NIH Center for Scientific Review

CSR Update

Noni Byrnes, Ph.D.
Director
Center for Scientific Review
September 23, 2024

Welcome: Continuing CSR Advisory Council Members

Anton Bennett, Ph.D.

Dorys McConnell Duberg Professor of Pharmacology
Professor of Comparative Medicine
Director, Yale Center for Molecular and Systems Metabolism
Director, BBS Minority Affairs

Leopoldo Cabassa, Ph.D.

Professor
Co-Director of the Center for Mental Health Services Research
Washington University in St. Louis

Jonathan Epstein, M.D.

Interim Executive Vice President, University of Pennsylvania for the Health System
Dean, Raymond and Ruth Perelman School of Medicine
University of Pennsylvania

Christine Hendon, Ph.D.

Vice Dean of Diversity and Strategic Partnerships
Associate Professor
Department of Electrical Engineering
Columbia University

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

Thomas J. Watkins Memorial Professor of Obstetrics and Gynecology
Associate Professor of Obstetrics and Gynecology (Maternal Fetal Medicine)
Feinberg School of Medicine
Northwestern University

Congratulations to

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

Professor
Biodesign Center for Personalized Diagnostics
Arizona State University

Inaugural Associate Dean
School of Medicine and Advanced Medical Engineering

Donna Ginther, Ph.D.

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

Inducted as AAAS Fellow

A special welcome to

Our newest member

Rodney Kiplin Guy, Ph.D.

Dean and Professor
Department of Pharmaceutical Sciences
College of Pharmacy
University of Kentucky

And our September 2024 ad-hocs

Manuel Ares, Jr., Ph.D.

HHMI Professor
Distinguished Professor
Department of Molecular, Cell and Developmental Biology
University of California, Santa Cruz

Blake Wiedenheft, Ph.D.

Professor
Department of Microbiology and Cell Biology
Montana State University

Elizabeth Zuniga-Sanchez, Ph.D.

Assistant Professor
Department of Ophthalmology
Baylor College of Medicine

A big THANK YOU to our retiring members!

Matthew Carpenter, Ph.D.

Professor, Endowed Chair
Departments of Psychiatry and Behavioral Sciences
Medical University of South Carolina

Congratulations!
Joseph W. Cullen Memorial Award - American Society of Preventive Oncology

- **Reviewer Evaluation Working Group**
- **Simplifying Review Criteria (Clinical Trials) Working Group**
- **ENQUIRE 18: Social and Behavioral Studies**

Michelle Janelsins-Benton, Ph.D.

Professor, Division of Supportive Care
Gary R. Morrow Distinguished Professor of Supportive Care
University of Rochester

- **Reviewer Recognition Working Group**
- **Simplifying Review Criteria (Clinical Trials) Working Group**
- **Simplifying Review Criteria (Non-Clinical Trials) Working Group**
- **ENQUIRE 8: Developmental and Regenerative Biology**
- **ENQUIRE 14: Microbiology and Infectious Diseases**
- **ENQUIRE 3: Brain Disorders: Clinical, Translational, and Neurotechnology**

Narasimhan Rajaram, Ph.D.

Associate Professor
Department of Biomedical Engineering
University of Arkansas at Fayetteville

- **Reviewer Evaluation Working Group**
- **Fellowship Review Working Group**
- **Bias Awareness Training Working Group**
- **ENQUIRE 13: Immunology and Respiratory Systems**

NIH

News

NIH Center for Scientific Review

Leadership Transitions at NIH

Kathleen M. Neuzil, M.D.
Director
Fogarty International Center

Carolyn M. Hutter, Ph.D.
Director
NIH Office of Strategic Coordination

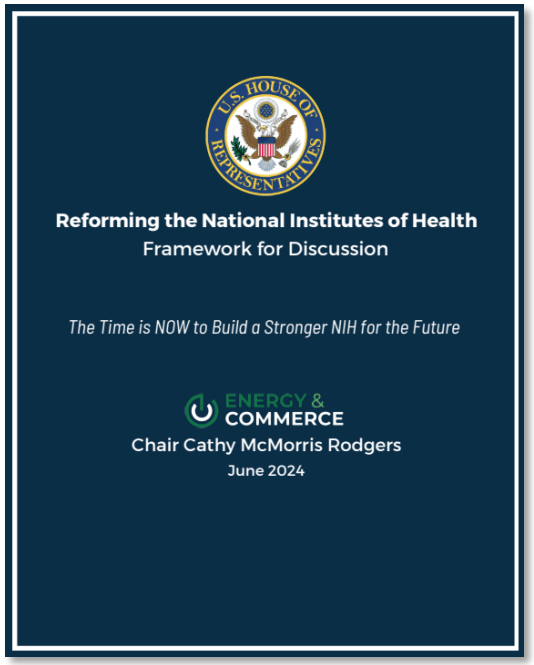
Geri R. Donenberg, Ph.D.
Director
NIH Office of AIDS Research (OAR)

Ongoing Searches: Directors - National Institute of Mental Health, National Library of Medicine

