Welcome: Continuing CSR Advisory Council Members

Leopoldo Cabassa, Ph.D.

Professor
George Warren Brown School
of Social Work
Washington University in St.
Louis

Matthew Carpenter, Ph.D.

Professor
Departments of Psychiatry and
Behavioral Sciences
Medical University of South Carolina
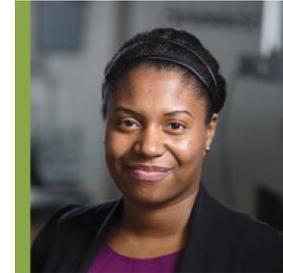
Christine Hendon, Ph.D.

Associate Professor
Department of Electrical Engineering
Columbia University

Michelle Janelsins, Ph.D.

Associate Professor
Division of Supportive Care in Cancer
Department of Surgery
University of Rochester

Narasimhan Rajaram, Ph.D.

Associate Professor
Department of Biomedical Engineering
University of Arkansas at Fayetteville
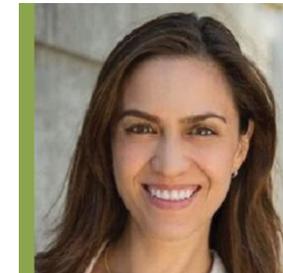
Elizabeth Villa, Ph.D.

Associate Professor
Section of Molecular Biology
Division of Biological Sciences
University of California, San Diego

Welcome...

Our newest member

Anton Bennett, Ph.D.

Professor
Department of Pharmacology
and Comparative Medicine
Yale University

And our ad-hoc for Sept 2022

Jonathan Epstein, M.D.

Executive Vice Dean and Chief Scientific Officer
Department of Cell and Developmental Biology
Perelman School of Medicine
University of Pennsylvania

And a big thank you to our retiring members

Jinming Gao, Ph.D.

Professor of Oncology, Pharmacology
and Otolaryngology
Simmons Comprehensive Cancer Center
Department of Pharmacology
University of Texas Southwestern
Medical Center

Review Integrity
Simplifying Review Criteria – non CT

Tonya Palermo, Ph.D.

Professor and Associate Director
Center for Child Health, Behavior
and Development
Seattle Children's Research
Institute

Review Integrity
Simplifying Review Criteria – non-CT
Simplifying Review Criteria - CT

Mark Peifer, Ph.D.

Hooker Distinguished Professor
Department of Biology
University of North Carolina-Chapel Hill

Early Career Reviewer Program

Overview: Mission, Strategic Framework & Scope

CSR's Mission

To ensure that NIH grant applications receive fair, independent, expert, and timely scientific reviews - free from inappropriate influences - so NIH can fund the most promising research.

Since 2019: CSR's Strategic Framework: Quality of Peer Review

Reviewers
- Reviewer Training
- Broaden/Diversify Reviewer Pool
- Incentivizing Service
- Reviewer Evaluation
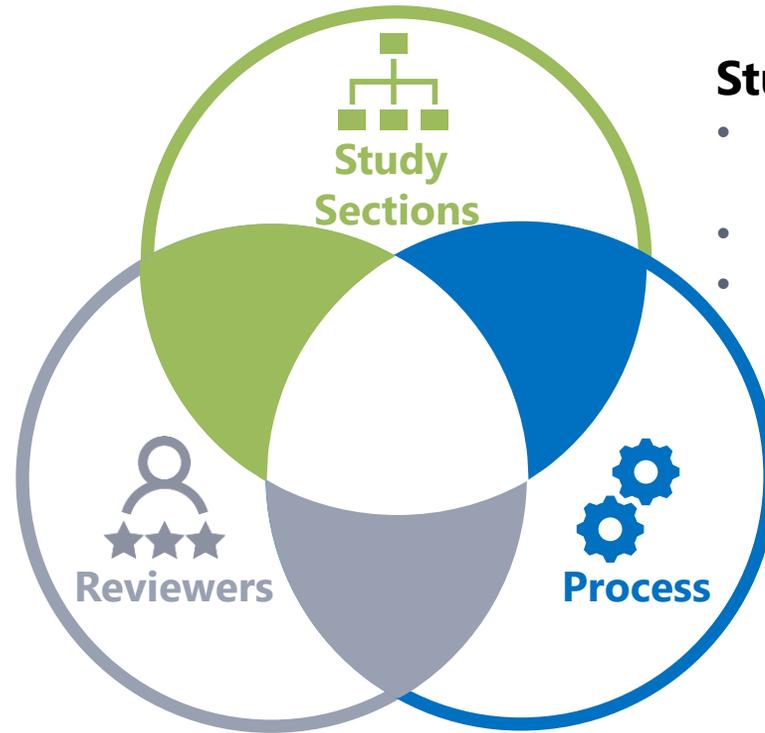
Study Sections
- Scientific Scope (relevance, adapting to emerging areas, not perpetuating stale science)
- Output (identification of meritorious science)
- Size appropriate for competition

Process
- Confidentiality/Integrity
- Fairness/Bias Mitigation
- Assignment/Referral of Applications
- Review Criteria and Scoring System

Transparency   Data-driven decisions   Stakeholder engagement   Open, multidirectional, respectful communications

Today's CSRAC agenda
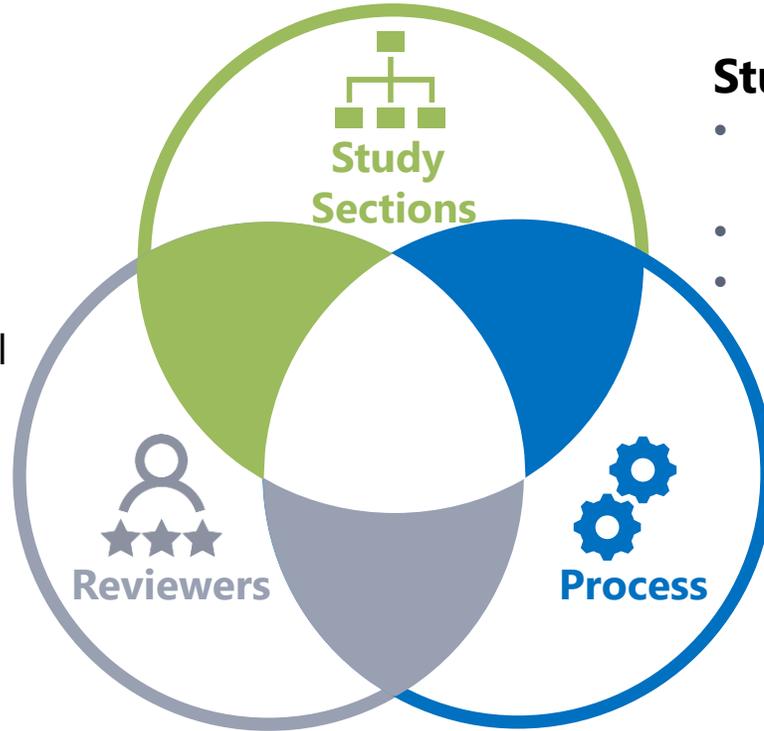
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- **Review Criteria and Scoring System**

