Part I - Overview Information

Department of Veterans Affairs

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

Forms of Participating Organizations
Biomedical Laboratory Research and Development (BLRD) Service

Title
BLRD Data Science Merit Review Award (I01)

Announcement Type
New

Catalog of Federal Domestic Assistance Number:
64.054

Note:
Hyperlinks direct the applicant to information and resources whenever possible.
- Blue hyperlinks redirect the applicant to other sites within this document and to outside information that is accessible to the public.
- Red hyperlinks are only accessible using the VA intranet environment.

Summary of Changes Incorporated into this Revision (12/28/2021):
- An approved LOI is no longer required for applications using MVP data, instead there is an intent to submit (ITS) requirement. See the updated guidance here.

Request for Applications (RFA) Number: BX-22-008

Key Dates
Release/Posted Date: October 4, 2021

Letter of Intent (LOI): A letter of intent is required for this funding opportunity. Letter of intent guidances, templates, and deadlines for LOI submission may be found: https://www.research.va.gov/services/shared_docs/resources.cfm#4.

Application Deadlines, Submission, Peer Review, and Start Dates: See Table 3.

Expiration Date: December 31, 2022

Application Instructions: Applications submitted in response to this RFA must be submitted electronically by the local VA R&D signing official to Grants.gov by the local VA R&D office signing official using the VA SF424 Research and Related (R&R) Forms (VA-SF424) as described in the SF424 (R&R) Application Guide for VA-ORD (VA-SF424 AG).
This RFA must be used in conjunction with the VA version of the Application Guide SF424 (R&R) available on the VA-ORD Intranet site. The instructions in this RFA may differ from, and supersede, the general instructions contained in the VA-SF424 AG.
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Part II - Full Text of Announcement

Section I. Funding Opportunity Description

1. Research Objectives

BLRD supports preclinical biomedical and behavioral studies of disorders and diseases affecting our Veterans. The goal of this RFA is to support data science approaches to advance Veterans’ health. To accomplish this goal, BLRD seeks to build a robust data science workforce in the VA intramural research program. This RFA will accept proposals to leverage VA data (including data from the Million Veteran Program [MVP]), apply Big Data science approaches, and develop cutting-edge big data analyses including but not limited to machine learning and/or deep learning algorithms developed for existing biomedical data, to advance knowledge of biological sciences and to promote Veterans’ health. This RFA will also support discovery research involving -omic data including related phenotypic data in studies to genetic risk factors, pathophysiological pathways, treatment target identification, and biomarker discovery.

The term “biomedical data” is used in a broad sense to include data from biological, biomedical, behavioral, sociocultural, epidemiological, environmental, therapeutic, imaging, or clinical studies and records relating to health and diseases. “Big Data” refers to structured or unstructured datasets that are large in volume, complex, and/or are generated/need to be processed quickly. They typically require advanced mathematical/statistical approaches and computing capabilities. Existing datasets may be obtained through VA or non-VA sources which include, but are not limited to, large databases or biorepositories, digital health data (e.g., pathology slides, imaging data, electrophysiological recordings), electronic health record (EHR) data, MVP data, and functional or behavioral data related to health and diseases.

Applicants are encouraged to submit innovative projects that address fundamental research questions to help elucidate the biological underpinnings of diseases relevant to the health of Veterans, develop computational tools to facilitate analyses of research and clinical data, or to analyze existing research and clinical datasets to inform clinical practice and improve treatment outcomes. Research topics of specific interest to BLRD include (but are not limited to):

- Harmonization or integration of existing clinical and biological data for future analyses.
- Meta-analysis of biological (e.g., -omics, genetic, physiological, molecular data, etc), phenotypical, or functional/behavioral data.
- Development of algorithms for data visualization or application of big data analytics (e.g., artificial intelligence and machine learning techniques)
  - to understand fundamental questions in biology and human disease.
  - to develop biomarkers or therapeutics.
  - to analyze and classify digital health data (e.g., pathology slides, imaging data, electrophysilogic recordings, EHR data, etc..) and functional/behavioral data.
  - to create predictive models to support clinical decision making, identify risk factors, or design clinical trials.

Applications that are not responsive to this RFA will not be reviewed. Applications that are not responsive include:

- Development of mathematical or engineering approaches, models, or algorithms that do not have a clear clinical focus or do not include a clear applicable plan to solving problems with clinical or biological datasets or addressing specific problems of Veterans.
• Applications focused solely on the creation of digital images, development of infrastructure, curating, and cataloging of data.
• Applications that involve wet lab data generation or human subject recruitment.
• Applications that involve studies of human fetal tissue.

Applications that seek to administer surveys or questionnaires (e.g. new clinical data collection) or perform medical procedures and treatments (including biopsies) or observational studies are outside of BLRD purview and should be submitted to other R&D Services as appropriate.

