U.S. Department of Veterans Affairs
Veterans Health Administration
Office of Research & Development

VA-ORD

Application Guide
SF 424 (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-G application packages

Revised January 12, 2022
Updated April 5, 2022

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PART I: Instructions for Preparing and Submitting an Application

1. Foreword

VA-ORD Application Guide SF 424 (R&R) Forms Version "G" (VA-ORD SF 424) application package contains new Forms (OMB Number: 4040-0001, Expiration Date: 12/31/2022).

Summary of Key Updates for April 4, 2022:

- Section 1.4 Before and After Application Submission: GSA's Unique Entity Identifier (UEI) has replaced the D-U-N-S® number and is now required for application submissions. Added VA SAM Administrator contact information.
- Section 2.6 Revision Applications and Section 3.2 SF 424 R&R Form, 8. Type of Application: a Revision application can only be used if specifically noted in a FOA/RFA.
- Section 3.2 SF 424 R&R Form, 4.a. Federal Identifier: a Pre-application (I02) award number should not be entered in the Federal Identifier field.
- Section 3.5 R&R Senior/Key Person Profile Form, Profile PD/PI and Profile Senior/Key Person, Attach Current and Pending Support: Other Support guidance and sample format.
- Part III, C. Patents and Inventions: VA Technology Transfer Program.

Summary of Key Updates for January 12, 2022:

- Transition from D-U-N-S® Number to a Unique Entity Identifier (UEI) issued by SAM.gov as the official identifier for doing business with the Federal government (NOT-OD-21-170).
- Updated Biographical Sketch template and Other Support format pages (NOT-OD-21-110).
- Use of Science Experts Network Curriculum Vitae (SciENcv) to help develop a biosketch.
- Updated country and state dropdown lists across all forms.
- Increased character limit to 100 characters for "Department" and "Division" fields.
- Expanded requirement for a Commons ID to all senior/key personnel (NOT-OD-21-109).
- Increased number of "Other" direct cost budget lines from three (3) to ten (10).
- Application submission deadline updated to 5:00 p.m. local VAMC time.
- Signing Official (SO) steps to access Summary Statements and impact scores in eRA Commons.

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. Review both the *VA-ORD SF 424* and Service-specific FOA/RFA when preparing an application.

1.1 Application Guide Format

This application guide is organized into three distinct parts:

Part I: Instructions for Preparing and Submitting the Application provides information on completing the SF 424 forms and submitting applications through Grants.gov Workspace or NIH Application Submission System & Interface for Submission Tracking (ASSIST).

Part II: Supplemental Instructions for Human Subjects Research assists in completing the Human Subjects section of the Research Plan if the proposed research involves Human Subjects.

Part III: Policies, Assurance, Definitions and Other Information provides information relating to submission of applications for traditional, solicited and unsolicited, investigator-initiated research projects to VA-ORD. Refer to this document and the Veterans Health Administration (VHA) Handbooks, Directives or VA-ORD Program Guides for each Service (see Service-specific web sites). These documents can be accessed on the VA web site at VHA Publications, VA-ORD Policies and Guidance Documents and ORD VHA Directive, Handbooks and Program Guides – 1200 Series.

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 helpful information about VA-ORD research programs.

For additional information about VA-ORD intramural research and research training programs, FOA/RFAs and the application process, contact the appropriate Service (see Service-specific FOA/RFAs for staff contact(s)) or the VA-ORD eRA Mailbox vhacordera.vhacordera@va.gov.

1.3 Interactions with VA-ORD Staff

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

1.4 Before and After Application Submission

Prepare to Apply: This VA-ORD SF 424 is a companion document to the SF 424 Forms. A complete application includes SF 424 Forms and all required attachments as indicated in this VA-ORD SF 424 and the Service-specific FOA/RFA.

Learn about the main systems involved in application submission: Grants.gov and eRA Commons. Determine which system is most convenient for application submission: Grants.gov Workspace or NIH Application Submission System & Interface for Submission Tracking (ASSIST). For an overview: https://grants.nih.gov/grants/how-to-apply-application-guide/prepare-to-apply-and-register/submission-options.htm.

Identify the right FOA/RFA for the research focus: see Service specific FOAs/RFAs (VA-ORD intranet RFAs and Program Announcements (va.gov); http://vaww.research.va.gov/funding/rfa.cfm) and in this VA-ORD SF 424, Section 2.2 Funding Opportunities.

Review the VA-ORD SF 424 and templates (VA-ORD intranet Proposal Guidance and Templates; http://vaww.research.va.gov/funding/electronic-submission.cfm).
Use an application package for the correct Service and FOA/RFA. Application packages are not interchangeable between Services or between FOA/RFAs within a specific Service.

Before Submission: The VA Medical Center (VAMC) Research and Development Office (R&D Office) Associate Chief of Staff/Research (ACOS/R) and/or Administrative Officer (AO) can assist with application completion and submission questions. The ACOS/AO may also contact VA-ORD staff with any questions.

For Grants.gov registration information, see Grants.gov For Applicants.

The General Services Administration's (GSA) Unique Entity Identifier (UEI) has replaced the Dun and Bradstreet Data Universal Numbering System (D-U-N-S®) nine (9)-character D-U-N-S® Number. The UEI is a twelve (12)-character unique number assigned to all entities (public and private companies, individuals, institutions or organizations) that must register to do business with the Federal government in the System for Award Management (SAM).

A UEI is required for registrations for both SAM and eRA Commons and for application submissions. 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. For additional information: Unique Entity Identifier Update | GSA.

The SAM Administrator for VA is Ms. Ellen Swinton (see contact information below). Please track the expiration date for your facility registration and and contact Ms. Swinton 30 days prior to the expiration to confirm that things are in order. Include the following information in your correspondence: Site, UEI Number, Expiration Date, and Contact Information of the individual Ms. Swinton is to work with.

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Investigators may also wish to learn about ORCID – a non-profit organization supported by a global community of organizational members, including research organizations, publishers, funders, professional associations and other stakeholders in the research ecosystem. ORCID provides a persistent global identify that can distinguish a researcher from every other researcher and, through integration in key research workflows such as manuscript and grant submission, supports automated

linkages between a research and their professional activities to help ensure their work is recognized. For information: https://orcid.org/about/What-is-orcid.

After Submission: The VA-ORD web site lists the recurring Scientific Review Groups (SRGs) and the local VAMC R&D Office may suggest/request assignment to a specific SRG on behalf of a Program Director/Principal Investigator's (PD/PI). 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 a PD/PI; reassignment requests may not be submitted directly by PD/PIs. Although requests submitted by the VAMC R&D Office will be considered, the Service will make the final determination.

After Assignment: PD/PIs may contact their SRO to discuss the review assignment and/or to discuss any review concerns (e.g., expertise needed to review an application, potential conflicts/reviewers that may have bias). Requests/suggestions for specific reviewers are not accepted.

NOTE: Not all Services allow submission of supplemental material and permission to submit additional material will be granted only in exceptionally rare instances.

Peer Review Process: See the Service-specific FOA/RFA to which an application is being submitted for information on the peer review process for that funding opportunity. (For a current listing of Service FOA/RFA see RFAs and Program Announcements.)

ORD is committed to supporting the highest ethical standards for the review process. This includes maintaining the confidentiality of review, preventing improper influences on reviewers and identifying and managing potential conflicts of influence during the review process. **The PD/PI, or any other interested party, must never contact reviewers regarding an application. Contact with reviewers (regardless of the source of contact) will result in permanent loss of eligibility to submit to any VA-ORD Service.** Reviewers are required to notify the Scientific Review Officer (SRO) if anyone contacts them (or attempts to contact them) concerning a submitted application.

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 be made available through the contact PD/PI's eRA Commons account and to users with a Signing Official (SO) role (see instructions below) on the Status Information screen. Percentiles may not be calculated for all award activity codes or for all SRGs. After receipt of the Summary Statement, the PD/PI may contact the appropriate awarding Service's SRO (noted on the Summary Statement):

- To discuss the review outcome of the application and obtain guidance on next steps.
- To get feedback and answers to any questions.
- To find out the meaning of a numerical designation pertaining to Human Subjects or Vertebrate Animals.

For R&D staff with the SO role:

- Log in to eRA Commons, go to the Status module and click General Search.
- Search for a grant (award) application and click the grant number from the Application/Award ID column or search by PD/PI name. The Status Information screen will appear, with expandable sections.
- To view scores, click to expand the Review section, where the impact score will be listed; a percentile may be available.
- To view Summary Statements, click to expand the Other Relevant Documents section and click the Summary Statement link to view a PDF.

1.5 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 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, Adobe Reader software is needed to view Portable Document Format (PDF) documents (including the application image assembled by eRA); a PDF generator to format all documents attached to application forms; and a web browser. (*NOTE:* eRA systems are no longer available using Internet Explorer.) For additional information, see Obtain Software.

PDF generator software is necessary to create the PDF as Adobe Reader *will not create* a PDF. Requests for PDF generator software must be made through the VAMC IRMS.

Attachments cannot be submitted 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. Text attachments should be prepared using any word processing program (following the creation and format guidance in Section 2.4) and converted to PDF flat files before uploading to the appropriate form in the application package.

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 (1) to seven (7) years, as specified in each FOA/RFA. Service-specific FOA/RFAs are posted on the VA-ORD intranet (http://vaww.research.va.gov/funding/rfa.cfm). A FOA/RFA for a particular award activity code may not be issued by every Service or for every review cycle.

The table below summarizes the activity codes VA-ORD currently uses to fund intramural research:

Type (*Activity Code*)	**Description**
Research Awards	
Merit Review Award (*I01*)	*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 five (5) years. Budget caps vary among the Services. These awards make up the largest category of VA-ORD funding.
Pilot Project/Small Project Awards/SPiRE* (*I21*)	*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 use the same format for submitting a Merit Review Award; page limits may differ. Funding for these awards may be limited to two (2) years.
Program Project Awards (*IP1*)	*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. These 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*)	*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 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.

Type (*Activity Code)*	**Description**
Center Award^ (*I50*)	*Center Awards* are RR&D intramural awards 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 (5)-year plans. Centers provide relatively stable core funding, enabling a critical mass of investigators to leverage that support and develop long-term programs of research and mentoring of new investigators.
Center of Innovation (COIN) Award^ (I50)	*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 five (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*)	*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*)	*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 two (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. Applicants 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 a CDA-2.
Career Development Award (CDA-2) (*IK2*)	*CDA-2 Awards* are made to eligible institutions on behalf of a PD/PI to provide salary and/or project funds to support a three (3) to five (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 awardees will have competed for independent VA research funding.
VA-ORD Research Career Development Award for Scientists Associated with Minority Serving Institutions (MSI-CDA) (*IK2*)	The *MSI-CDA* was created to increase the diversity of VA researchers and to increase opportunities for MSIs as defined under Title III of the Higher Education Act of 1965 (20 U.S.C. § 1067q(a)) to participate in Federally funded research. The MSI-CDA program is open to applicants affiliated with MSIs who desire to have a mentored research training experience with VA investigators. In this program, both clinically and non-clinically trained post-doctoral researchers may gain mentored research time intended to advance awardees toward independence as funded VA-ORD scientists. Implicit in all CDA applications is the understanding that the awardee plans to continue a career within VA. This CDA-2 award provides salary and/or project funds to

Type (*Activity Code)*	Description
	support a three (3)- to five (5)-year program of research career development and mentoring. Applicants must enlist the support of an appropriately qualified VA employee as their primary mentor, as well as a mentor affiliated with an MSI.
Nursing Research Initiative (NRI) Award (*IK3*)	*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.
Career Development Transition Award (CDTA) for VA Psychiatrists (*IK4*)	The *CDTA* offers salary support for psychiatrists who currently hold their first VA Merit Review award. The intent of the award is to provide VA psychiatrists with protected time to invest in their research activities, while also participating in clinical care activities. The award funds partial salary support for the duration of the award. With the urgent need to hire more psychiatrists (as stated for example in the Mental Health Hiring Initiative) and to further develop a competitive VA career pathway, this funding opportunity offers to further enhance research training opportunities specifically focused on psychiatry by creating a research career pathway for Psychiatrists.
Research Career Scientist[#] (RCS) (*IK6*)	*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 five (5) to seven (7) years of funding and undergo an interim review by ORD.
Other Award	
Shared Equipment Program[+] (ShEEP) (*IS1*)	The *ORD ShEEP* program encourages applications from groups of VA investigators to purchase or upgrade a single item of instrumentation or an integrated system (all components must be dedicated to the system and not used independently). Its purpose is to make available to VA Medical Centers expensive research equipment or instruments that are needed for VA-supported projects but cannot be acquired using other funding mechanisms. Types of instruments supported include, but are not limited to confocal and electron microscopes, biomedical imagers, mass spectrometers, DNA sequencers, biosensors, cell-sorters, X-ray diffraction systems, nuclear magnetic resonance (NMR) spectrometers, 3D motion capture systems, advanced 3D printing systems and large machine tools. To be eligible for this award the requested equipment or integrated system **must:** • cost more than $75,000 and less than $650,000; and • be used for research purposes only.

**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 Center or REAP applications, please refer to the appropriate RR&D FOA/RFA; for preparation of I50 Center of Innovation/COIN applications, please refer to the appropriate HSR&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.

2.2.1 Solicitations

Each Service issues 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-22-001).

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) or may include special emphasis areas within the Parent FOA/RFA.

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 SF 424*.**

In reading any VA-ORD FOA/RFA:

- A "release/posted date" refers to the date the FOA/RFA is posted on Grants.gov. Applicants 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, the Authorized Organizational Representative (AOR) cannot submit until the FOA/RFA "opening date".
- When accessing an application package, the FOA/RFA number and "expiration date" are auto-populated in the forms management screen. Have the correct application package before 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 "application submission deadline" 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 fatal errors that prevent application processing within eRA or cause an administrative withdrawal by VA-ORD.

2.3 Forms for a SF 424 Application to VA-ORD

The *SF 424 (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 *SF 424 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.

All required and optional forms are listed below and 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
SF 424 Research & Related (R&R) (Applicant Information, Project Title, etc.)	✔		Section 3.2
Project/Performance Site Locations	✔		Section 3.3
R&R 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, Financial Disclosure, Appendices)	Different FOA/RFAs and/or award activity codes may require different attachments		Section 3.4
R&R Senior / Key Person Profile (Expanded) (Biosketches and Current & Pending Support)	✔		Section 3.5
R&R Budget*	✔		Section 3.7

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

2.4 Creating and Formatting Text (PDF) Attachments

All text attachments to the application package must be submitted as PDF flat files 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.**

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. It is the PD/PI's and AOR's/SO's responsibility to check the e-Application within eRA Commons during the two (2)-business 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 (i.e., this occurs when PDF

attachments are not flat files). Applicants are also encouraged to take advantage of the Preview Application action in ASSIST or the Grantor Image tab in Workspace to identify any potential assembly issues prior to submission.

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 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.**

Options to use to avoid problems related to PDF attachments:

- If **Track Changes** has been used, "Accept All Changes in Document" and select "Final" and remove all comments before converting the file to PDF.
- Set the default paper size for printing to U.S. standard letter-sized paper (8.5 x 11 inches).
- **Disable all security features**. Security settings vary by PDF tool; therefore, ensure security settings are not marked to prevent NIH from opening and generating an assembled application image. **Do not** encrypt or password protect documents. Go to the Document Security tab under Document Properties (directly from the tab) and set the security parameters to ensure open access. **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 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 SF 424 application package) is submitted that has editable (fillable) fields, electronic signatures or has text boxes, images or comments inserted, it causes each element to represent a layer and data will be lost when the application image (e-Application) is created. This will result in errors that will prevent an application from processing. Flattening a PDF merges these separate elements into one flat layer. 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 unable to edit a file in the PDF, 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 an 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. If there are problems fixing the PDF settings, simply cut and paste from the PDF document into an 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 a text PDF is created properly 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.

- When attaching a PDF, an actual document is being uploaded, not just pointing to the location of an externally stored document. If the document is revised after it has been attached, it must be deleted and the revised document reattached 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 to combine letters from various individuals and institutions into a single attachment file. Do not scan text documents to produce other PDF attachments required for an application. Documents should be 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 an application and may cause the application to be rejected by Grants.gov or eRA Commons.

  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. Applications are viewed electronically, therefore a two-column format should be avoided.
- **Do not use bookmarks/hyperlinks/superscripts** that lead to another location within the application as the system cannot process these in an application.

PDF File Names:

- File names for **Attachments 1-10** are mandatory and may not be changed; incorrect file names will be flagged as errors.
- When attaching **Appendix** files (attachments 11 and higher), only the descriptor may be edited. The descriptor is the name of the appendix document. If descriptive text is included in an attachment name before the ".PDF" as described in the examples in bold, eRA will auto-generate a warning message concerning the attachment name. This warning can be ignored.
- Descriptors must be less than 50 characters and use only standard characters (A through Z, 0 through 9, spaces). Descriptors may not include special characters (&, *, %, /, etc.) or underscores. If a descriptor is more than one (1) word, use a space to separate them (no underscore, dash, etc.).
- File names are **not** case sensitive.

NOTE: Altering any other parts of appendix file names may cause parts of an application to be excluded from the final electronic image or for the attachments to appear in the wrong order.

2.4.2 Formatting Text (PDF) 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 will be administratively withdrawn 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: No more than 15 characters per horizontal inch, including characters and spaces
- Line Spacing: 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 ½ x 11 inches, not a European size such as A2.
- Margins: Use at least one-half inch (0.5") margins (top, bottom, left and right) for all pages. No information should appear in the margins; 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 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:

- 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.