FY25 Appropriations Bills

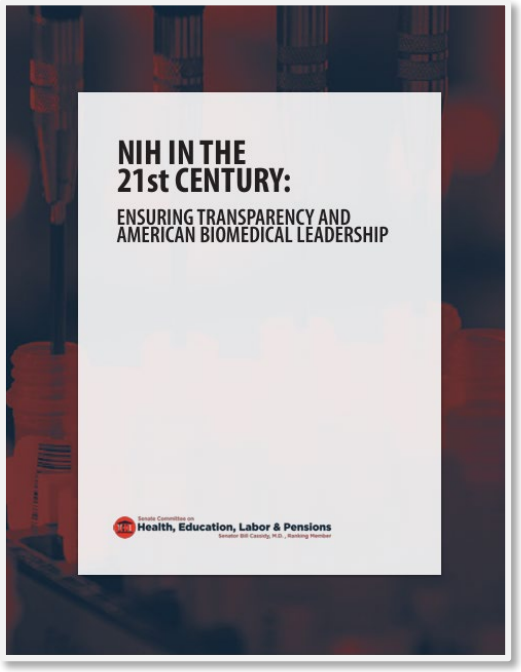
House Appropriations Bill

- NIH - $48.6B (increase over FY24 enacted level of $47.1B)
- 2024 Reforming the NIH: Framework for Discussion (House Energy and Commerce Chair McMorris Rodgers)
  - 27 institutes/centers to 15



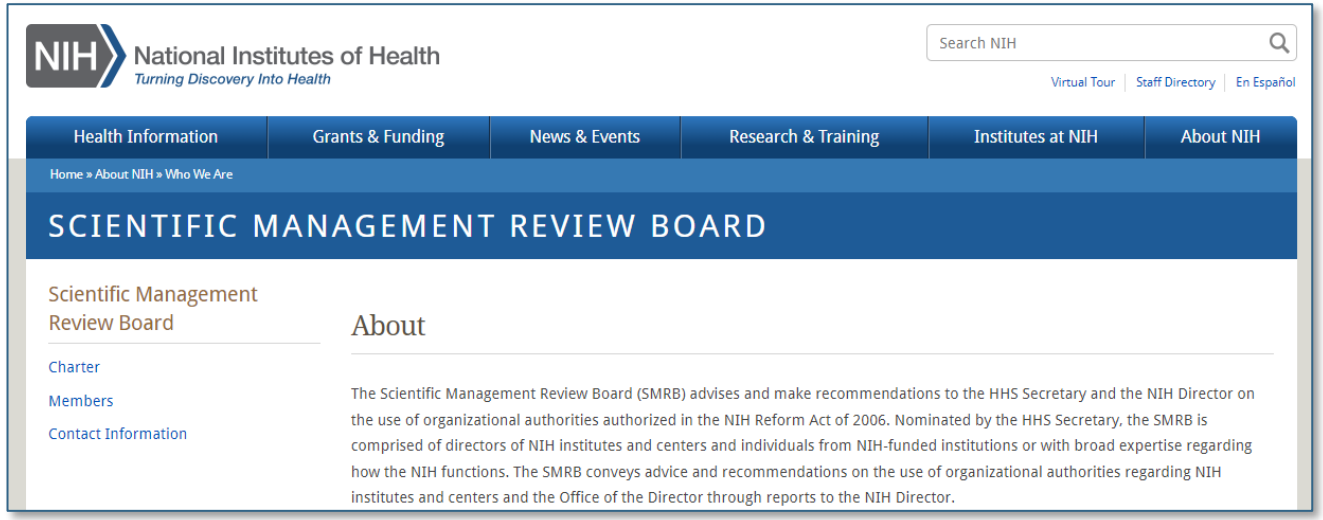
Senate Appropriations Bill

- NIH - $50.3B
- 2024 NIH in the 21st Century: Ensuring Transparency and American Biomedical Leadership (Senate HELP Committee Ranking Member Cassidy)
  - Term limits for IC Directors (10 yrs)



Reestablishment of the Scientific Management Review Board (SMRB)

- The board advises and makes recommendations to the HHS Secretary and the NIH Director on the use of organizational authorities to establish or abolish institutes/centers (IC), reorganize offices within the Office of the Director, reorganize within and across ICs.
- Nominated by the HHS Secretary, the SMRB comprises a few IC Directors and individuals from NIH-funded institutions or with broad expertise regarding the biomedical research enterprise.
- Deliberations will be informed by the two reform reports.



