Follow up on Changes to the VA Intramural Research Award Program

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Agenda

➤ Introduction

➤ Why are we making changes?

➤ What will replace the services?

➤ What are the changes to the application review process?

➤ What are the changes to the funding decision process?

➤ What is the new application review timeline?

In 2025 ORD will celebrate its 100-year anniversary!

Record of Accomplishments:

- First R-C clinical trial
- Cardiac pacemaker
- First liver transplant
- Seattle foot
- Deka arm
- Multiple Nobel Laureates

Choose VA

U.S. Department of Veterans Affairs

Why are we making changes?

What is the problem?

Overlapping service offerings and differing requirements lead to delays in review and rejected proposals, decreasing the ability to perform research.

How do we solve the problem?

Implement new processes that enable investigators to more efficiently navigate the VA Research application process to rapidly launch research that improves the health and healthcare of Veterans.
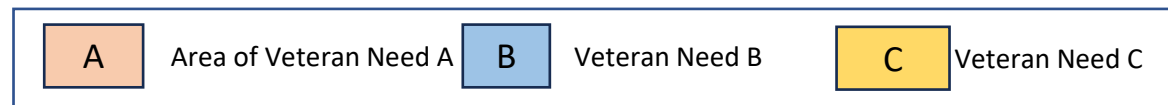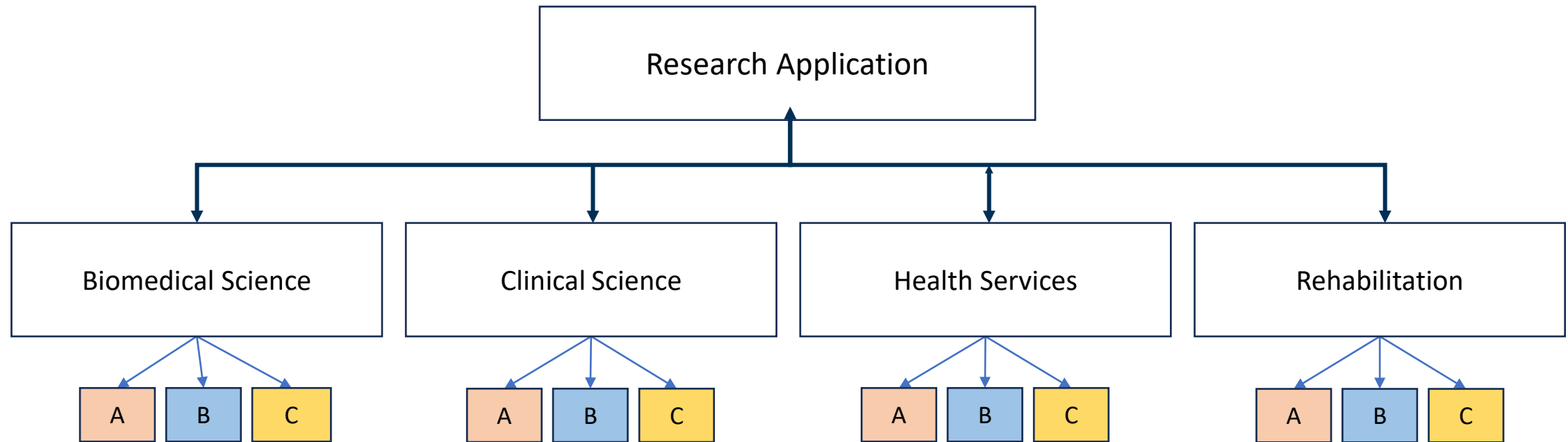
What will replace the services?

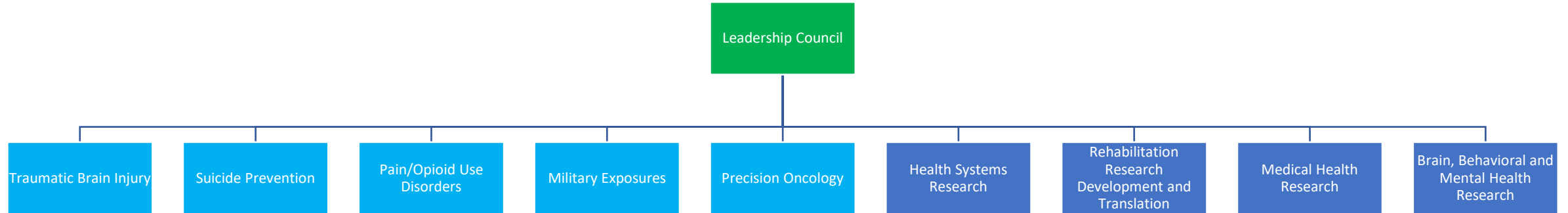# How the service-based structure addressed Veteran needs