Section II. Award Information

1. Mechanism of Support

This RFA uses the VA Merit Review Award (I01) mechanism for investigator-initiated VA research. The Merit Review Award Program is an intramural funding mechanism to support investigator-initiated research conducted by eligible VA investigators at VA Medical Centers (VAMCs) or VA-approved sites. Merit Review Awards are BLRD’s principal funding mechanism for preclinical biomedical and behavioral studies of disorders and diseases of importance to the health of Veterans.

Applications electronically submitted to BLRD through Grants.gov will be peer-reviewed by a Scientific Review Group (SRG) to provide the Director, BLRD with an evaluation of the scientific merit of the proposed research including recommendations on budgets, funding durations, and potential ethical concerns. All funding decisions are made by the Director, BLRD.

Before funds are released, all applicable regulatory and research compliance approvals must be obtained locally and submitted to the “Just-In-Time” (JIT) system. JIT requires the local assurance forms to ensure all VA regulations and policies are met. All JIT requirements must be completed within 180 days of selection to ensure availability of funding. Approval for funding may be withdrawn for applications that fail to clear JIT over 180 days. All Specific Aims of an application must be able to be cleared in JIT. If a portion of the application is not ready for JIT clearance, the funding decision may be rescinded.

2. Application Types Allowed

**New:** Proposals that have not been previously reviewed or funded by BLRD under this RFA will be accepted as “new” in response to this RFA.

**Resubmissions:** Submission of up to two revised applications (resubmissions) is allowed if the initial submission is not selected for funding. All resubmission applications must include a brief Introduction that addresses the concerns raised in the previous review. If an application is not funded after two resubmissions it is not eligible to receive funding and any new submission by the PD/PI must contain significantly revised Specific Aims. “New” applications submitted without significantly revised Specific Aims will be withdrawn from review.

**Renewals:** Funded Merit Review Awards can be renewed by competitive application for an additional project period of up to 4 years. If three attempts to renew an application do not result in a decision to fund, a “New” application must then be submitted.
Refer to the [VA-SF424 AG](#) for guidance on how to fill out the VA-SF424 Cover Form for each application type. *Note: Renewal applications that are being resubmitted should be marked as “Resubmission” in Box 8 of the SF424 (R&R) Form.*

### 3. Multiple Awards and Submissions

An investigator may submit concurrent applications to more than one BLRD RFA. An investigator may not be a PD/PI (either Contact PD/PI or one of multiple PD/PIs) for more than one application to the same RFA per review cycle. An investigator may only have one funded project for each RFA. An investigator may submit applications to a maximum of three RFAs in any given review cycle (combined submissions to BLRD and/or CSR&D). Concurrent awards for supporting multiple projects under different RFAs will only be considered in unusual cases such as exceptionally meritorious research that addresses high priority research areas and current programmatic needs.

Submission of multiple applications with similar subject matter to different BLRD and CSR&D RFAs may result in the applications being assigned to the same SRG; if this occurs BLRD will not entertain requests to move one of the applications to a different SRG.

### 4. Funds Available

**Duration of Merit Review Awards:** Merit Review Awards have durations of two to four years.

**Merit Review Award Budget Cap:** The recurring (annual) budget may not exceed $165,000 per year. The first year budget may include up to an additional $50,000 for equipment and other startup costs (for a total year 1 budget cap of $215,000). The salary for a non-clinician contact PD/PI identified in Box 14 of the SF424 (R&R) Cover Form is excluded from this cap. In an application with multiple PD/PIs, only the Contact PD/PI may have their salary excluded from this cap. A Merit Review Award budget must request at least $50,000 per year.

**Exceptions to the Budget Cap and/or Duration:** Applications may only exceed the budget and duration requirements if a copy of the letter of approval for a waiver is included in the Letters of Support section. Rare exceptions to the budget cap and/or maximum duration may be granted prior to application submission for fully justified and compelling circumstances. Waiver requests must be submitted by the local R&D Office to vhacoblcsrdrev@va.gov. Deadlines for submission are in Table 3.

### 5. Cost Sharing or Matching Funds

Not Applicable

### 6. Location of Research Space

All performance sites (VA and non-VA) must be included in the Project/Performance Site Locations Form of the SF424 (R&R) Application package. Provide a detailed description of the institutional facilities and resources available to the project. Specify the campus location (VAMC or affiliate) for each facility and resource cited.
It is expected that PD/PIs will perform VA-funded research within a VA facility or VA-leased space controlled by them. If any of the proposed work will be carried out in non-VA space controlled by a PD/PI or other VA investigator, a waiver to perform the research off-site must be obtained prior to the start of work done in an off-site research space. Work performed in a non-VA collaborator’s off-site laboratory or off-site Core Facility does not require an off-site research waiver, except when a VA investigator is the Core Facility Director. If available, a copy of the approval letter for the off-site waiver should be included in the Letters of Support attachment (refer to VHA Program Guide 1200.16).