https://www.nih.gov/scientific-management-review-board

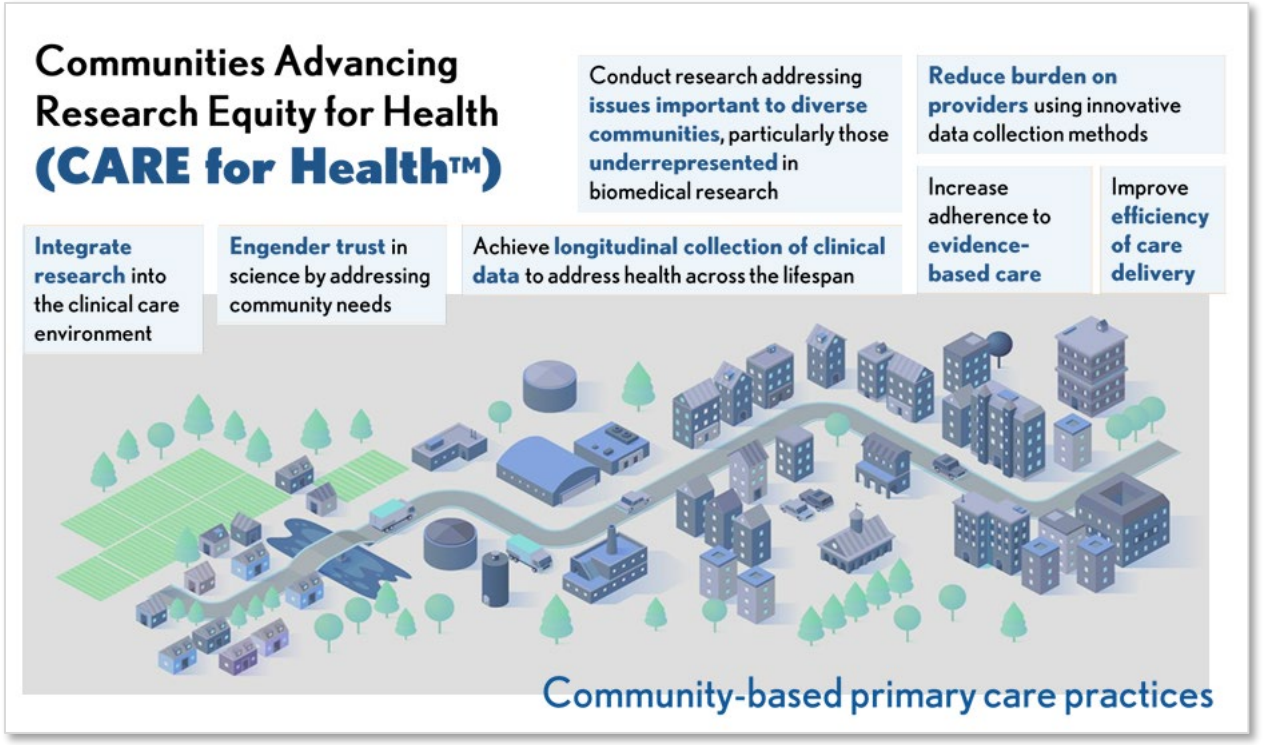
NIH CARE for Health

Goals

- Establish a **primary-care focused** clinical research network that is disease-agnostic, facilitating clinical research **in mission areas across all ICs**.
- **Integrate innovative research with routine clinical care** in real-world settings
- Create a foundation for sustained **engagement with communities underrepresented in clinical research**
- Focus on **rural communities**

Anticipated Budget

- $5M in FY24, $25M in FY25;
- anticipate increase to $50-100M/year after assessing feasibility and budget requirements



https://commonfund.nih.gov/clinical-research-primary-care

Engagement and Access for Research Active Institutions (EARA)

A UNITE-Inspired Initiative

https://diversity.nih.gov/build/engagement-and-access-research-active-institutions-eara

Goal: increase engagement of NIH ICs with institutions having <$25M/yr in NIH funds

- Increase awareness and utilization of NIH resources and funding opportunities
- Increase networks/connections of faculty/leadership with scientifically-relevant NIH IC staff
- Build a long-term relationship

CSR integrally involved in providing guidance and support for navigating peer review and application submission

EARA Advisory Committee (Byrnes); EARA Working Group (Kristin Kramer and Vonda Smith)

Re-envisioning NIH-Supported Postdoctoral Training

Advisory Committee to the NIH Director (ACD) Working Group (WG)

Major recommendation:

- **Increase pay and benefits for all NIH-supported postdoctoral scholars – recommended an increase to a $70K NRSA post-doctoral stipend in 2024**

Donna Ginther, Ph.D.
Member of ACD WG

NIH Commitment:

- **Stipend increased by 4% for predocs (to $28K), 8% for postdocs (to $61K) in FY24**
- NIH is committed to reaching the target stipend of $70K over the next 3-5 years, as appropriations and budgets allow.

Request for Information **seeking public input on some of the other recommendations - by October 23, 2024**

CSR

Update

NIH Center for Scientific Review

CSR Scientific Leadership/Management Transitions

Promotions

Sulagna Banerjee, Ph.D.
Review Branch Chief
Clinical Neuroscience

Sharon Gubanich, Ph.D.
Associate Director
Division of Receipt & Referral

Brian Scott, Ph.D.
Referral Officer
Division of Receipt & Referral

Jimok Kim, Ph.D.
Referral Officer
Division of Receipt & Referral

Retirements

Chris Melchior, Ph.D.
Senior Advisor
Office of the Director

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 Snapshot (FY24 numbers)

