

Part I - Overview Information

Department of Veterans Affairs

Funding Opportunity Announcement/Request for Applications (FOA/RFA) Number

HX-19-001

Title

HSR&D Merit Review Award (Parent IO1)

Participating Service

Health Services Research and Development (HSR&D) Service
Veterans Health Administration, Office of Research and Development (VA-ORD)

Announcement Type

New

Catalog of Federal Domestic Assistance Number

64.054

Competition Identification Number

HX-19-001

Summary of Important Items:

Important items are highlighted in **yellow** below and throughout the FOA/RFA.

- The previous FOA/RFAs for LHI Provider Behavior and LHI Data and Measurement Science have been consolidated under this FOA/RFA and added as Current Areas of Emphases under Research Priorities.
- HSR&D priorities have been reorganized to reflect VHA and ORD cross-service priorities.
- All involved personnel and collaborators are REQUIRED to be listed in the application.
- Review of research overlap is REQUIRED as a part of the Research Plan (under Innovation).
- The Project Summary/Abstract is REQUIRED in the format as described.
- An Implementation and Dissemination Plan is REQUIRED as part of the Research Plan.
- Instructions on describing Veteran engagement and common data elements are provided.
- Updated IPA policies are provided.
- Budget cap has increased from previous limit of \$1.1 million to \$1.2 million across project duration.

Important Note:

See [fatal errors](#) section for the list of errors that will result in an administratively withdrawn application.

NOTICE: Applications submitted in response to this FOA/RFA must be submitted using the VA SF424 Research and Related (R&R) forms, as described in the SF424 Application Guide for VA-ORD ([VA-SF424 AG](#)).

This FOA/RFA must be used in conjunction with the SF424 Application Guide for VA-ORD available on the VA-ORD Intranet site at <http://vaww.research.va.gov/funding/electronic-submission.cfm>. The instructions in this FOA/RFA may differ from, and supersede, the general instructions contained in the [VA-SF424 AG](#).

Key Dates*

RFA Release/Posted Date: April 15th (Summer) or October 15th (Winter)

Intent to Submit Receipt Date(s): April 15th to May 1st (Summer) or October 15th to November 1st (Winter)

Application Deadlines, Submission, Peer Review, and Start Dates: See [Table 4](#).

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

Note: Dates are subject to change.

Table of Contents

[Part I Overview Information](#)

[Part II Full Text of Announcement](#)

[Section I. Funding Opportunity Description](#)

1. Executive Summary
2. Research Priorities

[Section II. Award Information](#)

1. Mechanism of Support
2. Application Types Allowed
3. Multiple Awards and Submissions
4. Funds Available
5. Location of Research Space
6. Duplicate Submissions

[Section III. Eligibility Information](#)

1. Eligible Institutions
2. Eligible Individuals

[Section IV. Application and Submission Information](#)

1. Intent to Submit
2. Request Application Information
3. Content and Form of Application Submission
4. Submission Timelines and Processing Information
 - A. Deadline, Review, and Award Dates
 - B. Application Processing
5. Intergovernmental Review
6. Funding Restrictions
7. Other Submission Requirements

[Section V. Application Review Information](#)

1. Criteria
2. Review and Selection Process
 - A. Additional Review Considerations
 - B. Sharing Research Data
 - C. Sharing Research Resources
 - D. Disapproved Proposals
 - E. Appeals

[Section VI. Award Administration Information](#)

1. Award Notices
2. Administrative and National Policy Requirements

[Section VII. Agency Contacts](#)

1. Scientific/Research Contacts

Part II - Full Text of Announcement

Section I. Funding Opportunity Description

1. Executive Summary

This Funding Opportunity Announcement (FOA)/Request for Applications (RFA) will use the non-U.S. Department of Health & Human Services (HHS) Research Project (IO1) award mechanism.

Purpose. The VA Office of Research and Development (ORD) Health Services Research and Development (HSR&D) program is seeking applications of innovative health services research to inform improvements in quality and outcomes of care for Veterans. The Merit Review Award Program is an intramural funding mechanism to support investigator-initiated research conducted by eligible VA-ORD investigators at VA medical centers or VA-approved sites. Merit Review Awards are HSR&D's principal mechanism for funding health services research that examines the structure, implementation, processes, and outcomes of Veteran care. HSR&D funds empirical studies focused on improving quality and outcomes of health care for Veterans.

Background. The U.S. health care system is changing, and health services researchers must respond to the changing needs of VA, one of the largest single providers of health care in the U.S., as well as the changing needs of Veterans (e.g., [Atkins et al 2018](#)). Current trends that are altering health care in general and VA care in particular include the 1) rapid growth of new technologies (e.g., virtual care, mobile health) enabling care delivery outside the clinic walls, 2) increased desire from patients and families to be involved in health care decisions, especially with an aging population, 3) increased attention to the social determinants of health, 4) greater demand from health care leaders to show how clinical research leads to more rapid quality improvement, and 5) changing laws and policies regulating health care, and the challenge of making these policies work at the provider and clinic levels.

VA as a High-reliability Learning Health Care System. As in other U.S. health care systems and as articulated in recent reports on VHA health care including recent U.S. [Government Accountability Office](#) reports, VA is evolving towards achieving the principles of a Learning Health Care System, in which the National Academy of Medicine has defined as the process by which “clinical informatics, incentives, and culture are aligned to promote continuous improvement and innovation, with best practices seamlessly embedded in the delivery process and new knowledge captured as an integral by-product of the delivery experience.” In concert with the Learning Health Care System, VA is also focused on becoming a High-reliability Health Care System, particularly in response to the recent [Government Accountability Office](#) report highlighting the need for VA to deliver health care to Veterans optimally and consistently across different settings. High-reliability Health Care Systems empower frontline providers to lead performance improvement, where health care leaders encourage a culture focused on operations through preoccupation with failure, reluctance to simplify, deference to expertise, and commitment to resilience (Weick & Sutcliffe, 2015).

HSR&D's mission is to advance knowledge and promote innovations in quality, effectiveness, efficiency, cost and accessibility of health services to improve the health and care of Veterans and the nation. HSR&D funds studies that examine the organization, financing, management, and social factors of health care and their effects on health care delivery, quality, cost, access, and outcomes of importance to the health of Veterans. The HSR&D purview includes studies about health care services and health care delivery models that are available or feasible in regular clinical settings. The “laboratory” for health services research studies is the real world of clinical practice, where variations among patients, physicians, and other factors that affect health care cannot be fully controlled (and may, themselves, be the focus of the research). Input from end-users of health care especially from Veterans, their caregivers, and frontline providers/clinical managers, in addition to health care leaders, is also a crucial component of health services research to enhance Veteran and provider engagement as well as the substantial real-world impact of research findings. In general, studies involving treatments that are still regarded as experimental are not in the domain of health services research.

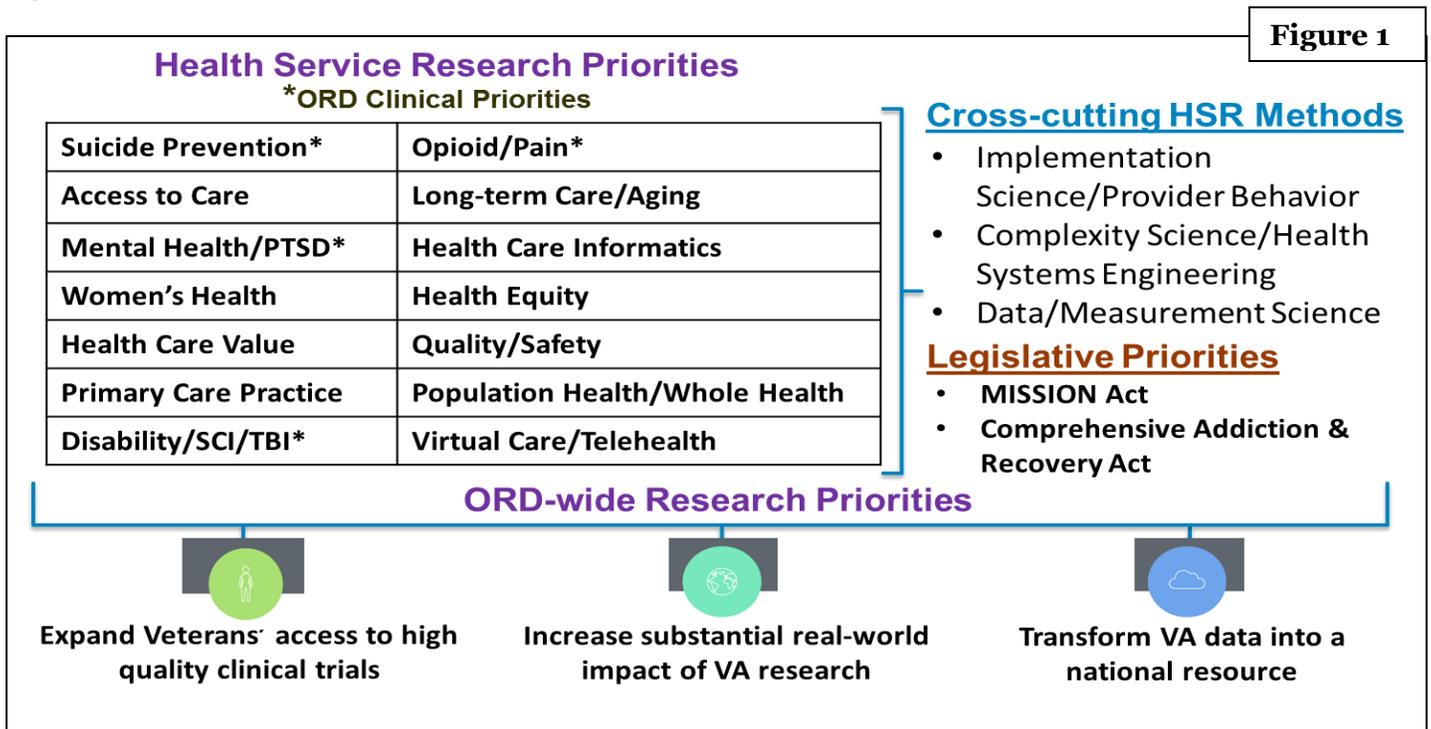
2. Research Priorities

The Merit Review Award Program is an intramural funding mechanism to support investigator-initiated health services research. Proposals demonstrating novel concepts and applying innovative methods that have a strong potential to impact VA health services, as well as proposals that involve inclusion of Veterans and other key stakeholders in the development and execution of the proposal are highly encouraged.

