Part I - Overview Information

Department of Veterans Affairs

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

Forms of Participating Organizations
Clinical Sciences Research and Development (CSR&D) Service, VA-ORD

Title
CSR&D Merit Review Award (Parent I01)

Announcement Type
Reissue of CX-18-001

Catalog of Federal Domestic Assistance Number:
64.054

Completion Identification Number
CX18001

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

Summary of Changes Incorporated into this Revision:
- (5/2018) Section III: Eligible Individuals updated
- (5/2018) Table 1: Summary of Required Forms and Attachments updated
- (5/2018) Table 2: RFA Specific Instructions for VA SF424 Forms and Attachments updated
- (5/2018) Budget Guidance updated

Request for Applications (RFA) Number: CX-18-001

Key Dates
Release/Posted Date: May 25, 2018

Letters of Intent Receipt Date(s): See the ORD Submission Calendar for submission dates.

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

Expiration Date: December 31, 2018

Application Instructions: Applications submitted in response to this RFA must be submitted electronically to Grants.gov using the VA SF424 Research and Related (R&R) Forms (VA-SF424) as described in the SF424 (R&R) Application Guide for VA-ORD (VA-SF424 AG).

This RFA must be used in conjunction with the VA version of the Application Guide SF424 (R&R) available on the VA-ORD Intranet site. The instructions in this RFA may differ from, and supersede, the general instructions contained in the VA-SF424 AG.

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Part II - Full Text of Announcement

Section I. Funding Opportunity Description

1. Research Objectives

CSR&D funds clinical, behavioral, and epidemiological research on disorders and diseases of importance to the health of Veterans. Studies supported under this RFA include experimental and observational studies involving human subjects for research purposes. Applications involving administration of survey instruments or questionnaires, the collection of medical histories from research subjects and/or performing medical procedures (including imaging studies or surgical biopsies) or treatment regimens in any of the specific aims can be submitted under this RFA. CSR&D supports interventional clinical trials only if a Letter of Intent (LOI) is approved in advance (see RFA CX-16-006). Observational studies that would fall within the purview of the Epidemiology (EPID) review panel also require a LOI approved in advance.

Eligible applicants are encouraged to submit innovative or highly impactful clinically relevant research with the potential to lead to significant advances in healthcare for Veterans. Examples of priority research areas of specific interest to CSR&D include focus on:

- Post-deployment-, military service- and Veteran-related behavioral, psychiatric and cognitive disorders
- Posttraumatic stress disorder including commonly occurring co-morbidities
- Suicide prevention
- Prevention/reduction in health-risk behaviors (e.g., substance abuse, addictive disorders)
- Women Veteran's health
- Pain mechanisms focused on treatment questions that have potential to advance care
- Diseases with a high healthcare burden in the Veteran population, including precision medicine studies especially focused on individual treatment response

Since these RFAs are the major research funding mechanism for funding clinical research involving Veterans, the Service Director will determine, based on numerous factors (e.g. purview, relevance and portfolio balance) appropriateness for CSR&D support. Therefore, applicants are encouraged to contact the relevant Research Program/Portfolio Manager-in advance of submitting an LOI or a new application to ensure acceptance prior to submission. (See https://www.research.va.gov/services/shared_docs/contacts.cfm)

Section II. Award Information

1. Mechanism of Support

This RFA will use the VA Merit Review Award (I01) mechanism for investigator-initiated VA research. The Merit Review Award Program is an intramural funding mechanism to support investigator-initiated research conducted by eligible VA investigators at VA Medical Centers (VAMCs) or VA-approved sites. Merit Review Awards are CSR&D's principal mechanism for funding.

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

Before funds are released, all applicable regulatory and research compliance approvals must be obtained locally. The "Just In Time" (JIT) system requires the local assurance forms to ensure all VA regulations and policies are met. All JIT requirements must be completed within 180 days of selection to ensure availability of funding. All Specific Aims of an application must be able to be cleared in JIT. If a portion of the application is not ready for JIT clearance, the funding decision may be rescinded; partial funding of an application will not be considered.

2. Application Types Allowed

New: Proposals that have not been previously reviewed or funded by CSR&D under this RFA will be accepted as "new" in response to this RFA.

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

Renewals: Funded Merit Review Awards can be renewed by competitive application for an additional project period of up to 4 years. If three attempts to renew an application do not result in a decision to fund, a "New" application must then be submitted.

