

VA Intramural Research Award Program Panel Discussions

Investigators, Scientific Review and Management (ISRM)

Chris Bever, MD, MBA: Deputy to the DCRADO, ISRM; Amy Kilbourne, PhD: Acting DCRADO for ISRM; Joseph Constans, PhD: Suicide Prevention; Stuart Hoffman, PhD: Traumatic Brain Injury; Carol Fowler, PhD/Cathie Plouzek, PhD, PMP: Pain & Opioid Use Disorder





In 2025 ORD will celebrate its 100-year anniversary!



Preparing for the next 100 years!

- New organizational structure built around Veteran needs and designed to improve health system performance.
- New processes to accelerate innovation, speed implementation and rapidly respond to changing requirements.



ISRM Organization

DRCADO ISRM, Amy Kilbourne

Special Assistant to DRCADO ISRM, Pauline Cilladi-Rehrer ISRM Leadership Council

Broad Portfolio (BP) Directors, Actively Managed Portfolio (AMP) Directors, Program Directors, DCRADO of ISRM, Research Integration Director, Operations Director

Actively Managed Portfolio (AMP) Directors

Military Exposure (MER), Rudy Johnson

Pain & Opioid Use (POU), Jayanthi Sankar¹

Precision Oncology (POP), Ken Myrie

Suicide Prevention (SPR), Joe Constans

Traumatic Brain Injury (TBI), Stu Hoffman

Program Directors

Epidemiology & Public Health, Vickey Davey

Gulf War Illnesses (GWI), Karen Block

Clinical Genomics, Ron Przygodzki

Director of Research Integration (Vacant)

RIGs:

Aging, Clinical Genomics, Clinical Trial Research, DEI, Precision Oncology, Women's Health, Scientific Impacts

←→ <u>IPTs:</u>

CDA, Center Award, Data Science, Multi-Site Planning Award, Non-Clinical Trial Research, Pandemic, Pilot Research, Pre-application, Project Modification, RCS, Shared Equipment, Translational **Broad Portfolio (BP) Directors**

Brain, Behavioral, and Mental Health
(BMH), Miriam Smyth

Health Systems Research (HSR), Kristina Cordasco

→ Medical Health (MED), Holly Krull

Rehabilitation Research & Development (RDT), Patricia Dorn

Director of Operations, Michael Burgio

Business Management Team Budget, HR, Project Mgmt

Information & Process Management Team
Data Analytics, Records, Quality

Program Analysis & Review Teams (I, II)
RFA, App Review, Pre Award, SOP

Clinical Trials Operations

Investigator Workforce Development

1. POU ownership is shared: Audrey Kusiak, Carol Fowler, Jayanthi Sankar, Cathie B. Plouzek





Major Changes to the ISRM Intramural Process

- ISRM research and application process
 - Services converted to Portfolios, accepting applications across translational spectrum
 - Investigators have up to 4 opportunities to submit per year and not limited by Service
- Application submission process: <u>Pre-applications required</u>
 - Select notice of special interest (NOSI), note opportunities beyond a single Portfolio
 - Identify scientific review group (SRG)
 - Select cross-portfolio RFA (e.g., clinical trial, non-clinical trial, pilot)
- Actively Managed Portfolios have their own dedicated NOSIs





New Application Process: Key Steps

- Go to: https://vaww.research.va.gov/funding/rfa.cfm
- (VA network access only)
- 1. Identify the NOSI the application is most responsive to
- 2. Choose the appropriate RFA (e.g., IIR, CDA) the NOSI accepts
- 3. Select study section/SRG:
 https://vaww.research.va.gov/funding/docs/ISRM-SRG-Purviews-and-Review-Cycles.pdf
- 4. Determine your due dates and ID appropriate RFA pre-application
- 5. Contact SRG point of contact with any questions





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
RD-01-CDA2: ISRM Career Development Award (CDA-2) (IK2)	(IK1/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





Winter Review Cycle SRGs and Application Timeline

Scientific Review Group (SRG) Purviews and Scientific Review Officers (SROs) can be found at: ISRM-SRG-Purviews

Health Systems Research Portfolio:

HSR1: Health Care & Clinical Management

HSR2: Behavioral, Social & Cultural Determinants

of Health

HSR3: Health Care Informatics

HSR4: Mental and Behavioral Health*

HSR5: Health Care System Organization &

Delivery and Women's Health

HSR6: Aging, Recovery, & Workforce

HSR7: Special Emphasis Topics

HSR8 HQ5, HQ8: Quality Enhancement Research

Initiative (QUERI)

*Panel assigned to BBMH Portfolio for priority alignment but still meets Winter/Summer

Rehabilitation Research, Development, Translation:

RRDA: Spinal Cord Injuries/Disorders & Neuropathic

Pain

RRD0: Regenerative Rehabilitation Medicine

RRD1/B: Brain Health*

RRD2: Musculoskeletal Health & Injury

RRD3: Sensory Systems & Communications

Disorders

RRD4: Behavioral Health & Social Reintegration*

RRD5: Rehabilitation Engineering &

Prosthetics/Orthotics

RRD6: Chronic Medical Conditions & Aging

RRD7: Research Career Scientist

RRD8: Career Development Program- Panel 1

RRD9: Career Development Program - Panel 2

RRDC: Centers/Research Enhancement Award

Programs (REAPS)

Million Veteran Program (MVP) Data

Use¹ Request:

CT, CDA, TT: All Other:

¹not for

screening/enrollment

Pre-Application:

CT, CDA, TT:

All Other:

eRA closes to full

apps

Review Panels Meet

Deadlines

July 1 October 1

August 1

December 10

November 1

Late February/ Early March

CT = Clinical Trial application
CDA = Career Development Award
TT = Technology Development application

Forms and Instructions for each Deadline can be found at: NOSIs and RFAs, Submission Guidance and Templates





Spring Review Cycle SRGs and Application Timeline

Scientific Review Group (SRG) Purviews and Scientific Review Officers (SROs) can be found at: ISRM-SRG-Purviews

MHBA: Preclinical Mental Health

MHBC: Clinical Mental Health

MHBP: PTSD

NURA: Substance Abuse

NURB: Peripheral Neuropathy & Epilepsy, Multiple

Sclerosis

NURC: SCI & TBI

NURD: Alzheimer's Disease, Dementia, Aging

Brain, Neurodegeneration and Cognitive

Dysfunction

NURM: Movement Disorders, Parkinson's,

Huntington's, ALS, Dystonia, Neurodegeneration

NURF: Sensory Dysfunction

NURR: Sleep

NURP: Pain

Medical Health Portfolio:

CARA/B: Cardiology

CAMM: Cellular & Molecular Medicine

Geroscience

ENDA: Endocrinology,

ENDB: Frailty, musculoskeletal health

GAST: Gastroenterology

HEMA: Hematology

IMMA: Immunology

INFA/B: Infectious Diseases

NEPH: Nephrology

ONCA/B/C/D/E: Oncology

PULM: Pulmonology

SPLD: Gulf War

SURG: Surgery

	Deadlines
Million Veteran Program (MVP) Data Use¹ Request: CT, CDA, TT All Other ¹not for screening/enrollment	October 1
Non-Clinician Eligibility Packet	November 1
Pre-Application: CT, CDA TT Pre-Application: All Othe	February 1
eRA Closes to Full Apps	March 10
Review Panels Meet	Late May/ Early June

CT = Clinical Trial application
CDA = Career Development Award
TT = Technology Development application

Forms and Instructions for each Deadline can be found at: NOSIs and RFAs, Submission Guidance and Template





Summer Review Cycle SRGs and Application Timeline

Scientific Review Group (SRG) Purviews and Scientific Review Officers (SROs) can be found at: ISRM-SRG-Purviews

HSR1: Health Care & Clinical Management

HSR2: Behavioral, Social & Cultural Determinants

of Health

HSR3: Health Care Informatics

HSR4: Mental and Behavioral Health*

HSR5: Health Care System Organization &

Delivery and Women's Health

HSR6: Aging, Recovery, & Workforce

HSR7: Special Emphasis Topics

HSR8 HQ5, HQ8: Quality Enhancement Research

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RRDA: Spinal Cord Injuries/Disorders & Neuropathic

Pain

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RRD1/B: Brain Health*

RRD2: Musculoskeletal Health & Injury

RRD3: Sensory Systems & Communications

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RRD5: Rehabilitation Engineering &