Printer settings in the PDF conversion software may need to be changed to "remove margins" and then redo the PDF conversion.

Reduction of font size may not be readily apparent in the converted PDF file. To ensure font and margin requirements have been met, the PD/PI and AOR should print a page from each section of the e-Application from an attachment (i.e., Research Plan, Specific Aims, etc.) during the two (2)-business day application viewing window.

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: Fonts must be clear and readily legible and follow the font typeface requirement. A smaller font point size may be used but it must be in a black font color. 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 an MS Word document.

- All text in the body of the table:
  - may not exceed 17 characters per horizontal inch, and
  - must be single-spaced.
- All text in table and figure legends:
  - may not exceed 20 characters per horizontal inch, and
  - 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 the PD/PI or AOR during the two (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 (no use of URLs or video clips); thus, URLs and video clips may not be used to provide information necessary to the review. URLs may only be placed in the *Biographical Sketch* and *Bibliography and References Cited* attachments. PD/PIs should carefully review the application for URLs prior to submission. **Any submission with URLs placed anywhere else except the *Biographical Sketch* and/or *Bibliography and References Cited* attachments will be withdrawn from review.**

URLs **are** allowed within official documents that cannot be altered, such as letterhead (Letters of Support) or published articles/manuscripts (Appendix attachments); however, URLs should **not** be included in the body/content of a Letter of Support.

NOTE: Reviewers are under no obligation to view supplemental material; moreover, they are cautioned that they should not directly access a website, as it could compromise their anonymity. 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 the “Remove Hidden Information” function in Adobe Pro (Tools, Protect, Remove Hidden Information, Remove; then Save As Other, optimized PDF, discard object).
- Use Ctrl+F (“Search” or “Find” feature) for ‘www’ and ‘http’.

- Use Ctrl+F ("Search" or "Find" feature) for the following: .com, .edu, .gov, .net, and .org. If there is a sentence that starts with a word beginning with these first three letters (such as 'Communication'), the system may pick up the preceding period (.) and the 'Com' and return 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. PDF images may contain hidden URLs or other codes which can cause system errors.

Grantspersonship: 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 *VA-ORD SF 424* 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 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), Financial Disclosure	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)
Bibliography & References Cited	Four (4) pages	See Instructions.
Biographical Sketches	Five (5) pages	No more than five (5) 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.

2.5 "Resubmission" (Revised) Applications

Up to two (2) revised applications (identified as "Resubmission" applications on the *SF 424 (R&R) Form*) are allowed, with the exception of HSR&D Pilot and RR&D SPiRE submissions (I21) for which only one (1) revised application will be accepted.

In general, it is expected that the timeframe will be three (3) application submissions within six (6) review cycles for mechanisms that allow three (3) submissions and two (2) application submissions within three (3) review cycles for mechanisms that allow two (2) submissions. BLR&D and CSR&D allow three (3) submissions over four (4) review cycles for Career Development Awards, Clinical Trials and Epidemiology (EPIDs), as specified in the Letter of Intent (LOI) approval letter.

In submitting a resubmission application, it should be noted 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.

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.

A previously reviewed application submitted to another VA-ORD Service without substantial scientific changes will be considered a "Resubmission". 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.

If an application includes substantial scientific changes in response to the previous review and will now be submitted to a different Service, 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.

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 the PD/PI 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.

There are four (4) 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 (-01 or -01A1) 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 being responded to, 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 changes. Describe deleted sections, **do not** mark as deletions. If 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 (3) 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. A new application will 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. 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

Competing supplemental applications (known as "Revision" applications) which request additional support for expansion of an existing project's scope or research protocol are only used if specifically noted in a FOA/RFA.

2.7 Similar, Essentially Identical or Identical Applications

Simultaneous submission of identical (or essentially identical) applications to one or more Services is 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 easily identify multiple applications for essentially the same project. In these cases, application processing may be delayed or the application(s) withdrawn from review.

2.8 Submitting an Application

There are two (2) options for submitting applications: Grants.gov Workspace and NIH ASSIST.

On-time submission means that an application is submitted error free (to both Grants.gov and eRA Commons) **before 5 p.m. local time of the VAMC on the application submission deadline date**. PD/PIs are encouraged to submit application(s) several days early to ensure enough time to correct any errors before the deadline. Changed/Corrected applications submitted after the application submission deadline 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 Workspace go to Workspace Process or the Grants.gov Online User Guide. Guidance on tapping the full potential of Workspace is available on the Grants.gov Community Blog; or a two (2)-minute YouTube video 'Getting Started on Your Application'.

Workspace provides for the following:

- Multiple users can concurrently complete the application forms
- Reuse/copy existing Workspace forms
- Upfront validation so application errors can be corrected prior to submission
- Seamless integration between online webforms and offline PDF forms
- Collaboration with users external to the PD/PI's 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 *SF 424 (R&R) Form* set and to submit through Grants.gov to NIH. A FOA/RFA number (i.e., RX-22-001) is needed to initiate an application and active Grants.gov and eRA Commons credentials. For step-by-step guidance on using ASSIST go to ASSIST Login or the ASSIST User Guide.

ASSIST provides for the following:

- Leverage current eRA Commons credentials to access
- Delegation of application preparation responsibilities to multiple users within and outside a VAMC while maintaining appropriate access control and security
- Populates data from established eRA Commons profiles
- Runs validations on Federalwide and VA-ORD business rules prior to submission
- Automatically generates Table of Contents, headers, footers, page numbers, etc.
- Print/Previews applications prior to submission
- Presents to reviewers clear, color PDF images rather than scanned versions
- Allows tracking of an application with a single login through Grants.gov to eRA Commons

2.9 After Submitting an Application

For a fair review, it's important that all applicants competing together for funding have adhered to the same rules. Once an application is submitted to Grants.gov, three (3) basic application checks are performed - by Grants.gov, eRA and by VA-ORD staff – before it's referred for review. These business rule checks are also referred to as "validations".

For a successful submission and to pass validations:

- Follow the *VA-ORD SF 424* and Service-specific FOA/RFA instructions; and
- Submit early enough to allow time to address any system identified errors, correct the errors and submit a changed/corrected application by the application submission deadline.

If an issue is identified, Grants.gov will reject the application with a "Rejected with Errors" status. All errors must be corrected and the application resubmitted (changed/corrected application). If no issues are identified, Grants.gov places the application in a queue for VA-ORD retrieval.

PD/PIs must check the status of their application in eRA Commons. If issues are identified in an application, 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 an application from moving forward and are addressed at the PD/PI's discretion.

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

There is a two (2)-business day application viewing window to check an assembled e-Application. An 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 AOR/SO in eRA Commons.

Submit:

- Submit early – this provides time to track an application, view and correct any errors and submit a changed/corrected application before the application submission deadline.
- The specific actions to submit an application will vary by submission method used (ASSIST or Workspace).
- Each application is assigned a Grants.gov tracking number (e.g., GRANT12345678). Save this number to track the submission.
- A Grants.gov timestamp noting the official submission date/time is provided. (*NOTE:* Grants.gov's timestamp is in Eastern time.)
- An error-free application must be submitted by **5:00 p.m. local time** of the VAMC.
- If there are no system validation errors, the PD/PI, 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. Grants.gov will indicate that the agency tracking number has been assigned and reflect both numbers. In subsequent interaction with eRA Commons, the agency accession number will be used to refer to the application.

Track:

- The PD/PI and AOR/SO are responsible for tracking an application through Grants.gov to an assembled e-Application image in eRA Commons.
- eRA system notices will be sent to the PD/PI, AOR/SO and Contact PD/PI summarizing download and validation results.
- Any **errors** identified in Grants.gov and eRA Commons must be corrected and a changed/corrected application submitted before the application submission deadline. See Section 2.10 Correcting Errors.
- To track an application status in Grants.gov, ASSIST or eRA Commons:
  - For Workspace go to 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.

View:

- The assembled e-Application image in eRA Commons is the document used by VA-ORD staff and reviewers.
- Use the two (2) business day application viewing window (Monday – Friday, excluding weekends and Federal holidays) to check the assembled e-Application to ensure content is complete and format requirements are met. If no action is taken, on the third (3rd) business day the application will automatically move forward for final processing. I
- If there is a need to submit a changed/corrected application during the application viewing window the **AOR/SO must first REJECT the previously submitted application** before the changed/corrected application is submitted. If multiple versions are submitted and verify, all versions may be withdrawn without review. See Section 2.10 Correcting Errors.

- After the “Down to the Wire” submission deadline, the two (2) business day application viewing window cannot be used.
- If a changed/corrected application is needed after the application viewing window has closed and ONLY if the submission deadline hasn’t passed, the AOR/SO can request VA-ORD (Agency Contact listed in the FOA/RFA) to withdraw an application from the system to allow for a changed/corrected application to be submitted.
- A changed/corrected application replaces the previous submission – the corrected submission cannot be rejected/withdrawn in order to return to a previous submission.
- Changed/corrected applications must be submitted by 5 p.m. local time of the VAMC on the application submission deadline.
- Once verified, an application is considered final and no other version will be accepted for review.

2.10 Correcting Errors

Changed/corrected applications must meet both deadlines (submission and verification; see Deadline, Review and Award Dates in the Service-specific FOA/RFA).

The application will only be assigned for scientific review once all errors are resolved. Applications that fail Grants.gov, eRA or VA-ORD system validations or staff administrative review will not be accepted. The AOR/SO and PD/PI may be contacted by VA-ORD staff if further corrections/clarifications are needed.

Prior to the submission deadline, corrections can be made and a changed/corrected application submitted. See View above and Section 2.12 Application Due Dates.

If errors or warnings result from the system validation process, the PD/PI) AOR/SO and Contact PD/PI will receive an email with instructions to log on to eRA Commons to review the list of warnings/errors identified during the validation process.

The **difference between *errors* and *warnings*:** An *error* is used for any condition that causes the application to be deemed unacceptable for further consideration. Generally, errors will indicate significant inaccuracies, inconsistencies, omissions or incorrect formatting identified during system validations. **Errors must be corrected and a changed/corrected application submitted in order for the application to be accepted.**

A *warning* is for any condition that may be acceptable, at least for the time being, but is worthy of bringing to the PD/PI’s and AOR/SO’s 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 the PD/PI’s and AOR/SO’s discretion.

NOTE: Warnings do not stop further system application processing. If no action is taken, an application with warnings (but not errors) will automatically move forward in eRA on the third (3rd) business day after the two (2)-business day application viewing window closes.

Failure to comply with stated VA-ORD policies can also result in a submitted application not being considered for review. For this reason, review all warnings to ensure that they require no further attention and confirm validation results. Warnings and errors can be corrected in the same manner. A changed/corrected application may also be submitted if the e-Application, as viewed in eRA Commons, is incomplete or inaccurate.

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

- **Grants.gov Workspace:** Check 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).
- 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).
- **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, *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, *Application Errors and Warnings Results*).
- **eRA Commons:** Log on to Commons using the PD/PI's or SO's 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 (AN).
  - PD/PIs: Click Recent/Pending eSubmissions to automatically display a hit list.

To correct errors and resubmit an application:

- Changed/Corrected Applications cannot be submitted after the application submission deadline in Grants.gov. Any 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 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 (2)-business day application viewing window, subsequent changed/corrected applications will not be accepted unless the application is withdrawn by VA-ORD staff (Agency Contact listed in the FOA/RFA); do not submit another "New" application to circumvent contacting VA-ORD staff.
- Make whatever corrections are necessary, wherever appropriate – to the local copy of the application and/or within the system through which 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 the PD/PI is correcting in Item 4c Previous Grants.gov Tracking ID. The tracking number can be obtained from the AOR/SO.
- For a **Resubmission** or **Renewal Application** (Item 8 = Resubmission or Renewal) enter only the two (2)-letter Service designation and serial number of the previously assigned full research e-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). The full research e-application number can be obtained from the previous Summary Statement. In addition, the tracking number assigned by Grants.gov (e.g., GRANT123456) to the immediately previous application that is being corrected must be entered in Item 4c Previous Grants.gov Tracking ID. *NOTE:* An application may be marked as "Renewal" for only the initial submission; the two (2) successive submissions must be marked as "Resubmission".
- The AOR/SO must submit the changed/corrected application package. A new Grants.gov tracking number is 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 SF 424*, by a Service-specific FOA/RFA or solicited by the SRO, post-submission application materials (supplementary or corrective material) will not be accepted after an application verifies.

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 the 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 5:00 p.m. (local VAMC time) of the application submission deadline.
AND

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

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 or Winter).

Application Assignment Information: Applications successfully submitted will be processed through VA-ORD and 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 (2) 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 a PD/PI may suggest/request assignment to a specific SRG or Service through the VAMC R&D Office (ACOS/R and/or AO). Although these suggestions will be taken into consideration, final determination will be made by the Service(s) participating in each (FOA/RFA).

After the due date, usually within four (4) weeks, the PD/PI and 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, the VAMC R&D Office may request reassignment on behalf of the PD/PI.

If assignment information is not available in eRA Commons within four (4) 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, the PD/PI will receive notification.

Contact with the SRG is not Permitted: The PD/PI 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 a serious breach of confidentiality and conflict of interest in the peer review process. From the time of assignment to the time the review of an application is complete, all questions must be directed 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 there is 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 and may in fact make an issue worse if advice is followed based on NIH requirements.

2.14.1 VA-ORD Help for Application Preparation and Submission

The VAMC R&D Office must submit all inquiries/problems concerning application submissions to the **VA-ORD eRA Mailbox** (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 a PD/PI directly contacts individuals at VA-ORD (by phone or email) and they are on leave or otherwise unavailable, their 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: Commonsplus (nih.gov)
eRA Commons On-line Resources and Web Ticketing: Need Help? | eRA (nih.gov)
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: Have the following information readily available to help expedite an eRA Service Desk request have the following information readily available. 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 *SF 424 R&R Forms*

3.1 Overview

This section contains all of the instructions needed to complete the *SF 424 (R&R) Forms*. **Conformance to all instructions is required and strictly enforced. Applications that are not consistent with these instructions will be withdrawn from review.**

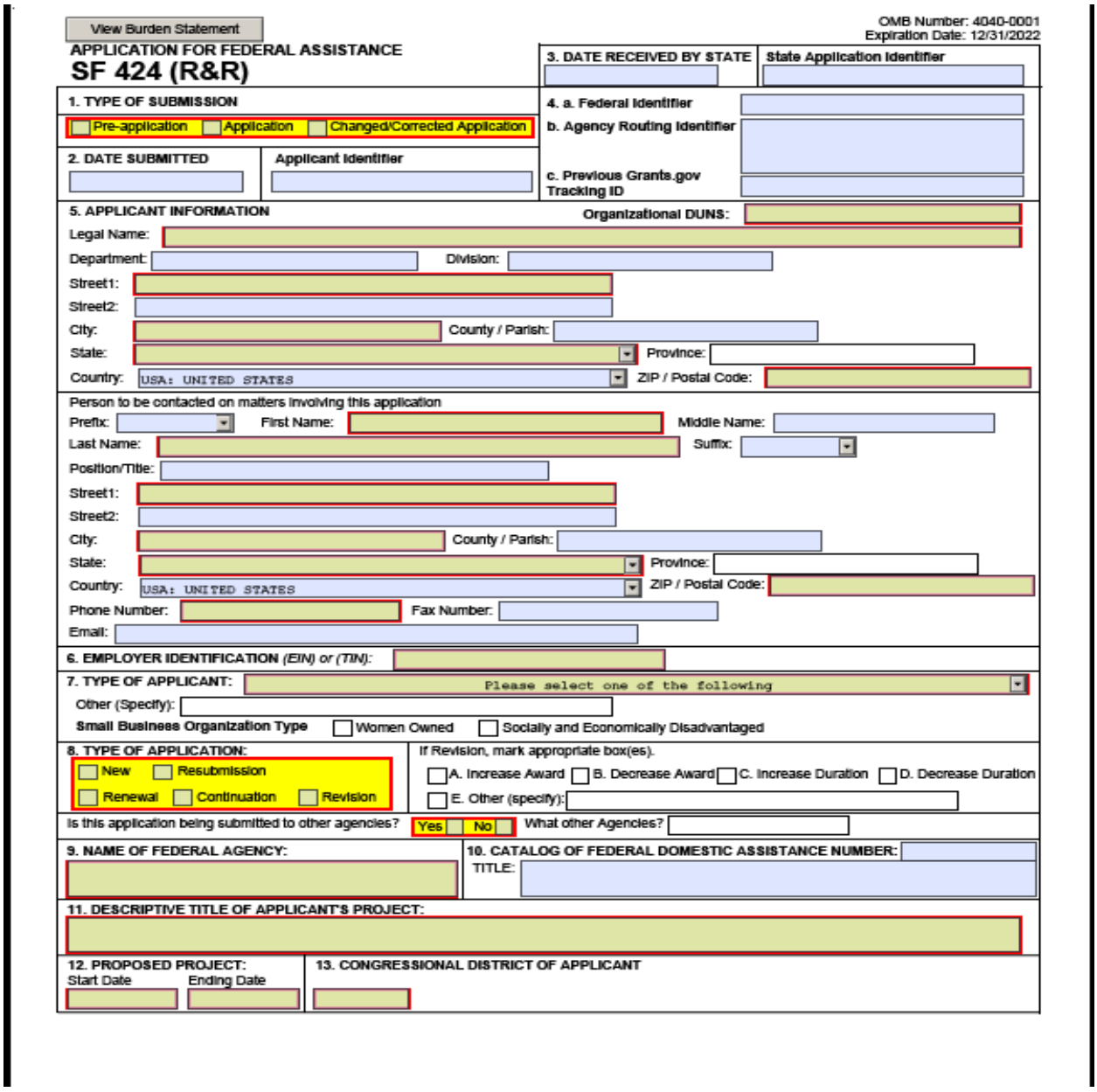
When navigating through *SF 424 Forms*, required fields are highlighted in yellow and outlined in red. Optional fields and completed fields are displayed in white. **However, there may be required fields for VA-ORD applications that are not highlighted on these forms.**

Data entered into a specific field is not accepted until navigation has been made to the next field. If invalid or incomplete information is entered in a required field, an error message will be received.

