The values 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 appear 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.

3.8 Special Instructions for Preparing Applications with a Subaward/Consortium

When multiple VAMCs are involved in the project, the submitting VA is considered the primary performance site. Separate budget(s) for additional participating VAMC sites should be included in separate sections of the **SBW**. Subaward budgets cannot be used to justify or create contracts with non-VA institutions. NOTE: Separate budgets are required only for sites that perform a substantive portion of the project.

Do NOT complete a subaward/consortium budget form.

SBW: Contains sections for additional performance sites. Enter costs for all requested budget items by site. The total of all site budgets from the worksheet is auto-calculated and displayed in “Subtotal Other Sites” and included under “Subtotal Costs”.

R&R Budget Form: Enter all remaining project costs from the SBW on [Section F, Line 8](#) (Other Direct Costs).

Budget Justification: Include the required justification for all items in Sections A-F under a heading for the primary performance site, followed by a complete justification for Sections A-F under headings for each additional performance site in sequence.

4. Peer Review Process

Overview

Most research applications will be reviewed through a two-tier system.

The first level of review will be performed by a 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 you (as applicant), the PD/PI, or any other interested party 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 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 Service.

Discussed and Not Discussed Applications

Before the review meeting, multiple reviewers who have confirmed that they have no conflict of interest with any PD/PI or other Senior/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” an application 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.

If an application is not discussed, the PD/PI will not be given a priority score or summary points, and will be advised that a) the application was not discussed by the full panel, and b) any resubmission needs to address the key issues raised in the written critiques. ALL applications are reviewed and receive written critiques; however, not all applications need to be discussed.

Scoring

SRG members are instructed to evaluate research applications by addressing the review criteria described below. For each application that is discussed, a final global priority score (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. Service-specific FOA/RFAs for different types of funding opportunities may have different and/or additional review criteria.

You (as PD/PI) 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 applications 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 award activity codes and/or SRGs. Information about SRG membership may also be obtained from the appropriate Service.

Research Project Evaluation Criteria

Please see the Service-specific FOA/RFAs for research project evaluation criteria for that Service and activity code.

5. Supplemental Instructions for Preparing a Career Development Award and Research Career Scientist Application

5.1 Introduction

Career Development Award applicants must use the SF424 R&R forms and follow the instructional information in this Application Guide. The supplemental instructions found in this section are for Career Development Award (CDA1, CDA2, or NRI) applications. Guidance and instructional information is ONLY noted when there is a difference in the required information to be submitted or there is a need for more specificity for an individual Career Development Award. Therefore, these supplemental instructions must be used along with the information found in Parts I.1 – I.4 of this document.

It is imperative that you become familiar with the Career Development activity codes and award types for which support may be requested. Before applying for a Career Development Award, you should carefully review the Service-specific FOA/RFA for the Career Development Award of interest, noting especially the eligibility requirements, review criteria, award provisions, and any special application instructions. Each Service's FOA/RFA contains more specific information associated with the award activity code and includes names of Service-specific 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 Career Development Awards, including availability, may vary among Services. For this reason, it is strongly recommended that you consult with the Scientific/Research contact of the awarding Service prior to submitting an application. FOA/RFAs (<http://vaww.research.va.gov/funding/rfa.cfm>) and other submission guidelines (<http://vaww.research.va.gov/funding/electronic-submission.cfm>) are available on the VA-ORD intranet.

Research Career Scientist Awards (IK6)

For specific guidance on the preparation of Research Career Scientist (RCS) applications using the IK6 activity code, please refer to the appropriate Service-specific FOA/RFA along with this SF424 application guide. RCS FOA/RFAs (<http://vaww.research.va.gov/funding/rfa.cfm>) and other submission guidelines (<http://vaww.research.va.gov/funding/electronic-submission.cfm>) are available on the VA-ORD intranet.

5.2 Career Development Awards

Summary of Career Development Awards

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

5.3 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 table above. The letters should be from individuals not directly involved in the application, but who are familiar with your qualifications, training, and interests. Your mentor/co-mentor(s) 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](#). **Applications that are missing the required letters of reference will not be accepted for review.**

The reference letters are critically important and should address your competence and potential to develop into an independent biomedical or behavioral investigator. Only those individuals who can make the most meaningful comments about the your professional training and qualifications for a research career should be used as referees. Where possible, some referees who are not from your current department or organization, but are knowledgeable about your qualifications, should be selected.

