

**HSR&D Merit Review Award (Parent I01)**  
**Department of Veterans Affairs, Office of Research & Development**

Version: 1

HX-22-001

September 22, 2021

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## Part I - Overview Information

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**Funding Opportunity Announcement/Request for Applications (FOA/RFA) Number: HX-22-001**

**Title: HSR&D Merit Review Award (Parent I01)**

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

**Announcement Type: New**

**Catalog of Federal Domestic Assistance Number: 64.054**

**Competition Identification Number: HX-22-001**

### Key Dates\*

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

*NOTE: Dates are subject to change.*

**RFA Release/Posted Date:** Sept. 23 (Winter) or March 25 (Summer)

**Intent to Submit Receipt Date(s):** Oct. 21 – Nov. 4 (Winter) or April 22 – May 6 (Summer)

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

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

Applications submitted in response to this FOA/RFA must be submitted using the VA-ORD *Application Guide SF424 Research and Related (R&R)* forms and forms available on the VA-ORD Intranet: <http://vaww.research.va.gov/funding/electronic-submission.cfm>.

See [Fatal Errors](#) for errors that will result in **an administratively withdrawn application**.

*NOTE:* The instructions in this FOA/RFA may differ from the general instructions in the VA-ORD SF424: <http://vaww.research.va.gov/funding/docs/VA-SF424-RRGuide.pdf>

**The instructions in this FOA/RFA supersede all other guidance documents.**

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## Part II - Full Text of Announcement

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### Section I. Funding Opportunity Description

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#### 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 (I01) 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 (VAMC) 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.

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 in an ever-changing health care landscape. 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 and are more appropriate for funding opportunities of the Clinical Sciences Research and Development (CSR&D) service.

**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 ([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 underscored in the landmark [National Academy of Medicine Future of Health Services Research report](#), more attention is needed on solving the complex health system and implementation issues facing large health care organizations, such as VHA, in a timely manner. In addition, Foundations for Evidence-based Policymaking Act ([Evidence Act](#)) requires all U.S. Government Cabinet-level agencies including the VA to use evidence and evaluation to inform policies and budgets.

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. The National Academy of Medicine has defined a Learning Health Care System 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.” The VA is also focused on becoming a High Reliability Organization (HRO), 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. HROs 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). VHA is striving to become an HRO by implementing the MISSION Act, the Electronic Health Record Modernization (EHRM) with the transition to Cerner and other initiatives.

On February 21-22, 2019, leaders from 18 VISNs and leadership from VHA Central Office convened for an HRO Summit in Orlando, Florida, for a 2-day overview and training meeting. This was the official kick off to what will ultimately encompass all VHA facilities as part of the HRO journey in 2020. 18 facilities will be leading the initial roll-out of the HRO and will provide critical information in refining the approach, and sharing lessons learned to create a true VHA-wide HRO. Detailed information and resources are available on the VA SharePoint site: <https://dvagov.sharepoint.com/sites/OHT-PMO/high-reliability/Pages/default.aspx>.

This is an opportunity for HSR&D to inform this HRO initiative through evidence-based research that addresses existing gaps in identifying and/or implementing high reliability approaches to increasing safety, reducing errors, and promoting continuous quality improvement. For further background on research related to HROs, see the most recent [HSR&D Evidence Synthesis Program report](#).

**VA Phenomics Library Initiative:** [The Centralized Interactive Phenomics Resource \(CIPHER\)](#) (previously the VA Phenomics Library [VAPheLib]) is a catalog and knowledge sharing platform of VA electronic health record (EHR)-based phenotype algorithms, definitions and metadata that aims to optimize Veterans’ health data, drive collaborative research and improve clinical operations. CIPHER initially began as a collaborative effort within the VA to build on the Million Veteran Program (MVP) and Cooperative Studies Program (CSP) Phenotype Annotation Library. CIPHER includes an online user interface to easily access a curated knowledgebase of standardized VA phenotype metadata. The web-based platform is also a tool for storing and sharing phenotyping methods, resources, and best practices, with the goal of enhancing collaboration and communication across the VA research, operations, and clinical communities. CIPHER is currently supported by the MVP on behalf of ORD, CSP and VA Informatics and Computing Infrastructure (VINCI). This effort is part of an enterprise-wide approach to provide a resource for phenotypes that can be used in ORD supported research and for investigators to share their work.

Applicants proposing to develop and validate new phenotypes as part of their VA-funded research should plan to contribute their phenotyping algorithm, codes, and validation processes to the CIPHER. Researchers also should check to see if a phenotype they need is already in the library. The VA Phenomics Library contains a total of 2,035 phenotypes at different stages of development. Browse CIPHER and learn more about CIPHER through an archived Cyberseminar.

## 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](#) 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 [priority areas](#) that should be considered in developing research proposals. Priority areas for HSR&D fall into three (3) broad categories (as shown in Figure 1):

- A) Priority areas identified by VHA/ORD based on the health care needs of Veterans
- B) Health services priorities related to current policy, changes in VA or key legislation
- C) Priorities for advancing health services research methods, especially in areas that cut across conditions or care settings

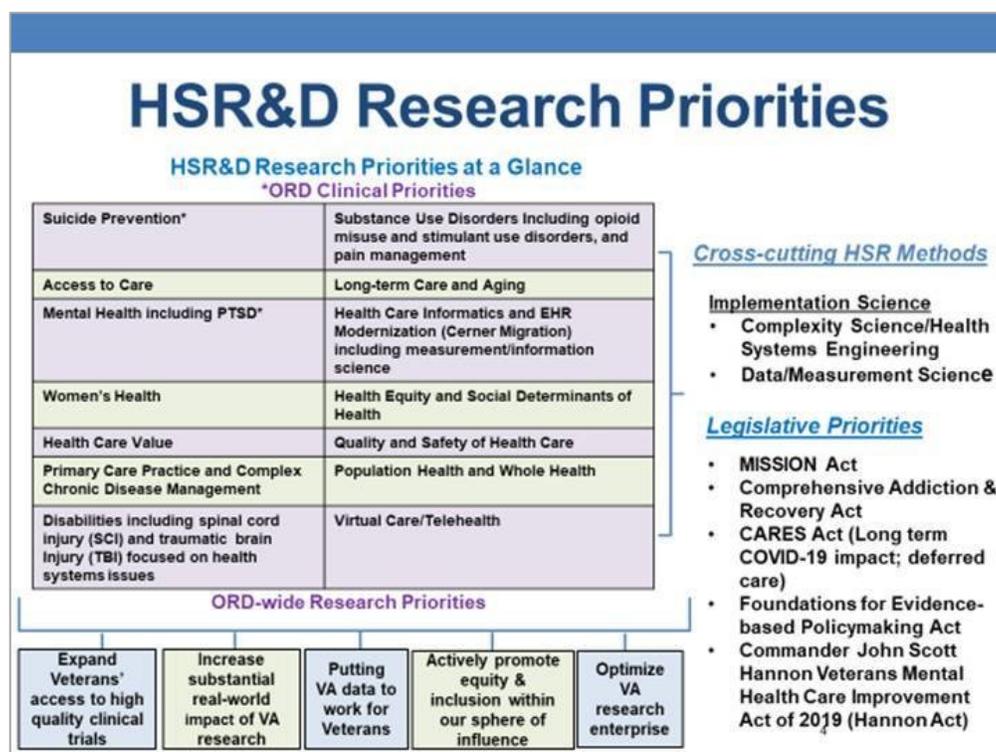


Figure 1

The VA is undergoing major transformations in the way it provides care, most notably with the passing of the MISSION Act, and expansion of an integrated and seamless system of quality care. These transformations afford unique opportunities to address the long-term impacts of selected sections of the MISSION Act. The following priority sections were selected based on a review by VHA operations leaders responsible for implementation of the MISSION Act's key components:

#### **Research on Community Care Program Implementation (Title I)**

- **Section 104:** The impact of standards of access and quality of care used to determine referral to community care on Veteran outcomes
- **Section 109:** The impact of programs to remediate medical service lines (e.g., specific provider or clinical programs such as temporary personnel assistance, mobile deployment teams, hiring/retention incentives, direct hiring authority, or provider training opportunities) on access to and quality of care based on standards set in Section 104
- **Section 105:** Access to walk-in care for Veterans in VA or community care
- **Section 131:** The establishment of processes to ensure safe opioid prescribing practices by non-VA health care providers

- **Section 134:** VA participation in a national network of state-based prescription drug monitoring programs
- **Section 151:** The long-term impact of VA's expanded authority to provide telemedicine, on access to care, quality, and outcomes for Veterans
- **Section 152:** Development of innovative approaches to testing payment and service delivery models that lead to enhanced quality of care, patient satisfaction and cost savings

#### **Research on Health Care in Underserved Areas (Title IV)**

- **Section 402:** Pilot programs for medically underserved areas using mobile deployment teams
- **Section 403:** Pilot program for graduate medical education/residencies

Proposals should address at least one (1) of [HSR&D's priority areas](#) and are encouraged to address more than one (1) where appropriate. For example, a study using new HSR methods to examine a clinical priority area or to evaluate the impact of legislation.