Prosthetics/Orthotics

RRD6: Chronic Medical Conditions & Aging

RRD7: Research Career Scientist

RRD8: Career Development Program- Panel 1

RRD9: Career Development Program – Panel 2

RRDC: Centers/Research Enhancement Award

Programs (REAPS)

Deadlines
Million Veteran

Program (MVP) Data Use¹ Request:

> CT, CDA, TT: All Other:

January 2 April 1

¹not for screening/enrollment

Pre-Application:

CT, CDA, TT All Other

eRA closes to full

apps

Review Panels Meet

February 1

June 10

May 1

Late July/ Early August

CT = Clinical Trial application CDA = Career Development Award TT = Technology Development application

Forms and Instructions for each Deadline can be found at: NOSIs and RFAs, Submission Guidance and Templates





Fall Review Cycle SRGs and Application Timeline

Scientific Review Group (SRG) Purviews and Scientific Review Officers (SROs) can be found at: ISRM-SRG-Purviews

MHBA: Preclinical Mental Health

MHBC: Clinical Mental Health

MHBP: PTSD

NURA: Substance Abuse

NURB: Peripheral Neuropathy & Epilepsy, Multiple

Sclerosis

NURC: SCI & TBI

NURD: Alzheimer's Disease, Dementia, Aging

Brain, Neurodegeneration and Cognitive

Dysfunction

NURM: Movement Disorders, Parkinson's,

Huntington's, ALS, Dystonia, Neurodegeneration

NURF: Sensory Dysfunction

NURR: Sleep

NURP: Pain

CARA/B: Cardiology

CAMM: Cellular & Molecular Medicine,

Geroscience

ENDA: Endocrinology,

ENDB: Frailty, musculoskeletal health

GAST: Gastroenterology

HEMA: Hematology

IMMA: Immunology

INFA/B: Infectious Diseases

NEPH: Nephrology

ONCA/B/C/D/E: Oncology

PULM: Pulmonology

SPLD: Gulf War

SURG: Surgery

	Deadlines	
Million Veteran Program (MVP) Data Use¹ Request: CT, CDA, TT: All Other: ¹not for screening/enrollment	April 1 July 1	
Non Clinician Eligibility Packet	May 1	
Pre Application: CT, CDA, TT Pre Application: All Other	May 1 August 1	
eRA Closes to Full Apps	September 10	
Review Panels Meet	Late November/ Early December	

CT = Clinical Trial application CDA = Career Development Award TT = Technology Development application

Forms and Instructions for each Deadline can be found at: NOSIs and RFAs, Submission Guidance and Templates





ISRM Portfolio Points of Contact

Broad Portfolios (BPs)	POC
Medical Health (MED)	Holly Krull
Brain, Behavioral, and Mental Health (BMH)	Miriam Smyth
Rehabilitation (RDT)	Tricia Dorn
Health Systems (HSR)	Amy Kilbourne, Kristina Cordasco (effective Jan 2025)
Actively Managed Portfolios (AMPs)	POC
Pain/Opioid Use (POU)	Audrey Kusiak, Carol Fowler, Jayanthi Sankar, Cathie B. Plouzek
Precision Oncology (POP)	Ken Myrie
Suicide Prevention (SPR)	Joseph Constans
Traumatic Brain Injury (TBI)	Stuart Hoffman
Military Exposure (MER)	Rudy Johnson
Special Program ¹	POC
Gulf War Illness (GWI)	Karen Block





Suicide Prevention Actively Managed Portfolio (SP AMP): FY25 Research Opportunities and Next Steps





Suicide Prevention Actively Managed Portfolio



Office of Research and Development Investigators, Scientific Review and Management (ISRM)

Notice of Special Interest: Studies on Suicide Prevention Actively Managed Portfolio NOT-RD-01-SPR

Release Date: September 3, 2024

For Research Application Submissions: All Cycles

Expiration Date: Not applicable.

