

Part I - Overview Information

Department of Veterans Affairs

Funding Opportunity Announcement (FOA)/Request for Applications (RFA) Number: RX-19-003

Title: RR&D Small Projects in Rehabilitation Research (SPiRE) (I21)

Catalog of Federal Domestic Assistance Number(s): 64.054

Participating Organizations

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

Components of Participating Organizations

Rehabilitation Research and Development Service (RR&D), VA-ORD

Announcement Type: New; Update July 16, 2018

Update: Updates relating to this announcement are highlighted in Yellow.

NOTICE: Applications submitted in response to this FOA/RFA must be submitted using the VA-ORD Application Guide SF424 (R&R) and forms available on the VA-ORD Intranet site at <http://vaww.research.va.gov/funding/electronic-submission.cfm>. **NOTE: The instructions in this FOA/RFA may differ from, and supersede, the general instructions contained in the VA-ORD Application Guide SF424 (R&R).**

Key Dates

Release/Posted Date: June 28, 2018; Update July 16, 2018

Letter of Intent (LOI) Receipt Date(s): Standard dates apply; see [Table 2](#), Part II, Section IV.

Opening (earliest submission) Date(s): Standard dates apply; see [Table 2](#), Part II, Section IV.

Application Deadline(s): Standard dates apply; see [Table 2](#), Part II, Section IV; and the VA-ORD Application Guide SF424 (R&R).

It is strongly recommended that submissions to Grants.gov be completed by the [Down to the Wire Deadline](#) in [Table 2](#) to ensure sufficient time to correct any errors that may be identified by either Grants.gov or eRA Commons.

Peer Review Date(s): Standard dates apply; see [Table 2](#), Part II, Section IV.

Earliest Anticipated Start Date(s): Standard dates apply; see [Table 2](#), Part II, Section IV.

Expiration Date: December 31, 2019

Additional Overview Content

Executive Summary

- **Purpose.** The Small Projects in Rehabilitation Research (SPiRE) Program is an intramural funding mechanism to support investigator-initiated research conducted by eligible VA-ORD investigators at VA Medical Centers (VAMCs) or VA-approved sites. SPiRE Awards are RR&D's mechanism to support projects that are more appropriately addressed by shorter and smaller investigations. These experiments may include applications that have high risk, but high potential impact, applications from early career stage investigators, and senior investigators seeking to explore new research approaches in areas where they have not previously been funded.

Studies with efficacy/effectiveness aims requiring inferential statistical hypothesis testing, large sample sizes with long recruitment or follow up periods, and/or multiple study sites are not responsive to the award mechanism (See Part II, Section I.1). Requests for cost extensions (CEs) for this award will not be considered.

The goal of RR&D is to maximize functional recovery. Research appropriate to RR&D has clearly evident potential for translation to clinical rehabilitation. Research areas of interest to RR&D are broad and expansive and may include preclinical, clinical or applied rehabilitation research with functional outcomes demonstrating strong implications for translation into clinical practice to advance the rehabilitative health care of Veterans.

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

- Prosthetic needs of women Veterans
- Exoskeleton research, including externally-powered motorized orthoses for stroke, traumatic brain injury, or other non-SCI/D Veteran populations
- Non-pharmacological activity-based interventions for chronic pain impacting outcomes that may include pain reduction, medication use, ADL, and QoL
- Substance-use disorder, particularly opiates, on long-term outcomes from Traumatic Brain Injury

You are highly encouraged to discuss proposed applications with the RR&D Scientific Program Manager relevant to your area of study. A more detailed description of the research programs supported by RR&D and staff contact information may be found at:

<http://www.rehab.research.va.gov/guid/meritreview.html>.

Applications electronically submitted to RR&D through Grants.gov will be peer-reviewed to provide the Director of RR&D with evaluations of the quality of the research proposed and make recommendations on scientific merit, budgets, and funding durations.

- **Mechanism of Support.** This FOA/RFA will use the Non-HHS Developmental/Exploratory Award (I21) activity code for investigator-initiated VA research.

