Part I: Overview Information

Department of Veterans Affairs

Funding Opportunity Announcement/Request for Applications (FOA/RFA) Number: RX-22-004

Title: RR&D Merit Review Award (Parent I01)

Catalog of Federal Domestic Assistance Number(s): 64.054

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

Components of Participating Organizations: Rehabilitation Research and Development Service (RR&D)

Announcement Type: New

Applications submitted in response to this FOA/RFA must be submitted through Grants.gov using the *VA-ORD Application Guide SF 424 Research & Related (R&R) (VA-ORD SF 424)* and other forms available on the VA-ORD intranet: http://vaww.research.va.gov/funding/electronic-submission.cfm.

NOTE: The instructions in this FOA/RFA may differ from the general instructions in the *VA-ORD SF 424.* **The instructions in this FOA/RFA supersede all other guides.**

Companion FOA/RFA: RX-22-100 RR&D Pre-application (I02) found at http://vaww.research.va.gov/funding/rfa.cfm

Key Dates

Release/Posted Date: October 1, 2021
Pre-application Receipt Date(s): Standard dates apply; see Table 2 in Part II, Section III.
Opening (earliest submission) Date(s): Standard dates apply; see Table 2 in Part II, Section III.
Application Deadline(s): Standard dates apply; see Table 2 in Part II, Section III.
Peer Review Date(s): Standard dates apply; see Table 2 in Part II, Section III.
Earliest Anticipated Start Date(s): Standard dates apply; see Table 2 in Part II, Section III.
Additional Information: Not applicable
Expiration Date: December 31, 2023

Executive Summary

Purpose: The RR&D Merit Review Award is an intramural funding mechanism to support investigator-initiated research conducted by eligible VA-ORD investigators at VA Medical Centers (VAMCs) or VA-ORD approved sites. Merit Review Awards are RR&D's principal mechanism for funding basic, translational and clinical studies of disorders and diseases of importance to the rehabilitation of Veterans.

The goal of RR&D is to maximize Veterans' functional independence, quality of life and participation in their lives and community. The RR&D purview includes clinical, preclinical or applied rehabilitation research to enable translation into clinical practice. To meet the RR&D mission, rehabilitation research may restore, replace or return Veterans' function to improve their quality of life:

- Restore the structure and function of body tissues impaired by injury or disease through pioneering research to maximize Veterans' physical, psychological and social function;
- Replace damaged body tissues and functions with innovative approaches to allow Veterans to achieve the best quality of life possible; or
- Return Veterans with disabling conditions to full and productive lives by moving discoveries into healthcare practice.

Special Emphasis Areas: Of particular interest this cycle are studies that include aims addressing:

- Impact of COVID-19 on Veterans' physical, sensory, cognitive and psychosocial function by:
  - Understanding the onset of, severity, duration and recovery from disability in Veterans following COVID-19 while considering the influence of comorbidities (e.g., pre-existing pulmonary, cardiometabolic, oncologic, mental health, immunological or other disorders, etc.) and other risk factors (e.g., race/ethnicity, age, living conditions, environmental exposures, etc.);
  - Revealing late or delayed effects of secondary conditions related to COVID-19 infections on impairment and disability;
  - Examining COVID-19-specific rehabilitation interventions and responses to treatment; or
  - Determining the impact of social distancing on functional status in healthy, disabled and at-risk Veterans (e.g., substance use and mental health disorders, homelessness).
- Health Disparities and conditions that impact underserved Veterans including but not limited to racial and ethnic minority Veterans, Veterans with disabilities and LGBTQ+ Veterans within the context of understanding the onset, severity, duration, rehabilitation, and recovery from disability.
- Prosthetic and other assistive technology needs of women Veterans.
- Exoskeleton research, including externally powered motorized orthoses for Veterans with stroke, traumatic brain injury or conditions other than non-spinal cord injury/diseases (SCI/D).
- Non-pharmacological activity-based interventions for chronic pain impacting outcomes that may include pain reduction, medication use, ADL and QoL.

- Effect of prolonged exposure to opioids (used or misused) on long-term outcomes from traumatic brain injury. While opioids are the primary interest, other commonly used illicit substances or misused prescription drugs may be considered.
- Suicide prevention interventions that improve functional outcomes of Veterans by investigating:
  - Interventions such as, but not limited to, vocational rehabilitation and recreational interventions, that focus on participation in life roles; or
  - Treatments such as, but not limited to, Cognitive Behavioral Therapy and Transcranial Magnetic Stimulation, that influence participation in life roles. Interventions that use community partners such as Veteran Service Organizations and/or involve Veterans not currently receiving VA healthcare are encouraged.

