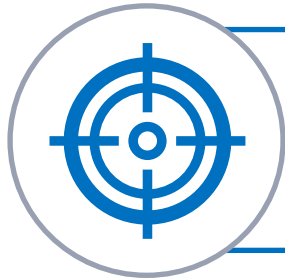# CSR's Initiatives to Strengthen Peer Review

Noni Byrnes, Ph.D.
Director
Center for Scientific Review

Council of Councils
May 11, 2023

# Overview: Mission & 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.

# Scope [FY23 applications]

**~79,000**
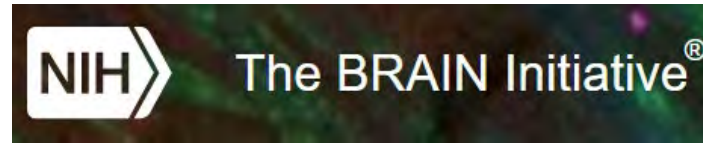NIH Applications

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

**94%** of NIH R01s — ~32,000

**96%** of NIH SBIRs-STTRs — ~6,300

**84%** of NIH NRSA Fellowships — ~5,000

**~275 SROs, ~19,000 reviewers, ~1,200 meetings**
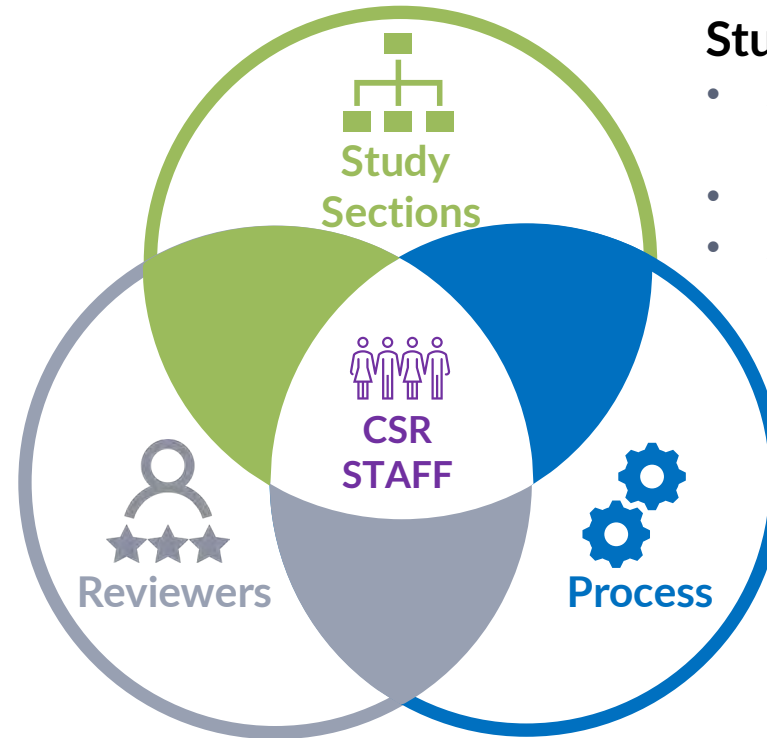
# FY23: 161 Special Initiatives Reviewed by CSR