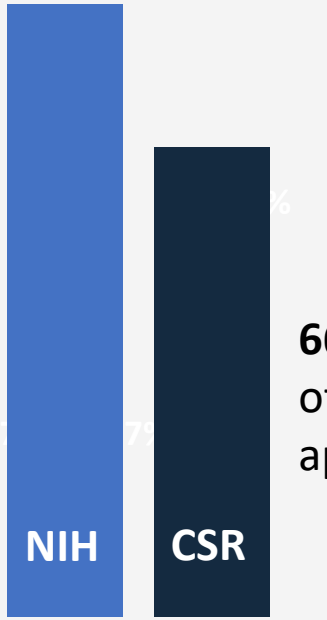
~19,000 reviewers

~255 Scientific Review Officers

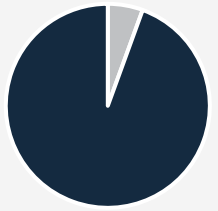
~1200 review meetings

~550 standing study sections

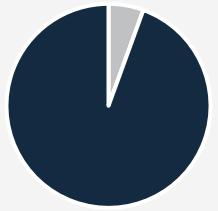
~650 special emphasis panels



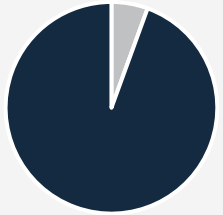
66,700 (77%)
of all NIH applications



35,512 (94%)
NIH R01s



7,727 (96%)
NIH SBIRs-STTRs

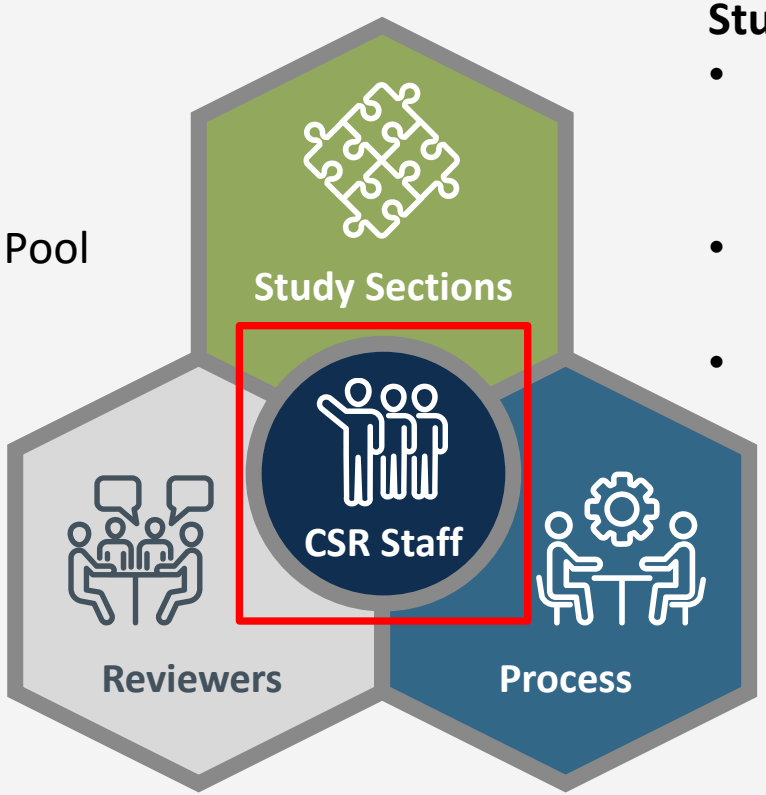


5,486 (85%)
NIH Fellowships

Plus, CSR reviewed **164 special initiatives**, such as:

CSR's Strategic Framework → Quality, Fairness and Integrity 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** **Staff engagement, training, development**

Today's Update for Council

The changing landscape of NIH peer review

Successes and challenges in implementing large-scale culture change to optimize the quality of peer review

Thoughts on quality of NIH peer review

Ideal measurement of peer review quality = ability to prospectively identify the most promising, impactful research of the future.

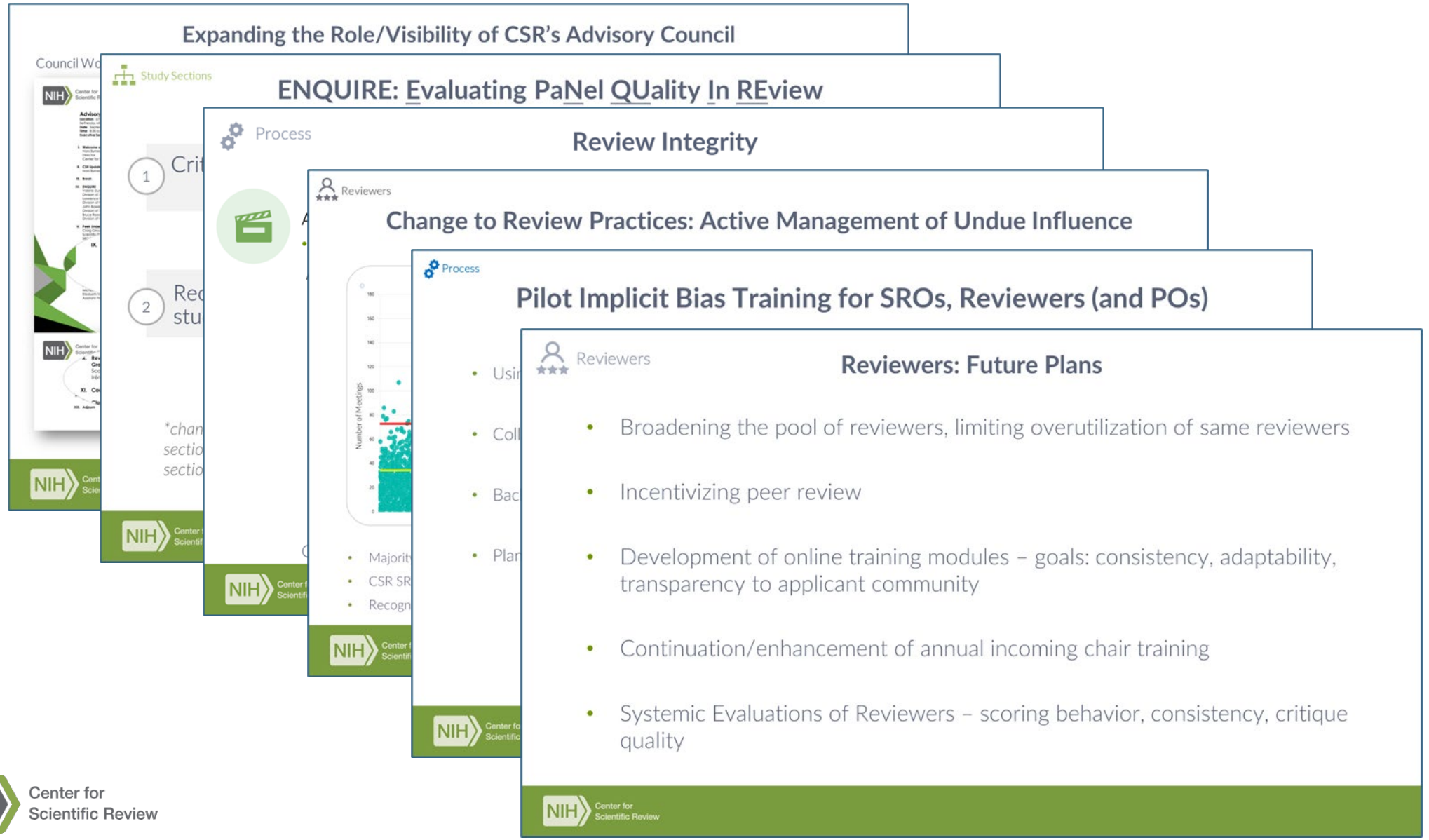
- Some possible measures, such as publication numbers; patents; journal impact factors; citation; Relative Citation Ratio (RCR); H-index; etc. can be subject to manipulation and field-specific variability.
- Many thoughtful research publications on this topic [e.g. Ginther and Heggeness, Res Policy. 2020 May; 49(4): 103953]
- ***No validated measure of the output of peer review***