To ensure their proposed area of research is of interest to RR&D, investigators are strongly encouraged to consult the RR&D program purview and portfolio descriptions on the RR&D website and contact the listed the RR&D Scientific Program Manager (SPM) relevant to their area of study.

Mechanism of Support: This FOA/RFA will use the Merit Review Award (I01) activity code for investigator-initiated VA research and Just-in-Time (JIT) information concepts to ensure all VA regulations and policies are met.

Funds Available and Anticipated Number of Awards: Availability of funds is dependent on Congressional appropriation.

Eligible Institutions/Organizations: All VAMCs with an active research program are eligible.

Eligible Project Directors/Principal Investigators (PD/PIs): Investigators assigned the PD/PI role must have at least a 5/8ths VA appointment at the time the Merit Review Award is funded (see Program Guide 1200.15: Eligibility for VA Research Support). In addition, PD/PIs must be current with all requirements related to intellectual property (VA invention documents and certifications); submission of annual progress reports (Research Performance Progress Reports/RPPRs); final RPPRs; clinical trials registration; and results reporting (i.e., ART/clinicaltrials.gov) for existing and previous awards.

Number of Applications and Funded Awards: An investigator may submit more than one (1) application to RR&D in any given review cycle in response to the same FOA/RFA or to multiple FOAs/RFAs; however, an application that is submitted to RR&D **may not** be submitted concurrently to any other R&D Service within VA-ORD (Biomedical Laboratory Research and Development Service [BLR&D], Clinical Science Research and Development Service [CSR&D] or Health Services Research and Development Service [HSR&D]).

Resubmissions: If a Merit Review Award application is reviewed, but not selected for funding, RR&D allows the submission of up to two (2) revised (Resubmission) applications. In general, it is expected that PD/PIs would submit three (3) applications within six (6) cycles. *NOTE:* A Pre-application must be submitted for each review cycle. See FOA/RFA RX-22-100 Pre-application (I02) for instructions found at http://vaww.research.va.gov/funding/rfa.cfm.

Renewals: Funded RR&D Merit Review Awards can be renewed by submitting a competitive application for an additional project period of up to four (4) years. A renewal application may be submitted up to one year prior to the end date of the ongoing Merit Review Award. *NOTE:* A Pre-application must be submitted for each review cycle. See FOA/RFA RX-22-100 Pre-application (I02) for instructions found at http://vaww.research.va.gov/funding/rfa.cfm.

Number of PD/PIs: Multiple PD/PIs are accepted for the RR&D Merit Review Award.

Application Materials: See Section III for application materials.

General Information: For general information on *VA-ORD SF 424* and electronic submission to VA-ORD, see http://vaww.research.va.gov/funding/electronic-submission.cfm.

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Part II: Full Text of Announcement

Section I. Funding Opportunity Description

Research Objectives

The primary focus of research supported by RR&D is to provide a translational pathway to improve the care of our Veterans and to reintegrate the Veteran back into their community; thus, this FOA/RFA does not consider the following to be priority programmatic areas:

- Applications that do not involve behavioral or neuropsychological endpoints
- Applications that recruit primarily from non-Veteran populations
- Applications that utilize acute treatments to study the chronic effects of such treatments

Any study for which common data elements (CDE) are available, this FOA/RFA expects that investigators will use the applicable core measures (see NIH CDE Collections). If the proposed research is not compatible with the CDEs, investigators must supply a detailed justification as to why these CDEs will not be incorporated into the research.

For studies addressing pain outcomes, please refer to the NIH PROMIS site for data elements. If the proposed research is not compatible with the core rehabilitation CDEs, investigators must supply a detailed justification as to why these CDEs will not be incorporated into the research.

Section II. Award Information

Funds Available

Duration and Budget: PD/PIs may request funding for a maximum of four (4) years, based on the total project maximum amount outlined below. There is no annual budget cap; thus, variable funding may be utilized as long as the overall budget cap (based on years requested) is maintained. The salary for all personnel, including the contact PD/PI identified in Box 14 of the *SF 424 Cover Form*, is included in this cap.

1 year = $300,000 max
2 years = $600,000 max
3 years = $900,000 max
4 years = $1,200,000 max

Four-year awards are generally reserved for projects with long-term survival, follow up and chronic data acquisition and analysis periods. All funding is contingent on availability of funds; budget adjustments may be imposed after an award is initiated.

Exceptions to the Duration and/or Budget Caps: Rare exceptions to the award duration and/or budget caps may be granted prior to application submission for compelling circumstances. A duration and/or budget exception waiver request must be submitted as a part of the Pre-application (I02) submission to Grants.gov/eRA. See the companion FOA/RFA RX-22-100 for Pre-application (I02) instructions for waiver requests found at http://vaww.research.va.gov/funding/rfa.cfm.