Caution: When a required field is “clicked”, it may not be undone or left blank. If this occurs, entering two (2) spaces or “N/A” to satisfy the error check for the required field; if this does not work, a new application may need to be started.

Do not cut and paste from any other program (i.e., WORD or ePROMISe) to complete fields on SF 424 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.

3.2 SF 424 (R&R) Form



View Burden Statement

OMB Number: 4040-0001
Expiration Date: 12/31/2022

APPLICATION FOR FEDERAL ASSISTANCE
SF 424 (R&R)

3. DATE RECEIVED BY STATE	State Application Identifier

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

2. DATE SUBMITTED | **Applicant Identifier**

4. a. Federal Identifier
b. Agency Routing Identifier
c. Previous Grants.gov Tracking ID

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

Person to be contacted on matters involving this application
Prefix: First Name: Middle Name:
Last Name: Suffix:
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 ☐ Women Owned ☐ Socially and Economically Disadvantaged

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

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

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

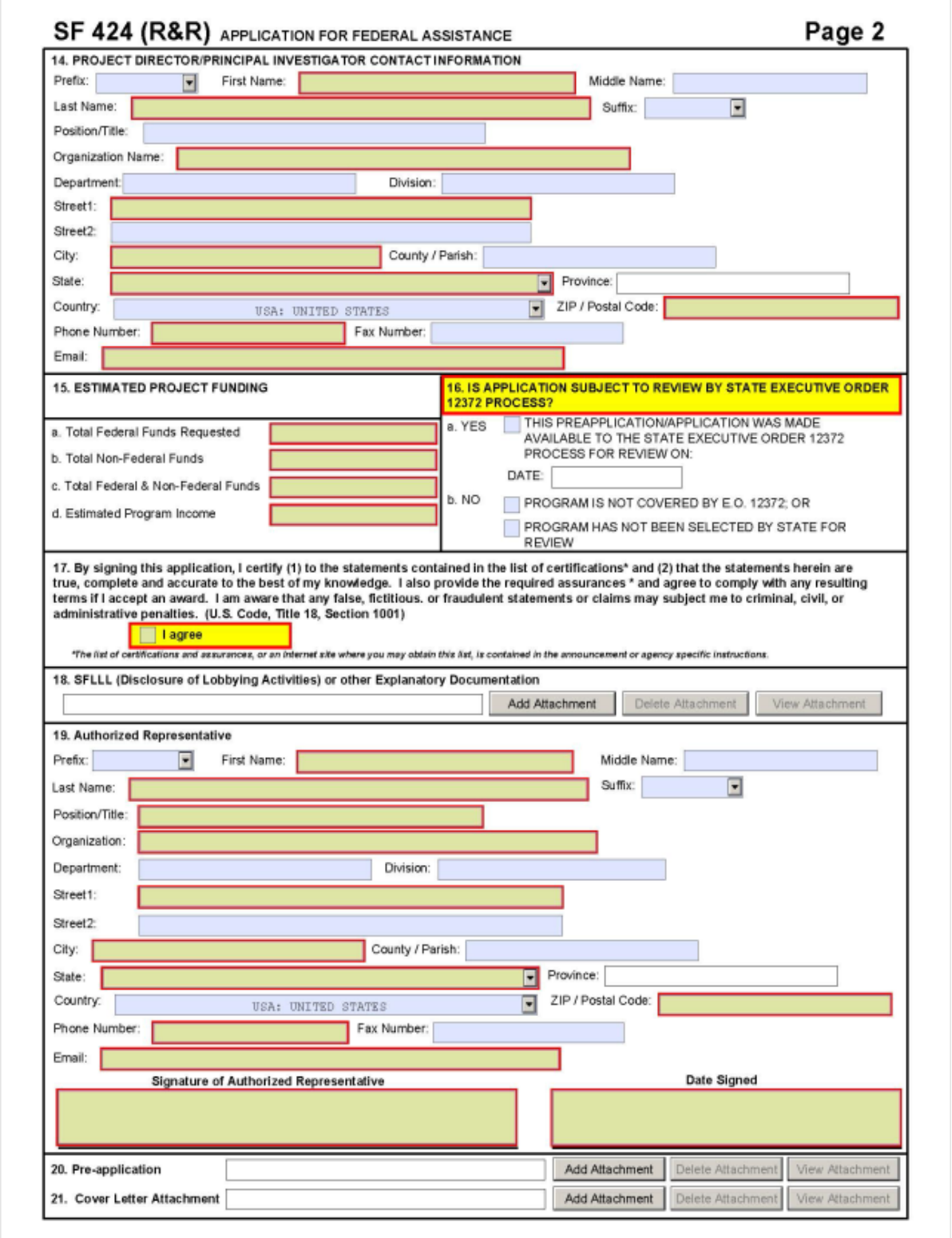
9. NAME OF FEDERAL AGENCY:

10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER:
TITLE:

11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT:

12. PROPOSED PROJECT:
Start Date Ending Date

13. CONGRESSIONAL DISTRICT OF APPLICANT



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

14. PROJECT DIRECTOR/PRINCIPAL INVESTIGATOR CONTACT INFORMATION

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

15. ESTIMATED PROJECT FUNDING

a. Total Federal Funds Requested
b. Total Non-Federal Funds
c. Total Federal & Non-Federal Funds
d. Estimated Program Income

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

a. YES THIS PREAPPLICATION/APPLICATION WAS MADE AVAILABLE TO THE STATE EXECUTIVE ORDER 12372 PROCESS FOR REVIEW ON:
DATE:
b. NO PROGRAM IS NOT COVERED BY E.O. 12372; OR
PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW

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

I agree

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

18. SFLLL (Disclosure of Lobbying Activities) or other Explanatory Documentation

Add Attachment Delete Attachment View Attachment

19. Authorized Representative

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

Signature of Authorized Representative Date Signed

20. Pre-application Add Attachment Delete Attachment View Attachment

21. Cover Letter Attachment Add Attachment Delete Attachment View Attachment

1. Type of Submission (*Required Field*)

Check one box.

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 submission due date, this box must be used if submitting 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 two (2)-business day application viewing window. See Section 2.10 Correcting Errors.

2. Date Submitted and Applicant Identifier

This field will auto-populate upon application submission.

For the Applicant Identifier field, enter the control numbers created by the 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 fields blank.

4.a. Federal Identifier

For applications marked "New" in Box 8, leave field blank.

For "Resubmission" or "Renewal" applications, enter only the two (2)-letter Service designation and serial number from the previously assigned full research e-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). **Do not** enter a Pre-application (I02) award number in this field.

The correct previous full research e-application number must be used; if the wrong Federal Identifier is entered the system will not be able to process the 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-	Grants.gov tracking ID (e.g., GRANT123456)

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
			Tampa). A Center name may also be included.	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 AOR/SO.

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

Include only the two (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

If Changed/Corrected Application box is checked for Type of Submission, this field is required. Enter the previous Grants.gov tracking number (example, GRANT12345678) obtained from the VAMC AOR/SO.

5. Applicant Information (*Required Field*)

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

Field Name	Instruction
Unique Entity Identifier (UEI)	Enter the UEI of the VAMC. This UEI must match the number entered in the eRA Commons Institutional Profile (IPF) for the VAMC. The AOR should confirm that a UEI has been entered into the eRA Commons IPF prior to application submission. The same UEI should be used in the eRA Commons IPF, Grants.gov, SAM registration and in the UEI field in the application. If the PD/PI's organization does not already have a UEI, they will need to go to SAM.gov to register and obtain a UEI.
Legal Name	Enter the legal name of the PD/PI's **VAMC**.
Department	Enter the name of the primary organizational department, service, laboratory or equivalent level within the VAMC that will undertake the assistance activity.
Division	Enter the name of the primary organizational division, office or major subdivision within the VAMC that will undertake the assistance activity.
Street1	This field is required. Enter the first line of the VAMC's street address.

Field Name	Instruction
Street2	Enter the second line of the VAMC' street address, if applicable.
City	This field is required. Enter the city for address of the VAMC.
County/Parish	Enter the VAMC's county/parish for address.
State	Enter the state where the VAMC is located.
Province	Leave this blank.
Country	Select United States.
ZIP/Postal Code	This field is required. Enter the ZIP+4 of the VAMC.

Person to be contacted on matters involving this application: This information is for the VAMC AO, not the PD/PI or designee. This individual will be notified if additional information is needed and/or if an award is made. The information provided in this section must match the AO profile information in eRA Commons. (See eRA Commons YouTube video: Maintaining Your Personal Profile).

Field Name	Instruction
Prefix	Enter or select the prefix, if applicable, for the name of the person to contact on matters related to this application.
First Name	This field is required. Enter the first (given) name of the person to contact on matters related to this application.
Middle Name	Enter the middle name of the person to contact on matters related to this application.
Last Name	This field is required. Enter the last (family) name of the person to contact on matters related to this application.
Suffix	Enter or select the suffix, if applicable, for the name of the person to contact on matters related to this application.
Position/Title	Enter the Position/Title for the person to contact on matters related to this application.
Street 1	This field is required. Enter the first line of the street address for the person to contact on matters related to this application.
Street 2	Enter the second line of the street address for the person to contact on matters related to this application.
City	This field is required. Enter the city for the address of the person to contact on matters related to this application.

Field Name	Instruction
County/Parish	Enter the county/parish for the address of the person to contact on matters related to this application.
State	This field is required. Enter the State where the person to contact on matters related to this application is located.
Province	Leave this blank.
Country	This field is required. Select United States.
ZIP/Postal Code	This field is required. Enter the ZIP+4 for the person to contact on matters related to this application.
Phone Number	This field is required. 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 one (1) email address for the person to contact on matters related to this application.

6. Employer Identification (*Required Field*)

Enter the Taxpayer Identification Number (TIN) or Employer Identification Number (EIN) as assigned by the Internal Revenue Service. If the EIN is twelve (12)-digits, enter all twelve (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	Instruction
Type of Applicant	Select X: Other (specify).
Other (Specify)	Enter “VA-ORD”.
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	Instruction
Type of Application	Select the type from the following list. Check only one: **New:** An application that is being submitted to VA-ORD for the first time. **Resubmission:** Check this option when submitting a revised (altered or corrected) or amended application; this includes resubmission of Renewal applications. Resubmissions must be marked as "Resubmission" in Box 8; all others must be marked as "New." **Renewal*:** Check this option if 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 if the applicant were applying for the first time. Applications for renewal of a previously funded awards should be marked as "Renewal". An application may be marked as "Renewal" for only the initial submission; the two (2) successive submissions must be marked as "Resubmission." After three (3) unsuccessful submissions (initial + two (2) resubmissions) a "New" application must be submitted. *NOTE:* Not all Services accept renewal applications or for all types of awards. **Continuation:** Do not check this box. VA-ORD does not accept Continuation applications. **Revision:** Only use if specifically noted in a FOA/RFA.
Is this application being submitted to other agencies?	This field is required. Check the box "yes" if one or more of the specific aims submitted in the application are also contained in a similar, identical or essentially identical application submitted to another Federal agency. Indicate the agency or agencies to which the application has been submitted.
What Other Agencies?	Enter the other Federal agency name(s). Include private foundations, etc.

9. Name of Federal Agency

This field auto-populates from the opportunity package (Office of Research and Development).

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

This field auto-populates from the opportunity package.

This field may be blank. When this field is blank, leave it blank; the field does not allow 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 limited to 200 characters, including spaces 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.

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 Pre-application/LOI was submitted, the appropriate Service must be notified before changing the title in the application from that submitted for the ITS or LOI. (See Service-specific FOA/RFAs for staff contact(s).)

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

Start Date: Enter the proposed (estimated) start date of the project.
Ending Date: Enter the proposed ending date of the project. The project period should not exceed what is allowed in the FOA/RFA.

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

Enter the Congressional District for the VAMC named in Box 5 Applicant Information: two (2)-character State Abbreviation, a hyphen (-), and a three (3)-character District Number.

Examples: CA-005 for California's 5th district*, CA-012* for California's 12th district.

To locate a congressional district, visit the U.S. House of Representatives website by entering the VAMC Zip Code+4. To look up a Zip Code+4, go to: http://zip4.usps.com/zip4/welcome.jsp. Alternatively, the Congressional Directory may be used with the PD/PI's Zip Code+4 to search; if the zip code is part of multiple districts, an address must be entered.

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 entered here and affiliated in eRA Commons with the VAMC (entered in Box 5. Applicant Information). All PD/PIs are required to 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, information provided in this section must match the PD/PI profile information contained in eRA Commons. (See eRA Commons: Maintaining Your Personal Profile.)

All PD/PIs must meet the eligibility requirement(s) of the Service to which the application is being submitted.

Field Name	Instruction
Prefix	Enter or select the prefix, if applicable, for the name of the PD/PI.
First Name	This field is required. Enter the first (given) name of the PD/PI.
Middle Name	Enter the middle name of the PD/PI.
Last Name	This field is required. Enter the last (family) name of the PD/PI.
Suffix	Enter or select the suffix for 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 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 Form*.
Organization Name	This field is required. Enter the name of the VAMC or VA Health Care System where the PD/PI is employed.
Department	Enter the name of the VAMC primary organizational department, service, laboratory or equivalent level for the PD/PI.
Division	Enter the name of the VAMC primary organizational division, office or major subdivision for the PD/PI.
Street1	This field is required. Enter the first line of the street address for the PD/PI.
Street2	Enter the second line of the street address for the PD/PI, if applicable.
City	This field is required. Enter the city for address of the PD/PI.
County/Parish	Enter the county/parish for address of the PD/PI.
State	This field is required. Enter the State where the PD/PI is located.
Province	Leave this blank.
Country	Select United States.
ZIP/Postal Code	This field is required. Enter the ZIP+4 of the PD/PI.
Phone Number	This field is required. Enter the daytime telephone number for the PD/PI.
Fax Number	Enter the fax number for the PD/PI.
Email	This field is required. Enter one (1) email address for the PD/PI.

15. Estimated Project Funding (*Required Fields*)

Field Name	Instruction
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 entered for item 15a.
d. Estimated Program Income	Enter $0 (zero) unless program income may/has result(ed) from technology, etc., that was licensed, then enter the anticipated/known dollar amount and provide a description of the income source in the *Budget Justificatio*n.

16. Is Application Subject to Review by State Executive Order 12372 Process?

(*Required Field*)

Check “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. For VA-ORD see 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 AOR in Grants.gov or SO in eRA Commons – the VAMC person with authority to sign for an application.

Field Name	Instruction
Prefix	Enter or select the prefix, if applicable, for the name of the AOR/SO.
First Name	This field is required. Enter the first (given) name of the AOR/SO.
Middle Name	Enter the middle name of the AOR/SO.
Last Name	This field is required. Enter the last (family) name of the AOR/SO.
Suffix	Enter or select the suffix, if applicable, for the AOR/SO.
Position/Title	This field is required. Enter the position/title of the AOR/SO.
Organization	This field is required. Enter the name of the VAMC or VA Health Care System for the AOR/SO.

Field Name	Instruction
Department	Enter the name of the VAMC primary organizational department, service, laboratory or equivalent level for the AOR/SO.
Division	Enter the name of the VAMC primary organizational division, office or major subdivision for the AOR/SO.
Street1	This field is required. Enter the first line of the street address for the AOR/SO.
Street2	Enter the second line of the street address for the AOR/SO, if applicable.
City	This field is required. Enter the city for the address of the AOR/SO.
County/Parish	Enter the county/parish for the address of the AOR/SO.
State	This field is required. Enter the state where the AOR/SO is located.
Province	Leave this blank.
Country	Select United States.
ZIP/Postal Code	This field is required. Enter th**e ZIP+4** of the AOR/SO.
Phone Number	This field is required. Enter the daytime phone number for the AOR/SO.
Fax Number	Enter the fax number for the AOR/SO.
Email	This field is required. Enter one (1) email address for the AOR/SO.
Signature of Authorized Representative	Grants.gov will record an 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.