- **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. See the VA-ORD Application Guide SF424 (R&R).
- **Eligible Project Directors/Principal Investigators (PD/PIs).** The SPiRE Program is an intramural program and only funds research conducted by VA-ORD investigators at VAMCs or VA-approved sites. See [Section III.1](#) and the VA-ORD Application Guide SF424 (R&R).
- **Number of Applications and Funded Awards.** You may submit one SPiRE application to RR&D in a review cycle and if you already have an active SPiRE award, may submit a new SPiRE application 18 months into the current funding cycle. Also, you may hold no more than one SPiRE award at a time. This relates to the intent of this award mechanism for SPiRE projects to ultimately lead to full Merit award application submissions. Note that an application that is submitted to RR&D may not be submitted concurrently to any other VA-ORD Service (i.e., Biomedical Laboratory Research and Development Service, Clinical Science Research and Development Service, or Health Services Research and Development Service).
- **Resubmissions.** For SPiRE applications that have been reviewed, but not selected for funding, RR&D will accept one revised (Resubmission) application. After two unsuccessful submissions, a new application must be submitted. An LOI must be submitted for each review cycle.
- **Renewals.** Not applicable for SPiRE projects.
- **Number of PD/PIs.** Only one PD/PI may be designated in the application.
- **Application Materials.** See [Section IV.1](#) for application materials.
- **General Information.** For general information on VA-ORD Application Guide SF424 (R&R) 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

1. Research Objectives

The Small Projects in Rehabilitation Research (SPiRE) Program is an intramural funding mechanism to support investigator-initiated research conducted by eligible VA-ORD investigators at VAMCs or VA-approved sites. SPiRE Awards are RR&D's mechanism for funding research that is smaller in scope (i.e., less time and resource intensive). The goal of RR&D is to maximize functional recovery. Research appropriate to RR&D has clearly evident potential for translation to clinical rehabilitation. Please see <http://www.rehab.research.va.gov/staff/science1.html> for a more detailed description of the research programs supported by RR&D. You are highly encouraged to contact the appropriate Scientific Program Manager prior to submission of an application to the SPiRE program.

SPiRE projects are expected to support research that is more appropriately executed through shorter and smaller investigations. These experiments may include applications that have: 1) high risk, but high potential impact, 2) applications from early career stage investigators (i.e., an investigator who has not previously competed successfully for a nationally peer-reviewed research award other than a career development or small research award) who lack preliminary data, 3) senior investigators seeking to explore new research approaches in areas where they have not previously been funded and lack preliminary data, 4) as well as those that lack preliminary data. The intent of this award mechanism is for SPiRE projects to ultimately lead to full Merit award application submissions.

Examples of studies considered responsive to the SPiRE award mechanism include, but are not limited to:

Pre-clinical studies:

- Test method/product in an animal model
- Develop and test new animal models (requires prior discussion with the appropriate Scientific Program Manager to ensure it falls within RR&D purview)
- Develop prototype device or refine features of prototype design
- Demonstrate feasibility *in vitro/ex vivo*
- Establish implantation/ transplantation procedures

Studies with human participants:

- Establish feasibility and acceptability
- Evaluate recruitment strategies and sample characteristics
- Develop/refine new intervention and delivery (or in a new setting or for a new population)
- Develop/refine outcome measurement tools or processes and tolerability

- Evaluate preliminary participant response to an intervention, including acceptability or safety of low risk products (but not efficacy)

Section II. Award Information

1. Mechanism of Support

This FOA/RFA will use the Non-HHS Developmental/Exploratory Award (I21) activity code for investigator-initiated VA research and “Just-in-Time” information concepts to ensure all VA regulations and policies are met.

2. Funds Available

Duration and Budget of SPiRE Awards: SPiRE projects can be 1 – 2 years in duration. The budget cap is \$100,000 per project year, not to exceed \$200,000. The annual maximum of \$100,000 may be increased in a single project year as long as the overall budget cap does not exceed \$200,000. Using Intergovernmental Personnel Agreements (IPAs) is not encouraged. The salary for all personnel, including the contact PD/PI identified in Box 14 of the SF424 (R&R) Cover Form, is included in this cap.

NOTE: Requests for cost extensions for SPiRE projects will not be considered.

Section III. Eligibility Information

1. Eligible Applicants

1.A. Eligible Institutions

Applications may be submitted from any VAMC with an active research program.