Before applying, applicants should review existing HSR&D studies (available at: <https://www.hsr.d.research.va.gov/research/default.cfm>) to ensure their proposal will complement, but not duplicate, previous efforts.

To ensure that the needs of Veterans and VA are met, HSR&D has identified priorities that should be considered in developing research proposals. For details on updated HSR&D research priorities, please visit <https://www.hsr.d.research.va.gov/funding/PriorityDomains2019.pdf>

Priority areas for HSR&D fall into three broad categories as shown in Figure 1: A) priority areas identified by VHA/ORD based on needs of **Veteran and their common conditions**, B) health services priorities related to **current policy/practice or key legislation** (e.g., *VA Maintaining Systems & Strengthening Integrated Outside Networks (MISSION) Act*, and C) priorities for advancing **health services research methods** in areas that cut across conditions or care settings, notably implementation science (including provider behavior), complexity science/health systems engineering, and data and measurement science. Proposals should address at least one of HSR&D’s priority areas, and are encouraged to address more than one where appropriate (for example, a study using new HSR methods to examine a clinical priority area or to evaluate the impact of legislation).



NOTE: Proposals electronically submitted to HSR&D through Grants.gov will be peer-reviewed by the HSR&D’s Scientific Merit Review Board (SMRB) to provide the Director of HSR&D with evaluations of the quality of the research proposed and make recommendations on scientific merit, budgets, and funding durations. The final funding decisions by HSR&D will include consideration of the overall value of the study to the Service’s investment in improving Veteran care.

Section II. Award Information

1. Mechanism of Support

This FOA/RFA will use the Merit Review Award (IO1) mechanism for investigator-initiated VA research.

Before funds are released, all applicable regulatory and research compliance approvals must be obtained locally through the “Just In Time” (JIT) system.

2. Application Types Allowed

Refer to the [VA-SF424 AG](#) for guidance on how to fill out the VA-SF424 Cover Form for each application type.

Note: Resubmitted applications should be marked as “Resubmission” in Box 8 of the SF424 (R&R) Form.

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

Resubmissions: Submission of up to two revised applications (resubmissions) is allowed if the initial submission is not selected for funding.

Renewals: Not Applicable.

3. Multiple Awards and Submissions

Applicants may submit more than one application to HSR&D per review cycle in response to the same FOA/RFA or to multiple FOA/RFAs. HSR&D will not accept or review an application from an applicant who has an overdue Final Report in ART or for ClinicalTrials.gov for the project. Applicants may receive funding for more than one HSR&D project. Please be sure to submit your application to the correct VA-ORD Service. Application packages are not interchangeable between R&D Services, nor between FOA/RFAs within a specific service.

4. Funds Available

Availability of funds is dependent on Congressional appropriation.

Budget of Merit Review Awards: Merit Review project budgets are capped. The budget may not exceed a total of \$1,200,000 for the project. Projects can be for a maximum of four (4) years with a maximum total project budget of \$1.2 million.

Salary increases (cost of living adjustments - maximum of 2% per year) are permitted for all current VA salaried personnel (including the contact PD/PI), and may be budgeted in out years (Year 2; Year 3; Year 4). Cost of living adjustments are not permitted for any other budget category; including Intergovernmental Personnel Act agreements (IPAs). Cost of living adjustments may not be used to exceed the total project budget cap. Salaries are to include actual fringe benefits for all current VA salaried personnel and no more than 30% fringe benefits for all “to be determined” positions.

Duration of Merit Review Awards: Merit Review projects are limited to 4 years. All funding is contingent on available funds and adjustments to budgets may be imposed after an award is initiated.

Exceptions to the Duration and/or Budget Caps: Rare exceptions to the duration and/or total project budget cap may be granted prior to proposal submission for compelling circumstances. Exceptions may be requested in the form of a waiver submitted to vhacoscirev@va.gov. Standard due dates apply; please see [Table 4](#). **Proposals submitted with total project durations that exceed 4 years, OR total project budgets that exceed the \$1.2 million cap will not be accepted for review unless a copy of the total project duration/budget cap waiver approval letter from HSR&D is included in the “Letters of Support” section of the “Other Attachments” (Item 12) in the “Other Project Information” form of the SF424 (R&R) Application.**

Note: In cases where budget waiver requests have been approved for prior submissions to an application, the approval documentation from HSR&D should be included in the Letters of Support section of the current application (re-submission). Prior budget waiver request approvals may be used only if ALL the criteria below are met.

1. The proposal is being submitted in response to the same FOA/RFA.
2. There are no gaps between review cycles (e.g., *initial application was in the winter, resubmission must be in the summer, not the next winter, etc.*) and/or up to 12 months from the time of approval.
3. The scope of the project remains the same.
4. The total budget remains the same.

If **any one** of the criteria above is not met, a new budget waiver request must be submitted for approval.

A detailed justification for the additional time and/or budget amount requested must include:

1. A cover sheet listing the following information in the order specified:
 - (a) Type of waiver requested (Budget and/or Duration).
 - (b) VA medical center name and address.
 - (c) Investigator's name and degree(s).
 - (d) Investigator's title and VA appointment (in 8ths).
 - (e) Title of investigator's research proposal (for ongoing programs).
 - (f) Name, title, and signature of the Associate Chief of Staff for Research and Development.
 - (g) Name, title, and signature of the medical center Director.
2. A narrative (**1-page limit**) describing the following:
 - (a) Provide a budget for the proposed project. Include total costs and specify major elements of the personnel, equipment, consultants, supplies, and all other expenses categories.
 - (b) Justify each category.
 - (c) For the equipment category, the justification needs to include a discussion of why the equipment is needed and why existing equipment cannot be used. Describe the equipment used or to be used in the generation of pilot data for the research proposal.
 - (d) Explain why the project requires special funding consideration based on the topic, the nature of the study, unusual resource requirements, or other factors.
 - (e) Describe how the proposed study could be completed or modified if the request to exceed the budget limit is denied.

If a duration and/or budget cap waiver is granted, a copy of the waiver approval letter from HSR&D must be included in the "Letters of Support" section of the "Other Attachments" portion of the "Other Project Information" section of the SF424 (R&R) Application. **Proposals submitted with a total project duration that exceeds 4 years OR a total project budget that exceeds the \$1.2 million budget cap will not be accepted for review without a waiver.** A waiver does not guarantee that a project will be funded at the level requested.

5. 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. If any portion of the proposed work will be carried out in laboratory space assigned to (i.e., controlled by) a PD/PI or VA co-investigator/collaborator at any other location(s), a waiver to perform the research offsite must be obtained for that investigator **prior to submitting the proposal** (refer to [VHA Handbook 1200.16](#)). The use of an off-site core facility or an offsite non-VA collaborator's laboratory does **not** require an off-site waiver, except when the VA investigator is the director of the core facility.

Guidelines for submitting an application for an off-site waiver are described in the [VHA Handbook 1200.16](#), VA Off-site Research Handbook. Standard due dates apply; please see [Table 4](#). Guidelines for submitting an application for an off-site waiver are described in the [VHA Handbook 1200.16](#), VA Off-site Research Handbook. A copy of the approval letter for the off-site waiver must be included in the "Letters of Support"

section of the “Other Attachments” (Item 12) in the “Other Project Information” form of the SF424 (R&R) Application.

Although the use of VA leased space does not require an off-site waiver, VA-ORD must approve a plan for local VA oversight of the research activities performed in the leased space (refer to [VHA Handbook 1200.16](#)).

6. Duplicate Submissions

An application that is submitted to this FOA/RFA may not be submitted concurrently to any other Funding organization or other component of VA-ORD (i.e., Biomedical Laboratory Research and Development (BLR&D) Service, Clinical Science Research and Development (CSR&D) Service, or Rehabilitation Research and Development (RR&D) Service).

