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# CSR Advisory Council Update

March 27, 2023

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

# Welcome: Continuing CSR Advisory Council Members



**Leopoldo Cabassa, Ph.D.**

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



**Michelle Janelsins-Benton, Ph.D.**

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



**Matthew Carpenter, Ph.D.**

Professor  
Departments of Psychiatry and  
Behavioral Sciences  
Medical University of South Carolina



**Narasimhan Rajaram, Ph.D.**

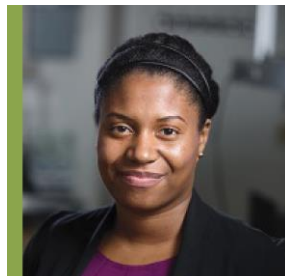
Associate Professor  
Department of Biomedical Engineering  
University of Arkansas at Fayetteville

## Not attending March 2023 Council



**Anton Bennett, Ph.D.**

Professor  
Department of Pharmacology  
and Comparative Medicine  
Yale University



**Christine Hendon, Ph.D.**

Associate Professor  
Department of Electrical Engineering  
Columbia University



**Elizabeth Villa, Ph.D.**

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

# Welcome...

## Our newest members



**Karen Anderson, M.D., Ph.D.**

Professor  
Biodesign Institute  
School of Life Sciences  
Arizona State University



**Lynn Yee, M.D., M.P.H.**

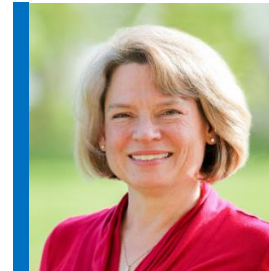
Associate Professor  
Division of Maternal-Fetal Medicine  
Department of Obstetrics and Gynecology  
Feinberg School of Medicine  
Northwestern University

## And our ad-hocs for March 27, 2023



**Jonathan Epstein, M.D.**

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



**Donna Ginther, Ph.D.**

Roy A. Roberts & Regents Distinguished Professor  
of Economics  
Director, Institute for Policy and Social Research  
University of Kansas

# CSR News: Leadership and Management Transitions



**Aruna Behera, Ph.D.**

Branch Chief  
Biobehavioral Processes  
Division of AIDS, Behavioral and  
Population Sciences



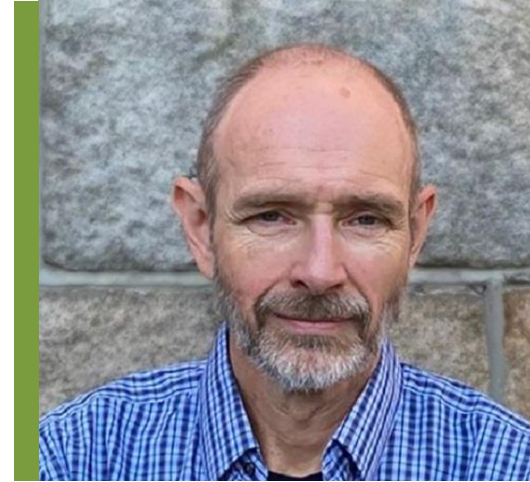
**Raul Rojas, Ph.D.**

Branch Chief  
Immunology and Infectious Diseases B  
Division of Physiological and  
Pathological Sciences



**Roy Wheat, B.S.**

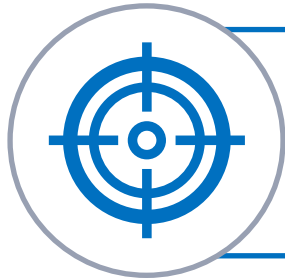
Branch Chief  
Scientific Review Evaluation Activity  
Division of Management Services



**Duane Price, Ph.D.**

Director

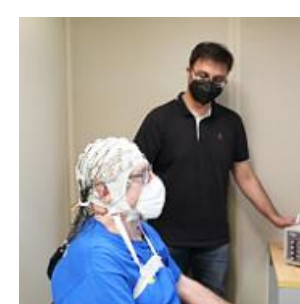
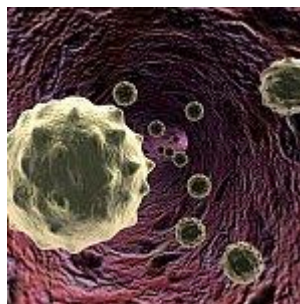
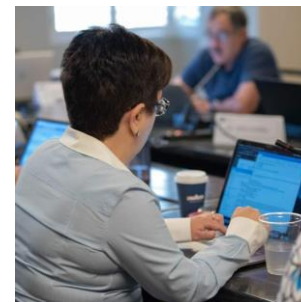
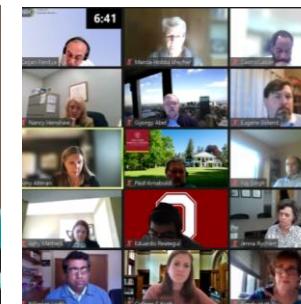
Division of Receipt and Referral