Refer to the VA -SF424 AG for guidance on how to fill out the VA-SF424 Cover Form for each application type. *Note: Resubmitted, renewal applications should be marked as "Resubmission" in Box 8 of the SF424 (R&R) Form.*

3. Multiple Awards and Submissions

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

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

4. Funds Available

Merit Review Award Budget Cap: The recurring (annual) budget may not exceed $150,000 per year. The first year budget may include up to an additional $50,000 for equipment and other startup costs (for a total year 1 budget cap of $200,000). The salary for a non-clinician contact PD/PI identified in Box 14 of the SF424 (R&R) Cover Form is excluded from this cap. In an application with multiple PD/PIs, only the Contact PD/PI may have their salary excluded from this cap. A Merit Review Award budget must request at least $50,000 per year.

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

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

5. Cost Sharing or Matching Funds

Not Applicable

6. Location of Research Space

All performance sites (VA and non-VA) must be included in the Project/Performance Site Locations Form of the SF424 (R&R) Application package. Provide a detailed description of the institutional facilities and resources available to the project. Specify the campus location (VAMC or affiliate) for each facility and resource cited.

It is expected that PD/PIs will perform funded research within a VA facility or VA-leased space controlled by them. If any of the proposed work will be carried out in non-VA space controlled by a PD/PI or other VA investigator, a waiver to perform the research off-site must be obtained prior to the start of work done in an off-site research space. Work performed in a non-VA collaborator's off-site laboratory or off-site Core Facility does not require an off-site research waiver, except when a VA investigator is the Core Facility Director. If available, a copy of the approval letter for the off-site waiver should be included in the Letters of Support attachment (refer to VHA Handbook 1200.16)

7. Duplicate Submissions

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

Section III. Eligibility Information

1. Eligible Institutions

Applications may be submitted from any VAMC with an active Federalwide Assurance (FWA) of compliance with the US federal regulations for the protection of human subjects in research. A letter of support for the application from the Medical Center Director must be included as a separate attachment.

2. Eligible Individuals

The Merit Review Award Program is an intramural program to fund research conducted by VA-salaried investigators at VAMCs or VA-approved sites. A PD/PI shall hold an MD, PhD, or equivalent doctoral degree in a medical, biological, or behavioral science field. All PD/PIs must have a VA paid appointment of at least 25 hours per week (5/8ths) to receive ORD research funding (VHA Handbook 1200.15). Contract clinicians are not VA employees. Local site investigators in a multi-site clinical trial must also be eligible.

The VA employment status, including 8ths appointment of each PD/PI must be indicated in the letter of support of the Medical Center Director in the application. If a clinician PD/PI does not have a current, 5/8ths VA paid appointment then the letter of support from the Medical Center Director must include a commitment to offer the PD/PI a 5/8ths (or greater) appointment at the VAMC if the application is approved for funding.

Non-clinician scientists applying to CSR&D may apply without a specific eligibility approval, as long as they have a 5/8ths or greater VA appointment and dedicated VA research space to conduct their VA funded research by the time the funding begins. These two requirements should be clearly and specifically stated in the Director, VAMC, letter included in each application. **Any application submitted to CSR&D by a non-clinician who should have submitted to BLR&D will be withdrawn from review, if the non-clinician does not have BLR&D eligibility.** *Note*: funding by any other service (CSR&D, RR&D, or HSR&D) does not confer eligibility to submit to BLR&D.

VA Career Development Awardees: Investigators with a VA Career Development Award (CDA) may submit an initial Merit Review Award application during the last two years of their CDA award.

Multiple PD/PIs: The "Contact" PD/PI identified in the VA-SF424 Cover Form will be responsible for all communication between the PD/PIs and VA-ORD. Only individuals assigned the PD/PI role in the Budget Form and the Key Personnel Form are considered as PD/PIs. All PD/PIs must meet the eligibility requirements described above. The inclusion of a non-eligible Co-PI/MPI may lead to the administrative withdrawal of the application. The justification for inclusion of more than one PD/PI must be included in a Multiple PD/PI Leadership Plan and each of the multiple PD/PIs must be assigned the PD/PI role. Co-PD/PI role is no longer recognized by eRA or VA-ORD.

Each PD/PI listed on an application will be considered to have made their one allowable submission to this RFA. Reviewers may include the structure and governance of the PD/PI leadership team, as well as the knowledge, skills, and experience of the individual PD/PIs, into their assessment of the application. Multiple PD/PIs on a project share the authority and responsibility for leading and directing the project intellectually, financially, and logistically. Each PD/PI is responsible and accountable for the proper conduct of the approved protocol, including the submission of all required reports.