20. Pre-application

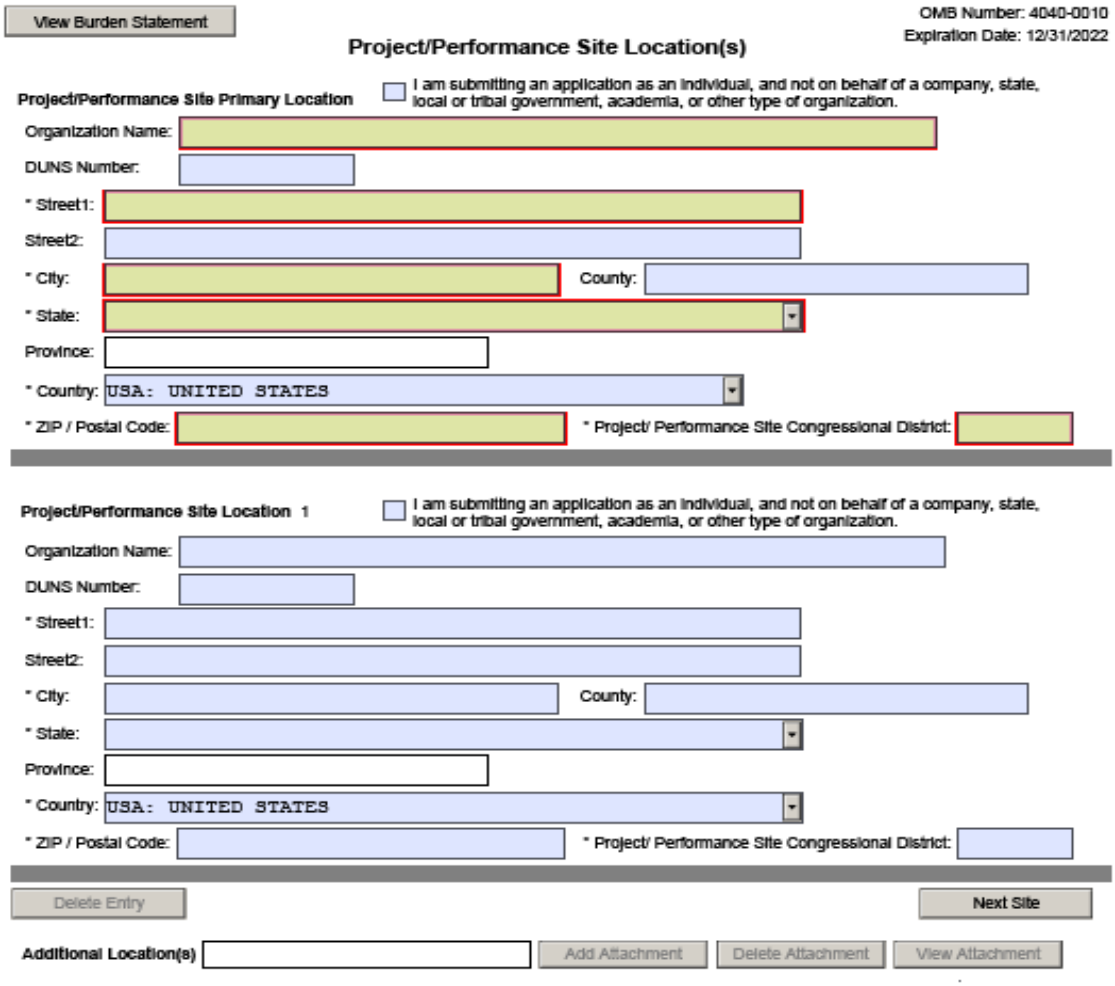
Unless specifically noted in a FOA/RFA, the Pre-application option is not used. The Pre-application attachment field should not be used for any other purpose.

Check the Service-specific FOA/RFA for details on submitting an ITS, Pre-application (LOI) or waiver requests for approval. If permitted by the companion FOA/RFA, attach this information as a single PDF flat file.

21. Cover Letter Attachment

Do not upload any attachment – an error will be received. This is a system validation.

3.3 Project/Performance Site Location(s) Form



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 *SF 424 (R&R)*.

An off-site primary location is only permitted if a full off-site waiver (see ORD Program Guide 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 an approved full off-site waiver must be included in Letters of Support, 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 Federalwide Assurance for the protection of human subjects and complies with VA Policy on the requirements for the protection of human subjects in research (VHA Directive 1200.05(1) Requirements for the Protection of Human Subjects in Research) and other VA human subject related instructions and policies as described in Part II and Part III.

For research involving live vertebrate animals, the VAMC must ensure that all Project/Performance Sites comply with VHA Handbook 1200.07: Use of Animals in Research and as described in Part II.

Field Name	Instruction
Organization Name	This field is required. Enter the name of the primary performance site where the work will be performed.
Unique Entity Identifier (UEI)	This field is required for the primary performance site.
Street1	This field is required. 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	This field is required. Enter the city for address of the primary performance site location.
County	Enter the county of the primary performance site location.
State	This field is required. Enter the state where the primary performance site is located.
Province	Leave this blank.
Country	This field is required. Select United States.
ZIP/Postal Code	This field is required. Enter the ZIP+4 of the primary performance site location.

Field Name	Instruction
Project/Performance Site Congressional District	Enter the Congressional District in the format: two (2)-character State Abbreviation – three (3)-character District Number. *Examples: CA-005* for California's 5th district, *CA-012* for California's 12th district. If all districts in a state are affected, enter "all" for the district number. *Example: MD-all* for all congressional districts in Maryland. If nationwide (all districts in all states), enter U.S.-all. If the program/project is outside the U.S., enter 00-0000. To locate a congressional district, visit the Grants.gov web site. This field may be identical to the "Congressional District of Applicant" field. For States and U.S. territories with only a single congressional district, enter "001" for the district code. For jurisdictions with no representative, enter "099". For jurisdictions with a nonvoting delegate, enter "098" for the district number. *Example: DC-098, PR-098.*

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

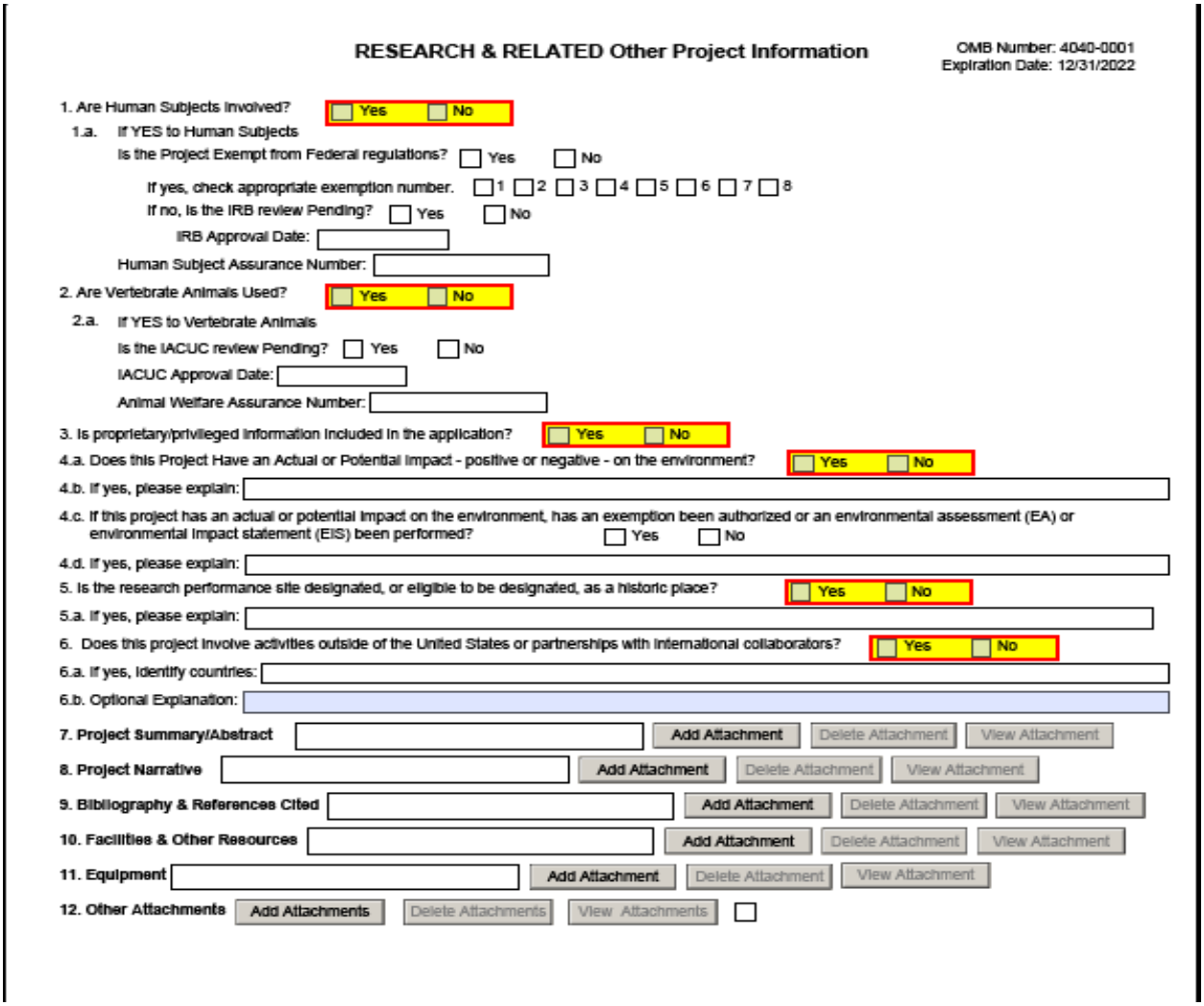
Field Name	Instruction
Organization Name	Enter the name of organization of the first additional performance site location.
Unique Entity Identifier (UEI)	Enter the UEI for the first additional performance site.
Street1	This field is required. Enter the first line of the street address of the additional performance site location.
Street2	Enter the second line of the street address of the additional performance site location, if applicable.
City	This field is required. Enter the city of the additional performance site location.
County	Enter the county or parish of the primary performance site location.
State	This field is required. Enter the state where the performance site is located.
Province	Leave this blank.
Country	This field is required. Select the country of the performance site location.
ZIP/Postal Code	This field is required. Enter the ZIP+4 of the performance site location.
Project/Performance Site Congressional District	Enter the Congressional District in the format: two-character State Abbreviation – three-character District Number. *Examples: CA-005* for California's 5th district, *CA-012* for California's 12th district. If all districts in a state are affected, enter "all" for the district number. *Example: MD-all* for all congressional districts in Maryland. If nationwide (all districts in all states), enter U.S.-all. If the program/project is outside the U.S. enter 00-0000.

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

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

If more than 300 locations (primary plus 299 additional sites) are needed, 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 R&R Other Project Information Form



RESEARCH & RELATED Other Project Information

OMB Number: 4040-0001
Expiration Date: 12/31/2022

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 — Add Attachment | Delete Attachment | View Attachment
8. Project Narrative — Add Attachment | Delete Attachment | View Attachment
9. Bibliography & References Cited — Add Attachment | Delete Attachment | View Attachment
10. Facilities & Other Resources — Add Attachment | Delete Attachment | View Attachment
11. Equipment — Add Attachment | Delete Attachment | View Attachment
12. Other Attachments — Add Attachments | Delete Attachments | View Attachments

1. Are Human Subjects Involved? (*Required Field*)

Check "Yes" if:

- Activities involving human subjects are planned at any time during the proposed project at the VAMC (applicant organization) or at any performance site or collaborating institution.
- Tissues (e.g., biopsies, banked material or whole organs) or samples (i.e., blood, sputum, etc.) from human subjects will be used.
- The proposed research has been determined by an Institutional Review Board (IRB) to be exempt from Regulations for the Protection of Human Subjects (this is still human subjects research).
- A human subject is a living individual about whom an investigator (whether professional or student) is conducting research, and:
  - obtains information or biospecimens through intervention or interaction with the individual, and uses, studies or analyzes the information or biospecimens; or
  - obtains, uses, studies, analyzes or generates identifiable private information or identifiable biospecimens (38 CFR 16. 102(e)(1).

Check “No” if:

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

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

1.a. If YES to Human Subjects

Is project exempt from Federal Regulations? Yes/No

Check “No” for this question. Check “No” even if the IRB review is complete and a determination of exemption status has been made by the IRB. **Do not** check any of the exemption 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.

NOTE: If “Yes” is checked and the box below for IRB Approval Date is clicked, 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: Enter the IRB approval date if available. An IRB Approval Date is not required at the time of submission. Assurance of completion of IRB approval will be requested later in the award cycle as a Just-In-Time (JIT) compliance requirement.

Human Subject Assurance Number: Enter the approved Federalwide Assurance (FWA) Number that the VAMC has on file with the Office for Human Research Protections (OHRP), 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, the assurance number may be entered 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.

If the VA Central IRB is used, be sure to use the correct assurance number of the VA Central IRB. 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. *NOTE:* The generation of custom antibodies constitutes an activity involving vertebrate animals.

If “Yes” is checked, a Vertebrate Animals attachment must be provided in Item 12. Other Attachments.

Check “No” if no activities involving vertebrate animals are not 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.

NOTE: If “Yes” is checked and the box below for IACUC Approval Date is clicked, 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 2.a.

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 the PD/PI’s VAMC holds an Animal Welfare Assurance, go to the Office of Laboratory Animal Welfare, Institutions with a PHS Approved Animal Welfare Assurance. 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, enter the assurance number for the affiliate.

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 the PD/PI, 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 an international site(s) (not within the United States, its territories or Commonwealths) or if either human biological specimens or human data originating from an international site(s) 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
This field is optional, unless Question 6 is “Yes” then provide a brief explanation (limited to 55 characters) for involvement with outside entities.

If the international special resources or characteristics of the research project involve human subject populations, this description should be included in the Human Subjects attachment in Item 12. Other Attachments.

7. Project Summary/Abstract (*Required Field; Maximum 40 lines of Text – System Validation*)
The Project Summary/Abstract is meant to serve as a succinct and accurate description of the proposed work and should 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 first person. Text must follow required font and margin specifications.

Do not begin the Project Summary with the extra words: "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 the entry. The attachment must be a PDF flat file (see Section 2.4 on creating and formatting PDF attachments).

8. Project Narrative (*Required Field; Maximum 10 lines of Text*)
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 become public information.

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 a PDF flat file (see Section 2.4 on creating and formatting PDF attachments).

9. Bibliography & References Cited (*Required Field; Page Limit: 4 – System Validation*)
Include all references cited in the Research Plan attachment. References should be limited to relevant and current literature; it is important to be concise and select only those literature references pertinent to the proposed research. For references with more than three (3) authors, "et al" may be used after the 3rd author has been listed. **Applications that do not include full references (i.e., title, authors, etc.) 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. Prior to final submission, review all references cited for accuracy and correct order within the e-Application and check that any software used to generate this document uses a default font typeface and font size that meets font requirements (see Section 2.4.2 Formatting PDF (Text) Attachments).

Do not use bookmarks/hyperlinks/superscripts that lead to another location within the application – inclusion will cause eRA system processing to fail.

Internet website addresses (URLs) may be included in this attachment. 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 this document, 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 e-Application in eRA Commons.

An example of how to cite a web-based resource such as CDC without including a URL:

> *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. 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, 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), describe the biocontainment resources available at each site.

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.

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 PDF flat files must be attached in Item 12 to provide required project information that was not included in Items 1-11 above. Required attachments are described in the Table below.

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 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).

File Naming and Formatting Guidelines: File names for **Attachments 1-10** are mandatory and may not be changed; incorrect file names will be flagged as errors. See Table 1 for all file naming conventions.

When attaching **Appendix** files (attachments 11 and higher), only the descriptor may be edited. The descriptor is the name of the appendix document. If descriptive text is included in an attachment name before the ".PDF" as described in the examples in bold, eRA will auto-generate a warning message concerning the attachment name. This warning can be ignored. Descriptors must be less than 50 characters and use only standard characters (A through Z, 0 through 9, spaces). Descriptors may not include special characters (&, *, %, /, etc.) or underscores. If a descriptor is more than one (1) word, use a space to separate them (no underscore, dash, etc.). File names are **not** case sensitive. Altering any other parts of appendix file names may cause parts of an application to be excluded from the final electronic image or for the attachments to appear in the wrong order.

NOTE: Attachments for Appendices 11, 12, … etc., must be uploaded in the order in which they should appear in the final e-Application. 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.

For a set of templates, with mandatory file names for each attachment, see 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 flat file and attached (see Section 2.4). VA-ORD general attachment page limits are noted below; check the Service-specific FOA/RFA for any exceptions.