Data Analytics and Technology Support

Fellowship Review WG

**Transparency**   **Data-driven decisions**   **Stakeholder engagement**   **Open, multidirectional, respectful communications**

CSR Update for Council touches on multiple ongoing efforts
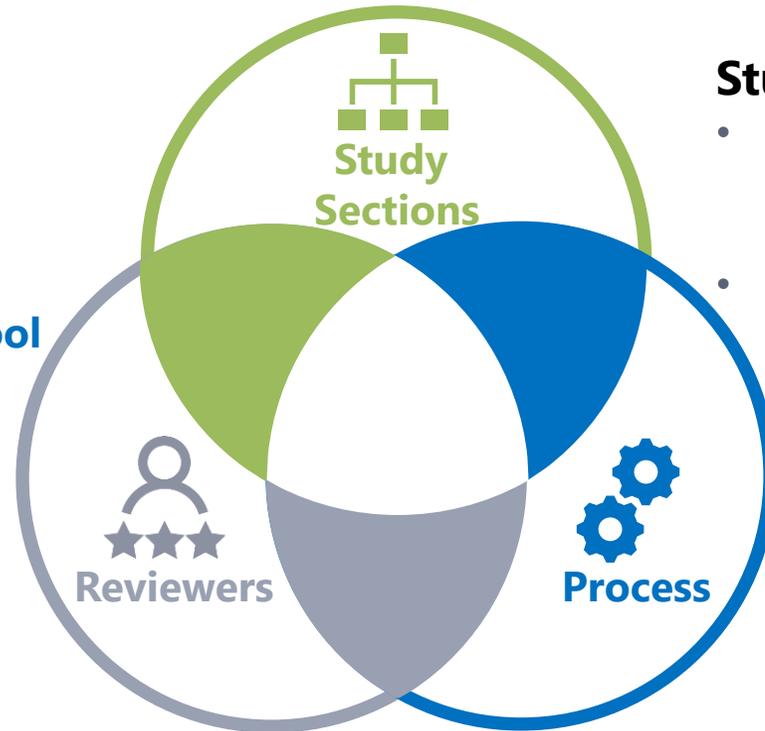
Reviewers
- **Reviewer Training**
- **Broaden/Diversify Reviewer Pool**
- Incentivizing Service
- Reviewer Evaluation

Study Sections [ENQUIRE]
- **Scientific Scope (relevance, adapting to emerging areas, not perpetuating stale science)**
- **Output (identification of meritorious science)**
Size appropriate for competition

Process
- **Confidentiality/Integrity**
- **Fairness/Bias Mitigation**
- Assignment/Referral of Applications
- **Review Criteria and Scoring System**

Study Sections

Reviewers

Process

Transparency **Data-driven decisions** **Stakeholder engagement** **Open, multidirectional, respectful communications**

NIH Center for Scientific Review

8

CSR's Strategic Plan 2022-2027 Released

Strategic Goals

Goal 1
Maintain scientific review groups that provide appropriate scientific coverage and review settings for all of NIH science.

Goal 2
Further develop a large cadre of diverse, well-trained, and scientifically qualified experts to serve as reviewers.

Goal 3
Further develop an outstanding, engaged, and diverse staff.

Goal 4
Implement changes to the peer review process to make it more fair, effective, and efficient.

Goal 5
Achieve our mission through transparency, engagement with the scientific community, and a data-driven approach to decision-making.

Center for
Scientific Review

NATIONAL INSTITUTES OF HEALTH

2022-2027
STRATEGIC PLAN
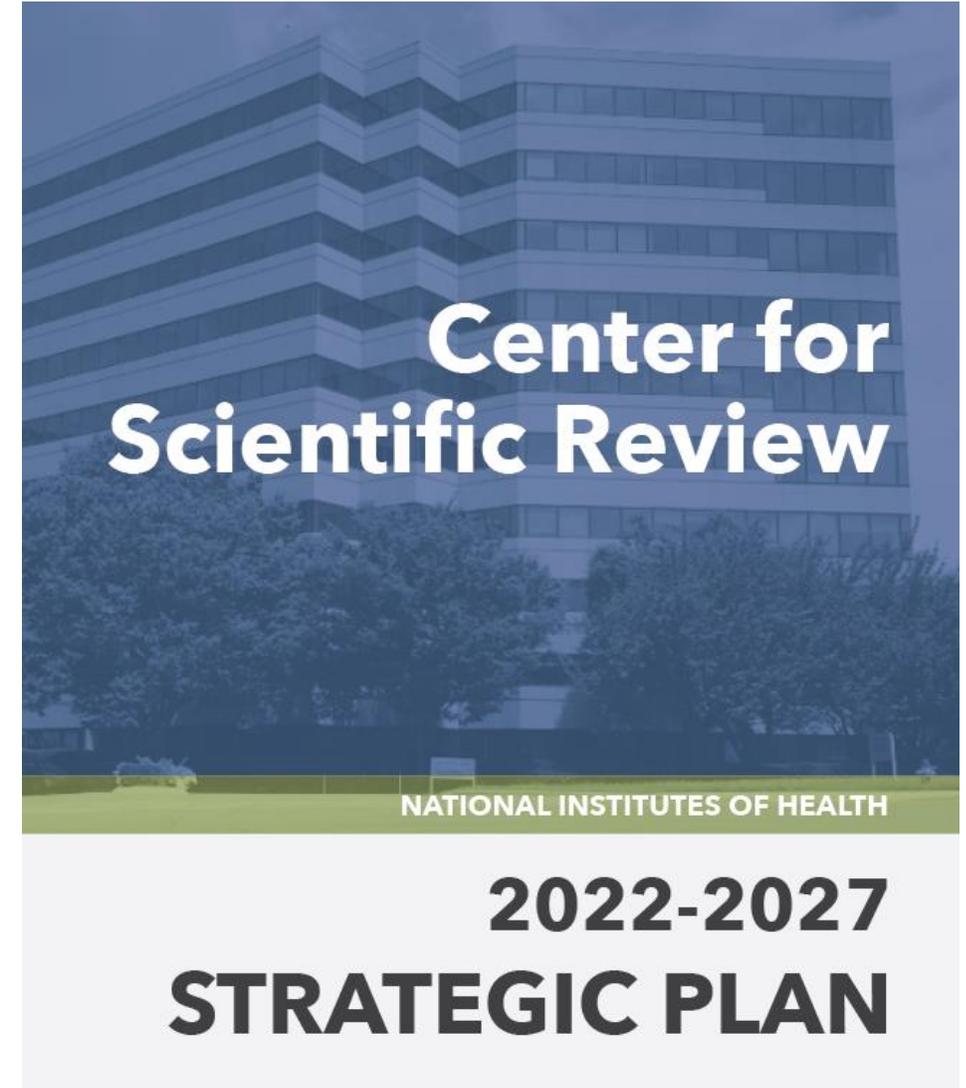
CSR Scope - Fiscal Year 2022