## **Overview: Mission, Scope & Strategic Framework**

# 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.

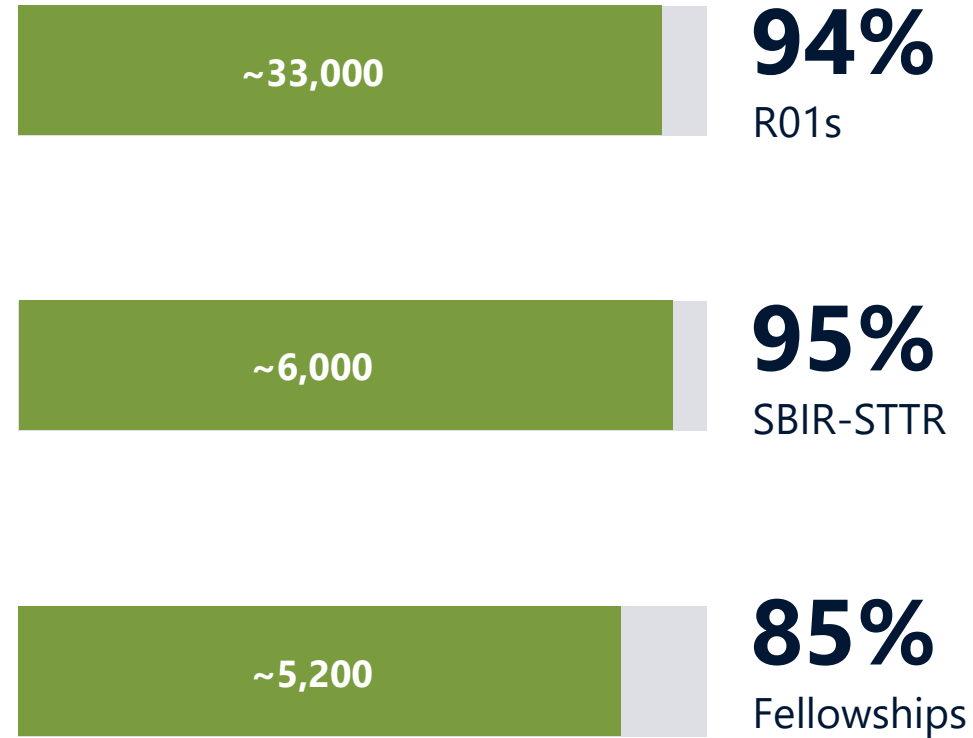


# CSR Scope - Fiscal Year 2022

**NIH**  
~80,424  
NIH Applications

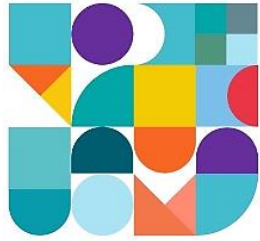


**NIH** Center for Scientific Review  
~61,378 (76%)  
Reviewed by CSR



~19,000 reviewers, ~1,200 meetings

# FY22: 167 Special Initiatives Reviewed by CSR



Transformative  
Research to  
Address Health  
Disparities  
and Advance  
Health Equity