# 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

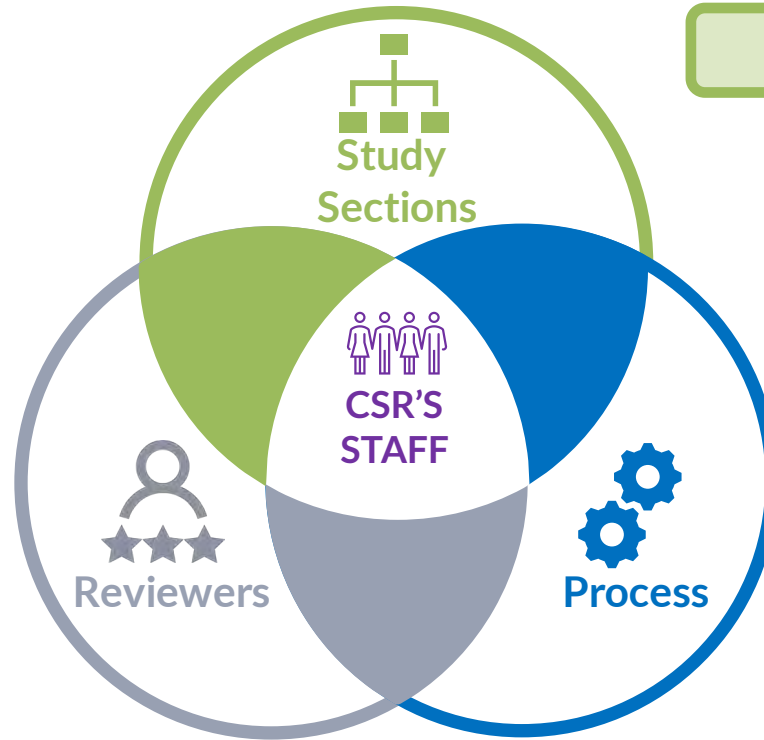**Transparency**   **Data-driven decisions**   **Stakeholder engagement**   **Staff engagement, training, development**
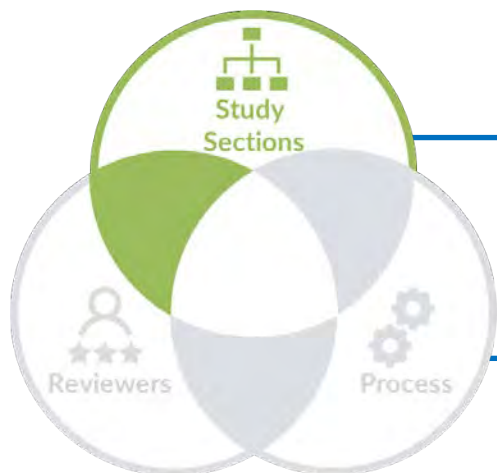
# Today's Topics