HSR&D also considers Health Disparities and conditions that impact underserved Veterans including but not limited to racial and ethnic minority Veterans, Veterans with disabilities and LGBTQ+ Veterans, as a priority.

#### **Capitalizing on Unique Capabilities of the VHA for Health Services Research**

VA HSR&D occupies a unique position as a research division within a national, integrated health care system, caring for a complex patient population, with over two decades of clinical data from electronic health records. This informs our Research Priorities in several important ways:

- We emphasize research that takes advantage of our **unique capabilities** to answer questions that other funders cannot easily answer. For example, how can we learn from variation in a diverse system to identify best practices and improve care at low-performing sites? How can we use our rich data to most effectively inform patient, provider, and policy decisions?
- We are interested in research that can be **scaled and sustained** effectively across a diverse health system to impact care. Proposals should be informed by the processes that help spread new practices across VA, and by understanding the relevant decision makers and the evidence relevant to their decisions (see [Table 2](#) for requirements of the Dissemination and Implementation plan).
- We emphasize research that will be **relevant in a fast-changing health care system**. Proposals should consider ongoing initiatives within VA, their timing and likely changes that may affect the relevance of the research. Applicants should consider 1) how they might build research into new clinical initiatives so we can quickly learn how to make them more effective and efficient and 2) how projects might provide timely information to inform clinical and policy decisions at multiple levels of the VA health care system: individual facility, network and national.

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## **Section II. Award Information**

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*NOTE:* Proposals electronically submitted to HSR&D through Grants.gov will be peer-reviewed by 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.

### **1. Mechanism of Support**

This FOA/RFA will use the Merit Review Award (I01) 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-ORD SF424](#) for guidance on how to fill out the VA-ORD SF424 Cover Form for each application type. *NOTE*: Resubmitted applications should be marked as “Resubmission” in Box 8 of the VA-ORD SF424.

**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 (2) revised applications (resubmissions) is allowed if the initial submission is not selected for funding. To qualify as a new submission, rather than a resubmission, applications must include all of the following:

- Significantly different aims from any previous submission
- A new study title
- Approved Waiver from HSR&D (Proposals that are submitted for a fourth review or reworked as a new proposal without having a signed waiver from HSR&D will be rejected).

Authorization to have an application reviewed a fourth time is rare and can only be authorized by HSR&D leadership through the waiver process. HSR&D requires a written request with clear justification as to why a waiver to exceed the three (3) submission policy is warranted. This must be submitted to the HSR&D scientific review mailbox in accordance with the posted waiver deadlines. We urge you to contact your Scientific Review Officer before the ITS window opens to discuss whether the changes would qualify for a waiver.

**Note:** *Having your proposal receive a score that just missed being funded is not sufficient reason for a fourth submission.*

**Renewals:** Not Applicable.

## 3. Multiple Awards and Submissions

Applicants may submit more than one (1) application to HSR&D per review cycle in response to the same FOA/RFA or to multiple FOA/RFAs. Applicants may receive funding for more than one (1) HSR&D project. Applicants must submit applications 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 & Waivers

Availability of funds is dependent on Congressional appropriation.

### Budget & Duration of Merit Review Awards

The budget for Merit Review projects may not exceed \$1.2 million and can last no longer than four (4) years. All funding is contingent on available funds and adjustments to budgets may be imposed after an award is initiated.

Rare exceptions may be granted to the project duration and/or budget cap prior to proposal submission for compelling circumstances. Proposals submitted with total project durations that exceed four (4) years, OR total project budgets that exceed \$1.2 million **will not be accepted for**

**review unless a waiver is obtained.** Exceptions may be requested in the form of a waiver submitted to [vhacoscirev@va.gov](mailto:vhacoscirev@va.gov). Standard due dates apply; see [Table 4](#).

## Duration & Budget Waivers

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 *VA-ORD SF424* (under Other Project Information, Other Attachments). **A waiver does not guarantee that a project will be funded at the level requested.**

*NOTE:* In cases where budget waiver requests have been approved for prior submissions to an application, the approval documentation should be included in the Letters of Support section of the new application (resubmission). 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 (For example, if the initial application was submitted in the winter cycle, the resubmission must be in the summer, not the following winter).
3. The scope of the project remains the same.
4. The total budget remains the same.

If any of the criteria above is not met, a new budget waiver request must be submitted for approval and the approval documentation from HSR&D must be included in the **Letters of Support** section of the current application (or resubmission).

If additional time and/or budget is being requested, the applicant must include a detailed justification letter with the following components:

1. A cover sheet listing the following information in the order specified:
  - a. Type of waiver requested (budget and/or duration)
  - b. VAMC name and address
  - c. PD/PI's name and degree(s)
  - d. PD/PI's title and VA appointment (in 8ths)
  - e. Title of PD/PI's research proposal (for ongoing programs)
  - f. Name, title, and signature of the Associate Chief of Staff for Research & Development
  - g. Name, title, and signature of the medical center Director
2. A narrative (1-page limit) describing the following:
  - a. Explain why the project requires special funding consideration based on the topic, the nature of the study, unusual resource requirements or other factors.
  - b. Describe how the proposed study could be completed or modified if the request to exceed the budget limit is denied.
  - c. For resubmissions, describe whether an increase in funding is being requested in response to reviewer comments and if so, please cite the specific comments.
3. Provide a budget for the proposed project.
  - a. Include total costs and specify major elements of the personnel, equipment, consultants, supplies and all other expense categories.
  - b. Justify each category.
  - c. For the equipment category, the justification must 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.

## IPA Waivers

VA research is an intramural program which depends on building robust VA research infrastructure. Non-VA experts can provide important expertise to VA projects, but we discourage excessive use of non-VA personnel rather than building internal capacity. As a result, HSRD requires waivers if the total cost for IPA's will exceed 30% of the total budget (including value of donated time of VA clinicians). For projects whose Principal Investigator is not located at a HSRD COIN, a 40% threshold is allowed. A detailed justification for an Intergovernmental Personnel Act (IPA) waiver must include:

1. A cover sheet listing the following information in the order specified:
  - a. Type of waiver requested (IPA)
  - b. VAMC name and address
  - c. PD/PI's name and degree(s)
  - d. PDPI's title and VA appointment (in 8ths)
  - e. Title of PD/PI's research proposal (for ongoing programs)
  - f. Name, title, and signature of the Associate Chief of Staff for Research & Development
  - g. Name, title, and signature of the medical center Director
  
2. A narrative (1-page limit) describing the following:
  - a. Explain why the project requires special consideration to exceed the cap for IPAs. Refer to the [IPA Personnel Salary section](#) in [Table 3](#) for more information on Centers of Innovation (COIN).
  - b. Describe how the proposed study would be staffed or how it would be modified if the request to exceed the IPA limit is denied.
  - c. For resubmissions, describe whether the increase in IPAs funding is being requested in response to reviewer comments and if so, please cite the specific comments.
  
3. Provide a budget for the proposed project. Include:
  - a. Total costs and specify major elements of the personnel, equipment, consultants, supplies and all other expense categories.
  - b. A written justification for each category.
  - c. For each individual on an IPA, include the following information:
    - i. Detailed description of their specific role(s) in the study
    - ii. Unique expertise that enables them to fulfill their study role(s)
    - iii. Explanation for why VA personnel cannot be assigned to perform the specific role(s) proposed for individuals on IPAs

\*For purposes of IPA calculation, "total budget" equals all costs in all categories plus the equivalent of donated costs for VA personnel with contributed time. For example, 10% donated time of a Chief Grade 15 primary care physician as a Co-Investigator (Co-I) with salary and fringe of \$285,000 would be equivalent to \$28,500 which should be added to all costs.

## Off-Site Waivers

Guidelines for submitting an application for an off-site waiver are described in the [Program Guide 1200.16: Offsite Research](#). Standard due dates apply; see [Table 4](#). A copy of the approval letter for the off-site waiver must be included in the Letters of Support section of the VA-ORD SF424 (under Other Project Information, Other Attachments). 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.