~80,424
NIH Applications

~61,378 (76%)
Reviewed by CSR

~33,000 — **94%** R01s

~6,000 — **95%** SBIR-STTR

~5,200 — **85%** Fellowships

~19,000 reviewers, ~1,200 meetings
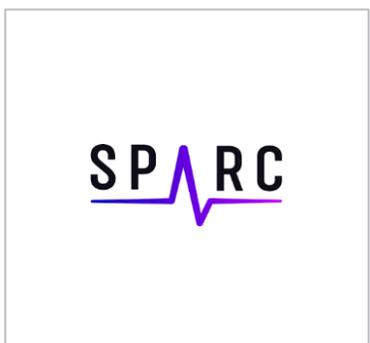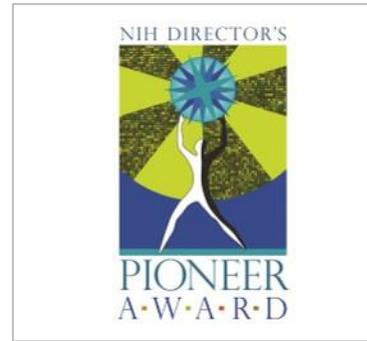
FY22 saw a drop in overall NIH & CSR application numbers

	2016	2017	2018	2019	2020	2021	2022
CSR Reviewed Applications	60108	61073	62360	62252	64636	66627	61378
Total NIH Applications	80785	81482	81978	82471	84843	88080	80424
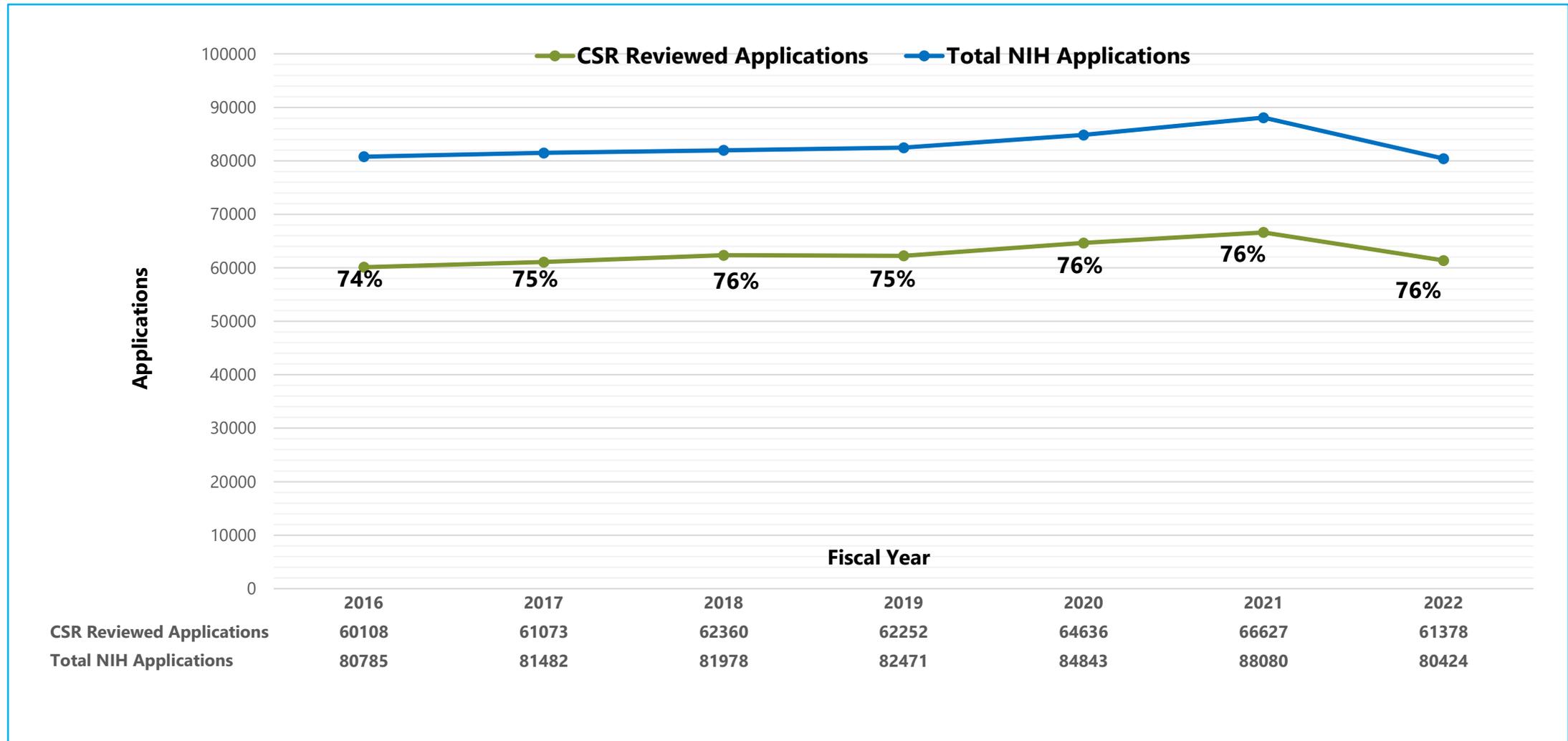
R01 Submissions (May 2019 - May 2022)
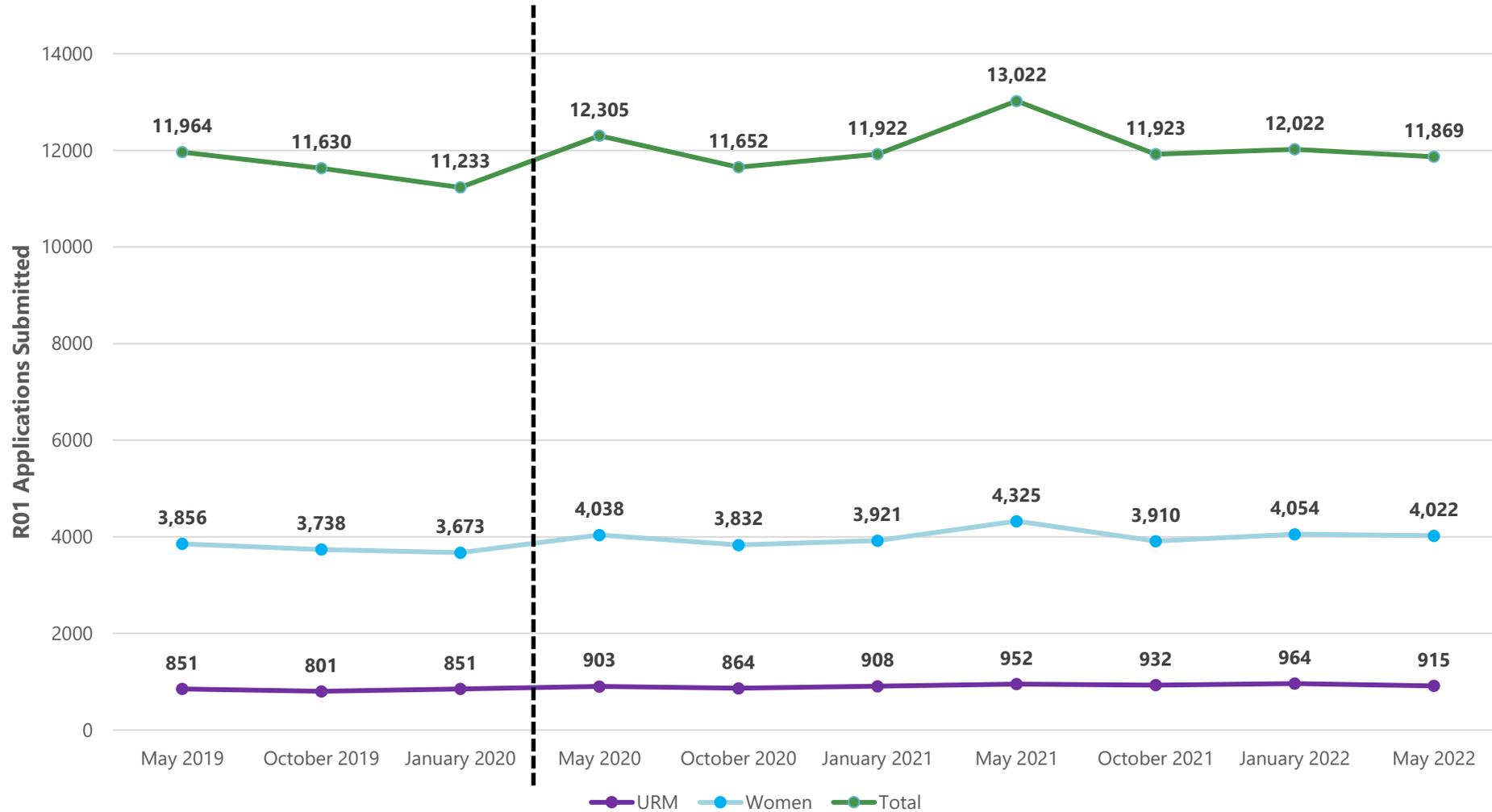
CSR News & Updates

