U.S. Department of Health & Human Services

NIH Center for Scientific Review

# CSR's Initiatives to Strengthen Peer Review

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Director
Center for Scientific Review

National Advisory Council for Nursing Research
September 12, 2023

# Overview: Mission & Scope

# CSR's Mission

NIH Center for Scientific Review

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.

# Scope [FY23 applications]

**~79,000**
NIH Applications

**~60,000 (76%)**
**Reviewed by CSR**


**94%**
of NIH R01s


**96%**
of NIH SBIRs-STTRs


**84%**
of NIH NRSA Fellowships

**~275 SROs, ~19,000 reviewers, ~1,200 meetings**

# FY23: 161 Special Initiatives Reviewed by CSR

Transformative Research to Address Health Disparities and Advance Health Equity

ComPASS
Community Partnerships to Advance Science for Society

CGE
Somatic Cell Genome Editing

FIRST
Faculty Institutional Recruitment for Sustainable Transformation


RECOVER
Researching COVID to Enhance Recovery

NIH DIRECTOR'S
TRANSFORMATIVE RESEARCH AWARD

NIH DIRECTOR'S
NEW INNOVATOR AWARD

NIH DIRECTOR'S
PIONEER AWARD

NIH DIRECTOR'S
EARLY INDEPENDENCE AWARD

NIH HEAL INITIATIVE

Tobacco Regulatory Science Program

MaHT

HuBMAP
Human BioMolecular Atlas Program

4D Nucleome

CryoEM

DS-I Africa
Data Science for Health Discovery and Innovation in Africa

SenNet

ECHO
Environmental influences on Child Health Outcomes
A program supported by the NIH

National Institutes of Health
Counter ACT
Countermeasures Against Chemical Threats

All of Us
RESEARCH PROGRAM

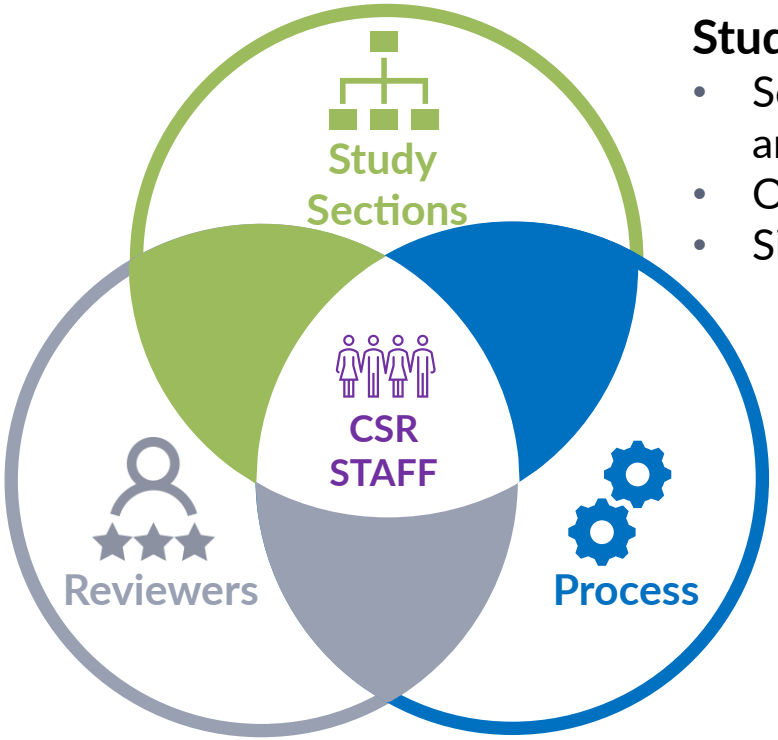
IMPROVE Initiative
Implementing a Maternal health and PRegnancy Outcomes Vision for Everyone

NIH The BRAIN Initiative®

Native American Research Centers for Health (NARCH)

# Strategic Framework & Initiatives

# Since 2019: CSR's Strategic Framework for Optimizing Peer Review




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

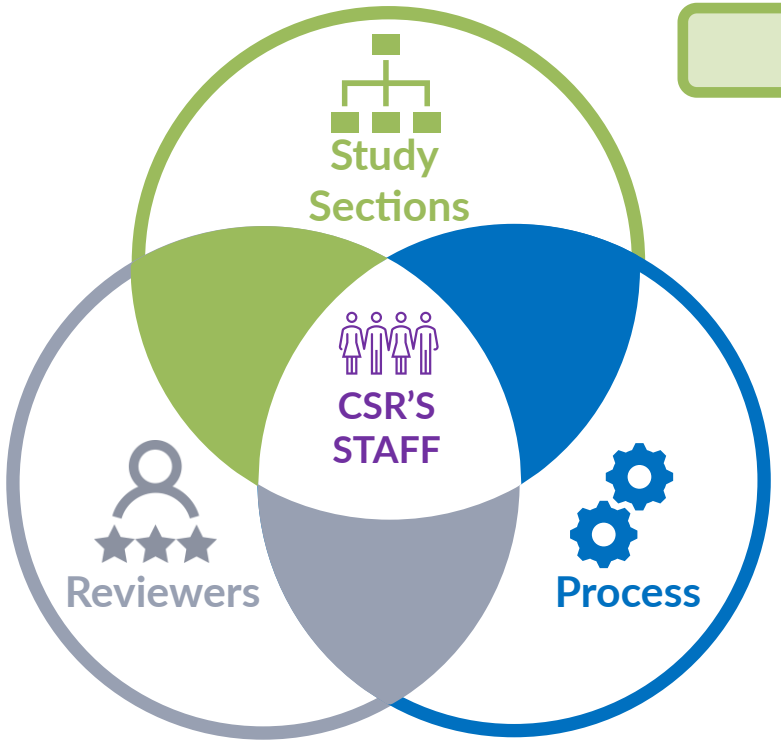
**Reviewers**
- Reviewer Training
- Broaden/Diversify Reviewer Pool
- Incentivizing Service
- Reviewer Evaluation