## Eligibility Waivers

To meet the special needs of VA, exceptions to the eligibility requirements are considered on a case-by-case basis. The facility Director, on behalf of the prospective investigator, must submit such requests in writing to the Director of HSR&D, with the endorsement of the facility Associate Chief of Staff (ACOS) for R&D and the facility Chief of Staff. Requests for a waiver of the 5/8ths eligibility criterion must be made 30 days in advance of the submission deadline ([Table 4](#)). The approval letter of an eligibility waiver from the Director of HSR&D must be included with the Medical Center Director's Letter of Support as an attachment.

### **Waivers for non-Veteran:**

HSR&D **WILL NOT** require non-Veteran enrollment waiver requests prior to funding decisions being made. If your project is selected for funding and you will be enrolling non-Veterans, you will be asked to submit a non-Veteran enrollment waiver during the JIT process.

### **Waivers for 4<sup>th</sup> Submissions:**

Authorization to have an application reviewed a fourth time is rare and can only be authorized by HSR&D leadership through the waiver process. HSR&D requires a written request to the HSR&D Director with clear justification as to why a waiver to exceed the three (3) submission policy is warranted. This must be submitted to the HSR&D Scientific Review mailbox ([vhacoscirev@va.gov](mailto:vhacoscirev@va.gov)) in accordance with the posted waiver deadlines ([Table 4](#)).

Prior to submitting a waiver request, contact your Scientific Review Officer before the ITS window opens to discuss whether the changes would qualify for a waiver. Additionally, having your proposal receive a score that just missed being funded is not a sufficient reason for a fourth submission.

## **5. Location of Research Space**

It is expected that the PD/PI and VA Co-I will perform all funded research in a VA space or VA-leased space. If any portion of the proposed work will be carried out in laboratory space assigned to (controlled by) a PD/PI or VA Co-I and/or collaborator at any other location(s), a waiver must be obtained for that investigator prior to submitting the proposal. The use of an off-site core facility or an off-site non-VA collaborator's laboratory does **not** require an off-site waiver, except when the VA investigator is the director of the core facility.

## **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 (Biomedical Laboratory Research and Development [BLR&D], Clinical Science Research and Development [CSR&D], or Rehabilitation Research and Development [RR&D]).

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## **Section III. Eligibility Information**

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### **1. Eligible Institutions**

All VAMCs with an active research program are eligible. Each VAMC 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 VAMCs or VA-approved sites. A PD/PI shall hold an M.D., Ph.D., 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 of the project must have a VA-paid appointment of at least 25 hours per week (5/8ths) at the time the Merit Review Award is funded. Contract clinicians **cannot** be VA employees (have a direct, VA-paid appointment) and therefore may not seek research funding from ORD, even if the terms of the contract permit or include research activities.

The VA employment status, including a 5/8ths appointment of each PD/PI must be indicated in the Letter of Support of the Medical Center Director. If a clinician PD/PI does **not** have a current, 5/8ths VA-paid appointment, 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.

In addition, the PD/PI must be current with all requirements related to intellectual property (VA invention documents and certifications); submission of annual progress reports (Research Performance Progress Reports [RPPRs]) and Final RPPRs; clinical trials registration; and clinical trials results reporting for existing and previous awards.

To meet the special needs of VA, exceptions to the eligibility requirements are considered on a case-by-case basis. The facility Director, on behalf of the prospective investigator, must submit such requests in writing to the Director of HSR&D, with the endorsement of the facility Associate Chief of Staff (ACOS) for R&D and the facility Chief of Staff. Requests for a waiver of the 5/8ths eligibility criterion must be made 30 days in advance of the submission deadline ([Table 4](#)). The approval letter of an eligibility waiver from the Director of HSR&D must be included with the Medical Center Director's Letter of Support as an attachment.

Non-VA investigators who have an MD/PhD equivalent are eligible to serve in the role of Co-investigator, **but they cannot be listed as such on the budget forms**. The Co-investigator role may be described in the proposal narrative and in the written budget justification. **On the budget forms they should be reflected as a consultant or as having an Intergovernmental Personnel Act (IPA) assignment, if appropriate**. If they are providing research services to the VA through a contract, the cost of the contract should be included on the budget forms under all other expenses. Collaborators from outside of the U.S. may only serve as consultants.

A Site PI must meet the same qualifications as a Study PI; this includes a minimum of a 5/8th VA appointment or waiver of the 5/8th appointment eligibility requirement, a MD/PhD or equivalent; and be registered in ePromise at their current site.

See [Program Guide 1200.15: Eligibility for VA Research Support](#) for additional guidance.

**VA-ORD will not accept or review an application from an applicant who has an overdue report** (annual progress reports or RPPRs), final reports, clinical trials registration and results reporting (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 VA-ORD SF424 Cover Form) and the applicant VAMC, and should be determined by the goals of the project. The Contact PD/PI must be affiliated with the VAMC in eRA, 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 R&R Budget Form and the Key Personnel Form are considered PD/Pis. The justification for including more than one (1) 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. Reference the [HSR&D Multiple Principal Investigator \(MPI\) Eligibility Policy](#) for more information.

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## Section IV. Application and Submission Information

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Several registration processes must be completed by the local R&D Service before an electronic application can be submitted (see Section 1.5 of the [VA-ORD SF424](#)). 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 eRA.

### 1. Intent to Submit

HSR&D requires Intent to Submit (ITS) notification through HSR&D's ART website (<http://art.puget-sound.med.va.gov/IntentSubmitIntro.cfm>). The ITS is a key step in the proposal submission process and assists HSR&D by ensuring that the proposed research is appropriate to the goals of HSR&D and VA. See [Table 4](#) for submission deadlines. The ITS process is separate from the requirements for Grants.gov submissions.

**NEW REQUIREMENT THIS CYCLE:** Completion of the Involved Personnel and Collaborators Spreadsheet information in ART. (This is a fatal error, if not completed.)

A list of **ALL named** personnel and collaborators must be updated in your ITS between November 15, 2021 and December 14, 2021 (2-business days after the Grants.gov submission deadline).

**ALL personnel and collaborators who are named in the application, including but not limited to:** PD/PI(s), co-investigators, personnel with any role in the study, IPAs, consultants, mentors, collaborators, advisory panel members, letter writers, active partners (Program offices) must be included. If someone is only named in the bibliography or biosketch, they do not need to be included.

**If the information is not added to the ITS in ART, this will be considered a fatal error and your application may not be reviewed.**

**NOTE:** A new ITS must be submitted each cycle. **Applications submitted to Grants.gov without a completed ITS will not be accepted or reviewed.**

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 [yhacoscirev@va.gov](mailto:yhacoscirev@va.gov) by the deadline found in [Table 4](#).

### 2. Request Application Information

Use either the [Grants.gov Workspace Process](#) or the [eRA 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 [here](#); there are also [several training videos](#) available.

eRA Commons ASSIST training resources (a recorded presentation, user guides and some other helpful resources) are available [here](#). An NIH/VA-ORD Webinar recording on the use of ASSIST can be viewed at <http://vaww.research.va.gov/funding/electronic-submission.cfm> under Helpful Links for eRA Commons, or at <http://vaww.research.va.gov/funding/default.cfm> under Application & Submission Process.

### 3. Content and Form of Application Submission

Prepare all applications responding to this FOA/RFA using the VA-ORD SF424 guidance, found at <http://vaww.research.va.gov/funding/electronic-submission.cfm>. See [Table 1](#) for a summary of the main components required for this application. The instructions in [Table 2](#) may differ from the general instructions in the [VA-ORD SF424](#). The instructions in this FOA/RFA supersede all other guides. **Failure to follow instructions may cause delays in submission or withdrawal of proposals from review.**

**Use of hyperlinks:** All applications must be self-contained within specified page limits (no use of URLs or video clips); thus, URLs/hyperlinks are prohibited **except** in the *Biographical Sketch* and *Bibliography & References Cited* attachments. **Any submission with URLs placed anywhere else except the *Biographical Sketch* and/or *Bibliography and References Cited* attachments will be withdrawn from review.** Additionally, the inclusion of links to videos within an application is not acceptable and will **cause the application to be withdrawn from review.**

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 an attachment; **this will cause the application to be withdrawn from review.** PD/PIs must contact the Scientific Program Manager (SPM) at least three (3) weeks prior to the application deadline 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 (see Item 12, Other Attachments, 8b. Letters of Support).

The video must adhere to the following guidelines:

- Embedded in a PDF file
- Maximum file size of 25 MB
- No longer than two (2) minutes
- Submitted directly to the SPM prior to the application deadline.

