Health Services Scientific Merit Winter 2022 Request for Applications

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

 a) Yes
 b) No

Poll Question

What is your role in VA?

    a) Investigator

    b) Coordinator, Project Manager, Analyst

    c) ACOS, AO, or Research leadership

    d) Operations leadership/staff

    e) Grant and Award administrator

    f) Other

HSR&D Research Priorities

HSR&D Research Priorities at a Glance
*ORD Clinical Priorities

Suicide Prevention*	Substance Use Disorders Including opioid misuse and stimulant use disorders, and pain management
Access to Care	Long-term Care and Aging
Mental Health including PTSD*	Health Care Informatics and EHR Modernization (Cerner Migration) including measurement/information science
Women's Health	Health Equity and Social Determinants of Health
Health Care Value	Quality and Safety of Health Care
Primary Care Practice and Complex Chronic Disease Management	Population Health and Whole Health
Disabilities including spinal cord injury (SCI) and traumatic brain Injury (TBI) focused on health systems issues	Virtual Care/Telehealth

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)**

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What is New?

1. VA HSR&D Minority Serving Institutions (MSI) Research Scientist Training Program (RSTP) Award

2. 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.

 3. NEW MANDATORY 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.

What is New?

4. HX-22-024 Opioid Safety and Opioid Use Disorder:
   Only open to applicants who applied but were not selected for funding from the Winter or Summer HX-21-024 RFA.

5. HX-22-023 Social Determinants of Health and Racial and Ethnic Disparities
   Only open to applicants who applied but were not selected for funding from the HX-20-023 and HX-21-023 RFAs.

6. Updated VA Application Guide SF 424
   (updated no later than October 4, 2021)

7. Director letters
   New requirements: letter must include language supporting protected time for clinician researchers

HSR&D Request for Applications

RFA	RFA #
HSR&D Merit Review Award (Parent I01)	HX-22-001
HSR&D Merit Review Award Pilot Project Program (I21)	HX-22-002
HSR&D Targeted Solicitation for Service Directed Research on Veteran Suicide Prevention	HX-22-005
HSR&D Research Career Development Award (CDA-2)	HX-22-009
VA HSR&D Minority Serving Institutions (MSI) Research Scientist Training Program (RSTP) Award	HX-22-010
HSR&D Innovation Initiative Program (Phase II/ Implementation)	HX-22-021
HSR&D Targeted Solicitation for Service Directed Research on Social Determinants of Health and Racial and Ethnic Disparities	HX-22-023
HSR&D Targeted Solicitation for Service Directed Research on Opioid Safety and Opioid Use Disorder	HX-22-024
HSR&D Targeted Solicitation for Service Directed Research on Pandemic-Related Disrupted and Deferred Care	HX-22-025

Eligibility

- 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

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.

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.

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. Note: this section will not be factored into scoring during scientific review.

Letters of Support

Director's Letter

New requirements: letter must include language supporting protected time for clinician researchers

Letters of Support

PD/PI

Co-investigators

Collaborators and consultants (VA and non-VA)

Program Offices

Other Stakeholders

A single letter of support is sufficient from all individuals as the same institution.

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

Waviers

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

- **Waiver Categories: Offsite Research, Exceeding Duration or Budget Cap, Inclusion of Videos, PI Eligibility, Resubmissions, and Exceeding IPA Percentage of Budget**
- **Deadline: November 11, 2021**

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.

Enrollment of non-Veterans in ORD funded research REQUIRED FOR ALL PROJECTS WITH NON-VETERANS IF AWARDED

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:

Oct. 21 - Nov. 4, 2021

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

Mentored awards (CDA & RSTP) must have an approved Letter of Intent (LOI) or an LOI that is under review to submit an ITS. LOIs are emailed to robert.small@va.gov.

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.

Note: QUERI ITS Window: October 1-November 15, 2021.

Involved Personnel in ITS

Involved Personnel and Collaborators information in ART.

A list of **ALL NAMED individuals** must be updated in your ITS between **November 15, 2021 and December 14, 2021.**

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.**

Intent to Submit (ITS)

Involved Personnel Update

ART

November 15, 2021   ITS opens for Involved Personnel

December 14, 2021   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:

- **Name (Last, First)**
- **Degree**
- **Project Role**
- **VA Medical Center (if applicable)**
- **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

Patient Experience and Veteran Engagement

HSRD position:

*   Most of our research would benefit from ensuring we had considered the patients perspective – on clinical care, health outcomes, implementation, and research (including interpretation of study findings).
*   Encourage efforts to obtain Veteran input into health outcomes, interventions, study recruitment, and design. Options for obtaining input include focus groups and Veteran engagement panels.

Recruitment

*   A large proportion of HSRD trials 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 want to see the PLAN B for recruiting.

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.

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/PriorityDomains2019.pdf**

Pilot Project Award

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

Only one resubmission allowed.

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

Targeted Suicide Prevention

Emphasis on Veteran groups that are at high risk for suicide and other risky behaviors.

- Veterans recently experiencing issues related to the social, economic and psychological impact of COVID 19; **NEW**
- Veterans in transition from military to Veteran status;
- Veterans recently discharged from in-patient hospital stays;
- Veterans with a previous suicide attempt;
- Veterans who are part of sexual and gender minorities, including women;
- Older Veterans (> age 50);
- OEF/OIF/OND Veterans;
- Veterans experiencing financial difficulties;
- Veterans struggling with chronic pain;
- Veterans who are homeless and/or at risk for becoming homeless;
- Veterans with access to lethal means (e.g., firearms, illicit drugs, engagement in risky behaviors, etc.);
- Veterans who are not currently receiving VHA care; and
- Veterans with a less than honorable discharge

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Social Determinants of Health and Racial and Ethnic Disparities

Merit: $1,200,000 (max) for 4 years;

Pilot $200,000 (max) for 18 Months

Resubmissions only

Only open to applicants who applied but were not selected for funding from the HX-20-023 and HX-21-023 RFAs.

