Health Systems Research Winter 2025 Scientific Merit Request for Applications

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Health Systems Research (HSR), Investigators, Scientific Review and Management (ISRM)

What's New for the Winter 2025 Cycle

- **HSR Broad Portfolio (BP) and ISRM research and application process**
  - **Investigators have up to 4 opportunities to submit per year and not limited by Service**
  - **Services converting to Portfolios, most accepting health services-related proposals**
- **Application submission process: Pre-applications required**
  - **Select notice of special interest (NOSI), note opportunities beyond HSR**
  - **Identify scientific merit review group (SRG, SMRB)**
  - **Select cross-portfolio RFA (e.g., clinical trial, non-clinical trial, pilot)**
- **IPA waivers are no longer required**
- **Changes to HSR CDA application submission and review**
  - **HSR will now accept CDA-1 applications, as well as CDA-2 applications**
  - **All CDA applications will be reviewed by the HSR SRGs that meet its purview**
- **The RCS RFA will now be released for the Winter cycle instead of the Fall cycle**
  - **The Winter 2025 RCS RFA will accept NEW and RENEWAL applications**
  - **RCS applications will be reviewed on the MRA0 SRG**
- **QUERI RFAs have not changed (ITS still in effect, no pre-application required)**

New Application Process: Key Steps

Go to: https://vaww.research.va.gov/funding/rfa.cfm#hsr

(VA network access only)

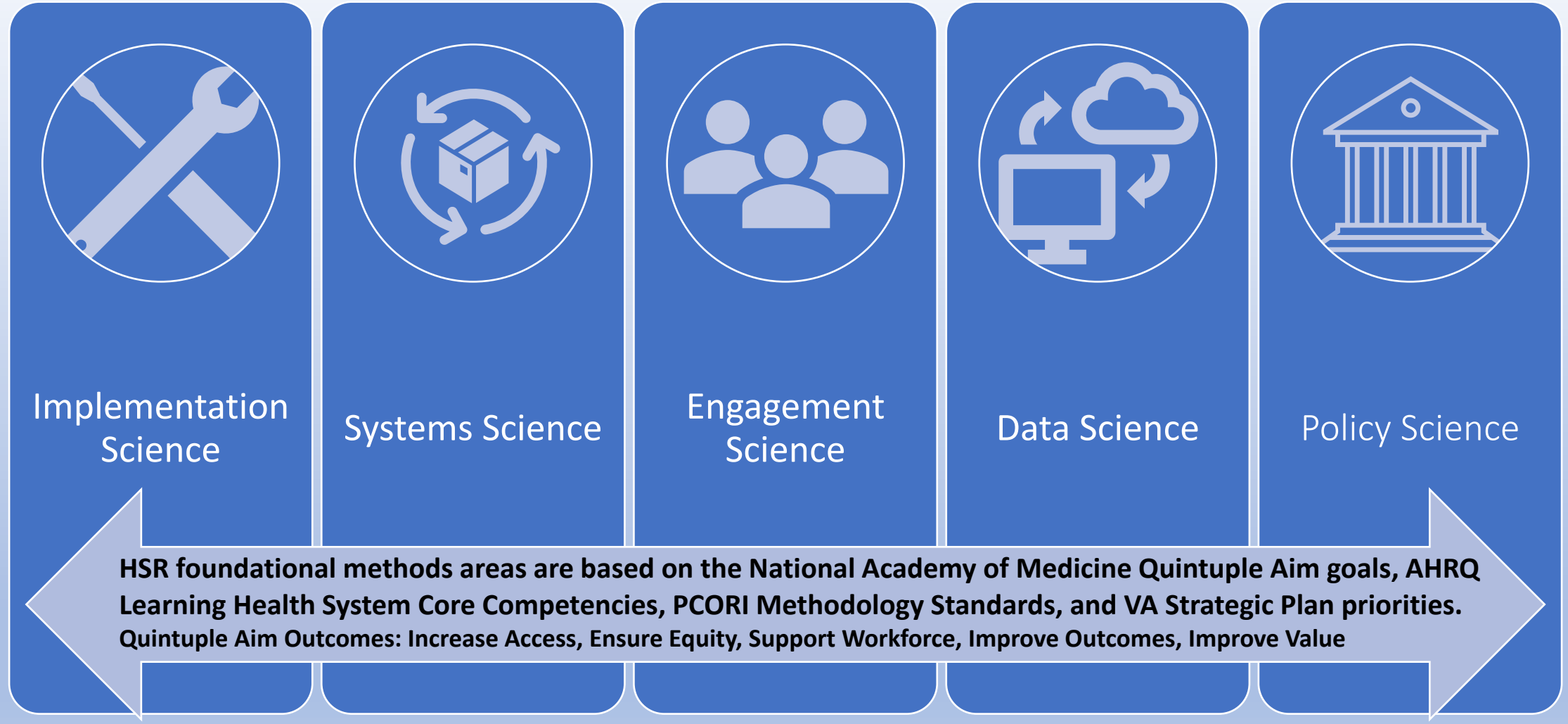
1. Identify the NOSI the application is most responsive to
2. Select study section/SRG: https://vaww.research.va.gov/funding/docs/ISRM-SRG-Purviews-and-Review-Cycles.pdf
3. Choose the appropriate RFA (e.g., IIR, CDA)
4. Contact SRG point of contact with any questions