1.B. Eligible Individuals

Determinations regarding eligibility are made by an individual Service. The general policy for eligibility to receive research support from VA-ORD is described in VHA Handbook 1200.15 [Eligibility for VA Research Support](#).

The RR&D SPiRE Award Program is an intramural program to fund research conducted by VA-salaried investigators at VAMCs or VA-approved sites. To be eligible to submit a SPiRE application to RR&D, you (as the PD/PI) must have at least a 5/8ths time VA appointment **at the time the SPiRE Award is funded** (refer to [VHA Handbook 1200.15](#)). **Contract clinicians cannot be VA employees** (i.e., have a direct, VA-paid appointment) and therefore may not seek research funding from VA-ORD, even if the terms of the contract permits or includes research activities.

Preference for funding is given first to early career stage investigators (i.e., an investigator who has not previously competed successfully for a nationally peer-reviewed research award other than a career development or small research award), and then to established investigators seeking to explore new research approaches in content areas where they have not previously been funded and lack preliminary data.

Only individuals who have **an accepted LOI for the current review cycle** may respond to this funding announcement.

In addition, you (as the PD/PI) must be current with all requirements related to submission of annual progress reports (Research Performance Progress Reports/RPPRs), final reports, clinical trials registration and results reporting (i.e., ART/clinicaltrials.gov) for existing and previous awards.

2. Cost Sharing or Matching

Not Applicable.

3. Other—Special Criteria

3. A. Location of Research Space

It is expected that the PD/PI and VA co-investigators will perform all of the funded research in VA space or VA-leased space in accordance with VHA Handbook 1200.16 [Off-site Research](#). If all of the proposed work will be conducted in non-VA space, a full offsite waiver is required prior to application submission. If only a portion of the proposed work will be conducted in non-VA space, a partial offsite will be required as part of the Just-In-Time (JIT) requirements prior to the research being funded. (See also [Instructions for Preparation and Submission of Requests for Off-Site Waivers](#)).

All performance sites (VA and non-VA) must be included in the Project/Performance Site Locations Form of the SF424 (R&R) application package and the work clearly described in the Research Plan.

3. B. Duplicate Submissions

An application submitted to RR&D may not be concurrently submitted to any other Service.

Section IV. Application and Submission Information

1. Request Application Information

See the VA-ORD Application Guide SF424 (R&R) for step-by-step guidance on submitting an application through Grants.gov Workspace or NIH Application Submission System & Interface for Submission Tracking (ASSIST) in response to this FOA/RFA.

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 FOA/RFA. The forms package associated with this FOA/RFA includes all applicable forms, required and optional.

Guidance specific for this FOA/RFA:

Unless otherwise noted in this FOA/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 1 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. The VA-ORD Application Guide SF424 (R&R) and templates are available on the VA-ORD Intranet found at: <http://vaww.research.va.gov/funding/electronic-submission.cfm>.

*Note: The file names for Attachments #1-9 are **mandatory** and may not be changed. Altered file names will cause a system error. Only the descriptor may be changed in the file name for additional Appendices (i.e., 10, 11, 12...etc.). These file names can include descriptors of 50 characters or less using only standard characters: A through Z, a through z, o (zero) through 9, and spaces. Do NOT use any special characters (example: “&”, “*”, “%”, “/”, or “#”) or underscore (_) in multiple word descriptors. File names are NOT case sensitive. Altering any 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 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. Reviewers are under no obligation to view supplemental material, moreover, they are cautioned that they should not directly access an Internet site as it could compromise their anonymity. URLs may only be placed in the Biographical Sketch and Bibliography and References Cited attachments. VA-ORD strongly encourages you to take the time necessary to carefully review the application for inclusion of URLs prior to application submission. **Any submission with URLs placed anywhere else except the Biographical Sketch and Bibliography and References Cited will be withdrawn from review.** NOTE: URLs within official documents that cannot be altered, such as letterhead (i.e., Letters of Support attachment) or published articles/manuscripts (i.e., Appendix attachments), will be accepted.

