U.S. Department of Veterans Affairs

Health Services Scientific Merit Request for Applications Winter 2024

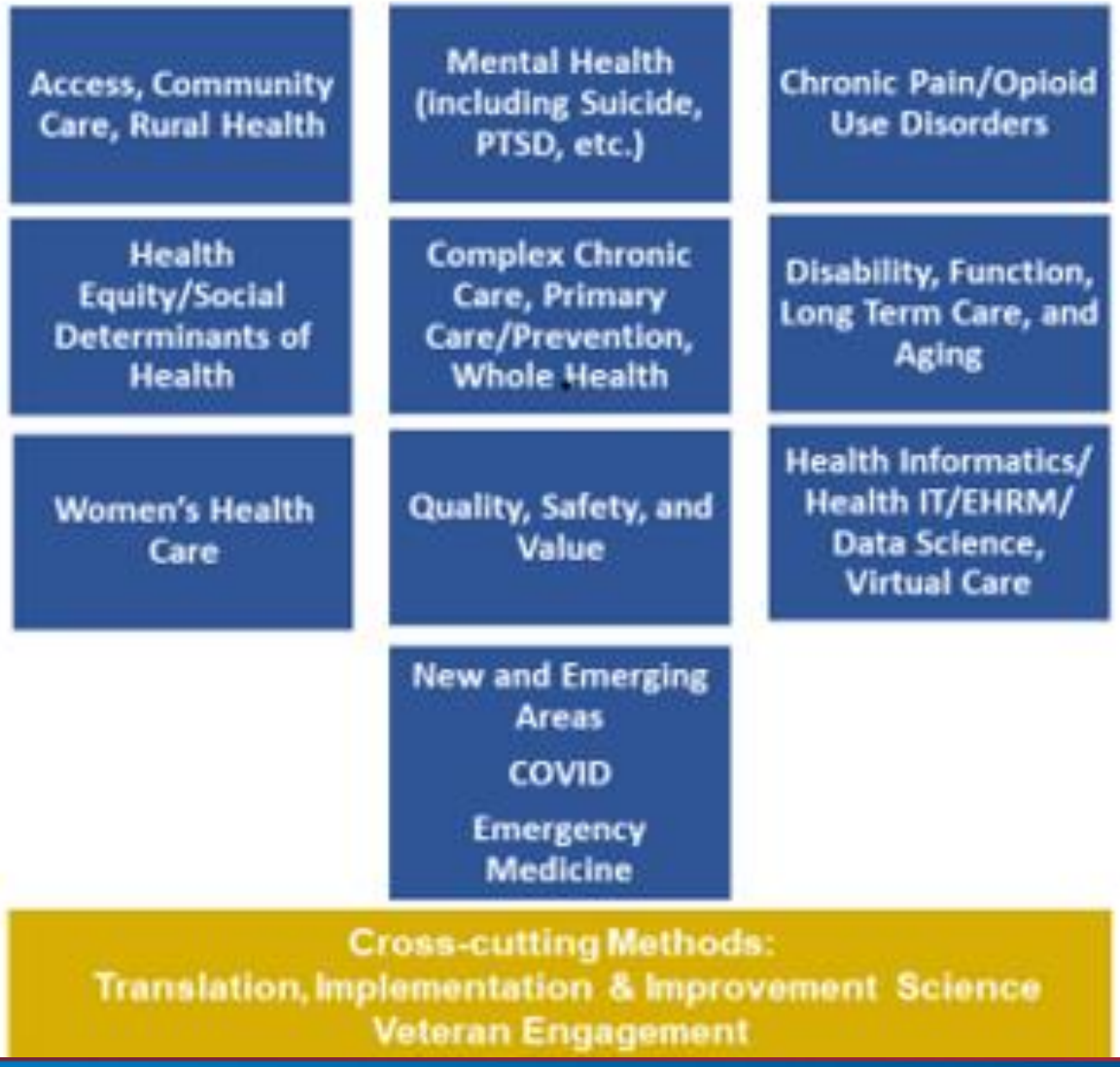
October 2, 2023

WHAT IS NEW?