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

5.4 Specific Instructions for Career Development Award Applications

Standard instructions found in Sections I1 – I4 should be followed with the exceptions detailed below along with guidance provided in the Service-specific FOA/RFA. Section numbers referenced below reflect those found in this SF424 Part I.

5.4.1 Special Instructions for 3.2 SF424 (R&R) Form

Item 8. Type of Application: Check either “New” or “Resubmission.” 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.

Item 14. Project Director/Principal Investigator (PD/PI) Contact Information: Provide your name as the individual candidate (considered the PD/PI for Career Development Awards). If you are not located at the applicant VAMC at the time the application is submitted, the information in Item 14 should reflect where you can be reached prior to the date requested in Item 12 (Proposed Project: Award Start Date). If you (as candidate, PD/PI) are not located at the applicant VAMC at the time of submission, your eRA Commons account must be affiliated with the applicant VAMC. For additional information on creating affiliations for users in eRA Commons, see: http://era.nih.gov/commons/user_guide.cfm.

5.4.2 Special Instructions for 3.3 Project/Performance Site Locations Form

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.**

5.4.3 Special Instructions for 3.4 Research and Related Other Project Information Form

Item 7. [Project Summary/Abstract](#) (Do NOT exceed 40 lines of text – this is a system validation): Provide an abstract of the entire application (candidate, environment, and research). In addition to a description of the research project as indicated in [Section 3.4.7](#), **include the your immediate and long-term career goals, and key elements of the research career development plan.**

Item 10. [Facilities & Other Resources](#): Provide a detailed description of the institutional facilities and resources available to you, following the instructions in [Section 3.4.10](#). 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 [Attachments and Required Filenames Table](#) must be followed, with the following additions:

2b. Career Plan–

[Your \(as Candidate\) 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. You are strongly encouraged to delay applying for independent funding until the last two 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 - You, as the candidate, must complete this plan. 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 your career development plan. Describe the mentors' respective areas of expertise and how they will be combined to enhance your 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.

8b. 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 Service.

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 your 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.
- 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 supporting and acknowledging a commitment to review the candidate's progress and development as a VA research scientist at least annually.

A letter from the appropriate Service Chief or Section Head describing the candidate's proposed clinical duties upon receiving the Career Development Award. An indication of the candidate'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 mentors, 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.

Inclusion of **Consultant Letters** is encouraged by the candidate. These letters would include other individuals and institutions willing to provide support and resources to the development of the candidate's research career. Any rate/charges for consultant services should be specified.

5.4.4 Special Instructions for 3.5 Research and Related Senior/Key Person Profile(s) Form

5.4.4.1 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 eRA Commons and be assigned the PI role within Commons. To register as a PD/PI in Commons, refer to the eRA Commons System Users Guide (http://era.nih.gov/commons/user_guide.cfm). Note that VA-ORD policies concerning “Multiple PD/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 5 pages**) is required for the Career Development Award candidate. **Do NOT** use the [Additional Instructions for Biographical Sketches](#). **The candidate’s biographical sketch must follow the instructions below.** The [Biographical Sketch Format Page](#), OMB No. 0925-0001 and 0925-0002 (Rev. 10/15 Approved Through 10/31/2018) or (Rev. 09/17 Approved Through 03/31/2020) **MUST** be used ([Biographical Sketch Format Page](#) and [Biographical Sketch Sample](#)); see additional instructions [below](#). Versions of the form that cannot be verified by VA-ORD staff as the correct format, will **NOT** be accepted, and if included, the application will be withdrawn from review. **NOTE:** Biographical Sketch form (Rev. 10/15 Approved Through 10/31/2018) may continue to be used through October 31, 2018.

Position Title: If you (as candidate) are 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. The relevant factors may include aspects of your training; your previous experimental work on this specific topic or related topics; your technical expertise; your collaborators or scientific environment; and your past performance in this or related fields (you may mention specific contributions to science that are not included in Section C). Also, you may identify up to four peer reviewed publications that specifically highlight your experience and qualifications for this project. If you wish to explain impediments to your past

productivity, you may include a description of factors such as family care responsibilities, illness, disability, and active duty military service.

B. Research and/or Professional Experience

Use the headings 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 you are 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.