Section III. Eligibility Information

1. Eligible Institutions

All VA medical centers with an active research program are eligible. Each VA medical center must be registered as an applicant organization in Grants.gov and eRA Commons before any proposals can be submitted.

2. Eligible Individuals

The Merit Review Award Program is an intramural program to fund research conducted by VA-salaried investigators at VA medical centers or VA-approved sites. A PD/PI shall hold an MD, PhD, or equivalent doctoral degree in a medical, biological, or behavioral science field.

To be eligible to submit a Merit Review proposal to HSR&D, the PD/PI must have at least a 5/8ths time VA appointment **at the time the Merit Review 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 ORD, even if the terms of the contract permits or includes research activities.

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.

VA-ORD will not accept or review an application from an applicant who has an overdue report (e.g., annual progress reports or Research Performance Progress Reports/RPPRs), final reports, clinical trials registration, and results reporting (i.e., ART/clinicaltrials.gov) for existing and previous awards.

Multiple PDs/PIs. The decision of whether to submit an application with a single PD/PI or multiple PD/PIs is the responsibility of the “contact” PD/PI identified in Box 14 of the SF424 (R&R) Cover Form and applicant VA medical center, and should be determined by the goals of the project. The “contact PD/PI” must be affiliated in the eRA Commons with the VA medical center, be the primary lead on the proposed work, and be the contact for all communications about the proposed work. 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 justification for inclusion of more than one PD/PI must be included in a Multiple PD/PI Leadership Plan and may be considered by reviewers as part of their evaluation of the application. Co-PD/PI role is no longer recognized by eRA or VA-ORD. Identification of multiple PDs/PIs may not be used to exceed budget caps. See also the HSR&D Multiple Principal Investigator (MPI) Eligibility Policy at <http://www.hsr.d.research.va.gov/funding/multi-pi-policy.pdf>.

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 1.5 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. Intent to Submit

HSR&D requires Intent to Submit (ITS) notification through HSR&D's ART website.

The ITS is required for this funding opportunity. The ITS is a process separate from the requirements for Grants.gov submission. The ITS is a key step in the proposal submission process and assists investigators by ensuring that their research is appropriate to the goals of HSR&D and VA. ITS is an electronic submission which can be accessed at <http://art.puget-sound.med.va.gov/IntentSubmitIntro.cfm>. **Applications submitted to Grants.gov without a completed ITS will not be accepted or reviewed.**

The deadlines for ITS may be found in [Table 4](#).

NOTE: The ITS title and the full proposal title must match. Once an ITS has been approved by the ACOS, titles may NOT be changed without a formal request from the ACOS to the Director of HSR&D. Title change requests must be submitted to vhacoscirev@va.gov by the deadline found in [Table 4](#).

2. Request Application Information

Use either **Grants.gov Workspace Process** or **eRA Commons Application Submission System & Interface for Submission Tracking (ASSIST)** to prepare and submit an application in response to this FOA/RFA.

Training resources for the **Grants.gov Workspace Process** are available at <https://www.grants.gov/web/grants/applicants/workspace-overview/workspace-process.html>. Additionally, there are several videos available at <https://www.youtube.com/user/GrantsGovUS>.

eRA Commons ASSIST training resources (a recorded presentation, user guides and some other helpful resources) are available at https://era.nih.gov/era_training/assist.cfm (note that VA applications are Single-Project). There is a video targeted to Small Business Innovation Research (SBIR) initiatives, but this information also works for VA-ORD applications: https://grants.nih.gov/news/virtual-learning/upcoming_webinars.htm.

3. Content and Form of Application Submission

Prepare all applications responding to this FOA/RFA using the SF424 (R&R) application forms in accordance with the VA Application Guide SF424 found at <http://vaww.research.va.gov/funding/electronic-submission.cfm>. 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 FOA/RFA. **The instructions in [Table 2](#) may differ from – in which case they supersede – the general instructions contained in the VA-SF424 Application Guide.** Unless otherwise noted, all instructions contained in the VA-SF424 Application Guide must be followed. Failure to follow instructions may cause delays in submission or withdrawal of proposals from review.

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 Bibliography & References Cited attachments. Any submission with URLs placed anywhere else except the Biographical Sketch, and Bibliography & References Cited attachments 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. **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.

HSR&D will only accept videos for demonstration of devices, products under development or interventions aimed at providers or patients that cannot be sufficiently depicted in text or screenshots. **The video cannot be included in the application in any attachment;** this will cause the application to be withdrawn from review. PIs must contact the SPM during the application process for approval to submit supplemental video material. If the SPM approves, the SPM approval email must be included as a PDF attachment to the application and 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 SPM via email at least 30 calendar days prior to the review meeting. **A missing SPM approval email attachment will cause the application to be subject to withdrawal from review.**

Information Regarding Attachments for Item 12: 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.

Table 1. Summary of Required Forms and Attachments for this FOA/RFA

Forms, Attachments, and Templates with Size Limits as Applicable	Required When?	VA-SF424 Instructions	
SF424 (R&R) Form	Always	Section 3.2	
Project/Performance Site Locations Form	Always	Section 3.3	
SF424 (R&R) Other Project Information Form:			
Project Summary/Abstract (40 lines of text)*	Always	Section 3.4	
Project Narrative (10 lines of text)	Always		
Bibliography & References Cited (4-page limit)	Always		
Facilities & Other Resources	Always		
Equipment	Always		
Other Attachments (Item 12):			
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	Never Submit		
4. Human Subjects*	If Applicable		
5. Vertebrate Animals	Never Submit		
6. Multiple PD/PI Leadership Plan*	If Applicable		
7. Consortium/Contractual Arrangements*	If Applicable		
8. Director's Letter	Always		
8a. R&D Committee Letter	Never Submit		
8b. Letters of Support*	Always		
9. Data Management and Access Plan	Always		
Appendices: *			
10. List of Abbreviations	Always		
SF424 (R&R) Senior/Key Person Profile(s)*	Always	Section 3.5	
SF424 (R&R) Budget*	Always	Section 3.7	

* These sections have special instructions for this FOA/RFA that are in addition to or supersede instructions in the VA SF424. See Tables 2 and 3 below.

The instructions below consist of HSR&D-specific instructions for completing the SF424 Form and Other Attachments in Section 3.4 of the SF424. All SF424 instructions must be followed, but you will find HSR&D-specific clarifications and instructions below.

Table 2: HSR&D-Specific Instructions for SF424 (R&R) Forms and Attachments

SF424 (R&R) Other Project Information Form	Project Summary/Abstract
<p>SEE SF424, SECTION 3.4, ITEM 7, FOR ADDITIONAL INSTRUCTIONS.</p> <p>The Project Summary/Abstract is REQUIRED in the following format with headers are described:</p> <ul style="list-style-type: none"> • Background: Briefly present the ideas and reasoning behind the work including a scientific rationale. • Significance/Impact: State the proposed relevance to Veterans’ health, disease burden, gaps in care, and VHA/ORD/HSR&D priorities. • Innovation: Summarize the innovative aspects of the project. • Specific Aims: Provide a numbered list of the specific aims of the project including objectives and/or hypotheses as appropriate. • Methodology: Describe the study design and target population. • Next Steps/Implementation: What will be the next steps to move research into practice to improve care or health outcomes for Veterans or to improve VHA policy or organization (for example, we will use findings of this research to work with partners to improve performance measures in SAIL; test ability to implement intervention in wider array of facilities, etc.). 	
Other Attachments	1. Introduction to Revised Application (for Resubmission only)
<p>SEE SF424, SECTION 3.4, ITEM 12, FOR ADDITIONAL INSTRUCTIONS.</p> <p>PAGE LIMIT: 3</p> <p>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>	
Other Attachments	2a. Research Plan
<p>SEE SF424, SECTION 3.4, ITEM 12, FOR ADDITIONAL INSTRUCTIONS.</p> <p>PAGE LIMIT: 14</p>	

Acceptance by HSR&D to review a revised application automatically supersedes previous submissions and the revised application becomes the document of record.

Do not repeat the Specific Aims in the Research Plan.

In general, the Research Plan should include the following sections:

Background

Briefly sketch the background leading to the present application, critically evaluate existing knowledge, and specifically identify the gaps that the project is intended to fill. Provide evidence addressing:

1. The scientific rationale and theoretical framework for the proposed research. Discuss relevant research, completed or underway, inside and outside VA, the state of current knowledge, and existing areas of uncertainty
2. The context in which the study will be conducted and results applied
3. How or why this study will succeed in answering questions that have eluded other researchers (e.g., better design, larger sample, longer follow-up, etc.)

Significance

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.