TRANSFORMATIVE  
RESEARCH  
AWARD

NIH DIRECTOR'S  
NEW INNOVATOR  
AWARD



PIONEER  
A·W·A·R·D



NIH DIRECTOR'S  
EARLY  
INDEPENDENCE  
AWARD

NIH  
HEAL  
INITIATIVE



Tobacco Regulatory Science Program





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

## Today's Presentations

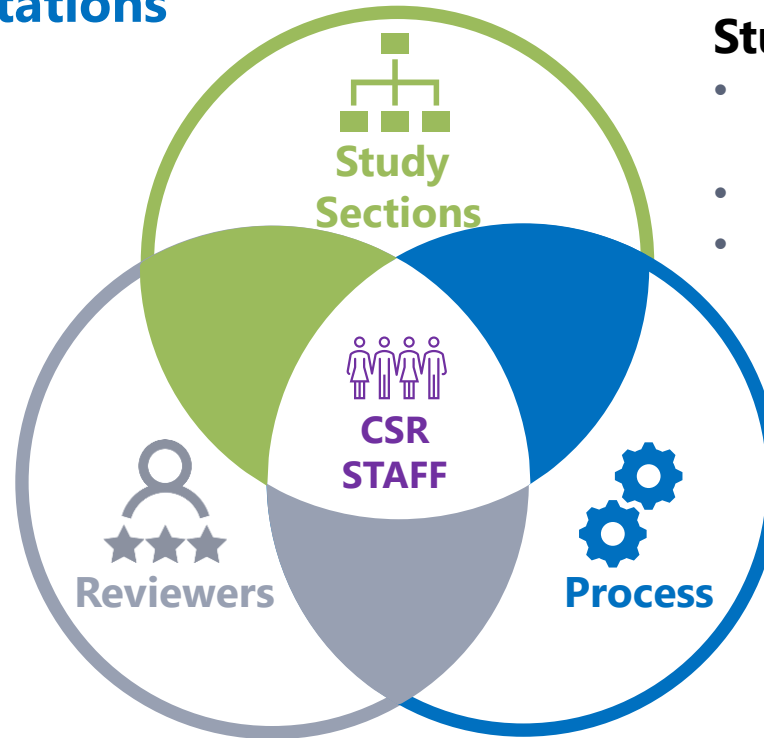


**Miriam Mintzer,  
Ph.D.**

**Reviewer and Staff  
Training**

## 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**



**Delia Olufokunbi-Sam, Ph.D.**

**ENQUIRE -Brain Disorders:  
Clinical, Translational and  
Neurotechnology**

## 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  
development**

# Plus...



## **Peer Review and the Mission of NIH**

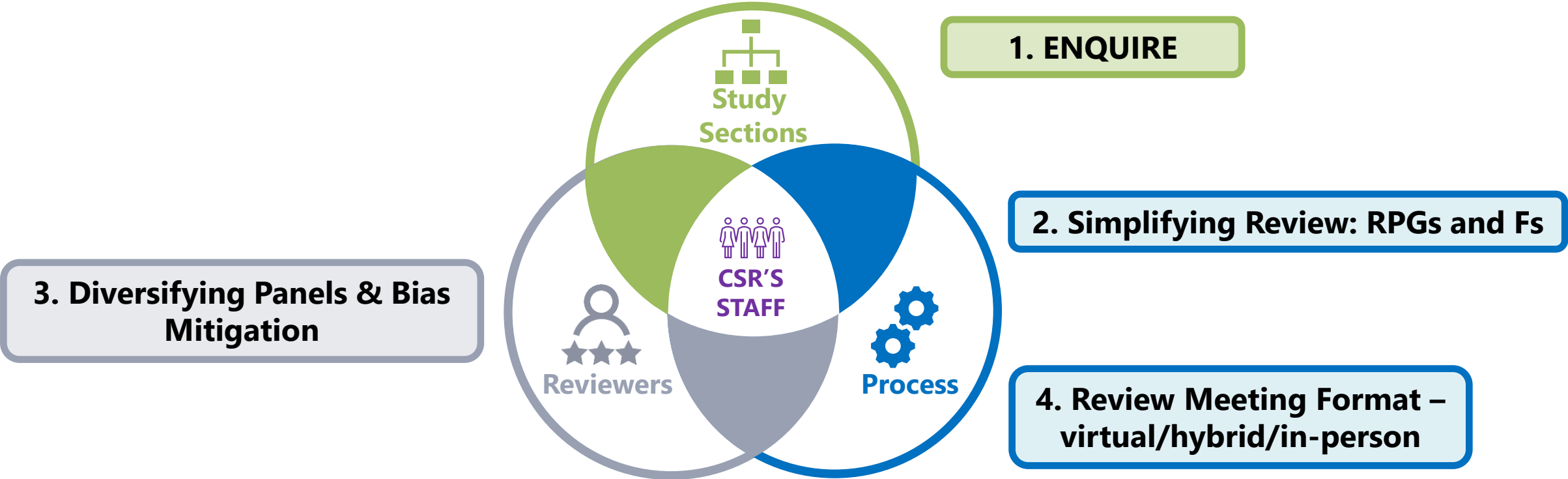
Lawrence A. Tabak, D.D.S., Ph.D.  
Performing the Duties of the NIH Director



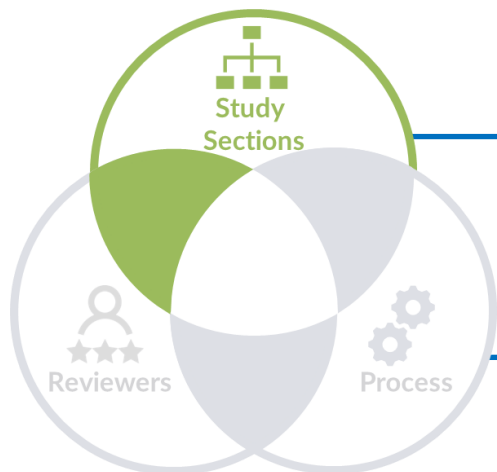
## **Reflections on Race, Ethnicity & NIH Research Awards: What We've Learned from a Decade of Research**

Donna Ginther, Ph.D.  
Roy A. Roberts & Regents Distinguished Professor of Economics  
Director, Institute for Policy and Social Research  
University of Kansas