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

**Transparency** | **Data-driven decisions** | **Stakeholder engagement** | **Staff engagement, training, development**

# Today's Topics

1. ENQUIRE




2. Simplifying Review: RPGs

3. Improving Review of NRSA Fs

4. Promoting Fairness

5. Diversifying Panels


# 1. ENQUIRE

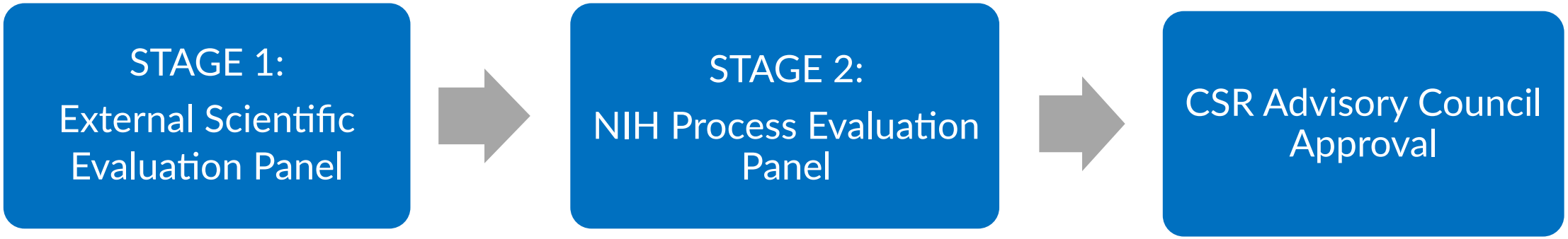
# Study Section Evaluation, Restructuring

## ENQUIRE: Evaluating Panel Quality In Review

**Launched in 2019, a systematic, data-driven, continuous** process to evaluate study sections – about 20% of CSR study sections assessed per year, i.e. each study section assessed every five years

**Stage 1 [Scientific Evaluation]**: Evaluate scientific currency of study sections to optimize identification of high impact research. Identify emerging areas, declining areas, create/merge/sunset study sections *(panel provided with output/publication data, ESI outcomes data, sample abstracts/aims, & more)*

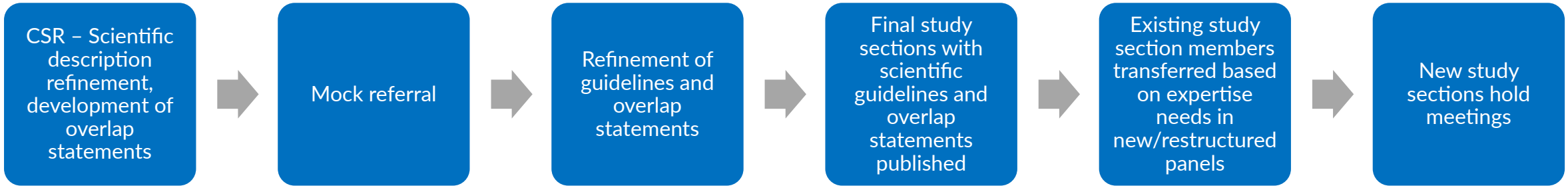
**Stage 2 [Process Evaluation]:** Evaluate study section function and recommend changes to optimize identification of highest impact research *(panel provided with application number trends, score distributions, roster expertise, reports of meeting dynamics through study section site visits, program feedback & more)*




**The entire ENQUIRE process is overseen by CSR's Scientific Division Directors.**

# ENQUIRE Implementation Process

## Multiple steps following CSR Advisory Council approval




**ENQUIRE takes about 12-18 months from initiation to implementation of new or restructured study sections.**

# Thirteen scientific clusters (152 study sections) 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/Translational Neuroscience
- Molecular and Cellular Basic Sciences
- Immunology/Inflammation and Respiratory Systems
- Cancer Biology
- Social and Behavioral Studies
- Developmental Biology and Regeneration

# ENQUIRE, in general, results in substantive changes in study sections

## Elimination/merging of smaller, boutique panels, refreshing scientific guidelines, new study sections, incorporation of growing/emerging scientific areas

*some examples….*

**Therapeutics: Late-stage preclinical drug discovery, biologics/drug delivery**


**Social Determinants of Health**

**Mobile Health Technologies**

**Cancer Immunotherapy**


# 2. Simplifying Review of NIH Research Project Grant (RPG) Applications

# Goal: Optimize identification of the most promising scientific research

- **Remove administrative/policy compliance items from the peer review,** reducing burden on scientific expert reviewers and allowing them to focus on the singular goal of first-level peer review - providing advice to the agency regarding the scientific merit of grant applications,

- **Evaluate Investigator and Environment within the context of the proposed research project,** mitigating the undue influence of personal/institutional reputation on the evaluation of the science

# Overview of Changes to Peer Review Framework for RPGs

## MAIN REVIEW FACTORS – all affect Overall Impact score

- **Factor 1: Importance of the Research [scored]** - strengths/weaknesses
*Significance, Innovation*

- **Factor 2: Rigor and Feasibility [scored]** - strengths/weaknesses
*Approach*

- **Factor 3: Expertise and Resources [not scored** - drop down- appropriate, or identify gaps]
*Investigators, Environment*

- Study Timeline (for CT only)
- Inclusion plans – sex/gender, race/ethnicity, based on age (HS and CT)

## ADDITIONAL CRITERIA – not scored, but can affect Overall Impact score

- ~~Study Timeline (for CT only)~~
- Human Subject Protections (for HS and CT)
- ~~Inclusion of Women, Minorities, and Children (for HS and CT)~~
- Vertebrate Animal Protections
- Biohazards
- Resubmission/Renewal/Revisions

*Most "Additional Review Considerations", which had no bearing on Overall Impact Score,* ***removed*** *from first-level peer review.*

*Reviewers briefly comment on Budget and Chem/Bio resources authentication plans*

# Community Input, Process and Timeline

**Jan 2020 – April 2021:**

- **Initial input gathering through blog posts** (Open Mike, Review Matters), strong response (>400 comments), content analyses
- **Convened two CSR Advisory Council working groups** with overlapping membership to consider non-clinical trials (~90% of NIH applications) and clinical trials RPGs.
- **Legal and regulatory guardrails provided:** *5 review criteria (Significance, Investigators, Innovation, Approach, Environment) are defined by PHS C.F.R. 52.h.8– NIH has discretion about how to interpret or group them, and on all matters of scoring.* Working groups held 11 virtual meetings to develop framework and recommendations
- **Full CSR Advisory Council approval** of recommendations, publication of working group report.