Social Determinants of Health and Racial and Ethnic Disparities

- **Expanded Focus Includes Racial/Ethnic Equity**
  - Areas of emphasis include interventions to reduce disparities and under-studied populations of racial/ethnic minority Veterans

- **Equity Evaluation Plan**
  - Required for all proposals planning to test interventions or evaluate existing programs
  - Goal is to guard against unintended consequences (introduction of new or exacerbation of existing disparities)

- **Guidance Regarding Community-Based Participatory Research**
  - Studies may propose local strategies to address unmet social needs
  - Implementation/Dissemination Plans must discuss generalizability

Opioid Safety and Opioid Use Disorder

Merit: $1,200,000 (max) for 4 years;

Pilot $200,000 (max) for 18 Months

Resubmissions Only

Only open to applicants who applied but were not selected for funding from the Winter or Summer HX-21-024 RFA.

Opioid Safety and Opioid Use Disorder

Overarching Themes:

- Study of opioids safety and Opioid Use Disorder (OUD) management for **older Veterans**
- Development and deployment of more effective strategies for **reducing racial and ethnic disparities** in the treatment and management of pain and OUD
- Examination and development of interventions and models of care that can be **scaled within the VA**

Priorities:

- Improve **implementation of evidence-based medication for opioid use disorder (MOUD)** by examining barriers and facilitators of MOUD in the VA setting
- Identification and development of appropriate and successful strategies for **opioid tapering**
- Examination of the **potential role of buprenorphine/naloxone** in managing pain in patients with a history of OUD
- Studies of **behavioral health and exercise/movement** interventions for chronic pain, and for patients with OUD
- Development of more effective approaches to **monitor patient outcomes** for guiding treatment

Pandemic-Related Disrupted and Deferred Care

Disrupted Care Merit Applications
- o Up to 2 years
- o Budget may not exceed $700K

Goals
- Examination of health outcomes, care delivery, and other impacts across patient populations and geographic regions
- Projects developed and conducted in collaboration with partners
- Ideal projects will focus on a suite of related health outcomes, rather than one specific outcome

Link to CyberSeminars:

https://www.hsrd.research.va.gov/for_researchers/cyber_seminars/archives/video_archive.cfm?SessionID=3957&Seriesid=60

https://www.hsrd.research.va.gov/for_researchers/cyber_seminars/archives/video_archive.cfm?SessionID=3956&Seriesid=60

Pandemic-Related Disrupted and Deferred Care

Provide evidence-based information to better serve Veterans during the ongoing pandemic response and recovery, as well as possible future public health emergencies where care may be reduced or disrupted.

Study Areas:

- Contribution of deferred or disrupted care to specific increases in mortality and adverse health outcomes.

- Examine changes in reliance on VA healthcare vs. community healthcare How changes in non-COVID health outcomes are influenced by the local severity of the COVID-19 outbreak, state-level and facility-level responses to COVID-19, and patient-level factors

- Assess if efforts to mitigate effects of the pandemic were effective in reducing adverse health impacts

- Understand behavior changes during the pandemic, impact on access or quality of care, and barriers or facilitators to initiating new practices to mitigate interrupted care.

Career Development Award Mentored Research

The narrative page limit is 14 pages.

==Letter of Intent – Deadline October 15, 2021:== reviewed for acceptance

ITS required (ART) Window: ==Oct. 21 - Nov. 4, 2021==

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

Minority Serving Institutions (MSI) Research Scientist Training Program

Letter of Intent – Deadline October 15, 2021: reviewed for acceptance

ITS required (ART) Window: **Oct. 21 - Nov. 4, 2021**
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 1-3
- Follows CDA-2 application format
- Candidate's training, experience and research accomplishments
- Career Plan and Mentoring Plan

Calendar

Date	Event
October 15, 2021	CDA Letter of Intent due
October 21, 2021	ITS Opens and CDA ITS opens
November 4, 2021	ITS Closes and CDA ITS close
November 11, 2021	Waiver deadline
November 15, 2021	Grants.gov opens
November 15, 2021	ITS opens for Involved Personnel
December 8, 2021	Down to the Wire Submission
December 10, 2021	Last Submission Date Grants.gov
December 14, 2021	ITS closes for Involved Personnel
December 15, 2021	Verification Deadline
March 2022	Scientific Merit Review

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

Please direct questions:
ORDCOVI19@va.gov

RFAs

RFAs can be downloaded from the VA ORD intranet site:

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

(VA network access only).

QUERI RFAs

QUERI RFA CyberSeminar
October 8, 2021

1:00 pm ET

Registration link:
https://www.hsrd.research.va.gov/cyberseminars/catalog-upcoming-session.cfm?UID=4042

Questions

vhacoscirev@va.gov
Pandemic-Related Disrupted and Deferred Care RFA:
VHACOHSRDDisruptedCa@va.gov
HSR&D RFAs:
http://vaww.research.va.gov/funding/rfa.cfm

Thank you for your attendance. Please stay safe.

We hope to review your application soon!

HSR&D
VA Health Services Research & Development Service

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