# Today's CSR Update for Council



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



# 1. ENQUIRE Update

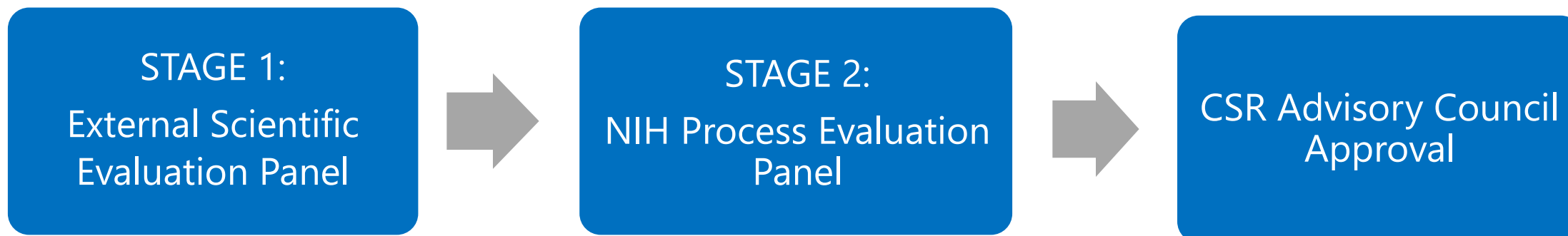
# Study Section Evaluation, Restructuring

## 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*)

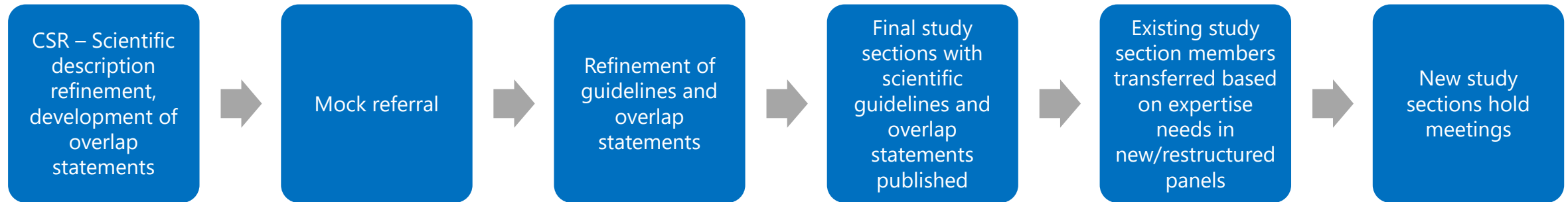
**Stage 2 [Process Evaluation]:** Evaluate study section function and recommend changes to optimize identification of highest impact research (*panel provided with application number trends, score distributions, roster expertise, reports of meeting dynamics through study section site visits, program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



**Mobile Health Technologies**



**Cancer Immunotherapy**



# ENQUIRE Evaluation

- Examine **referral patterns** – do the applications match the new study section guidelines?
- Analyze **roster expertise** – does the distribution of expertise/perspective reflect the new study section guidelines?
- Follow-up on **targeted concerns** in specific scientific area or study section (e.g. sub-field “camps”, low numbers of applications, dearth of ESIs submitting or succeeding, integrity issues, etc.) identified by CSR, ICs, the external scientific community, ENQUIRE external/internal panels

**Evaluation approach includes a combination of community feedback via surveys (reviewers, SROs, NIH program staff) and objective data gathering/analysis (referral/expertise/panel-specific issues).**



## 2. SIMPLIFYING REVIEW – Research Project Grants

# Proposed Changes to Review Framework: Research Project Grant (RPG)

**Main goal to facilitate the mission of scientific peer review: identification of the strongest, potentially highest-impact research**

## **Two approaches:**

- **Reduce the distraction of administrative questions** and allow peer reviewers to focus on the scientific impact, research rigor, and feasibility of the proposed research
- **Mitigate reputational bias in the peer review process** by refocusing the evaluation of investigator and environment to occur within the context of the proposed research project

## CURRENT

## PROPOSED

### Main Review Criteria (affect Overall Impact Score)

- Significance [scored]
- Investigator(s) [scored]
- Innovation [scored]
- Approach [scored]
- Environment [scored]

- **Factor 1: Importance of the Research [scored]**  
- *Significance, Innovation*
- **Factor 2: Rigor and Feasibility [scored]** -  
*Approach*
- **Factor 3: Expertise and Resources [not scored]**  
- drop down- appropriate, or identify gaps]  
*Investigators, Environment*

Most “Additional Review Criteria”, which affect Overall Impact Score (Human Subjects/Vertebrate Animals) remain **unchanged**.