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. Contribution to Science

Briefly describe up to five of your most significant contributions to science. For each contribution, indicate the historical background that frames the scientific problem; the central finding(s); the influence of the finding(s) on the progress of science or the application of those finding(s) to health or technology; and your specific role in the described work. For each of these contributions, reference up to four peer-reviewed publications or other non-publication research products (can include audio or video products; patents; data and research materials; databases; educational aids or curricula; instruments or equipment; models; protocols; and software or netware) that are relevant to the described contribution. The description of each contribution should be no longer than one half page including figures and citations. You may also provide a URL to a full list of your published work as found in a publicly available digital database such as SciENcv or My Bibliography, which are maintained by the U.S. National Library of Medicine.

Internet website addresses (URLs), may be included in this attachment. When including links in the Biographical Sketch, spell out the URL in full, beginning with 'http://' (e.g., <http://grants.nih.gov/grants/oer.htm>). Do NOT include the link as hyperlinked text (e.g., [NIH Grants Web page](#)) as eRA system processing will not retain the active link in the assembled application image in eRA Commons.

Reminder: Internet website addresses (URLs) are only allowed in the Biographical Sketches and the Bibliography & References Cited documents. URLs should not be included in any other areas of the application or the application will be withdrawn from review.

You 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 should be included along with the full reference.

Do NOT include manuscripts submitted or in preparation.

D. Additional Information: Research Support and/or Scholastic Performance

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.

Scholastic Performance

Predocctoral applicants/candidates (including undergraduates and post-baccalaureates): List by institution and year **all** undergraduate and graduate courses, with grades. In addition, explain any grading system used if it differs from a 1-100 scale; an A, B, C, D, F system; or a 0-4.0 scale. Also indicate the levels required for a passing grade.

Postdoctoral applicants: List by institution and year **all** graduate scientific and/or professional courses with grades. In addition, explain any grading system used if it differs from a 1-100 scale; an A, B, C, D, F system; or a 0-4.0 scale. Also indicate the levels required for a passing grade.

5.4.4.2 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 VA personnel who are committing specified measurable effort should be included in Section B of the R&R Budget Form (and [Other Project Role](#) Category in the Senior/Key Person Profile(s) form).

Biographical Sketch for Mentor/Co-mentor(s) and Other Senior/Key Persons:

For the biographical sketch for all individuals other than the candidate, follow the [Additional Instructions for Biographical Sketches](#).

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\(s\) \(Expanded\)](#) 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 (JIT) process for applications selected for funding.

5.4.5 Special Instructions for [3.6 Selecting the Appropriate Budget Form](#)

Career Development Award mechanisms use the R&R Budget Form with only a few budget categories actually used. Information regarding allowable costs for the candidate and any allowable research development or other costs is included in each Service-specific Career Development Award FOA/RFA. You are advised to contact the Service if uncertain about allowable amounts for

the applicable Career Development Award mechanism, keeping in mind that amounts may vary by Service.

Instructions for completing the R&R Budget Forms are provided below. Additional guidance may also be provided in the Service-specific FOA/RFA.

5.4.6 Special Instructions for [3.7 Research and Related Budget Form](#)

Follow the instructions provided in [Section.3.7.1](#) with the following exceptions:

Changes to 3.7.1. A. [Senior/Key Person](#): This section should include only the candidate's name.

If salary will be requested for the candidate (clinician or non-clinician PD/PI), it must be included in the submitted budget and the calendar months entered that reflect the actual effort that will be expended on the Career Development Award; salary consistent with his/her total VA effort may be requested. See the Service-specific FOA/RFA for guidance on salary allowed for each award. Describe the investigator's contribution to the proposed research, as well as the other activities comprising their total VA effort, in the budget justification. Total VA effort includes the work anticipated in this application, participation in other VA and non-VA research, service toward core facilities, teaching, supervision of students/trainees, participation in research centers, service on committees, etc.

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. You should include information on actual institutional base salary and the actual amount of salary and fringe being requested. A Service 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 3.7.1. B. [Other Personnel](#): Include in Section B, other Senior/Key Persons who are requesting salary and committing a specific measurable effort to the project if they are VA salaried or without compensation personnel. In the Budget Justification, individually list the names, project role (e.g., technician), associated Calendar Months, grade, step, and salary & fringe benefits requested for all individuals included in Section B. On the R&R Budget Form, complete only the last row of Section B with the subtotals for personnel, calendar months effort, salary and fringe. **Mentor(s) should not be included in the budget section of the application and salary compensation may not be requested.**

Non-VA personnel contributing to the project should be included in Section F.