1. Consider how common, serious, or urgent the problem is in VA that this research addresses.
2. What are the potential contributions of the proposed research? For example, how will the proposed research extend knowledge and/or contribute to improved quality, effectiveness, or efficiency of VA health care or the health of eligible Veterans? How will it enhance health care management or clinical decision-making? How does this research represent a unique opportunity for VA? Will it inform ongoing clinical initiatives? How will it contribute to development of generalizable knowledge and/or advancement of innovative methodologies in the field?
3. Describe the audience for the results of the research and how might they use the information or product(s)?
4. Articulate clearly how the proposed research is responsive HSR&D research priorities, especially those that address legislative and methods priorities (see above)

Innovation, Including Potential for Overlap

Describe the ability of the project to yield results that can be expected to change practice, influence scientific methods, disrupt the previous order of things, or introduce novel ideas or methods. Specifically, applications should note the potential value, innovation, and impact of their proposed work towards the field of health services research:

1. Describe how the study involves broader care improvements and/or new methods or treatments for a broader Veteran population, rather than “one-off” studies of previously established treatments in small select subpopulations.
2. Describe how the project breaks new scientific ground, deploys novel designs or methods, or contributes to a new way of thinking about healthcare delivery or a new paradigm in science
3. Describe how the proposed work involves new directions or insight into feasibility or sustainability of treatments or clinical practices
4. **REQUIRED:** Provide an explanation of how this project will fill the gap in the current research funded by HSR&D, VA, and other funding agencies. List similar studies in an Appendix, based on a keyword search on HSR&D and QUERI studies (<https://www.hsr.d.research.va.gov/research/default.cfm>; https://www.queri.research.va.gov/national_partnered_evaluations/default.cfm), the Clinical Trials website (<https://clinicaltrials.gov/>), the US National Library of Medicine Health Services Research Projects in Progress website (https://www.cfm.nlm.nih.gov/hsr_project/home_proj.cfm), and the US National Institutes of Health Research Portfolio On-line Reporting Tool (RePORTER) (<https://projectreporter.nih.gov/reporter.cfm>). Include the number of similar studies and how this

project will uniquely contribute to our knowledge and impact Veterans health. For clinical trials, comment on any recent meta-analyses of the intervention being studied.

Patient Experience and Veteran Engagement

VA strives to be a patient-centered healthcare system and includes patient experience as a critical measure of how well the healthcare system is functioning. Engaging Veterans as interventions are developed can provide important insights into what outcomes matter most, what interventions might be acceptable, and what designs might be more acceptable to Veteran patients.

Describe how the outcomes of this study are important to improving Veteran's health care, and plans for Veteran and /or caregiver engagement as well as plans for incorporating Veteran's perspectives. Specifically, HSR&D expects the majority of research regarding Veteran healthcare would benefit from Veteran's and/or their caregivers' input. We encourage researchers to describe the process they used to gain Veteran's and/or their caregivers' input into the proposal and their plan for continuing Veteran engagement in the proposed project once the proposal is funded and executed. Applicants should also note whether they have incorporated Veteran's perspectives in the study design or in plans for dissemination of results.

Veteran Engagement may include discussions with a local Veteran engagement board, the inclusion of a Veteran on the study team, the development of a project-specific Veteran consultation group, information from focus groups or prior qualitative research, or other approaches. Details regarding how Veterans were engaged and the impact their advice had on the study plan is encouraged. The applicant should also include qualitative and/or quantitative measures of patient experience as outcomes of new interventions, if appropriate.

For projects where investigators have determined that Veteran engagement is not applicable, a brief rationale for that decision is also encouraged. For more information see the HSR&D Toolkit on Veteran Engagement visit: https://www.hsrd.research.va.gov/for_researchers/serve/.

Research Design and Methods

Describe the research plan completely and in detail, including the basic study design, sampling plan, control or comparison groups, methods for data collections and analysis, and specific techniques and measures. Specify the kinds or sources of data to be used, data accessibility, how hypotheses will be tested, aggregate and subgroup analyses, and provisions for ensuring data quality and adherence to the study protocol.

Address:

1. How is the study design suited to the specific research question(s) and population? What are the advantages and disadvantages of this approach? Describe new methodologies to be used and why they are preferred over existing methods. Discuss potential problems and limitations to the proposed methods and/or procedures and possible alternative approaches to achieve specific aims.
2. If the study uses "usual care" as either the baseline or as a comparison group, usual care must be defined.
3. Where will the study take place? Why is this setting or geographic location appropriate? Will the results be applicable to other places or populations?
4. What are the characteristics of the study population? How will the sample be selected and what steps will be taken to secure and retain the needed number of subjects (and controls, if applicable)? What steps will be taken to ensure adequate representation of women and minorities? What is the estimated sample size and how was it derived? What assumptions were made regarding the magnitude of the expected treatment effect? At what level of power can inferences be drawn?
5. Describe key outcomes to be ascertained, including common data elements*. Provide information on common outcomes measured that are based on VA national quality standards (e.g., [Strategic Analytics for Improvement and Learning-SAIL](#)) and if applicable, the [National Research Action Plan](#) measures for mental health/substance use disorders (Appropriate measures are found at <https://www.phenxtoolkit.org/>)
6. How will the major variables be measured and how will they be linked in the analysis? Comment on the reliability, validity, and appropriateness of the proposed measures for the study. NOTE: If new or

unpublished measures are to be used, the data collection instruments must be submitted as part of the appendix.

7. What is the data collection strategy and timeline? What are the potential problems in collecting data and controlling data quality? How will these problems (e.g., missing data, respondent drop-out, interviewer bias) be addressed?
8. What is the strategy for data analysis? Outline the planned analyses, indicating which variables will be used in which analyses and the order in which analyses will be done (do not merely name proposed statistical tests). What are the strengths and limitations of this analytic strategy? Include power calculations as appropriate. Power calculations should be described in terms of clinical significance, if appropriate, as well as statistical significance.
9. If a clinical trial or recruitment is used, what challenges are anticipated and how will they be overcome? What strategies will be used to ensure participation of selected sites and subjects?

*Common Data Elements Requirement: For research focused on the areas of mental health, substance use, suicide prevention, and TBI, the [National Research Action Plan](#) requires that studies funded by the VA, NIH, and the DoD use the Common Data Elements to improve comparability of data across studies. Appropriate measures are found at <https://www.phenxtoolkit.org/>. In addition, where appropriate, applications should incorporate measures based on the VA Integrated Service Network ([VISN](#))/[Facility Performance Plan goals](#), notably the [Strategic Analytics for Improvement and Learning \(SAIL\)](#) Metrics.

Implementation and Dissemination Plan (REQUIRED)

The goal of HSR&D research is to improve the care delivered to Veterans. Towards that goal, all applicants should plan their research with the end in mind, that is, how their research findings will be translated into changes in policy or practice, and to determine proactively the steps required to accomplish that. For projects whose aim is developing or testing a clinical intervention or model of care, an implementation and dissemination plan must be included. For projects that are more methodological or exploratory in nature, application should discuss how objectives are aligned with the goals of specific VA stakeholders and what next steps are contemplated to apply research findings to achieve changes in care or policy.

A conceptual plan must be included that indicates how and when research findings will be disseminated and, if appropriate, implemented, among provider and Veteran groups. Discuss how the study is aligned with leadership/stakeholder goals, who the key stakeholders are for further implementation, as well as conditions or barriers to implementing the eventual findings or products, and identify any plans and promising mechanisms (beyond professional publications) to facilitate dissemination and implementation.

1. **For ALL studies:** Describe how the study is aligned with VA national priority goals, [VISN/Facility Performance Plan goals](#), performance metrics (e.g., SAIL), or other program office priorities. Describe key VA “champions” to support uptake of study results within the VA system as well as other systemic or provider barriers and facilitators of change. Describe which operations partner (e.g., VISN or VHA national Program Office) might potentially “own” the study results, and for intervention studies, the implementation of the intervention if proven effective. If applicable, provide a letter of support describing the operations partner’s role in further implementation and dissemination of study findings.
2. **For intervention studies only:** Describe how you intend to collect information on the implementation of the treatment or intervention during the trial, including qualitative and/or quantitative data on potential barriers and facilitators at the patient, provider, and health care facility/organization levels. Specify the implementation framework used to help guide the ascertainment of this information (see [QUERI Implementation Guide](#) for more information).
3. **For ALL studies:** Future Directions: Describe plans for how you would approach the further dissemination or implementation of the effective treatment beyond the study sites, describing how you intend to take into account findings from the study. Also describe engagement of key stakeholders (e.g., leaders, providers, Veterans/family members) to inform more effective dissemination and implementation post-study. **For intervention studies only:** Describe how existing providers will be able to implement the intervention post-trial, assuming treatment is shown to be effective.

Also include as part of the protocol:

1. Timelines. Be sure to include dissemination and implementation timelines into the Gantt chart for the project.
2. Intended audiences for the research, including frontline providers, clinical managers, policymakers, and Veterans and their caregivers, and identify what channels will be used to reach these audiences. A clearly delineated strategy for dissemination and, if appropriate, implementation for each intended audience must be included.
3. Implementation impact metrics: describe how you intend to ascertain impact of dissemination or implementation. Possible measures of impact could include:
 - a. Return on research investment (e.g., intervention or research products/services developed, software/educational tools, and if applicable, invention disclosures, amount of royalty income)
 - b. Whether research led to or shaped VA national policy or legislative changes
 - c. Whether ORD-funded projects led to improvements in key outcomes including access to patient-centered care, quality of care, provider and Veteran satisfaction, and clinical outcomes (e.g., SAIL)
4. An estimated budget. Dissemination and/or implementation funds will not be disbursed until findings for the intended audience are validated. Successful projects may be eligible for supplemental funds for expanded dissemination or implementation.