HSR Mission: What We Fund

*HSR supports groundbreaking science that addresses national **VA priorities** in order to improve **Veteran care access, outcomes, equity, experience, and value,** using foundational **learning health system** methods in implementation, data, engagement, systems, and policy.*

For more information, visit: https://onlinelibrary.wiley.com/doi/10.1111/1475-6773.14374

HSR Foundational Learning Health System Methods



HSR Foundational Methods Support Achievement of Quintuple Aim Goals in Learning Health Systems for a Given Priority

Reference: https://onlinelibrary.wiley.com/doi/10.1111/1475-6773.14374:

1. ***Implementation Science.*** **Discover and optimize strategies to get effective treatments to Veterans faster and sustain their use in real-world practice**
2. ***Data Science.*** **Design, validate, and apply data science and knowledge management tools that improve Veteran health and health care**
3. ***Engagement Science.*** **Create and test novel approaches for engaging end-users (e.g., Veterans, providers, communities, etc.) that support improved outcomes**
4. ***Systems Science.*** **Design and apply new systems science methods to improve Veteran provider workforce effectiveness, satisfaction, diversity, and retention**
5. ***Policy Science/Evaluation.*** **Develop, assess, and improve VA and national policies to improve Veteran outcomes, with a focus on underserved populations**

VA Research has Seven Cross-Cutting Clinical Priorities

Military Environmental Exposures / Toxic Exposures

Posttraumatic Stress Disorder

Suicide Prevention

Traumatic Brain Injury

Precision Oncology

Pain and Opioid Use

Women Veterans' Health

HSR NOSI Priorities Based on VA Leadership, End-User Input

- **Connect Veterans to the soonest and best care:** optimize Veteran access, quality, efficiency, experience, and equity of care across in-person, virtual, and community care services
- **Implement value-based care solutions:** design and refine value-based care models and tools to ensure care provided in the community leads to improved quality of care and outcomes for Veterans
- **Build an integrated delivery network to meet the diverse and changing needs of Veterans:** identify efficient staffing and care models for primary care, specialty care, and mental health services across different regions and health care settings, especially for the aging Veteran population
- **Retain, invest in, and support VA employees:** implement and evaluate programs focused on employee health and well-being, education, zero harm, innovation, leadership development, and technology training

HSR NOSI Priorities Based on VA Leadership, End-User Input

- **Drive a culture of learning, knowledge translation, and innovation:** identify opportunities where emerging technologies (e.g., artificial intelligence (AI), virtual reality), predictive models, and other promising innovations can make VA services more efficient and reduce provider burden associated with burnout
- **Prevent Veteran suicide:** prevent Veteran suicide using a public health approach e.g., partnerships with community service organizations (also see the Suicide Prevention Actively Managed Portfolio NOSI)
- **Address health disparities:** ensure at-risk, underserved, and older Veterans receive early interventions and supportive services to address social determinants of health and preventable harm

For more information on how HSR sets its priorities see: https://onlinelibrary.wiley.com/doi/10.1111/1475-6773.13944

ISRM Transitioned from Services to Portfolios: Key Advantages

- **Tailored support for Veteran needs:** ISRM will transition to a Portfolio-based structure, aligning research funding with specific Veteran health priorities
- **Accelerated research impact:** Actively Managed Portfolios will focus resources on critical areas, driving faster advancements in Veteran care
- **Continued breadth of support:** Broad Portfolios will maintain funding for a diverse range of research, including early-stage discovery, translational studies, and investigator development
- **Enhanced investigator experience**: The new structure will provide streamlined support and resources to facilitate research and innovation, avoids siloing by service or translational stage

New Cross-Portfolio RFAs

RFAs	Corresponding Pre-applications
RD-01-MRA: ISRM Parent Merit Review Award (Non-Clinical Trials/I01)	RD-01-PREM: Pre-Application – Merit Clinical Trial (I01)
RD-01-MRCT: ISRM Parent Merit Review Award (Clinical Trials/I01)	RD-01-PRET: Pre-Application – Merit Non-Clinical Trials (I01)
RD-01-PILT: ISRM Pilot Project Award (I21)	RD-01-PREP: Pre-Application – Pilot (I21)
RD-01-CDA1: ISRM Career Development Award (CDA-1) (IK1)	RD-01-PREC: Pre-Application – Career Development Award (IK1/IK2)
RD-01-CDA2: ISRM Career Development Award (CDA-2) (IK2)	
RD-01-RCS ISRM Research Career Scientist Award (IK6)	RD-01-PRER: Pre-Application – Research Career Scientist (IK6)
RD-01-CTRO: ISRM COnsortia of REsearch (CORE) Award (I50)	RD-01-PRCO: Pre-Application – HSR CORE Awards (I50)

Portfolio Notices of Special Interest

On the Pre-App, indicate the NOSI that best matches the proposal topic

Based upon Portfolio purviews

- Brain, Behavior, and Mental Health Broad Portfolio
- Health Systems Broad Portfolio*
- Medical Health Broad Portfolio
- Rehabilitation Broad Portfolio
- Military Exposure Actively Managed Portfolio
- Pain / Opioid Use Actively Managed Portfolio
- Precision Oncology Actively Managed Portfolio
- Suicide Prevention Actively Managed Portfolio
- Traumatic Brain Injury Actively Managed Portfolio

Critical Research Areas/Cross Portfolio

- Women's Health and Healthcare
- Durability of Rehabilitation Interventions for Veterans
- Chronic Effects of Neurotrauma
- Studies on Lethal Means Safety Approaches to Suicide Prevention

***HSR Broad Portfolio NOSI full name:**

"Optimizing Veteran Health through Evidence-based Learning Health Systems Science Broad Portfolio:"
https://vaww.research.va.gov/funding/docs/broad/NOT-RD-01-HSR-BP.pdf

Other ISRM NOSIs Include Health Systems Research Topics

Take the opportunity to carefully review the cross-portfolio RFAs/Pre-applications, and NOSIs relevant to your areas of research.