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 Form](#) 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, sputum, 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 (whether professional or student) 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 by 38 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 a FOA/RFA, (a) the Research Plan, and (b) the Human Subjects attachments.

(a) [Research Plan attachment](#)

Specific FOA/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 Form (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 Service-specific FOA/RFA; if not provided completely, application processing may be delayed or the application may be returned 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 Form](#) 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 1200.05](#)). Written justifications for these exemptions would be submitted to your IRB after you receive a notification of award. 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 Research Performance Progress Reports (RPPRs) submitted to eRA, 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 your IRB and subsequently to the Service for approval prior to the accrual of human subjects. The reporting of Adverse Events must be reported to the IRB, the 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 1200.05](#)) and [38 CFR 16.102\(f\)](#) define a human subject is a living

individual about whom an investigator (whether professional or student) conducting research obtains:

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

Individuals who receive test articles or who serve as controls in clinical investigations, including clinical investigations as defined under FDA regulations in 21 CFR 50.3, 312.3(b), and 812.3(h), are also considered human subjects for the purposes of this Handbook.

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.

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

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)).

Investigator: VA considers the term investigator to include anyone involved in conducting the research, including principal investigators, co-investigators, sub-investigators, and local site investigators.

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 health record). Private information must be *individually identifiable* (i.e., the identity of the subject is provided or may readily be ascertained 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 and 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. Policies

A. Resubmission of Unpaid FOA/RFA Applications and Resubmission of Applications with a Changed Award Activity Code

The majority of research applications submitted to VA-ORD each year are investigator-initiated submitted through a Service-specific Parent FOA/RFA. However, Services also solicit applications on specific topics through the use of additional FOAs/RFAs. Resubmissions of applications fall into the following categories:

1. Applications that were originally submitted using one award activity code (e.g., a Merit Review Award using the IO1 activity code) and subsequently resubmitted using a different award activity code (e.g., a small project, Pilot, or SPiRE, using the I21 activity code).

Since a change of an award activity code 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 award activity code.

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 FOA/RFA that has not been re-issued or extended and then resubmitted to the Parent FOA/RFA.
3. Applications that were originally submitted as investigator-initiated applications and subsequently resubmitted in response to a topic-specific FOA/RFA.

If the two FOA/RFAs are from the same Service and do not differ in terms of an award activity code, 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 FOA/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 (see B. Submission of a Revised (Amended) Application below for details).

POLICY: This general policy on application resubmission, stated below, applies to all award activity codes that might be solicited via an FOA/RFA and to instances where there is a change in activity code. There may, however, be exceptions to this policy, which will be clearly identified in the original FOA/RFA or in a follow-up FOA/RFA.

1. When an unfunded application that was reviewed for a particular research award activity code is to be submitted for a different award activity code, it **must** be submitted as a **new** application.
2. When an application that was submitted in response to an FOA/RFA is not funded and the investigator wishes to submit a revised application to an FOA/RFA from a different Service it **must** be submitted as a **new** application.
3. When an application that was submitted in response to an FOA/RFA is not funded and the investigator wishes to submit a revised application to a different FOA/RFA from the same Service it **may** be submitted as a **resubmission** application, provided the subject matter is within the scope of the new FOA/RFA. Changing FOA/RFAs will not be viewed as grounds for allowing more than the 3 allowed applications.
4. In all cases, submitted applications must conform to the instructions in the Service-specific FOA/RFA being responded to.

B. Submission of a Revised (Amended) Application

Up to two revised applications (identified as “Resubmission” applications on the SF424 (R&R) Form) are allowed, with the exception of HSR&D Pilot and RR&D SPiRE submissions (I21) for which only one revised application will be accepted. There is no restriction on the resubmission timeframe, with the exception of the timeframe for resubmissions to BLR&D and CSR&D for Career Development Awards, Clinical Trials, and Epidemiology (EPIDs), which allow for three submissions over four review cycles. Resubmission applications will be denoted as -01A1 and -01A2 in the eRA-generated application number. **No further resubmissions will be accepted for review.**

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. PD/PIs and their VAMCs 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.

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 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 Service prior to the submission of any application requesting a budget that exceeds the budget cap (per year or total award) for that Service. Due dates for requesting a waiver from the budget caps can be found on the [ORD Submission Calendar](#) and Service-specific FOA/RFA.