This partial drawing of ORD's structure is for illustration purposes only

The New Structure and Shared Governance

Leadership Council
Shared Governance

Actively Managed Portfolios
Focused purviews

Broad Portfolios
Broad purviews

Scientific Review Groups have been assigned to the Broad Portfolios

Brain, Behavioral & Mental Health	Health Systems Research	Medical Health	Rehabilitation
HSR4: Mental and Behavioral Health **MHBA:** Preclinical Mental Health **MHBC:** Clinical Mental Health **MHBP:** PTSD **NURA:** Substance Abuse **NURB:** Peripheral Neuropathy & Epilepsy **NURC:** SCI & TBI **NURD:** Alzheimer's Disease, Dementia, Aging Brain, Neurodegeneration and Cognitive Dysfunction **NURE:** Movement Disorders, Parkinson's, Huntington's, ALS, Dystonia, Neurodegeneration **NURF:** Sensory Dysfunction **NURR:** Sleep **NURP:** Pain **RRD1/B:** Brain Health **RRD4:** Behavioral Health & Social Reintegration	**HSR1:** Health Care & Clinical Management **HSR2:** Behavioral, Social & Cultural Determinants of Health **HSR3:** Health Care Informatics **HSR5:** Health Care System Organization & Delivery and Women's Health **HSR6:** Long Term Care & Aging & Support Services **HSR7:** Special Emphasis Topics **HSR8:** QUERI **MRA0:** Career Development **HQ5, HQ8:** QUERI	**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:** GW **SURG:** Surgery	**RRDA:** Spinal Cord Injuries/Disorders & Neuropathic Pain **RRD0:** Regenerative Rehabilitation Medicine **RRD2:** Musculoskeletal Health & Injury **RRD3:** Sensory Systems & Communications Disorders **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/REAPs **MRA1:** Mentored Physician and Clinical Psychologist Scientist Award in Alzheimer's Disease and Related Dementias (MPCPS-ADRD)

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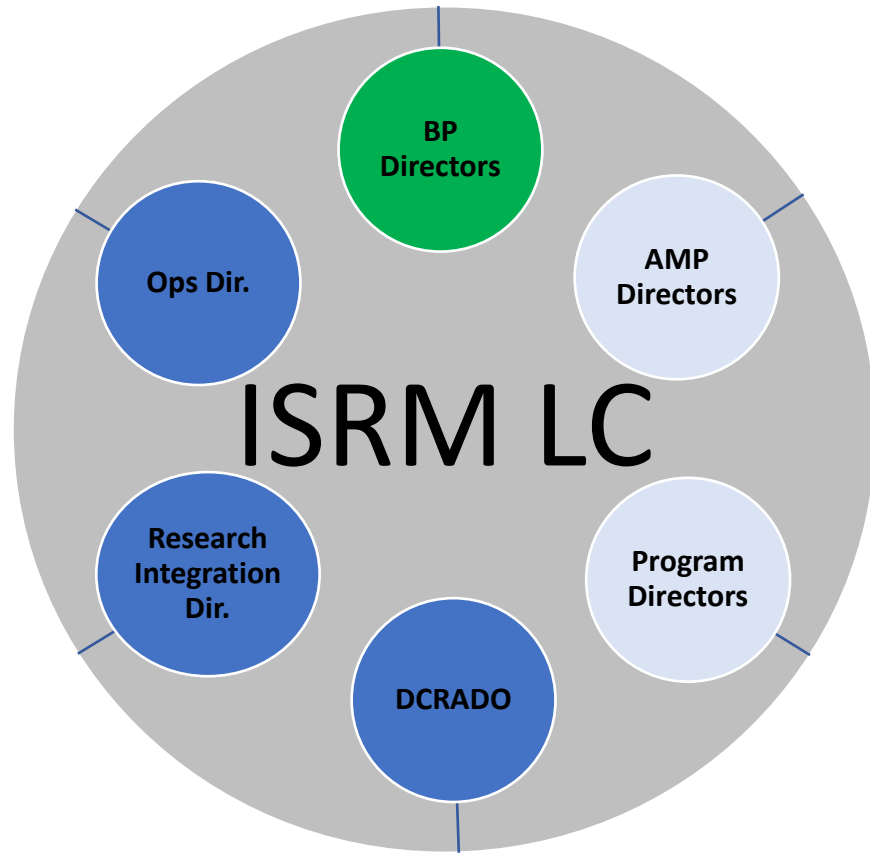| Brain, Behavioral & Mental Health	Health Systems Research	Medical Health	Rehabilitation R&D & Translation
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MHBA: Preclinical Mental Health	HSR2: Behavioral, Social & Cultural Determinants of Health	CAMM: Cellular & Molecular Medicine, Geroscience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