Cross-portfolio RFAs include implementation science and engagement science, and most NOSIs cover HSR-related topics.

With a centralized RFA process, the potential funding pool is wider especially if responding to another Broad Portfolio than if applying for HSR-specific funding only.

Examples of HSR Topics in other NOSIs

Military Exposures Research Program: https://vaww.research.va.gov/funding/docs/amp/NOT-RD-01-MER-Military-Exposures-AMP.pdf
e.g., "Studies addressing military toxic exposures which have adverse health outcomes for Women Veterans."

Precision Oncology: https://vaww.research.va.gov/funding/docs/amp/NOT-RD-01-POP-Precision-Onco-AMP.pdf:
e.g., "Quality Assessment: Improve quality assessment for precision oncology research with a focus on safety, effectiveness, equity, patient centeredness, timeliness, and efficiency."

Studies on Pain and Opioid Use: https://vaww.research.va.gov/funding/docs/amp/NOT-RD-01-POU-Pain-Opiod-AMP.pdf
e.g. "Identification and evaluation of environmental, social, and policy changes addressing social determinants to prevent opioid misuse (including policies related to telehealth/virtual care, Veterans benefits, jail diversion programs, etc.)."

TBI: https://vaww.research.va.gov/funding/docs/amp/NOT-RD-01-TBI-AMP.pdf
e.g., "Development and implementation of strategies that will increase the completion rate for Comprehensive TBI Evaluation for Veterans screening positive for TBI"

Winter – Summer Cycle Scientific Review Groups

Full list of ISRM SRGs: https://vaww.research.va.gov/funding/docs/ISRM-SRG-Purviews-and-Review-Cycles.pdf

Brain, Behavioral & Mental Health	Health Systems Research	Medical Health	Rehabilitation R&D & Translation
HSR4: Mental and Behavioral Health	**HSR1:** Health Care & Clinical Management	**CARA/B:** Cardiology	**RRDA:** Spinal Cord Injuries/Disorders & Neuropathic Pain
MHBA: Preclinical Mental Health	**HSR2:** Behavioral, Social & Cultural Determinants of Health	**CAMM:** Cellular & Molecular Medicine, Geroscience	**RRD0:** Regenerative Rehabilitation Medicine
MHBC: Clinical Mental Health	**HSR3:** Health Care Informatics	**ENDA:** Endocrinology,	**RRD2:** Musculoskeletal Health & Injury
MHBP: PTSD	**HSR5:** Health Care System Organization & Delivery and Women's Health	**ENDB:** Frailty, musculoskeletal health	**RRD3:** Sensory Systems & Communications Disorders
NURA: Substance Abuse	**HSR6:** Long Term Care & Aging & Support Services	**GAST:** Gastroenterology	**RRD5:** Rehabilitation Engineering & Prosthetics/Orthotics
NURB: Peripheral Neuropathy & Epilepsy	**HSR7:** Capacity Building	**HEMA:** Hematology	**RRD6:** Chronic Medical Conditions & Aging
NURC: SCI & TBI	**MRA0:** Research Career Scientist	**IMMA:** Immunology	**RRD7:** Research Career Scientist
NURD: Alzheimer's Disease, Dementia, Aging Brain, Neurodegeneration and Cognitive Dysfunction	**HSR8:** QUERI	**INFA/B:** Infectious Diseases	**RRD8:** Career Development Program- Panel 1
NURE: Movement Disorders, Parkinson's, Huntington's, ALS, Dystonia, Neurodegeneration	**HQ5, HQ8:** QUERI	**NEPH:** Nephrology	**RRD9:** Career Development Program – Panel 2
NURF: Sensory Dysfunction		**ONCA/B/C/D/E:** Oncology	**RRDC:** Centers/REAPs
NURR: Sleep		**PULM:** Pulmonology	**MRA1:** Mentored Physician and Clinical Psychologist Scientist Award in Alzheimer's Disease and Related Dementias (MPCPS-ADRD)
NURP: Pain		**SPLD:** GW	
RRD1/B: Brain Health		**SURG:** Surgery	
RRD4: Behavioral Health & Social Reintegration			

Spring – Fall Cycle Scientific Review Groups

Full list of ISRM SRGs: https://vaww.research.va.gov/funding/docs/ISRM-SRG-Purviews-and-Review-Cycles.pdf