1. ENQUIRE

4. Promoting Fairness
5. Diversifying Panels

2. Simplifying Review: RPGs
3. Improving Review of NRSA Fs

Study Sections

CSR'S STAFF
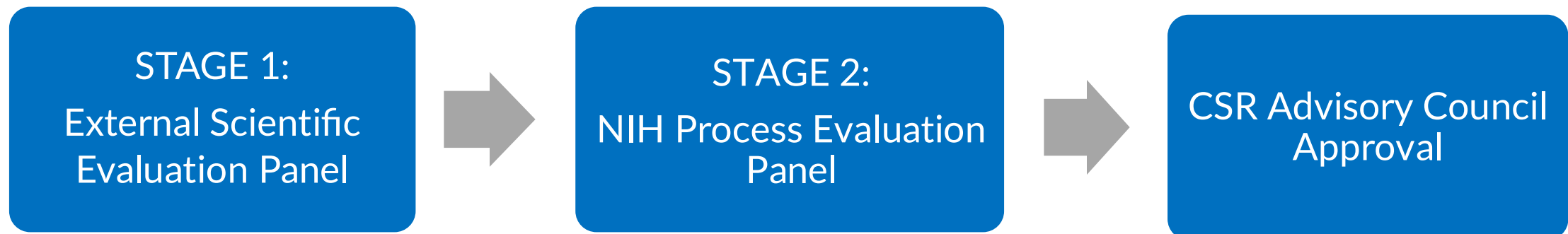
Reviewers

Process

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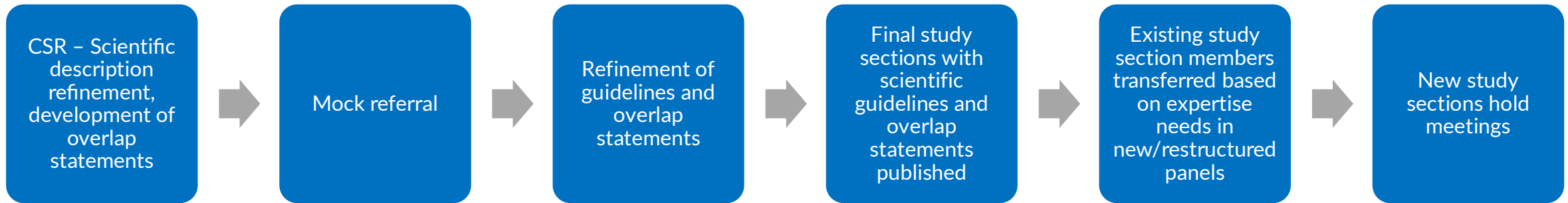
**Stage 2 [Process Evaluation]**: Evaluate study section function and recommend changes to optimize identification of highest impact research *(panel provided with application number trends, score distributions, roster expertise, reports of meeting dynamics through study section site visits, program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

| 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.**

# ENQUIRE Implementation Process

## Multiple steps following CSR Advisory Council approval

```
CSR – Scientific          Mock referral        Refinement of       Final study         Existing study       New study
description                                    guidelines and      sections with       section members      sections hold
refinement,                                    overlap             scientific          transferred based    meetings
development of                                 statements          guidelines and      on expertise
overlap                                                            overlap             needs in
statements                                                         statements          new/restructured
                                                                   published           panels
```

**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

# Two main goals of the proposed changes (RPGs)

- **Refocus first-level peer review on its singular role of providing advice to the agency regarding the scientific/technical merit of grant applications**, *relieving reviewers of responsibility for administrative/policy compliance items, reducing burden and incentivizing participation in review*

- **Mitigate reputational bias in the peer review process** – *specifically, refocusing the evaluation of investigator and environment to in the <u>context of the proposed research project</u>*

**Facilitate the overarching goal of peer review: identification of the strongest, potentially highest-impact research**

# Process and Timeline

- **Scope**: RPGs, including R01s/R21s

- **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** - *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.*

- **Jan 2020 – March 2021:** Input gathering through blog posts (Open Mike, Review Matters), content analyses provided to working groups, 11 virtual meetings to develop framework and recommendation

- **April 2021:** 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 sought through NIH Request for Information (RFI)

NIH Center for Scientific Review

# Proposed New Peer Review Framework for NIH Research Project Grants

**Criteria grouped in three Main Factors (all affect Overall Impact Score 1-9)**

> **Factor 1: Importance of the Research [individually scored 1-9]**
> *Significance, Innovation*
> **Factor 2: Rigor and Feasibility [individually scored 1-9]**
> *Approach*
> **Factor 3: Expertise and Resources [not scored → either "appropriate" or "gaps identified"**
> *Investigators, Environment*

Most "Additional Review Criteria", which may affect Overall Impact Score (e.g. Human Subjects/Vertebrate Animals) remain **unchanged**.

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

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# Simplifying Review (RPGs): Current Status and Next Steps

- **RFI** closed on March 10, 2023, >800 responses (~780 individuals, 30 scientific societies, 23 academic institutions)

- **Majority of respondents were very supportive** - not surprising given that these changes were developed with significant, sustained input from the broader extramural scientific community

- Minority felt that Factor 3 should be scored; smaller minority suggested blinded reviews

- Most recommended that CSR develop **strong training resources** to socialize the change for reviewers, study section chairs, and scientific review officers

- **Trans-NIH implementation committee** with deep, multidimensional domain expertise in peer review, reviewer training, staff training, eRA systems, communications, policy – will consider RFI input, develop roll-out strategy

**Tentative Implementation: October 2024 receipt dates (Feb/Mar 2025 review, May 2025 Council)**

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

## CSR Advisory Council

**Jinming Gao, Ph.D. (non-CT)**
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Deputy Director
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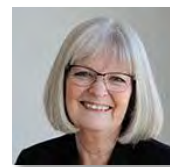
**Sally Amero, Ph.D. (Both)**
Review Policy Officer (Retired)
NIH Office of Extramural Research

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

# Background and Approach: <u>NRSA Fellowships</u>

**Background:**

- CSR Advisory Council Working Group convened in 2022. They gathered data and community feedback. Held 14 virtual meetings to develop recommendations.