Leadership and Management Transitions

Gagan Pandya, Ph.D.
Branch Chief
Basic Neuroscience Review
Branch
Division of Neuroscience,
Development, and Aging

Wei-Qin Zhao, Ph.D.
Branch Chief
Aging and Neurodegeneration
Review Branch
Division of Neuroscience,
Development, and Aging

Jian Cao, M.D.
Referral Officer
Basic and Translational Cancer
Review Branch
Division of Basic and Integrative
Biological Sciences

Aurea De Sousa, Ph.D.
Referral Officer
Aging and Neurodegeneration
Review Branch
Division of Neuroscience,
Development, and Aging

Afia Sultana, Ph.D.
Referral Officer
Neurotechnology and Vision
Review Branch
Division of Neuroscience,
Development, and Aging

Mark Vosvick, Ph.D.
Referral Officer
Clinical Care and Health Interventions
Review Branch
Division of AIDS, Behavior and
Population Sciences

Blair Gosnell, M.B.A
Branch Chief
Administrative Services Branch
Division of Management Services

Rashid Shah, M.S.
Branch Chief
Strategic Planning and
Implementation Branch
Division of Planning, Analysis, and
Information Management

Leo Wu, M.B.A
Branch Chief
IT Services and Solutions Branch
Division of Planning, Analysis, and
Information Management

Current* Plans for Future Peer Review Meetings

subject to change based on COVID-19 rates

In-person

- 1 of 3 meetings per year for study sections with standing/recurring membership

- *Roughly 200 meetings per year*

Virtual

- 2 of 3 meetings per year for study sections with standing/recurring membership

- All special emphasis panels

- *Roughly 1000 meetings per year*

Approach based on a balance of considerations – data on reviewer engagement/preference, environmental and fiscal factors.

CSR Reviewer Surveys [2020 and 2021] of Zoom vs. In-person meetings: Reviewer surveys – Zoom review experience

June 2022 study section members re: fall in-person attendance

Would you be able to attend your upcoming Fall review meeting in-person?