Brain, Behavioral & Mental Health	Health Systems Research	Medical Health	Rehabilitation R&D & Translation
HSR4: Mental and Behavioral Health	**HSR1:** Health Care & Clinical Management	**CARA/B:** Cardiology	**RRDA:** Spinal Cord Injuries/Disorders & Neuropathic Pain
MHBA: Preclinical Mental Health	**HSR2:** Behavioral, Social & Cultural Determinants of Health	**CAMM:** Cellular & Molecular Medicine, Geroscience	**RRD0:** Regenerative Rehabilitation Medicine
MHBC: Clinical Mental Health	**HSR3:** Health Care Informatics	**ENDA:** Endocrinology,	**RRD2:** Musculoskeletal Health & Injury
MHBP: PTSD	**HSR5:** Health Care System Organization & Delivery and Women's Health	**ENDB:** Frailty, musculoskeletal health	**RRD3:** Sensory Systems & Communications Disorders
NURA: Substance Abuse	**HSR6:** Long Term Care & Aging & Support Services	**GAST:** Gastroenterology	**RRD5:** Rehabilitation Engineering & Prosthetics/Orthotics
NURB: Peripheral Neuropathy & Epilepsy	**HSR7:** Capacity Building	**HEMA:** Hematology	**RRD6:** Chronic Medical Conditions & Aging
NURC: SCI & TBI	**MRA0:** Research Career Scientist	**IMMA:** Immunology	**RRD7:** Research Career Scientist
NURD: Alzheimer's Disease, Dementia, Aging Brain, Neurodegeneration and Cognitive Dysfunction	**HSR8:** QUERI	**INFA/B:** Infectious Diseases	**RRD8:** Career Development Program- Panel 1
NURE: Movement Disorders, Parkinson's, Huntington's, ALS, Dystonia, Neurodegeneration	**HQ5, HQ8:** QUERI	**NEPH:** Nephrology	**RRD9:** Career Development Program – Panel 2
NURF: Sensory Dysfunction		**ONCA/B/C/D/E:** Oncology	**RRDC:** Centers/REAPs
NURR: Sleep		**PULM:** Pulmonology	**MRA1:** Mentored Physician and Clinical Psychologist Scientist Award in Alzheimer's Disease and Related Dementias (MPCPS-ADRD)
NURP: Pain		**SPLD:** GW	
RRD1/B: Brain Health		**SURG:** Surgery	
RRD4: Behavioral Health & Social Reintegration			

HSR Scientific Review Groups and Points of Contact

Full list of ISRM SRGs: https://vaww.research.va.gov/funding/docs/ISRM-SRG-Purviews-and-Review-Cycles.pdf

HSR1: Health Care and Clinical Management	**Cathie Plouzek, Ph.D.** **Cathie.Plouzek@va.gov**	**Health care systems and delivery (HSR1) reviews research on medical care; medical/surgical management; provider preferences and behaviors; diagnosis; prognosis; best practices; guidelines; quality and safety of health care; chronic pain management; opioid use and management; POU AMP; pharmacology; and pharmacotherapeutics.**
HSR2: Behavioral, Social, and Cultural Determinants of Health and Care	**Crystal Henderson, Ed.D.** **Crystal.Henderson1@va.gov**	**HSR2 reviews research on patient preferences, perceptions, and behaviors (including engagement and self-management); personal, sociodemographic, rural health, and cultural factors affecting health and health care (patient/ population/ provider/ community); complementary, alternative or integrative health; patient decision-making; focused patient-centered health care improvements and innovations; care of Gulf War Veterans, homelessness/ housing, economic security and social determinants, whole health, patient-provider interactions and communication; population-based programs and policies affecting populations with disparities in health (underserved populations, LGBTQIA+, etc.); and health equity.**

HSR Scientific Review Groups and Points of Contact

Full list of ISRM SRGs: https://vaww.research.va.gov/funding/docs/ISRM-SRG-Purviews-and-Review-Cycles.pdf

HSR3: Healthcare Informatics & Access to Care	**Lolita Kachay, MPH** **Lolita.Kachay@va.gov**	**HSR3 reviews research in informatics, data science, and health information technology (HIT) tools and systems to enhance effectiveness, efficiency, and quality of VHA care, including impact of new information technology on patient experience, clinical analysis of big data to generate new evidence and scientific discovery (MVP data; genomics data, phenotypic data; emerging health data, CIPHER); development, testing and evaluation of novel and innovative digital HIT tools, emerging health data standards, ethical/trustworthy use of data and artificial intelligence tools, EHR Modernization and research methods; and access to care and related factors that affect access to care.**
HSR4: Mental and Behavioral Health	**Joe Constans, Ph.D.** **Joseph.Constans@va.gov**	**HSR4 reviews research using health systems methods and outcomes related to assessment, treatment, and prevention of mental health conditions (such as anxiety, depression, serious mental illness, and PTSD) and behavioral health disorders (such as substance use disorder and other addictive disorders); suicide prevention and suicide ideation; mental health-primary care integration (MH-PCI); measurement-based care; access to and delivery of mental health and behavioral health care.**

HSR Scientific Review Groups and Points of Contact

Full list of ISRM SRGs: https://vaww.research.va.gov/funding/docs/ISRM-SRG-Purviews-and-Review-Cycles.pdf