Sample Recruitment

If the project is a clinical trial requiring recruitment of individual subjects, describe the data used to estimate your recruitment goals, including number of eligible subjects, estimates of participation rates, and estimates of dropout rates. Please indicate if these estimates are based on pilot data or on data from comparable studies and indicate any differences (for example, site, patient population) that may affect whether they are applicable to your study. Please indicate any barriers to recruitment and retention, including presence of any concurrent studies recruiting similar subjects. Describe plans for monitoring recruitment, strategies to deal with lagging recruitment and criteria for modifying recruitment plans (for example, adding a new site).

Project Management Plan

Include a description of the following:

1. The project management plan and timeline. Present the project timeline in Gantt Chart format. Measurable milestones for each quarter are required.
2. The role and tasks of each member of the research team and how their work will be coordinated. If 3 or more co-Is are included on the project, include a leadership and communication plan.
3. Any proposed collaboration with institutions or investigators outside the PI's facility and how the work will be coordinated. Include a description of the role of consultants, contractors, and other non-VA employees.
4. A plan for including Veterans as a part of the team, consultants, and/or subject matter experts, if applicable.

Note: Investigators are encouraged to affiliate with an HSR&D or QUERI Center if one is present at their site to enhance opportunities for collaboration.

Other Attachments	4. Human Subjects
--------------------------	--------------------------

SEE SF424, SECTION 3.4, ITEM 12, FOR ADDITIONAL INSTRUCTIONS.

Since HSR&D proposals usually require IRB approval or exemption, "Yes" should be checked and this attachment included.

This section covers the information regarding the Protection of Human Subjects. In this attachment, the following four headings should be used and fully described. Refer to Parts II and III of the VA Application Guide SF424 (R&R).

Data and Safety Monitoring Plan. DSMB oversight is required for multisite (2 or more sites) intervention trials which include human participants. Describe the plans for monitoring the safety of participants and the accuracy and integrity of the data. Describe steps to ensure adequate subject recruitment and enrollment, including if necessary, replacement of study sites.

Other Attachments	6. Multiple PD/PI Leadership Plan
<p>SEE SF424, SECTION 3.4, ITEM 12, FOR ADDITIONAL INSTRUCTIONS.</p>	
<p>A leadership plan is required if more than one individual is assigned the role of PD/PI in the Senior/Key Person Profile(s).</p>	
<p>Multiple PDs/PIs on a project share the authority and responsibility for leading and directing the project, intellectually and logistically. Each PD/PI is responsible and accountable to VA for the proper scientific, fiscal, and ethical conduct of the project, including the submission of all required reports.</p>	
<p>The rationale for choosing a multiple PD/PI approach must be clearly described in the plan. The governance and organizational structure of the leadership team and the research project must be described, including the communication plan, process for making decisions on scientific direction, and procedures for resolving conflicts. The roles, knowledge, skills, and experience, and administrative, technical, and scientific responsibilities for the project or program, must be clearly described for each PD/PI, in addition to the distribution of resources to specific components of the project or to individual PDs/PIs. These components will be factored into the assessment of the overall scientific merit of the application. See http://www.hsrcd.research.va.gov/funding/multi-pi-policy.pdf.</p>	
Other Attachments	7. Consortium/Contractual Agreements
<p>SEE SF424, SECTION 3.4, ITEM 12, FOR ADDITIONAL INSTRUCTIONS.</p>	
<p>This attachment should not be used to describe or to justify the required sub-award budgets for multi-site projects.</p>	
Other Attachments	8b. Letters of Support
<p>SEE SF424, SECTION 3.4, ITEM 12, FOR ADDITIONAL INSTRUCTIONS.</p>	
<p>Please DO NOT send separate original hard copies or email PDF copies of Letters of Support to the Director of HS&RD. For these letters to be considered as a part of the proposal they must be included as a scanned part of the Letters of Support attachment.</p>	
<p>For Resubmission applications, a Letter of Support may be resubmitted if the date of the original letter is within the last year, i.e., it can't be more than one year since the letter of support was first submitted.</p>	
<p>All memoranda and budget limit letters should be addressed to the Director, HSR&D, and must include the Corresponding PI's name, project title, VA facility, signature and date.</p>	
<p>For individuals from a site other than that of the PI, letters of endorsement/commitment are also required on the letterhead of their supporting institution.</p>	
<p>Letters of support are NOT required from participating persons within the same center/institution as the submitting PI. However, each participating or affected organizational element, institution, collaborator, and consultant must provide a letter of support, whether or not they are VA employees. The letter must indicate concurrence of the affected person or institution with their specific role or contribution as described in the application, their willingness to fulfill the duties described in the application, and their rate/charge for consulting services, if applicable.</p>	
<p>If a budget waiver is requested and granted, the project budget cap exception approval letter must be included in this section.</p>	
Other Attachments	10., 11., 12... Appendices

SEE SF424, SECTION 3.4, ITEM 12, FOR ADDITIONAL INSTRUCTIONS.

Do not include Informed Consent forms as an appendix, even if already approved by the IRB.

- **Note: Published manuscripts and/or abstracts that have a free, publicly available online journal should not be included in the appendix material.** The full reference should be included in the Bibliography & References Cited section, and/or the Biographical Sketch section, as appropriate.

Other:

- **No videos of any type will be accepted**, whether linked to in a URL or embedded in the PDF.
- All materials must be submitted electronically in PDF format.

**SF424 (R&R)
Senior/Key Person
Profile Form**

Senior/Key Person Profile(s)

SEE SF424, SECTION 3.5, FOR ADDITIONAL INSTRUCTIONS.

A R&R Senior/Key Person Profile is REQUIRED to be completed for ALL involved personnel and collaborators, to include the following:

- **Senior/Key Personnel** (defined as all individuals who contribute in a substantive, measurable way to the scientific development or execution of the project, whether or not salaries are requested)
 - Includes PD/PI(s), co-investigators
- **Other Significant Contributors (OSCs)** (defined as individuals who have committed to contribute to the scientific development or execution of the project, but are not committing any specified measurable effort (in person months) to the project)
 - Includes consultants, mentors, contributors, and advisory panel members
- **Project personnel** (defined as other staff who are listed in the budget justification by name (e.g. people who have the role of Project Coordinator, Data Analyst) either to-be-funded via allocated funds or via IPA)
- **Partners** (defined as individual(s) committed at the partnering program office(s) and if applicable Veterans Service Organizations)
- **Support persons** (defined as individual(s) who write letters of support)

IMPORTANT NOTES:

1. Project personnel, partners, and support persons may be added as Other Professional or Other.
2. **The biosketch and Other Support document are not required for project personnel, partners, support persons, and Susan Zickmund (if listed as Other Professional/CTSP; see item 3 below).** However, you **must** upload an attachment to both the Biosketch and Other Support fields with the words “Not Required,” or you WILL receive a system error message. The biosketch and Other Support document are required for Senior/Key Personnel and Other Significant Contributors (OSCs), per the instructions in the [VA-SF424 AG](#), Section 3.5.
3. If Centralized Transcription Service Program (CTSP) services are proposed, please add Dr. Susan Zickmund as Other Professional, typing in ‘CTSP’ under Other Project Role Category. The biosketch or Other Support document are not required, however, you **must** upload an attachment to both the Biosketch and Other Support fields with the words “Not Required,” or you WILL receive a system error message. If Dr. Susan Zickmund is a collaborator or co-investigator in the research, please follow the general instructions.

The instructions below consist of HSR&D-specific instructions for completing the Summary Budget Worksheet and R&R Budget Form in Part I, Section 3.7 of the SF424. All SF424 instructions must be followed, but you will find HSR&D-specific clarifications and instructions below.

Summary Budget Worksheet

The Summary Budget Worksheet template can be accessed at:

<http://vaww.research.va.gov/funding/docs/SummaryBudgetWorksheetTemplate.xlsx>.

R&R Budget Form

Please see the [VA-SF424 AG](#), Section 3.7 for instructions on filling out the Summary Budget Worksheet and R&R Budget Form.