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

# Preliminary information from RFI (closed on March 10, 2023)

- >800 responses (~780 individuals, 30 scientific societies, 23 academic institutions)
  - AAI, AAMC, AAN, AGS, AOA, ASA, ASBMB, ASCB, ASEM, FASEB, and more
- Majority were **very supportive** - not surprising given that these changes were developed with significant, sustained input from the broader extramural scientific community
- Minority felt **scoring Factor 3** was important; smaller minority suggested doing **blinded** reviews
- A few societies suggested **piloting the changes** – one suggested all of the above (blinding, piloting, scoring Factor 3)
- Most recommended that CSR develop **strong training resources** to socialize the change for reviewers, study section chairs, and scientific review officers

**Full Report by: April 30**

# Thoughts on blinding application reviews....

Conceptually a good idea to mitigate bias – by statute, NIH peer reviewers must assess Investigator(s) and Environment, so “partial blinding” can be explored

- **Anonymizing scientific research is challenging** and about 20% of the time, anonymization fails, i.e. reviewers can correctly identify PI despite redaction of identifiers. [source: published CSR anonymization study, first-year evaluation of the partially-anonymized tR01 review process]
- **Scalability:** A multi-stage, partially blinded review process is labor-intensive and time-consuming, could be practical for a limited-scope program, but difficult to implement for >20,000 applications received three times per year.
- **Other organizations cited as successfully implementing blinded proposal reviews:** CSR continues to engage with other federal agencies, foundations, and international programs (e.g. Wellcome Trust, Health Research Alliance). Those who utilize blinded reviews – e.g. Gates Foundation Global Grand Challenges, DOD, NASA – do so for one or a few programs, across the board. In all cases, the scope is much smaller than that of NIH peer review.
- **CSR has also been conducting partially-blinded reviews for a smaller, focused program** - the NIH Common Fund Transformative Research Award (tR01) program – a three-stage review process that receives an average of ~170 applications per year. Currently in the 3<sup>rd</sup> year of the partly-blinded process.

# Trans-NIH Executive Committee in place to consider RFI input, make adjustments as needed, plan rollout/implementation

**TRAINING PLANS** for reviewers and SROs



**COMMUNICATIONS** to extramural scientific community

**SYSTEMS UPDATES:** eRA systems, policy guides, Notice of Funding Opportunities (NOFOs) – former Funding Opportunity Announcements (FOAs)

**INTEGRATION** of rigorous CT (clinical trials) reviews and BRAIN initiative's PEDP (Plans to Enhance Diverse Perspectives) into RPG review framework

**Tentative implementation: Receipt dates Oct 2024 (reviews in Feb/Mar 2025, May 2025 Council funding)**

# Simplifying Review Criteria – Evaluation Plans

- Ongoing surveys of reviewers, chairs, NIH SROs & program staff; refinement of approach based on feedback
- Examination of outcomes from peer review, e.g. score distributions to see if there's a broader representation of institution types (e.g. highly-resourced, resource-limited, HBCUs, etc.), career-stages, current PI funding-levels represented in the high-impact range
- However, isolating the effect of the simplified review framework based on these outcomes is challenging, given multiple parallel interventions [*more diverse review committees; bias training for reviewers, chairs, staff; NIH-wide efforts to increase pool of R01 applicants; etc.*]
- Council thoughts/input?



# Update on Simplifying Review: NRSA Fellowships

**Main goal to facilitate the mission of scientific peer review: identify highly promising research scientists of the future**

## **Background:**

- Community feedback indicated concern that groups that are typically disadvantaged in science are disadvantaged in fellowship review. Concerns about how applicant qualifications are defined and the content of fellowship applications.
- Data analysis -> fellowship applications are concentrated in a small number of institutions and applications from those do better in review, suggesting that the knowledge and other resources that support writing a good application are very unevenly distributed.
- **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 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.
- **Revise the fellowship application** to align with the new criteria, 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.

## CURRENT

## PROPOSED

### Main Review Criteria (all individually scored and affect Overall Impact Score)

- Fellowship Applicant
- Sponsors, Collaborators, & Consultants
- Research Training Plan
- Training Potential
- Institutional Environment & Commitment to Training

- Scientific potential, fellowship goals, and preparedness of the applicant
- Science and scientific resources
- Training plan and training resources

### Recommended Changes to the Application

- Eliminate grades in courses
- Align the Fellowship Applicant section with review criteria for presentation of their scientific thinking, needs, qualifications, and goals
- Align the Sponsors, Collaborators and Consultants section with review criteria – greater emphasis on sponsor’s mentorship approach for *this* trainee; eliminate peer review of financial support (sponsor funding)
- Revise letters of support to address trainee-specific questions and discourage boilerplate language
- Allow an optional statement of special circumstances

# Update on Simplifying Review: NRSA Fellowships

- **Sept 2022:** CSR Advisory Council approved recommendations
- **Oct 2022:** Publication of CSRAC Fellowship Working Group report
- **Nov 2022:** Endorsement of recommendations by ICs, NIH leadership
- **Dec 2022:** Advisory Committee to the Director, NIH presentation
- **April 2023: NIH will release RFI to get public input on NSRA peer review proposal**