Attachment *File Name*	**Instruction**
Introduction to Revised Application *01_VA_Intro.pdf*	**Page Limit: See Service-specific FOA/RFA** Use only if you are submitting a Resubmission application (SF 424 (R&R) Form Item 8) for a previously reviewed e-Application submitted through Grants.gov. **URLs are not allowed**.
Specific Aims *02_VA_Specific_Aims.pdf*	**Page Limit: 1** 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. 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. **URLs are not allowed.**
Research Plan *02a_VA_Research_Plan.pdf*	**Page Limit: See Service-specific FOA/RFA** 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. **Do not** repeat the Specific Aims. **Do not** include the Progress Report (for renewal applications). 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. 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. **URLs are not allowed.**
VA Career Plan *02b_VA_Career_Plan.pdf*	See Service-specific CDA FOA/RFA
Mentoring Plan *02c_VA_Mentoring_Plan.pdf*	See Service-specific CDA FOA/RFA
Progress Report *03_VA_Prog_Report_Pubs.pdf*	**Page Limit: See Service-specific FOA/RFA** A Progress Report must be included for all **renewal** applications. Provide the beginning and ending dates for the period covered since the project was last reviewed competitively. Summarize the previous application's specific aims and the importance of the findings. Provide a succinct

Attachment *File Name*	**Instruction**
	account of published and unpublished results, indicating progress toward their achievement. 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. **Do not** include URLs or PMC submission identification numbers for publicly available citations; copies of these publications are not accepted as appendix material. **Do not** include unpublished theses or abstracts/ manuscripts submitted, but not accepted for publication.
Human Subjects *04_VA_Human_Subjects.pdf*	**No Page Limit** **If "Yes" for** Question 1 (Are Human Subjects Involved?), this attachment is required. This section covers the information regarding the Protection of Human Subjects. Refer to Part II Human Subjects Research Requirements. **Do not** include the protocol in this appendix. Address only the requested issues noted below. Use the following headings and fully describe: 1. Risk to Subjects. • *Human Subjects Involvement and Characteristics:* Describe the anticipated number, age range, and health status of the subject population. Identify the criteria for inclusion or exclusion of any subpopulation. Explain the rationale for the involvement of special classes of subjects or others who may be considered vulnerable populations. Indicate whether all subjects recruited for the study will be Veterans or whether non-Veterans will also be included. **Justification must be provided for use of non-Veteran subjects in VA-ORD funded research projects.** • *Sources of Materials:* Identify the sources of research material and indicate whether the material or data will be obtained specifically for research purposes or if existing specimens, records, or data will be used. • *Potential Risks:* Describe the potential risks to subjects (physical, psychological, social, legal, or other) and assess their likelihood and seriousness to the subjects. Differentiate therapeutic risk from research risk. 2. Adequacy of Protection from Risk • *Recruitment and Informed Consent:* Describe plans for the recruitment of subjects and the process for obtaining informed consent. *NOTE:* The informed consent document may not be submitted at this

Attachment *File Name*	**Instruction**
	time; if the application is selected for funding, it will be requested as a part of the JIT process. • *Protection Against Risk:* Describe the planned procedures for preventing or minimizing potential risks (including risks to confidentiality and data security). Specify methods for collecting data on complications of treatment, adverse and serious adverse events for safety monitoring. 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. Payment or compensation should not be included as a benefit of participation. 4. Importance of knowledge to be gained. 5. 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. The Data and Safety Monitoring Plan may include monitoring by a Data and Safety Monitoring Board (DSMB) or Data Monitoring Committee (DMC). 6. Address the inclusion of women, minorities and/or children. Research involving children must be reviewed by the 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 Directive 1200.05(1) Requirements for the Protection of Human Subjects in Research)
Vertebrate Animals *05_VA_Animals.pdf*	**No Page Limit** **If "Yes" for** Question 2 (Are Vertebrate Animals Used?), this attachment is required and must address four (4) key points noted below. 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. Additionally, research that uses any canine, feline or non-human primates must be directly related to an illness or injury that is combat-related. Provide a detailed explanation with scientific citation support of how the proposed study meets the requirement that the scientific objectives "are directly related to an illness or injury that is combat-related". Also, a detailed description of how this work fits into the regulatory pathway to an IND must be included. If the study involves non-Human Primate research involving a drug or biological agents, must also provide toxicology study findings from smaller animal model (e.g., rats, mice) sufficient to address FDA IND requirements. **Do not** include a copy of the ACORP.

Attachment *File Name*	**Instruction**
	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, *in vitro*). 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.
Multiple PD/PI Leadership Plan *06_VA_Multiple_PI.pdf*	**No Page Limit.** **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. 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. Describe the rationale for choosing a multiple PD/PI approach. Describe the governance and organizational structure of the PD/PI leadership team, as well as the knowledge, skills and experience of the individual PD/PIs, including communication plans and procedures for resolving conflicts. For the PD/PIs, delineate the shared authority and responsibility for the administrative, technical and scientific responsibilities for directing the project or program.
Consortium/Contractual Agreements *07_VA_Agreements.pdf*	**No Page Limit** Describe only **existing** consortium or contractual agreements that are relevant to the proposed research. Explain the programmatic, fiscal and administrative arrangements that exist between the VAMC and any consortium or contractual organization(s). New consortium or contractual agreements will not be considered binding to VA contractually.

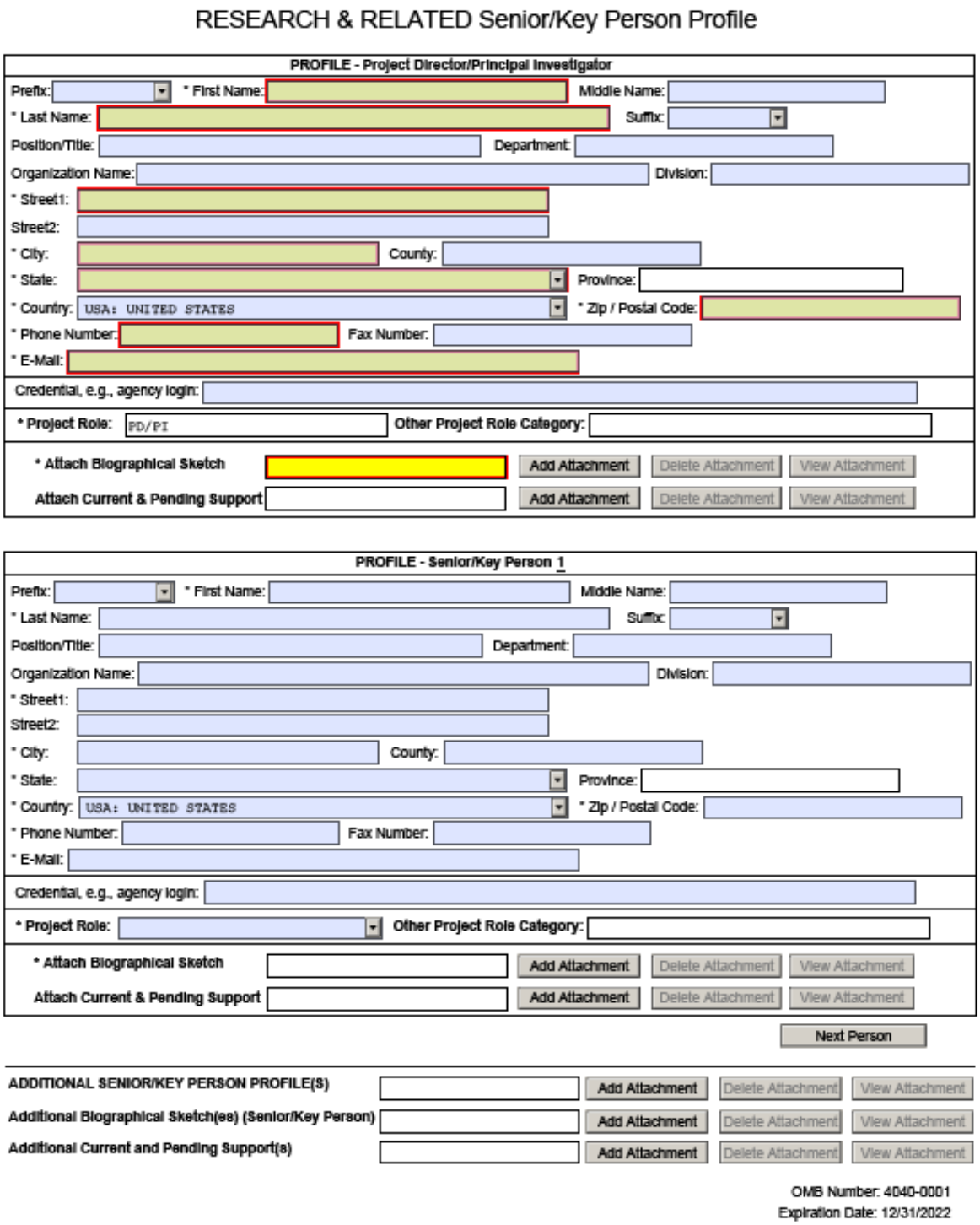
Attachment *File Name*	**Instruction**
	Do not include costs for additional performance sites of multi-site projects here. **Do not** include IPAs (Interagency Personnel Agreement) here.
Director's Letter *08_VA_Director_Letter.pdf*	**No Page Limit** A signed (e-signature accepted) and dated (within the last year) Letter of Support from the VAMC Director is required and must include the following: • A statement that the Director understands the impact of the proposed research on the facility's organization and that they endorse the project. • An explicit statement of where research will be conducted, whether it is in VA space, VA-leased space, or space at the affiliate; that appropriate off-site waivers have been requested and that the VA space described in the application and necessary support of the VA facility will be available. • If human samples are used, an explicit statement of source of samples. • Current VA employment status of the PD/PI, including 8ths. **If the current 8ths are less than 5/8ths**, a statement indicating that the PD/PI's VA effort will be increased to a minimum of 5/8ths at the time of the award. • If a 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 appointment of at least 5/8ths time. • **If the PD/PI is a clinician,** a statement committing support from the facility to cover clinical effort impacted by the proposed research effort as needed for the project (up to 3/8ths, Reference from VA Handbook: VA ORD Guidance for Protected Time for Research Staff **).** *NOTE:* For multiple PD/PI applications where the PIs are at different VAMCs, a letter from **each** VAMC Director is required. **Applications submitted without this attachment will not be accepted for review.**
R&D Committee Letter *08a_VA_R_D_Committee_letter.pdf*	See specific FOA/RFAs for guidance on the use of this attachment.
Letters of Support *08b_VA_Letters_of_Support.pdf*	**No Page Limit** Attach appropriate letters (scanned and submitted as a single PDF flat file) 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).

Attachment *File Name*	**Instruction**
	All letters of support are expected to be dated within twelve (12) months of the submission date. **New** letters of support may be needed for one or more of the allowable resubmissions. **Do not** include Biosketches. **Do not include URLs in the content of any letter of support**.
Data Management and Access Plan *09_VA_DMAP.pdf*	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. **Applications submitted without this attachment will not be accepted for review.**
Financial Disclosure Statement *10_VA_Financial_Disclosure.pdf*	**No Page Limit** All proposals for VA research must include a Financial Disclosure statement. Provide a clear statement disclosing any financial conflict of interest that each PD/PI may have with the proposed research (e.g., purchase of a device or specialized compound from a company in which the PD/PI has a financial interest). VA researchers with outside consulting, employment or royalty payment opportunities should disclose those potential opportunities to their local VA facility to ensure compliance with the facility policy on financial conflict of interest. Use a single page containing "N/A" or "No Disclosures" if there is nothing to disclose. A sample document can be found at: http://vaww.research.va.gov/funding/electronic-submission.cfm. **Applications submitted without this attachment will not be accepted for review.**
Appendices *11_VA_Appendix_1_descriptor.pdf* *12_VA_Appendix_2_descriptor.pdf* *13_VA_Appendix_3_descriptor.pdf*	Upload one (1) PDF flat file for each appendix. A summary sheet listing all of the items included as appendices may be included in the first appendix attachment; this is encouraged, but not required. **REQUIRED ATTACHMENTS:** See the Service-specific FOA/RFA. Upload files in the order in which they should appear in the e-Application. **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. Name Appendices using no more than 50 characters including spaces with the convention in the following order: • Appendix number, starting with 11, then 12, 13, etc. • Underscore

Attachment *File Name*	**Instruction**

	• The phrase "VA_Appendix"
	• Underscore
	• Appendix number starting with 1 then 2, 3, etc.
	• Underscore
	• Brief description of the contents (e.g., Abbreviations, Accepted Manuscripts, Patents); 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
	
	Unless otherwise specified in the FOA/RFA, the first appendix should be an alphabetized list of abbreviations used in the application. Use the descriptor "Abbreviations" in the file name (11_VA_Appendix_1_Abbreviations.pdf)
	
	Similar appendix material should be combined within an attachment. For example, place all accepted, but not yet published, manuscripts in one attachment.
	• **Up to three** (3) of the following types of publications:
	  ○ Manuscripts accepted for publication but not yet published.
	  ○ Manuscripts published, but a free, online, publicly available journal link is not available. **Do not** include published manuscripts that have a free, publicly available online journal.
	  ○ Patents directly relevant to the project.
	  ○ Chapters from review or textbooks.
	• Surveys, questionnaires, data collection instruments, clinical protocols. **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 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 R&R Senior/Key Person Profile Form


RESEARCH & RELATED Senior/Key Person Profile

PROFILE - Project Director/Principal Investigator

Prefix: * First Name: Middle Name:
* Last Name: Suffix:
Position/Title: Department:
Organization Name: Division:
* Street1:
Street2:
* City: County:
* State: Province:
* Country: USA: UNITED STATES * Zip / Postal Code:
* Phone Number: Fax Number:
* E-Mail:
Credential, e.g., agency login:
* Project Role: PD/PI Other Project Role Category:
* Attach Biographical Sketch Add Attachment Delete Attachment View Attachment
Attach Current & Pending Support Add Attachment Delete Attachment View Attachment

PROFILE - Senior/Key Person 1

Prefix: * First Name: Middle Name:
* Last Name: Suffix:
Position/Title: Department:
Organization Name: Division:
* Street1:
Street2:
* City: County:
* State: Province:
* Country: USA: UNITED STATES * Zip / Postal Code:
* Phone Number: Fax Number:
* E-Mail:
Credential, e.g., agency login:
* Project Role: Other Project Role Category:
* Attach Biographical Sketch Add Attachment Delete Attachment View Attachment
Attach Current & Pending Support Add Attachment Delete Attachment View Attachment

Next Person

ADDITIONAL SENIOR/KEY PERSON PROFILE(S) Add Attachment Delete Attachment View Attachment
Additional Biographical Sketch(es) (Senior/Key Person) Add Attachment Delete Attachment View Attachment
Additional Current and Pending Support(s) Add Attachment Delete Attachment View Attachment

OMB Number: 4040-0001
Expiration Date: 12/31/2022

This form collects 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. Information for the PD/PI is auto-populated from the *SF 424 (R&R) Form*. See Section 3.2 *SF 424 (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 confirm. When submitting an application involving Multiple PD/PIs, the Contact PI must be listed as the PD/PI in Box 14 of the *SF 424 (R&R) Form* (see Section 3.2.14). That information auto-populates the first Senior/Key Person Profile record in this form. For 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 *SF 424 R&R Other Project Information Form*, Item 12. Other Attachments, a Multiple PD/PI Leadership Plan is required.

The PD/PI must have an eRA Commons account with the PI role and the account must be affiliated with the VAMC. (*NOTE:* Other roles such as SO or IAR will not give PD/PIs the appropriate access to application records). **The PD/PI's eRA Commons ID must be included in the Credential field and be consistent with the Commons ID in the ePROMISe investigator profile.**

When completing the *Summary Budget Worksheet* (*SBW*) and *Budget Justification* (see Section 3.7) 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 (Expanded) Form* (i.e., an individual must be identified as a PD/PI in both places).

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

Field Name	Instruction
Prefix	Auto-populated from the *SF 424 (R&R)* and reflects the prefix for the name of the PD/PI.
First Name	This field is required. Auto-populated from the *SF 424 (R&R)* and reflects the first (given) name of the PD/PI.
Middle Name	Auto-populated from the *SF 424 (R&R)* and reflects the middle name of the PD/PI.
Last Name	This field is required. Auto-populated from the *SF 424 (R&R)* and reflects the last (family) name of the PD/PI.
Suffix	Auto-populated from the *SF 424 (R&R)* and reflects the suffix for the name of the PD/PI. **Do not** use this field to indicate degrees.

Field Name	Instruction
Position/Title	Auto-populated from the *SF 424 (R&R)* and reflects the title of the PD/PI.
Department	Auto-populated from the *SF 424 (R&R)* and reflects the name of primary organizational department, service, laboratory or equivalent level within the VAMC of the PD/PI.
Organization Name	This field is required. Auto-populated from the *SF 424 (R&R)* and reflects the name of the VAMC or VA Health Care System of the PD/PI.
Division	Auto-populated from the *SF 424 (R&R)* and reflects the name of primary organizational division, office or major subdivision of the PD/PI.
Street1	This field is required. Auto-populated from the *SF 424 (R&R*) and reflects the first line of the street address for the PD/PI.
Street2	Auto-populated from the *SF 424 (R&R)* and reflects the second line of the street address for the PD/PI, if applicable.
City	This field is required. Auto-populated from the *SF 424 (R&R)* and reflects the city for the address of the PD/PI.
County/Parish	Auto-populated from the *SF 424 (R&R)* and reflects the county/parish for the address of the PD/PI.
State	This field is required. Auto-populated from the *SF 424 (R&R)* and reflects the state where the PD/PI is located.
Province	Leave blank.
Country	This field is required. Auto-populated from the *SF 424 (R&R)* and reflects the country in which the PD/PI is located.
ZIP/Postal Code	This field is required. Auto-populated from the *SF 424 (R&R)* and reflects the postal code of the PD/PI.
Phone Number	This field is required. Auto-populated from the *SF 424 (R&R)* and reflects the daytime phone number for the PD/PI.
Fax Number	Auto-populated from the *SF 424 (R&R)* and reflects the fax number for the PD/PI.
Email	This field is required. Auto-populated from the SF 424 (R&R) and reflects the email address for the PD/PI.
Credential, e.g., agency login	This field is required. An eRA Commons Username (the unique name used to log into the system) is required for all PD/PIs. The eRA Commons username must hold the PI role and be affiliated with the VAMC. **Applications will not pass eRA system validations without a valid eRA Commons username.**
Project Role	Type PD/PI in this field. **Do not** type “PI” or “PI/PD” or “Principal Investigator” etc. Entering anything other than “PD/PI” will cause an error.
Other Project Role Category	Leave field blank; no other role can be added to the PD/PI role.