**July 2021 – Sept 2022:**

- Internal NIH input/modifications to the framework, **approval by IC and NIH leadership**

**Dec 2022 – March 2023:**

- **Public input** through NIH Request for Information (RFI) – majority supportive of changes [RFI report]

**Implementation planned for applications received January 2025, reviewed in summer 2025, October 2025 funding**

# Next Steps: Between Now and January 2025

**Fall 2023:**

- Issue Guide Notice announcing changes
- Public webinar providing an overview of changes
- Staff webinar providing overview of changes and timeline for implementation

**Over the next year:**

- Refining application instructions and getting higher-level approvals (Office of Management and Budget)
- Changes to eRA systems
- **Development and dissemination of training/outreach resources to socialize the change for reviewers, chairs, applicants, staff**

# Acknowledgment: CSR Advisory Council Working Groups on Simplifying RPG Review

## CSR Advisory Council

**Jinming Gao, Ph.D.** (non-CT)
Elaine Dewey Sammons Distinguished Chair in Cancer Research
Professor of Oncology, Pharmacology, Otolaryngology, and Cell Biology
UT Southwestern Medical Center

**Alfred George, M.D.** (Both)
Magerstadt Chair and Alfred Newton Richards Professor of Pharmacology
Director, Center for Pharmacogenomics
Northwestern School of Medicine

**Yasmin Hurd, Ph.D.** (Both)
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Director of the Addiction Institute
Icahn School of Medicine, Mt. Sinai

**Deanna Kroetz, Ph.D.** (non-CT)
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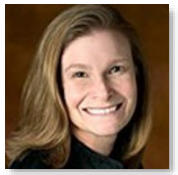
**José López, M.D.** (non-CT)
Professor, Division of Hematology,
University of Washington
Member, Bloodworks Northwest Research Institute



**Tonya Palermo, Ph.D. (Co-Chair)** (Both)
Professor, Anesthesiology and Pain Medicine
Associate Director of the Center for Child Health, Behavior and Development
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## Ad-hoc

**Brian Boyd, Ph.D.** (CT)
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**Matthew Carpenter, Ph.D.** (CT)
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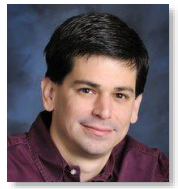

**Brooks King-Casas, Ph.D.** (Both)
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UCSF Helen Diller Family Comprehensive Cancer Center

## NIH Staff

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Deputy Director
NIH Center for Scientific Review