- Data supported feedback -> fellowship applications are concentrated in a small number of institutions and applications from those do better in review; review outcomes for fellowships improve as the rank of the sponsor increases

- **NIH is potentially leaving out highly promising scientists because of a process that too heavily favors elite institutions, senior, well-known sponsors, and an overly narrow emphasis on traditional markers of early academic success.**

**Two approaches:**

- **Revise the fellowship application** to present the candidate's accomplishments in the context of the opportunities they've had, consideration of characteristics that lead to success in research (e.g. tenacity, persistence), and require a training plan that is targeted to the candidate's specific training needs [Recommendation 1]

- **Revise the review criteria** to better focus on the potential of the applicant, strength of the science, and quality of the training plan, without inappropriate influence of the sponsor's/institution's reputation [Recommendation 2]

**Facilitate the goal of NRSA fellowship peer review: to identify the most promising trainees and the excellent, individualized training programs that will help them become the outstanding scientists of the next generation.**

# Recommendation 1: Change the Fellowship <u>Application</u> (i.e. information provided to reviewers)

- **Eliminate grades**

- **Revise the Fellowship Applicant section** *to better align with review criteria; to allow applicants to present their scientific thinking, their needs, qualifications, and goals*

- **No changes to the current Research Training Plan** (*Specific Aims, Research strategy, respective contributions, RCR, etc.*)

- **Revise the Sponsors, Collaborators and Consultants section** *to align with review criteria; place greater emphasis on sponsor's training/mentorship approach and plan for this particular student (not simply track record), eliminate peer review of financial support (sponsor funding)*

- **Revise letters of support** *to address targeted, trainee-specific questions in structured fields to discourages boilerplate language, makes it easier for reviewers to differentiate and evaluate*

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

# Recommendation 2: Change the Fellowship <u>Review Criteria</u>
## 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

**Recommended**

1. Scientific potential, fellowship goals, and preparedness of the applicant

2. Science and scientific resources

3. Training plan and training resources

*In 2022, CSR Advisory Council Working Group recommendations were approved by full CSR Advisory Council, endorsed by NIH leadership.*

# Improving NRSA Fellowship Reviews – Next Steps

**Request for Information (RFI)** published in March, open through June 23, 2023

https://rfi.grants.nih.gov/?s=642ed5def0356688b20e6be3

**More background, detailed information at:**

- CSR Review Matters blog, cross-posted on NIH Open Mike blog.

https://www.csr.nih.gov/reviewmatters/2023/04/25/update-on-improving-fellowship-review-a-request-for-information/

# 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.**
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**Barbara Kazmierczak, MD, Ph.D.**
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**Scott Miller, Ph.D.**
Yale University

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**Nathan Vanderford, Ph.D.**
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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

Orientation for New Study Section Chairs – 2022

**CSR provided orientation and guidance** to incoming study section chairs. While the material is geared towards chairs, others in the community might find it useful in better understanding the review process and how meetings are conducted.