# 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)**  
 Professor, Ward-Coleman Chair of Translational Neuroscience  
 Director of the Addiction Institute  
 Icahn School of Medicine, Mt. Sinai



**Deanna Kroetz, Ph.D. (non-CT)**  
 Jere E. Goyan Presidential Chair, Department of Bioengineering and Therapeutic Sciences  
 UCSF School of Pharmacy



**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  
 Seattle Children's Research Institute

## Ad-hoc



**Brian Boyd, Ph.D. (CT)**  
 William C. Friday Distinguished Professor in Education  
 University of North Carolina at Chapel Hill



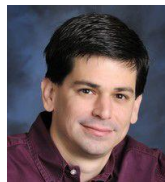
**Matthew Carpenter, Ph.D. (CT)**  
 Professor, Depts. of Psychiatry & Behavioral Sciences, and Public Health Sciences,  
 Co-Director, Tobacco Research and Cancer Control Programs, Hollings Cancer Center  
 Medical University of South Carolina



**Kevin Corbett, Ph.D. (non-CT)**  
 Associate Professor of Cellular and Molecular Medicine  
 UC San Diego



**Michelle Janelsins-Benton, Ph.D. (Both)**  
 Associate Professor of Surgery  
 Member, Prevention and Control Program, Wilmot Cancer Institute  
 University of Rochester School of Medicine



**Brooks King-Casas, Ph.D. (Both)**  
 Associate Professor, Department of Psychiatry and Behavioral Medicine  
 Fralin Biomedical Research Institute  
 Virginia Tech School of Medicine



**Pamela Munster, M.D. (CT)**  
 Professor, Department of Medicine, Hematology/Oncology,  
 Director, Early Phase Clinical Trials Unit  
 UCSF Helen Diller Family Comprehensive Cancer Center