Section IV. Application and Submission Information

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

1. Request Application Information

Applicants must download the specific VA-SF424 (R&R) application forms for this RFA through **Grants.gov/Apply**. Click on the link to "Download a Grant Application Package" (Step 1) and then enter the RFA number from page 1 of this announcement in the middle box labeled "Funding Opportunity Number." VA-ORD RFA Numbers cannot be found by using the Grants.gov search engine (Search Grants). This forms package must be used to submit an application to this solicitation. Detailed instructions for this submission are provided in Part 1, Section 2 of the VA-SF424 AG.

Additional resources for applicants are available from Grants.gov at:
http://www.grants.gov/web/grants/applicants.html

It is recommended that you use the latest version of Adobe for your submission; however the compatibility of any Adobe version may be verified at:
http://www.grants.gov/web/grants/applicants/adobe-software-compatibility.html

For Assistance downloading this or any Grants.gov application package, please contact Grants.gov Customer Support at: http://www.grants.gov/web/grants/support.html

2. Content and Form of Application Submission

Prepare all applications using the VA-SF424 (R &R) application forms for this RFA in accordance with the VA-SF424 AG, which must be followed because specific file names are required in order to upload the components of your application into the grants.gov system. A summary of the main components required for this application is shown below in Table 1. Table 2 below contains instructions for SF424 Research and Related Forms specific to this RFA. Instructions in Table 2 are in addition to, or supersede, instructions in the VA-SF424 AG as appropriate.

Use of Common Data Elements (CDE): For human studies of the causes and mechanisms underlying posttraumatic stress disorder (PTSD), traumatic brain injury (TBI), and other co-occurring outcomes like suicide, depression, and substance abuse disorder it is expected investigators will use CDEs established by the PhenX Measures for Mental Health Research Project. If the proposed research is not compatible with these core CDEs, the investigator(s) must provide detailed justification why these measures will not be incorporated.

Use of hyperlinks: All applications must be self-contained (i.e., without the use of URLs/hyperlinks), within specified page limits. The use of URLs/hyperlinks is prohibited except in the Biographical Sketch and References Cited attachments. Any submission with URLs placed anywhere else except the biographical Sketch and Referenced Cited will be withdrawn from

review. The inclusion of links to videos within an application is not acceptable and will cause the application to be withdrawn from review.

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

A set of templates, with mandatory file names for each attachment, is available on the VA-ORD intranet site (http://vaww.research.va.gov/funding/electronic-submission.cfm). Information for each attachment in Item 12. must be saved in a single PDF file and attached. See instructions for creating/attaching PDF documents

Table 1. Summary of Required Forms and Attachments

Forms, Attachments, and Templates with Size Limits as Applicable	Required When?	VA-SF424 Instructions
SF424 (R&R) Form	Always	Section 4.2
Project/Performance Site Locations Form	Always	Section 4.3
Other Project Information Form:		Section 4.4
Project Summary/Abstract (40 lines of text)	Always	
Project Narrative (10 lines of text)	Always	
Bibliography & References Cited (4 page limit)	Always	
Facilities & Other Resources	Always	
Equipment	Always	
Other Attachments:		
1. Introduction to Revised Application (3 page limit)	Resubmission	
2. Specific Aims (1 page limit)	Always	
2a. Research Plan (14 page limit)*	Always	
2b. VA Career Plan	Never Submit	
2c. Mentoring Plan	Never Submit	
3. Progress Report (5 page limit)*	Renewal†	
4. Human Subjects	If Applicable	
5. Vertebrate Animals	If Applicable	
6. Multiple PD/PI Leadership Plan	If Applicable	
7. Consortium/Contractual Arrangements	If Applicable	
8. Signed Directors Letter	Always	
8a. R&D Committee Letter	Never Submit	
8b. Letters of Support	If Applicable	
9. Data Management and Access Plan	Always	
Appendices:*		
10. List of Appendix Items*	Always	
11. List of Abbreviations*	Always	
12. Financial Disclosures*	Always	

13. SRG Request Memo*	Always	
SF424 (R&R) Senior / Key Person Profile(s)	Always	Section 4.5
SF424 (R&R) Budget	Always	Section 4.7
SF424 Summary Budget Worksheet	Always	Section 4.7

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

† New applications from previous awardees may also require a progress report. See Table 2 below.