**Sally Amero, Ph.D.** (Both)
Review Policy Officer (Retired)
NIH Office of Extramural Research

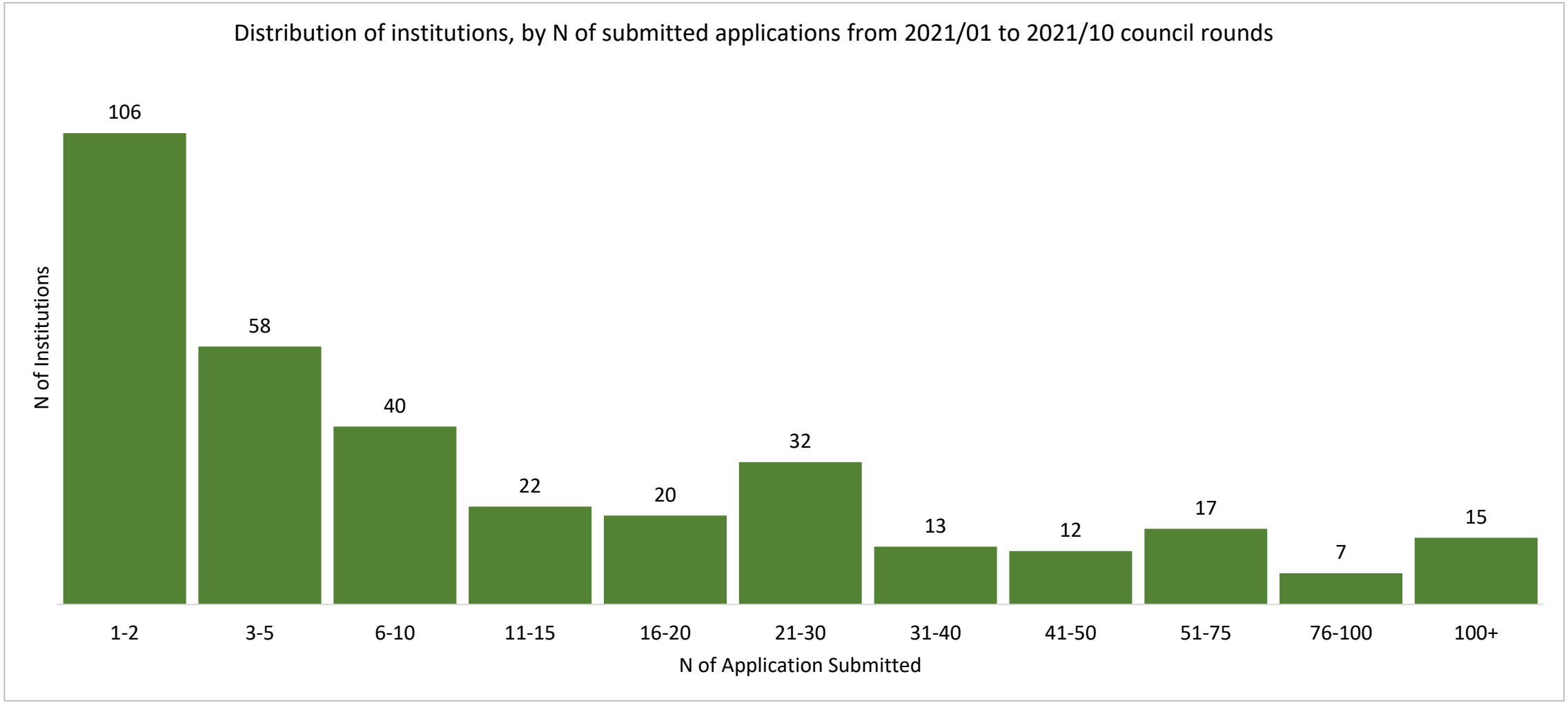

# 3. Improving the Review of NRSA Fellowship (F) Applications

# Goal: Optimize the identification and training of the most promising scientists of the next generation.

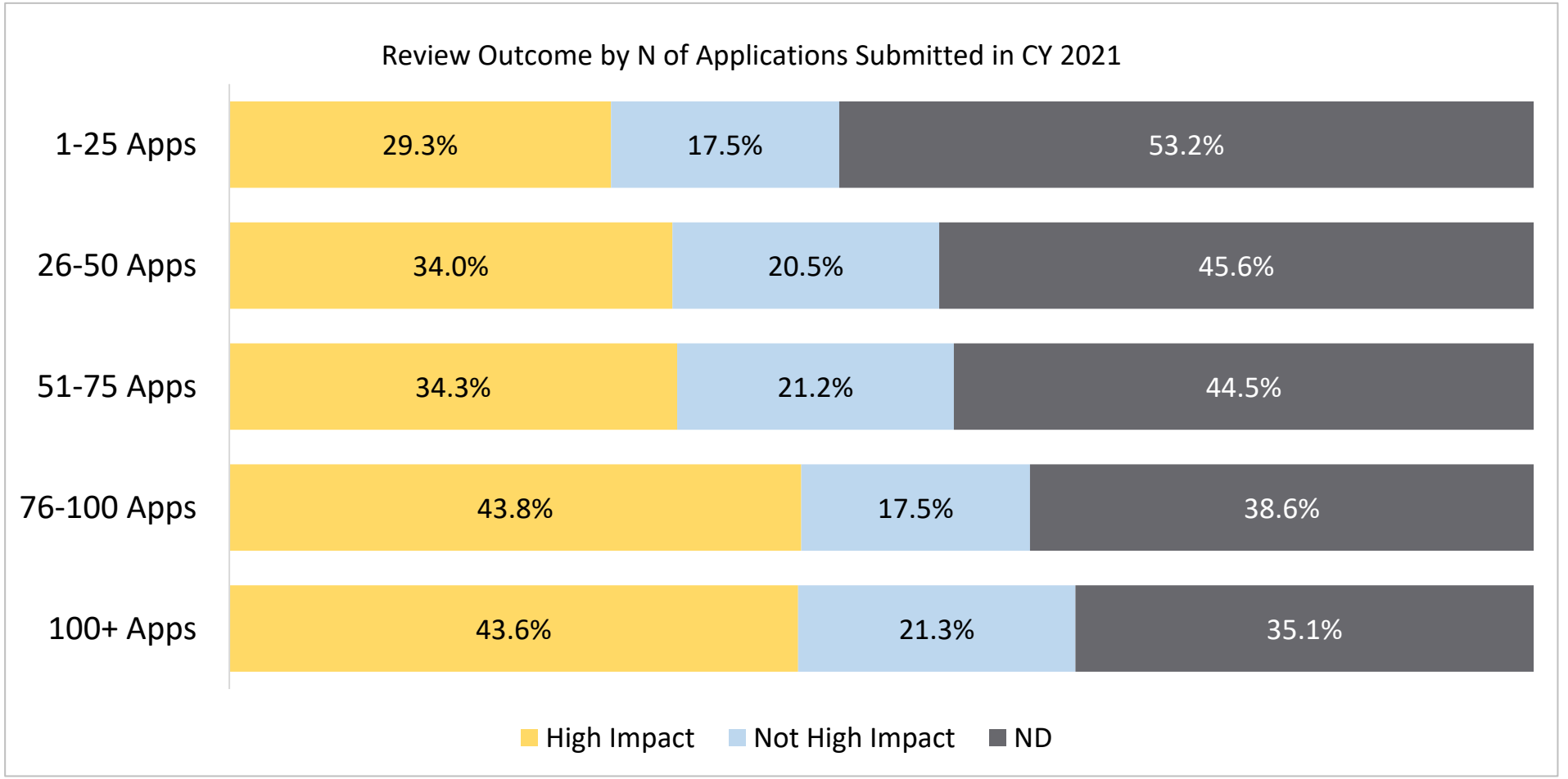
- **Concerns from the scientific community that NIH is potentially leaving out very promising research scientists of the future because of a process that favors elite institutions, and senior, well-known sponsors**

- Data analysis of >6,000 applications supported those concerns
  - Fellowship applications are concentrated in a small number of institutions
  - Applications from those submitting a large number do better in review
  - Review outcomes for fellowships improve as the rank of the sponsor increases

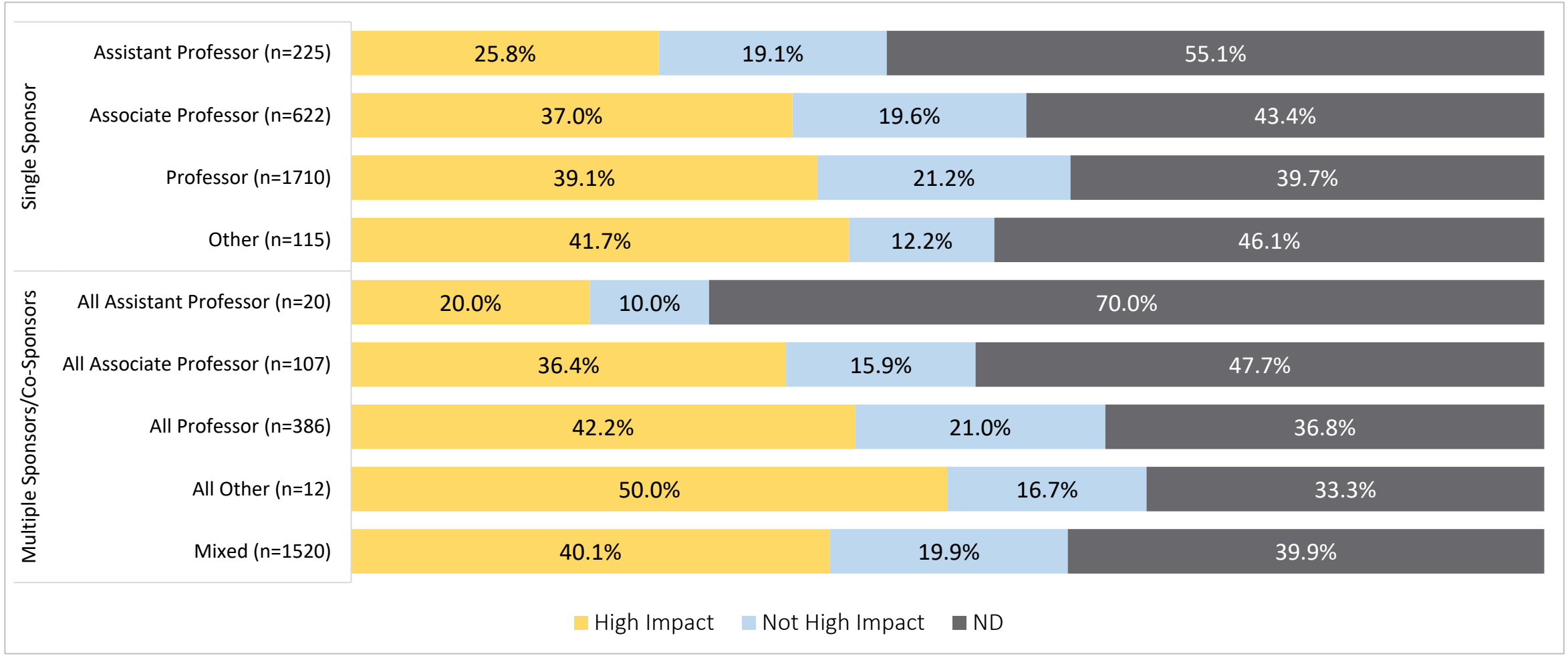
# A large number of NIH NRSA Fellowship applications are submitted by a small number of institutions



# Applications from institutions that submit low number of fellowship applications have worse review outcomes



# Review outcomes improve as the academic rank of the sponsors rises



# Recommendation 1: Change the Fellowship Review Criteria

## Focus on potential of applicant, strength of science, quality of training plan

### Current

1. Fellowship Applicant
2. Sponsors, Collaborators, & Consultants
3. Research Training Plan
4. Training Potential
5. Institutional Environment & Commitment to Training