Applications submitted with more than four (4) project years or a budget exceeding the total award budget cap will not be accepted for review without a waiver approval memo. If a waiver is granted, a copy of the waiver approval memo must be included in the Letters of Support. A waiver does not guarantee that a project will be funded at the level requested.

Cost Sharing or Matching

Not applicable.

Other—Special Criteria

Location of Research Space: It is expected that the PD/PI and VA co-investigators will perform all of the VA-funded research within a VA facility or VA-leased space in accordance with Program Guide 1200.16: Offsite Research. If any of the proposed work will be carried out in non-VA space, a waiver to perform the research off-site must be obtained. The waiver request must indicate if there is a memorandum of agreement, memorandum of understanding or any such arrangement with the owner of the off-site space.

If all the proposed work will be conducted in non-VA space, **a full off-site waiver is required prior to application submission**. The full off-site waiver request must be submitted as a part of the Pre-application (I02) submission to Grants.gov/eRA. See the companion FOA/RFA RX-22-100 for Pre-application (I02) instructions for waiver requests found at http://vaww.research.va.gov/funding/rfa.cfm.

If only a portion of the proposed work will be conducted in non-VA space, **a partial off-site waiver will be required as part of the JIT process** for applications selected with an intent-to-fund.

Section III. Application and Submission Information

Request Application Information

See the *VA-ORD SF 424* for step-by-step guidance.

Content and Form of Application Submission

Prepare applications using this FOA/RFA and *VA-ORD SF 424* guidance, application forms and applicable templates found on the VA-ORD intranet at http://vaww.research.va.gov/funding/electronic-submission.cfm.

Unless otherwise noted in this FOA/RFA, all instructions contained in the *VA-ORD SF 424* must be followed. **Failure to follow instructions may cause delays in submission or withdrawal of applications from review. The instructions in this FOA/RFA supersede all other guides.**

Research and Related Other Project Information Form: Table 1 explains the content required for each file attached to Item 12 "Other Attachments" of the *Research and Related Other Project Information Form*.

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. *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.

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. VA-ORD strongly encourages PD/PIs to 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.

Table 1: Other Project Information Form Attachments for Item 12

Attachment *File Name*	**Instruction** (See the *VA-ORD SF 424, Attachments for Item 12* for further guidance.)
Introduction to Revised Application *01_VA_Intro.pdf*	**Page Limit: 3** For Resubmissions only. Substantial scientific changes must

Attachment *File Name*	**Instruction** (See the *VA-ORD SF 424, Attachments for Item 12* for further guidance.)
	be marked in the text of the application by bracketing, indenting or changing typography. A vertical bar drawn in the margin may be used as long as changes in text are also indicated by bracketing, indenting or changing typography. Do not underline or shade the changes. Deleted sections should be removed and described, rather than retained and marked as deletions. If the changes are so extensive that essentially all of the text would be marked, explain this in the introduction.
Specific Aims *02_VA_Specific_Aims.pdf*	**Page Limit: 1**
Research Plan *02a_VA_Research_Plan.pdf*	**Page Limit: 14** The organization of the plan is at the discretion of the PI. Although there is no specified page limit for each section, be as succinct as possible. In general, the Research Plan should include the following sections: **Background and Significance** • Briefly sketch the background leading to the present application, critically evaluate existing knowledge (published literature, clinical trials, etc.) and specifically identify the gaps that the project is intended to fill. • State concisely the importance and health relevance of the research described in this application by relating the specific aims to the broad, long-term objectives. • Explain how achieving the aims of the application will advance scientific knowledge or clinical practice. • Describe the effect of these studies on the concepts, methods, technologies, treatments, services or preventative interventions that drive this field. • Explain the use of drugs, including pharmacological and toxicological data as appropriate. For clinical trials, include references to preliminary findings, meta-analysis studies or other supporting data, if appropriate. **Preliminary Studies** Provide an account of the PD/PI's preliminary studies pertinent to this application, including his/her preliminary experience with and outreach to the proposed racial/ethnic group members, when relevant. This information will help establish the investigator's background and experience that qualifies them to pursue the proposed project. Scientific Review Groups (SRGs) generally view preliminary data as an

Attachment *File Name*	**Instruction** (See the *VA-ORD SF 424, Attachments for Item 12* for further guidance.)
	essential part of a research application. Preliminary data often aids the reviewers in assessing the likelihood of the success of the proposed project. **Research Design and Methods** • Describe the research design conceptual or clinical framework, procedures and analyses required 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 required. • Discuss the potential difficulties and limitations of the proposed procedures and alternative approaches to achieve the aims. • Provide a tentative sequence or timetable for the project. • Point out any procedures, situations or materials that may be hazardous to personnel and the precautions to be exercised. • Clearly identify all animal models, cell lines and/or sources of tissue to be used. For epidemiology research applications, this section must include: • Descriptions of various comparison groups. • Participant recruitment strategies, if applicable, including control groups. • The criteria to be used for participant selection, the criteria for assignments to various study groups and the number of participants expected to be recruited each year until the conclusion of the study should be clearly detailed. • Data describing participant population inclusion/exclusion criteria at recruiting sites, including number of participants available, should be provided as evidence of feasibility. *NOTE:* A targeted/planned recruitment summary table and targeted/planned enrollment table must be included as appendices. • Description of the statistical analysis plan including the statistical approach to the questions being investigated, calculations of sample size and other comparative measurements. • Explanation of how various data measures will be categorized and assessed.