Table 2: RFA Specific Instructions for VA SF424 Forms and Attachments

Form/Attachment Name **Page Limit** ***Required File Name***	**Instructions**
2a. Research Plan **14 Page Limit** *02a_VA_Research_Plan.pdf*	The Research Plan must include sufficient information for evaluation of the project, independent of any other document (e.g., previous application). Be specific and informative. 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 (e.g., published literature, clinical trials, etc.), and specify the gaps that the project is intended to fill. State concisely the importance and Veteran health relevance of the research described in this application. Relate the specific aims to the broad, long-term objective of improving Veteran health. If the aims of the application are achieved, state how scientific knowledge or clinical practice will be advanced. Additionally, describe the effect of these studies on the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field. Use of drug compounds should be detailed, including pharmacological and toxicological data. Include references to preliminary findings, meta-analyses, and other supporting data. **Preliminary Studies** 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 establish the experience and competence of the investigator to pursue the proposed project. For epidemiology research applications, pilot data demonstrating the feasibility of obtaining samples, recruiting subjects, and/or data needed for the project must be included, if applicable. **Research Design and Methods** 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,

Form/Attachment Name **Page Limit** ***Required File Name***	**Instructions**
	tools, or technologies for the proposed studies. Describe steps that will be carried out to minimize subjective bias (e.g. randomization, experimental and control group matching, blinded assessment of outcomes, etc). Discuss the potential difficulties and limitations of the proposed procedures and alternative approaches to achieve the aims. As part of this section, provide a 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. For animal studies, include estimates of samples sizes, study power, and the statistical methods used to obtain them. Explain how relevant biological variable such as species, strain, sex, developmental stage (age), and weight are factored into the research design and analysis. All animal models, cell lines and/or sources of tissue to be used must be clearly identified and described in this section. For molecular epidemiology research applications this section must include: • Description of various comparison groups • Subjects 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 year until the conclusion of the study should be clearly detailed. • Data describing subject population inclusion/exclusion criteria at recruiting sites, including the number of subjects available, should be provided as evidence of feasibility. • The statistical analysis plan, including the statistical approach to the questions being investigated, calculations of sample size, and other comparative measurements should be described. The application also needs to detail how various data measures will be categorized and assessed. Do not repeat the Specific Aims in the Research Plan. Do not include the Progress Report for renewal applications in the Research Plan.

Form/Attachment Name **Page Limit** ***Required File Name***	**Instructions**
3. Progress Report **5 Page Limit** *03_VA_Prog_Report_Pubs.pdf*	Progress Reports are required for all applications that have a PI who has had previous VA funding. Progress Reports are required for all renewal applications. In addition, VA Career Development and Merit Review awardees who are submitting a 'New' application are required to submit a progress report for their previous award.
4. Human Subjects **No Page Limit** *04_VA_Human_Subjects.pdf*	It is expected that all CSR&D studies will be focused on the Veteran population, requests for enrollment of or data and samples from non-Veterans will be reviewed administratively.
8b. Letters of Support *08b_VA_Letters.pdf*	If applicable, the LOI approval letter should be included here. See https://www.research.va.gov/services/shared_docs/MR-EPID-LOI_08012016.pdf for guidance on submitting a Merit Review Epidemiology Letter of Intent (LOI).
10, 11, 12... Appendices *10_VA_Appendix_1.pdf* *11_VA_Appendix_2.pdf* *12_VA_Appendix_3.pdf* (additional attachments as needed: same file name format)	The file names for PDF Attachments 1 - 9 under Section 3.4 Research and Related Other Project Information Form, Item 12. Other Attachments, are mandatory and may not be changed (refer to specific FOA/RFA, Table 2). Altered file names will cause an error to be generated. Mandatory file names and corresponding template MS Word files can be found on the VA-ORD Intranet: http://vaww.research.va.gov/funding/electronic-submission.cfm. Only the descriptor in the file name for additional Appendices (i.e., 10, 11, 12...) may be changed. These file names can include descriptors of 50 characters or less using only standard characters: A through Z, a through z, 0 (zero) through 9, and spaces. Do NOT use any special characters (example: "&", "*", "%", "/", or "#") or underscore (_) in multiple word descriptors between words if a multiple word descriptor is used. NOTE: If using ASSIST, the system will automatically change a space to an underscore between each word in a multiple word descriptor file name. File names are NOT case sensitive. A 0 (zero) byte attachment (empty) is an invalid PDF and will result in the application being rejected by the eRA system. Appendices should be named using the following convention in the following order: • Attachment number, starting with 10, then 11, 12, etc.