Field Name	Instruction
Degree Type	Enter the highest academic or professional degree or other credentials (e.g., RN).
Degree Year	Enter the year the highest degree or other credential was obtained.
Attach Biographical Sketch	Upload a biographical sketch for the PD/PI. Biographical Sketch Format (template) **OMB No. 0925-0001 and 0925 0002 (Rev. 10/2021 Approved Through 09/30/2024) is required;** see also Sketch Sample and additional instructions below.
Attach Current and Pending Support	**This information is required for the Contact PD/PI listed in Box 14 of the *SF 424 (R&R)* at the time of application submission.** This information will be used to check that the proposed research has not already been Federally funded. There is no SF 424 form page. Follow the *Other Support Information Sample Format*. The sample is intended to provide guidance regarding the type and extent of information requested. For the PD/PI or other Senior Key Personnel Certification, handwritten and electronic signatures are acceptable; typed names in the signature box will not be approved. Be sure to complete the date field when handwritten signatures are used. If the proposal is selected for Intent to Award, the awarding Service may request complete and up-to-date information as part of JIT. **Other Support Policy** *Other Support* includes all resources made available to researchers or senior/key personnel in support of and/or related to all of their research endeavors, regardless of whether or not they have monetary value and regardless of whether they are based at the institution the researcher identifies for the current award. This includes resources and/or financial support from all foreign and domestic entities that are available to the researcher. This includes, but is not limited to, financial support for laboratory personnel and provision of high-value materials that are not freely available (e.g., biologics, chemicals, model systems, technology, etc.). Institutional resources, such as core facilities or shared equipment that are made broadly available, should not be included in Other Support, but rather listed under Facilities and Other Resources. Other Support also includes in-kind contributions (such as office/laboratory space, equipment, supplies or employees or students supported by an outside source). *NOTE:* Licensed medical professionals donate their effort and do not provide in-kind support. • If in-kind contributions **are intended for use on the project being proposed** to VA-ORD in this application, the information must be included as part of the Facilities and Other Resources or Equipment section of the application and need not be replicated on this form. • In-kind contributions **not intended for use on the project/proposal being proposed** in this application must be reported below. If the time commitment or dollar value is not readily ascertainable, reasonable estimates should be provided. Institutions are required to submit copies of contracts specific to Senior/Key Personnel foreign appointments and/or employment with a foreign institution for all foreign activities and resources that are reported in Other Support. If they are not in English, recipients must provide translated copies. This does not include personal service contracts or employment contracts for fellows supported by foreign entities.

Field Name	Instruction
	NOTE: Other Support does not include training awards, prizes, gifts or start-up support provided to the individual by the VAMC. *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* occurs at the time of award.

Profile – Senior/Key Person [*n*]: The remaining Senior/Key Person Profiles should be listed in alphabetical order. Alphabetical order is preferred, but not required; profiles will appear in the application (and to reviewers) in the order 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 [WOC]) with calendar months' effort greater than zero, even if no salary is requested, must be included in the *Senior/Key Person Profile (Expanded) Form*, the last row of Section B (Other Personnel) of the *R&R Budget Form* and in the *SBW* totals.

All Senior/Key Personnel listed on the *R&R Senior/Key Person Profile (Expanded) Form* on an application must enter a valid eRA Commons username (Commons ID) in the "Credential, e.g. agency login" field. **This is a system validation; if an invalid eRA Commons username is included, an error will be received** that must be corrected in order to successully submit the application.

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." 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 (Expanded) 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 (Expanded) Form*.

A biosketch and *Other Support* document are required for all Senior/Key persons and OSCs at the time of application submission 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 twenty (20) additional Senior/Key Persons, save the application, close 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 have been provided.

Field Name	Instruction
Prefix	Enter or select the prefix for the Senior/Key Person.
First Name	This field is required. Enter the first (given) name of the Senior/Key Person.
Middle Name	Enter the middle name of the Senior/Key Person, if applicable.
Last Name	This field is required. Enter the last (family) name of the Senior/Key Person.
Suffix	Enter or select the suffix 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	This field is required. Enter the name of organization of the Senior/Key Person.
Division	Enter the name of primary organizational division, office or major subdivision of the Senior/Key Person.
Street1	This field is required. Enter first line of the street address for the Senior/Key Person.
Street2	Enter second line of the street address for the Senior/Key Person, if applicable.
City	This field is required. Enter the city for the address of the Senior/Key Person.
County/Parish	Enter the county or parish for the address of the Senior/Key Person.
State	This field is required if the Senior/Key Person is located in the United States. Enter the State where the Senior/Key Person is located.

Field Name	Instruction
Province	Leave blank.
Country	This field is required. Enter the country for the Senior/Key Person address.
ZIP/Postal Code	This field is required if the Senior/Key Person is located in the United States. Enter the Zip+4 of the Senior/Key Person address.
Phone Number	This field is required. Enter the daytime telephone number for the Senior/Key Person.
Fax Number	Enter the fax number for the Senior/Key Person.
Email	This field is required. Enter the email address for the Senior/Key Person.
Credential, e.g., agency login	This field is required. An eRA Commons Username (the unique name used to log into the system) is required for all Senior/Key Personnel and OSCs. **Applications will not pass eRA system validations without a valid eRA Commons username.**
Project Role	Select one. Investigators other than the PD/PI may be designated roles such as "collaborator" using the "Other – Specify" option. For applications with Multiple PD/PIs, all such individuals must be assigned the PD/PI role and a leadership plan 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. **Ensure that the selected role matches the role noted in the *SBW* and *Budget Justification* documents. Include Senior/Key Persons identified in any other performance sites.**
Other Project Role Category	Complete if "Other Professional" or "Other (Specify)" is selected as a project role.
Degree Type	Enter the highest academic or professional degree or other credentials (e.g., RN).
Degree Year	Enter the year the highest degree or other credential was obtained.
Attach Biographical Sketch	Upload a biographical sketch for the PD/PI. Biographical Sketch Format (template) **OMB No. 0925-0001 and 0925 0002 (Rev. 10/2021 Approved Through 09/30/2024) is required;** see also Sketch Sample and additional instructions below.
Attach Current & Pending Support	**This information is required at the time of application submission.** A separate Current & Pending Support attachment must be provided for each Senior/Key Person and OSC. See Other Support guidance. There is no SF 424 form page for Other Support. Follow the Other Support Information Sample Format. For additional details see Attach Current & Pending Support for the PD/PI. If there is no current "Other Support", upload a PDF flat file attachment that has the heading "Other Support" and indicate "None" in the body of the attachment.

Additional Senior/Key Person Profile(s): If more than 99 Senior/Key Person profiles are proposed, enter the information in a separate file and attach it here. For greater than 100 profiles, see a sample Additional Senior/Key Person Profiles format page.

Additional Biographical Sketch(es) (Senior/Key Person): Provide a biographical sketch (Biographical Sketch Format Page (template) and Biographical Sketch Sample) for each Senior/Key Person included in the *Additional Senior/Key Person Profile (Expanded) Form* attachment. Save in a single PDF flat file and attach. The Biographical Sketch template **OMB No. 0925-0001 and 0925 0002 (Rev. 10/2021 Approved Through 09/30/2024) is required. Other versions of the form will not be accepted, and if included, the application will be withdrawn from review. Do not** alter the template by removing the OMB header or other template information. If VA-ORD staff is unable to verify that the correct template format is used, the application will be withdrawn from review.

Investigators may also use Science Experts Network Curriculum Vitae (SciENcv), a tool supporting multiple research agencies, to help develop a biosketch and automatically format it according to VA-ORD requirements. SciENcv gathers and compiles information on expertise, employment, education and professional accomplishments. SciENcv can be used to create and maintain biosketches that are submitted with applications and annual reports (Research Performance Project Reports [RPPRs]). SciENcv allows researchers to describe and highlight their scientific contributions in their own words.

Additional Current and Pending Support: 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) 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.

If the *Additional Senior/Key Person Profile (Expanded) Form* 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 (*Page Limit: 5*)**:** Review the *sample* format (Biographical Sketch Sample) when preparing this section for all applications. Include biographical sketches for all Senior/Key Personnel and OSCs. The five (5)-page limit includes the table at the top of the first page.

All Senior/Key Personnel listed on the *R&R Senior/Key Person Profile (Expanded) Form* on an application must enter a valid eRA Commons username (Commons ID) in the "Credential, e.g. agency login" field. Applications will not pass eRA system validations without a valid eRA Commons username in this field.

Complete the educational block at the top of the format page: Begin with the baccalaureate or other initial professional education, such as nursing. Include postdoctoral, residency and clinical fellowship training, as applicable, listing each separately.

For each entry provide the:

- Name and location of the institution;
- Degree received (if applicable);
- Month and year of end date (or expected end date); and
- Field of study (for residency entries, the field of study should reflect the area of residency training).

Following the educational block, complete Sections A, B and C as described below:

A. Personal Statement

Briefly describe why you are well-suited for your role(s) in this project. 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/or your past performance in this or related fields, including ongoing and completed research projects from the past three (3) years that you want to draw attention to (previously captured under Section D. Research Support).

Up to four (4) publications or research products may be cited that highlight your experience and qualifications for this project. Research products can include, but are not limited to audio or video products; conference proceedings such as meeting abstracts, posters or other presentations; patents; data and research materials; databases; educational aids or curricula; instruments or equipment; models; protocols; and software or netware. **Use of hyperlinks and URLs to cite these items is not allowed. Figures, tables or graphics are not allowed.**

Interim research products may also be cited.

Note the following additional instructions:

- If you wish to explain factors that affected your past productivity, such as family care responsibilities, illness, disability or military service, you may address them in this "A. Personal Statement" section.
- Indicate whether you have published or created research products under another name.
- You may mention specific contributions to science that are not included in Section C. **Do not** present or expand on materials that should be described in other sections of this Biosketch or application.

B. Positions, Scientific Appointments and Honors

List in reverse chronological order all current positions and scientific appointments both domestic and foreign, including affiliations with foreign entities or governments. This includes titled academic, professional or institutional appointments whether or not remuneration is received, and whether full-time, part-time or voluntary (including adjunct, visiting or honorary). For individuals who are not currently located at the VAMC (applicant organization), include the expected position at the VAMC and expected start date.

List any relevant academic and professional achievements and honors. In particular:

- Postdoctorates and junior faculty should include scholarships, traineeships, fellowships and development awards, as applicable.
- Clinicians should include information on any clinical licensures and specialty board certifications that they have achieved.

C. Contributions to Science

Briefly describe up to five (5) of your most significant contributions to science. The description of each contribution should be no longer than one half page, including citations. **Figures, tables or graphics are not allowed.**

For each contribution, indicate the following:

- Historical background that frames the scientific problem;
- Central finding(s);
- 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.

Complete List of Published Work in MyBibliography

A URL may be provided 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.

3.6 Selecting the Appropriate Budget Form

The application forms package associated with VA-ORD funding opportunities are the *R&R Budget Form* and the *Summary Budget Worksheet* (contained within the *Budget Justification* Section L). The *SF 424 (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 R&R Budget Form

The *Summary Budget Worksheet* (*SBW*; ver. 6.30.2017) 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 five (5) sites, or up to twenty (20) sites). Leave cells blank or enter zero (0) for extra sites or budget periods. It is recommended that the ***SBW* be completed first** then the *R&R Budget Form*.

The *R&R Budget Form* includes three (3) 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 *VA-ORD SF 424* guidance and instructions provided within the submission system being used (Workspace or ASSIST). **A separate budget must be completed for each year of support requested.** The form will automatically generate a cumulative budget for the total project period.

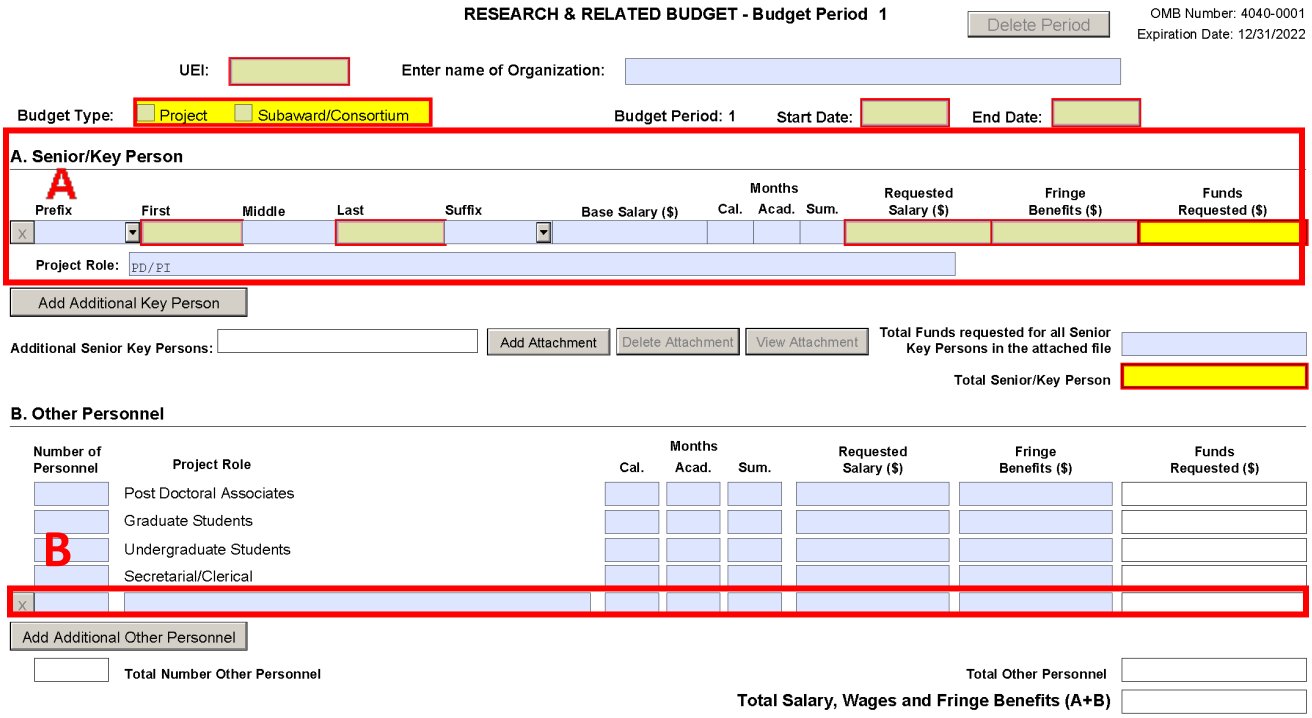
If no funds are requested for a required field (as indicated by yellow highlight), enter zero (0). For fields that are not required and when no funds are being requested, leave field blank. All dollar fields should be presented in whole numbers and rounded to the nearest whole dollar.

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 the form for the next budget period. Follow the same instructions for subsequent budget periods.

All required information (i.e., those fields that are highlighted in yellow, outlined in red) must be completed. For any new application package, information entered onto the budget forms will auto-populate 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. **Dates must be manually updated for budget periods 2-5.**

Budget cap and duration limitations noted in the Service-specific FOA/RFA must be maintained. **If an application requests a duration or amount that exceeds the caps specified in a FOA/RFA, the application may not be accepted for review.**

3.7.1 Sections A and B



Unique Entity Identifier (*Required Field*)
This field may be pre-populated and should reflect the UEI of the VAMC (applicant organization).

Enter name of Organization
This field may be pre-populated from the *SF 424 (R&R) Form.* Changes to the organization's legal name in this field on the budget form can only be made on the *SF 424 (R&R) Form*.

NOTE: Also enter the name of the VAMC on the *SBW*.

Budget Type (*Required Field*)
Check the Project box. 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 *SF 424 (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 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 must be manually updated to reflect the correct project budget period (year).

Section A. Senior/Key Person: Include **only the name of a single PD/PI**.

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 (Expanded) 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, 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 two (2) percent 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. To request salary for non-clinician MDs who are not licensed to practice medicine and do not see patients in the VA or at any other facility, they must agree to accept a Health Science Specialist appointment.

Clinician salaries (VA or non-VA) or salaries for Nurses or Licensed Medical Professionals (Hybrid Title 38 occupations with clinical appointments) are not allowed 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 *SF 424 (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 *R&R Budget Form* multiply the Percent Effort (last column in 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 the 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 the individual works elsewhere.

Special Instructions for Joint University and VA Appointments: Calendar months for VA investigators must be based on the VA 40-hour work week (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 twelve (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 SO on the application certifies that: (1) the individual is applying as part of a joint appointment specified by a formal Memorandum of Understanding (MOU) between the University and 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	Instruction
Prefix / Degree	*SBW:* Enter highest professional degree. *R&R Budget:* Enter the prefix for the name of the PD/PI.
First Name	*SBW:* Not applicable. *R&R Budget:* This field is required. Enter the first (given) name of the PD/PI.
Middle Name	*SBW:* Not applicable. *R&R Budget:* Enter the middle name of the PD/PI, if applicable.
Last Name	*SBW:* Not applicable. *R&R Budget:* This field is required. Enter the last (family) name of the PD/PI.
Suffix	*SBW:* Not applicable. *R&R Budget:* Enter the suffix of the PD/PI. **Do not** use this field to indicate degrees (e.g., M.D. or Ph.D.).
Base Salary ($)	*R&R Budget:* Leave blank. This information may be requested 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 work week (e.g., 5/8th appointment = 25 hrs./wk. = 7.5 months). See instructions for Joint VA-University appointments. *SBW:* Enter the number of PD/PI **calendar months** devoted to the project for Year 1.

Field Name	Instruction
	R&R Budget: Enter the number of PD/PI **calendar months** devoted to the project.
Acad. Months	Do not use.
Sum. Months	Do not use.
Requested Salary ($) / PI Salary	*SBW:* Indicate the amount of salary being requested for each budget period for the PD/PI. *R&R Budget:* This field is required. Retype the PD/PI salary from the *SBW*.
Fringe Benefits ($) / PI Fringe	For current VA personnel, actual fringe benefits may be requested. *SBW:* Enter applicable fringe benefits for the PD/PI each budget period. *R&R Budget:* Retype the PD/PI fringe from the *SBW*.
Funds Requested ($)	*SBW:* Not applicable. *R&R Budget:* This field is auto-calculated and reflects the total requested salary and fringe benefits for the PD/PI.
Project Role	*SBW:* Not applicable. *R&R Budget:* Identify only the individual serving as the PD/PI. The role of the PD/PI is auto-populated in Budget Period 1. **Do not** change or edit this field. 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*. *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 available in the Biosketch.
Additional Senior/Key Persons	*SBW:* Not applicable. *R&R Budget:* Leave blank. Include additional personnel in Section B.
Total Funds requested for all Senior/Key Persons in the attached file	*SBW:* Not applicable. *R&R Budget:* Leave blank. Include additional personnel in Section B.
Total Senior/Key Persons	*SBW:* Not applicable. *R&R Budget:* The total funds requested will auto-calculate for the PD/PI.