### New

1. Scientific potential, fellowship goals, and preparedness of the applicant
   - *Fellowship Applicant*
2. Science and scientific resources
   - *Research Training Plan*
   - Elements of: *Sponsor, Collaborators, & Consultants; Institutional Environment & Commitment to Training*
3. Training plan and training resources
   - Elements of: *Sponsor, Collaborators, & Consultants; Institutional Environment & Commitment to Training*

# Recommendation 2: Revise the Fellowship Application (i.e. information provided to reviewers)

## No change

**Research Training Plan** *Specific Aims, Research strategy, respective contributions, RCR, etc.*

## Revised to align with new review criteria

- **Fellowship Applicant section** *to allow applicants to present their scientific thinking, their needs, qualifications, and goals.* ***Eliminate grades.***
- **Sponsors, Collaborators and Consultants section** *- greater emphasis on training and mentorship approach and plan for* ***this particular*** *student, eliminate peer review of financial support (sponsor funding)*
- **Letters of support** *to address targeted, trainee-specific questions in structured fields - discourages boilerplate language, easier for reviewers to differentiate and evaluate*

## New

**Allow an optional statement of special circumstances** *to address situations that might have hindered the trainee's progress such as harassment, the COVID-19 pandemic, or other circumstances*

# Community Input, Process and Timeline

**Sept 2021- October 2022:**

- **Convened a CSR Advisory Council working group** to consider how peer review of fellowship applications could be strengthened
- **Initial input gathering through blog posts** (Open Mike, Review Matters), strong response (>100 comments), content analyses
- **Data provided** to the working group throughout their thinking process
- **Full CSR Advisory Council approval** of recommendations, publication of working group report

**October 2022-November 2022:**

- Internal NIH input, **approval by IC and NIH leadership**

**April 2023 – June 2023:**

- **Public input** through NIH Request for Information (RFI) – majority supportive of changes [RFI report to be published in September 2023]

**Implementation planned for applications received January 2025, reviewed in summer 2025, October 2025 funding**

# Acknowledgment: CSRAC Working Group: NRSA Fellowship Review Criteria

## CSR Advisory Council

Chair

**Elizabeth Villa, Ph.D.**

University of California San Diego

**Narasimhan Rajaram, Ph.D.**

University of Arkansas at Fayetteville

## Working Group Ad Hocs

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University of Texas at Dallas

**Katherine Friedman, Ph.D.**

Vanderbilt University

**Barbara Kazmierczak, MD, Ph.D.**

Yale University

**Scott Miller, Ph.D.**

Yale University

**Robin Queen, Ph.D.**

Virginia Tech

**Nathan Vanderford, Ph.D.**

University of Kentucky

**Judith Yanowitz, Ph.D.**

Magee-Women's Research Institute

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**Alison Gammie, Ph.D.**

Division of Training, Workforce Development, and Diversity, National Institute of General Medical Sciences

**Lystranne Maynard-Smith, Ph.D.**

Center for Scientific Review

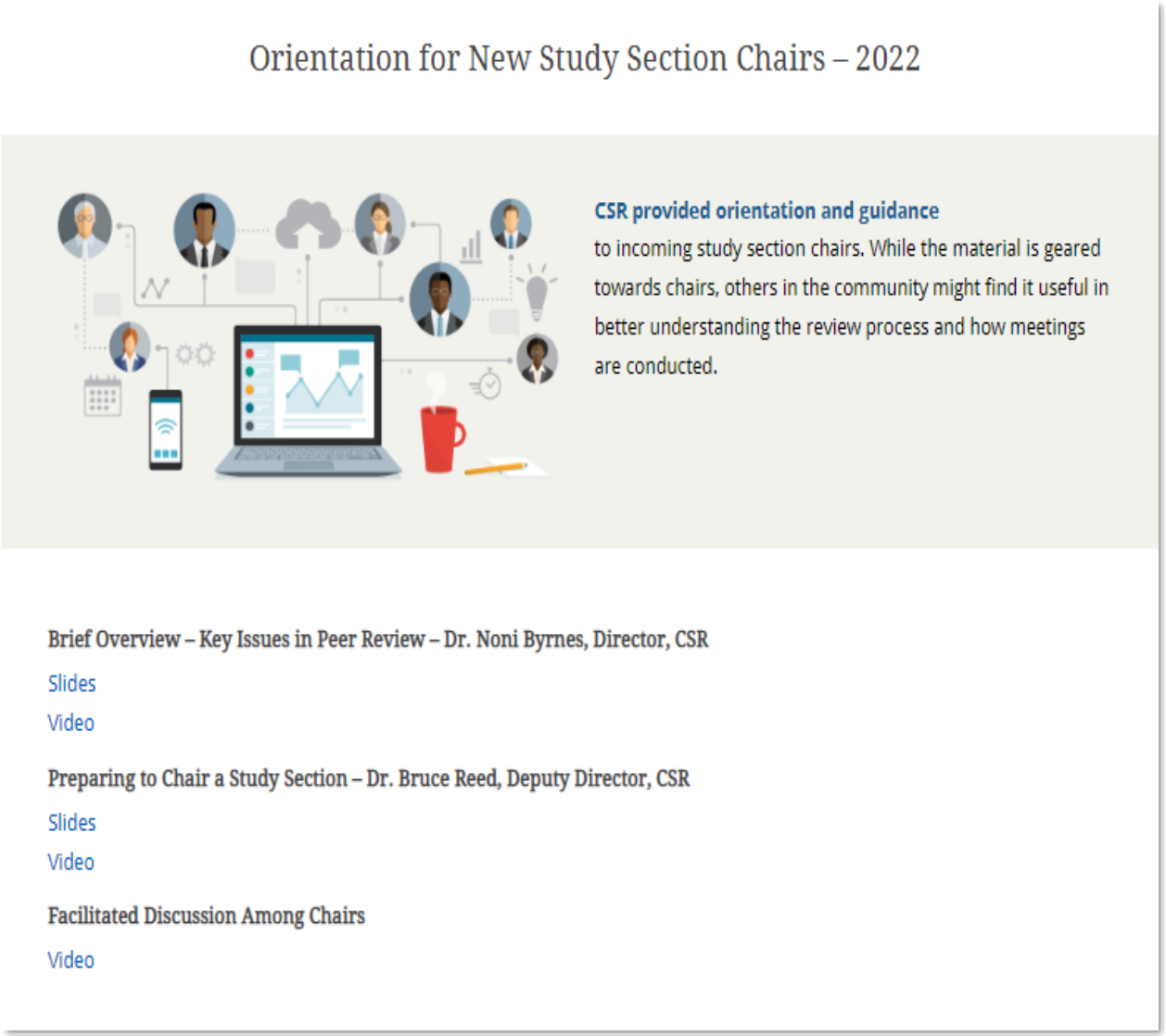
**Cibu Thomas, Ph.D.**

Center for Scientific Review


# 4. Promoting Fairness in Review

# CSR conducts annual summer Chair Orientation Sessions

## ~90 Incoming Study Section Chairs/year, 9-10 sessions




**Two-hour, interactive, facilitated session**

- 15-min overview
- 15-min nuts-and-bolts of chairing
- 1.5 hours of interactive discussion, using a vignette-based framework