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 VA-ORD program staff as early as possible to ensure that a Service would be willing to accept the application.

This prior acceptance policy does not apply to applications submitted in response to FOA/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 (**per year** or total award) for a particular 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 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 PD/PI's VAMC 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](#) attachment of the application will avoid this problem. Therefore, VA-ORD strongly encourages PD/PIs to contact appropriate staff in the specific Service 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 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 Directive 1200.18 [Determination of Rights for Inventions and Discoveries](#). 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 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 VAMC 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 Service 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 research 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 [3.4 Other Project Information Form](#), 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 application. If multiple informed consents are needed, the consent form title may be the application 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 1200.07](#), Use of Animals in Research, Appendix D): If vertebrate animals are involved a copy of the ACORP, with all appropriate signatures, must be provided upon request to VA-ORD for review by the Chief Veterinary Medical Officer (CVMO).
- 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 applications 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 Application: 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 Award application (project title) of Dr. PD/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 Senior/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(s) form.

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 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. Prizes or gifts are not included.

Information on Other Support assists VA-ORD 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 Senior/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 when completing the information:

- Information on active and pending Other Support is required for all Senior/Key Personnel, including OSCs. 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. If the support is provided under a consortium/other performance site arrangement or is part of a multi-project 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-ORD 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		
<u>ACTIVE/PENDING</u>		
Project Number (PD/PI) Source Title of Project (<i>or Subproject</i>)	Dates of Approved/Proposed Project Annual Direct Costs	Person Months (Cal/Acad/ Summer)
The major goals of this project are...		
<u>OVERLAP</u> (<i>summarized for all listed projects with a separate section for each project</i>)		

Sample

OTHER SUPPORT		
ANDERSON, R.R.		
<u>ACTIVE</u>		
2 R01 HL 00000-13 (Anderson) NIH/NHLBI Chloride and Sodium Transport in Airway Epithelial Cells 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.	3/1/1997 – 2/28/2002 \$186,529	3.60 calendar
5 R01 HL 00000-07 (Baker) NIH/NHLBI Ion Transport in Lungs The major goal of this project is to study chloride and sodium transport in normal and diseased lungs.	4/1/1994 – 3/31/2002 \$122,717	1.20 calendar
R000 (Anderson) Cystic Fibrosis Foundation Gene Transfer of CFTR to the Airway Epithelium The major goals of this project are to identify and isolate airway epithelium progenitor cells and express human CFTR in airway epithelial cells.	9/1/1996 – 8/31/2002 \$43,123	1.20 calendar
<u>PENDING</u>		
DCB 950000 (Anderson) National Science Foundation Liposome Membrane Composition and Function The major goals of this project are to define biochemical properties of liposome membrane components and maximize liposome uptake into cells.	12/01/2002 – 11/30/2004 \$82,163	2.40 calendar
<u>OVERLAP</u>		
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-ORD research-appropriated funds.

II. Assurances and Certifications

Each application requires that the following assurances and certifications be verified by the Authorized Organizational Representative (AOR, a.k.a. Signing Official) for the Applicant Organization on the SF424 (R&R) form (Item 19) 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 eRA 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 usernames 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 1200.05](#)) 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 eighteen 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). When verifying the submitted application in eRA Commons, the duly authorized representative of the VAMC certifies that the proposed research is in compliance with all applicable Federal rules and regulations.

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. VA-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 a VA-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. VA-ORD requires verification of approval of the research by the IRB before any award of VA funding will be made, but there is no longer any requirement that that approval be secured before peer review of an application. IRB approval will be verified in “just-in-time” prior to award.

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 Biotechnology Activities web site at <http://osp.od.nih.gov/office-biotechnology-activities>.

NOTE: Under VA-ORD 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 1200.05](#), [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 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 must be provided from the VA facility 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-ORD website at <http://www.research.va.gov/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 1200.05](#)) states that research in which the subject is either a fetus, or human fetal tissue, in-utero or ex-utero (or uses human fetal tissue) cannot be conducted by VA investigators while on official duty, or at VA facilities, or at approved off-site facilities. Use of stem cells shall be governed by the policy set by NIH for recipients of NIH research funding. In addition, research that involves provision of in vitro fertilization services cannot 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 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 eRA Commons, the duly authorized representative of the VAMC certifies that if research using human embryonic stem cells is proposed, the VAMC 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 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 VA-ORD CRADO, upon the recommendation of a 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. When verifying the submitted application in eRA Commons, the duly authorized representative of the VAMC certifies that the proposed research is in compliance with all associated VA-ORD policies.