7. Duplicate Submissions

No portion of the proposed research may be simultaneously submitted to more than one RFA in the same review cycle. Applications submitted to BLRD should not be submitted to any other VA-ORD Service. In cases where it is not clear which Service’s purview is the best fit for a particular application, the VAMC research office should seek advice from ORD program staff about where to submit.

Section III. Eligibility Information

1. Eligible Institutions

Applications may be submitted from any VAMC with an active Federalwide Assurance (FWA) of compliance with the US federal regulations for the protection of human subjects in research.

2. Eligible Individuals

This RFA is open to data scientists who do not have BLRD eligibility conferred based on BLRD eligibility committee review or clinician status. For the purposes of this RFA a data scientist is an individual with expertise in analysis and management of large datasets. Such individuals typically have the following qualifications:

- Having a Ph.D. or equivalent degree in Mathematics, Statistics, Computer Science, Informatics, Physics, or Engineering Disciplines, or
- Having experience and accomplishments demonstrating mastery of computational analytics of big data science and informatics approaches including modeling and artificial intelligence, as evidenced by post-graduate or post-doctoral training, and/or first-authored peer-reviewed publications.
- A PhD, MD or other terminal degree is required by ORD to serve as a principal investigator.

Applicants without current eligibility must include a Letter of Support from the Medical Center Director to verify a commitment to offer the applicant a 5/8ths (or greater) appointment at the VAMC if the application is approved for funding.

Note: that the eligibility criteria for this funding mechanism differ from those for most other BLRD funding opportunities. Additionally, receiving this Data Science Merit Award will not automatically confer eligibility to submit an application to Merit Review Award or Pilot Project Award RFAs issued by the BLRD Service.
The Merit Review Award Program is an intramural program to fund research conducted by VA-salaried investigators at VAMCs or VA-approved sites. If selected for funding, all PD/PIs must have a VA paid appointment of 5/8th or higher to receive ORD research funding (VHA Program Guide 1200.15). Contract clinicians are not VA employees.

Multiple PD/PIs: Multiple PD/PIs or MPIs are not allowed for applications responding to this RFA.

Section IV. Application and Submission Information

Several registration processes must be completed by the local R&D Service before submission of an electronic application (see Section 2.2 of the VA-SF424 AG). Applications must be submitted to Grants.gov by the local research signing official (SO). Applicants are highly encouraged to start the submission process well in advance of the submission deadline to ensure it passes the validations performed at Grants.gov and the eRA.

1. Request Application Information

See the VA-ORD Application Guide SF424 (R&R) for step-by-step guidance.

2. Content and Form of Application Submission

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

A summary of the main components required for this application is shown below in Table 1. Table 2 below contains instructions for SF424 Research and Related Forms specific to this RFA. Instructions in Table 2 are in addition to, or supersede, instructions in the VA-SF424 AG as appropriate.

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

Research and Related Other Project Information Form

Table 2 below contains descriptions of the required content of the separate files that must be attached to Item 12 “Other Attachments” of the Research and Related Other Project Information Form. For guidance on the creation of attachments and format specifications see the VA-ORD Application Guide SF424 (R&R) on the VA-ORD Intranet at http://vaww.research.va.gov/funding/electronic-submission.cfm.

Note: The file names for Attachments #1-10 are mandatory and may not be changed. Altered file names will cause an error to be generated. Only the descriptor in the file names for Appendices #11, 12, 13… etc., may be changed. Altering any other part of the file name may result in parts of your application being excluded from the final electronic image that the reviewers receive or for the attachments to appear in the wrong order.

All applications must be self-contained (i.e., without use of URLs or video clips) within specified page limits. Internet website addresses (URLs) and video clips may not be used to provide
information necessary to the review. URLs may only be placed in the Biographical Sketch and Bibliography and References Cited attachments.
Table 1. Summary of Required Forms and Attachments