**Applications missing an SPM approval email attachment may be withdrawn from review.**

#### Required Forms and Attachments for this FOA/RFA

A set of templates with mandatory file names for each attachment, is available on the VA-ORD intranet (<http://vaww.research.va.gov/funding/electronic-submission.cfm>). A list of the required forms for this solicitation are summarized in [Table 1](#). All general VA-ORD SF424 instructions must be followed, but any HSR&D-specific clarifications and instructions are listed below.

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

Forms, Attachments & Templates (with size limits, if applicable)	Required When?	VA-ORD SF424 Instructions
VA-ORD SF424	Always	Sect. 3.2
Project/Performance Site Locations Form	Always	Sect. 3.3
VA-ORD SF424 Other Project Information Form		Sect. 3.4
Project Summary/Abstract (40 lines of text)*	Always	
Project Narrative (10 lines of text)	Always	
Bibliography & References Cited (4-page limit)	Always	
Facilities & Other Resources	Always	
Equipment	Always	
Other Attachments (Item 12):		
1. Introduction to Revised Application (3-page limit)*	Resubmission	
2. Specific Aims (1-page limit) List the specific aims in a numbered list, with a description of the component of the study relevant to each Aim.	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 (DMAP)	Always	
10. Financial Disclosure*	Always	
Appendices: *		
11. List of Abbreviations	Always	
VA-ORD SF424 Senior/Key Person Profile(s)*	Always	Sect. 3.5
VA-ORD SF424 Budget*	Always	Sect. 3.7

\*These sections have special instructions specific to this FOA/RFA that are in addition to and supersede instructions in the VA-ORD SF424. See [Tables 2](#) and [3](#).

## HSR&D-Specific Instructions for VA-ORD SF424 Forms & Attachments

[Table 2](#) provides HSR&D-specific instructions for completing VA-ORD SF424 forms and attachments.

Information for each attachment in Item 12 must be attached as a single PDF. The file naming standards for Attachments 1 – 10 are mandatory and may not be changed. **Altered file names will cause a system error to be generated.** Only the descriptor in the file names for Appendices 11, 12, 13, etc. may be changed.

**Table 2: HSR&D-Specific Instructions for VA-ORD SF424 Forms and Attachments**

*\*Unless otherwise noted, see VA-ORD SF424, Section 3.4, Item 12, for additional instructions.*

Other Project Information Form	Project Summary/Abstract
See VA-ORD SF424, Section 3.4, Item 7, for additional instructions.	
The Project Summary/Abstract is required in the following format, with headers as described:	
<p><b>Background:</b> Briefly present the ideas and reasoning behind the work, including a scientific rationale.</p> <p><b>Significance:</b> State the relevance of the proposed work to Veterans' health, disease burden, gaps in care and VHA/ORD/HSR&amp;D priorities.</p> <p><b>Innovation &amp; Impact:</b> Summarize the innovative aspects of the project and why they are likely to improve care if the project is successful.</p> <p><b>Specific Aims:</b> Provide a numbered list of the specific aims of the project, including objectives and/or hypotheses as appropriate.</p> <p><b>Methodology:</b> Describe the study design, including target population and outcomes, and include data sources. For interventional studies, use a PICOT format to describe the population, intervention, comparison, outcomes, and timing of the study.</p> <p><b>Next Steps/Implementation:</b> How will the project be sustained? What will the next steps be to move research into practice? For example: "We will use the findings of this research to work with partners to improve performance measures in SAIL and test ability to implement intervention in a wider array of facilities."</p>	
Other Attachments	1. Introduction to Revised Application (for resubmissions only)

**Page Limit: 3**

The substantial scientific changes must be marked in the application by bracketing, indenting, or changing typography. A vertical bar drawn in the margin may be used as long as changes in text are also indicated by bracketing, indenting, or changing typography. Do not underline or shade the changes. If a section is deleted, it may be entirely removed/all text and headings deleted, but should still be described in this attachment. If the changes are so extensive that essentially all of the text would be marked, explain this in the Introduction.

**Other Attachments****2a. Research Plan****Page Limit: 14**

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 Specific Aims (*Other Attachment 2*) in the Research Plan. The organization of the plan is at the discretion of the PD/PI. Although not all areas of the plan have a specific page limit, be as succinct as possible in each area.

The Research Plan should include the following sections:

**Background**

Briefly explain the background leading to the present application, critically evaluate existing knowledge and specifically identify the gaps that the research 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 areas of uncertainty.
2. The context in which the study will be conducted and how the results will be applied.
3. How or why this study will succeed in answering questions that have eluded other researchers (better design, larger sample, longer follow-up, etc.).

**Significance**

State the importance and health relevance of the research described in this application by relating the specific aims to the broad, long-term objectives. Explain how the aims of the application, if achieved, will advance scientific knowledge or clinical practice. Describe the effect of these studies on the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field.

1. Consider how common, serious, or urgent the research problem is within VA.
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 the development of generalizable knowledge or advancement of innovative field methodologies?
3. Describe the audience for the research results and how they might use the information or product(s).
4. Clearly articulate how the proposed research addresses HSR&D [Research Priorities](#), especially those that address legislative and methods priorities.

**Innovation & Impact**

Describe the project's potential to challenge or change current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches, methodologies or interventions that result in meaningful improvements in Veterans' care and health outcomes, or make substantial contributions to the field of health services research, specifically:

1. Describe how the project breaks new scientific ground; uses novel frameworks, designs or methods; develops new technologies or applies technologies in new ways; transforms the health care system and the delivery of health care; and/or changes current research paradigms or clinical practices.
2. Describe how the study will lead to major improvements in clinical or population health outcomes that have a significant impact and are applicable to a broader Veteran population, rather than "one-off" studies of previously established treatments in small select subpopulations.
3. Describe how the proposed work involves new directions for health services research.
4. Describe how the research takes advantage of unique capabilities of the VHA health system to explore questions that might be difficult to answer in other systems.

**Patient Experience & Veteran Engagement**

VA strives to be a patient-centered health care system and includes patient experience as a critical measure of how well the health care system is functioning. Engagement could include conducting discussions with a local Veteran engagement board, including a Veteran on the study team, developing a project-specific Veteran consultation group, or gathering information from focus groups or prior qualitative research. By engaging Veterans as

interventions and other study designs are developed, VA can provide important insights into what outcomes matter most, what interventions and other study designs might be acceptable and what designs might be favored by Veterans.

1. Describe what processes are planned to gain Veterans' and/or their caregivers' input into the proposal and the plan for continuing Veteran engagement once the project is funded and executed.
2. Provide details on how Veterans were engaged and the impact their advice had on the study plan.
3. Include qualitative and/or quantitative measures of patient experience as outcomes, if appropriate.
4. Describe the plan for effectively disseminating the research findings with Veterans, and whether Veterans' perspectives have been incorporated in plans for disseminating results.

Proposals should include Veteran engagement; if investigators determine that Veteran engagement is not applicable, the PD/PI must provide a rationale for that decision. For more information, see the [HSR&D Toolkit on Veteran Engagement](#).

### Overlap

Provide an explanation of how this project will fill the gap in the current research funded by HSR&D, VA, and other funding agencies, and prove that it does not substantially overlap with any published or currently funded studies. List similar studies in an appendix, based on a keyword search on [HSR&D](#) and [QUERI](#) studies; the [Clinical Trials website](#); the [US National Library of Medicine Health Services Research Projects in Progress website](#); Dimensions for Veterans Affairs; and the [US National Institutes of Health Research Portfolio On-line Reporting Tool \(RePORTER\)](#). Include the number of similar studies and how this project will uniquely contribute to our knowledge and affect Veterans' health. For clinical trials and other interventional studies, document a search for recent systematic reviews or meta-analyses of the intervention being studied and comment on how the study will improve current evidence.

### Research Design & Methods

*NOTE:* Due to unforeseen impacts caused by the coronavirus pandemic, on Aug. 6, 2020, VA revised the deployment schedule for implementation of its new EHR system. The revised timeline preserves the department's 10-year plan to roll out the EHR nationwide by 2028. The new VA-wide EHR system and associated Cerner systems will Go Live in the Pacific Northwest (VISN 20) in 2021, with future deployment continuing by [VISN across the country over the next 10 years](#). In designing your studies please beware that the transition has potential implications for data availability. If you have questions about potential impact of the Cerner implementation on your research plans, please email the ORD EHRM workgroup [ResearchEHRM@va.gov](mailto:ResearchEHRM@va.gov). Resource links, current updates and FAQs can be found on the [EHRM and Research](#) page of the Research Resource Guide (RRG). For administrative purposes, your proposal should discuss possible ways you could mitigate the effects of any data disruption. *NOTE:* This section will **not** be factored into scoring during scientific review.

