Health Services Scientific Merit Request for Applications Summer 2022

March 31, 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) Grant and Award administrator
    e) Other

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)**

WHAT IS NEW?

- **Updated HSRD Priorities Document (dated March 2022)**

- **Updated HSR&D Gaps in Research (Parent & Pilot RFAs)**

- **Updated SF424 VA Application Guide (Posted ~4/1/2022)**

- **Engagement of Veterans in the Design and Implementation of Research**

- **Director Letters:**
  - **Letter must include language supporting protected time for clinician researchers**

- **Updated guidance for Letters of Support**

- **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 May 15, 2022 and June 14, 2022.**

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 Targeted Solicitation for Service Directed Research on Pandemic-Related Disrupted and Deferred Care	HX-22-025

RFAs can be downloaded from the VA ORD intranet site:

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

(VA network access only).

- 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.

- 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 unpaid 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.

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.

- **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**
- **<mark>Deadline: May 13, 2022</mark>**

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

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:

April 22 – May 6, 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 & 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.

Note: QUERI ITS Window: April 1 – May 13, 2022.

Involved Personnel and Collaborators information in ART.

A list of **ALL NAMED individuals** must be updated in your ITS between **May 15, 2022 and June 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

May 15, 2022   **ITS opens for Involved Personnel**
June 14, 2022   **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**

Project Summary/Abstract is **<u>REQUIRED</u>** 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

Engagement of Veterans in the Design and Implementation of Research

- Most research would benefit from engaging Veterans at all stages of the research process – study design, development, study recruitment, research, dissemination, and implementation.
- Veterans and their care-givers 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.

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.**

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: $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: $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

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.

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;
- 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

PANDEMIC-RELATED DISRUPTED AND DEFERRED CARE

Disrupted Care Merit Applications

- o Up to 2 years
- o Budget may not exceed $700K
- o This RFA is only open to applicants who applied but were not selected for funding from the Summer HX-21-025 or the Winter HX-22-025 RFA.
- o New applications on this topic may be submitted to HX-22-001 or HX-22-002

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

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Goal:

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.

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

Please direct questions: ORDCOVID19@va.gov

The narrative page limit is 14 pages.

Letter of Intent – Deadline April 15, 2022: reviewed for acceptance
ITS required (ART) Window:
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**

Letter of Intent – Deadline April 15, 2022 : reviewed for acceptance
ITS required (ART) Window:
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**

Date	Event
April 15, 2022	CDA Letter of Intent due
April 22, 2022	ITS Opens and CDA ITS opens
May 6, 2022	ITS Closes and CDA ITS close
May 13, 2022	Waiver deadline
May 15, 2022	Grants.gov opens
May 15, 2022	ITS opens for Involved Personnel
June 8, 2022	Down to the Wire Submission
June 10, 2022	Last Submission Date Grants.gov
June 14, 2022	ITS closes for Involved Personnel
June 15, 2022	Verification Deadline
August 2022	Scientific Merit Review

QUERI RFA CyberSeminar
April 11, 2022

1:00 pm ET

Registration link

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!