Table 1. Other Project Information Form Attachments for Item 12

Attachment and Required File Name	Instructions
<p>1. Introduction to Revised Application (for Resubmission only) <i>o1_VA_Intro.pdf</i></p>	<p>See the VA-ORD Application Guide SF424 (R&R), Attachments for Item 12, for guidance on this document.</p> <p>In addition: The substantial scientific changes must be marked in the text of the application by bracketing, indenting, or change of typography. A vertical bar drawn in the margin may be used as long as changes in text are also indicated by bracketing, indenting or change of typography. <u>Do not underline or shade the changes.</u> Deleted sections should be described but not marked as deletions.</p> <p>If the changes are so extensive that essentially all of the text would be marked, explain this in the Introduction.</p> <p>Page Limit: 2</p>
<p>2. Specific Aims <i>o2_VA_Specific_Aims.pdf</i></p>	<p>See the VA-ORD Application Guide SF424 (R&R), Attachments for Item 12, for guidance on this document.</p> <p>Page Limit: 1</p>
<p>2a. Research Plan <i>o2a_VA_Research_Plan.pdf</i></p>	<p>See the VA-ORD Application Guide SF424 (R&R), Attachments for Item 12, for guidance on this document.</p> <p>Page Limit: 6 Total</p> <p>In addition: The organization of the plan within the 6-page limit is at your discretion. Although a specific number of page(s) in each area of the plan are not being recommended, be as succinct as possible in each area. You should include comment on how this project may ultimately lead to the submission of a full Merit award application.</p> <p>In general, the Research Plan should include the following sections:</p> <p>Background and Significance</p> <p>Briefly sketch the background leading to the present application, critically evaluate existing knowledge (i.e., 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. If the aims of the application are achieved, state how scientific knowledge or clinical practice will be advanced. Describe the effect of these studies on the concepts, methods, technologies, treatments, services, or preventive interventions that drive this field.</p> <p>Preliminary Studies</p> <p>Use this section to 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 also help to</p>

Attachment and Required File Name	Instructions
2a. Research Plan (continued)	<p>establish your experience and competence as an investigator to pursue the proposed project (e.g., model, analytical techniques, clinical population). For epidemiology research applications, pilot data demonstrating the ability to obtain participants, samples and/or data needed for the project must be included, if applicable. The SPiRE award program is designed to fund small, high-risk projects that lack preliminary data, as well as studies for feasibility of an intervention. Powered studies that involve clinical trials, include large sample sizes with long follow up periods or have multiple study sites are not responsive to the award mechanism.</p> <p>Research Design and Methods</p> <p>Describe the research design conceptual or clinical 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. Discuss the potential difficulties and limitations of the proposed procedures and alternative approaches to achieve the aims. As part of this section, provide a tentative sequence or timetable for the project. This timetable should include precise details of subject recruitment (e.g., number of subjects recruited per quarter), length of follow up, if any, as well as realistic timeframe to analyze all data collected. Point out any procedures, situations, or materials that may be hazardous to personnel and the precautions to be exercised.</p> <p>Clearly identify all animal models, cell lines and/or sources of tissue to be used.</p> <p>This section must also include:</p> <ul style="list-style-type: none"> • Description of various comparison groups. • Subject recruitment strategies, if applicable, including control groups. The criteria to be used for subject selection, the criteria for assignments to various study groups, and the number of subjects expected to be recruited each quarter until the conclusion of the study, and length of follow up period should be clearly detailed. • Data describing subject population inclusion/ exclusion criteria at the recruiting site, including number of subjects available, should be provided as evidence of feasibility. NOTE: A targeted/planned enrollment table will be included as a separate appendix. • Any statistical analysis plan including the statistical approach to the questions being investigated, justification of sample size (this does not mean a power calculation, but evidence that sample can be obtained), and other comparative measurements should be described. The application also needs to detail how various data measures will be categorized and assessed.