Attachment *File Name*	**Instruction** (See the *VA-ORD SF 424, Attachments for Item 12* for further guidance.)
VA Career Plan	Do not use. Does not apply.
Mentoring Plan	Do not use. Does not apply.
Progress Report *03_VA_Prog_Report_Pubs.pdf*	**Page Limit: 5**
Human Subjects *04_VA_Human_Subjects.pdf*	**No Page Limit** *NOTE:* A targeted/planned recruitment summary table (in addition to targeted/planned enrollment table) must be included as a separate appendix. This recruitment summary table guides a proactive approach toward recruitment to ensure on time completion of the study. In the event the study falls behind the benchmarks provided in the recruitment table, be prepared to submit a contingency plan via a *Project Modification Request* to RR&D for review. The required targeted/planned recruitment summary table and targeted/planned enrollment table templates can be found at: http://vaww.research.va.gov/funding/electronic-submission.cfm under Additional Format Pages, Service-Specific. In accordance with 38 CFR 17.45, 17.92 and VHA Directive 1200.01, non-Veterans may only be entered into VA studies when there are insufficient Veteran patients suitable for the study (not simply because a non-Veteran population is easily accessible to the investigator), or for studies that will generally benefit Veterans and their well-being, but would not include Veterans as subjects. Examples include surveys of VA providers, studies involving Veterans' family members, or studies including active duty military personnel. Although active duty military personnel are not considered Veterans, they should be included in VA studies whenever appropriate. RR&D requires that investigators make every effort to recruit Veterans and the investigator is encouraged to contact the SPM to discuss strategies. After all alternatives have been considered and changes to the enrollment plan are needed to include non-Veterans, then a non-Veteran enrollment waiver request must be sent to rrdreviews@va.gov for RR&D Director review and approval. For studies that will generally benefit Veterans and their well-being, but would not include Veterans as subjects, RR&D will

Attachment *File Name*	**Instruction** (See the *VA-ORD SF 424, Attachments for Item 12* for further guidance.)
	require a non-Veteran enrollment waiver request with sufficient justification for inclusion of non-Veterans as part of JIT.
Vertebrate Animals *05_VA_Animals.pdf*	**No Page Limit** Additionally, research that uses any canine, feline, or non-human primate must be directly related to an illness or injury that is combat-related. Provide an explanation of how the proposed study meets the requirement that the scientific objectives "are directly related to an illness or injury that is combat-related". Work proposed with these species must also include a detailed description of how it fits into the regulatory pathway seeking approval for investigational use. If the study involves a drug or biological agent in non-Human Primates, the application must additionally include toxicology study findings from smaller animal models (e.g., rats, mice) sufficient to address FDA IND requirements.
Multiple PD/PI Leadership Plan *06_VA_Multiple_PI.pdf*	**No Page Limit** When considering multiple PD/PIs, please be aware that the structure and governance of the PD/PI leadership team, as well as the knowledge, skills and experience of the individual PD/PIs, will be factored into the assessment of the overall scientific merit of the application. Multiple PD/PIs on a project share the authority and responsibility for leading and directing the project, intellectually and logistically. Each PD/PI is responsible and accountable to the VA for the proper conduct of the project or program, including the submission of all required reports.
Consortium/Contractual Agreements *07_VA_Agreements.pdf*	**No Page Limit**
Director's Letter *08_VA_Director_Letter.pdf*	**No Page Limit**
R&D Committee Letter	Do not use. Does not apply.
Letters of Support *08b_VA_Letters_of_Support.pdf*	**No Page Limit** Letters of Support may be addressed to Dr. Patricia Dorn, Director of RR&D. Do not include the Pre-application acceptance notice in this attachment. **Do not** include URLs in