## NIH Staff



**Bruce Reed, Ph.D. (Co-Chair) (Both)**  
 Deputy Director  
 NIH Center for Scientific Review



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

# Acknowledgment: CSRAC Working Group on NRSA Fellowship Review

## 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 Hoc



**Michael Burton, Ph.D.**

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.**

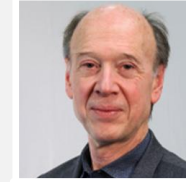
University of Kentucky



**Judith Yanowitz, Ph.D.**

Magee-Women's Research  
Institute

## NIH Staff



**Co-Chair**

**Bruce Reed, Ph.D.**

Center for Scientific Review



**Ericka Boone, Ph.D.**

Division of Biomedical Research  
Workforce, Office of Extramural  
Research



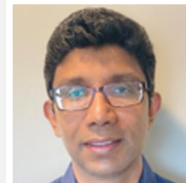
**Alison Gammie, Ph.D.**

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



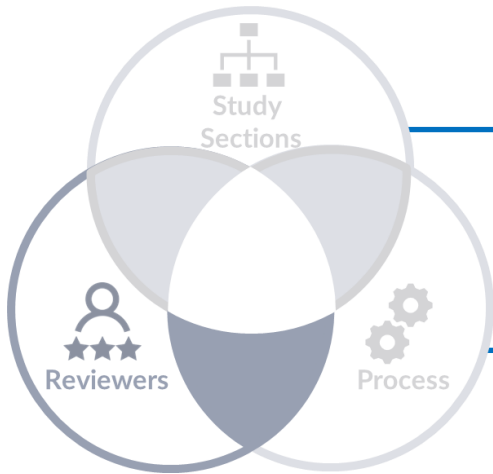
**Lystranne Maynard-Smith,  
Ph.D.**

Center for Scientific Review



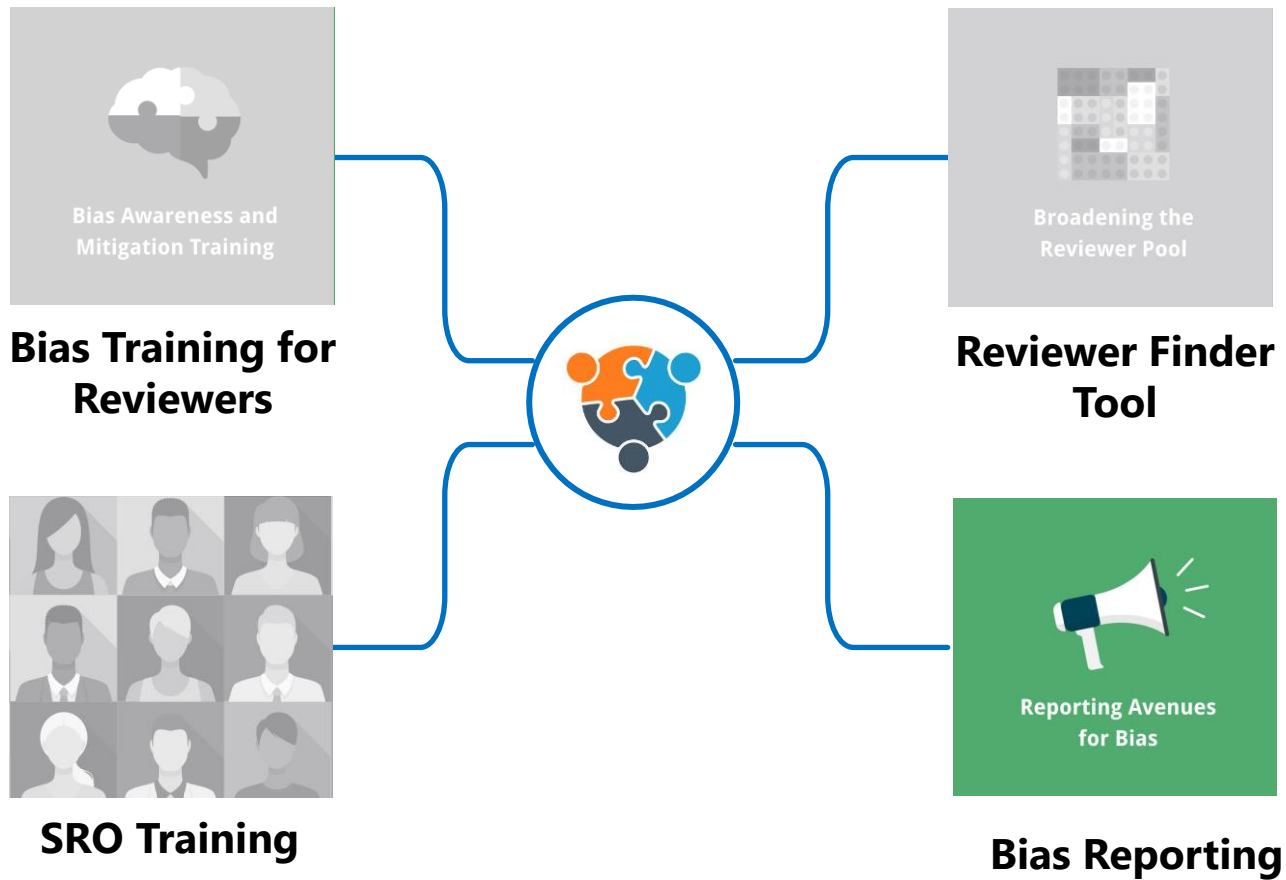
**Cibu Thomas, Ph.D.**

Center for Scientific Review



## 3. Mitigating Bias & Diversifying Panels

# A shifting culture: tools, training and process

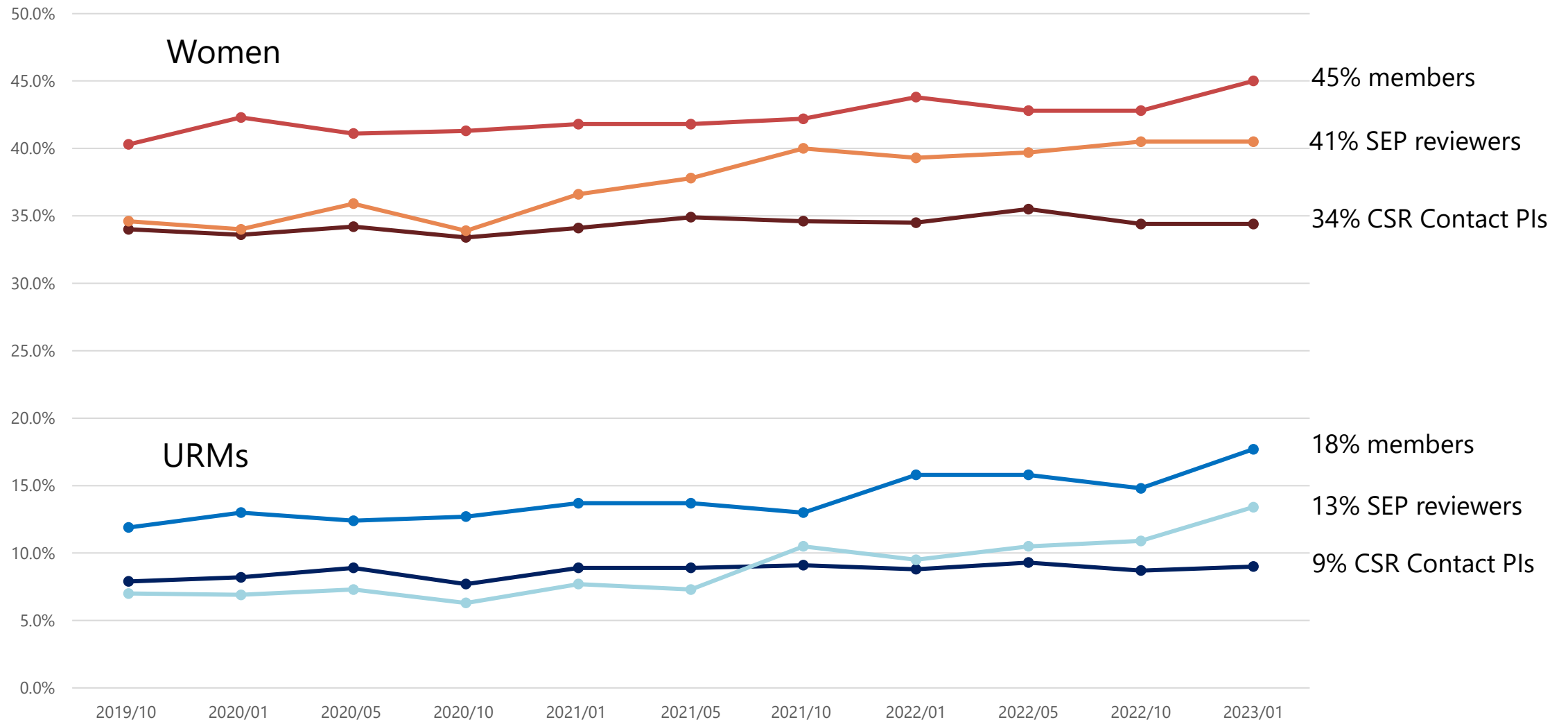


**CSR has a direct reporting mailbox [G.Fosu\\_AssocDir@csr.nih.gov](mailto:G.Fosu_AssocDir@csr.nih.gov) for applicants, reviewers, program staff to report instances of bias in review**

- Every allegation is carefully investigated by senior management (Dr. Gabriel Fosu and the 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

**A majority of CSR's decisions to re-review an application due to an unfair/biased review result from our SROs' diligence – screening premeeting critiques, monitoring/intervening during the meeting, or post-meeting review.**

# CSR continues to increase the diversity of its reviewer pool







## 4. Review Meeting Format (Virtual, Hybrid, In-person)

# As planned, in-person study section meetings began in fall 2022

- Oct/Nov 2022: **76** in-person study section meetings
- Feb/Mar 2023: **57** in-person study section meetings, plus **1** hybrid (some reviewers joining via Zoom)
- A **big kudos** to our SROs, administrative and technical assistance teams – took a lot of training, planning communication, support to pull these off at local hotels no longer used to holding NIH meetings!
- June/July 2023: **46** in-person plus **~10-15 hybrid** study section meetings planned – *in CSR space*