If No/Unsure, primary reason

Response Rate: 77%
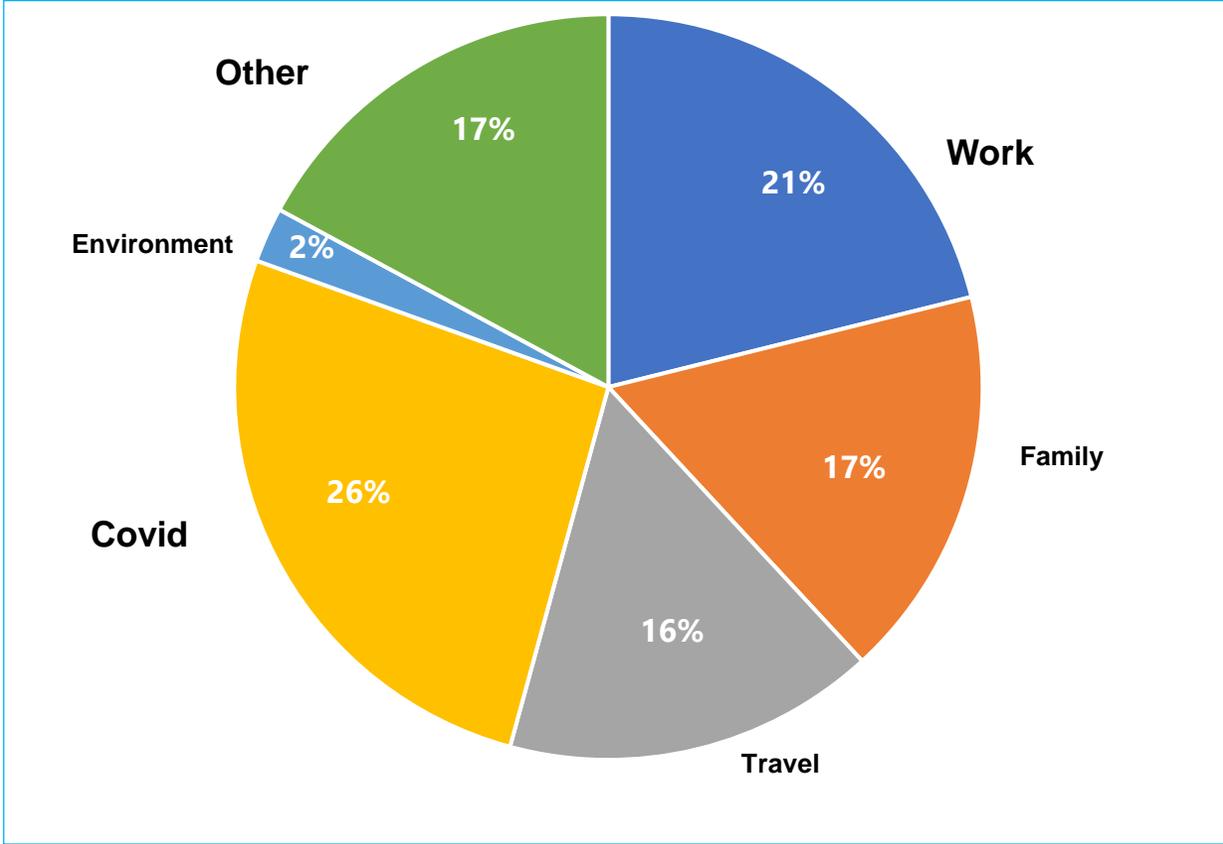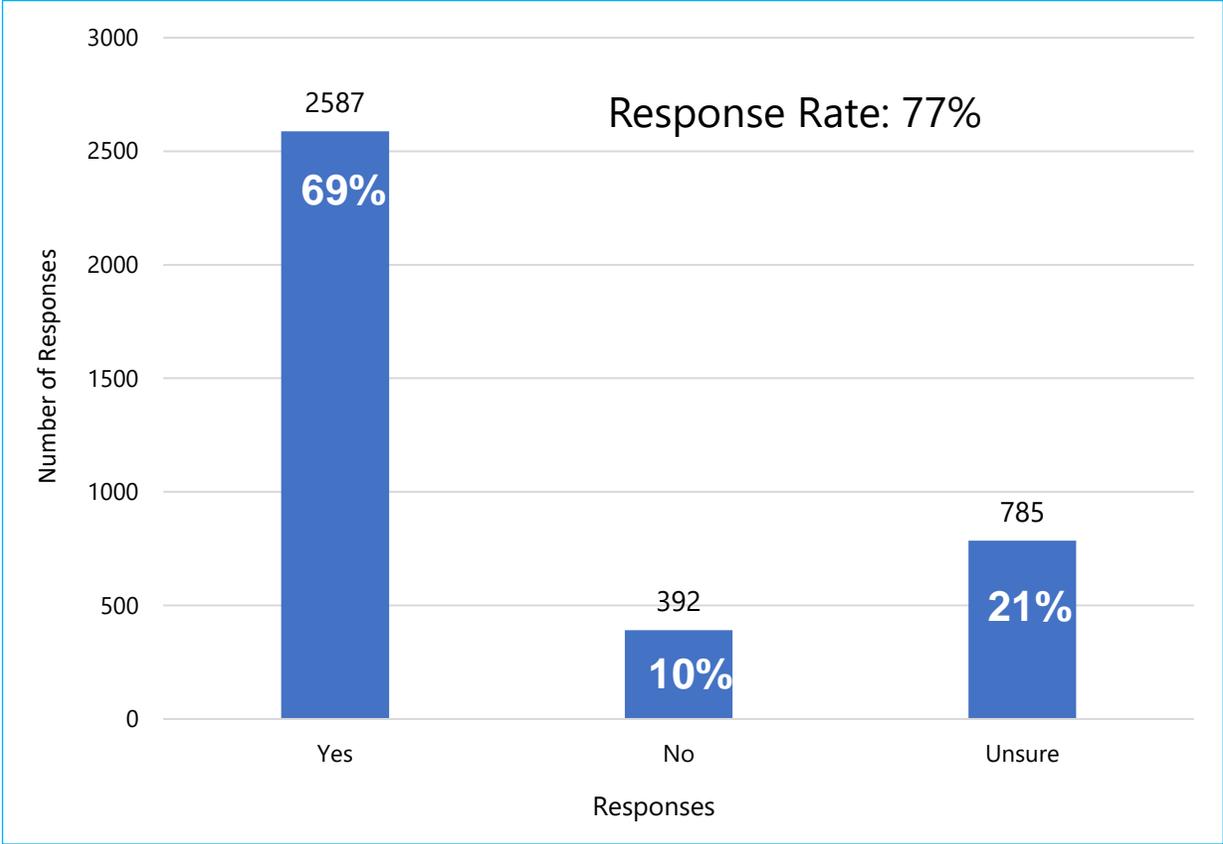
It all begins this fall

- >65 meetings (just under 1/3 of our standing panels) are planned as in-person this fall (Oct/Nov 2022)

- Those meeting virtually in the fall will hold an in-person meeting in either Feb/Mar 2023 or June/July 2023

- Hybrid option (some reviewers joining via Zoom) to be piloted beginning in Feb/Mar 2023 - technology and training/best-practices for SROs/Chairs to ensure equity for remote participants.