<table>
<thead>
<tr>
<th>Forms, Attachments, and Templates with Size Limits as Applicable</th>
<th>Required When?</th>
<th>VA-SF424 Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>SF424 (R&amp;R) Form</td>
<td>Always</td>
<td>Section 3.2</td>
</tr>
<tr>
<td>Project/Performance Site Locations Form</td>
<td>Always</td>
<td>Section 3.3</td>
</tr>
<tr>
<td>Research and Related Other Project Information Form:</td>
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<tr>
<td>Project Summary/Abstract (40 lines of text)</td>
<td>Always</td>
<td></td>
</tr>
<tr>
<td>Project Narrative (10 lines of text)</td>
<td>Always</td>
<td></td>
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<tr>
<td>Bibliography &amp; References Cited (4 page limit)</td>
<td>Always</td>
<td></td>
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<tr>
<td>Facilities &amp; Other Resources</td>
<td>Always</td>
<td></td>
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<tr>
<td>Equipment</td>
<td>Always</td>
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<td>Other Attachments:</td>
<td></td>
<td></td>
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<tr>
<td>1. Introduction to Revised Application (3 page limit)</td>
<td>Resubmission</td>
<td>Section 3.4</td>
</tr>
<tr>
<td>2. Specific Aims (1 page limit)</td>
<td>Always</td>
<td></td>
</tr>
<tr>
<td>2a. Research Plan (14 page limit)*</td>
<td>Always</td>
<td></td>
</tr>
<tr>
<td>3. Progress Report (5 page limit)*</td>
<td>Renewal†</td>
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</tr>
<tr>
<td>4. Human Subjects</td>
<td>If Applicable</td>
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<tr>
<td>5. Vertebrate Animals</td>
<td>Not Applicable</td>
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<tr>
<td>6. Multiple PD/PI Leadership Plan</td>
<td>Not Applicable</td>
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<tr>
<td>7. Consortium/Contractual Arrangements</td>
<td>If Applicable</td>
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<tr>
<td>8. Signed Directors Letter*</td>
<td>Always</td>
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<tr>
<td>8b. Letters of Support</td>
<td>If Applicable</td>
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<tr>
<td>9. Data Management and Access Plan</td>
<td>Always</td>
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<tr>
<td>10. Financial Disclosure</td>
<td>Always</td>
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<tr>
<td>Appendices:*</td>
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<tr>
<td>11. List of Appendix Items*</td>
<td>Always</td>
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<tr>
<td>12. List of Abbreviations*</td>
<td>Always</td>
<td></td>
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<tr>
<td>13. SRG Request*</td>
<td>Always</td>
<td></td>
</tr>
<tr>
<td>14. LOI Approval Memo*</td>
<td>Always</td>
<td></td>
</tr>
<tr>
<td>SF424 (R&amp;R) Senior / Key Person Profile(s)</td>
<td>Always</td>
<td>Section 3.5</td>
</tr>
<tr>
<td>SF424 (R&amp;R) Budget</td>
<td>Always</td>
<td>Section 3.7</td>
</tr>
<tr>
<td>SF424 Summary Budget Worksheet</td>
<td>Always</td>
<td>Section 3.7</td>
</tr>
</tbody>
</table>

* These sections have special instructions for this RFA that are in addition to or supersede instructions in the VA SF424. See Table 2 below.

† New applications from previous awardees require a progress report. See Table 2 below.
### Table 2. RFA Specific Instructions for VA SF424 Forms and Attachments

<table>
<thead>
<tr>
<th>Form/Attachment Name</th>
<th>Page Limit</th>
<th>Required File Name</th>
<th>Instructions</th>
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<tbody>
<tr>
<td>2a. Research Plan 14 Page Limit 02a_VA_Research_Plan.pdf</td>
<td>The Research Plan must include sufficient information for evaluation of the project, independent of any other document (e.g., previous application). Be specific and informative.</td>
<td>In general, the Research Plan should include the following sections:</td>
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<tr>
<td><strong>Background and Significance</strong></td>
<td>Briefly sketch the background leading to the present application, critically evaluate existing knowledge (e.g., published literature, etc.), and specify the gaps that the project is intended to fill. State concisely the importance and Veteran health relevance of the research described in this application. Relate the specific aims to the broad, long-term objective of improving Veteran health. If the aims of the application are achieved, state how scientific knowledge or clinical practice will be advanced. Additionally, describe the effect of these studies on the concepts, methods, technologies, treatments, services, or preventative interventions that drive the field.</td>
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<tr>
<td><strong>Preliminary Studies</strong></td>
<td>Use this section to provide an account of the PD/PI’s preliminary studies pertinent to this application. This information will also help to establish the experience and competence of the investigator to pursue the proposed project. For clinical and epidemiology research applications, pilot data demonstrating the feasibility of obtaining samples, recruiting subjects, and/or data needed for the project must be included, if applicable.</td>
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<tr>
<td><strong>Research Design and Methods</strong></td>
<td>Describe the research design framework, procedures, and analyses to be used to accomplish the specific aims of the project. Include how the data will be collected, analyzed, and interpreted. Describe any new methodology and its advantage over existing methodologies. Describe any novel concepts, approaches, tools, or technologies for the proposed studies. Describe steps that will be carried out to minimize subjective bias (e.g., randomization, experimental and control group matching, blinded assessment of outcomes, etc.). Discuss the potential difficulties and limitations of the proposed procedures and alternative approaches to achieve the aims. As part of this section, provide a timetable for the project.</td>
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<td><strong>Required File Name</strong></td>
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<tr>
<td><strong>Instructions</strong></td>
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<tr>
<td>Do not repeat the Specific Aims in the Research Plan.</td>
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<tr>
<td>Do not include the Progress Report for renewal applications in the Research Plan.</td>
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</tbody>
</table>

**3. Progress Report**

**Page Limit**

5

**Required File Name**

03_VA_Prog_Report_Pubs.pdf

**Instructions**

Progress Reports are required for all applications from a PI who has had any VA funding including on-going or completed Merit or Career Development from any VA-ORD Service. Progress Reports are required for all renewal applications.