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 VHA Policy ([VHA Handbook 1200.05](#), 19. Research Involving Children as Research Subjects).

VA is authorized to care for Veterans and to conduct research that supports the mission of VHA and that enhances the quality of health care delivery to Veterans. Therefore, research involving children should be reviewed carefully by the IRB for its relevance to VA and cannot be greater than minimal risk. Children are persons who have not attained the legal age to consent to treatments or procedures involved in the research under the applicable law of the jurisdiction in which the research will be conducted. Research involving biological specimens or data obtained from children is considered to be research involving children even if de-identified. The VA Medical facility Director must approve participation in the proposed research that includes children (see VHA Handbook 1200.05 guidance at: <http://www.research.va.gov/resources/policies/default.cfm>).

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

If research involving children is approved by the Medical facility Director, 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. When verifying the submitted application in eRA Commons, the duly authorized representative of the VAMC certifies that the proposed research is in compliance with VHA and all applicable Federal rules 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 is set forth in [VHA Handbook 1200.07](#), and requires that each VA facility that receives funding from VA-ORD in support of research activities involving vertebrate animals have in place a written Animal Welfare Assurance, establishing policies and procedures approved by the [Office of Laboratory Animal Welfare](#) (OLAW), to ensure the humane care and use of the animals.

VA policy also requires compliance with all other applicable Federal statutes and regulations relating to use of animals, including the Animal Welfare Act ([7 USC 2131-2159](#)), the [USDA Animal Welfare Act Regulations and Standards](#) ([9 CFR Parts 1-3](#)), and the regulations regarding Select Agents and Toxins ([42 CFR Part 73](#)). Furthermore, VA policy requires that, unless a specific waiver has been granted through the office of the CVMO, any animal facility in which animals are housed for VA research must be accredited by the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) International. VA policy (see http://www.research.va.gov/programs/animal_research/ for additional information) establishes the minimum standards for the care and use of laboratory animals in VA research, and does not limit compliance with any applicable state or local laws or regulations that impose more stringent standards.

VA-ORD requires verification of Institutional Animal Care and Use Committee (IACUC) approval of the research before any award of VA funding will be made, but there is no longer any requirement that that approval be secured before peer review of an application.

The SRG will still evaluate the appropriateness of the proposed animal usage and the measures to be taken to protect animal welfare, as part of the peer review process, but IACUC approval will only be verified in “just-in-time” prior to award.

When verifying the submitted application in eRA Commons, the duly authorized representative of the VAMC certifies that that center is operating in accordance with an Animal Welfare Assurance approved by OLAW, and in compliance with VA policy on the use of animals in research.

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 VAMC on the [4.2 SF424 \(R&R\) Form](#) of the application serves as certification that the institution will comply with VHA Handbook 1058.06 [Research Misconduct](#), which establishes the procedures and other requirements for handling allegations of misconduct in 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, rickettsia, fungi, toxins, and recombinant deoxyribonucleic acid [DNA]) designated by the Centers for Disease Control (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](#). 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 Animal and Plant Health Inspection Service (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 CFR 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. When verifying the submitted application in eRA Commons, the duly authorized representative of the VAMC certifies that registration with the National Select Agent Registry will be submitted for approval following notification of award by VA-ORD.

For additional information regarding Select Agents 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.selectagents.gov/Regulations.html>

Center for Disease Control Select Agent Program:

<http://www.cdc.gov/od/sap/index.htm>

CDC-NIH:

[Biosafety in Microbiological and Biomedical Laboratories; http://www.cdc.gov/biosafety/](http://www.cdc.gov/biosafety/Biosafety%20in%20Microbiological%20and%20Biomedical%20Laboratories)

NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules:

http://osp.od.nih.gov/sites/default/files/NIH_Guidelines.html

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:

https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-and-animal-product-import-information/SA_Ag_Select_Agent

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 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 Senior/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 into 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 VA-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 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 applications or awards, regardless of the funding source.

Feasibility. The extent to which a study or project may be done practically and successfully.