- Training/support for new CSR review staff (SROs and ESAs)

- **Plan to systematically evaluate recruitment patterns (diversity, success) and survey reviewers again – report in Mar '23 CSRAC**

Reviewer Training: CSR's New Review Integrity Training Module

- Launched in August 2022 - interactive, scenario-based training [~30 min]

- Content based on input from 2019 CSR Advisory Council Working Group on Reviewer Integrity

- CSR/OER-eRA collaborating to make it available NIH-wide, easier to require/track

- ***THANK YOU*** *to CSR staff who made it happen in time for the fall reviews - Office of Training & Development, DPAIM, and all the CSR actors! And to Scott Miller (former CSRAC member) and Tonya Palermo for their preview and feedback!*

There can be tricky integrity issues to navigate even before the meeting begins.

Review Integrity

CSR Advisory Council Members

Scott Miller, Ph.D., Yale University

Dr. Jinming Gao, Ph.D., UT Southwestern Medical Center

Dr. Deanna Kroetz, Ph.D., University of California San Francisco

Dr. Tonya Palermo, Ph.D., University of Washington

Dr. Denise Wilfley, Ph.D., Washington University St. Louis

NIH Staff

Dr. Kathyrn Koeller, Ph.D., CSR Research & Review Integrity Officer

Dr. Miriam Mintzer, Ph.D., CSR

Dr. Raul Rojas, Ph.D., CSR

More Updates from the CSR Office of Training & Development

- **Bias Awareness Training** – also slated for integration with eRA/IAR

- CSR held **New Chair Orientations** this summer – 9 sessions, 2 hours, ~90 incoming chartered study section chairs, facilitated, interactive sessions covering a range of topics: fairness, bias, time-management, facilitating discussions, promoting inclusive study section culture

- **Multiple trainings for SROs**, new SRO, SRO workshops, development of policy resources – bias, integrity, active meeting presence/intervention

- Upcoming expansion of Office to include systems training and training/development program for support staff

March 2023 CSRAC - OTD Director, Dr. Miriam Mintzer

w a New Chair Orientation Session: https://public.csr.nih.gov/ForReviewers/MeetingOverview/NewChairOrientation2021

CSR Staffing Update

SRO staffing levels have improved significantly over the last year

- **Proactive approach** to recruit and onboard strong candidates replaced prior "reactive" approach to backfill vacancies created by attrition, retirements → CSR was always in a significant deficit.

- **Concerted hiring effort** by our supervisors, with outreach via social media, formal networks such as NIH Global Recruitment Unit, personal networks, and paid advertisements

- Offering **remote work option** puts us at a competitive advantage and has broadened the applicant pool

- **Focus on retention** – active workload management, staff engagement, creation of advancement opportunities

- **Also have multiple ongoing efforts focused on recruiting/retaining our strong review support, administrative, technical staff - critical to our scientific mission**

Update: Simplifying Review Criteria Initiative

Non-Clinical Trials (non-CT) WG

CSR Advisory Council Members

Jinming Gao, Ph.D., UT Southwestern Medical Center

Alfred George, M.D., Northwestern University

Yasmin Hurd, Ph.D., Mount Sinai School of Medicine

Deanna Kroetz, Ph.D., University of California, San Francisco

José López, M.D., Bloodworks Northwest Research Institute

Tonya Palermo, Ph.D., University of Washington
Co-chair

Working Group Ad Hocs

Kevin Corbett, Ph.D., University of California, San Diego

Michelle Janelsins, Ph.D., University of Rochester Medical Center

Brooks King-Casas, Ph.D., Virginia Tech University

NIH Staff

Sally Amero, Ph.D., Office of Extramural Research

Bruce Reed, Ph.D., **Co-Chair**

Clinical Trials (CT) WG

CSR Advisory Council Members

Alfred George, M.D., Northwestern University

Yasmin Hurd, Ph.D., Mount Sinai School of Medicine

Tonya Palermo, Ph.D., University of Washington
Co-chair

Working Group Ad Hocs

Brian Boyd, Ph.D., University of Kansas

Matthew Carpenter, Ph.D., Medical University of South Carolina

Michelle Janelsins, Ph.D., University of Rochester Medical Center

Brooks King-Casas, Ph.D., Virginia Tech University

Pamela Munster, M.D., University of California San Francisco

NIH Staff

Sally Amero, Ph.D., Office of Extramural Research

Bruce Reed, Ph.D., **Co-Chair**

- Jan 2020 – Convened CSRAC Working Group on Simplifying Review Criteria

- **Charge**: Recommend simplified review criteria to improve quality of review through a refocus on scientific merit assessment

- **Scope**: RPGs, with a focus on R01s/R21s

- **Group split into two –** WG1 focused on less complex non-CTs (~90% of NIH applications), then bring additional expertise in WG2 to focus on CTs.

- **Recommendations approved by full CSR Advisory Council – Mar 2021**

Working Group Recommendations

- Note: NIH's 5 review criteria *(Significance, Innovation, Investigators, Approach, Environment)* are defined by PHS C.F.R. 52.h.8 – **the agency cannot change them but has discretion about how to interpret or group them, and on all matters of scoring**

- **Main recommendations:** Group 5 criteria into 3 factors

     Factor 1: Importance of the Science

     Significance, Innovation

     Factor 2: Feasibility and Rigor

     Approach

     Factor 3: Investigators and Environment

     Investigators, Environment

- Multiple other recommendations re: Additional Criteria, Considerations

CSR Advisory Council Working Groups on Simplifying Review - Report
https://public.csr.nih.gov/sites/default/files/2021-04/Recommendations_of_the_CSRAC_Working_Group_on_Simplifying_Review-non-CT_and_CT.pdf

Update on Working Group Recommendations

- After receiving full Council approval in March 2021, the concept was supported by an NIH senior leadership committee, which formed an NIH working group to further vet and develop the recommendations.

- This NIH working group [co-chaired by Jon Lorsch, NIGMS & Noni Byrnes, CSR], focused on non-CT (non-clinical trials) criteria, and proposed a set of restructured criteria for research project grants (RPGs) based on the WG recommendations, retaining the 3-factor framework, ***with some modifications in scoring and language to reduce the effects of reputational bias in scientific peer review.***

    *** **New framework was approved by NIH leadership in April 2022** ***

- Ongoing 2nd NIH working group tackling the large and complex task of integrating strong, rigorous review of Clinical Trial RPGs into the approved 3-factor framework – expected to be completed in a few months.

- Tentative plan, barring any unanticipated delays, is to roll out changes for both CT/non-CT RPG reviews together, for applications in the October 2024 council round.

- Trans-NIH implementation team, led by OER and CSR, is already developing systematic training, communications and outreach plans for socializing changes across the extramural community.

Stay tuned for much more detailed information – coming soon!