NIH peer review has been criticized for at least two decades *(since the NIH budget doubling ended).*

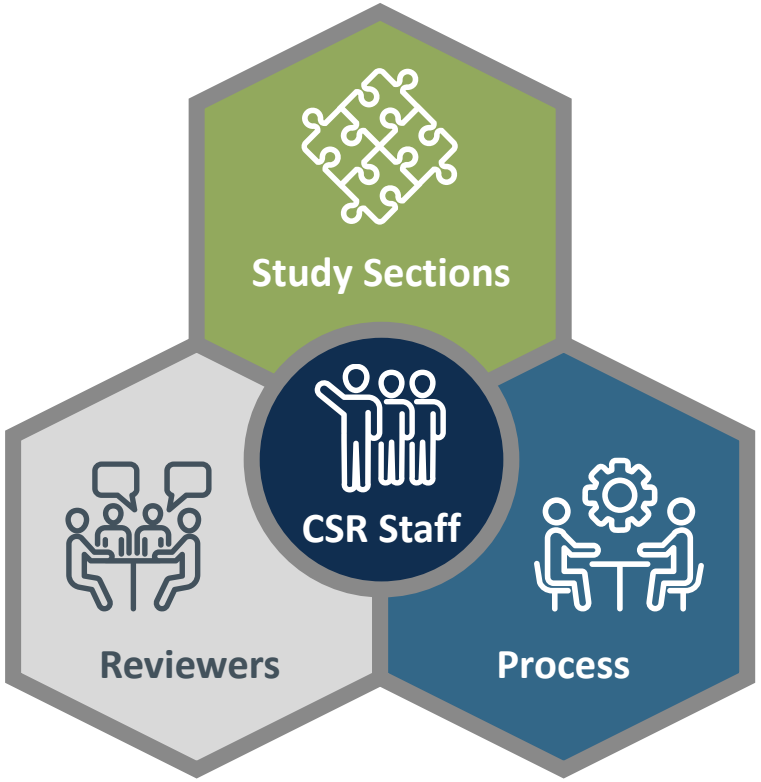
- Alternatives to "peer" review are proposed and are sometimes intriguing (random selection of awards by NIH, or use of AI/ML to select grant applications). However, investigators are less comfortable with experimenting with other approaches when it comes to their own applications.
- Novel approaches in peer review in other agencies, other countries, foundations, etc. are also intriguing. The scale of NIH review makes broad implementation of those cumbersome, but several are being used in smaller, targeted programs in CSR and NIH.
- ***NIH peer review, albeit imperfect, remains the most credible gold standard across the world.***

Optimizing the quality of the output of peer review → optimizing the process of peer review to maximize competition and ensure a level playing field to enable the most promising, impactful research to be identified.

In 2019, at the CSR Advisory Council meeting, a number of new initiatives were proposed to improve the quality of peer review