Applications will be accepted through this Notice of Special Interest (NOSI) to the following RFAs:

- RD-01-MRA ISRM Parent Merit Review Award (Non-Clinical Trials/I01)
- RD-01-MRCT ISRM Parent Merit Review Award (Clinical Trials/I01)
- RD-01-PILT ISRM Pilot Project Award (I21)

Participating VA-ORD Research Portfolio: Suicide Prevention Actively Managed Portfolio (AMP), Portfolio Identifier = SPR

Purpose: The Veterans Health Administration (VHA) Office of Research and Development (VA-ORD), through the Suicide Prevention AMP, releases this Notice of Special Interest (NOSI) for studies that seek to improve the understanding of suicide and prevent suicidal behavior. This NOSI supports the full spectrum of research methods including preclinical, translational, clinical, and health services/implementation studies.

Suicide Prevention Actively Managed Portfolio: PURVIEW STATEMENT

The Suicide Prevention Actively Managed Portfolio (AMP) will include research involving preclinical, translational, clinical, and health services/implementation studies that seek to improve the understanding of suicide and prevent suicidal behavior.

Contained within this portfolio will be research using a wide variety of methods and approaches including, but not limited to, studies involving animal models, human tissues and genetic samples, clinical trials of pharmacological and non-pharmacological treatments, application of new technologies, implementation studies (including hybrid studies), observational and epidemiological studies, development of assessment measures, studies concerning risk identification, and studies that seek to understand or address the influence of community on suicidality including investigations on family, caregiver, and peer support, as well as investigations on education, public service announcements, recreation, housing, geospatial location, and employment.





Where we are for funding priorities





Approach to Identifying Priorities



- Veteran Engagement Council
- VISN Suicide Prevention Coordinator Leads
- Chief Mental Health Officers
- VA Suicide Prevention Investigators

5 domains considered by Executive Steering Committee

<u>Phase I: Understanding Existing Suicide</u> Prevention Priorities in Federal Research

Collected and categorized <u>186 priorities</u> set by 10 organizations invested in Suicide Prevention.

Expert raters reduced to 18 domains

Phase III: Executive Committee Finalizes the SP AMP
Critical Research Priorities

Establishment of Priorities





SP AMP Collaboration Partners: Determining Priorities & Establishing a Strategic Roadmap

SP AMP
Executive
Steering
Committee

Name	Role	ESC Function	
Department of Veterans Affairs – Office of Research & Development		Constituency	
Wendy Tenhula	Deputy Chief Research and Development Officer (CRADO), ORD, Dept. of Veterans Affairs	Voting Member	
David Atkins	Former Director, HSR&D, Dept. of Veterans Affairs, VA WOC employee	Voting Member	
Kara Beck	QUERI Representative, ORD, Dept. of Veterans Affairs	Voting Member	
Joseph Constans	SP AMP Lead, ORD, Dept. of Veterans Affairs	Non-Voting, Ex Officio	
Robert O'Brien	SPM, HSR&D, ORD, Dept. of Veterans Affairs	Non-Voting, Ex Officio	
Vetisha McClair	SPM, CSR&D, ORD, Dept. of Veterans Affairs	Non-Voting, Ex Officio	
Peter Hunt	SPM, RR&D, ORD, Dept. of Veterans Affairs	Non-Voting, Ex Officio	
Department of Vet	erans Affairs – ORD funded Suicide Prevention Research Centers	Constituency	
Steven Dobscha	Co-Director, Suicide Prevention Research Impact NeTwork (SPRINT)	Non-Voting Member	
Brian Marx	Co-Director, Suicide Prevention Research Impact NeTwork (SPRINT)	Non-Voting Member	
		Constituency	
Matt Miller	Director, Suicide Prevention, Office of Mental Health and Suicide Prevention	Voting Member	
Susan Strickland	Director of Research Coordination, Office of Mental Health and Suicide Prevention	Voting Member	
Edgar Villareal	National Clinical Director, Office of Mental Health and Suicide Prevention	Voting Member	
VHA Stakeholders	VHA Stakeholders Constituency		
Jodi Trafton	Director, VA Program Evaluation and Resource Center	Member	
Bradley Watts	Research Director, VHA Office of Rural Health	Member	
Lisa Brenner	Director, Rocky Mountain MIRECC	Non-Voting Member	
Stephanie Gamble	Director, CoE for Suicide Prevention	Non-Voting Member	
Veteran Representative (Federal Employee) from Veteran Engagement Council			
External Federal F	unding Agency Constituency	,	
Stephen O'Conno	NIH Representative	Voting Member	
Melissa Mehalick	DoD Representative	Voting Member	