HSR5: **Health Care System Organization and Delivery and Women's Heath**	**Amanda Borsky, Dr.PH., MPP** **Amanda.Borsky@va.gov**	**HSR5 reviews research on (1) healthcare delivery for all Veterans and/or (2) women Veteran's health and healthcare, especially in health areas that affect women Veterans uniquely, disproportionately, or differently from men. This includes research on organizational models, interventions, or policies affecting delivery of care across systems (e.g., different care settings or healthcare systems). It also includes best practices in implementation of health care interventions and improvements, methods to improve the efficiency and quality of care for Veterans, systems science including health care efficiency and redesign, value-based care, resource optimization, and human factors affecting care. Women's health and healthcare research is focused on improving healthcare delivery across the lifespan for women Veterans to address their unique healthcare needs and lingering sex- and gender-based disparities in care.**
HSR6: **Aging, Recovery, and Workforce**	**Amelia Schlak, Ph.D., RN** **Amelia.Schlak@va.gov**	**HSR6 reviews applications on research focused on three broad areas: (1) aging; (2) quality of life and recovery during activity, mobility and exercise; and (3) workforce practice, management, and outcomes.** **1. Aging related health issues, their medical management, and outcomes. Care settings that are focused on aging populations. Additional areas of interest include caregiving, palliative services, end-of-life care, and supportive services (e.g., transportation; respite).** **2. Quality of life and recovery during activity, mobility and exercise. This includes studies related to neurological disorders and spinal cord injury.** **3. VA workforce outcomes such as burnout, turnover, retention, engagement, and performance. Note: Workforce is not specific to any care setting or medical specialty.**

HSR Scientific Review Groups and Points of Contact

Full list of ISRM SRGs: https://vaww.research.va.gov/funding/docs/ISRM-SRG-Purviews-and-Review-Cycles.pdf

HSR 7 – Capacity Building	**Bonnie J. BootsMiller, PhD** **Bonnie.BootsMiller@va.gov**	**Capacity building in Learning Health Systems methods, health systems research knowledge management, including curation of research, data sources, and impacts pertaining to VA and ORD priority topics with an emphasis on Veteran Quintuple Aim goals across the translation spectrum. Consortia of Research (COREs)**
MRA0 – Research Career Scientist	**Bonnie J. BootsMiller, PhD** **Bonnie.BootsMiller@va.gov**	**Research Career Scientist applications: new and renewals**

HSR Scientific Review Groups and Points of Contact

Full list of ISRM SRGs: https://vaww.research.va.gov/funding/docs/ISRM-SRG-Purviews-and-Review-Cycles.pdf

HQ5/HQ8 - QUERI	**Kara Beck, PhD** **Kara.Beck@va.gov**	**QUERI: Partnered initiatives/centers focused on addressing VA priorities, supporting VHA's transformation to a Learning Health System, and moving the needle on quality of care for Veterans by leveraging evidence-based implementation, evaluation, and/or quality improvement non-research methods and partnering closely with health system leaders, managers, and frontline staff to support the uptake of effective programs, policies, and practices across VHA.**

Note: Examples of other SRGs that review HSR-related topics involving clinical outcomes/epidemiology include:
Mental Health- Clinical (MHBC) or MHBP (for PTSD): clinical studies of the etiology, pathobiology, diagnosis and treatment of psychiatric and behavioral disorders including psychotic disorders, mood and anxiety disorders.
Neurobiology – Dementia [NURD]: neurodegenerative conditions, e.g., Alzheimer's disease and its related dementias
RRD4: Behavioral Health & Social Reintegration, etc., etc.- see full list of SRGs
HSR no longer has a separate panels for CDAs, each panel reviews all applications for the HSR BP that meet the SRG's purview

Updated Review Process for HSR Investigators

ISRM Notices of Special Interest (NOSIs) and Requests for Applications (RFAs) (va.gov)

1 Align on Portfolio & SRG Scope

The investigator reviews NOSIs and RFAs and picks the Portfolio and SRG with the appropriate purviews for their proposed study.

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2 Pre-Application Submission

Complete the standardized pre-application providing basic project information and the requested cross-portfolio RFA and SRG and submit to the Portfolio Pre-Application RFA in eRA for approval.

→

3 Application Submission

Upon approval of your Pre-application in eRA, submit a full application through the ORD-Wide RFA including the approval letter which indicates the NOSI being responded to and the assigned SRG.

→

4 Receive Funding Decision

The investigator receives scores and summary statement and an intent-to fund (if applicable).

- All Pre-application RFAs provide detailed information on how to complete the SF-424 cover page and what information is needed on the Pre-application cover page
- Applications previously reviewed on an HSR SRG will be considered resubmissions to the new ISRM RFAs and the Pre-applications detail how you should identify your resubmissions
- Submit waiver requests through the pre-application (Note: waivers for IPAs no longer required)
- Approved waivers for resubmissions prior to October 1st will be honored and must be included in the Pre-application and full application. Note: approved waivers are rare and considered on a case-by case basis by ISRM Leadership Council

ISRM Pre-application RFA Timing for the Winter 2024 Cycle

- **Clinical Trials, Career Development, RCS and Tech Transfer Awards**
  - Pre-applications due **October 1, 2024**
  - Administrative + Technical review with feedback
  - Stations notified of concerns/disapprovals within 4 weeks of receipt via eRA
  - Exceptions needed for 10/1/24 deadlines
- **Merits, Pilots, and CORE RFAs**
  - Pre-Applications due **November 1, 2024**
  - Administrative review with optional technical review and feedback
  - Stations notified of concerns/disapprovals within 3 weeks of receipt via eRA