Form/Attachment Name **Page Limit** ***Required File Name***	**Instructions**
	• Underscore • The phrase "VA_Appendix" • Underscore • Appendix number starting with 1, then 2, 3, etc. • Underscore • Brief description of the contents (e.g., Abbreviations, Accepted Manuscripts, Patents); if a multiple work descriptor is used, place a SPACE between each word. Do not use an underscore (_). • ".pdf" NOTE: If using ASSIST, the system will automatically change a space to an underscore between each word in a multiple word descriptor file name. The first appendix should be a summary sheet listing all of the items included in the appendices; it should be named: **"10_VA_Appendix_1_Summary.pdf."** The second appendix should be the alphabetized list of abbreviations used in the application; it should be named: **"11_VA_Appendix_2_Abbreviations.pdf."** The third appendix should be a Financial Disclosure Statement; it should be named: **"12_VA_Appendix_3_Financial Disclosure.pdf."** 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. The fourth appendix should be a brief letter stating what panel the PD/PI would like the application assigned to; it should be named: **"13_VA_Appendix_4_SRG Request.pdf"** See the BL/CSR&D Merit Review Panel Purview

Form/Attachment Name Page Limit *Required File Name*	Instructions
	document for a description of the purview of each of the review panels. Additional appendices can be added using the file name conventions described above. Please refer to the SF424 AG for guidance on allowable appendix attachments.

Summary Budget Worksheet and R&R Budget Form

Budget Guidance
See the VA Application Guide SF424 (R&R), Section 4.7 Summary Budget Worksheet and R&R Budget Form for guidance on budget content for Sections A-K. Both of these forms are mandatory for each application.

Personnel (section A): For a non-clinician PD/PI enter the calendar months that indicate the actual effort that the investigator will expend for the research described in this application only; salary consistent with their total VA effort may be requested. Describe the PD/PI's contribution to the proposed research, as well as the other activities comprising their total VA effort, in the Budget Justification section.

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

Salary support may be requested only for activities that are uncompensated from other sources, such as the academic affiliate or other funding agencies. Any differences in the calendar months effort for the work proposed and total VA effort (salary support) must be fully described in the budget justification.

Personnel (Section B): The last row of Section B should include all VA personnel involved in the project, except the PD/PI named in Section A.

Applications with Multiple PD/PIs: When multiple PD/PIs are proposed, only the Contact PD/PI (identified in Box 14 of the SF424 (R&R) Cover Form) is eligible to receive salary above the budget cap. Identification of multiple PD/PIs may not be used to exceed budget caps. Cost of living adjustments for personnel other than contact PD/PI may not cause the budget to exceed the stated cap.

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

Equipment Description: Start-up Costs (maximum of $50,000, excluded from the $150,000 budget cap in Year 1) are intended to support the one-time purchase of non-recurring items. Start-up costs are limited to items of major equipment (> $5,000 per item), small equipment (< $5,000 per item), or one-time purchase of transgenic mice for breeding. Start-up

costs should be included on the equipment line of the Summary Budget Worksheet and in Section F, Line 8 of the R&R Budget Form.

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

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

Budgets requesting start-up costs that do not meet the above definition will be considered to be in excess of the $150,000 recurring budget cap and the application may not be accepted for review.

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

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

3. Submission Dates and Times

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

Renewal of Awards: Submission of renewal applications for review one year prior to the award's end date is encouraged. For example, if the award ends September 30th, the renewal application is normally due for the Spring review cycle. This allows the PD/PI to submit an application and one revision (if the renewal is not funded) without experiencing a funding gap. If the submission is approved for funding, the PD/PI may opt for one of the following scenarios: delay the new project start date until the conclusion of the currently funded project; or start the new project at the earliest possible start date, terminating the currently funded project before its conclusion.

Submitting renewal applications more than 1 year prior to the end date is discouraged. If the early submission is approved for funding the PD/PI will have two options: (1) replace the ongoing project with the new Award, losing the remaining time on the currently funded project; or (2) reject the new award and continue the ongoing project. Delaying the start of the new award until the conclusion of the currently funded project is not an option.