ENQUIRE
EVALUATING PANEL QUALITY IN REVIEW

Two-stage, systematic, data-driven, continuous process – about 20% of CSR study sections evaluated per year, i.e. each study section evaluated every five years

Stage 1 [Scientific Evaluation]: Evaluate scientific currency of study sections in cluster, ensure that they map onto current directions in the field. Identify emerging areas, declining areas, create/merge/sunset study sections to optimize identification of highest impact research

Stage 2 [Process Evaluation]: Evaluate review process, adequate size to ensure competition, scoring patterns, ESI outcomes, expertise on rosters, appropriateness of assignments and meeting dynamics [PO/reviewer surveys, report of site visits to study section meetings] and recommend changes to optimize identification of highest impact research

STAGE 1: External Scientific Evaluation Panel	→	STAGE 2: NIH Process Evaluation Panel	→	CSR Advisory Council Approval
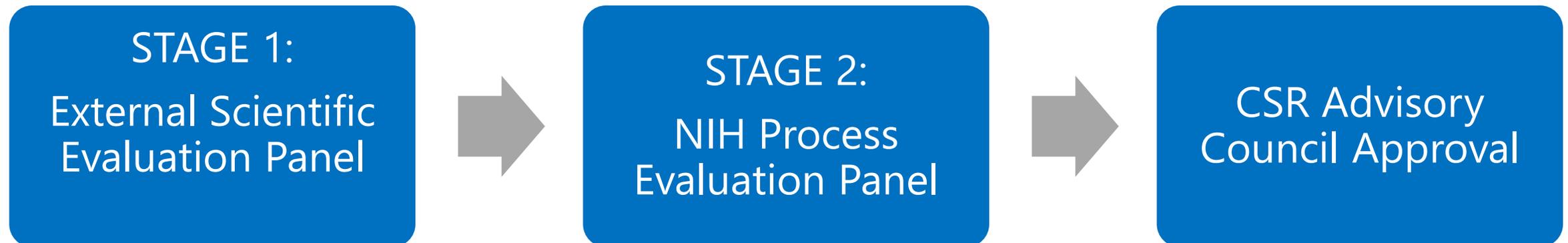
The entire ENQUIRE process is overseen by CSR's Scientific Division Directors

What happens after CSRAC?
Implementation of ENQUIRE requires many steps and many hands!

| CSR - Guideline refinement, development of overlap statements | → | MOCK REFERRAL | → | Refinement of guidelines and overlap statements | → | Final Study Sections with scientific guidelines and overlap statements published | → | Existing study section members transferred based on expertise needs in new/restructured panels | → | New Study Sections hold meetings |
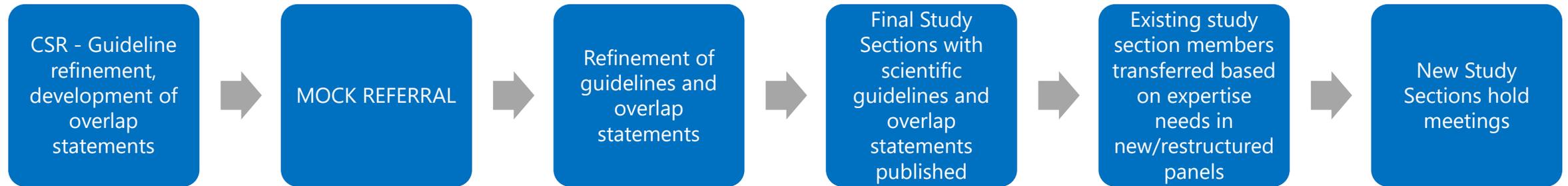
Acknowledgment

Scientific Review Branch Chiefs, SROs

Public Health Analysts & Survey Team

Division of Planning, Analysis and Information Management (DPAIM)

Division of Receipt and Referral

Divisional Management Analysts, Divisional Leads

Committee Management Branch, and more!

Eleven scientific clusters completed or in progress

Healthcare Delivery/Patient Outcomes

Population Sciences and Epidemiology

GI, Renal, Endocrine, Metabolism

Drug Discovery

Functional/Cognitive Neuroscience

Microbiology/Infectious Disease

Cardiac, Vascular, Hematology

Clinical Neuroscience

Molecular and Cellular Basic Sciences

Immunology/Inflammation and Respiratory Systems

Cancer Biology

Next up (Mar 2023 CSRAC): ENQUIRE analysis plans - Fidelity of referral, appropriate expertise, application #s, ESI outcomes, & more

Update: CSR Initiatives to Address Bias in Peer Review

New webpage launched with details, analyses, data

**https://public.csr.nih.gov/AboutCSR/Address-Bias-in-Peer-Review**

Previously discussed with CSRAC: Strategies for Diversifying Review Panels

- Emphasizing **critical need** for the NIH to hear diverse perspectives to fulfill peer review's mission of identifying the best, most disruptive, novel science.

- The most effective, highest-quality review committees are **broadly diverse in multiple dimensions**. These include: 1) scientific background and perspective; 2) demographic/geographic; 3) career stage and; 4) peer review experience

- Standing study section membership process is thorough, multiple levels of oversight and approval. We are focusing on enhancing diversity on **Special Emphasis Panels**

- **Raising collective awareness,** setting expectations, sharing panel-level data with management/staff

- Providing **tools** for SROs to find "lesser-known" well-qualified reviewers, building up database with multiple sources of scientific experts [Reviewer Finder]

- SRO **training**, esp. SRO-to-SRO sharing of best practices in broader recruitment strategies

