

Health Services Scientific Merit Request for Applications Winter 2023

September 29, 2022



 Have you ever applied or contributed to an application for HSR&D funding?

- a) Yes
- b) No



What is your role in VA?

- a) Investigator
- b) Coordinator, Project Manager, Analyst
- c) ACOS, AO, or Research leadership
- d) Award administrator
- e) Other



- Updated HSRD Priorities Document (dated September 2022)
- Updated guidance and requirements for Letters of Support
- Rural Health RFA

 Pandemic-Related Disrupted and Deferred Care RFA is discontinued



2022 New

Priorities

HSR&D RESEARCH PRIORITIES

HSR&D Research Priorities at a Glance

Suicide Prevention*		Mental Health including PTSD*			
Access to Care		Long-term Care and Aging			
Substance Use Disorders Including Opioid Misuse and Stimulant Use Disorders, and Pain Management		Health Care Informatics and EHR Modernization (Cerner Migration) including Measurement/Information Science			
Women's Health		Population Health and Whole Health			
Health Care Value		Quality and Safety of Health Care			
Health Equity and Social Determinants of Health		Primary Care Practice and Complex Chronic Disease Management			
Virtual Care/Telehealth		Disabilities including Spinal Cord Injury (SCI) and Traumatic Brain Injury (TBI) focused on Health Systems Issues			
Emergency Medicine		Rural Health			
COVID					
ORD-wide Research Priorities					
Expand Veterans' access to high quality clinical trials	Increase substantial real-world impact of VA research	Putting VA data to work for Veterans	Actively promote equity & inclusion within our sphere of influence	Optimize VA research enterprise	

Cross-cutting HSR Methods

Implementation Science

- Complexity Science/Health Systems Engineering
- Data/Measurement Science

Legislative Priorities

- MISSION Act
- Comprehensive Addiction & Recovery Act
- CARES Act (Long term COVID-19 impact; deferred care)
- Foundations for Evidence-based Policymaking Act
- Commander John Scott Hannon Veterans Mental Health Care Improvement Act of 2019 (Hannon Act)
- PACT Act



ELIGIBILITY-PI



- PI must have a MD, PhD, or equivalent doctoral degree in a medical, biological, or behavioral science field.
- PI must have a VA paid appointment of at least 25 hours/week (5/8th FTE) in place before funding can begin; the Directors letter must confirm a commitment for a 5/8 appointment if funded.
 - Investigators with less than a 5/8th VA paid appointment must obtain HSR&D approval of a waiver of the 5/8th FTE eligibility requirement for inclusion with their application for funding.
- All VA medical centers with an active research program are eligible.
- Each VA medical center must be registered as an applicant organization in Grants.gov and eRA Commons before any proposals can be submitted.



ELIGIBILITY-CO-I



- A Site PI must meet the same qualifications as a PI and be registered in ePromise at their current site.
- 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 Coinvestigator 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 unpaid consultants.



- Non-Veteran Enrollment Waiver: see VHA Directive 1200.01
- Eligibility Waiver see: Program Guide 1200.15
- Off Site Waiver see: Program Guide 1200.16

Waivers are project specific.

- Waiver Categories: Offsite Research, Exceeding Duration or Budget Cap, Inclusion of Videos, PI Eligibility, Resubmissions, and Exceeding IPA Percentage of Budget
- Deadline: November 10, 2022

Copy of waiver approval letters from HSR&D must be included in the "Letters of Support" section of the application. Missing letters are considered fatal errors.

Non-Veterans: Approved Enrollment of non-Veterans in ORD funded research is required for all projects with non-veterans (including employees) if awarded



HSRD is no longer requiring quotes from CTSP for transcription. If you decide to use CTSP services for transcription, please follow the directions in the RFA so that funds can be transferred.

MANDATORY REQUIREMENT:

 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, 2022 and December 14, 2022.



LETTERS OF SUPPORT



NEW MANDATORY REQUIREMENTS

- 1. Director's Letter must include language supporting protected time for clinician researchers
- 2. A TABLE OF CONTENTS for the letters of support must be included that lists each letter writer's
 - Name
 - Position
 - Office/institution

STRONGLY SUGGESTED

Although not required this cycle, electronic signatures are strongly encouraged to verify that the letter writer wrote the letter of support. Please inform the letter writers when making your letter of support request.



LETTERS OF SUPPORT



A single letter of support is sufficient from all individuals at the same institution if all individuals at the institution sign the letter. Individual letters are still acceptable.

- PD/PI
- Co-investigators
- Collaborators and consultants (VA and non-VA)
- Program Offices
- Other Stakeholders

Resubmission: a previously submitted letter can only be reused if it is less than one year old.