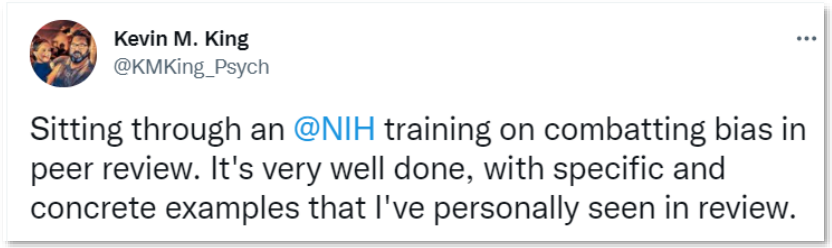
**Fairness of the Peer Review Process**

**What Can You Do As Chair?**

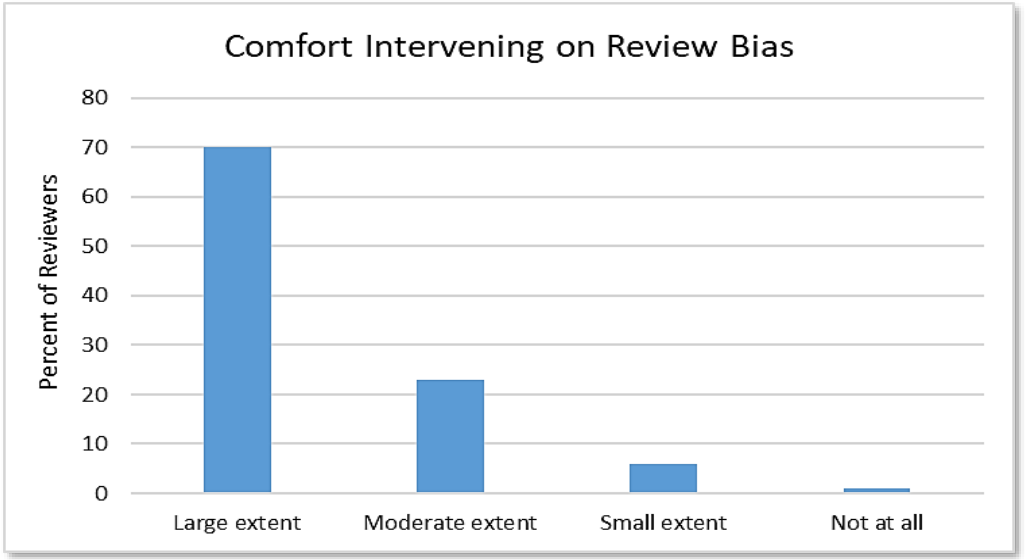
- Recognize your influence - in setting and changing the study section culture
- Actively foster a positive study section culture - confidentiality, integrity, encouraging broader participation/inclusion across the committee, call out statements that bias the scientific assessment (institution, career-stage, field, race/gender)
- Promote a focus on significance (ask the question), and consistency in scoring - score/word match, aligned to score guidance

# CSR's Bias Awareness Training for Reviewers – since August 2021

- Specifically targeted toward mitigating the most common (not all) biases in the peer review process. *Not implicit bias training* - includes personal testimonials, interactive exercises, narrated mock study section
- 30-min, delivered to reviewers ~4 weeks prior to the review meetings.
- >22,000 CSR reviewers have taken the training.
- Very well-received by scientific community - survey results indicate increased ability of reviewers to identify bias, increased comfort in intervening
- **To be required for all NIH reviewers beginning with May 2024 Council review meetings**








**Full Survey Analysis:** https://public.csr.nih.gov/sites/default/files/2022-04/Reviewer_Bias_Training_Survey_Report_2022-01_Council_Round_final.pdf

# CSR's Review Integrity Training Module (updated v.2 in Aug 2022)

- Interactive, scenario-based training [~30 min] on the reviewer's role in protecting confidentiality, integrity of the NIH review process -- before, during and after the meeting
- Content based on actual cases and input from 2019 CSR Advisory Council Working Group on Review Integrity (original version 1)
- >16,000 CSR reviewers have completed the training since its launch in Fall 2022
- **To be required for all NIH reviewers beginning with Feb/Mar 2024 review meetings**

# Direct Bias Reporting Mechanism – applicants, reviewers, program staff

**G.Fosu_AssocDir@csr.nih.gov**

- Included in signature of all CSR staff on outgoing emails
- Every allegation is carefully investigated by CSR senior management (Dr. Fosu and Scientific Division Director)
- If we agree re: biased/flawed review – CSR will re-review application in same council round.
- If we don't agree, the official NIH appeals process through IC council remains available to all investigators.
- Follow-up with reviewer and actions, as necessary, by CSR Scientific Division Director → foster culture change in review community