Winter – Summer Cycle Scientific Review Groups

Brain, Behavioral & Mental Health	Health Systems Research	Medical Health	Rehabilitation R&D & Translation
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NURC: SCI & TBI		**HEMA:** Hematology	**RRD6:** Chronic Medical Conditions & Aging
NURD: Alzheimer's Disease, Dementia, Aging Brain, Neurodegeneration and Cognitive Dysfunction		**IMMA:** Immunology	**RRD7:** Research Career Scientist
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NURP: Pain	**MRA0:** Career Development	**SURG:** Surgery	**MRA1:** Mentored Physician and Clinical Psychologist Scientist Award in Alzheimer's Disease and Related Dementias (MPCPS-ADRD)
RRD1/B: Brain Health	**HQ5, HQ8:** QUERI		
RRD4: Behavioral Health & Social Reintegration			

Spring – Fall Cycle Scientific Review Groups

Brain, Behavioral & Mental Health	Health Systems Research	Medical Health	Rehabilitation R&D & Translation
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ISRM Leadership Council

- **Structure:**
  - DCRADO, Director of Research Integration, Director of Operations Portfolio Directors, Program Directors are voting members

- **Functions:**
  - Oversight of portfolio activities
  - Promoting cross-portfolio communications
  - Communication with ORD leadership

Key Points

The current services will be replaced by portfolios of Veteran need.

Actively managed portfolios will provide funding to address specific areas of Veteran need.

Broad portfolios will continue to provide funding for a wide range of investigator-initiated research from discovery to translation and support the Career Development, Research Career Scientist, Centers, and Service Award programs.

What are the changes to the application review process?

New Cross-Portfolio RFAs Posted 9/3

RFAs

Career Development Award 1 (IK1)

Career Development Award 2 (IK2)

Research Career Scientist (IK6)

Pilot Research (I21)

Parent Merit Review – Clinical Trials (I01)

Parent Merit Review –Non-Clinical Trials (I01)

CORE (I50)

Pre-Applications

Pre-Application – Career Development Award (IK1/IK2)

Pre-Application – Research Career Scientist (IK6)

Pre-Application – Pilot (I21)

Pre-Application – Parent Merit Clinical Trial (I01)

Pre-Application – Parent Merit Non-Clinical Trials (I01)

Pre-Application – CORE (I50)

Portfolio Notices of Special Interest Posted 9/3

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

Gulf War

Critical Research Areas/Cross Portfolio

Women's Health

Durability of Rehabilitation Interventions for Veterans

Chronic Effects of Neurotrauma

Studies on Lethal Means Safety Approaches to Suicide Prevention

ISRM Non-Clinician Investigator Eligibility

- Career Development:
  - At least 5/8 VA employed at the time of funding
  - Research Career Scientist follows current requirements

- Merit & Pilot Awards
  - 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 and approved by the ISRM Leadership Council
  - **New NCI pre-applications for Spring and Fall cycles only:** Cap of 2 per VA facility (1 for MH & 1 for BBMH). Waiver required for an additional slot. Resubmissions of new NCI applications continue to count toward the facility cap. AMP Directors may propose investigators for waivers. Does not apply to new applications for CADE.

New Review Timeline

	Winter	Spring	Summer	Fall
Site waivers for 2nd new NCI slot	N/A	10/15	N/A	4/15
CT, CDA, TT Pre-apps due	8/1 (W24: 10/1)	11/1	2/1	5/1
MVP data use apps due	10/1	1/1	4/1	7/1
Other Research Pre-apps due	11/1	2/1	5/1	8/1
DTTW deadline for full apps	12/8	3/8	6/8	9/8
eRA closes to full apps	12/10	3/10	6/10	9/10

Pre-application due dates and pre-application notification to investigators for the current winter cycle slightly differ by RFA