New Review Timeline Due Dates

	Winter 2025 Cycle	Summer 2025 Cycle
CT, CDA, TT Pre-apps	10/1/2024 *(8/1 for future Winter cycles)*	2/1/2025
MVP data use apps	10/1/2024	4/1/2025
Other Research Pre-apps	11/1/2024	5/1/2025
DTTW deadline for full	12/8/2024	6/8/2025
eRA closes to full apps	12/10/2024	6/10/2025

ISRM Parent Merit Review Award (Non-Clinical Trials/I01): RD-01-MRA

- PI may receive funding for up to 3 Merit awards.
- Non-clinician PI salary, 3/8 allowed above the cap for corresponding PI only. Any additional salary requirements must be taken from the research award.
- $200K per year cap for up to 4 years
- Waivers approved by the ISRM Leadership Council (must be submitted with Pre-application)

ISRM Parent Merit Review Award (Clinical Trials/I01): RD-01-MRCT

- No restriction on the number of trials per investigator (but need to track).
- Non-clinician PI salary paid under the budget cap (may add the 3/8 above the cap for future rounds)

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 For a 3 or more sites a total: • Additional $100,000 per site per year for each additional site added to total budget cap
Duration	Up to four (4) years	Up to five (5) years

- Budget cap waivers approved by the ISRM Leadership Council (must be submitted with Pre-application)

ISRM Pilot Project Awards (IK2): RD-01-PILT

- At least 5/8 VA employed at time of funding
- VA or VA-leased space assigned to the investigator
- Waivers can be requested from the portfolio when submitting your Pre-application and will be approved by the ISRM Leadership Council

ISRM Career Development Award (IK1/IK2): RD-01-CDA1/RD-01-CDA2

- **HSR will now accept CDA-1 applications as well as CDA-2 applications**
- **CDA applications will be reviewed by the HSR SRGs that align with their respective purview**
  - Resubmission applications assigned to the original SRG unless otherwise requested.
- **Be sure to review SRG descriptions to determine appropriate SRG (**https://vaww.research.va.gov/funding/rfa.cfm)

ISRM Career Development Award (IK1/IK2): RD-01-CDA1/RD-01-CDA2

- CDA-1
  - This award is intended for individuals early in their research career who are no more than two years past award of their terminal degree or clinical training experience following the terminal degree and do not currently hold or previously held independent peer-reviewed funding
  - Duration: 2 years
  - Funding: PI salary and up to $40,000 in research support
  - Narrative page limit is 9 pages

ISRM Career Development Award (IK1/IK2): RD-01-CDA1/RD-01-CDA2

- CDA-2
  - For early career researchers with one first author publication in a relevant discipline
  - Clinician applicants
    - no more than 10 years past terminal degree
    - and not more than 5 years past their most recent clinical training
  - Non-clinician applicants
    - must be no more than 5 years past award of the terminal degree or most recent training
  - Duration: 3 to 5 years
  - Funding: PI salary and up to $75,000 in research support per year
    - Applicants may request a first-year supplement (< $30,000) must be identified in the pre-application
  - Narrative 19-page limit

ISRM Research Career Scientist Award (IK6): RD-01-RCS

- Source of funding will come from new Broad Portfolios
- A VAMC may submit a total of two new or revised RCS applications to each Broad Portfolio
- Resubmissions are allowed – ORD will accept up to 2 revised applications
- No limits on renewals
- HSR will accept new & renewal applications for Winter 2025 review cycle
- Current, non-clinician VA investigators are eligible to apply

ISRM Consortia of Research (CORE) Award (I50): RD-01-CTRO

- COREs are interdisciplinary centers that promote VA research impacts in a high-priority areas
  - Work closely with relevant VA-ORD Broad and/or Actively Managed Portfolios and VA national Program Offices, and include investigators across the translation spectrum

- Goals
  - enhance collaboration
  - promote partner engagement in research
  - help move research toward implementation into practice

- Funding is $500,000 for a maximum of 5 years

CORE Major Activities

- Curate prioritized set of research initiatives and summarize the state of the research in the topic area by translation spectrum
- Assess and report impacts of research and evaluation activities for VA-ORD and the greater scientific community
- Identify effective interventions, programs, and policies ready for further evaluation, dissemination, and/or implementation
- Identify and curate novel and existing data and infrastructure resources for researchers and relevant program offices
- Cultivate a collaborative network of researchers and program partners
- Assist VA-ORD and partners in providing timely responses to key stakeholders

CORE Priority Areas: FY25

1. Access/Community Care (funded through November 2028)
2. Virtual Care (funded through May 2025)
3. Women's Health (funded through September 2026)
4. Health Care Workflow Efficiency
5. Housing/Economic Security/Homelessness
6. Cancer/Precision Oncology
7. Caregiving/Long Term Care/Aging
8. Traumatic Brain Injury/Brain Health
9. Artificial Intelligence/Digital Health

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.