Specific NOSI:

Lethal Means Safety

Office of Research & Development

Notice of Special Interest (NOSI): Studies on Lethal Means Safety approaches to Suicide Prevention

Release Date: August 1, 2024

First Available Due Date: October 1, 2024 Expiration Date: September 30, 2026

Participating ORD Research Services:

Suicide Prevention Actively Managed Portfolio (AMP)

Purpose. The Veterans Health Administration (VHA) Office of Research and Development (ORD), through the Suicide Prevention AMP, releases this focused NOSI for studies that seek to improve the state of the science for lethal means interventions to prevent suicide, including lethal means safety (LMS) counseling, LMS messaging, and other strategies that limit access to lethal means during periods of suicidality. This focused NOSI supports translational, clinical, health systems, implementation, and hybrid studies.

Background: Veteran suicide deaths disproportionately involve firearms, and Veteran firearm suicide rates exceed those of non-Veterans. Veterans are more likely than civilian counterparts to own firearms, and many Veteran firearm owners acknowledge storage of unloaded and unlocked firearms. As highlighted in the 2024 VA / DoD Suicide Prevention Clinical Practice Guidelines, ready availability of a firearm confers additional suicide risk and divestment of firearms can decrease suicide. However, there is limited evidence concerning the best approaches to promote voluntary firearm safety in Veterans, and there is limited efficacy and effectiveness data on existing approaches including LMS counseling and LMS messaging. This NOSI is intended to support research that will ultimately lead to evidence-based interventions that will reduce suicide in the Veteran population.





Where we are going





Input from Various Stakeholders

Priority Questionnaire Distribution to Field

• A survey was sent out to investigators within the SPRINT database. We collected responses from 54 respondents, each listing ranked research priorities. These priorities were coded into the categories developed in Phase 1.

• Veteran's Engagement Council Discussion

• Our team met with a Veteran's Engagement Council in December to hold a discussion and gather research topics of interest to veterans.

VISN Suicide Prevention Lead – Open Discussion

 Understanding Research Priorities from the perspective of VISN Leads for Suicide Prevention Coordinators.

Discussion with VA Investigators

Discussion of qualitative data obtained and solicitations of recommendations for quantitative survey.

Discussion with CMHO

• Discussion of survey data, differences in between respondent groups.





Phase 2: VISN Suicide Prevention Lead / VISN CMHOS — Open Discussion

Key Questions for Audience:

- 1. What areas in suicide prevention do you think needs more research to support your clinical decision-making?
- 2. How does your program implement current research evidence or data regarding assessing suicide risk? What would make risk assessment processes or resulting risk information more useful or actionable?
- 3. How do you use the information you have now regarding effectiveness of suicide prevention interventions and treatments? What new information would help your program make evidence-informed treatment planning decisions?
- 4. Are there certain patient characteristics that are important to study or to include in VA research?

Research Priorities Discussed during Meeting

- Risk Identification Process*
 - Needs modification
 - Clinician burden too high
- Clinical Trial Feasibility*
 - Psychotherapy
 - Small trials will not advance practice
- Community Interventions
- Education, Training, and Messaging
- Firearms, Lethal Means Safety
- Safety Planning
- Older Veterans
- Female Veterans

* - priority areas





Phase 2: Veteran's Engagement Council Discussion

Key Questions for Audience:

- 1. What suicide prevention research topics come to mind as most important for Veterans from your perspective?
- 2. Are there specific patient populations it would be important to study (if this has not come up)?
- 3. Are there any research topics you don't think are as high a priority?
- 4. Are there particular topics within this area that come to mind that would be important for VA researchers to work on?