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 types 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 the following:

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 required 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 can be found on the PhenX Toolkit site.
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 (missing data, respondent drop-out, interviewer bias, etc.) 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?

**NOTE:** Any submission proposing the use of non-VA secondary data sets must also provide evidence of availability and access to these data sets.

\*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 DoD use the Common Data Elements to improve comparability of data across studies. Appropriate measures can be found on the [PhenX Toolkit Site](#). Where appropriate, applications should incorporate measures based on the VA Integrated Service Network ([VISN](#))/[Facility Performance Plan goals](#), notably the [SAIL](#) Metrics.

### Sample Recruitment

If the project is a clinical trial requiring recruitment of individual subjects:

1. Describe the data used to estimate the recruitment goals, including number of eligible subjects and estimates of participation and dropout rates. Indicate if these estimates are based on pilot data or on data from comparable studies and indicate any differences (site, patient population, etc.) that may affect whether they are applicable to the study.
2. Identify any barriers to recruitment and retention, including any concurrent studies recruiting similar subjects.
3. Describe plans for monitoring recruitment, strategies to deal with lagging recruitment and criteria for modifying recruitment plans (e.g., adding a new site).

### Implementation & Dissemination Plan

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. An Implementation and Dissemination plan is required for projects intended to develop or test a clinical intervention or model of care.

1. Describe how the research findings will be translated into changes in policy or practice, and to determine proactively the steps required to accomplish that.
2. For projects that are more methodological or exploratory in nature, 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.
3. Include a conceptual plan that indicates how and when research findings will be disseminated and, if appropriate, implemented, among provider and Veteran groups.
4. Explain how the study is aligned with leadership/stakeholder goals, and discuss the key stakeholders who will eventually implement/disseminate the final project.
5. Identify any conditions or barriers that may preclude implementation of the research findings or products.
6. Identify plans and promising mechanisms (beyond professional publications) that may be used to facilitate dissemination and implementation.

### VA National and Program Office Priorities

All studies should also 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. Additionally:

1. 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.
2. Describe which operations partner (e.g., VISN or VHA National Program Office) might potentially “own” the study results, and for intervention studies, implementing 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.

### Long-Term Usage & Goals

Describe plans for further disseminating or implementing the effective treatment beyond the study sites, and explain the plan for factoring in 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 the plans for collecting 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. Describe how existing providers will be able to implement the intervention post-trial, assuming treatment is shown to be effective. Specify the implementation framework used to help guide the ascertainment of this information (see [QUERI Implementation Guide](#) for more information).

**The Implementation & Dissemination plan should also include:**

1. **Timelines:** Include dissemination and implementation timelines into the Gantt chart.
2. **Audience:** Describe the 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. Also include a clearly delineated strategy for dissemination and, if appropriate, implementation for each intended audience.
3. **Impact Metrics:** Explain how the impact of dissemination or implementation will be measured. Possible metrics could include:
  - a. Return on research investment (e.g., intervention or research products/services developed, software/educational tools, development and validation of phenotyping that could be added to [CIPHER](#) and if applicable, invention disclosures, amount of royalty income)
  - b. Whether research will lead to or shape 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. **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 through a project modification.
5. **Phenotypes** (if relevant): Applicants proposing to develop and validate new phenotypes as part of their VA-funded research should plan to contribute their phenotyping algorithm, codes, and validation processes to CIPHER. Researchers should also check to see if a phenotype they need is already in the library. The VA Phenomics Library contains a total of 2,035 phenotypes at different stages of development. [Click here](#) for more information in the Executive Summary.

**Project Management Plan**

Include a description of the following:

1. The project management plan and 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 PD/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**

Since the majority of HSR&D proposals use Human Subjects and require Institutional Review Board (IRB) approval or exemption, check "Yes" on the R&R Other Project Information Form and include this attachment. This section covers the information regarding the Protection of Human Subjects. Refer to the *VA-ORD SF424* for additional information on Human Subjects Research Requirements.

Multi-site (2 or more) intervention trials that involve human participants must include a data and safety monitoring plan and have oversight from a Data and Safety Monitoring Board (DSMB). 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**

A leadership plan is required if more than one (1) individual is assigned the role of PD/PI in the Senior/Key Person Profile(s). 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.

The plan must explain:

1. The rationale for choosing a multiple PD/PI approach
2. The governance and organizational structure of the leadership team and the research project, including the communication plan, process for making decisions on scientific direction and procedures for resolving conflicts.

3. Each PD/PI's roles, knowledge, skills, and experience, as well as administrative, technical, and scientific responsibilities for the project or program
4. How resources will be dispersed across all elements of the project and/or to individual PD/PIs. These components will be factored into the assessment of the overall scientific merit of the application. Refer to the [HSR&D MPI Eligibility Policy](#).

**Other Attachments****7. Consortium/Contractual Agreements**

This attachment should not be used to describe or to justify the required sub-award budgets for multi-site projects. Reference the *VA-ORD SF424* for further information.

**Other Attachments****8. Director's Letter**

All proposals must include an attachment containing a signed (e-signature accepted) and dated (within the last year) copy of a Letter of Support from the Director of the Medical Center documenting that sufficient resources (space, equipment, time, appointment, etc.) are available to the investigator.

The Letter of Support must indicate the VA employment status, including 5/8ths appointment of each PD/PI. If a clinician PD/PI does not have a current, 5/8ths VA-paid appointment, the letter 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.

**Note: New requirements outlined in the SF424 require that the Directors letter include language supporting protected time for clinician researchers (see VA-ORD SF424).**

**Other Attachments****8b. Letters of Support**

**Do not** send separate original hard copies or email PDF copies of Letters of Support (LOS) to the Director of HSR&D. These letters must be included as a scanned part of the Letters of Support attachment (Item 12, Other Attachments, 8b. Letters of Support) to be considered a part of the proposal. Letters should be submitted on the official letterhead of the individual's supporting institution.

All memoranda and budget limit letters should be addressed to the Director of HSR&D, and must include the corresponding PD/PI's name, project title, VA facility, signature, and date.

The following individuals require an LOS from their supporting institution:

- PD/PI
- Co-I
- Collaborators and consultants (VA and non-VA)

**A single LOS is sufficient for all individuals at the same institution.**

**For Resubmissions:** An LOS may only be resubmitted within the same year it was originally dated/submitted.

**Waivers:** This section must include approval letters for all waivers (budget cap, duration of study, off-site research, eligibility, inclusion of videos, enrollment of non-Veterans).

**Other Attachments****10. Financial Disclosure**

See the *VA-ORD SF424, Attachments for Item 12*, for guidance on this document.

A sample financial disclosure document can be found at: <http://vaww.research.va.gov/funding/electronic-submission.cfm>.

**Other Attachments****Appendices: 11, 12, 13, etc.**

**Do not** include the following in the Appendix:

- **Informed Consent forms**, even if already approved by the IRB
- **Published manuscripts and/or abstracts** that have a free, publicly available online journal. The full reference should be included in the Bibliography & References Cited and/or Biographical Sketch sections, as appropriate.
- **Videos of any type**, whether linked with a URL or embedded in the PDF

All materials must be submitted electronically in PDF format.	
<b>Senior/Key Person Profile Form</b>	<b>Senior/Key Person Profile(s)</b>
See VA-ORD SF424, Section 3.5, for additional instructions.	
A Senior/Key Person Profile form is required for all involved personnel and collaborators, to include the following: <ul style="list-style-type: none"> <li>• <b>Senior/Key Personnel:</b> All individuals who contribute in a substantive, measurable way to the scientific development or execution of the project, whether or not salaries are requested; this includes PD/PI(s) and Co-I's.</li> </ul>	
<b>Important notes:</b>	
<ul style="list-style-type: none"> <li>• If Centralized Transcription Service Program (CTSP) services are proposed, add Dr. Susan Zickmund as an "Other Professional," by typing "CTSP" under the Other Project Role category. <ul style="list-style-type: none"> <li>○ Biosketch or Other Support documents are not required; however, applicants must upload an attachment to both the Biosketch and Other Support fields with the words "Not Required," or they will receive a system error message.</li> </ul> </li> <li>• If Dr. Susan Zickmund is a collaborator or Co-I in the research (as opposed to CTSP services), please follow the general instructions.</li> </ul>	

### HSR&D-Specific Instructions for Summary Budget Worksheet and R&R Budget Form

The instructions in [Table 3](#) provide HSR&D-specific clarifications and instructions for completing the Summary Budget Worksheet and the R&R Budget Form in Part I, Section 3.7 of the VA-ORD SF424.