1

Career Development 1 &2, Research including Clinical Trials, and Tech Transfer Key Dates:	Research Career Scientist, Pilot Award, Research not including Clinical Trials, and CORE RFAs Key Dates:
9/3: 7 RFAs and NOSIs posted	**9/3:** 7 RFAs and NOSIs posted
10/1: Pre-applications for relevant scientific review groups (SRGs)* due	**11/1:** Pre-applications for relevant scientific review groups (SRGs)* due
11/1: Investigators notified of the status of their pre-application (accepted, rejected, or assigned to a new SRG or Portfolio)	**11/22:** Investigators notified of the status of their pre-application (accepted, rejected, or assigned to a new SRG or Portfolio)
12/8: Final date to submit full application	**12/8:** Final date to submit full application
March 2025: Summary scores and statements released to investigators	**March 2025:** Summary scores and statements released to investigators

*A listing of winter cycle SRGs are located in the Appendix

ISRM Pre-application RFA Timing

- Clinical Trials, Career Development and Tech Transfer Development Awards
  - Pre-apps due 8/1*, 11/1, 2/1, 5/1
  - Administrative + Technical review with feedback
  - Stations notified of concerns/disapprovals within four weeks of receipt
  - Exceptions needed for 8/1/24 deadlines
- Other Research (Merits, Pilots…)
  - Pre-Apps due six weeks before full application due date
  - Administrative review with optional technical review and feedback
  - Stations notified of concerns/disapprovals within three weeks of receipt

RFA for Merit Award including an interventional clinical trial

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

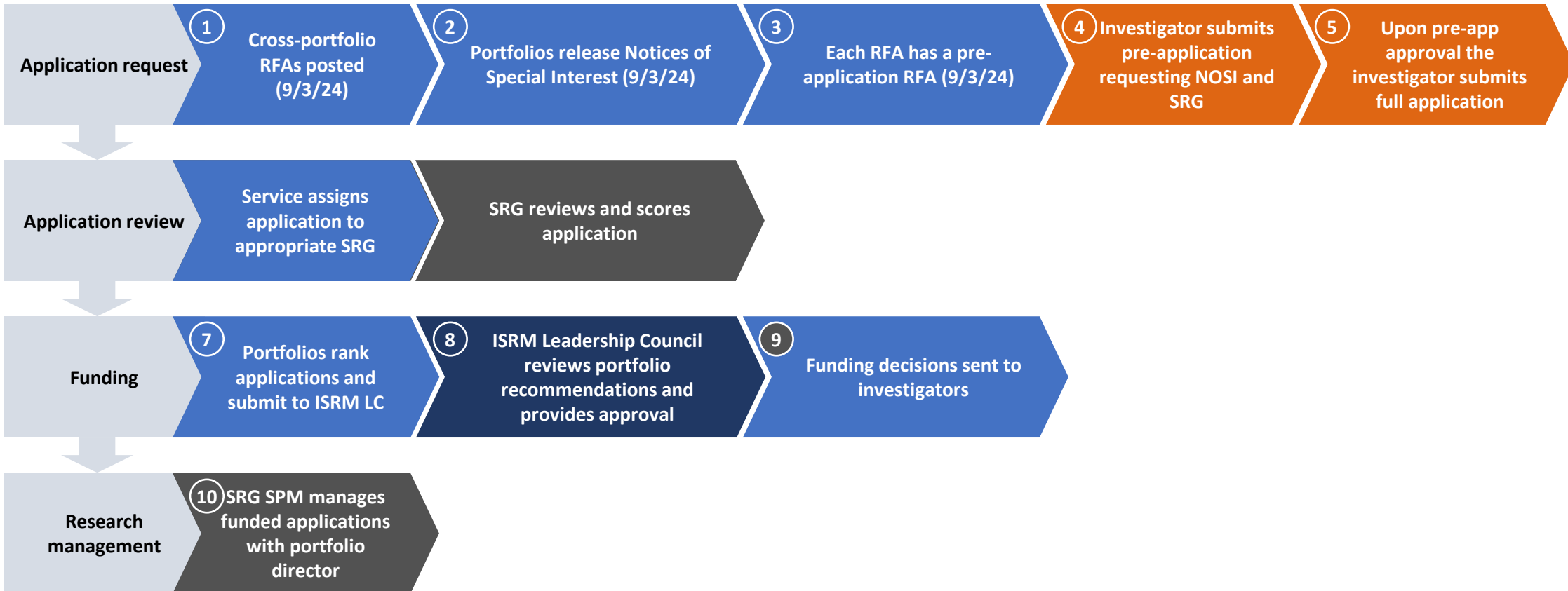- Budget cap waivers approved by the ISRM Leadership Council

RFA for Merit Award not including an interventional clinical trial

- PI may receive funding for up to 3 Merit awards
- Non-clinician PI salary, 3/8 allowed above the cap. 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