Table 3: HSR&D-Specific Instructions for Summary Budget Worksheet and R&R Budget Form

Personnel - (SF424, Section 3.7.1, Sections A)	
• Clerical support	Clerical support may not be included as study personnel.
• IPAs	Costs for IPAs must NOT be listed under Section A or B of the R&R Budget Component. See “All Other Expenses” section of this table for HSR&D-specific IPA instructions. IPAs must be officially recognized by VA as authorized.
• Consultant	Services may be obtained by contract or through a letter of agreement. Consultant fees will be set in accordance with VHA Handbook 5007. Limit of \$500 per consultation and \$2,500 per annum. Physicians may not be paid as consultants.
• Note on salary	HSR&D will pay salary only for the actual time the PI or other VA paid study personnel spend on the project. One of the major differences between how BLR&D and HSR&D operates is that BLR&D will pay “up to the entire” VA Salary of a PI on a project, regardless of his/her effort on the project.
Equipment - (SF424, Section 3.7.2, Section C)	
• Computers	Computers (and IT expenditures) should not be listed in the budget section.
Supplies - (SF424, Section 3.7.3)	
• Books, journals, or reprints	Not authorized. However, payment for reasonable page/publication costs for research resulting from HSR&D studies may be included up to \$3,000, which is requested at the time of publication, so it should not be included in the application budget.
All Other Expenses - (SF424, Sections 3.7.2 and 3.7.3)	
• IPAs	<p>IPAs provide for salary and fringe benefit reimbursements; they do not allow for “overhead” costs. IPAs may not be used for physicians or other clinical medical service providers. IPAs may not be used for any individual assigned the PD/PI role.</p> <p>It is essential that core funds go to VA employees since this is an intramural research program. A waiver must be requested and approved for IPAs as below.</p> <ul style="list-style-type: none"> • For studies at sites with an HSR&D COIN: If the total cost for IPAs exceeds 30% of the core budget (excluding estimated costs for donated time). • For studies at sites with no HSR&D COIN: If the total cost for IPAs exceeds 40% of the core budget (excluding estimated costs for donated time) <p>Use the same procedures as required for submitting a budget waiver as found in Section II.4 of this FOA/RFA. The deadline for the IPA waiver is the same as the deadline for the budget waiver.</p>
• Travel	There are four categories of travel:

	<p>1) Travel necessary for the conduct of research. Project related travel expenses must be fully explained and a cogent justification provided. Explain why e-mails, conference calls, or teleconferencing are not sufficient to accomplish the goals of the requested travel.</p> <p>2) Travel to Implement or disseminate findings within VHA.</p> <ul style="list-style-type: none"> • This is not travel to present research findings at professional meetings but is the travel necessary to conduct face-to-face meetings or conferences that will facilitate the adoption of the research into practice. • A dissemination plan with an estimated budget must be included in the proposal, but funds will not be disbursed until study results are available and dissemination/ implementation is warranted. • Requests for release of funds need to be submitted through the ACOS/R&D to the assigned Scientific Program Manager at least 3 months prior to the project end date. • A justification, not to exceed one page, must accompany the request for release of funds. Any changes to the dissemination and/or implementation plan described in the original proposal must be highlighted. <p>3) Travel to present final research results at professional meetings, should not be included in project budgets.</p> <ul style="list-style-type: none"> • HSR&D will consider one request per project to travel to present study findings on a case-by-case basis. Requests for travel funds including an estimate of travel expenses and a justification must be submitted to HSR&D at least two months in advance of the meeting. • The presentation may occur up to March of the next fiscal year and before carryover funds expire, but travel funds must be requested before the project end date. <p>Project travel needs to be requested in the budget justification using the table format displayed in SF424 Application Guide, Section 3.7.2, Section D. Travel.</p> <p>4) Professional Development travel – not allowed in project budgets.</p> <ul style="list-style-type: none"> • Not authorized for non-VA employees • HSR&D will consider requests from funded PD/PIs, not affiliated with a Center of Innovation (COIN), to allow participation of the PD/PIs or their project team designee in scientific meeting/professional development activities. This consideration will occur outside of the scientific merit review process. <ul style="list-style-type: none"> ○ Requests for Professional development funds including an estimate of travel expenses and a justification must be submitted to HSR&D at least two months in advance of the meeting. ○ The maximum in professional development travel funds that will be distributed to a PD/PI is \$1,200 per year, irrespective of the number of projects awarded to the PD/PI. • PD/PIs with only Pilot Project funding are not eligible for professional development travel funds. • PD/PIs or their project team designee affiliated with COINs should not submit their request to Central Office, and instead submit their request locally for use of funds distributed directly to the COIN for professional development travel. <ul style="list-style-type: none"> ○ The amount of travel funds allocated for professional development travel is at the discretion of the COIN Director.
<ul style="list-style-type: none"> • Transcription Services 	<p>HSR&D has funded a Centralized Transcription Service Program (CTSP) with the capacity to fulfill existing and emerging transcription needs for HSR&D research.</p>

	<p>Use of these services is not mandatory. However, if the proposal includes transcription services, HSR&D requires the research team to contact the CTSP (VHASLCTSP@va.gov) or Dr. Susan Zickmund, Ph.D. (Susan.Zickmund@va.gov) to request a formal proposal, including cost, for the potential use of CTSP's services in the study. The CTSP may be able to provide a more cost effective, secure, and efficient mechanism that is designed to meet your research transcription needs without the need for contracting. Regardless of whether you utilize CTSP's services, if the proposal includes transcription services, you must include in your budget justification a brief summary of the reason(s) for not utilizing the CTSP.</p> <p>If you should decide to utilize CTSP services:</p> <ul style="list-style-type: none"> • You do NOT need to attach a letter of support, biosketch, or an Other Support document for Dr. Zickmund (see Table 2). • Include the CTSP transcription services costing in the R&R budget form. <ul style="list-style-type: none"> ○ If Salt Lake City (SLC) is not already a research site, SLC should be added as an additional site to the budget with Susan Zickmund listed as the site investigator who is responsible for the funds sent to and the work performed at SLC. • For Dr. Zickmund's percent effort, please list "N/A" and list her salary as "contributed." <ul style="list-style-type: none"> ○ If SLC is already a research site, Susan Zickmund need not be listed as site investigator if one already exists. ○ In addition, list "CTSP Transcription Services (SLC)" along with associated funds under "Other direct costs" on the summary budget worksheet. • Include a brief description of the CTSP quote in the written budget justification and if not using CTSP include a brief summary of the reason for not utilizing CTSP.
--	---

4. Submission Timelines and Processing Information

4.A. Deadline, Review, and Award Dates

Deadlines. Avoid delays and misunderstandings by reading and following the instructions carefully. [Table 4](#) below contains deadlines for Merit Review Award Program applications. Depending on the investigator's particular circumstance, requests for off-site waiver, eligibility determination, or approval to exceed budget limits may be needed. The Office of the ACOS for R&D or HSR&D Scientific Review Administrators can help determine which approvals may be required.

Table 4. Deadline, Review and Award Dates Health Services Research & Development (HSR&D)		
SUBMISSION CYCLES:	WINTER 2019	SUMMER 2019
Intent to Submit Window*	October 15, 2018 to November 1, 2018 (8:00pm EST)	April 15, 2019 to May 1, 2019 (8:00pm EST)
Waiver for Offsite Research, Waiver for Exceeding Duration or Budget Cap, and IPA Waiver*	November 15, 2018	May 15, 2019
First day to submit Merit Review Award applications to Grants.gov*	November 15, 2018	May 15, 2019
Deadline to request a title change*	December 1, 2018	June 1, 2019
Down to the Wire Submission Deadline to Grants.gov This deadline allows errors identified by Grants.gov, eRA, or the PI/SO during the two-business day examination period to be corrected. All changed/corrected applications must be submitted by this date. NOTE: After this date the two-business day correction window CANNOT be used to identify errors and resubmit a corrected/changed application as a resubmission at this time would miss the eRA verification deadline.	December 10, 2018	June 10, 2019
Last Possible Submission Date to Grants.gov NOTE: Any errors identified at this time CANNOT be corrected. WARNING: If you submit an application on this date to Grants.gov and there are errors identified by Grants.gov or eRA, you CANNOT fix the errors and resubmit on or after this date, as the application will not meet the eRA submission and verification deadlines. If your proposal is accepted by eRA (with no errors) on this date, do not withdraw the application during the two-business day examination window as <u>you will not be able to resubmit and meet the verification deadline.</u>	December 12, 2018	June 12, 2019
Verification Deadline in eRA * ‡ Once verified, an application is considered final and no other version will be accepted for review.	December 15, 2018	June 15, 2019
REVIEW AND AWARD CYCLES:		
Scientific Merit Review	March 2019	August 2019
Administrative Review	April-May 2019	October-November 2019
Earliest Project Start Date Note: VA-ORD R&D Services 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.	July 1, 2019	January 1, 2020

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

‡ Verification occurs on the third business day at 12:01 am after receipt of an application with no errors or only warnings.

4.B. Application Processing

All new or changed/corrected applications must meet 2 separate deadlines:

1. Submission and acceptance in Grants.gov on or before 6:00 pm (local time) of the **Last Possible Submission Date** (submission deadline) in [Table 4](#)

AND

2. Verification by eRA Commons on or before the **Verification Deadline** in [Table 4](#)

All applications should be proofread carefully prior to submission.

Applications that miss either deadline will not be accepted for review.

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 explicitly rejected (withdrawn) by the signing official (SO) during the 2-day application viewing window. However, if an application is submitted AFTER the Down to the Wire Submission deadline, the 2-day examination window CANNOT be used to identify errors and resubmit a changed/corrected application.

Once an application package has been successfully submitted through Grants.gov, any errors have been addressed, and the assembled application has been created in the eRA Commons, the PD/PI and the Authorized Organization Representative/Signing Official (AOR/SO) have 2 business days to view the application image (ONLY if submitted on or before the Down to the Wire Submission deadline).

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 2-day application viewing window.

During the 2-business day examination period, the electronic image of submitted proposals (e-application in eRA Commons) must be reviewed to ensure that there are no transmission errors. PIs are responsible for printing out and reviewing the electronic image of the e-application during the 2-business day period in order to check the submission for format, transmission or content errors.

Please remember that some warnings may not be applicable or may only need to be addressed after application submission. Reminder: warnings do not stop further application processing. If an application submission results in warnings (but no errors), it will automatically move forward after two business days if no action is taken.