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

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

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

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

Table 3. Standard Dates for Application Deadlines for 2018

SUBMISSION CYCLES:	Spring 2018	Fall 2018
Deadline for requests for Eligibility and/or Acceptance into the Non-Clinician Intramural Research Program	December 1	June 1
Deadline for waiver requests (offsite research or budget cap)	December 1	June 1
First day to submit applications to Grants.gov	February 1	August 1
Deadline to submit to Grants.gov (After this date the full two-day correction window cannot be used.)	March 8	September 10
Last Possible Submission Date (to Grants.gov) **WARNING:** If you submit an application on the Last Possible Submission Date and errors are identified by either Grants.gov or eRA Commons there may not be enough time to fix the errors, resubmit, and have the application received and verified by eRA. If your application is accepted by eRA with no errors, do not withdraw the application during the two-business day examination window unless there is sufficient time to resubmit a changed/corrected application by the submission deadline. Changed/Corrected applications submitted after the Last Possible Submission Date will not be accepted for review.	March 12 6:00 pm local time	September 12 6:00 pm local time
Review and Award Cycles:	**CYCLE I (Spring)**	**CYCLE II (Fall)**
Scientific Merit Review	May - June	November-December
Administrative Review	July - August	January - February
Earliest Project Start Date§	October 1	April 1

§CSR&D may not always be able to honor the requested start date of an application; therefore, applicants should make no commitments or obligations until confirmation of the start date by the awarding service.

3.A.1. Letter of Intent

An approved LOI is required for applications that would fall within the purview of the Epidemiology (EPID) review panel. Guidance for submitting an LOI for Merit Review Epidemiology applications can be found on the BLR&D/CSR&D Merit Review Program page (http://www.research.va.gov/services/shared_docs/merit_review.cfm).

3.B. Application Processing

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

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

Section V. Application Review Information

An overview of the Merit Review process is described in Part 1, Section 6 of the VA-SF424 AG. The following review criteria described below will be considered in the review process for applications submitted to this RFA.

1. Review Criteria

Research Project Evaluation Criteria

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

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

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

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

Investigators: Do the PD/PI(s) and other key personnel have the expertise, experience, and record of accomplishments to enable successful completion of the proposed research? If applicable (Multiple PI/PD), how well are the efforts of the investigators and/or research

teams integrated and is the collaboration synergistic or complementary? For Renewal applications, has the applicant been productive and shown research progress in the last funding period?

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

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

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

2. Other Considerations

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

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

Budget: Please indicate any specific comments you may have concerning the requested budget (amount and duration). Including overlap with other funded projects listed as "Other support" for any of the key personnel. For all years, determine whether all categories of the budget are appropriate and justified. Provide a rationale for each suggested modification in amount or duration of support.

Foreign/international studies: Identify any collaborations or involvement of foreign entity.

Inclusion of Women, Minorities, and Children: When human participants are involved in the proposed clinical research, describe the proposed plans for inclusion of minorities and members of both sexes/genders. The VAMC Director must approve participation in proposed research that includes children. (see VHA Handbook 1200.05 Requirements for the Protection of Human Subjects Research).

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

Resubmission (if applicable): Please indicate whether the applicant has responded to all or only some of the concerns raised in the previous Summary Statement and whether the responses are appropriate. Please comment on whether the application has been improved as a result of the revisions. Specific comments regarding the impact of revisions should be included, as appropriate, in the sections above for the individual review criteria.

Sharing Research Data: Comment on whether the Data Sharing Plan or the rationale for not sharing data is reasonable.

Vertebrate Animals: Describe 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) appropriate of methods of euthanasia. At the time of review, special attention will be given to applications that propose research using dogs, cats, and non-human primates.

Other Issues: Please identify any: foreign/international studies, or studies involving the use of human fetal tissue or anything that derives from it; Human Embryonic Stem Cell (HESC) use; and the use of Select Agents. Additionally, identify any potential overlap issues with other funded studies.

3. Disapproved Applications

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

- Applications that are disapproved are not given a numerical score and may not be resubmitted.
- Studies disapproved for ethical considerations may not be carried out in VA space, with VA resources, even if the project is funded by another agency.

4. Appeals

The basis for an appeal and the procedure for submitting an appeal are detailed in the guidance document located at:
http://www.research.va.gov/services/shared_docs/merit_review_guidance_docs/appeal-process.doc

Section VI. Award Administration Information

1. Award Notices

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

2. Administrative and National Policy Requirements

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

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

Deliberate falsification or misrepresentation of research data will result in withdrawal of an application, possible suspension or termination of an Award, and potentially, suspension of the investigator's eligibility to submit applications to CSR&D.

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

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

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

Section VII. Agency Contacts

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

1. Scientific/Research Contacts:

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

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

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

Applicants may contact the appropriate Scientific Review Officer (SRO) directly with questions specifically related to issues raised in the summary statement. SRO contact information for individual SRGs may be found at: BL and CSR&D Contact Information)

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

2. Financial Management Contact:

Sara Clark at Sara.Clark@va.gov