**8. Signed Directors Letter**

**Page Limit**

0

**Required File Name**

08_VA_Director_Letter.pdf

**Instructions**

A signed (e-signature accepted) and dated (within the last year) copy of a 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 offsite 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 PI, including 8ths.
• Eligibility status for non-clinicians
• 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.

Applications submitted without this signed letter attachment will not be accepted for review.

**11, 12, 13... Appendices**

**Page Limit**

1

**Required File Name**

11_VA_Appendix_1.pdf
12_VA_Appendix_2.pdf
13_VA_Appendix_3.pdf

(Additional attachments as needed: same file name format)

**Instructions**

See the VA-ORD Application Guide SF424 (R&R), Attachments for Item 12, for guidance on content and naming of files of appendices.

Appendices must be uploaded in the order in which you wish them to appear in the e-application. To check for the correct ordering of attachments, review the Bookmarks and Table of Contents (ToC) within the final e-application.

The first appendix should be a summary sheet listing all of the items included in the appendices; it should be named:
<table>
<thead>
<tr>
<th>Form/Attachment Name</th>
<th>Page Limit</th>
<th>Required File Name</th>
<th>Instructions</th>
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</thead>
<tbody>
<tr>
<td>Instructions</td>
<td></td>
<td></td>
<td>“11_VA_Appendix_1_List of Appendix Items.pdf.”</td>
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<tr>
<td></td>
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<td>The second appendix should be the alphabetized list of abbreviations used in the application; it should be named: “12_VA_Appendix_2_List of Abbreviations.pdf.”</td>
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<td>The third appendix should be a brief document stating what panel the PD/PI would like the application assigned; no other information should be included in this document. The document should be named: “13_VA_Appendix_3_SRG Request.pdf”</td>
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<td></td>
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<td>See the BL/CSR&amp;D Merit Review Panel Purview document for a description of the purview of each of the review panels.</td>
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<td>The fourth appendix should be a copy of the approved LOI approval letter; it should be named: “14_VA_Appendix_4_LOI Approval Memo.pdf”</td>
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<td></td>
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<td>Additional appendices can be added using the file name conventions described above. Please refer to the SF424 AG for guidance on allowable appendix attachments.</td>
</tr>
</tbody>
</table>

**Summary Budget Worksheet and R&R Budget Form**

**Budget Guidance**

See the VA Application Guide SF424 (R&R), Section 3.7 Summary Budget Worksheet and R&R Budget Form for guidance on budget content for Sections A-L. Both of these forms are mandatory for each application.

**Personnel (Section A):** For a non-clinician PD/PI enter the calendar months that indicate the actual effort that the investigator will expend for the research described in this application only; salary consistent with their total VA effort may be requested. 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 section.

If the PD/PI is a Research Career Scientist, enter the calendar months that indicate the actual effort that the investigator will expend for the proposed research, but do not include salary in the budget. In the Budget Justification section discuss the investigator’s contribution to the proposed research only.

Salary support may be requested only for activities that are uncompensated from other sources, such as the academic affiliate or other funding agencies. Any differences in the calendar months effort for the work proposed and total VA effort (salary support) must be fully described in the budget justification.
**Personnel (Section B):** The last row of Section B should include all VA personnel involved in the project, except the PD/PI named in Section A.

**Applications with Multiple PD/PIs:** Applications with Multiple PD/PIs are not allowed for applications responding to this RFA.

**Other Direct Costs (Section F):** All Other Direct Costs described below should be totaled and entered in Section F, Line 8 of the R&R Budget Form. Leave all other fields blank in Section F (1-7, 9, and 10).

**Equipment Description:** Start-up Costs (maximum of $50,000, excluded from the $165,000 budget cap in Year 1) are intended to support the one-time purchase of non-recurring items. Start-up costs are limited to items of major equipment (> $5,000 per item) or small equipment (< $5,000 per item). Start-up costs should be included on the equipment line of the Summary Budget Worksheet and in Section F, Line 8 of the R&R Budget Form.