- Updated information on phenotyping and CIPHER
- New requirement: Million Veteran Program Data Use Request
- Update to Budget Waiver Requests Requirements
  - **Budget waiver requests will not be allowed for new submissions**
- Engagement of Veterans in the Design & Implementation of Research is now a **required section** in the Research Plan
- Veteran Engagement Plan is a **scorable** section of the application

HSR&D RESEARCH PRIORITIES

Health System Portfolio Research Priorities at a Glance



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 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.

WAIVERS

- 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.

NEW THIS CYCLE: Due to budget constraints, HSRD will not accept Budget Waiver requests for first submissions in 2023 and 2024. For Resubmissions, response to reviewer comments should be used to justify changes that require going above the $1.2 million cap.

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

Deadline: November 9, 2023

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

REMINDERS

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, 2023 and December 14, 2023.**

LETTERS OF SUPPORT

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.
- **Your proposal should discuss possible ways you could mitigate the effects of any data disruption.**

NEW: MVP Data Use Request

Goal– ensure that investigators are submitting project proposals that can be done with the MVP data and environment available before the scientific review process

MVP data use request form is in the appendix of the current MVP guidance

- Brief description of aims
- Required data types for project
- Additional software/tools request
- Which service/portfolio/RFA do you plan on submitting to

Rolling submission

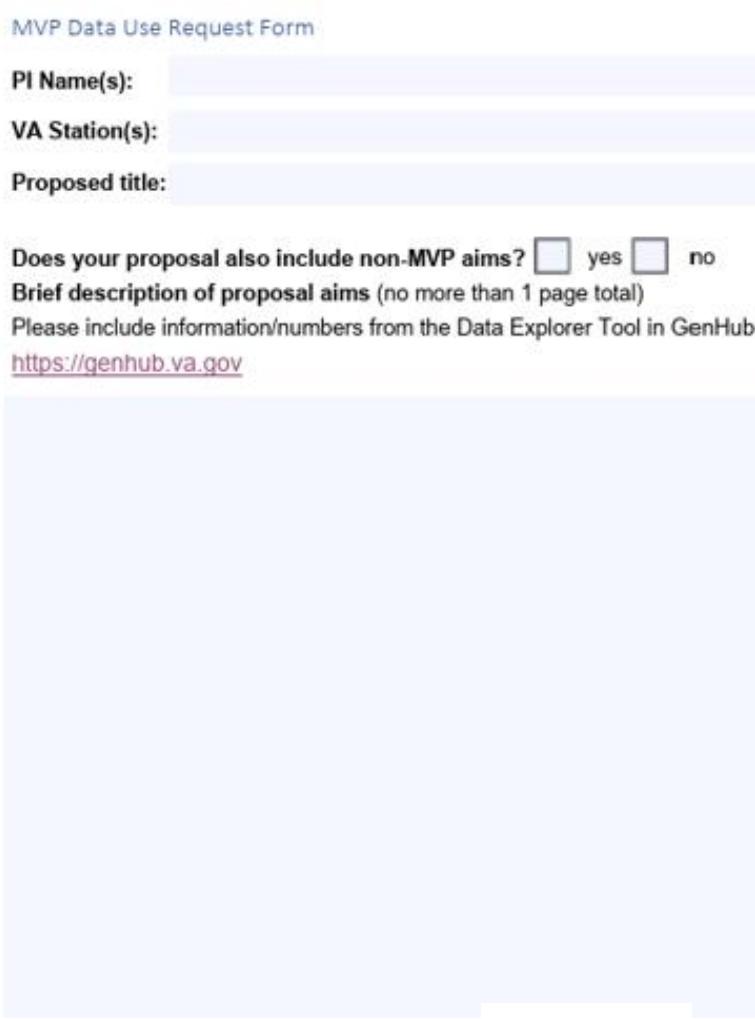
- Ensure that you submit your MVP data use request several weeks prior to the due date for your LOI/preapplication/ITS or full submission. Remember that you may want to leave time for discussion with MVP.
- MVP staff will review your application for feasibility and provide an approval memo

Attach the MVP approval memo to your LOI/ITS/pre-application or full application

Any LOI/ITS/Pre-Application or Merit application with MVP aims that does not have an Approval Memo will be administratively rejected

Detailed guidance available as of 9/19/2023 here: Community - File : GenHub (va.gov)

Questions can be sent to MVPLOI@va.gov


MVP Data Use Request Form

PI Name(s):

VA Station(s):

Proposed title:

Does your proposal also include non-MVP aims? ☐ yes ☐ no

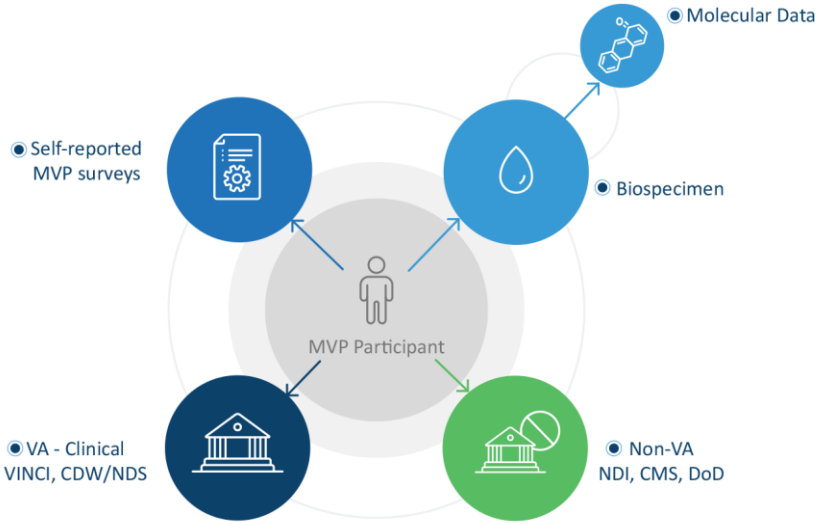
Brief description of proposal aims (no more than 1 page total)

Please include information/numbers from the Data Explorer Tool in GenHub https://genhub.va.gov

ADDITIONAL MVP DATA ACCESS GUIDANCE

1. MVP access is for VA investigators with VA funded research projects with MVP aims
   - The applicant PI and/or MPI (if applicable) should be VA employee(s) and should meet eligibility requirements of the Service/portfolio to which they are applying.
   - Any person on the application requiring access to the MVP data must be research credentialed with a VA appointment OR a without compensation (WOC) VA appointment.

2. MVP data available for request includes:
   - EHR data from VINCI
   - MVP surveys
   - Genotypes (650k), Whole genome sequences (100k), methylation (40k)
   - Nutrition data



3. Regulatory notes:
   - MVP projects are submitted to Central IRB
   - Access to MVP data is project specific
   - MVP data cannot be requested for existing VA projects or non-VA funded projects
   - Bringing in outside data into MVP can be done under certain circumstances and requires a DUA
4. Phenotypes generated through MVP projects should be deposited into CIPHER

CIPHER Program

Centralized Interactive Phenomics Resource

Overview

- **Collection of phenotypes began as part of the Million Veteran Program (MVP)**
- **Formal VA Office of Research and Development (ORD) funding started FY20**
- **CIPHER's directive from VA ORD is to reach 10K phenotypes over 5 years**

Mission

To provide an encyclopedia of VHA EHR-based phenotyping through integration of phenomics work across the VA, to optimize and expedite VA data use for both research and clinical operations and to serve the VA community

https://vhacdwdwhweb100.vha.med.va.gov/phenotype/index.php/VA_Phenomics_Library__Centralized_Interactive_Phenomics_Resource_(CIPHER)

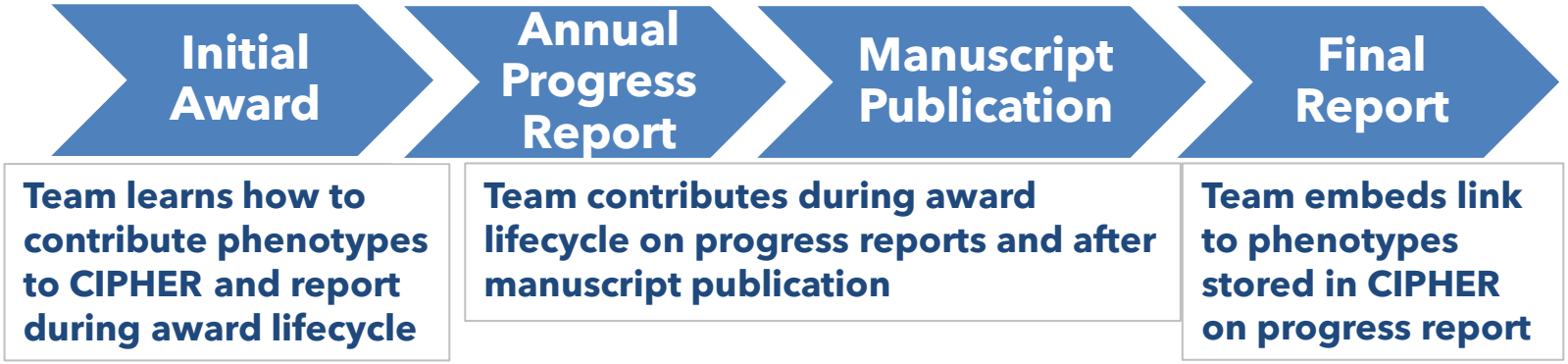
- ✓ Scalability
- ✓ Reusability
- ✓ Efficiency
- ✓ Communication
- ✓ Collaboration