- As expected, anecdotal response for in-person meetings has been very positive – exciting/energizing to meet in-person after the long dry spell of Zoom for three years. **Sustained excitement**, balanced with travel/time burden, **remains a question.**



# CSR has completed a preliminary analysis of in-person vs virtual study sections [Oct/Nov 2022 meetings only]

## Reviewer Surveys

- **Meeting format preference** (in-person or virtual)
- **Impressions of quality of review** (productivity of discussion, engagement of reviewers, ability to prioritize applications; influence of discussions on outcomes)
- **Reviewers' personal participation level** (contribution to discussions, confidence in voicing opinions, comfort voting outside the range, attention span, and more)

and

## Objective Data

- **Diversity** (participation of women, URMs)
- **Seniority** (asst/assoc/full professors)
- **Experience level of ad hoc reviewers** (prior review service, recruitment of new reviewers)
- **Scoring** (overall distributions, pre-discussion vs post-discussion final scores, proportion of discussed applications, high-impact, out-of-range scores)

# Our preliminary analysis of fall 2022 in-person vs. virtual study sections

- **Roster analysis** indicated no significant differences in virtual vs. in-person participation of women/URMs, senior/midcareer/junior, experienced/new, overall score distributions
- **Scoring analysis** indicated minor differences in overall impact scores (slightly better in virtual) and proportion of discussed applications (slightly higher in in-person)
- **Reviewer surveys** indicated high ratings for overall quality of review regardless of meeting format, some differences in preference of format (in-person attendees strongly preferred in-person formats, virtual attendees had a more evenly-distributed preference), engagement was rated lower in virtual meetings
- **Full report with complete data/analyses will be published shortly**

## In the near future, CSR will continue to:

- **Hold an in-person meeting once a year** for standing study sections
- **Expand hybrid capabilities** to optimize technology/practices and provide a hybrid option once a year
- **Gather/analyze data** in subsequent council rounds to assess broader trends/sustainability in recruitment diversity, scoring, and reviewer experience/preference

# Upcoming activities/new initiatives

**Reviewer Evaluation**  
**Reviewer Recognition**



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

# Discussion