The revised research application process

Key
- 🔵 *Portfolio actions*
- 🟠 *Investigator actions*
- ⚫ *Scientific Review Group (SRG) actions*
- 🔵 *ISRM Leadership Council actions*

Application request

1. Cross-portfolio RFAs posted (9/3/24)
2. Portfolios release Notices of Special Interest (9/3/24)
3. Each RFA has a pre-application RFA (9/3/24)
4. Investigator submits pre-application requesting NOSI and SRG
5. Upon pre-app approval the investigator submits full application

Application review

Service assigns application to appropriate SRG

SRG reviews and scores application

Funding

7. Portfolios rank applications and submit to ISRM LC
8. ISRM Leadership Council reviews portfolio recommendations and provides approval
9. Funding decisions sent to investigators

Research management

10. SRG SPM manages funded applications with portfolio director

Investigator View

Summary of New Process for Investigators

1 **Align on Portfolio & SRG Scope**

The investigator picks the Portfolio NOSI, RFA and SRG with the appropriate purviews for their proposed study.

→

2 **Pre-Application Submission**

Complete the standardized pre-application providing basic project information and the requested portfolio NOSI and SRG and submit.
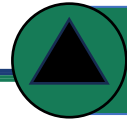
→

3 **Application Submission**

Upon approval, submit a full application through the cross-portfolio 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).

What has changed

- Funding opportunities are organized by the type of research proposed.

- Accepted Pre-Applications are required prior to any full application submission for most applications.

- Pre-applications are submitted to the cross-portfolio pre-application RFAs (I02).

- The scientific review groups review for all Portfolios (not just a single Service).

- Scored proposals will be ranked in the Portfolio funding meeting.

- The ranked applications will go to the ISRM Leadership Council which will provide oversight and final approvals.

- Funded projects will be managed by the SPM who managed the review working with the director of the Portfolio to which it was submitted.

= What has NOT changed

- RFAs are posted and applications are submitted through Grants.gov and eRA Commons.

- ORD-wide RFAs will still support the full range of research activities and disciplines.

- The purview of scientific review groups (SRGs) and timing of SRG meetings (every 6 months).

- The Scientific Portfolio Managers who manage the SRGs have not changed.

- Review by a specific scientific review group can be requested.

- Applications not funded may be resubmitted no more than 2 times (-A1 and -A2).

- Once a decision has been made about an application, a notice of intent to fund or not to fund will be sent.

- PIs with approved applications will be required to complete just-in-time requirements.

- If funded, the SPM who managed the review of the application will manage your project.

What are the Changes to the Funding Decision Process?

Portfolio Funding Process

- The budget for each portfolio is determined by the ISRM Leadership Council at the beginning of each fiscal year.

  - Value of projects from end of the prior fiscal year

    +

  - Additional specific funding provided in ORD budget

- The ISRM LC has the authority to transfer funds between portfolios during the fiscal year if required.

Project Funding Process

- Applications for funding will be reviewed in either the standing scientific review groups or the special review groups.

- Portfolios will hold funding ranking meetings for each review cycle.

- Ranked lists will be submitted for approval to the Leadership Council.

- Deviations from the ranked score will require approval.

What is the New Application Review Timeline?

Key Components to the Revised Application Review Transition Timeline

Staying the same:

Due dates for **pre-applications, full applications, reviews, and margin meetings** will **remain** on the **same cycle** as we transition from Services to Portfolios

- SRGs that were originally in **HSRD** (*to become HSR Broad Portfolio*) and **RRD** (*to become RRD Broad Portfolio*) will remain Summer/Winter

- SRGs that were originally in **BLRD** (*to become MHA Broad Portfolio*) and **CSRD** *(to become BBMH Broad Portfolio*) will remain Spring/Fall
    - January '25 – Final "Service" Margin meetings for BL and CS to conclude application cycle

Changing:

September 3, 2024, was the **launch date for new ORD-Wide RFAs, Portfolio Pre-Applications** , and **Notices of Special Interest**

- Old HSRD and RRD RFAs will be taken down in October 2024.

- Old BLRD and CSRD RFAs will be taken down in October 2024.

Conclusion

- On October 1, 2024, ISRM will transition from four Services to nine Portfolios.
- Service RFAs have been replaced by cross-portfolio RFAs and portfolio Notices of Special Interest
- Peer-review panels (SRGs) will remain the same.
- Portfolio funding recommendations will be reviewed by the ISRM Leadership Council which will have representation from all portfolios.

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.

Q&A

? • *Questions? Email Christopher.Bever@va.gov*