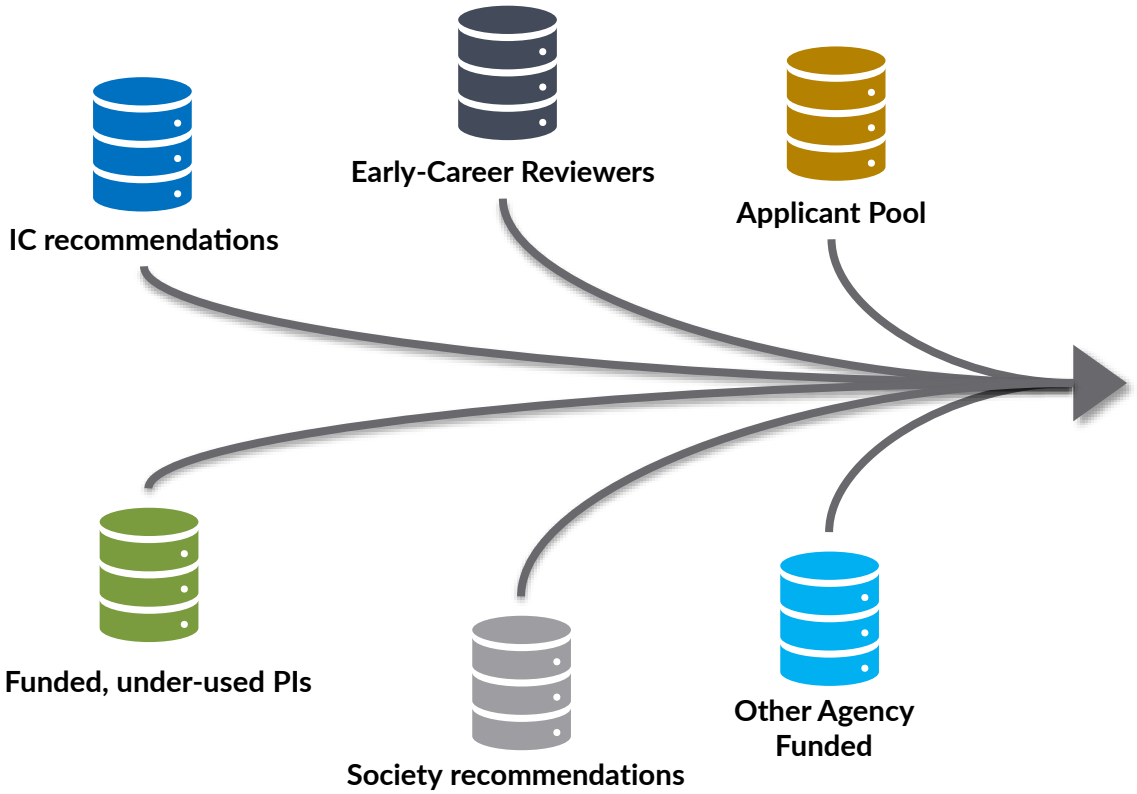
**Gabriel Fosu, Ph.D.**

CSR Associate Director for Diversity and Workforce Development [Chief Diversity Officer]