Attachment *File Name*	**Instruction** (See the *VA-ORD SF 424, Attachments for Item 12* for further guidance.)
	the body/content of a Letter of Support.
Data Management and Access Plan *09_VA_DMAP.pdf*	**No Page Limit** The required DMAP template (Version: 7/29/2016) can be found at http://vaww.research.va.gov/funding/electronic-submission.cfm.
Financial Disclosure *10_VA_Financial_Disclosure.pdf*	**No Page Limit** A sample document can be found at http://vaww.research.va.gov/funding/electronic-submission.cfm.
Appendices (11, 12, etc.) *11_VA_Appendix_1_Descriptor.pdf* *12_VA_Appendix_2_Descriptor.pdf*	Appendices must be uploaded in the preferred order for 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 an alphabetized list of abbreviations used in the application. Use the descriptor "Abbreviations" in the file name (11_VA_Appendix_1_Abbreviations.pdf) If Human Subjects will be included in the project, Appendices 2 and 3 should be a targeted/planned recruitment summary table and a targeted/planned enrollment table, respectively. (For template files, see http://vaww.research.va.gov/funding/electronic-submission.cfm, Additional Format Pages, Service Specific). **2nd Appendix Descriptor:** Recruitment Table **3rd Appendix Descriptor:** Enrollment Table **For approved supplemental materials:** After the application has been assigned to a SRG in eRA Commons, contact the Scientific Review Officer (SRO) to discuss logistics for submission. Supplemental materials must be received by the SRO 30 calendar days prior to the peer review meeting. Only include videos that demonstrate devices and experimental data with a temporal element (shows how something functions or occurs over time or demonstrates movement or change). No devices or other media will be accepted. If the video is included in an attachment, **the application will be withdrawn from review.** If the video has been approved by the SRO, it should be emailed to the SRO at least 30 calendar

Attachment *File Name*	**Instruction** (See the *VA-ORD SF 424, Attachments for Item 12* for further guidance.)
	days prior to the review meeting for upload under Additions for Review in the grant folder. The video should not exceed 2 minutes; .mp4, .mov, .avi, and .wmv formats are accepted. The file may not exceed 25 MB. Sufficient descriptive information must be provided within the research plan to understand the information presented in the video, as not all reviewers may be able to access the video, depending on technological constraints.

Summary Budget Worksheet and R&R Budget Form
See the *VA-ORD SF 424, Section 3.7 Summary Budget Worksheet* (SBW) and *R&R Budget Forms* for guidance on budget content for Sections A-L. The SBW worksheet template is available at http://vaww.research.va.gov/funding/electronic-submission.cfm. Verify that the total in the *Summary Budget Worksheet* and *R&R Budget Forms* match and that the budget request does not exceed the allowable amount (per year and project total) found in the FOA/RFA unless an approved waiver has been obtained.

Personnel (Sections A & B): It is RR&D's policy to only reimburse salary commensurate with the actual effort expended on the project by the PI (or other study personnel). Salaries are included in the budget cap. Furthermore, salary support may be requested only for activities that are uncompensated from other sources.

IPAs (Interagency Personnel Agreement) with 5/8ths (7.5 calendar months) effort or greater for the duration of the award will require strong justification for why these individuals are not VA.

Travel (Section D): Leave Section D blank. Travel costs must be included in Section F, Line 8. Travel costs for presenting research findings at scientific meetings may not exceed $2,000/year (in total). Individuals traveling must be VA employees. Expenses in year one will require strong justification to explain how results will be available for dissemination so soon in the project. Travel costs required to perform the proposed specific aims are permitted if included in the travel table and clearly justified in the Budget Justification (Section L).

Publication Costs (Section F): Publication costs in year one will require strong justification to explain how results will be available for dissemination so soon in the project.

Submission, Review and Anticipated Start Dates

Deadlines: Avoid delays and misunderstandings by reading and following the instructions carefully. Table 2 contains deadlines for Merit Review Award Program applications. Depending on the investigator's particular circumstance, requests for off-site or eligibility waivers or approval to exceed

budget limits may be needed. The VAMC R&D Office's Associate Chief of Staff (ACOS) and Administrative Officer (AO) can help determine which approvals may be required.

Table 2. Deadline*, Review and Award Dates

Submission Cycles	Cycle I (Winter)	Cycle III (Summer)
Pre-application (I02) – Letter of Intent & Waiver Request Submission Deadline Applications submitted without a letter of intent for the current review cycle and necessary waiver approvals will be withdrawn.	November 1	May 1
Begin Submitting Award Applications to Companion RFA	November 15	May 15
Down-to-the-Wire Application Submission Deadline After this date the full two (2)-business day application viewing window cannot be used.	5 business days prior to the Verification Deadline	
Application Submission Deadline to Grants.gov Changed/corrected applications submitted after this date will be withdrawn.	3 business days prior to the Verification Deadline	
Verification‡ Deadline in eRA Once verified, an application is considered final and no other version will be accepted for review.	December 15	June 15
Review and Award Cycles	**Cycle I (Winter)**	**Cycle III (Summer)**
Scientific Merit Review	February	August
Administrative Review	March – April	August – September
Earliest Project Start Date	Upon completion of JIT	Upon completion of JIT

*If the deadline falls on a weekend or Federal holiday, the due date is the next business day.