Section 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.

To request salary for non-clinician MDs who are not licensed to practice medicine and do not see patients in the VA or at any other facility, they must agree to accept a Health Science Specialist appointment.

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 consultants, 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 *R&R Budget Form*.

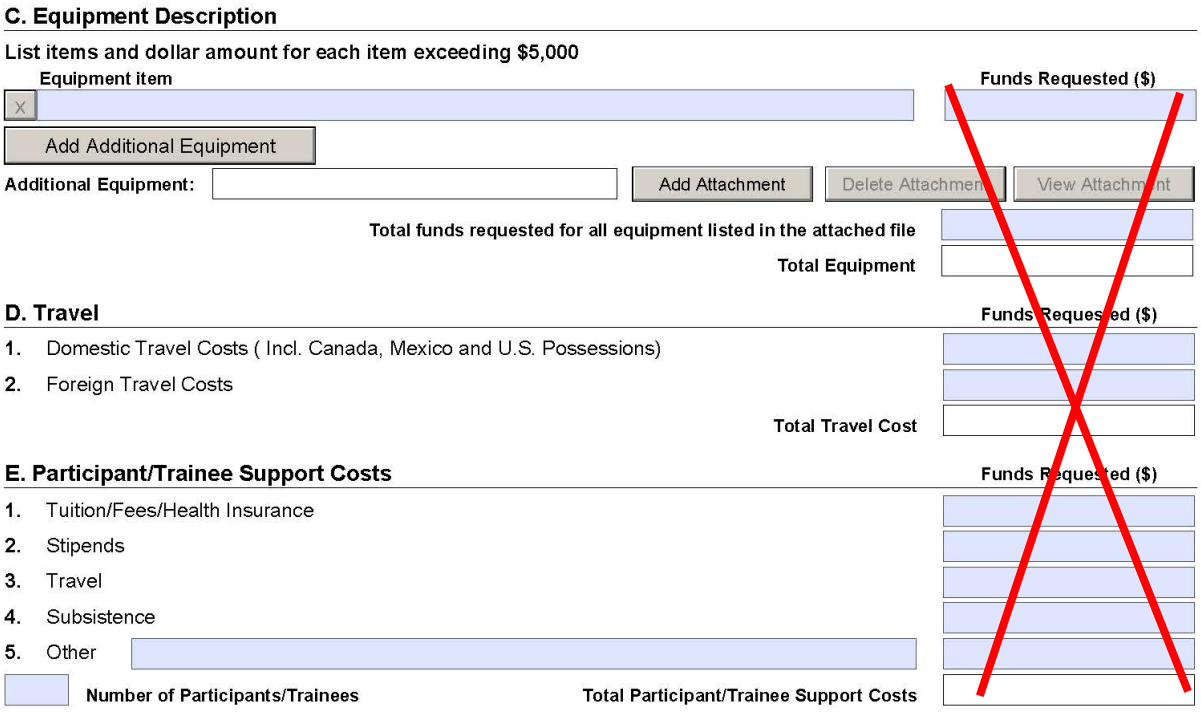
Field Name	Instruction
Number of Personnel/ # unique staff	*SBW:* List the number of unique VA personnel contributing (current or to-be-hired [TBH]) during the lifetime of the project in second to last column. *R&R Budget:* Last row of Section B, retype the number of unique VA personnel proposed. Leave all other rows blank. *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 available in the Biosketch. Role noted should correspond to the role on the *Senior/Key Person Profile(s) (Expanded) Form*.
Project Role	*SBW:* Not applicable. *R&R Budget:* Last row under project role, enter "unique VA personnel." Leave all other rows blank.
Cal. Months / Cal. Mo.	*SBW:* List the total calendar months of effort devoted to the project for VA personnel during Year 1 of the project. Provide separate subtotals for VA personnel already hired and TBH. **Do not** include IPA or contract personnel. *R&R Budget***:** Last row, retype the total calendar months effort of all VA personnel during the budget period.
Acad. Months	**Do not use.**
Sum. Months	**Do not use.**
Requested Salary ($) / Hired Salary or TBH Salary	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 COLA adjustments or salary increases (maximum of two percent (2%) per year) may be requested in Years 2-5 for all VA-paid personnel, but will be adjusted in accordance with OPM approved salary rates in any given calendar year and anticipated personnel actions (e.g., within grade increases). Salary support is not authorized for any licensed medical professional with a clinical appointment in VA unless a waiver has been granted by the funding Service Director. 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. 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; **do not** include salary in the budget. Clerical support may not be included as study personnel unless the support provided can be justified as necessary to the conduct of the research. Costs for tuition remission for graduate students or graduate student stipends are not allowed in VA-ORD budgets. Although graduate students may be paid as technicians, they must be listed as such in the budget.

Field Name	Instruction
	SBW: 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 TBH. *R&R Budget:* Last row, retype the salary/wages being requested for VA personnel from "Total Other Personnel" on the *SBW*. Leave all other rows blank.
Fringe Benefits ($) / Hired or TBH Fringe	For current VA-employees, actual fringe benefits may be requested. For TBH positions, fringe benefits may not exceed thirty percent (30%). *SBW:* List funds requested for fringe for each project budget period. Provide separate subtotals for VA personnel already hired and TBH. *R&R Budget:* Last row, retype the fringe benefits being requested for VA personnel from "Total Other Personnel" on the *SBW*. Leave all other rows blank.
Funds Requested	*SBW:* Not applicable. *R&R Budget:* This total will auto-calculate.
Total Number of Other Personnel	*SBW:* Not applicable. *R&R Budget:* This total will auto-calculate.
Total Other Personnel	*SBW:* Not applicable. *R&R Budget***:** The total funds requested for all other Personnel will auto-calculate.
Total Salary, Wages and Fringe Benefits (A+B) / Total Personnel	*SBW:* 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***. These values must match.**

To navigate to the next page (Sections C through E), click the Next button at the top of the *SF 424 (R&R) Budget Form* or use the scroll bar on the left-hand side of the screen.

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



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.

Section 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 (1) 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 used as part of routine and customary patient care.

Field Name	Instruction
Equipment item / Equipment/Start-up	*SBW:* Enter the total cost of equipment requested for the project. For multi-site projects, list the equipment requested at each site on the equipment line for the requesting site. *R&R Budget:* Leave Section C blank. Costs will be included in Section F, Line 8. *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.
Funds Requested / Equipment/Start-up	*SBW:* List the total cost of all equipment including shipping and any maintenance costs and agreements. **Do not** include IT costs. *R&R Budget:* Leave Section C blank. Costs will be included in Section F, Line 8.
Additional Equipment	*SBW:* Not applicable. *R&R Budget:* 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:* **Do not** attach a file.
Total Equipment	*SBW:* Not applicable. *R&R Budget:* This total will auto-calculate and should be **blank**.

Section D. Travel: Expenses for domestic travel that are 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.

<table>
<tr><th>Field Name</th><th>Instruction</th></tr>
<tr><td>Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions) / Travel</td><td>SBW: Identify the total funds requested for travel.
R&R Budget: Leave Section D blank. Costs will be included in Section F, Line 8.
Budget Justification: The table below is required if travel is requested. Include the 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.
<table>
<tr><td>Traveler</td><td>Status (VA, IPA, or consultant)</td><td>Purpose</td><td>Destination</td><td>Date</td><td>Estimated Cost</td></tr>
<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>
</table></td></tr>
<tr><td>Foreign Travel Costs / Travel</td><td>Funds for foreign travel may be requested as part of a budget if adequately justified.</td></tr>
</table>

Field Name	Instruction
	SBW: Identify the total funds requested for travel. *R&R Budget*: 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.
Total Travel Cost	*SBW:* Not applicable. *R&R Budget:* This total will auto-calculate and should be blank.

Section E. Participant/Trainee Support Costs: Unless specifically stated otherwise in an FOA/RFA, leave Section E. blank.

NOTE: Tuition remission and/or stipends for graduate students are not allowed.

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

3.7.3 Sections F through L

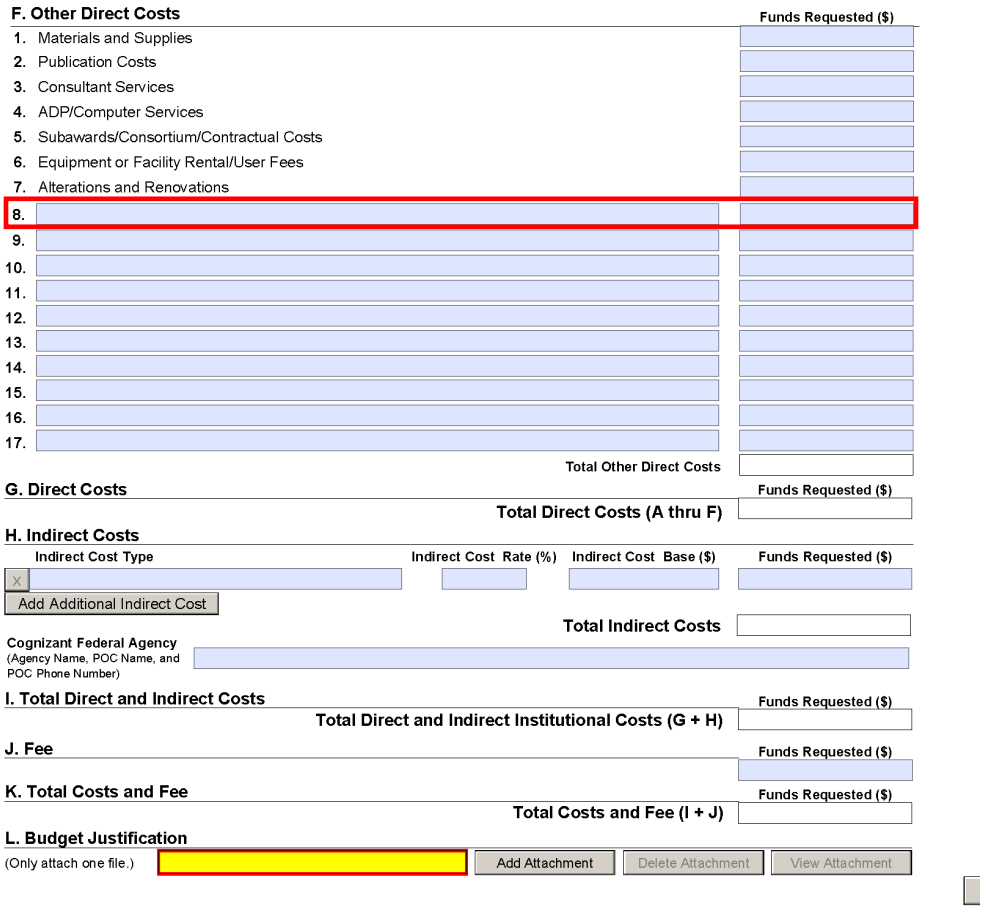
Investigators are encouraged to review the list of Unauthorized Budget Items to ensure compliance with VA-ORD budget policy.

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 **clinical appointment** in VA (Hybrid 38 occupations with clinical responsibilities) unless a waiver has been granted by the funding Service Director. 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) are not allowed in the budget. However, these expenditures may be itemized 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.
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.

Section F. Other Direct Costs: 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	Instruction
1. Materials and Supplies	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. *SBW:* 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." *R&R Budget:* Leave this item blank.

Field Name	Instruction
	Budget Justification: Itemize expendable supplies in separate categories, such as glassware, chemicals, etc., including an amount for each category**.** If vertebrate 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 animals required in the research. Categories less than $1,000 do not have to be itemized.
2. Publication Costs	Include the costs of documenting, preparing, publishing or otherwise making available to others the findings and products of the work conducted under the award. *SBW:* Include publication costs under single line item of Other Direct Costs. *R&R Budget:* Leave blank. *Budget Justification:* List the costs and justify how the publication will be a direct result of the project. Include supporting information.
3. Consultant Services	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*. *SBW:* 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. *R&R Budget:* Leave blank. *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.
4. ADP/Computer Services	**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. For more information, refer to "FY22 ORD Research IT FAQs and Guidance". *SBW:* 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. *R&R Budget:* Leave blank. *Budget Justification:* For items that meet the definition of scientific computing, list items and costs and justify individually. 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; **do not** include the costs in the Budget. If a project is considered for Intent to Award, a request will be made during JIT to provide an assurance memo from local IT that these items are available for the conduct of the study.

<table>
<tr><th>Field Name</th><th>Instruction</th></tr>
<tr><td></td><td>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.
<table>
<tr><th colspan="5">Planned IT Expenditures Table</th></tr>
<tr><td>Category</td><td>Type</td><td>Amount Year 1</td><td>Amount Year 2</td><td>Amount Year 3</td></tr>
<tr><td>Hardware</td><td>Purchased</td><td></td><td></td><td></td></tr>
<tr><td></td><td>Leased</td><td></td><td></td><td></td></tr>
<tr><td></td><td>Services</td><td></td><td></td><td></td></tr>
<tr><td>Software</td><td>Purchased</td><td></td><td></td><td></td></tr>
<tr><td></td><td>Leased</td><td></td><td></td><td></td></tr>
<tr><td></td><td>Services</td><td></td><td></td><td></td></tr>
<tr><td>Telecommunications</td><td>Purchased</td><td></td><td></td><td></td></tr>
<tr><td></td><td>Leased</td><td></td><td></td><td></td></tr>
<tr><td></td><td>Services</td><td></td><td></td><td></td></tr>
<tr><td>IT Supplies and Materials</td><td>Purchased</td><td></td><td></td><td></td></tr>
<tr><td></td><td>Leased</td><td></td><td></td><td></td></tr>
<tr><td></td><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>
</table></td></tr>
<tr><td>5. Subawards/Consortium/ Contractual Costs</td><td>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.

SBW: 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.

R&R Budget: Leave blank.

Budget Justification: Complete a budget justification for each site sequentially and include in the single attachment in Section L.</td></tr>
<tr><td>6. Equipment or Facility Rental/User Fees</td><td>Limits on funds for such fees are identified in individual FOA/RFAs.

SBW: 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.

R&R Budget: Leave blank.

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.</td></tr>
<tr><td>7. Alterations and Renovations</td><td>Requests for funds for facility alterations or renovations are not allowed.</td></tr>
<tr><td>8-10. Other</td><td>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.

• 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., M.D.s, RNP, PA, etc.), administrative</td></tr>
</table>

Field Name	Instruction
	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 percent 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. Contracting for clinical services or identify the individual(s) who will provide the service(s) is not allowed. 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 IRB and ethics policies. Non-physician VA employees may receive reimbursement for participating in research studies in accordance with VHA Directive 1200.05(1) Requirements for the Protection of Human Subjects in Research. Payments to physicians for serving as research subjects/participants are not authorized. *SBW:* 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." • **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. *R&R Budget:* Retype Subtotal Costs from the *SBW* in Section F, Line 8. *Budget Justification:* • **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.

Field Name	Instruction
Total Other Direct Costs / Subtotal Costs	*SBW:* Subtotal Costs include equipment, travel, other direct costs and all funds requested from all sites except the primary performance site. *R&R Budget:* This total will auto-calculate and reflect the total funds requested for all other direct costs.

Section G. Direct Costs (A through F)

SBW: Total project.
R&R Budget: Automatically populated for the total funds requested.

Section H. Indirect Costs

R&R Budget: Indirect costs are not allowed. Leave blank.

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

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

Section J. Fee

R&R Budget: Fees are not allowed. Leave blank.

Section K. Total Costs and Fee (I +J)

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

Section 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 PDF flat file to Section L of the *SF 424 (R&R) Budget*. Use the *Budget Justification* to provide additional information requested in each budget category identified above and any other information necessary to support the budget request. Insufficiently justified categories (i.e., equipment) may be deleted from the requested budget.

NOTE: There is a single justification document for all budget years, requiring information for all years to be included in the same file. **Only one PDF flat file may be attached** and it must be uploaded before the Add Period button is activated.

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, a separate detailed *R&R Budget Form* must be completed for each year of support requested. All required information (i.e., those fields that are highlighted in yellow/outlined in red) must be entered and auto-populated information (i.e., start and end dates from budget Period 1 will auto populate for budget Periods 2-X) must be confirmed and/or edited. If no funds are requested for a required field, enter zero (0).

3.7.4 Cumulative Budget

All values on this form are auto-calculated. The values present the summations of the amounts entered previously under Sections A through K for each of the individual budget periods. No data entry is required in order to complete this section.

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

RESEARCH & RELATED BUDGET - Cumulative Budget

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

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

4.1 Introduction

Career Development Award (CDA) applicants must use the *SF 424 R&R Forms* and follow the instructions in this *VA-ORD SF 424*. These supplemental instructions are for CDA (CDA1, CDA2 or NRI) applications. Instructions are 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 CDA. These supplemental instructions must be used along with the information found in Parts I.1 – I.4.

Become familiar with the VA-ORD CDA activity codes and award types. Before applying for a CDA, carefully review the Service-specific FOA/RFA for the CDA of interest, noting the eligibility requirements, review criteria, award provisions and any special instructions. Each Service's FOA/RFA contains specific information associated with the award activity code and includes names of Service-specific staff that may be contacted for questions prior to submission of an application.