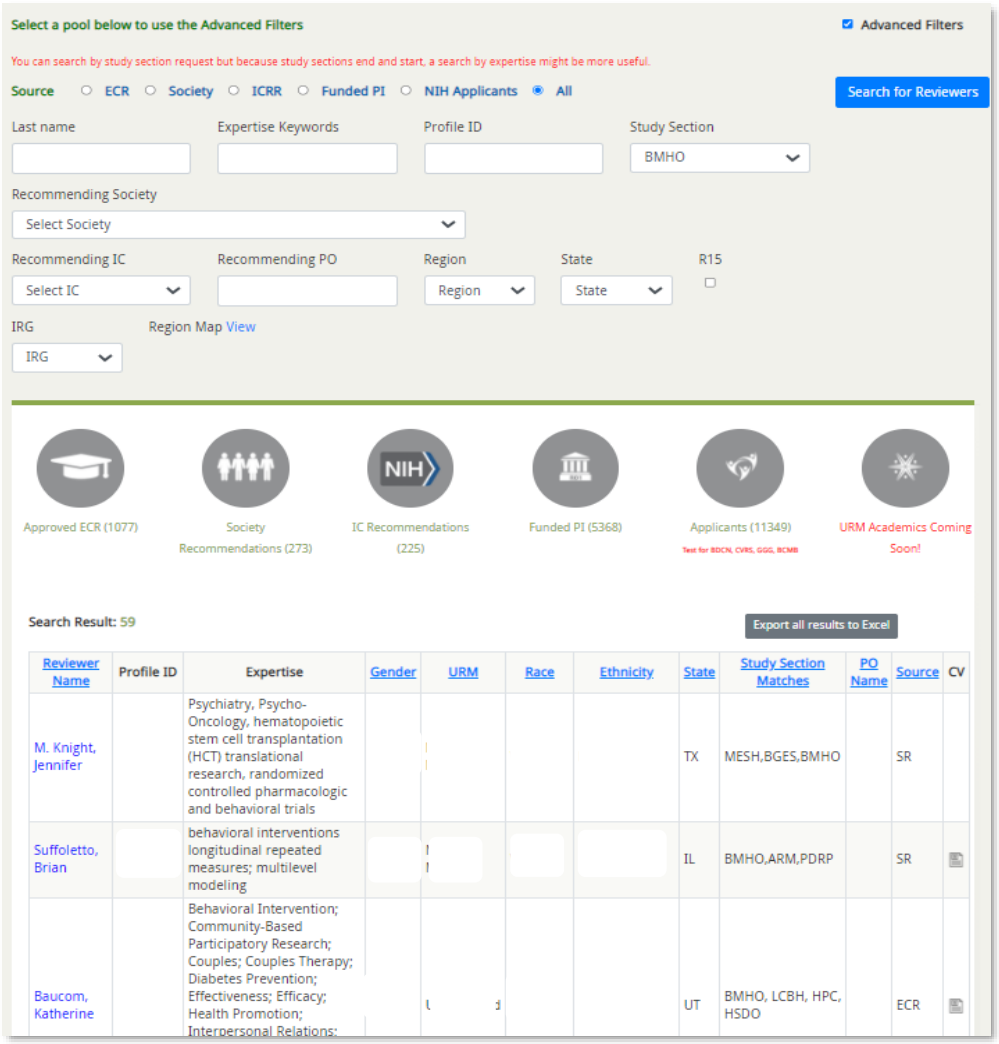

# 5. Diversifying Review Panels

# Broadening the Pool of Reviewers

## CSR Reviewer Finder Tool (for SROs to find "lesser-known" qualified reviewers)




Multiple Data Sources

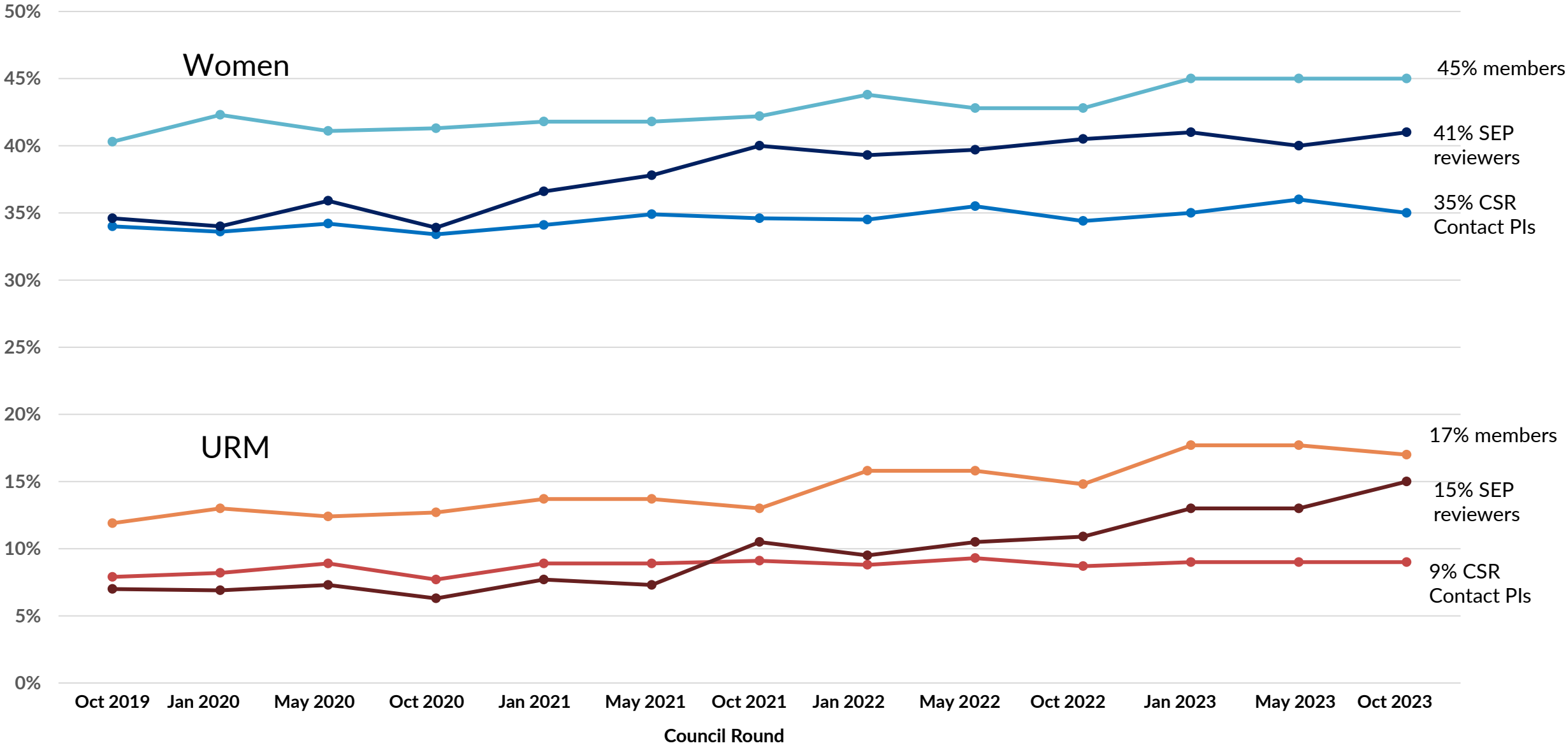



One interface – user-friendly for SROs

# CSR's Strategies for Diversifying Review Panels

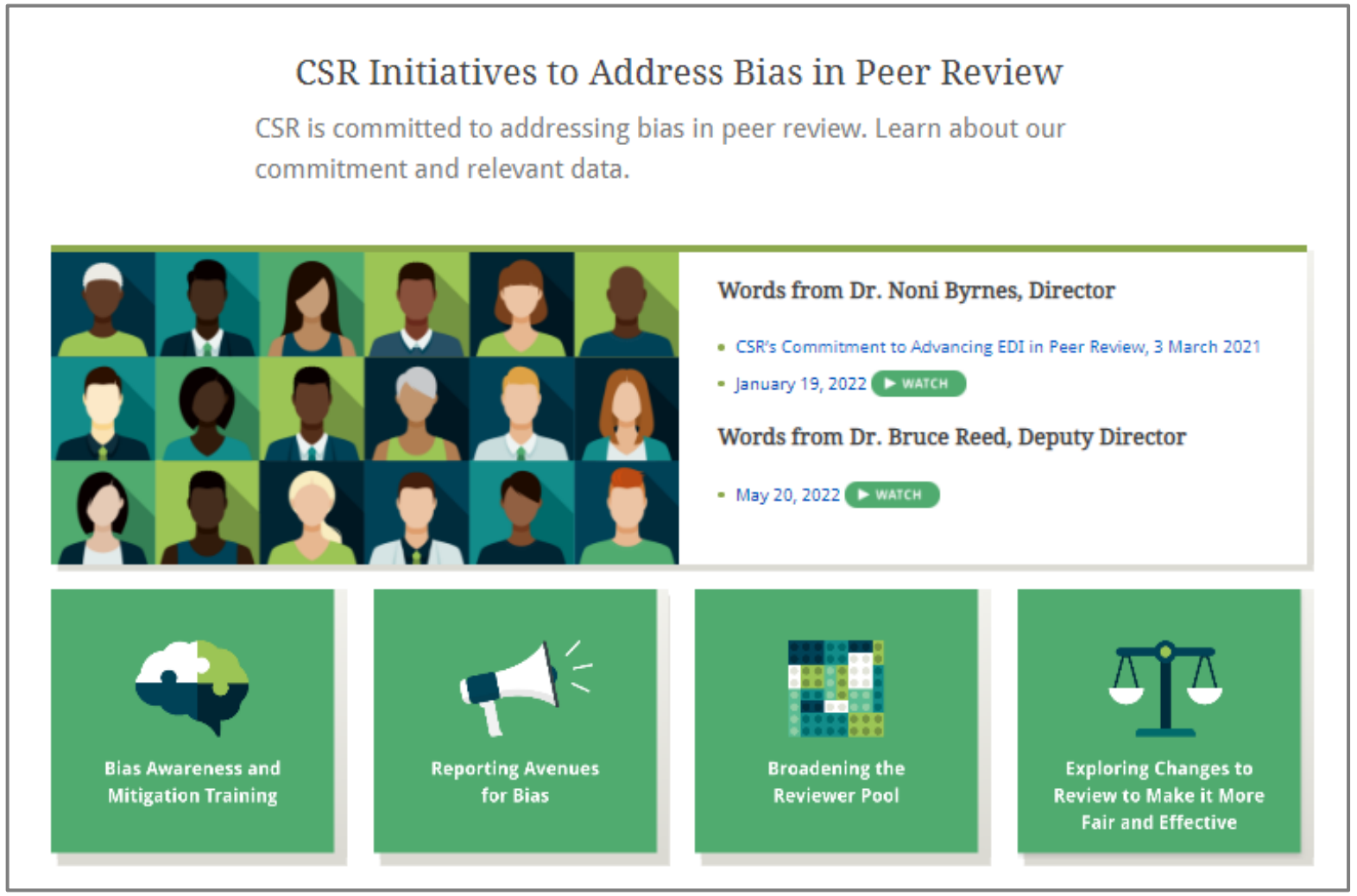
- Emphasizing **critical need** for the NIH to hear diverse perspectives to fulfill peer review's mission of identifying the best, most disruptive, novel science.
- The most effective, highest-quality review committees are **broadly diverse in multiple dimensions**. These include: 1) scientific background 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

# CSR continues to increase the diversity of its reviewer pool



# CSR Initiatives to Address Bias in Peer Review

**Details, data, analyses at: *https://public.csr.nih.gov/AboutCSR/Address-Bias-in-Peer-Review***



# Discussion