- **Waiver Categories:**
  - **Offsite Research**
  - **Exceeding Duration or Budget Cap**
  - **PI Eligibility**

Deadline: See RFAs

Waivers

- **Copy of waiver approval letters must be included in the "Letters of Support" section of the application.**

- **Missing letters are considered fatal errors.**

- **Recruitment of Non-Veterans:**

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

Requirements for Full Application

MANDATORY REQUIREMENT:

A table of contents for the letters of support that lists each letter writer's:

- **Name**
- **Position**
- **Office/institution**
- **Director's Letter must include language supporting protected time for clinician researchers**

Letters of Support

- A single letter of support from all individuals at the same institution is OK:
  - If all individuals at the institution sign the letter.
- Individual letters are still acceptable.
  - PD/PI
  - Co-investigators
  - Collaborators & consultants (VA & non-VA)
  - Program Offices
  - Other Stakeholders

Inclusion of Women

- VA mandates that all research proposals reviewed and funded by ORD include women in their study populations to the extent possible. See Part II of the VA-ORD SF 424. This can help ensure that results are applicable to all Veterans.
- When Human Subjects are involved in the proposed research, reviewers will assess the consideration of sex and/or gender especially in health areas and conditions that affect women Veterans uniquely, disproportionately, or differently from men. This includes considering where applicable:
  - Plans to include subjects from all sex and/or gender groups that are broadly representative and consistent with the specific goals of the project;
  - The adequacy of representation by sex and/or gender, taking into account the prevalence of the condition by sex and/or gender among the Veteran population; and
  - Whether there are plans to investigate or report study findings or differences by sex and/or gender to advance knowledge for women's health.

Guidance on recruitment of women Veterans is available from the Women's Enhanced Recruitment Process (WERP) toolkit at: https://cipherwiki.va.gov/phenotype/index.php?title=WERP_Toolkit.

Notable Sections in RFAs: End-User Engagement

- **Engagement of End-Users (e.g., Veterans, Providers) in the Design and Implementation of Research**
  - Aligns with Learning Health System Engagement Science Core Methodology
  - Veterans, caregivers, and the frontline clinicians who care for them can provide important insights into what outcomes matter most, and the feasibility and acceptance of the proposed interventions and study designs.
  - Options for obtaining input include interaction with Veteran engagement groups as well as including Veterans on the research team, and for clinicians, interaction with the providers at the involved study sites as well as field advisory committees sponsored by VHA national program offices.
- Contact QUERI Center for Evaluation and Implementation Resources for clinician and frontline provider engagement best practices, as well as input on relevant local, regional, and national VA clinician groups
- CyberSeminar: How to Integrate Veteran Engagement from Research Plan to Publication
- Toolkit: Strengthening Excellence in Research through Veteran Engagement (SERVE) Toolkit 2.0

Notable Sections in RFAs: Dissemination & Implementation

- Dissemination of manuscripts and to partners is insufficient to lead in reducing the 17-year research to practice gap
- Explicitly discuss next steps after project is completed to move the research along the translational pathway and/or into practice
- Collect exploratory study data on Veteran/patient, provider, clinical manager, and leadership perspectives regarding feasibility of scaling up intervention (if proven effective)
- Need to consider who "owns" the problem the study is attempting to solve
  - Identify potential barriers to further implementation, and how to overcome
  - Who will be the partner to implement the project? Letters of support to demonstrate commitment of local, regional and national VA partners
- Studies of interventions should consider how they can collect information relevant to implementation during the efficacy/effectiveness study (e.g., use of hybrid designs)
- For more information visit the HSR/QUERI Center for Evaluation and Implementation Resources (https://www.queri.research.va.gov/ceir/ceir.cfm) and HSR/QUERI Evidence, Policy, and Implementation Center (EPIC): https://www.queri.research.va.gov/EPIC-Executive-Summary.pdf

Human Subjects Recruitment

- A large proportion of studies fail to meet recruitment goals.
- Trials need to explicitly justify the data used to estimate recruitment --
  - e.g., pilot data, prior studies, etc.
  - comment on mitigation strategies if recruitment lags.
- Include a PLAN B as part of your proposed recruitment strategy.