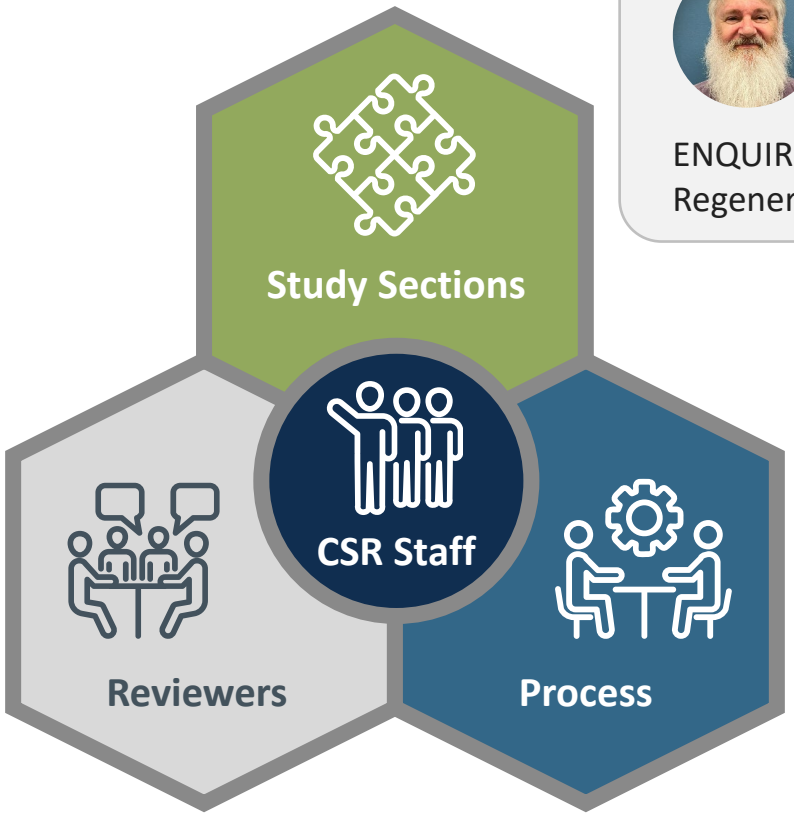


Since then, many CSR initiatives have been implemented – all focused on improving the <u>quality</u> of the output of scientific peer review



- **ENQUIRE study section restructuring** *to ensure maximum competition, incorporation of emerging science*
- **Simplified Review Framework (Research Project Grants)** *to reduce burden and distraction of administrative compliance, better focus on the science and identify the most promising research projects without undue influence of institutional reputation or investigator pedigree*
- **Revised Review Criteria (Fellowships)** *to reduce biases in the review process, allowing identification of the most promising research scientists of the next generation, sponsored by scientists across all career stages, from a broad range of institutions*
- **Bias Awareness & Mitigation Training** *to enable all reviewers to identify bias in the peer review process, and provide tools for intervention, allowing the best science to emerge*
- **Review Integrity Training** *to ensure that all reviewers learn how violation of confidentiality or inappropriate influence seriously undermines the ability of peer review to identify the best scientific ideas, and provide them with reporting tools*
- ***Broadening the reviewer pool***
- ***Direct Bias/Unfair Review Reporting mailbox***

Today's Council presentations report on progress of many of the initiatives



1


John Bowers, Ph.D.
Ray Jacobson, Ph.D.

ENQUIRE Cluster 8: Developmental and Regenerative Biology

2

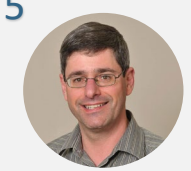

Lia Fleming, MPH
Bruce Reed, Ph.D.

ENQUIRE Initiative Evaluation

3


Delia Olufokunbi Sam, Ph.D.
Lynn Yee, M.D., MPH

Reviewer Evaluation

5


Mark Caprara, Ph.D.
Lisa Steele, Ph.D.

Simplifying Review Framework

7

Miriam Mintzer, Ph.D.

Office of Training and Development Update

4


Michelle Janelsins-Benton, Ph.D.
Kristin Kramer, Ph.D.

Reviewer Recognition

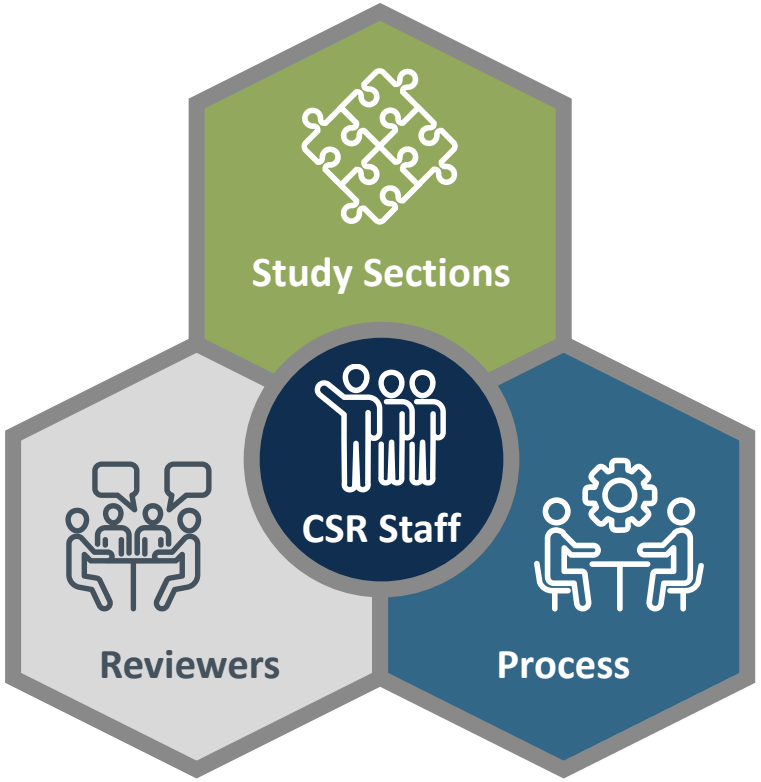
6


Mufeng Li, Ph.D.
Lystranne Maynard-Smith, Ph.D.