Research Priorities Discussed during Meeting

- Hard to Reach Veterans (Isolating Veterans/ Veterans not in VA care/ Rural Veterans / Transitioning to civilian)
- Continuity of Care*
- Community Research (including family)
- Developing Novel Treatments (including provider perspective)
- Moral Injury/Spiritual
- Lethal Means Safety
- Messaging
- Peer Support
- Messaging
- Data Studies
- Racial/Ethnic/Sexual Minorities
- Brain/TBI/Genomics

* - category not identified through investigator survey





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TBI Actively Managed Portfolio





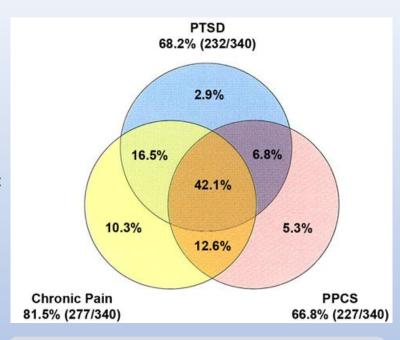
The impact of TBI on Brain Health and Function is complex

TBI can stem from a Veterans life-long history of injury or exposure, and can present itself in mild to severe forms

- Concussions are an example of mild TBI (mTBI) that can occur repetitively, leading multiple comorbidities
- At least 1/3 that report mTBI have a first occurrence < 18 years old
- Long-term effects of injury can promote chronic inflammation and neurodegeneration

TBI has many co-occurring conditions

- Sensory
- Mental Health (PTSD, depression, SUD, suicide)
- Chronic Pain
- Mobility
- Cognitive
- Executive Function
- Effortful Control
- Endocrine
- Epilepsy



The complexity of TBI was demonstrated in 2009 and treatment of combined brain and mental conditions remains today

Lew et al,. JRRD, Volume 46, Number 6, 2009

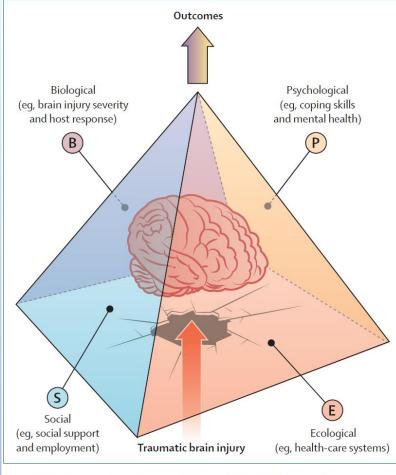


Figure 8: Outcomes after a traumatic brain injury: the bio-psycho-socioecological model Lancet Neurol 2022; 21: 1004–60



What is the Traumatic Brain Injury AMP?



Purview

The purview of the Traumatic Brain Injury Actively Managed Portfolio (TBI AMP) includes preclinical, translational, clinical, epidemiological, and health services/implementation research where the focus is on the consequences of TBI exposure(s) across the lifespan and where TBI is the precipitating condition for the development of brain and mental health disorders.



Purpose

Strategically identify and fund research that seeks to answer specific, real-world questions that are important to Veterans, providers, and/or the healthcare system that results in the improvement of health, care and well-being of Veterans with TBI and ensure that scientific research discoveries within the portfolio translate into clinical practice and inform healthcare decision making



People

- TBI AMP Lead: Dr. Stuart Hoffman (35+ years of TBI and behavioral neuroscience research experience)
- 3 core SPMs, with 5 consulting SPMs representing AMPs and existing portfolios of reintegration, mental health, suicide prevention, pain/opioid use, SUD, and neurodegeneration/dementia.

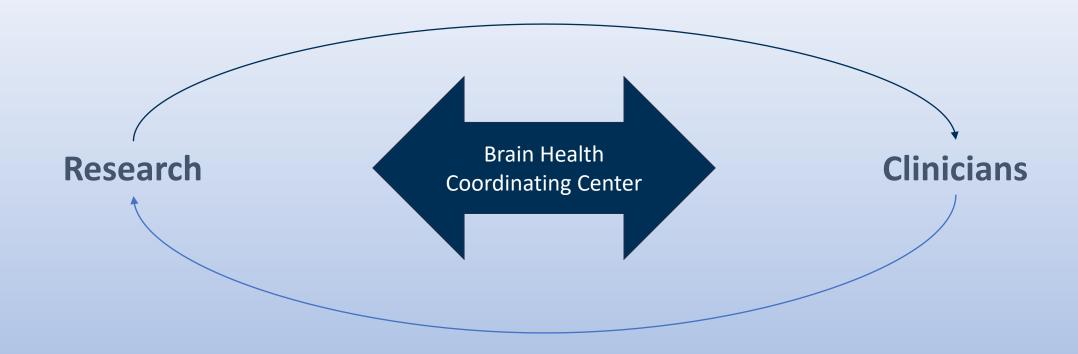


Current Project Examples

- Characterization, Evaluation, and Implementation of Innovative TBI Intensive Evaluation and Treatment Programs (IETP)
- Open Field Based TBI Blast Core Facility
- Total Brain Diagnostics (TBD)
- Brain Health Coordinating Center