Applications which fail to follow formatting and content requirements or are incomplete will be administratively withdrawn and not reviewed. No exceptions will be made. It is the responsibility of the PI to check that each and every page is correct and that all elements of the proposal have been included. After an application has been submitted, the application should be checked for problems with font type, font size, margins, characters per inch and lines per inch. It is advised that PIs print out a page of the Research Plan during the 2-business day examination period and MANUALLY check for these types of errors as eRA does not generate an error message for them. However, such errors WILL cause the proposal to be administratively withdrawn.

HSR&D will consider the errors listed below as fatal. Applications submitted with these errors will be administratively withdrawn and will not be reviewed.

- Missing budget page(s). Applications must include a completed budget page for each year of study (if funds are being used).
- Missing duration/budget waiver approval letter, if the total project duration exceeds 4 years OR the total project budget (for all years) exceeds \$1,200,000. Resubmissions should include the letter (or notice) from a prior submission of the same proposal in which a budget waiver was granted.
- Missing IPA waiver approval letter.
- Missing off-site waiver approval letter, if off-site research is proposed.

- Not listing all involved personnel and collaborators in the application (using the VA-SF424 R&R Senior/Key Person Profile form).
- Missing documents required for submission.
 - If this is a resubmission, the application must include the “Introduction to Revised Application”.
 - The application must include a review of research overlap in the Research Plan (under Innovation).
 - The application must include an Implementation and Dissemination Plan.
- Missing or unsigned Director’s letter of support.
- Exceeding specified page limits in the Research Plan or as noted in attachments.
- Using a version of the biographical sketch other than the one specified in the SF424.
- Any submission with URLs placed anywhere else except the Biographical Sketch, and Bibliography & References Cited will be withdrawn from review.
- Failure to meet specified content or formatting requirements for Text (PDF) attachments in e-application. Research plans should be carefully checked for formatting and PDF conversion errors.
- Missing Data Management and Access Plan (DMAP).

A previously submitted application must be rejected/withdrawn before a changed/corrected application can be submitted.

If an application is accepted by eRA with no errors, do not reject/withdraw an application during the 2-business day examination window unless there is sufficient time to resubmit a changed/corrected application by the submission deadline. The 2-business day examination window CANNOT be used if an application has been submitted on the Last Possible Submission date.

If everything is acceptable, no further action is necessary. The application will automatically move forward for processing after 2 business days and will become verified at 12:01 am on the third business day. Both the AOR/SO and PD/PI will receive e-mail notifications when the application is rejected or the application automatically moves forward in the process after 2 days.

Once an application becomes verified it is considered final and no changed/corrected application will be accepted for review.

VA-ORD will not penalize the applicant 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.

Once an application becomes verified, it will be evaluated for completeness by the HSR&D Program Review staff. **Applications which fail to meet content and formatting requirements will be administratively withdrawn by HSR&D Program Review staff and will not be reviewed.**

No additional or replacement information will be accepted after submission of the proposal, 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 Scientific Merit Review Program Manager (vhacoscirev@va.gov) at any time.

All Merit Review proposals must include an attachment containing a signed copy of the letter of support from the Director of the Medical Center documenting that sufficient resources (i.e., space, equipment, time, appointment, etc.) are available to the investigator. Review of applications submitted to VA-ORD without this attachment will not be accepted for review.

There will be an acknowledgement of receipt of applications from Grants.gov and eRA Commons. The submitting AOR receives the Grants.gov acknowledgments. The AOR and the PD/PI receive eRA Commons acknowledgments. Information related to the assignment of an application to a Merit Review Panel is also in eRA Commons.

The eRA system will make every effort to send an email to the PD/PI and AOR/SO summarizing the download and validation results.

NOTE: Since email can be unreliable, it is the responsibility of the PD/PI applicant and AOR/Signing Official(s) to periodically check on the application's status in eRA Commons.

VA-ORD will not accept any application in response to this FOA/RFA that is essentially the same as one currently pending initial merit review unless the applicant withdraws the pending application. VA-ORD will not accept any application that is essentially the same as one already reviewed. This does not preclude the submission of an application already reviewed with substantial changes, but such application must include an "Introduction" (3 pages maximum) addressing the previous critiques. Note that such an application is considered a "resubmission" for the SF424 (R&R).

5. Intergovernmental Review

Not Applicable.

6. Funding Restrictions

Not Applicable.

7. Other Submission Requirements

ePromise

The investigator profile (Page 18) in ePromise must be completed (including the Commons ID) for all PDs/Pis.

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 HSR&D's Scientific Merit Review Board (SMRB), sometimes referred to as a "review panel" or "review committee." The SMRB is a Federal Advisory Committee Act board charged to evaluate the scientific and technical merit of applications. The SMRB is an advisory committee and does not make funding decisions. Information about SMRB membership may be obtained from the HSR&D web site at <http://www.hsr.d.research.va.gov/>.

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

Not Discussed/Unscored Applications

The initial scientific peer review of research applications may include a time management process in which only those applications deemed by the reviewers to have the highest scientific merit will be discussed and assigned a priority score at the SMRB meeting. The purpose of not discussing some applications is to increase the time available for providing feedback on studies that have the most potential for funding (either in the current review or a subsequent review). This will also help HSR&D to better manage scarce resources.

If an application is not discussed, the PI will not be given a priority score and will be advised that a) the

proposal was not discussed by the full panel, and b) any resubmission needs to address the key issues raised in the written critiques. ALL applications are reviewed and receive written critiques; however, not all applications need to be discussed. (An application that is not discussed may be very appropriate for resubmission, depending on the comments in the written critiques.)

Scoring

SMRB members are instructed to evaluate research applications using the review criteria described below, and to assign a single, global score for each scored application. The score will reflect the scientific merit of the proposed research and its overall impact on advancing science and the health and healthcare of Veterans. Other FOAs or RFAs may have different and/or additional review criteria. For information on the scoring guidelines, go to http://www.hsrp.research.va.gov/for_researchers/merit_review/ScoringGuidelines.pdf.

All PIs will receive a written **Summary Statement** which includes a cover page, the Program Description/Abstract section from the submitted application, each assigned reviewer's written comments, and a roster of the review meeting participants.

Criteria for Review and Scoring of the Proposal

The following criteria are considered during scientific merit review:

Significance. This criterion refers to the scientific importance or value of the project, and its value to Veterans health care and health outcomes. Reviewers will assess the scientific significance and theoretical foundation of the stated goals, and specific research questions and/or hypotheses. Reviewers will consider the proposed research in relation to information and/or pilot data that the investigators provide regarding prior work (by self and others), as well as information from other sources that relates to the scientific significance and likely contribution of the proposed work. (Focus should be on the significance of the proposed project, if it is successfully executed, and not simply the field in general or the health condition.)

Reviewers will be asked to comment specifically on the following questions:

- Did the investigator provide an explanation of how their project will fill a gap in research from HSR&D, QUERI, VA, and other funding agencies?
- Do the aims address an important problem or critical barrier to progress in the field?
- Is there a strong scientific premise for the project?
- If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved?
- How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?
- While science is incremental, is the advancement in science large enough to be meaningful and generalizable?

Approach. Reviewers will assess the appropriateness of the research design and specific methods proposed for conducting the research. Reviewers evaluate the adequacy of data for the proposed study. For primary data, reviewers consider the adequacy of the proposed data collection instrument(s) or the plan for developing and testing new instruments, as well as the feasibility and appropriateness of data collection procedures. Secondary data issues to be considered include: appropriateness, availability, accuracy, and completeness of data. Applicants proposing to use existing databases need to provide evidence of familiarity with these, and an awareness of the availability, idiosyncrasies, and limitations of the data. For all types of data, reliability, validity, and adequacy of quality control procedures are important issues.

Reviewers will be asked to comment specifically on the following questions:

- Is the overall research plan well-reasoned and appropriate to the aims of the study?
- Does the application demonstrate feasibility?
- When applicable, reviewers will be asked to comment on:
 - Adequacy of methods to answer question with enough specificity to advance knowledge
 - Data quality
 - Appropriately constructed or identified control group for intervention studies

- Accuracy of power calculations based on prevalence/incidence of condition of population
- Sample recruitment timeline and enrollment feasibility

Implementation

The implementation and dissemination plan should identify key VA operations partners or “champions” to support uptake of the study findings within the VA system, and for interventions, also describe potential systemic or provider barriers and facilitators of change.

Reviewers will be asked to comment specifically on the following questions:

- How does the study align with VA national priority goals, [VISN/Facility Performance Plan goals](#), and/or performance metrics (e.g., Strategic Analytics for Improvement and Learning, SAIL)?
- Which VA operations partners might potentially “own” (i.e., apply) the study results?
- For interventions, does the study collect information on the implementation of the treatment or intervention during the trial, including qualitative and/or quantitative data on potential barriers and facilitators at the patient, provider, and health care facility/organization levels? Is the intervention feasible to implement by existing providers not paid for by the study?
- How will further dissemination or implementation of study results beyond the study sites occur?