Revisions to Fellowship Review and Application

NIH Center for Scientific Review

The change that has, perhaps, caused the most disruption in the status quo



- **ENQUIRE study section restructuring** *to ensure maximum competition, incorporation of emerging science*
- **Simplified Review Framework (Research Project Grants)** *to reduce burden and distraction of administrative compliance, better focus on the science and identify the most promising research projects without undue influence of institutional reputation or investigator pedigree.*
- **Revised Review Criteria (Fellowships)** *to reduce burden and reduce biases in the review process, allowing identification of the most promising research scientists of the next generation, sponsored by scientists across all career stages, from a broad range of institutions.*
- **Bias Awareness & Mitigation Training** *to enable all reviewers to identify bias in the peer review process, and provide tools for intervention, allowing the best science to emerge*
- **Review Integrity Training** *to ensure that all reviewers learn how violation of confidentiality or inappropriate influence seriously undermines the ability of peer review to identify the best scientific ideas, and provide them with reporting tools*
- ***Broadening the reviewer pool***
- ***Direct Bias/Unfair Review Reporting mailbox***

How does a broader reviewer pool improve quality?

- Infuses fresh perspectives into NIH study sections to inform output of peer review

- Limits scientific gatekeeping by any individual or group of individuals to ensure that no one school of thought or ideology dominates the panel in any given field, which can prevent identification of new, emerging science

- Allows NIH peer review to draw from a broader range of qualified scientific experts, providing diversity of perspective in many dimensions (scientific, demographic/gender, career stage, level of experience in peer review)

The “Anecdata”

“the quality of critiques now is worse”

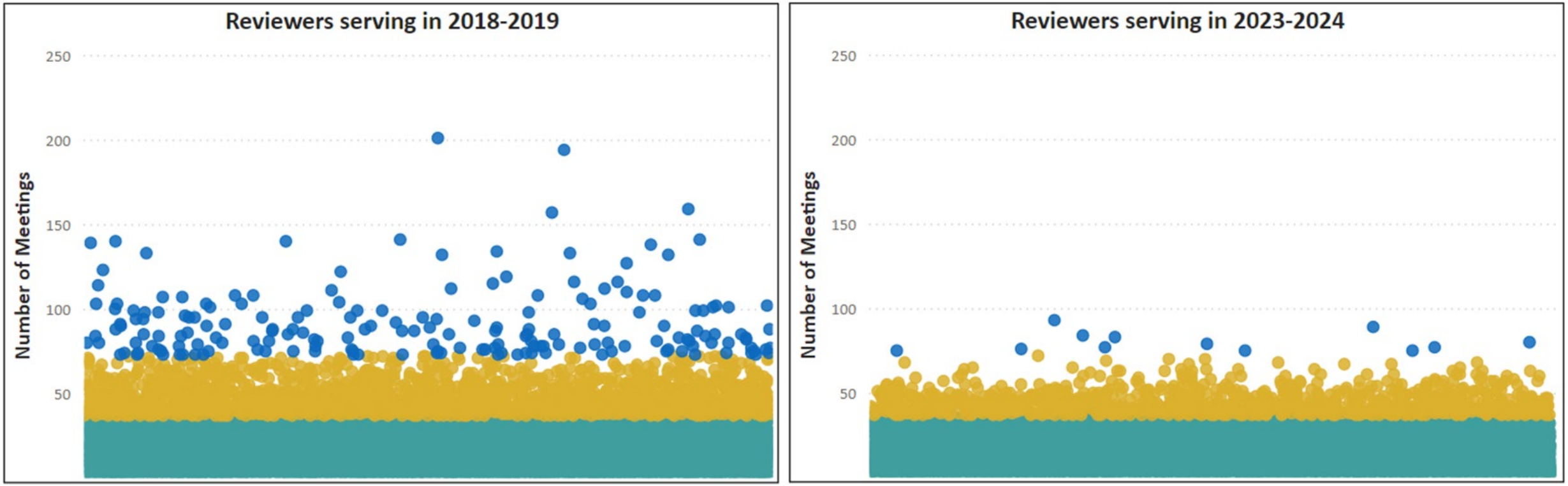
“more rookie mistakes”

“CSR doesn’t have senior scientists on its study sections anymore”

“too many assistant professors on study sections”

“a lot more people are complaining about the review quality”