The eligibility criteria, support levels and other important aspects of specific CDAs, including availability, may vary among Services. Because of this, it is important to consult with the Scientific/Research contact of the awarding Service prior to submitting an application.

For specific guidance on the preparation of **Research Career Scientist (RCS)** applications, refer to the appropriate Service-specific FOA/RFA along with this *VA-ORD SF 424*.

CDA and RCS FOA/RFAs and other submission guidelines are available on the VA-ORD intranet.

4.2 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
IK4	CDTA	Career Development Transition Award (CDTA) for VA Psychiatrists	No

4.3 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 awards. The letters should be from individuals not directly involved in the application, but who are familiar with the applicant's qualifications, training and interests. Mentor/co-mentor(s) cannot be counted toward the three (3) 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 the applicant'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 applicant's professional training and qualifications for a research career should be used as referees. Where possible, some referees who are not from the applicant's current department or organization, but are knowledgeable about their qualifications, should be selected.

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

4.4 Specific Instructions for CDA Applications

Standard instructions found in Sections I1 – I4 should be followed with the exceptions detailed below along with instructions provided in the Service-specific FOA/RFA. Section numbers referenced below reflect those found in this *VA-ORD SF 424,* Part I.

4.4.1 Special Instructions for 3.2 SF 424 (R&R) Form

Item 8. Type of Application: Check New or Resubmission. CDAs may not be renewed.

Item 14. PD/PI Contact Information: Provide the name of the individual applicant as PD/PI. If the PD/PI is not located at the VAMC (applicant organization) at the time of application submission, the information in Item 14 should reflect where the PD/PI can be reached prior to the date requested in Item 12 (Proposed Project: Award Start Date). If the PD/PI applicant is not located at the VAMC (applicant organization) at the time of submission, the PD/PI's eRA Commons account must be affiliated with the VAMC. For additional information on creating affiliations for users in eRA Commons.

4.4.2 Special Instructions for 3.3 Project/Performance Site Location(s) 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.

4.4.3 Special Instructions for 3.4 R&R Other Project Information Form

Item 7. Project Summary/Abstract: Provide an abstract of the entire application (applicant, environment and research). In addition to a description of the research project as indicated in Section 3.4.7, include 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, 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:

Career Plan

PD/PI (as applicant) Background: Use this section to provide any additional information not described in the Career Development PD/PI's Biographical Sketch Instructions such as research and/or clinical training experience or VA Service.

Career Goals and Objectives: Describe 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 the work has changed direction, the reasons for the change should be indicated. It is important to justify the award, including how it will enable the PD/PI to develop or expand their research career. Describe the expected results of the experience in terms of the benefit to VA and to the PD/PI in terms of their research program. Commitment to and goals for professional advancement within VA should be discussed. A timeline should be included with noted plans to apply for independent funding. Awardees are strongly encouraged to delay applying for independent funding until the last two (2) years of a CDA2 award; plans to apply earlier may indicate that the requested mentoring and training is not needed.

Training Activities During Award Period: Stress the new enhanced research skills and knowledge the PD/PI will acquire as a result of the proposed award. If the PD/PI has considerable research experience in the same areas as the proposed research, reviewers may determine that the application lacks potential to enhance their 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 the PD/PI is expected 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.

Mentoring/Training Plan

The PD/PI must complete this plan and summarize the entire mentoring plan. All mentors, consultants and collaborators involved with the proposed research and career development program should be identified. Briefly describe their roles, anticipated contributions and interactions with respect to the PD/PI's career development plan. Describe the mentors' respective areas of expertise and how they will be combined to enhance the PD/PI's career development.

Progress Report Publication List

Do not use. CDAs may not be renewed.

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 CDA and to provide at least 1/8th salary support during the award.

Letters of Support

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

A copy of the CDA LOI or ITS approval notice from the appropriate Service unless otherwise noted in the Service-specific FOA/RFA.

Copies of 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 PD/PI's research career.
The letter(s) must include the following:

- The plan for the PD/PI'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 PD/PI will be allowed to take with them to start their own research program.
- The nature and extent (percent effort) of supervision and mentoring of the PD/PI and commitment to their development that will occur during the award period.
- Description of the nature of any resources that will be committed to this CDA.
- A plan for transitioning the PD/PI from the mentored stage of their 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 PD/PI's progress and development as a VA research scientist at least annually.

A letter from the appropriate Service Chief or Section Head describing the PD/PI's proposed clinical duties upon receiving the CDA. An indication of the PD/PI's expected percent time in non-research activities should be included (not to exceed ten (10) hours per week).

Three (3) reference letters obtained from professional colleagues, former/current teachers, former mentors, etc. The reference letters are important and should address the PD/PI'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 PD/PI's professional training and qualifications for a research career should be used as references. Where possible, references who are not from the PD/PI's current department or organization, but are knowledgeable about their qualifications, should be selected.

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

4.4.4 Special Instructions for 3.5 R&R Senior/Key Person Profile (Expanded) Form

4.4.4.1 PD/PI as Applicant

For all CDA applications, the applicant is considered the PD/PI and must be registered in eRA Commons and assigned the PI role. To register as a PD/PI in Commons, refer to the eRA Commons System Users Guide. Note that VA-ORD policies concerning Multiple PD/PIs are not applicable to CDA applications; **do not** use the PD/PI role for any other Senior/Key Personnel.

Career Development PD/PI's Biographical Sketch Instructions (Page Limit: 5)
A biographical sketch attachment is required. Do not use the Additional Instructions for Biographical Sketches; follow the instructions below. The Biographical Sketch template **OMB No. 0925-0001 and 0925 0002 (Rev. 10/2021 Approved Through 09/30/2024) is required.** Other versions of the form will not be accepted, and if included, the application will be withdrawn from review.

Position Title: If the PD/PI is not currently located at the VAMC (applicant organization), include both "current" and "projected" position titles, labeling each accordingly.

Education: Complete the educational block at the top of the template 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 ten (10) years.

As the PD/PI applicant:

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 (4) 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, Scientific Appointments and Honors
Use the headings below instead of the instructions on the Biographical Sketch Sample. 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, whether 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 VAMC (applicant organization), include the projected employment position in this section as well.

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

Honors
List academic and professional honors chronologically, including research grants and competitive fellowships awarded.

C. Contribution to Science

Briefly describe up to five (5) 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 (4) 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.

The following may be substituted in lieu of publications:

- Original research and theoretical treatises;
- Non-experimental articles, e.g., review of literature in field, book chapters, etc.; and
- 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 the PD/PI 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.

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

The mentored CDA 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. 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 PD/PI applicant, follow the Additional Instructions for Biographical Sketches.

Current and Pending Support for Mentors/Co-mentors: For mentored CDAs modified Current and Pending Support pages must be included in the application for the mentor, co-mentor(s) and PD/PI applicant on the *R&R Senior/Key Person Profile(s) (Expanded) Form*. Each attachment is limited to four (4) pages. VA-ORD staff will request updated Other Support information as part of the JIT process for applications considered for Intent to Award.

4.4.5 Special Instructions for 3.6 Selecting the Appropriate Budget Form

CDA applications include the *R&R Budget Form* with only a few budget categories used. Information regarding allowable costs for the PD/PI and any allowable research development or other costs is included in each Service-specific CDA FOA/RFA. PD/PIs are advised to contact the Service if uncertain about allowable amounts for the applicable CDA mechanism as amounts may vary by Service.

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

4.4.6 Special Instructions for 3.7 R&R 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 PD/PI applicant's name.

If salary will be requested for the applicant (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 CDA; salary consistent with their total VA effort may be requested. See the Service-specific FOA/RFA for guidance on salary allowed for each award. Describe the PD/PI'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 PD/PI, 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 percent or nine (9) academic person months. 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:** Salary compensation may not be requested for a mentor(s).

Part II: Supplemental Instructions for Human Subjects

Human Subjects Research Requirements

Human Subjects Research

Question 1 and 1.a. on the Other Project Information Form of the VA-ORD SF 424 requires that the PD/PI determine whether or not their research involves human subjects, either at the VAMC (applicant organization) or at any other performance site or collaborating institution (e.g., subcontractors, consultants).

The research described in the 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 activities involving exempt or non-exempt human subjects research are planned at any time during the proposed project period, either at the VAMC (applicant organization) or at any other performance site or collaborating institution, then the answer to Question 1 is Yes. (Research determined by an IRB to be exempt from regulations for the protection of human subjects is still human subjects research.) 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, and:
- obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
- obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens (38 CFR 16. 102(e)(1)).

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(e)(2))

Interaction includes communication or interpersonal contact between investigator and subject (for example, questionnaires or surveys). (38 CFR 16.102(e)(3))

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 Office of Research Protections, Policy & Education (ORPPE) is a VA office whose mission is to protect participants in VA human research. ORPPE is responsible for all policy development and guidance, and all training and education in human research protection throughout the VA.

Requirements for describing proposed human subjects research are detailed in the two (2) specific sections of a FOA/RFA, the: (a) Research Plan, and (b) 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 and 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
This attachment is required if Yes is checked for Question 1 on the *Other Project Information Form* (Are Human Subjects involved?). The 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 the (1) requirements of the Federal regulations and VA policies on the protection of human subjects from research risks (38 CFR Part 16), (2) 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 withdrawn from review.

Exempt Human Subjects Research: Some human subjects research activities are exempt from the Federal Regulation for the Protection of Human Subjects (see also 38 CFR Part 16.104). Determination of exemption from VA policy can only be made by an IRB. Since VA-ORD does not require IRB approval or determination at time of application, no exemption categories should be marked in Question 1a on the Other Project Information Form of the *VA-ORD SF 424* 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 Directive 1200.05 Requirements for the Protection of Human Subjects in Research). Written justifications for these exemptions would be submitted to the PD/PI's IRB after receipt of 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: From 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 means a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related 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.
- Unless otherwise indicated, coded data or biospecimens are considered identifiable.

Data and Safety Monitoring Plan (DSMP): This plan is required for each clinical trial that will provide oversight and monitoring to ensure the safety of participants and the validity and integrity of the data. The level of monitoring should be commensurate with the risks and the size and complexity of the clinical trial. A detailed data and safety monitoring plan must be submitted to the PD/PI'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, 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) or Data and Safety Monitoring Board (DSMB): VA-ORD requires the establishment or use of a DMC or DSMB (refer to Service-specific guidance to determine format) 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 (2) 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 Directive 1200.05 Requirements for the Protection of Human Subjects in Research) and 38 CFR 16.102(e) define a human subject is a living individual about whom an investigator (whether professional or student) conducting research, and:

- obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or

- obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

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 humans subjects for the purposes of this Directive.

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(e)(5) and (6) when identifiable information may readily be ascertained or 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(e)(3)).

Intervention includes both physical procedures by which data are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. (38 CFR 16.102(e)(2)).

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 (e.g., 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(e)(5)).

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 generalizable knowledge. Activities which meet this definition constitute research for purposes of application submissions, 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. For the purposes of application submissions, clinical investigations, including clinical investigations as defined under FDA regulations in 21 CFR 50.3, 312.3(b), and 812.3(h), are considered research. For purposes of application submissions, the following activities are not considered research:

1) Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.
2) Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or human-made disasters).
3) Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.
4) Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

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 who 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(e), *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.

PART III: Policies, Assurances, Definitions and Other Information

I. Policies

A. Resubmission of Unfunded 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 FOA/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 I01 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 (2) 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 (2) 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 to Revised Application 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 (2) revised versions of this application, should that be necessary.

Policy: This general policy on application resubmission, stated below, applies to all award activity codes that might be solicited via a 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 a FOA/RFA is not funded and the investigator wishes to submit a revised application to a FOA/RFA from a different Service it must be submitted as a **New** application.
3. When an application that was submitted in response to a 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 three (3) allowed applications.
4. In all cases, submitted applications must conform to the instructions in the Service-specific FOA/RFA being responded to.

B. 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 is 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 is required. PD/PIs are strongly encouraged 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.

C. Inventions and Patents

VA Technology Transfer Program: According to VA Policy and Federal law, VA personnel must promptly report all of their inventions that are either conceived or actually reduced to practice during a time when they held an active VA appointment. 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 38 C.F.R. § 1.656 and may result in loss of the rights of the VA personnel inventors and other entities entitled to rights in the invention.

D. Just-In-Time (JIT) Policy

Several elements of an application are not required at the time of application submission. This information will be requested later in the review cycle (i.e., "just-in-time") to ensure that it is current. See Service-specific FOA/RFA for guidance on what is required for inclusion in an application submission.

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 [SO]) for the VAMC (applicant organization) on the *SF 424 (R&R) Form* (Item 19) of the application.

PD/PI and SO Verification: After the PD/PI and SO successfully submit an application, they will receive an system generated email requesting them to view and verify (or reject) the application online in eRA Commons. To do this, the PD/PI and SO must:

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

See VHA Directive 1200.05(1) Requirements for the Protection of Human Subjects in Research and Supplemental Instructions for Human Subjects Research Requirements.

VA policy on the protection of human subjects in research 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 twenty (20) Federal departments and agencies that have agreed to follow the Federal Policy for the Protection of Human Subjects (Common Rule), effective January 21, 2019 (see 83 Federal Register (FR) 28497). When verifying the submitted application in eRA Commons, the VAMC AOR 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 VAMCs (applicant organizations) conducting nonexempt human subjects research must have an Assurance of Compliance, or a Federalwide 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).

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 R&D Committee and its subcommittees (IRB, IACUC, SRS and/or IBC review) 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. R&D and its subcommittee approvals will be verified in JIT 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 the proposed 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.

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 the proposed work involves these areas or preclinical research that will support later work in these areas, see NIH Office of Science Policy.

NOTE: Under VA-ORD regulations to protect human subjects from research risks, certain research activities may be considered 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 and collected specifically for the purposes of research or 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 Directive 1200.05(1), 45 CFR Part 46 Subparts B, 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 or use of a DMC or DSMB for multi-site clinical trials involving interventions that entail potential risk to the participants, and generally for Phase III clinical trials. Refer to Service-specific guidance on clinical trials.

Required Education in the Protection of Human Research Participants: All individuals involved in conducting VA human subjects research are required to complete training in the ethical principles on which humans subjects research is to be conducted before initiating human subjects research and is to be updated every three years thereafter unless local SOPs require more frequent training. This training is required for all individuals involved in the conduct of VA human subjects research regardless of pay status, appointment type (title 38, title 5, IPA, or WOC) and length of time at the VA facility, including, but not limited to investigators, study coordinators, research assistants, other members of the research team and trainees, such as house officers and students. To meet VA-ORD's requirements using the

Collaborative Institutional Training Initiative (CITI) modules, VA-ORD requires Initial Training and Refresher Training. For additional information regarding these requirements and training in Good Clinical Practice go to OPPR&E. Note that all other applicable VA and VHA training requirements at the local and national level must be met (e.g., privacy and VA information security training).

B. Research Involving Pregnant Women, Human Fetuses and Neonates as Subjects

See VHA Directive 1200.05(1) Requirements for the Protection of Human Subjects in Research, 19. Research Involving Pregnant Women, Human Fetuses and Neonates as Subjects.

C. Research Using Human Embryonic Stem Cells

See VHA Directive 1200.05(1) Requirements for the Protection of Human Subjects in Research, 19. Research Involving Pregnant Women, Human Fetuses and Neonates as Subjects, c and d.

For the current list of approved human embryonic stem cell lines.

When verifying the submitted application in eRA Commons, the AOR 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" and "First Human Embryonic Stem Cells Approved for use under the NIH Guidelines for Human Stem Cell Research".

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, the VAMC AOR 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 (2) ethnic categories, "Hispanic or Latino" and "Not Hispanic or Latino." There are five (5) 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 (2) 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 (5) 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

See VHA Directive 1200.05(1) Requirements for the Protection of Human Subjects in Research, 21. Research Involving Children as Research Subjects

Research involving children must be reviewed carefully by the IRB for its relevance to VA and must not present greater than minimal risk to the children. The VA medical facility Director must approve participation in the proposed research that includes children.

F. Vertebrate Animals

See VHA Handbook 1200.07 Use of Animals in Research.

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 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 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 during JIT, before any award of VA funding will be made.
When verifying the submitted application in eRA Commons, the VAMC AOR certifies that the 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

See the VA Office of Research Oversight (ORO) and VHA Handbook 1058.06 Research Misconduct. The signature of the AOR on the *SF 424 (R&R) Form* of the application serves as certification that the institution will comply with VHA Handbook 1058.06 Research Misconduct.

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). For a list of hazardous agents: CDC for select agents and toxins and Animal and Plant Health Inspection Service (APHIS) for a list of regulated biological agents and toxins.

As a term of award, investigators who conduct research involving Select Agents and Toxins (see 42 CFR 73 for the list; and 7 CRF 331 and 9 CFR 121 for the relevant animal and plant pathogens) are reminded that they must complete registration with the National Select Agent Registry before using VA-ORD funds. No funds can be used for research involving Select Agents and Toxins if the final registration certificate is denied. When verifying the submitted application in eRA Commons, the AOR 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, NIH and USDA: Center for Disease Control Select Agent Program Public Laws

and Regulations; Center for Disease Control Select Agent Program; NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules.

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 VAMC (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 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 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 (2) 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 (2) 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. See VHA Directive 1200.05(1) Requirements for the Protection of Human Subjects in Research, 25. 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 (0) 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 PD/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 VAMC (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 (0) percent” effort or “as needed” are not acceptable levels for those designated as Senior/Key Personnel.

United States: The fifty (50) states, territories and possessions of the U.S., Commonwealth of Puerto Rico, Trust Territory of the Pacific Islands and District of Columbia.