Brief Overview – Key Issues in Peer Review – Dr. Noni Byrnes, Director, CSR

Slides
Video

Preparing to Chair a Study Section – Dr. Bruce Reed, Deputy Director, CSR

Slides
Video

Facilitated Discussion Among Chairs

Video

**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.

- >19,000 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**
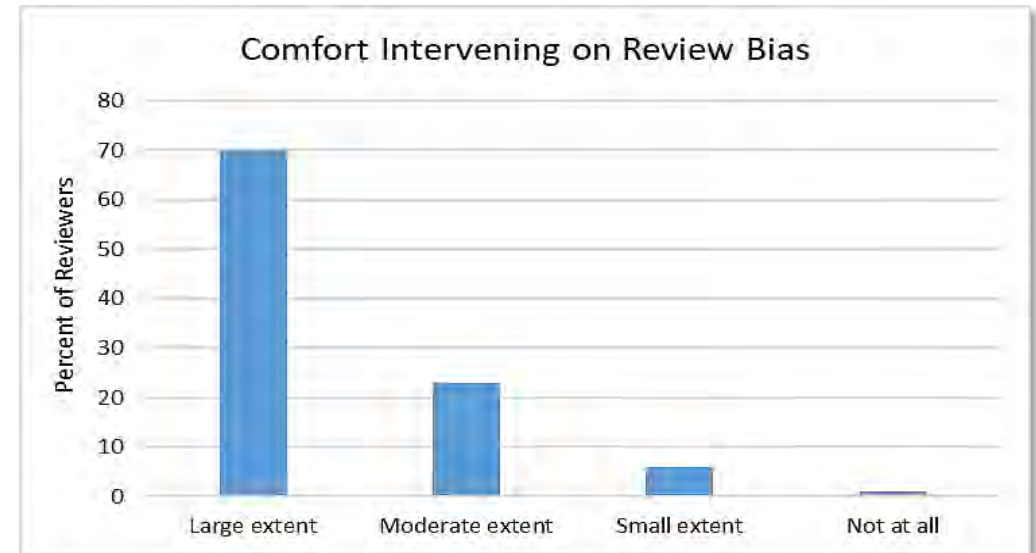


**Full Survey Analysis:** https://public.csr.nih.gov/sites/default/files/2022-04/Reviewer_Bias_Training_Survey_Report_2022-01_Council_Round_final.pdf

# 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)

- >12,000 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**



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

Let's meet Dr. Jensen who is a standing member of the ABCD study section.

I know the SRO said something about reporting seminar invitations, but I interact with other scientists in the field a lot and I know the integrity rules.
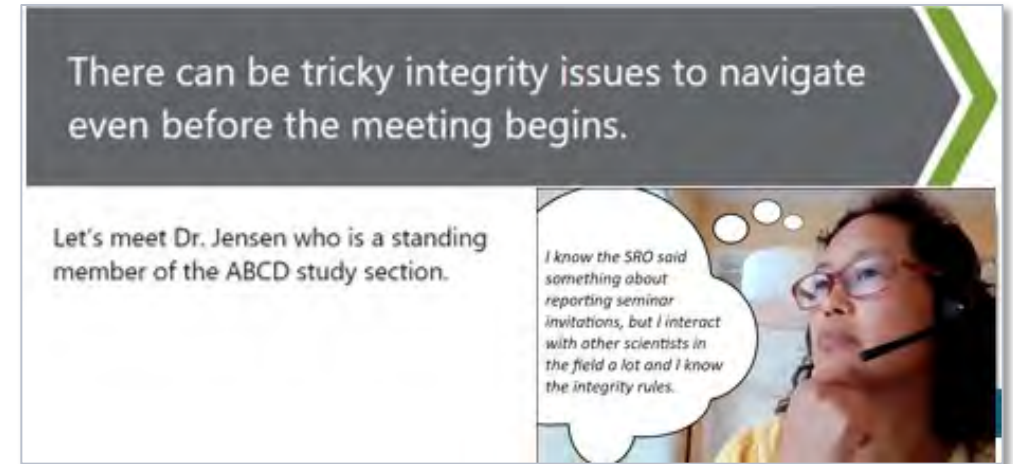
# Direct Bias Reporting Mechanism – applicants, reviewers, program staff

✉ **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]

# TRA Anonymization Check (TRAAC) Tool for DPCPSI/OSC tR01



- CSR-developed tool allows investigators to screen their specific aims and research strategy

- Ensures that all identifiers are redacted in compliance with tR01 program requirements and aids in partially-blinded review