Start-up costs may not be used for salaries, consumables unique to the first budget period, or advance purchase of recurring items (e.g., experimental animals, glassware, electrodes, antibodies, or tissue culture supplies) to be used beyond the first budget period. Only start-up costs may be used to purchase items of major equipment (> $5,000 per item). Start-up funds and recurring budget may not be combined to purchase additional or more expensive equipment.

In addition to the required budget justification for equipment, include a separate section for start-up funds requested. Include an itemized list of all items to be purchased with start-up funds, a justification for each item in the list, and the total amount of start-up funds.

Budgets requesting start-up costs that do not meet the above definition will be considered to be in excess of the $165,000 recurring budget cap and the application may not be accepted for review.

**Travel:** Travel costs for presenting research findings at scientific meetings may not exceed $2000 per year (total, not per individual). Travel costs required to perform the proposed specific aims are permitted if clearly justified in the budget justification section.

**Materials and Supplies (item 1):** Small equipment items (<$5,000 per item) may be requested as either Materials and Supplies or start-up costs. If requested as start-up costs, include on the equipment line of the Summary Budget Worksheet and Section F, Line 8 of the R&R Budget Form.

**3. Submission Dates and Times**

**Deadlines:** Table 3 below contains deadlines for Merit Review Award Program applications.

**Renewal of Awards:** In order to avoid a funding gap, submission of renewal applications for review one year prior to the award's end date is encouraged. If the submission is approved for funding prior to the end of the current award, the PD/PI may opt for one of the following scenarios: delay the new project start date until the conclusion of the currently funded project; or start the new project at the earliest possible start date, terminating the currently funded project before its conclusion.
Submitting renewal applications more than 1 year prior to the end date is discouraged. If the early submission is approved for funding the PD/PI will have two options: (1) replace the ongoing project with the new Award, losing the remaining time on the currently funded project; or (2) reject the new award and continue the ongoing project. Delaying the start of the new award until the conclusion of the currently funded project is not an option.

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

All new or changed/corrected applications must be submitted and accepted (error-free) in Grants.gov on or before 6 p.m. (local time) of the Last Possible Submission Date (submission deadline) in Table 3.

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

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

Once verified, an application is considered final and no other version will be accepted for review. It is the responsibility of the PD/PI and AOR/SO to check for errors during the examination window.
Table 3. Standard Dates for Application Deadlines for 2022

<table>
<thead>
<tr>
<th>SUBMISSION CYCLES:</th>
<th>Spring 2022</th>
<th>Fall 2022</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deadline for Letter of Intent for this RFA and budget cap waiver submission</td>
<td>November 1</td>
<td>May 1</td>
</tr>
<tr>
<td>First day to submit applications to Grants.gov</td>
<td>February 1</td>
<td>August 1</td>
</tr>
<tr>
<td>Deadline to submit to Grants.gov (After this date the full two-day correction window cannot be used.)</td>
<td>March 8</td>
<td>September 8</td>
</tr>
<tr>
<td>Last Possible Submission Date (to Grants.gov)</td>
<td>March 10</td>
<td>September 12</td>
</tr>
</tbody>
</table>

**WARNING:** If you submit an application on the Last Possible Submission Date and errors are identified by either Grants.gov or eRA Commons, there may not be enough time to fix the errors, resubmit, and have the application received and verified by eRA. If your application is accepted by eRA with no errors, do not withdraw the application during the two-business day examination window unless there is sufficient time to resubmit a changed/corrected application by the submission deadline. Changed/Corrected applications submitted after the Last Possible Submission Date will not be accepted for review.

<table>
<thead>
<tr>
<th>Review and Award Cycles:</th>
<th>Cycle I (Spring)</th>
<th>Cycle II (Fall)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scientific Merit Review</td>
<td>May - June</td>
<td>November-December</td>
</tr>
<tr>
<td>Administrative Review</td>
<td>July - August</td>
<td>January - February</td>
</tr>
<tr>
<td>Earliest Project Start Date(^8)</td>
<td>October 1</td>
<td>April 1</td>
</tr>
</tbody>
</table>

\(^8\)BLRD may not always be able to honor the requested start date of an application; therefore, applicants should make no commitments or obligations until confirmation of the start date by the awarding service.

### 3.A.1. Letter of Intent

Applicants to this RFA must submit a letter of intent (LOI) using the LOI template for this RFA. A copy of the LOI approval letter(s) must be included in the application.

For additional details, see: [https://www.research.va.gov/services/shared_docs/resources.cfm#4](https://www.research.va.gov/services/shared_docs/resources.cfm#4)
3.B. Application Processing

The local Research and Development Office (ACOS and/or AO) is responsible for submitting a notification of any system errors to the eRA mailbox (rd-era@va.gov) prior to the submission deadline (for Grants.gov issues) or validation deadline (for eRA issues).