Investment in Communication to Support Research and Clinical Collaboration



For TBI AMP, building a better **Communication Infrastructure** will **Improve Translation** and **Identify Gaps** in clinical knowledge for **Future Research Initiatives** that will **Improve TBI Care** in Veterans.



Office of Research and Development Pain and Opioid AMP

POU AMP FEATURES





Pain and Opioid Use AMP



Team-Led AMP

Proactively interact with:

- VA clinical/operations such as Pain Management Opioid Safety and Prescription Drug Monitoring (PMOP)
- NIH/DoD/ & other funder contacts

Proactive management of the portfolio community, including bringing together researchers and/or other stakeholders to accomplish goals

The ability to stand up agile funding mechanisms when required





CONTACTS



RR&T BBMH and MedHealth

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Audrey.Kusiak@va.gov Carol.Fowler@va.gov

HSR BBMH

Cathie Plouzek Jayanthi Sankar

Cathie.Plouzek@va.gov Jayanthi.Sankar@va.gov

Please reach out early and often!





NOT-RD-01-POU (Notice of special Interest - NOSI)



- Primary outcome measure must be pain and/or opioid use
- Study has to fall under the Pain Opioid Use AMP purview

https://www.research.va.gov/services/amp/pain_opiod.cfm





WHAT PAIN OUTCOMES SHOULD BE MEASURED?

Domain	Measure	# of Items
Subjective Health Status	Self-Rated Health (SRH)	1
Pain Intensity/Interference	$\underline{\textbf{P}}$ ain Intensity, Interference with $\underline{\textbf{E}}$ njoyment, Interference with $\underline{\textbf{G}}$ eneral Activity	3
Self-Efficacy	Pain Self-Efficacy Questionnaire, 2 Item (PSEQ-2)	2
Unhelpful Pain Thoughts (catastrophizing)	UW Concerns About Pain, 2 Item (CAP-2)	2
Sleep	Sleep Quality Scale (SQS)	1
Depression	Pain Health Questionnaire, 2 Item (PHQ-2)	2
Anxiety	Generalized Anxiety Disorder, 2 Item (GAD-2)	2
General Well-Being	Well-Being Signs Tool (WBS)	3
	TOTAL	16
Perceived Treatment Impact	Patient Global Impression of Change (PGIC Scale) – FOLLOW-UP ONLY	1
	TOTAL	17

01-POU NOSI PRIORITIES



- Clinical studies of the genetic, anatomical, and behavioral basis of pain, opioid tolerance, opioid dependence or addiction, opioid metabolism
- Implementation of treatments, approaches, and methods to enhance pain services, and evaluation of quality and safety of pain care, opioid use disorder care, and tapering of opioid medication.
- Preclinical development and translation of non-opioid therapies
- Clinical trials and observational studies for painful conditions or identifying mechanisms and modifiable targets related to opioid tolerance, withdrawal, or other harmful physiological adaptations to opioid use.
- Clinical trials and observational research of interventions to improve outcomes in opioid use disorder





01-POU NOSI PRIORITIES – CONT.



- Pragmatic clinical trials for treatment of painful conditions using nonpharmacological approaches including Whole Health, complementary and integrative health, and biobehavioral approaches
- Development and validation of predictive analytics and biomarkers to identify Veterans with high impact chronic pain, or who are at risk of developing chronic pain or opioid use disorder (OUD. Studies of interest are limited to data mining and analysis of Million Veteran Program (MVP) and/or EHR, and clinical studies involving human subjects.
- Studies of fentanyl adulterated with xylazine. (<u>FENTANYL-ADULTERATED-OR-ASSOCIATED-WITH-XYLAZINE-EMERGING-THREAT-RESPONSE-PLAN-Report-July-2023.pdf</u> (whitehouse.gov).
- Harm reduction services and treatment programs that reduce pain medication usage but not complete abstinence