# 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



Women

45% members
41% SEP reviewers
34% CSR Contact PIs

URM

18% members
13% SEP reviewers
9% CSR Contact PIs

Council Round
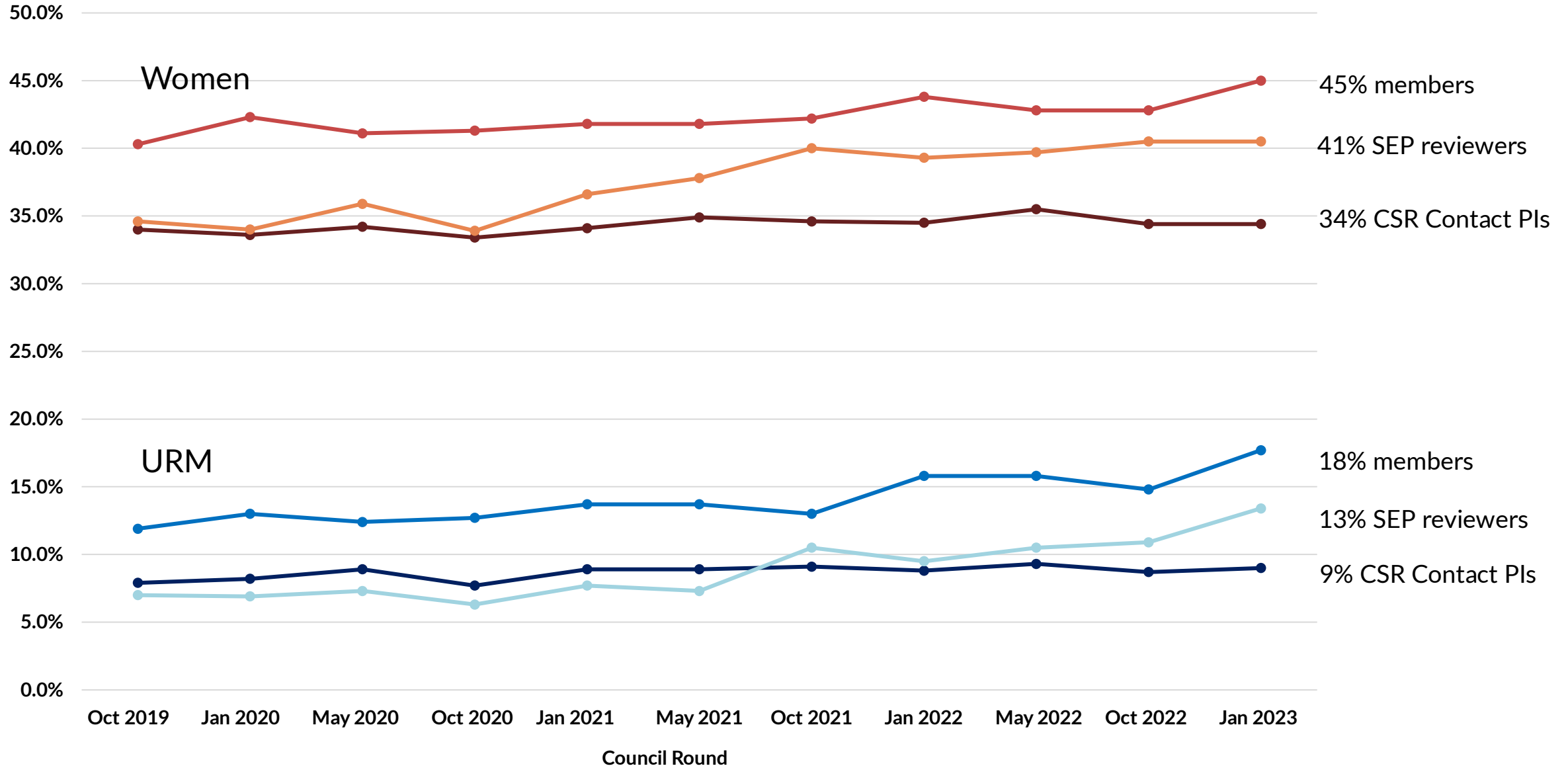
# CSR Initiatives to Address Bias in Peer Review

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

# Discussion

NIH Center for Scientific Review