Upon receipt, applications will be evaluated for completeness. Incomplete applications will not be reviewed. No additional or replacement information will be accepted after submission of the application unless requested by the Program Review staff. The only exceptions are official letters of acceptance for publication of manuscripts submitted by the PD/PI. These must be sent by e-mail to the Review Mailbox (vhacoblcsrdrev@va.gov).

Applications will be withdrawn from review for administrative non-compliance if they do not adhere to the following:

- All applications must be self-contained (i.e., without use of URLs/hyperlinks) within sections with specified page limits. URLs may only be placed in the Biographical Sketches and Bibliography and References Cited attachments. An eRA system validation provides detailed warning notifications about URLs found within an application. However, you should not rely solely on system validations to ensure a successful submission. **NOTE:** URLs within official documents that cannot be altered, such as letterhead (i.e., Letters of Support attachment) or published articles/manuscripts (i.e., Appendix attachments), will not cause a submission to be rejected.
- All applications must contain a Summary Budget Worksheet. Instructions for the budget section can be found in the VA-ORD Application Guide SF424 (R&R) and in this RFA. The worksheet template is available at http://vaww.research.va.gov/funding/electronic-submission.cfm. Verify that the total in the Summary Budget Worksheet and Research and Related Budget match and that the budget request does not exceed the allowable amount (per year and project total) found in the RFA, unless a waiver has been obtained.
- Applications not falling within BLRD purview may be returned without scientific peer review.

Section V. Application Review Information

An overview of the Peer Review process is described in Part 1, Section 4 of the VA-SF424 AG. The following review criteria described below will be considered in the review process for applications submitted to this RFA.

1. Review Criteria

Research Project Evaluation Criteria

**Significance:** Is there a strong scientific premise for the project? Does the proposed study address an important problem or critical knowledge gap in the field and specifically to the Veteran population? How do the research concepts, methods, technologies, treatments, services, or interventions advance the field? If successful, what is the likely impact of the proposed study on the scientific field and on Veterans’ healthcare? Is there a stated translational pathway?

**Innovation:** Does the application challenge existing paradigms, explore new concepts, methodologies, or technologies, or otherwise exhibit significant creativity? To what degree
does the proposed study represent more than an incremental advance on the published literature?

**Approach:** How well do the logical reasoning, critical review of the literature, and preliminary data support the rationale and the feasibility of the project? Are the hypotheses, aims, experimental design, methods, and analyses (including statistics) well developed? Are appropriate strategies to ensure a robust and unbiased approach presented? Are sample sizes and the statistical methods to obtain them described? Are relevant biological variables, such as species, strain, sex, developmental state (age), and weight considered? Are potential problems, alternative strategies, and benchmarks for success presented?

**Feasibility:** Is there sufficient evidence to determine that the proposed studies can be successfully completed? If applicable, is there sufficient evidence for successful recruitment and enrollment of subjects? Can the required animal models or samples be attained? Can the proposed study be completed within the duration of the award? Are proposed studies, including animal studies, adequately powered to answer the research questions?

**Investigators:** Do the PD/PI(s) and other key personnel have the expertise, experience, and record of accomplishments to enable successful completion of the proposed research? If applicable (Multiple PI/PD), how well are the efforts of the investigators and/or research teams integrated and is the collaboration synergistic or complementary? For Renewal applications, has the applicant been productive and shown research progress in the last funding period?

**Multiple PD/PI Leadership Plan (if applicable):** To what degree are the organizational plan, leadership approach, and roles and responsibilities of the PIs/PD appropriate with regard to expertise, resources, and commitment to ensure the completion of the project?

**Environment:** Do the scientific environment, facilities, and resources support the research requirements so as to enable the success of the project? Is there evidence of institutional support reflecting space, equipment, and other unique resources including availability of and access to populations adequate for the project proposed and/or to facilitate collaborative arrangements?

**Ethical/Safety Issues:** Are there any ethical, human subject, animal use, or biohazard concerns?

### 2. Other Considerations

In addition to the above criteria, the following additional instructions are provided to reviewers. These items will be considered; however, reviewers are instructed that these items should not influence their overall priority score.

**Budget:** Are there concerns with the requested budget (amount and duration)? Are there concerns with overlap with other funded projects listed as “Other support” for any of the key personnel? Is there appropriate justification for all categories of the budget?

**Sharing Research Data:** Is the Data Management and Access Plan or the rationale for not sharing data reasonable?
Resubmission (if applicable):  Has the applicant responded to all or only some of the concerns raised in the previous Summary Statement? Are the responses appropriate? Has the application has been improved as a result of the revisions?

Biohazards: Are the proposed materials or procedures hazardous to research personnel and/or the environment? Is the proposed protection adequate?

Foreign/international studies: Does the project have any collaborations or involvement of foreign entities?