#### 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-ORD SF424](#), Section 3.7 for instructions on filling out the R&R Budget Form and Summary Budget Worksheet.

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

<b>Personnel (VA-ORD SF424, Section 3.7.1, Section A)</b>	
<b>Clerical support</b>	Clerical support may <b>not</b> be included as study personnel.
<b>IPAs</b>	Costs for IPAs should <b>not</b> be included under Section A or B of the R&R Budget Form; see "All Other Expenses" section of this table for HSR&D-specific IPA instructions. IPAs must be officially recognized by VA as authorized.
<b>Consultant</b>	Consulting 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. <b>Physicians may not be paid as consultants.</b>
<b>Salary for VA Employees</b>	Salary increases (the maximum cost of living adjustment is 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 may not 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.  HSR&D will pay salary only for the actual time the PD/PI or other VA-paid personnel spend on the project. One of the major differences between how BLR&D and HSR&D operate is that BLR&D will pay "up to the entire" VA Salary of a PD/PI on a project, regardless of his/her effort on the project.
<b>Equipment Description (VA-ORD SF424, Section 3.7.2, Section C)</b>	

<b>Computers</b>	Computers (and other IT expenditures) should not be listed in the budget section.
<b>Supplies (VA-ORD SF424, Section 3.7.3)</b>	
<b>Books, Journals or Reprints</b>	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.
<b>All Other Expenses (VA-ORD SF424, Sections 3.7.2 and 3.7.3)</b>	
<b>Salary for Personnel on IPAs</b>	<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>As stated by the Office of Personnel Management (OPM), "Intergovernmental Personnel Act assignees appointed for more than one (1) year are eligible for within-grade increases. They are entitled to cost-of-living allowances and other pay differentials, and are allowed to accumulate and use leave to the same extent as other Federal employees. However, employees appointed to successive temporary appointments of one (1) year or less may not earn a within-grade increase, even if the time under the successive temporary appointments exceeds one (1) year."</p> <p><a href="#">Click here</a> for more information.</p> <p>It is essential that core funds go to VA employees since this is an intramural research program. Applicants must submit an IPA waiver for approval by HSR&amp;D, as listed below:</p> <ul style="list-style-type: none"> <li>• Studies at sites with an HSR&amp;D COIN: A waiver is required if the total cost for IPAs exceeds <b>30%</b> of the core budget (including estimated costs for donated time).</li> <li>• Studies at sites <b>with no HSR&amp;D COIN</b>: A waiver is required if the total cost for IPAs exceeds <b>40%</b> of the core budget (including estimated costs for donated time).</li> </ul> <p>See <a href="#">Section 2.4</a> of this FOA/RFA for detailed guidance on what must be included in an IPA waiver. The deadline to submit an IPA waiver is provided in <a href="#">Table 4</a>.</p>
<b>Travel</b>	<p>Project travel must be requested in the Budget Justification using the table format shown in VA-ORD SF424, Section 3.7.2, Section D: Travel. There are four (4) categories of travel:</p> <ol style="list-style-type: none"> <li><b>1. Travel necessary for the conduct of research</b> <ol style="list-style-type: none"> <li>a. Fully explain project-related travel expenses and provide a cogent justification.</li> <li>b. Explain why emails, conference calls or teleconferencing are not adequate to accomplish the goals of the requested travel.</li> </ol> </li> <li><b>2. Travel to implement or disseminate findings within VHA</b> <ol style="list-style-type: none"> <li>a. This is <b>not</b> travel to present research findings at professional meetings; rather, it is travel necessary to conduct face-to-face meetings or conferences that will facilitate the adoption of the research into practice.</li> <li>b. The proposal must include a dissemination plan with an estimated budget; however, funds will not be disbursed until study results are available and dissemination/ implementation is warranted.</li> <li>c. Requests for Release of Funds must be submitted through the ACOS/R&amp;D to the assigned SPM at least three (3) months prior to the project end date.</li> <li>d. A justification, not to exceed one (1) page, must accompany the Request for Release of Funds. Highlight any changes made to the dissemination and/or implementation plan described in the original proposal.</li> </ol> </li> <li><b>3. Travel to present final research results at professional meetings</b>  <b>NOTE: This type of travel should not be included in project budgets.</b> <ol style="list-style-type: none"> <li>a. On a case-by-case basis, HSR&amp;D will consider 1 request per project to travel to present study findings. Requests for travel funds,</li> </ol> </li> </ol>

	<p>including an estimate of travel expenses and a justification, must be submitted to HSR&amp;D at least two (2) months before the meeting.</p> <p>b. 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> <p><b>4. Professional Development Travel</b>  <b>NOTE:</b> This type of travel <b>should not be included in project budgets.</b></p> <p>a. Not authorized for non-VA employees</p> <p>b. HSR&amp;D will consider requests from funded PD/Pis, not affiliated with a COIN, to allow the PD/Pis or their project team designee to participate in scientific meeting/professional development activities. This consideration will occur outside of the Scientific Merit Review process.</p> <ul style="list-style-type: none"> <li>• Requests for Professional Development funds, including an estimate of travel expenses and a justification, must be submitted to HSR&amp;D at least two (2) months before the meeting.</li> <li>• A PD/PI may receive a maximum of \$1,200 in Professional Development travel funds per year, regardless of the number of projects awarded to them.</li> </ul> <p>c. PD/Pis with only Pilot Project funding are <b>not</b> eligible for Professional Development travel funds.</p> <p>d. PD/Pis (or their project team designee) affiliated with COINs should <b>not</b> submit requests for Professional Development travel funds to VA Central Office (VACO); instead, they should submit requests to their local COIN.</p> <ul style="list-style-type: none"> <li>• The amount of travel funds allocated for Professional Development travel is at the discretion of the COIN Director.</li> </ul>
<p><b>Transcription Services</b></p>	<p>HSRD is no longer requiring quotes from CTSP for transcription. If you decide to use CTSP services for transcription, please follow the directions below so that funds can be transferred.</p> <p>The research team should contact the CTSP (<a href="mailto:VHASLCTSP@va.gov">VHASLCTSP@va.gov</a>) or Dr. Susan Zickmund, Ph.D. (<a href="mailto:Susan.Zickmund@va.gov">Susan.Zickmund@va.gov</a>) to request a formal proposal, including cost, for the potential use of CTSP services in the study. The CTSP may be able to provide a more cost effective, secure, and efficient mechanism that is designed to meet the research transcription needs without the need for contracting.</p> <p><b>If the applicant plans to utilize CTSP services:</b></p> <ul style="list-style-type: none"> <li>• A Letter of Support, Biosketch and Other Support documents <b>are not required</b> for Dr. Zickmund (see <a href="#">Table 2</a>).</li> <li>• Include CTSP transcription services costing in the R&amp;R Budget Form.             <ul style="list-style-type: none"> <li>○ If Salt Lake City (SLC) is not already a research site, it should be added as an additional site to the budget. Dr. Susan Zickmund should be listed as the Site Investigator; the Site Investigator is responsible for the funds sent to and the work performed at SLC.</li> <li>○ If SLC is already a research site, Susan Zickmund need not be listed as site investigator if one already exists.                 <ul style="list-style-type: none"> <li>▪ Dr. Zickmund's Percent Effort: List "N/A" and list her salary as "contributed."</li> <li>▪ "Other Direct Costs" (in the Summary Budget Worksheet): List "CTSP Transcription Services (SLC)," along with associated costs.</li> </ul> </li> </ul> </li> <li>• Include a brief description of the CTSP transcription services required in the written Budget Justification.</li> <li>• For Dr. Zickmund's Budget Justification use this text if she is <b>ONLY</b> included for CTSP:</li> </ul> <p>Zickmund, Susan PhD (Effort: NA, Salary: Contributed): Dr. Zickmund is a Research Scientist at the Veteran Health Administration Salt Lake City and Director of the VA HSR&amp;D-funded Centralized Transcription Services Program (CTSP). She has supervised thousands of hours of qualitative data</p>

	collection and analysis including transcription. She supervises employees dedicated to producing verbatim transcriptions for research investigator.
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## 4. Submission Timelines and Processing Information