% of Women on CSR rosters Council Rounds 2019/10 to 2022/05
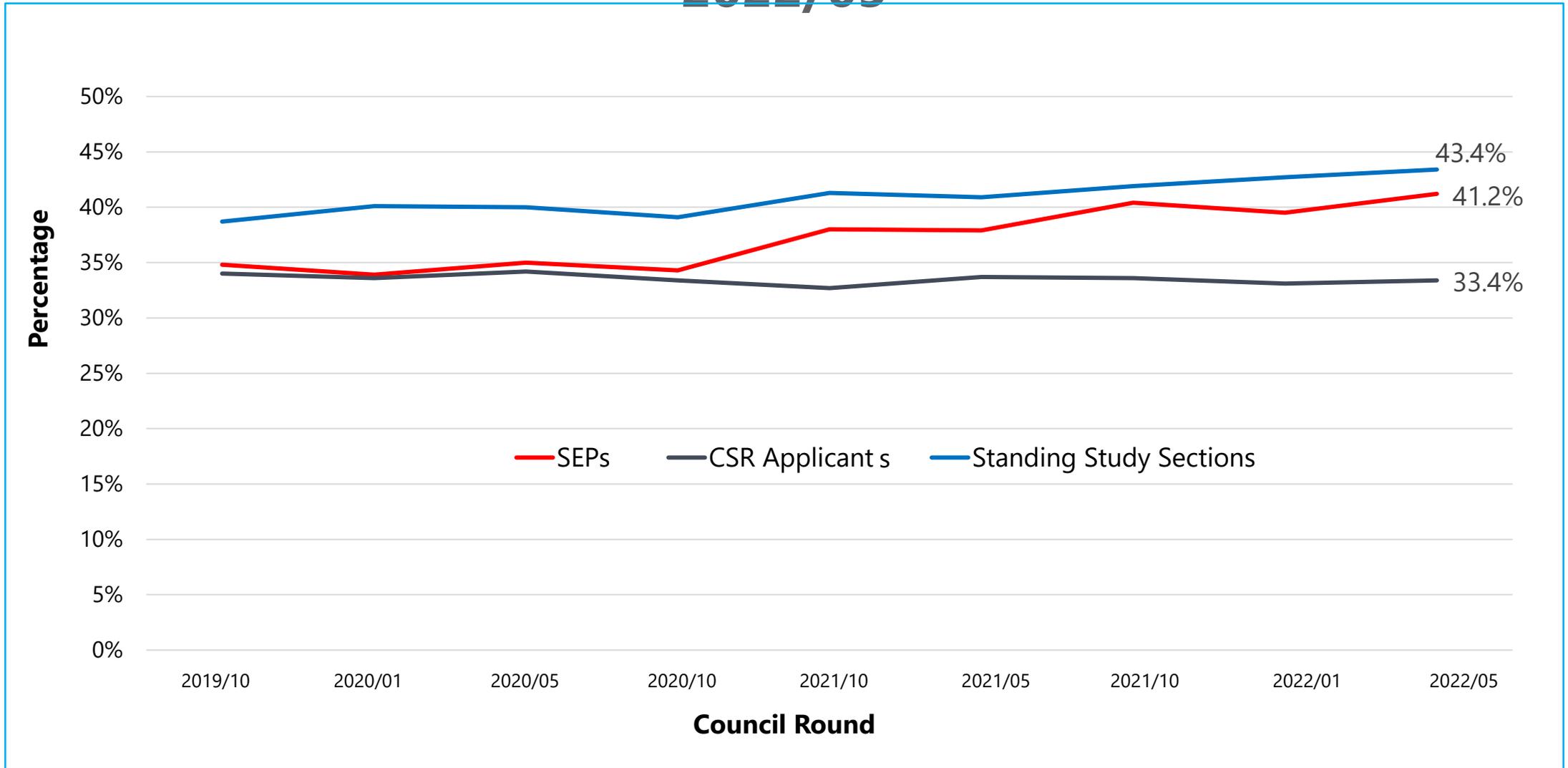
% of URM on CSR rosters Council Rounds 2019/10 to 2022/05
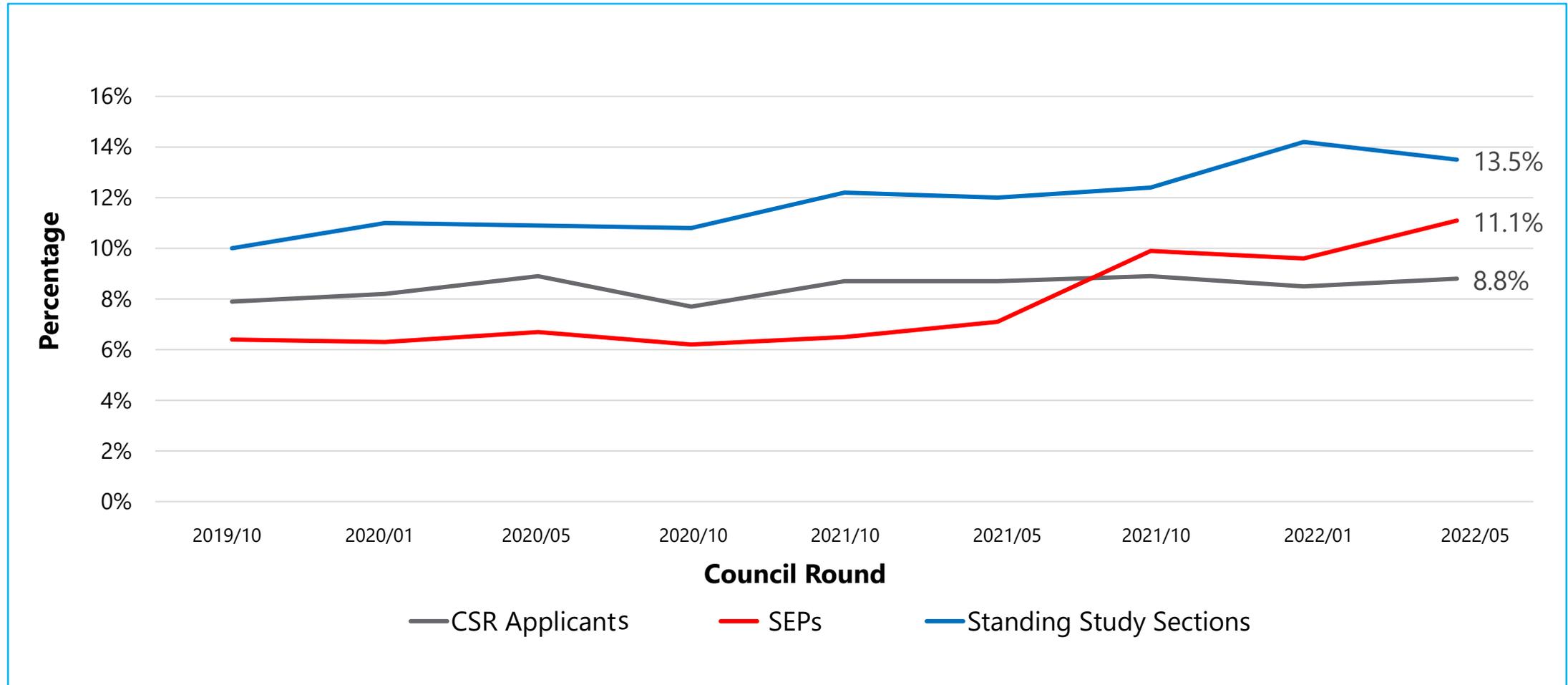
Acknowledgement

CSR's scientific, administrative, technical and support staff of federal employees and contractors!

Discussion