CERNER TRANSITION



- If you have questions about potential impact of the Cerner implementation on your research plans, please email the ORD EHRM workgroup ResearchEHRM@va.gov.
- Resource links, current updates, and FAQs can be found on the EHRM and Research page of the Research Resource Guide (RRG). Regarding EHRM-related research methods, please contact VA Coordinating Hub to Promote Research Optimizing Veteran-Centric EHR Networks (PROVEN) at PROVENHub@va.gov.
- For administrative purposes, your proposal should discuss possible ways you could mitigate the effects of any data disruption.



ORD COVID-19 SharePoint site: https://dvagov.sharepoint.com/sites/vacovhacomm/admin/projects/covid19

Please direct questions: ORDCOVID19@va.gov



INTENT TO SUBMIT (ITS)



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 window:

October 21 – November 4, 2022

ITS are used to determine panels, so an abstract that describes the project will assist in the assignment. Please include all the sites and personnel in the ITS. Please note that you will have an opportunity to update the list when you submit your application.

Applications submitted to Grants.gov without a completed ITS will not be accepted or reviewed.

Mentored awards (CDA & CDA MSI)

Must have an <u>approved Letter of Intent (LOI)</u> or an <u>LOI that is under</u> review to submit an ITS.

LOIs are emailed to robert.small@va.gov.



ART INVOLVED PERSONNEL ENTRY



Involved Personnel and Collaborators information in ART.

A list of **ALL NAMED individuals** must be updated in your ITS between **November 15, 2022 and December 14, 2022.**

ANYONE NAMED in the application needs to be included. If someone is only named in the bibliography or biosketch, they do not need to be included.

Failure to include all named individuals is a fatal error.

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



ART INVOLVED PERSONNEL ENTRY



ART

November 15, 2022 December 14, 2022 ITS opens for Involved Personnel ITS closes for Involved Personnel

ALL NAMED individuals must be added to your ITS in ART.

This is a fatal error.

Completed for each Involved Personnel/Collaborator/Named person:

- Name (Last, First)
- Degree
- Project Role
- VA Medical Center, City, State (if applicable), (listing just VHA is not sufficient)
- VA CBOC, City, State (if applicable)
- Academic Affiliate Institution(s) or Non-VA Organization Name(s), City,
 State



ABSTRACT FORMAT



Project Summary/Abstract is **REQUIRED** to comply with the format prescribed by the RFA.

Background:

Significance:

Innovation and Impact:

Specific Aims:

Methodology:

Next Steps/Implementation:

Abstracts are limited to 40 lines of text



NOTABLE SECTIONS IN RFA



Engagement of Veterans in the Design and Implementation of Research

- Most research benefits from engaging Veterans at all stages of the research process – study design, development, study recruitment, research, dissemination, and implementation.
- Veterans and their caregivers can provide important insights into what outcomes matter most and the feasibility and acceptance of proposed interventions and study designs.
- Options for obtaining input include interaction with Veteran engagement panels or Veteran advisory groups as well as including Veterans on the research team.
- We encourage pilot studies or smaller/shorter IIRs to advance the science of Veteran Engagement in research, including studies to examine different strategies to promote successful Veteran and Community Engagement.



NOTABLE SECTIONS IN RFA



Recruitment

- A large proportion of HSRD studies fail to meet recruitment goals.
- Trials will need to more explicitly justify data used to estimate recruitment -e.g., pilot data, prior studies, etc. -- and comment on mitigation strategies in recruitment lags.
- We expect to see your PLAN B for recruitment.



NOTABLE SECTIONS IN RFA



Implementation and Dissemination Plan

Dissemination in manuscripts and to partners is insufficient.

- Proposals will need to explicitly discuss what the next steps are after project is completed. What is the path to making a difference in VA care?
- Need to consider who "owns" the problem the study is attempting to solve; what are the potential barriers to implementation, and how to overcome them. Who will be the partner to implement the project?
- Studies of interventions should consider how they can collect information relevant to implementation during the efficacy/effectiveness study (e.g., use of hybrid designs).
- Need to compress cycle of understanding problem, testing interventions, scaling solutions.



HSR&D REQUEST FOR APPLICATIONS



RFA Description	RFA #
HSR&D Merit Review Award (Parent I01)	HX-23-001
HSR&D Merit Review Award Pilot Project Program (I21)	HX-23-002
HSR&D Targeted Solicitation for Service Directed Research on Veteran Suicide Prevention	HX-23-005
HSR&D Research Career Development Award (CDA-2)	HX-23-009
VA HSR&D Career Development Award for Scientists Associated with Minority Serving Institutions (MSI-CDA)	HX-23-010
Mentored Physician & Clinical Psychologist Award in Alzheimer's Disease and Related Dementias (MPCPS-ADRD)	HX-23-030
HSR&D Targeted Solicitation for Service Directed Research on Rural Health	HX-23-032
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RFAs can be downloaded from the VA ORD intranet site:

https://vaww.research.va.gov/funding/ rfa.cfm#hsrd

(VA network access only).