### 4.A. Deadline, Review and Award Dates

#### Deadlines

Avoid delays and misunderstandings by reading and following the following instructions carefully. [Table 4](#) contains deadlines for Merit Review Award Program applications. Depending on the investigator's particular circumstance, they may need to request any of the waivers types: Waiver for Offsite Research, Waiver for Exceeding Duration or Budget Cap, Inclusion of Videos, PI Eligibility Waiver, Enrollment of Non-Veterans, Resubmission Waiver and IPA Waiver.\* 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

<b>Submission Cycles</b> <i>*If the deadline falls on a weekend or Federal holiday, the due date is the next business day.</i>	<b>Platform</b>	<b>Winter 2022</b>	<b>Summer 2022</b>
<b>Intent to Submit Window*</b>	ART	Oct. 21 - Nov. 4, 2021 (8:00 pm EST)	April 22 – May 6, 2022 (8:00 pm EST)
<b>Waiver Submission Deadline</b> <a href="#">Click here for more waiver information</a>	HSR&D SciRev Inbox	November 11, 2021 (11:59 pm EST)	May 13, 2022 (11:59 pm EST)
<b>First day to submit application*</b>	Grants.gov	November 15, 2021	May 15, 2022
<b>Update Involved Personnel Information on ITS</b>	<b>ART</b>	<b>Nov. 15 - Dec. 14, 2021 (11:59 pm EST)</b>	<b>May 15 – June 14, 2022 (11:59 pm EST)</b>
<b>Deadline to request application title change*</b>	HSR&D SciRev Inbox	December 1, 2021 (11:59 pm EST)	June 1, 2022 (11:59 pm EST)
<b>Down-to-the-Wire Submission Deadline</b> Submitting by this date ensures applicants will have 2 bus. days to correct errors identified by the system(s).  Applications submitted <i>after</i> this date cannot be corrected/changed.	Grants.gov	December 8, 2021	June 8, 2022
<b>Last Possible Submission Date</b> Applications submitted on this date cannot be corrected/changed.  <b>Applications cannot be submitted after this date.</b>	Grants.gov	December 10, 2021 (6:00 pm, local time)	June 10, 2022 (6:00 pm, local time)
<b>Verification Deadline*</b> Once the system verifies an application, it is considered final and no other version will be accepted for review.  Applications are verified on the 2 <sup>nd</sup> business day after they are submitted (if there are no errors or only warnings).	eRA	December 15, 2021	June 15, 2022
<b>Review &amp; Award Cycles</b>		<b>Winter 2022</b>	<b>Summer 2022</b>
<b>Scientific Merit Review</b>		March 2022	August 2022
<b>Administrative Review</b>		April - May 2022	Sept. - Oct. 2022
<b>Earliest Project Start Date</b> <i>NOTE: VA-ORD R&amp;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.</i>		July 1, 2022	January 1, 2023

#### 4.B. Application Processing

All applications should be proofread carefully prior to submission. All new or changed/corrected applications must meet both of the following deadlines. **Applications that miss either of these deadlines will not be accepted for review.**

1. Submission and acceptance in Grants.gov on or before 6 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](#)

Applications must be accepted by both Grants.gov and eRA Commons. The AOR, SO and PD/PI will receive email notifications from the systems, whether the application is accepted or rejected.

If an application is submitted before the Down-to-the-Wire Submission date, PD/PIs, Authorized Organization Representative (AOR) and/or the SO, will have 2 business days to correct errors identified by the system(s). Applications submitted after this date cannot be corrected/changed. **It is the responsibility of the PD/PI and AOR/SO to check for errors during the 2-day application viewing window.**

During this window, the applicant must review the electronic image of the application (e-application in eRA Commons) to check for transmission, format (font type, margins, characters per inch, etc.) or content errors. PD/PIs are encouraged to print out the Research Plan during this period and manually check for these types of errors, as eRA will not generate a formatting error message; **however, such errors WILL cause the proposal to be administratively withdrawn.**

**Applications that are incomplete or fail to follow formatting and content requirements will be administratively withdrawn and not reviewed.** NOTE: Unlike errors, system-generated warnings will not automatically disrupt the application process. An application may receive warning(s) and will still move forward after two (2) business days.

A previously submitted application must be rejected/withdrawn before a changed/corrected application can be submitted. As long as an application is not withdrawn by the SO and there are no errors, the system automatically verifies applications on the 2nd business day after they are submitted. Once an application is verified, it is considered final and no other version will be accepted for review.

Two business days after the Down-to-the-Wire deadline, the application will automatically move forward for processing; eRA will officially verify the application on the third business day.

VA-ORD will not penalize the applicant for an eRA Commons or Grants.gov system issue, **as long as the applicant can provide documentation of a processing error at either Grants.gov or eRA Commons.**

After the last possible submission date, no additional or replacement information will be accepted, unless requested by the Program Review staff. The only exceptions are official Letters of Acceptance for publication of manuscripts submitted by the PD/PI. These may be emailed to the Scientific Merit Review Program Manager ([vhacoscirev@va.gov](mailto:vhacoscirev@va.gov)) at any time.

The AOR, SO and PD/PI will receive system-generated email notifications, acknowledging that their application has been received (whether the application was accepted or rejected by the system). Only the AOR will receive the email from Grants.gov; both the AOR and the PD/PI will receive the email from eRA Commons. In case there is a system error, AOR/SOs and PD/PI are encouraged to periodically check the application's status in eRA Commons.

VA-ORD will **not** accept any application in response to this FOA/RFA that resembles another application currently pending initial Merit Review **unless** the applicant withdraws the pending application. VA-ORD will **not** accept any application that resembles another application that has already been reviewed.

This policy does not apply to previously reviewed HSR&D applications that are resubmitted with substantial changes (resubmissions). To be considered, resubmissions **must** include an Introduction (3-page limit) addressing the previous critiques. See "[Application Types Allowed](#)" in Section II of this FOA/RFA and/or the VA-ORD SF424 for more information.

Once an application is verified, it will be evaluated for completeness by the HSR&D Program Review staff.

## Fatal Errors

HSR&D considers the following errors as "fatal." **Applications submitted with these errors will be administratively withdrawn and will not be reviewed.**

### Applications must include:

See [Table 2](#) for further guidance on each item

- Budget page(s) – a completed budget page for each year of the proposed study
- Duration/budget waiver approval letter
  - Missing letter is only considered fatal if the total project exceeds 4 years OR \$1.2 million
  - Resubmissions should include the letter (or notice) from a prior submission of the same proposal for which a budget waiver was granted.
- [IPA waiver approval letter](#)
- Off-site waiver approval letter (if off-site research is proposed)
- All documents required for submission
- A review of research overlap (in the Research Plan)
- Implementation and Dissemination Plan
- Director's Letter of Support (**must be signed**)
- [Data Management and Access Plan \(DMAP\)](#)
- **For resubmissions only:** Introduction to Revised Application

### The following are also considered **fatal errors**:

- Not including a list of **all** involved personnel and collaborators in ART. This information needs to be submitted in ART by the deadline in [Table 4](#).
- Exceeding specified page limits as noted in the RFA
- Using a version of the Biographical Sketch other than the one specified in the VA-ORD SF424
- Placing URLs anywhere **besides** the Biographical Sketch and Bibliography & References Cited sections
- Failure to meet specified content or formatting requirements for PDF attachments in the e-application.

## 5. Intergovernmental Review

Not Applicable.

## 6. Funding Restrictions

Not Applicable.

## 7. Other Submission Requirements

### ePromise

The investigator profile in ePromise must be completed (including the Commons ID) for all PDs/PIs. [Click here](#) for more information.

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## Section V. Application Review Information

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

### 1. Review and Selection Process

#### Overview

Applications submitted in response to this FOA/RFA will be reviewed through a 2-tier system. The first level of review will be performed by HSR&D's SMRB, sometimes referred to as a "review panel" or "review committee." The SMRB is a Federal Advisory Committee Act (FACA) 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 can be found on the [HSR&D website](#).

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. *NOTE: While not all applications need to be discussed, **all applications are reviewed** and receive written critiques; an application that is not discussed may be very appropriate for resubmission, depending on the comments in the written critiques.*

If an application is not discussed, the PD/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.

#### Scoring & Critiques

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 health care of Veterans. Other FOAs or RFAs may have different and/or additional review criteria. [Click here](#) for more information about HSR&D's scoring guidelines.

All PD/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.
- 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 of the project 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?
- If the aims of the project are achieved, how will they change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?
- While science is incremental, does this project have the potential to advance science in a meaningful and generalizable way?