Attachment and Required File Name	Instructions
2b. VA Career Plan	Do not use. Does not apply.
2c. Mentoring Plan	Do not use. Does not apply.
3. Progress Report Publication List	Not applicable for SPiRE Awards.
4. Human Subjects <i>04_VA_Human_Subjects.pdf</i>	See the VA-ORD Application Guide SF424 (R&R), Attachments for Item 12, for guidance on this document. NOTE: If Human Subjects, then a targeted/planned enrollment table must be included as a separate appendix. All applications requiring an IRB decision on exempt status (even if the decision has already been made) must indicate “Yes” for use of human subjects.
5. Vertebrate Animals <i>05_VA_Animals.pdf</i>	See the VA-ORD Application Guide SF424 (R&R), Attachments for Item 12, for guidance on this document.
6. Multiple PD/PI Leadership Plan	Not applicable for SPiRE Awards. Only <u>one</u> PD/PI may be designated in the application.
7. Consortium/Contractual Agreements <i>07_VA_Agreements.pdf</i>	See the VA-ORD Application Guide SF424 (R&R), Attachments for Item 12, for guidance on this document.
8. Director’s Letter <i>08_VA_Director_Letter.pdf</i>	See the VA-ORD Application Guide SF424 (R&R), Attachments for Item 12, for guidance on this document.
8a. R&D Committee Letter	Do not use. Does not apply.
8b. Letters of Support <i>08b_VA_Letters_of_Support.pdf</i>	See the VA-ORD Application Guide SF424 (R&R), Attachments for Item 12, for guidance on this document.
9. Data Management and Access Plan <i>09_VA_DMAP.pdf</i>	See the VA-ORD Application Guide SF424 (R&R), Attachments for Item 12, for guidance on this document. The DMAP template (Version: 7/29/2016) is required and can be found at: http://vaww.research.va.gov/funding/electronic-submission.cfm .
10, 11, 12. Appendices <i>10_VA_Appendix_1_Descriptor.pdf</i> <i>11_VA_Appendix_2_Descriptor.pdf</i> <i>12_VA_Appendix_3_Descriptor.pdf</i>	See the VA-ORD Application Guide SF424 (R&R), Attachments for Item 12, for guidance on naming files and content 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.

Attachment and Required File Name	Instructions
<p>10, 11, 12. Appendices (continued)</p> <p>(additional attachments as needed: same file name format)</p> <p>If descriptive text is included in an attachment name before the “.PDF” as described in the examples in bold, you will receive a warning message from eRA Commons concerning the attachment name. This warning can be safely ignored. Do not use an underscore within a multiple word descriptor.</p>	<p>In addition: The first appendix should be an alphabetized list of abbreviations used in the application.</p> <p>Use the following file name for the first appendix: <i>10_VA_Appendix_1_Abbreviations.pdf</i></p> <p>If Human Subjects will be included in the project, the second appendix should be a targeted/planned enrollment table. (See http://vaww.research.va.gov/funding/electronic-submission.cfm, Additional Format Pages, Targeted/Planned Enrollment Table Format Page).</p> <p>Use the following file name for the second appendix: <i>11_VA_Appendix_2_Enrollment Table.pdf</i></p> <p>The third appendix should be a Financial Disclosure Statement; it should provide a clear statement disclosing any financial conflict of interest that each PD/PI may have with the proposed research (e.g., purchase of a device or specialized compound from a company in which the PD/PI has a financial interest). VA researchers with outside consulting, employment, or royalty payment opportunities should disclose those potential opportunities to their local VA facility to ensure compliance with the facility policy on financial conflict of interest. A single page containing “N/A” or “No Disclosures” should be used if there is nothing to disclose.</p> <p>Use the following file name for the third appendix: <i>12_VA_Appendix_3_Financial Disclosure.pdf</i></p> <p>For approved supplemental materials, you should contact the scientific review officer (SRO) after the assignment of the application to a review group is visible in eRA Commons to discuss logistics for submission. Supplemental materials must be received by the SRO 30 calendar days prior to the peer review meeting.</p> <p>Only videos for demonstration of devices and experimental data with a temporal element, which refers to the need to show how something functions or occurs over time, or demonstrates movement or change. No devices or other media will be accepted.</p> <p>The video cannot be included in the application in any attachment; this will cause the application to be withdrawn from review. If SRO approved, the video must be embedded in a .pdf file with a maximum file size of 25 MB, not to exceed 2 minutes, and be submitted directly to the SRO via email at least 30 calendar days prior to the review meeting. 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.</p>

Summary Budget Worksheet and R&R Budget Form

See the VA-ORD Application Guide SF424 (R&R), Section 3.7 Summary Budget Worksheet (SBW) and R&R Budget Form for guidance on budget content for Sections A-L.