CIPHER as a VA-Wide Resource

- **Part of an enterprise-wide approach to provide a phenotyping resource for ORD supported research**
- **CIPHER collects phenotypes from VA programs and projects, including key partners *(MVP, VINCI, CSP & others)***
- **Support of priority programs**
  - **Office of Mental Health and Suicide Prevention**
  - **Precision oncology**
  - **Military exposures**
  - **Traumatic brain injury**
  - **EHR modernization and interoperability**

CIPHER

VA Awardees Phenotype Contribution During the Award Lifecycle



Messaging to VA awardees

- **Importance of participating in VA-wide expansion of phenomics knowledgebase**
- **Benefits of contributing phenotype algorithms to VA's central knowledgebase including visibility of research, more citations of published work, and enhance collaboration**
- **Becoming a VA SME partner for current and future CIPHER resources and innovation**
- **Access to project specific phenomics metadata for tracking, reporting and dissemination purposes**

- **Note that CIPHER language is already in the current HSRD Merit RFA**

COVID-19

ORD COVID-19 SharePoint site:
https://dvagov.sharepoint.com/sites/vacovhaccomm/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 20 – November 3, 2023

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 approved Letter of Intent (LOI) or an LOI that is under 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 **October 20 – November 3, 2023 .**

This includes PIs, co-investigators, consultants, advisors, anyone listed in the budget, and anyone providing a letter of support

ANYONE NAMED in the application needs to be included. This includes PIs and letter writers.

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, 2023	ITS opens for Involved Personnel
December 14, 2023	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 or VA CBOC, City, State (as applicable) (NOTE: listing just VHA is not sufficient)**
- **Academic Institution(s) or Non-VA Organization Name(s), City, State (as applicable)**
- **If individual has a joint VA and academic appointment, both must be listed**

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 need to explicitly justify the data used to estimate recruitment --
  e.g., pilot data, prior studies, etc. -- and comment on mitigation strategies if recruitment lags.
- We expect you to include a **PLAN B (and PLAN C)** as part of your proposed recruitment strategy.

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-24-001
HSR&D Merit Review Award Pilot Project Program (I21)	HX-24-002
HSR&D Targeted Solicitation for Service Directed Research on Veteran Suicide Prevention	HX-24-005
HSR&D Research Career Development Award (CDA-2)	HX-24-009
VA HSR&D Career Development Award for Scientists Associated with Minority Serving Institutions (MSI-CDA)	HX-24-010
HSR&D Targeted Solicitation for Service Directed Research on Rural Health	HX-24-032

ORD-WIDE REQUEST FOR APPLICATIONS

RFA Description	RFA #
Mentored Physician & Clinical Psychologist Award in Alzheimer's Disease and Related Dementias (MPCPS-ADRD)	HX-24-030
Parent Merit Review Award (Pain and Opioid Actively Managed Portfolio, I01)	HX-24-035
Pain and Opioid Actively Managed Portfolio (POU-AMP) Clinical Trials	HX-24-036
Pain and Opioid Use Actively Managed Portfolio - Pharmacogenomics/Biomarker Studies to Guide Clinical Care in Pain and OUD (I01)	HX-24-037
Pain and Opioid Actively Managed Portfolio (POU-AMP) Pre-application (I02)	HX-23-200

RFAS

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 PROJECT AWARD

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

RURAL HEALTH

- **$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: State of the Art Conference: Rural Health (va.gov)**

RURAL HEALTH

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

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.