Innovation, including Potential for Overlap. This criterion refers to the ability of the project to yield results that can be expected to change practice, influence scientific methods, disrupt the previous order of things, or introduce novel ideas or methods. Reviewers will assess the importance of the problem or question that the proposed research seeks to address, in terms of its prevalence, severity, urgency, cost, etc., for VA and the general public. (The importance of the problem is assessed independently of the investigator’s approach.) Are the plans for translating findings into practice adequate and sustainable?

NOTE: projects that study or assess broader care improvements and/or new methods or treatments for a broader Veteran population, rather than “one-off” studies of previously established treatments in small select subpopulations are preferable. Applicants are strongly encouraged to highlight how their proposed work breaks new scientific ground, deploys novel designs or methods, and/or offers new directions in promoting feasibility and/or sustainability of current treatments or practice.

Reviewers will be asked to comment specifically on the following questions:

- Does the project focus on broader care improvements in the VA healthcare system rather than within a specific subpopulation?
- Does the proposed work involve new directions or insight into feasibility or sustainability of treatments or clinical practices?
- Will the project contribute to new research methods, a new way of thinking about healthcare delivery or a new paradigm in science?
- Does the project take advantage of a time-sensitive opportunity?
- Will the project contribute to an area of practice or science where the field is ready for a change (e.g., where there is a need, where there is dissatisfaction with the current state of the science)?
- Will the project produce a lasting change in guidelines for care?
- If high risk work is proposed, is the risk worth the reward with early pay-off?
- Does the proposed work challenge or seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, or interventions?

Feasibility (including Sampling, Project Timeline and Staffing). Reviewers will be asked to comment on the sample recruitment, project management and communication plans. Reviewers assess the reasonableness of the project timeline, and whether proposed projects are staffed appropriately. The appropriateness of the proposed project period will be assessed in relation to the proposed research. (Some of this information may appear in the budget justification section of the application.)

Reviewers will be asked to comment specifically on the following questions:

- Are the power calculations appropriate?
- Will the sample size proposed be adequate to address the question asked?

- Are alternative recruitment strategies proposed?
- Will the management and communication plan be effective?
- Does the team management plan include a communication plan? Is the leadership and management of the work well coordinated?
- Is the project sustainable?
- Are the milestones achievable?

Investigator Qualifications. Reviewers will be asked to assess the expertise of each investigator and each major consultant, including professional credentials, institutional position, role in the project, expertise (especially as reflected in publications), and relevant experience. All reviewers will assess the combined strength of the team in relation to the objectives of the project and determine whether it encompasses all needed skills and competencies.

Reviewers will be asked to comment specifically on the following questions:

- Is the research team appropriate and does it capitalize on unique expertise or opportunity?
- Does the research team have a track record for success?
- When appropriate, reviewers will be asked to comment on:
 - Implementation expertise of study team
 - Qualifications for mixed methods or qualitative analyses

Multiple PD/PI Leadership Plan. If applicable, reviewers will assess the rationale for using a multiple PD/PI approach. Reviewers will evaluate the overall organization and management of the project with respect to whether the initiation, conduct, and completion of the proposed research are feasible. They will evaluate the role of each PD/PI in the project, particularly their unique expertise and potential contribution to the project.

Facilities and Resources. Reviewers will evaluate the adequacy of facilities and resources to carry out the proposed study. The proposal must include evidence of support from the applicant's VA facility, support from any additional study site(s), and documentation of any agreements with consultants, or commitment of non-VA resources to the study.

Adequacy of Response to Previous Feedback Regarding the Proposed Study. If the proposal is a resubmission, the applicant will have received detailed comments on the previously submitted proposal. Any subsequent proposal is expected to highlight changes made in response to such feedback, or to defend the earlier plan.

Protection of Human Subjects from Research Risk. The involvement of human subjects and protections from research risk relating to their participation in the proposed research will be assessed 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. See Part II of the [VA-SF424 AG](#). Plans for the recruitment and retention of subjects will also be evaluated. Use of non-Veteran subjects must be justified. Reviewers evaluate the risk/benefit ratio of the study, analyzing whether the study places human participants at risk of physical or psychological harm and evaluating the adequacy of provisions to minimize risk, protect participants' privacy and the confidentiality of their records or responses, ensure informed consent, and minimize respondent burden.

Inclusion of Women and Minorities in Research. When human subjects are involved in the proposed research, the Scientific Merit Review Board will also evaluate the adequacy of proposed plans to include subjects from both genders and all racial and ethnic groups (and subgroups), as appropriate for the scientific goals of the research. See Part II of the [VA-SF424 AG](#). VA mandates that all research proposals reviewed and funded by ORD include women and minorities in their study populations to the extent possible. HSR&D reviewers are responsible for considering the adequacy of representation and to assess whether investigators have made a substantive effort to include women and/or minorities in each research proposal.

Children may be included in VA-approved research conducted by VA investigators while on duty, or conducted at VA facilities or approved off-site locations only upon approval of the Medical Center Director. Refer to VHA Handbook 1200.05 dated November 12, 2014 Section 19, page 25 for additional information.

http://www1.va.gov/vhapublications/ViewPublication.asp?pub_ID=3052

2.A. Additional Review Considerations*

*Not considered in the scientific merit and priority score.

Budget and Period of Support. The appropriateness of the proposed budget in relation to the proposed research may be assessed by the reviewers. The priority score should not be affected by the evaluation of the budget. Project budgets need to be appropriate to the proposed work, sufficiently detailed, and well-justified. Reviewers assess the reasonableness of the project timeline and costs allocated to major budget categories. Personnel costs, and whether proposals are staffed appropriately, are key considerations. Prior to any funding decisions, all proposals under consideration will undergo administrative review of budgets by HSR&D staff. Items that appear to be outliers, line items that change markedly from one year to another, identical total annual requests, and large amounts for equipment, travel, or subcontracts are scrutinized. This review ensures that VA research funds are not used for any unauthorized purposes and that the proposed budget is well justified.

2.B. Sharing Research Data

Effective January 1, 2016, all **new proposals** for VA research to be funded by ORD must include a **Data Management and Access Plan (DMAP)** that describes how **publications** resulting from the research and the **final data sets** underlying such publications will be made available to the public. Reviewers should comment on whether the Data Sharing Plan, or the rationale for not sharing data, is reasonable. (Any issues will be addressed administratively, and should not be considered in the evaluation of scientific merit.)

2.C. Sharing Research Resources

Not Applicable.

2.D. Disapproved Proposals

A proposal may be disapproved if the SMRB determines that the proposed study is unethical, is unlikely to yield useful information, or is not relevant to VA's mission.

- Proposals 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.

2.E. Appeals

The appeals process is intended to ensure that the scientific review of all proposals is fair and equitable. It is not intended as a means to resolve differences in scientific opinion between the applicant and the reviewers, to adjust funding decisions, or to circumvent the peer review process. (See [VHA Handbook 1204.01](#))

If a PD/PI submits a revised application and an appeal of the previous application is subsequently sustained and funded before the revised application is reviewed, the revised application will be administratively withdrawn. If the revised application receives a fundable score and the appeal is sustained and fundable, only one of the two projects will be funded.

Note: Applicants are encouraged to revise and resubmit their Merit Review, if allowed, or submit a new Merit Review while an appeal is under review.

Section VI. Award Administration Information

1. Award Notices

After the peer review of the application is completed, the PD/PI (only) will be able to access his or her Final Score and Summary Statement (written critique) via the NIH [eRA Commons](#) once this information has been released by HSR&D Staff. A separate notification of the review meeting outcome will be sent to the medical center director, ACOS/R&D, AO/R&D and if there is an HSR&D Center at the PI's location, to the Center Director.

If the application is under consideration for funding, VA-ORD will request "Just-in-Time" information from the applicant. If an application is not selected for funding it will remain in eRA Commons in a "pending council review" status.

The summary statement can be accessed through eRA Commons.

2. Administrative and National Policy Requirements

Research Integrity. HSR&D is committed to the highest standards for the ethical conduct of research. Maintenance of high ethical standards requires that VA medical centers and investigators applying for, and receiving, Merit Review Awards have appropriate procedures to preclude the occurrence of unethical research practices. All research data must be retained for 5 years after completion of a research project.

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

Deliberate falsification or misrepresentation of research data will result in withdrawal of an application, possible suspension or termination of an award, and potentially, suspension of the investigator's eligibility to submit proposals to HSR&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 Handbook 1200.18](#)).

Section VII. Agency Contacts

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

All questions related to the Merit Review submission (e.g. FOA/RFA, SF424, financial management, etc.) should be directed to the Scientific Merit Review Program staff (vhacoscirev@va.gov). All questions concerning electronic submission (e.g. technical issues with Grants.gov and eRA) should be directed to the eRA mailbox at rd-era@va.gov. Telephone calls and/or emails sent to individual staff may go unanswered if that staff member is out of the office.

1. Scientific/Research Contacts

The PD/PI may contact the HSR&D Scientific Review Officer (SRO) with questions specifically related to scientific issues raised in the summary statement for a reviewed proposal or the scientific content of a proposal to be submitted. The Associate Chief of Staff for Research and Development (ACOS/R&D) should make all other contacts with HSR&D staff at VA central office (VACO), including questions relating to budget modifications noted in the summary statement. Contact information for the SROs for individual Merit Review Panels may be found at [HSR&D Scientific Merit Review Board](#).