### **Innovation & Impact**

This criterion refers to the project's ability to yield results that might:

- 1) Challenge or change current research and clinical practice paradigms, or
- 2) Introduce novel theoretical concepts, approaches, methodologies, or interventions that will lead to meaningful improvements in Veterans' care and health outcomes or make substantial contributions to the field of health services research.

HSR&D prefers 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.

Reviewers will consider:

- The problem or question 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 should be assessed independently of the research approach).
- How does the proposed work break new scientific ground, use novel designs or methods and/or offer new directions in current treatments or practice?
- Will the project contribute to new research methods, a new way of thinking about health care 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 (i.e., where there is a need or 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 and methodologies or interventions?

### **Approach**

Reviewers will consider:

- The appropriateness of the research design and specific methods proposed for conducting the research.
- The adequacy of data for the proposed study.
- The reliability, validity, and adequacy of quality control procedures (for all types of data).
- Is the overall Research Plan well-reasoned and appropriate to the aims of the study?
- Does the application demonstrate feasibility?

When applicable, reviewers will consider:

- Whether the proposed methods will address the research question(s) with adequate specificity to advance knowledge.
- Quality and completeness of data
- If control groups are appropriately constructed/identified (for intervention studies).
- The accuracy of power calculations based on the prevalence/incidence of condition of population.
- How feasible are the enrollment and sample recruitment timeline?

For **primary data**, reviewers will assess:

- The adequacy of the proposed data collection instrument(s).
- The plan for developing and testing new instruments.
- The feasibility and appropriateness of data collection procedures.

For **secondary data**, reviewers will assess:

- The appropriateness, availability, accuracy, and completeness of data.

For **studies that will use existing databases**: Applicants must provide evidence of familiarity with these databases, and an awareness of the availability, idiosyncrasies, and limitations of the data.

### **Feasibility**

This criterion refers to the reasonableness of the project's sampling, project timeline and staffing.

Reviewers will consider:

- The sample recruitment, project management and communication plans.
- Is the project timeline reasonable?
- Is the project staffed appropriately?
- Is the proposed project period appropriate for the proposed research? (Some of this information may appear in the Budget Justification section of the application.)
- Are the power calculations appropriate?
- Will the proposed sample size be adequate to address the question asked?
- Are alternative recruitment strategies proposed?
- Does the team management plan include a communication plan? Will the management and communication plan be effective?
- Is the leadership and management of the work well coordinated?
- Is the project sustainable?
- Are the milestones achievable?

### **Implementation**

The Implementation and Dissemination plan should identify key VA operations partners or program offices that are responsible for policies related to the research intervention topic and who would be in a position to incorporate study results into guideline, programmatic, clinical service, or policy changes. Specify how the program office could be in a position to support the uptake of study findings within the VA system, such as through provider training, communication and embedding of the research results into existing provider workflows including electronic health record or VHA

performance metrics, and/or policy changes such as a national directive. Describe any anticipated barriers to uptake such as potential for provider burden or administrative barriers.

Reviewers will consider:

- How does the study align with VA national priority goals, [VISN/Facility Performance Plan goals](#) and/or performance metrics (e.g., SAIL)?
- What is the return on policy changes or research investment (e.g., intervention or research products/services developed, software/educational tools, development and validation of phenotyping that could be added to the VA Phenomics Library and if applicable, invention disclosures, amount of royalty income)?
- Which VA operations partners might potentially “own” (apply) the study results?
- For intervention studies: Will the study collect information on a) the implementation of the treatment, or b) 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 study results be further disseminated or implemented beyond the study sites?
- How will the project be sustained after the award?

### **Investigator Qualifications**

Reviewers will assess:

- The expertise of each investigator and each major consultant, including professional credentials, institutional position, role in the project, expertise as reflected in publications and relevant experience.
- The combined strength of the team in relation to the objectives of the project, to determine whether the research team has all the required skills and competencies.
- 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 submitting a Multiple PD/PI plan, reviewers will assess:

- The rationale for using a multiple PD/PI approach.
- The overall organization and management of the project – are the initiation, conduct and completion feasible?
- The role of each PD/PI in the project, particularly their unique expertise and potential contributions.

### **Facilities & 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 and any additional study site(s), documentation of agreements with consultants and commitment of non-VA resources to the study.

### **Response to Previous Feedback Regarding the Proposed Study**

**FOR RESUBMISSIONS ONLY:** The applicant will have received detailed comments on the previous submission. All subsequent proposals are expected to highlight changes made in response to such feedback, or to defend the earlier plan.

### **Protection of Human Subjects from Research Risk**

Reviewers will assess the involvement of Human Subjects, and the efforts established to protect them from research risk, 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
5. Data and safety monitoring for clinical trials.

Reviewers will also assess:

- Plans for recruiting and retaining subjects
- The risk/benefit ratio of the study:
  - Does the study place human participants at risk of physical or psychological harm?
  - Are there adequate provisions to minimize risk, protect participants' privacy, ensure informed consent, and minimize respondent burden?

Use of [non-Veteran subjects](#) must be justified.

### **Inclusion of Women, Minorities and Children in Research**

VA mandates that all research proposals reviewed and funded by ORD include women and minorities in their study populations to the extent possible. See Part II of the [VA-ORD SF424](#).

When Human Subjects are involved in the proposed research, SMRB reviewers will assess:

- Plans to include subjects from both genders and all racial and ethnic groups (and subgroups), as appropriate for the scientific goals of the research.
- The adequacy of representation.
- 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 the [VHA Handbook 1200.05](#) (Section 21, page 39), dated January 8, 2019, for more information.

### **1.A. Additional Review Considerations\***

*\*not considered in the scientific merit and priority score*

#### **Budget and Period of Support**

Reviewers will assess:

- Is the project budget appropriate for the proposed research, sufficiently detailed and well-justified?
- How reasonable are the project timeline and costs allocated to major budget categories?
- Is the proposal staffed appropriately?
- Are personnel costs reasonable?

The priority score will not take the budget evaluation into consideration. Please note that a budget waiver indicates that HSR&D leadership approved the investigator request to submit a budget over the budget cap and does not imply final approval of the budget by HSR&D leadership.

Prior to funding decisions, HSR&D staff will administratively review the budgets of all proposals. HSR&D will scrutinize items that appear to be outliers; line items that change markedly from year-to-year; identical total annual requests; and large amounts for equipment, travel, or subcontracts.

### **1.B. Sharing Research Data**

Effective January 1, 2016, **all new applications** for VA-ORD funding 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 will assess whether the Data Sharing Plan, or the rationale for not sharing data, is reasonable; this assessment will **not** be considered in the scientific merit evaluation.

### 1.C. Sharing Research Resources

Not Applicable.

### 1.D. Disapproved Proposals

A proposal may be disapproved if the SMRB determines that the proposed study is unethical, unlikely to yield useful information or 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 or with VA resources, even if the project is funded by another agency.

### 1.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](#) for more information.

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.

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## Section VI. Award Administration Information

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### 1. Award Notices

After the peer review of the application is completed and the information is released by HSR&D staff, the PD/PI (only) will be able to access their Final Score and Summary Statement (written critique) using the NIH [eRA Commons](#). 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 PD/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.

### 2. Administrative and National Policy Requirements

#### Research Integrity

HSR&D is committed to the highest standards for the ethical conduct of research. Maintaining high ethical standards requires that VAMCs and investigators applying for, and receiving, Merit Review Awards have procedures in place to preclude unethical research practices. PD/PIs must retain all research data for five (5) years after the project is complete.

The PD/PI and others associated with the research must subscribe to accepted standards of rational experimental research design, accurate data recording, unbiased data reporting, 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 Directive 1200.19 Presentation of Research Results](#)).

**Failure to acknowledge VA affiliation and support may result in termination of the award.**

#### **Intellectual Property Rights**

By accepting a Merit Review Award, the PD/PI agrees to comply with VA policies regarding intellectual property disclosure obligations and Federal Government ownership rights resulting from the proposed work (see [VHA Directive 1200.18 Determination of Rights for Inventions and Discoveries](#)).

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## **Section VII. Agency Contacts**

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

All questions related to Merit Review submissions (FOA/RFA, VA-ORD SF424, financial management, etc.) should be directed to the Scientific Merit Review Program staff ([vhacoscirev@va.gov](mailto:vhacoscirev@va.gov)). All questions concerning electronic submissions (e.g., technical issues with Grants.gov and eRA) should be directed to the eRA mailbox ([rd-era@va.gov](mailto: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.

#### **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 ACOS/R&D should make all other contacts with HSR&D staff at 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 on the [HSR&D Scientific Merit Review Board](#) site.