PARENT MERIT REVIEW AWARD



Parent: \$1,200,000 (max) for 4 years

2 resubmissions allowed.

HSR&D has identified priority areas that should be considered in developing research proposals. For details on updated HSR&D research priorities, please visit https://www.hsrd.research.va.gov/funding/PriorityDomains.pdf



PILOT: \$200,000 (max) and up to 18 months

Only one resubmission allowed.



PILOT PROJECT AWARD



Pilot Goals and Next Steps should be very clear.

- Establish components of interventions, measurement characteristics of key outcome variables, and/or predictors for primary outcome measures.
- Seek non-statistical information about the optimal sources of subjects, recruitment techniques, estimates of yields and varying interpretation of questions by respondents, establishing the interest level of particular groups of potential subjects in proposed interventions, or the feasibility of completing the measurements that are proposed.
- Establish cross-disciplinary collaborations or test novel methods to support cross-disciplinary research
- Support a small innovative study that does not necessarily lead to an IIR.
- Conduct preliminary analysis of existing data to refine target populations, inform intervention development, and/or establish feasibility of a potential IIR project.

Methods should align with goals, be appropriate for pilot work



TARGETED SUICIDE PREVENTION



Merit: \$1,200,000 (max) for 4 years; Pilot \$200,000 (max) for 18 Months

Focus on observational studies, effectiveness trials, implementation studies (including hybrid studies), or population-based and community-level studies that advance the prevention of suicide among Veterans.



NEW THIS CYCLE:

- \$1,200,000 (max) for up to 4 years
- RFA goals developed from the Rural Health State of the Art conference
- Meeting materials available on HSRD website: <u>State</u> of the Art Conference: Rural Health (va.gov)



Focus on priority areas and incorporating the four cross-cutting themes:

Priorities:

- Implementation-effectiveness research to inform public health management of crises and promote health equity
- Rural Veterans' decisions/preferences about where they receive care and the quality of that care
- Innovations in infrastructure and human capital that can address disparities in rural workforce needs

Cross-cutting themes:

- Cultural context for rural populations
- Diversity, equity, and inclusion
- Innovations to improve access
- Mental health



CAREER DEVELOPMENT AWARD MENTORED RESEARCH



The narrative page limit is 14 pages.

Letter of Intent – Deadline October 15, 2022: reviewed for acceptance

ITS required (ART) Window: October 21 – November 4, 2022 https://www.hsrd.research.va.gov/cdp/default.cfm

- 5 years of Salary Support
- Supplement support funds \$40,000/year for Years 1-3 at COINs and \$50,000/year (Yrs 1-3) at facilities not affiliated with COINs
- Candidate's training, experience and research accomplishments
- Career Plan
- Mentoring Plan

VA-ORD cross-service award mechanism in collaboration with National Institute on Aging (NIA)

Letter of Intent – Deadline October 15, 2022

- Mentored award career development award (CDA2)
- Cross service award (BL/CS/RR/HS) investigating Alzheimer's disease or related dementias (ADRD) across the scientific spectrum
- 3-5 years duration
- \$75K per year Year 1 may include up to \$30K in start-up costs
- NIA administrative supplement up to \$175K per year for research expenses)

Letter of Intent – Deadline October 15, 2022: reviewed for acceptance

ITS required (ART) Window: October 21 – November 4, 2022 https://www.hsrd.research.va.gov/cdp/default.cfm

- VA primary mentor and a partner MSI co-mentor required
- Nominee must have earned degree at an MSI and must be affiliated with a MSI (employed as a postdoctoral fellow, lecturer, or assistant professor)
- 3-5 years of Salary Support
- Supplement project support funds up to \$75,000/year for yrs 1-
- Follows CDA-2 application format
- Candidate's training, experience and research accomplishments
- Career Plan and Mentoring Plan





Date	Event
October 15, 2022	CDA/MPCPS-ADRD Letter of
	Intent due
October 21, 2022	ITS Opens and CDA ITS opens
November 4, 2022	ITS Closes and CDA ITS close
November 10, 2022	Waiver deadline
November 15, 2022	Grants.gov opens
November 15, 2022	ITS opens for Involved Personnel
December 8, 2022	Down to the Wire Submission
December 12, 2022	Last Submission Date Grants.gov
December 14, 2022	ITS closes for Involved Personnel
December 15, 2022	Verification Deadline
March 2023	Scientific Merit Review





vhacoscirev@va.gov

HSR&D RFAs:

http://vaww.research.va.gov/funding/rfa.cfm

QUERI RFA seminar:
October 12, 2022, 1 pm ET
REGISTER to attend this session



Thank you for your attendance. Please stay safe.

We hope to review your application soon!