Million Veteran Program (MVP) Data Use

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

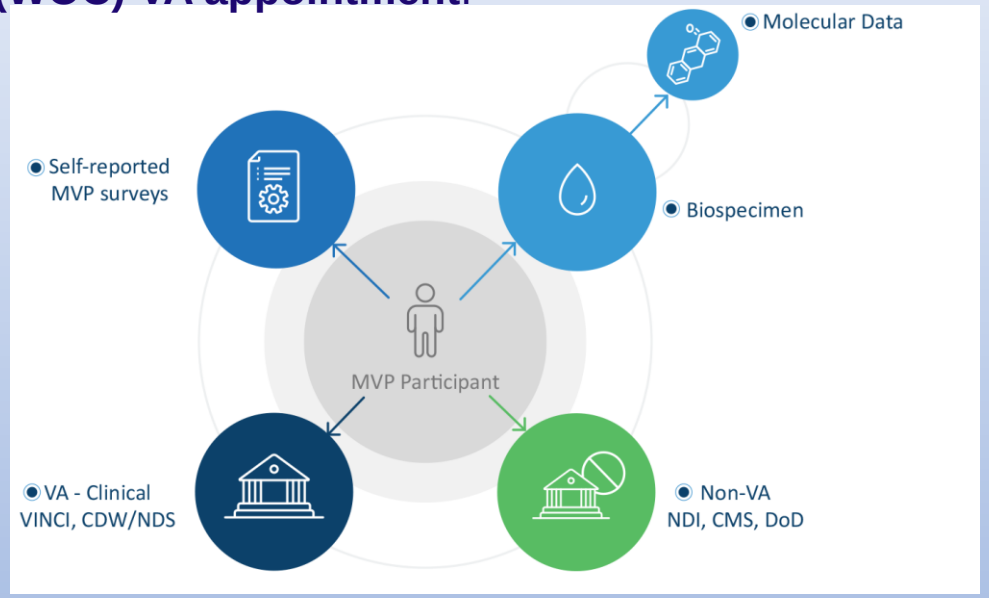
https://genhub.va.gov

MILLION VETERAN PROGRAM

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

Centralized Interactive Phenomics (CIPHER) Program

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

Recap: New Application Process: Key Steps

Go to: https://vaww.research.va.gov/funding/rfa.cfm#hsr

(VA network access only)

1. Identify the NOSI the application is most responsive to
2. Select study section/SRG: https://vaww.research.va.gov/funding/docs/ISRM-SRG-Purviews-and-Review-Cycles.pdf
3. Choose the appropriate RFA (e.g., IIR, CDA)
4. Contact SRG point of contact with any questions

Dates to Remember or the Winter 2025 Cycle

Winter 2025 Cycle Event	Date
Clinical Trials/CDA/RCS Pre-applications due	10/1/2024
MVP Data Use Applications Due	10/1/2024
Parent/Pilot/CORE RFA Research Pre-applications Due	11/1/2024
Down to the Wire Deadline for Full Applications	12/8/2024
Last Day to Submit Full Applications	12/10/2024

ADDITIONAL CONTACT INFORMATION

General questions should be sent to the ISRM mailbox: VHAISRM@va.gov

For Grants.gov or eRA Commons questions/issues: vhacordera.vhacordera@va.gov

CDA specific questions should be sent to the CDA mailbox: VHACADEReview@va.gov

Clinical trial questions should be sent to the CT mailbox: clin-review@va.gov

Answers to Frequently-Asked Questions

1. **The HSR and RDT Broad Portfolio NOSIs are Silent on non-clinician application limits. Please confirm that pre-applications submitted to these Broad Portfolio NOSIs have NO limit to how many NEW non-clinicians can apply per round of review.**

The restriction is based on the cycle not the portfolio, and Winter and Summer cycles have no limits on new non-clinician applicants.

2. **Similarly, the AMP NOSIs are silent on non-clinician application limits. Are pre-applications accepted for review to one of those AMP NOSIs without new non-clinician limits, even if the applications are reviewed by MedHealth or BBMH review panels?**

If the AMP NOSI is silent on non-clinician application limits then the limitation would be determined by the review cycle in which the requested Scientific Review group was meeting (Winter and Summer cycles have no limits)

3. **What if you have been a PI on funded Merit research in the past but are currently VA-paid as a Co-I, but not a PI (i.e. your own funding as PI has lapsed for > 12 months but you collaborate on other Merit work as Co-I)? Must you be a PI on current Merit funding to be considered an existing and not new non-clinician investigator?**

In that situation the PI would be considered "new."

4. **If non-clinician carries more than one award, can they request up to 3/8ths outside of the cap from each funded award? E.g. if three funded Merits, could full salary be covered outside of budget caps?**

They can request an additional 3/8 on a 2nd merit award and an additional 2/8 on a 3rd award.

Answers to Frequently-Asked Questions

5. Will new budget caps allow for non-clinicians to be full time within the VA system? There is some concern that this may drive investigators outside of the VA system for salary support, particularly those who have been fully supported under BLR&D.

To be full-time would require more than one merit award (or support from a center).

6. While on the topic of budget caps, can you confirm that the omission of allowance for one-time start-up costs (up to $50,000 in old RFAs) is intentional, and that start-up costs will no longer be allowed in Merit budgets, separate from the overall budget cap?

With the increase in the cap that was intentionally dropped.

7. Will there be a limit to the number of MERITs that a PI can hold? 3 Per Broad Portfolio? All 3 could be in one portfolio/AMP. Per AMP? Any overall limit in Merits across all Portfolios? 3

8. The new IRSM regulations indicate that work must be "conducted fully in VA or VA-leased space."

Our academic affiliate does not charge the VA rent for research space for VA Research performed at the affiliate; therefore, this is not VA leased space.

9. Will VA Research no longer be allowed at the academic affiliate in this situation? Full off-site waivers will be granted rarely and only with strong justification.

Answers to Frequently-Asked Questions

10.What is the threshold for granting waivers by the ISRM Leadership Council?

Partial offsite waiver requests with appropriate justification will be granted.

11. It appears that pre-application requirements are now quite extensive, including a 4-page "Research Plan" format. This will be new to BLR&D investigators and there is concern over how much "scientific review" is being done during the pre-application stage, rather than through peer review as it should be.

The pre-application is to allow ISRM to review portfolio and SRG assignments and plan SPM workloads, not for "scientific review."

12. Will a full pre-application be required for each round now in all portfolios, and is it expected to be updated in response to reviewer comments?

Full pre-applications are required for A1s and A2s

13. If so, the 8-week lead time may preclude the ability to receive and respond to reviewer comments.

If the reviewer comments are not available at the time that the pre-application is submitted that should be noted in the pre-application.

THANK YOU!

Questions?