‡Verification occurs on the 3rd business day after receipt of an application with no errors or only warnings.

Pre-application (I02): Submitting a Pre-application (I02) to Grants.gov/eRA (LOI and waiver requests [budget, duration, eligibility, full off-site]) is the first step in the application process. **A LOI is required for each review round, including resubmissions and renewals.** See Table 2 above. For guidance on submitting a Pre-application (I02), see the companion FOA/RFA RX-22-100 RR&D Pre-application found at http://vaww.research.va.gov/funding/rfa.cfm.

Application Submission and Processing: For guidance, see the *VA-ORD SF 424*.

VA-ORD will not penalize PD/PIs for an eRA Commons or Grants.gov system issue; however, unless there is documentation of a processing error at either Grants.gov or eRA Commons, **applications that fail to meet either the application submission or verification deadline will not be accepted for review.** In such cases, prior approval will be required for late submission. The Program Analysis and Review Section Administrator, Tiffany Asqueri (Tiffany.Asqueri@va.gov), must be notified of any system errors prior to the submission deadline (for Grants.gov issues) or the verification deadline (for eRA issues).

Upon receipt, applications will be evaluated for completeness by RR&D Program Review staff. **Applications that are incomplete or fail to meet formatting requirements outlined in the *VA-ORD SF 424* will not be accepted for review.**

Administrative non-compliance issues that will cause an application to be withdrawn from review, include but are not limited to:

- Applications submitted without an approved LOI/Pre-application for the current review cycle.
- 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. VA-ORD strongly encourages PD/PIs to carefully review the application for URLs prior to submission.
- Applications must contain a Summary Budget Worksheet. If the worksheet is missing, the application cannot be adequately evaluated.
- Applications must meet both the Application Submission Deadline to Grants.gov and Application Verification Deadline in eRA noted in Table 2.
- Appendices or other sections must not be used to circumvent the stated page limits.
- Biographical Sketch OMB No. 0925-0001 and 0925-0002, **Rev. 12/2020** Approved Through 2/28/2023 must be used. Other versions of the form will not be accepted.
- For Resubmission or Renewal applications, the correct previous application number (example RX001234) must be entered for the Federal Identifier (*SF 424 Cover Form*, 4.a.); entering the wrong Federal Identifier will prevent the system from processing the application or will mis-identify it as belonging to another investigator or project.

Once an application is submitted, no additions or changes will be accepted, unless requested by the Program Review staff. The only exceptions are official letters of acceptance for publication of manuscripts submitted by the PD/PI. These may be sent by email to the Program Analysis and Review Section Administrator (Tiffany Asqueri; Tiffany.Asqueri@va.gov) at any time prior to the meeting date.

Review and Selection Process

Overview: Applications submitted in response to this FOA/RFA will be reviewed through a two-tier system. The first level of review will be performed by an SRG composed of scientists who have expertise in relevant scientific disciplines and current research areas. The purpose of the SRG is to evaluate the scientific and technical merit of applications. The SRG does not make funding decisions.

The second level of review will be performed by RR&D, based not only on considerations of scientific merit (as judged by the SRGs), but also on the relevance of the proposed study to the mission, programs and priorities of VA-ORD and RR&D. Final funding decisions are made at the discretion and approval, of the Director RR&D.

Discussed and Non-Discussed Applications: The scientific peer review of research applications may include a process in which only those applications deemed by the reviewers to have the highest scientific merit, potentially the better half of the applications under review, will be discussed and assigned an impact score at the SRG meeting. This process allows the reviewers to focus their discussion on the most meritorious applications.

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

Scoring: SRG members are instructed to evaluate research applications by addressing the review criteria described below. Each application that is discussed will receive a final global impact score from each eligible Subcommittee member (without conflicts of interest) following the SRG discussion. Each member's global score will reflect his/her evaluation of the overall impact of the project in its entirety, rather than an arithmetic formula applied to the reviewer's evaluation of each criterion. The RR&D Merit Award uses a scoring scale of 1.0 to 5.0 (with 1.0 being the best possible score); the final impact score for each discussed application will be determined by calculating the arithmetic average of all the eligible members' scores and multiplying the average by 100.

Following the review meeting, PD/PIs will receive a written Summary Statement**,** which contains the Program Description/Abstract and Project Narrative (Relevance) sections from the submitted application, all of the reviewers' written comments and a roster of the review meeting participants.

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

Research Project Evaluation Criteria

Reviewers may recommend specific project modifications and will provide a rationale for the modifications if requested (e.g., changes to study personnel or their time commitment, study design including study arms and sample size, performance sites, project duration, etc.).