Personnel (Section A and 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 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): Travel costs for presenting research findings at scientific meetings may not exceed \$2,000 for the entire project (total, not per individual). 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. NOTE: Leave Section D blank. Travel costs must be included in Section F, Line 8.

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.

NOTE: SPiRE project budgets can only be for two (2) years, however, on the SBW, costs from Year 1 will auto-populate in Years 3 and 4 and must be manually deleted from the worksheet.

3. Submission Dates and Times

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

See [Table 2](#) below.

Deadlines. Avoid delays and misunderstandings by reading and following the instructions carefully. [Table 2](#) contains deadlines for SPiRE Award Program applications. Depending on your particular circumstance, requests for off-site waiver or approval to exceed budget limits may be needed. Your VAMC R&D Office's Associate Chief of Staff (ACOS) or Administrative Officer (AO) can help determine which approvals may be required.

Table 2. Deadline*, Review, and Award Dates

SUBMISSION CYCLES:	CYCLE II (SPRING)	CYCLE IV (FALL)
Deadline for submitting Letter of Intent and Waiver requests (eligibility, off-site research, or exceeding duration/budget caps). You are strongly encouraged to submit waiver requests early to allow sufficient time for processing. Applications submitted without the necessary approvals will be returned without review.	February 1	August 1
First day to submit SPiRE Award applications (to Grants.gov)	February 15	August 15
Down to the Wire Deadline (to Grants.gov) – after this date the 2-day application viewing window cannot be used.	5 business days prior to the Verification Deadline	
<p>Last Possible Submission Date (Submission Deadline to Grants.gov) – assumes no errors (Grants.gov or eRA) will be identified or need to be corrected.</p> <p>WARNING: If you submit an application on the Submission Deadline above and errors identified are 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.</p> <p>If your application is accepted by eRA with no errors, do not withdraw the application during the 2 business day application viewing window unless there is sufficient time to resubmit a changed/corrected application by this submission deadline.</p> <p><u>Changed/Corrected applications submitted after the Last Possible Submission Date will not be accepted for review.</u></p>	3 business days prior to the Verification Deadline	
<p>Verification[‡] Deadline (in eRA)</p> <p><u>Once verified, an application is considered final and no other version will be accepted for review.</u></p>	March 15	September 15
REVIEW AND AWARD CYCLES:	CYCLE II (SPRING)	CYCLE IV (FALL)
Scientific Merit Review	May	November
Administrative Review	July - August	January - February
<p>Earliest Project Start Date</p> <p>Note: A Service may not always be able to honor the requested start date of an application; therefore, you should make no commitments or obligations until confirmation of the start date by the awarding Service.</p>	October	April

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

[‡]Verification occurs 2 business days after receipt of an application with no errors or only warnings.

3.A.1. Letter of Intent

A letter of intent is required for each review round, including resubmissions and revisions. See [Table 2](#) above. Instructions for Submitting a Letter of Intent are available on the RR&D website at: <http://www.rehab.research.va.gov/guid/guide.html>

3.B. Submitting an Application Electronically

For guidance on submitting an application in response to this FOA/RFA, see the [VA-ORD Application Guide SF424 \(R&R\)](#).

3.C. Application Processing

For guidance on application processing, see the [VA-ORD Application Guide SF424 \(R&R\)](#).

VA-ORD will not penalize you 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 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 Manager, 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 the RR&D Program Review staff. **Incomplete applications will not be reviewed.**

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 specified page limits. URLs may only be placed in the Biographical Sketch and Bibliography and References Cited attachments. There is now an eRA system validation check which provides detailed warning notifications about URLs found within an application. NOTE: URLs within official documents that cannot be altered, such as letterhead (i.e., Letters of Support attachment) or published articles/manuscripts (i.e., Appendix attachments), will be accepted.
- All applications must contain a Summary Budget Worksheet (SBW). If the worksheet is missing, then the application cannot be adequately evaluated. Instructions for the budget section can be found in the VA-ORD Application Guide SF424 (R&R) and in this FOA/RFA. The SBW template is found at: <http://vaww.research.va.gov/funding/electronic-submission.cfm>. Verify that the total(s) on the SBW 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 a waiver has been obtained and included in the e-Application.
- All applications must contain a Data Management and Access Plan (DMAP) using the VA-ORD template (Version 7/29/2016) that is found at:

<http://vaww.research.va.gov/funding/electronic-submission.cfm>, under Guidance Documents; and on the Internet at <http://www.research.va.gov/funding/default.cfm>, under Application and Submission Process.