Select Agents: Is the use of select agents appropriate? Have the appropriate registrations for Select Agent(s) use been obtained? Are the procedures used to monitor possession use and transfer of Select Agent(s) appropriate? Are the plans for biosafety, biocontainment, and security of the Select Agent(s) appropriate?

Protection of Human Subjects: Are the human participant protections from research risk appropriate? Is the adequacy of protection against risks sufficient? Are there potential benefits of the proposed research to the participants and others? Importance of the knowledge to be gained; is there appropriate Data and safety monitoring for clinical trials?

Inclusion of Women, Minorities, and Children: Are the proposed plans for inclusion of minorities and members of both sexes/genders appropriate and adequate? The VAMC Director must approve participation in proposed research that includes children. (see VHA Handbook 1200.05 Requirements for the Protection of Human Subjects Research).

Vertebrate Animals: Is the proposed involvement and protection of vertebrate animals appropriate and adequate? Is there an appropriate and adequate justification for the use of animal species and numbers proposed? Is the proposed veterinary care adequate? Are the procedures for limiting pain and distress to that which is unavoidable appropriate? Are the methods of euthanasia appropriate?

For protocols which include canines, felines, or non-human primates, reviewers are asked to confirm that the research cannot be conducted with a) an alternative model involving less sentient species and b) that computer simulations and in vitro approaches such as tissue culture or organ-on-a chip technology cannot substitute for the proposed animal model, c) that procedures proposed are essential to meet the scientific goals of the project, and d) that the scientific value of the work proposed is sufficiently important to justify the use of canines, felines, or non-human primates.

For protocols which include canines, felines, or non-human primates, reviewers are asked to confirm that scientific objectives directly relate to an illness or injury that is combat-related, and the regulatory pathway to IND is comprehensive, logical and indicates where the current proposal fits into the pipeline.

For protocols with non-human primates, toxicology studies must have been completed on smaller animal models (e.g., rats, mice).

3. Disapproved Applications

An application may be disapproved if the SRG determines that the proposed studies are unethical.
• Applications that are disapproved are not given a numerical score and may not be resubmitted.
• Studies disapproved for ethical considerations may not be carried out in VA space, with VA resources, even if the project is funded by another agency.

4. Appeals

BLRD accepts letters of appeal for applications submitted to this RFA. The basis for an appeal and the procedure for submitting an appeal are detailed in the guidance document located: https://www.research.va.gov/services/shared_docs/merit_review_guidance_docs/BLRD-CSRD-Merit-Review-Appeals-Process.pdf

Section VI. Award Administration Information

1. Award Notices

After the peer review of the application is completed, the PD/PI will be able to access the Summary Statement via the NIH eRA Commons. If the application is under consideration for funding, VA-ORD will request “Just-in-Time” information from the applicant

2. Administrative and National Policy Requirements

**Research Integrity:** VA-ORD is committed to the highest standards for the ethical conduct of research. Maintenance of high ethical standards requires that VAMCs and investigators applying for, and receiving, Merit Review Awards have appropriate procedures to preclude the occurrence of unethical research practices.

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

Deliberate falsification or misrepresentation of research data will result in withdrawal of an application, possible suspension or termination of an Award, and potentially, suspension of the investigator’s eligibility to submit applications to VA-ORD.

**Acknowledging VA Research Support:** By accepting a Merit Review Award, the PD/PI agrees to properly acknowledge VA affiliation and support in all public reports and presentations (see VHA Directive 1200.19). Failure to acknowledge VA affiliation and support may result in termination of the Award.

**Intellectual Property Rights:** By accepting a Merit Review Award, the PD/PI agrees to comply with VA policies regarding intellectual property disclosure obligations and Federal Government ownership rights resulting from the proposed work (see VHA Directive 1200.18).

**Annual Reports:** By accepting a Merit Review Award, the PD/PI agrees to complete an annual Federal-wide research performance progress report (RPPR) for the project. Information and instructions for RPPR can be found here: http://www.research.va.gov/resources/RPPR.cfm.
Section VII. Agency Contacts

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

1. Scientific/Research Contacts:

To ensure a timely response prior to submission, all questions concerning electronic submission should be submitted by appropriate Research and Development Office staff to the eRA mailbox: rd-era@va.gov.

If the initial assignment to an R&D Service or SRG seems inappropriate, the local Research & Development Office may request reassignment on behalf of the PD/PI, only after initial review assignments have been completed.

Inquiries from the local Research & Development Office related to the review process should be directed to vhacoblsrdrev@va.gov.

Applicants may contact the appropriate Scientific Review Officer (SRO) directly after funding decisions have been made with questions specifically related to issues raised in the summary statement. SRO contact information for individual SRGs may be found: http://www.research.va.gov/services/shared_docs/joint-merit-review-panels.pdf

A representative of the individual R&D Service should be involved in any other communications with VA-ORD.