Reviewers will evaluate the following:

Significance:

- Is the scientific significance, theoretical foundation and originality of the proposed research reflected in the PD/PI's understanding and appreciation of other research done by others in the same field (e.g., thorough and current literature review) and its relationship to the proposed research clearly stated? In the Background Section and/or the Literature Review, does the PD/PI cite relevant prior work (by self and others) or other information (e.g., pilot data) that helps to establish the scientific significance of the proposed work?
- Does the study address an important Veterans' health problem?
- How will the project advance scientific knowledge or clinical practice?
- What effect will these studies have on the concepts, methods, technologies, treatments, services or preventive interventions that drive this field?

Innovation:

- Is the project original and innovative?
- Does the project challenge existing paradigms or clinical practice or address an innovative hypothesis or critical barrier to progress in the field?
- Does the project develop or employ novel concepts, approaches or methodologies, tools or technologies for this area?

Importance and Impact: Does the proposed research address a problem that is important and would a solution affect healthcare delivery and outcomes in the VA, nationwide and beyond?

Contribution to Veterans Health Administration:

- How will the research, if successful, improve the quality of life and functional independence of Veterans? While every reviewer may not be fully familiar with VA programs and policies, all reviewers will assess the cogency of the argument that the proposed research will make a positive difference in the delivery, management or outcomes of VA health services.
- Is there programmatic relevance to RR&D's mission, goals and priority areas?

Methods:

- Are the strengths and weaknesses of the research design and methods proposed, including whether the conceptual or clinical framework, design, methods and analyses are adequately developed, well-integrated, well-reasoned and appropriate to the aims of the project?
- Does the PD/PI acknowledge potential problem areas and consider alternative approaches?

Adequacy of Data:

- Is there sufficient evidence showing that the proposed studies can be successfully completed?
- If applicable, is there sufficient evidence for successful recruitment and enrollment of human participants or the availability of animal models; and the ability to attain samples and/or data, etc.?
- For primary data, is the proposed data collection instrument(s) or the plan for developing and testing new instruments adequate? Are the data collection procedures feasible and appropriate?
- If secondary data issues will be considered, are the data appropriate, available, accurate and complete for the purposes of the study?
- If proposing the use of existing databases, is there evidence that the PD/PI is familiar with the database and understands the data and its limitations?
- Are quality control procedures adequate, reliable and valid?

Project Organization and Management:

- Is there appropriate distribution of roles and responsibilities across project staff?
- Is there appropriate justification of full-time equivalent (FTE) allocations for each project year?
- Are there plans for coordinating multiple participants, tasks or sites?
- Is the timeline reasonable? Does it show important benchmarks and products and general feasibility of the management plan?

Investigator Qualifications:

- (Primary Reviewer only) Does each investigator and major consultant, have the professional credentials, institutional position, role in the project, expertise (especially as reflected in publications) and relevant experience needed for the proposed study?
- (All Reviewers) Does the combined strength of the team in relation to the objectives of the project bring the necessary, complementary and integrated skills and expertise to the project?

Facilities and Resources:

- Are the facilities and resources adequate in order to carry out the proposed study?
- Is there evidence of support from the PD/PI's VA facility, support from any additional study site(s) and documentation of any agreements with consultants or commitment of non-VA resources to the study?
- If any non-VA resources are used, are they adequately justified and essential to completing the proposed work?
- Does the scientific environment and its unique features, such as participant populations or collaborative arrangements, contribute to the success of the proposed study?

Additional Review Criteria and Considerations

When determining the scientific merit and impact score, reviewers will consider the following additional items if they are included in an application.

Resubmission Applications: Are responses to comments from the previous SRG review adequate and are improvements in the resubmission application appropriate?

Protection of Human Subjects: Are the inclusion of human participants and the guidelines in place to protect them appropriate? Reviewers will consider the following:

- Risk to participants
- Adequacy of protection against risks
- Potential benefits of the proposed research to the participants and others
- Importance of the knowledge to be gained
- Data and safety monitoring for clinical trials

Inclusion of Women, Minorities and Children:

- Proposed plans for inclusion of minorities
- Proposed plans for inclusion of members of both sexes/genders
- Approval from the VAMC Director if the proposed plans include children.

NOTE: For additional information see VHA Directive 1200.05 Requirements for the Protection of Human Subjects in Research.