International Research. Any VA-approved research conducted at international sites (i.e., not within the United States (U.S.), its territories, or Commonwealths), any VA-approved research using either identifiable or de-identified human biological specimens or identifiable or de-identified human data originating from international sites, or any VA-approved research that entails sending such specimens or data out of the U.S. This definition applies regardless of the funding source (funded or unfunded) and to research conducted through any mechanism of support including MOUs, CRADAs, grants, contracts, or other agreements. All international research must be approved explicitly in a document signed by the VA medical facility Director, except for CSP activities which must be approved by the CRADO. Applicants to VA-ORD must follow [VHA Handbook 1200.05](#), 26. International Research.

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.

Other Significant Contributors (OSCs). 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 OSCs). 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 VAMC may designate multiple individuals as PIs who share the authority and responsibility for leading and directing the project, intellectually and logistically. When multiple PIs are named, each is responsible and accountable to the VAMC, 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 award.

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 they 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

Research Award Activity Codes

The following table summarizes the major activity codes (previously “funding mechanisms”) VA-ORD currently uses to fund intramural research. Service-specific FOA/RFAs are posted on the [VA-ORD intranet](#) site. A FOA/RFA for a particular award activity code may not be issued by every Service or for every review cycle.

Type (Activity Code)	Description
Research Awards	
Merit Review Award (I01 activity code)	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 Services. These awards make up the largest category of VA-ORD funding.
Pilot Project/Small Project Awards/ SPiRE* (I21 activity code)	Pilot Project/Small Project Awards (SPiRE) are specifically directed at establishing project feasibility, or developing data, techniques, concepts or procedures as a preliminary step to undertaking a full Merit Review Award. 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. Applications are prepared using the same format for submitting a Merit Review Award; page limits may differ. Funding for Pilot Projects/SPiREs may be limited to 2-years.
Program Project Awards (IP1 activity code)	Program Project Awards are intramural awards 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 efforts 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 VAMC.
Research Enhancement Award Program (REAP) ^ (I50 activity code)	REAP awards are intramural awards to promote and support groups of VA investigators that are not affiliated under the domain of a currently funded RR&D Center 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 Award (I50 activity code) ^	Center awards are intramural awards 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.

Type (Activity Code)	Description
Research Awards (cont.)	
Center of Innovation (COIN) Award (I50 activity code) ^	COIN awards are intramural awards to support investigator-initiated research conducted by groups of eligible HSR&D investigators at VAMCs 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.
Cooperative Studies Program (CSP) Award+ (IU1 activity code)	The Cooperative Studies Program (CSP) supports the planning and conduct of multicenter clinical trials and epidemiological studies focused on providing definitive results for evidence-based care. CSP studies undergo a structured process of planning and execution that involves a set of established procedures carried out by VAMCs located in the field and coordinated through a CSP Coordinating Center.
Research Career Development Awards	
Career Development Award (CDA-1) (IK1 activity code)	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.
Career Development Award (CDA-2) (IK2 activity code)	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.
VA-ORD Historically Black College and University Research Scientist Training Program Award (IK2)	The HBCU program was created to increase the number of underrepresented minority scientists participating in VA research. Within this program is an HBCU focused Career Development Award (CDA-2/IK2 mechanism) to support early career scientists who are affiliated with HBCUs in collaboration with their local VA medical centers. HBCU Career Development awardees are selected through a peer-review process coordinated by each Service within VA-ORD. Both clinically and non-clinically trained post-doctoral researchers may gain mentored research time intended to advance awardees toward independence as funded VA-ORD scientists. This CDA-2 award provides salary and/or project funds to support a three- to five-year program of research career development and mentoring. Awardees must enlist the support of an appropriately qualified VA employee as a primary mentor, as well as an HBCU mentor.

Type (Activity Code)	Description
Research Career Development Awards (cont.)	
Nursing Research Initiative (NRI) Award (IK3 activity code)	The Nursing Research Initiative (NRI) is a mentored research and capacity-building program managed by HSR&D for the VA-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 activity code)	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.

*For specific guidance on the preparation of I21 (HSR&D Pilot Project or RR&D SPiRE) applications, please refer to the appropriate Service-specific FOA/RFA.

^ For specific guidance on the preparation of I50 (REAP or Center) applications, please refer to the appropriate RR&D FOA/RFA.

For specific guidance on the preparation of IK6 (RCS) applications, please refer to the appropriate Service-specific FOA/RFA.

+ For specific guidance on the preparation of IU1 (CSP) applications, please refer to the appropriate CSP FOA/RFA.