- All PI and Senior/Key Personnel must use the updated [Biographical Sketch Format Page](#) (Rev. 09/17 Approved Through 03/31/2020). **Note:** Biographical Sketch form (Rev. 10/15 Approved Through 10/31/2018) may continue to be used through October 31, 2018. **Do NOT** alter the Biographical Sketch template by removing the OMB header or other template information – if VA-ORD staff is unable to verify that the correct template format has been used, the application will be withdrawn from review.

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 may be sent by e-mail to the Program Analysis and Review Manager (Tiffany Asqueri; tiffany.asqueri@va.gov) at any time.

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process.

2. 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 a Scientific Review Group (SRG) composed of scientists who have expertise in relevant scientific disciplines and current research areas. The purpose of the SRG is to evaluate the scientific and technical merit of applications. The SRG does not make funding decisions.

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

Scoring

The assigned reviewers evaluate each research application with respect to the review criteria described below, assigning an overall designation of the application as Highly Meritorious (2), Average Merit (3), or Below-average Merit (4) that reflects the overall scientific merit and potential to improve the health and health care of Veterans. The final impact score is the arithmetic average of all the assigned reviewers' scores multiplied by 100. Given three reviewers

are assigned, this process results in a finite set of impact scores of 200, 233, 267, 300, 333, 367, or 400. NOTE: An impact score of 200 does not ensure a project will be funded.

Funding decisions are based on considerations of scientific merit (as judged by the assigned reviewers), as well as relevance of the proposed study to the mission, programs, priorities of VA-ORD and RR&D, and feasibility of study completion. In addition, preference is given first to early career stage investigators (i.e., an investigator who has not previously competed successfully for a nationally peer-reviewed research award other than a career development or small research award), and then to established investigators seeking to explore new research approaches in content areas where they have not previously been funded and lack preliminary data. FOA/RFAs for different types of funding opportunities may have different and/or additional review criteria.

You will receive a written “**Summary Statement**,” which contains the Program Description/Abstract and Project Narrative (Relevance) sections from the submitted application, the reviewers’ written comments, and a roster of the reviewer participants.

Research Project Evaluation Criteria

Significance: Does this study address an important Veterans’ health problem? If the aims of the application are achieved, how will scientific knowledge or clinical practice advance for rehabilitative healthcare in Veterans? What will be the effect of these studies on the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Approach: Are the conceptual or clinical framework, design, methods, and analyses adequately developed, well integrated, well-reasoned, and appropriate to the aims of the project? Do you acknowledge potential problem areas and consider alternative tactics?

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

Investigators: Are the investigators appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the PIs experience level and that of the other researchers? Does the investigative team bring complementary and integrated expertise to the project (if applicable)?

Environment: Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed studies benefit from unique features of the scientific environment or subject populations, or employ useful collaborative arrangements? Is there evidence of institutional support?

Design/Scope: Is there sufficient evidence to determine that the proposed studies can be successfully completed? Is there sufficient evidence for successful recruitment, enrollment and follow up of subjects? Does the recruitment, enrollment and follow up of subjects fit within the time constraints of a two-year award? If the study is examining feasibility of an intervention, is ‘feasibility’ adequately defined (e.g., tolerability of intervention, barriers to completing intervention, etc.). Does the investigator provide information regarding catchment population to ensure successful recruitment? If applicable, is there sufficient evidence for the availability of animal models, attainment of samples, and/or data, etc.?

2.A. Additional Review Criteria

In addition to the above criteria, the following items will be considered:

Resubmission Applications: Are the responses to comments from the previous scientific review group adequate? Are the improvements in the resubmission application appropriate?