CAREER DEVELOPMENT AWARD MENTORED RESEARCH

The narrative page limit is 14 pages.

Letter of Intent – Deadline October 15, 2023: reviewed for acceptance
ITS required (ART) Window: October 20 – November 3, 2023
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 AWARD

Letter of Intent – Deadline October 15, 2023 : reviewed for acceptance
ITS required (ART) Window: October 20 – November 3, 2023
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**

MENTORED PHYSICIAN & CLINICAL PSYCHOLOGIST AWARD IN ALZHEIMER'S DISEASE AND RELATED DEMENTIAS (MPCPS-ADRD)

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

Letter of Intent – Deadline October 15, 2023

- **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)**

POU AMP PRE-APPLICATION

ORD wide Pain Opioid Actively Managed Portfolio (POU AMP) requires a Pre-Application submitted through eRA Commons using the I02 Pre-Application form.

Pre-Application are due November 1, 2023 for Winter 2024 review cycle.

All waivers must be submitted with the pre-application.

PAIN OPIOID AMP PARENT RFA

PD/PIs may request funding for a maximum of four (4) years, based on the total project maximum amount outlined below.

There is no annual budget cap; thus, variable funding may be utilized as long as the overall budget cap (based on years requested) is maintained.

The salary for all personnel, including the contact PD/PI is included in this cap.

1 year = $300,000 max
2 years = $600,000 max
3 years = $900,000 max
4 years = $1,200,000 max

POU AMP SPECIAL EMPHASIS

Parent and Clinical Trial POU AMP RFAs

- Studies of fentanyl adulterated with xylazine
- Harm reduction services and treatment programs
- Development of pharmacological alternatives for treatment of pain and xylazine reversal

POU AMP CLINICAL TRIAL RFA

RFA accepts applications that involve:

- **Clinical research that include treatment regimens in any of the specific aims**
- **Clinical trials (includes a control group) that include treatment regimens in any of the specific aims**
- **Pragmatic clinical trials that include an intervention**
- **Comparative-effectiveness clinical trials that compare different interventions**
- **Implementation of treatments and approaches**

Clinical Trial Award Budget Cap and Duration

Budget Item	Limit for Single Site	Limit for Multi-VAMC Sites
Budget Cap	• For two (2) years, $600,000 • For three (3) years, $900,000 • For four (4) years, $1,200,000	For a 2-site a total: • For two (2) years, $600,000 • For three (3) years, $1,125,000 • For four (4) or five (5) years, $1,500,000 • Additional $100,000 per site per year for each additional site.
Duration	Up to four (4) years	Up to five (5) years

POU AMP PHARMACOGENOMIC/BIOMARKER

- Machine learning and AI methods to extract data from EHR, etc., to determine best course of treatment, or development of chronic pain.
- Studies identifying behavioral, clinical, genetic, and epigenetic risk factors to identify: 1) Individuals with high impact chronic pain (HICP); 2) Individuals at risk of progressing to HICP; 3) Individuals at risk of developing OUD as a result of prescribed opioids.
- Studies identifying factors that may predict responsiveness to specific pharmacologic or nonpharmacologic treatments for chronic painful conditions.
- Prospective studies validating biomarkers etc. to predict treatment approaches for individuals with HICP.

CALENDAR

Date	Event
October 15, 2023	CDA/MPCPS-ADRD Letter of Intent due
October 20, 2023	ITS Opens and CDA ITS opens
November 1, 2023	POU AMP Pre-Application due
November 3, 2023	ITS Closes and CDA ITS close
November 9, 2023	Waiver deadline
November 15, 2023	Grants.gov opens
November 15, 2023	ITS opens for Involved Personnel
December 8, 2023	Down to the Wire Submission
December 12, 2023	Last Submission Date Grants.gov
December 14, 2023	ITS closes for Involved Personnel
December 15, 2023	Verification Deadline
March 2024	Scientific Merit Review

QUESTIONS

vhacoscirev@va.gov

HSR&D RFAs:

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

QUERI RFA seminar:

October 24, 2023 at 2:00 pm ET

REGISTER to attend this session

Pain Opioid AMP RFA seminar

October 3, 2023 at 1:00 pm ET

U.S. Department of Veterans Affairs

Thank you for your attendance.

We hope to review your application soon!