Vertebrate Animals: Are the use of vertebrate animals and the guidelines in place to protect them appropriate? Reviewers will consider the following:

- Detailed description of the proposed use of the animals
- Justification for the use of animals and for the appropriateness of the species and numbers proposed
- Adequacy of proposed veterinary care
- Appropriate procedures for limiting pain and distress to that which is unavoidable
- Appropriate methods of euthanasia

For protocols which include canines, felines, or non-human primates can it be confirmed that the:

- scientific objectives directly relate to an illness or injury that is combat-related,
- scientific value of the work proposed is sufficiently important to justify the use of canines, felines, or non-human primates,
- research cannot be conducted with an alternative model involving less sentient species,
- computer simulations and in vitro approaches such as tissue culture or organ-on-a chip technology cannot substitute for the proposed animal model,
- procedures proposed are essential to meet the scientific goals of the project, and
- proposed regulatory pathway for an investigational new product application is comprehensive, logical and indicates where the current proposal fits into the pipeline?

For protocols with non-human primates, can it be confirmed that toxicology studies have been completed on smaller animal models (e.g., rats, mice)?

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

Budget (Unscored):

- Is the budget well-justified and adequate?
- Is the project timeline reasonable?
- Are costs appropriately allocated to major budget categories and personnel?
- Are projects staffed properly?
- Do any items appear to be outliers, i.e., do the line items change markedly from one year to another, or are there large amounts included for equipment, travel or subcontracts?

NOTE: Prior to any funding decisions, RR&D staff will review all projects to ensure that VA research funds are not used for any unauthorized purposes.

Sharing Research Data (Unscored): Is the Data Management and Access Plan (DMAP) or the rationale for not sharing data adequate?

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

Appeals: The appeals process ensures that the scientific review of all applications is fair and equitable. It is not intended as a means to resolve differences in scientific opinion between the PD/PI and the reviewers, to adjust funding decisions or to circumvent the peer review process.

The basis for an appeal and the procedure for submitting an appeal are detailed in the guidance document, *Merit Review Appeal Process* on the RR&D site.

If the PD/PI submits a revised application, and an appeal of the previous application is subsequently sustained and funded before the revised application is reviewed, the revised application will be administratively withdrawn. If the revised application receives a fundable score and the appeal is sustained and fundable, the single project rule applies and only one (1) of the two (2) projects will be funded. *NOTE:* PD/PIs are encouraged to resubmit their Merit Review Award while an appeal is under review.

Section V. Award Administration Information

Award Notices

After the application has been peer reviewed, PD/PIs can access their Summary Statement (summary of discussion and written critiques) via eRA Commons once this information has been released by RR&D staff.

If the application is under consideration for funding, RR&D will issue a Notice of Intent to Award to the PD/PI and their VAMC R&D Office's ACOS and AO. The PD/PI will also receive an email notification from eRA. All required JIT information will be listed in the VA JIT Document Manager. The PD/PI and their local R&D office are responsible for completing the required JIT documents to bring the study into compliance. For a project to remain under consideration for funding, RR&D must receive all JIT items via the VA JIT Document Manager within 180 days of the Notice of Intent to Award.

If an application is not selected for funding, it will remain in eRA Commons in a "pending council review" status and the PD/PI will receive an email notification from eRA.

Administrative and National Policy Requirements

Research Integrity: RR&D 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.

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 a PD/PI's eligibility to submit applications to RR&D.

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

Intellectual Property Rights: By accepting a Merit Review Award, PD/PIs agree to comply with VA policies regarding intellectual property (VA invention documents and certifications), disclosure

obligations and Federal Government ownership rights resulting from the proposed work (see VHA Directive 1200.18 Determination of Rights for Inventions and Discoveries).

Annual and Final Reports: By accepting a Merit Review Award, PD/PIs agree to complete and submit via eRA Commons an annual Federal-wide research performance progress report (RPPR) for the project and a Final RPPR in Closeout Status following the project period end date (PPED). Information and instructions can be found here.

Clinical Trials: By accepting a Merit Review Award, PD/PIs agree to comply with VA policies regarding clinical trial registration and summary results reporting. Information can be found here.

Integrity of Review: RR&D 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 interest during the review process. **Applicants who contact reviewers about their proposals or about the review process or otherwise attempt to influence the review process will be subject to sanctioning up to and including permanent loss of eligibility to submit.** Reviewers are expected to report to the SPM involved any attempts by applicants to contact them.

Section VI. Agency Contacts

RR&D encourages scientific/programmatic inquiries concerning this funding opportunity and welcomes the opportunity to answer any questions.

Scientific/Research Contacts

Programmatic inquiries related to Merit Review Award submission or review should be made by the PD/PI's ACOS or AO and directed to the Program Analysis and Review Section Administrator. Contact the RR&D Scientific Program Managers with questions regarding scientific issues raised in the summary statement or the scientific content of an application to be submitted. Contact information for RR&D staff may be found here.

For Grants.gov or eRA Commons questions/issues, email vhacordera.vhacordera@va.gov.

Financial Management Contact

Email Deborah Allen at Deborah.Allen8@va.gov.