Protection of Human Subjects: Reviewers will also evaluate the proposed use of human subjects and protections from research risk relating to their participation according to the following criteria: (1) Risk to subjects; (2) Adequacy of protection against risks; (3) Potential benefits of the proposed research to the subjects and others; (4) Importance of the knowledge to be gained; and (5) Data and safety monitoring for clinical trials.

Inclusion of Women, Minorities, and Children: When human subjects are involved in the proposed clinical research, reviewers will evaluate the proposed plans for inclusion of minorities and members of both sexes/genders. The VA medical facility Director must approve participation in proposed research that includes children. (see [VHA Handbook 1200.05](#)).

Vertebrate Animals: The SRG will evaluate any proposed involvement and protection of vertebrate animals for the following: (1) detailed description of the proposed use of the animals; (2) justification for the use of animals and for the appropriateness of the species and numbers proposed; (3) adequacy of proposed veterinary care; (4) appropriate procedures for limiting pain and distress to that which is unavoidable; and (5) appropriateness of methods of euthanasia.

Biohazards: If materials or procedures are proposed that are potentially hazardous to research personnel and/or the environment, determine if the proposed protection is adequate.

2.B. Additional Review Considerations

Budget and Period of Support: The appropriateness of the proposed budget and the requested period of support in relation to the proposed research may be assessed by the reviewers. The overall designation should not be affected by the evaluation of the budget.

2.C. Sharing Research Data

Reviewers will comment on whether the Data Management and Access Plan (DMAP) or the rationale for not sharing data is reasonable.

2.D. Disapproved Applications

An application may be disapproved if the SRG determines that the proposed studies are unethical.

- Applications that are disapproved are not scored 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

2.E. Appeals

The appeals process is intended to ensure 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 you 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, found at:

www.rehab.research.va.gov/guid/handbook/1203-1appendc.doc.

If you submit 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 of the two projects will be funded.

Note: You are encouraged to resubmit your SPiRE Award application while an appeal is under review.

Section VI. Award Administration Information

1. Award Notices

After the peer review of the application is completed, you will be able to access your “Summary Statement” 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 you and your VAMC R&D Office’s ACOS and AO. You will also receive an email notification from eRA. All required JIT information will be listed in the VA JIT Document Manager. It is RR&D's expectation, and your responsibility and your local R&D Office’s responsibility to move forward with the completion of 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 you will receive an email notification from eRA.

2. 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 SPiRE Awards have appropriate procedures to preclude the occurrence of unethical research practices.

You (as 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 subjects and vertebrate animals, 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 your eligibility to submit applications to RR&D.

Acknowledging VA Research Support. By accepting a SPiRE Award, you (as the PD/PI) agree to properly acknowledge VA affiliation and support in all public reports and presentations (see VHA Handbook 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 SPiRE Award, you agree 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 [Determination of Rights for Inventions and Discoveries](#)).

Annual Reports. By accepting a Merit Review Award, you agree to complete an annual Federal-wide research performance progress report (RPPR) for the project. Information and instructions for completing and submitting VA-ORD RPPRs can be found at: <http://www.research.va.gov/resources/RPPR.cfm>.

Clinical Trials. By accepting a Merit Review Award, you agree to comply with VA policies regarding clinical trial registration and summary results reporting. Information can be found at: [http://www.research.va.gov/resources/ORD Admin/clinical trials/](http://www.research.va.gov/resources/ORD_Admin/clinical_trials/).

Section VII. Agency Contacts

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

1. Scientific/Research Contacts:

Programmatic inquiries related to SPiRE submission or review should be made by your ACOS or AO and directed to the Program Analysis and Review Section Manager. You may contact the RR&D Scientific Program Managers with questions specifically related to scientific issues raised in the summary statement for a reviewed application or the scientific content of an application to be submitted. Contact information for RR&D staff may be found at:

<http://www.rehab.research.va.gov/staff/science1.html>.

For Grants.gov or eRA Commons questions/issues, please send an email to:

vhacordera.vhacordera@va.gov.

2. Financial Management Contact:

Deborah Allen at deborah.allen8@va.gov