The Data: Addressing Undue Influence



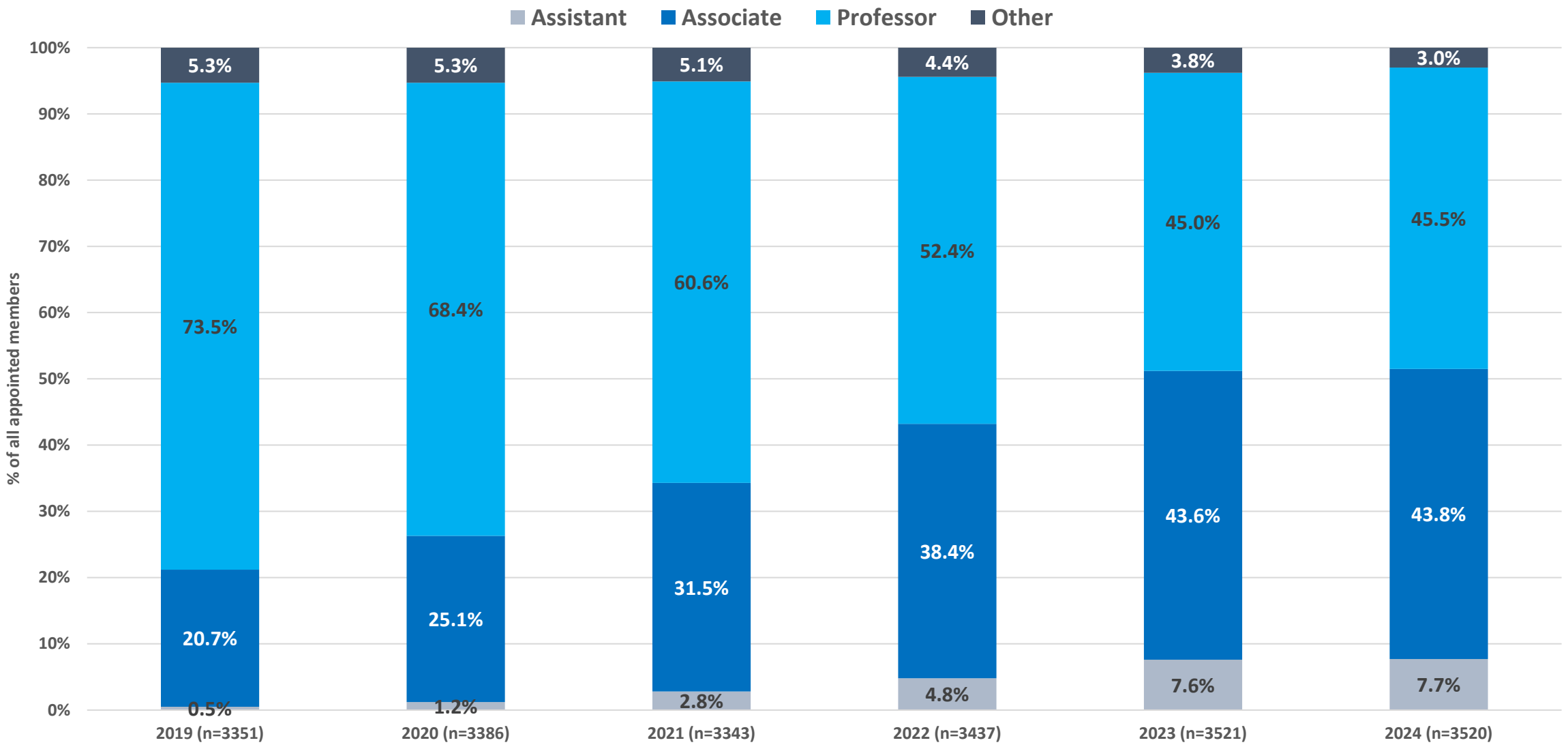
1-36 meetings
[36 = on average, once/round each round for 12 yrs]

37-72 meetings
[72= on average, twice/round each round for 12 yrs]

73+ meetings

Myth-busting: A majority of CSR reviewers served in 1-5 meetings, before and after – the major change occurred in those with the very highest service levels.

The Data: Academic Rank of Study Section Members 2019-2024



Myth busting: Assistant Professors represent <10% of members. The main change occurred in the balance of senior/midcareer scientists on committees

External input on nomination slates – CSR will not act upon generalized concerns and angst about qualified junior faculty

"My only concern about *[nominee 1] and [nominee 2]* – they are quite early in their careers and may not have the experience needed to serve on a study section at this point in time."

- Nominee 1, Asst Prof for 5 years, has 2 active R01s and a P20
- Nominee 2, Asst Prof for 5 years, has an active R01

"In my opinion, all proposed nominees are appropriate, except for [*nominee*] *…[nominee]* has not played a prominent role participating in original research articles as corresponding or last author, to indicate a leadership role."

- Nominee, Asst Prof, has 21 publications in the last 5 yrs, with 9 as first/last author, many in high impact journals
- Active R37, R03, K08

"IC has concerns about nominations for very junior faculty, in particular *[Nominee 1*] and *[Nominee 2*]. Membership at this point in their careers may/could be detrimental to their career progression and IC suggests that they can serve ad-hocs on occasion until they are in a less vulnerable position. IC recommends keeping this in mind, in general, in future selections for slates."

- Both Asst Profs, R01-supported, well-published, did excellent job as ad hocs.

I also want to mention that I am **"fundamentally opposed" to having young faculty sit as regular study section members…**they generally don't have the breadth of expertise needed.

These examples do not reflect a majority of the usually positive, laudatory comments on nomination slates

External input on nomination slates – CSR will act if there is credible concern regarding expertise or bias

Concerns about scientific bias

"I have found *[proposed nominee]* to be quite biased in his opinions and not open enough to new concepts that run counter to his own established 'dogma'. These concerns prevent me from recommending him as a reasonable panel member."	After conversation with external vetter, and subsequent internal discussion among staff, CSR agreed and **removed the nominee from the slate.**
"I have real concerns about [*proposed nominee*] ….. tends to have highly entrenched scientific views and, in my opinion, does not provide fair reviews when a proposal potentially conflicts with those views. I have observed this over the years both in grant and manuscript reviews, the latter as an editor."	Input from external members of the scientific community and from within NIH was consistent and suggested a scientific bias. We **removed nominee from the slate.**

Comments on expertise – match between nominees and study section

"….examining his publication record, a number of the papers appear to be more superficial and a big part of his research portfolio is not focused on [*scientific focus of new ENQUIRE-driven study section*]. I would have concerns about his experience."	These concerns led to conversations with another standing member, and observations of the nominee at a review meeting by CSR staff. We **removed the nominee from the slate**.

A recent, major change in peer review [as of 2021] is the ability to directly report a flawed or biased review to CSR - allows potential corrective action without the delay of an appeal

reportbias@csr.nih.gov

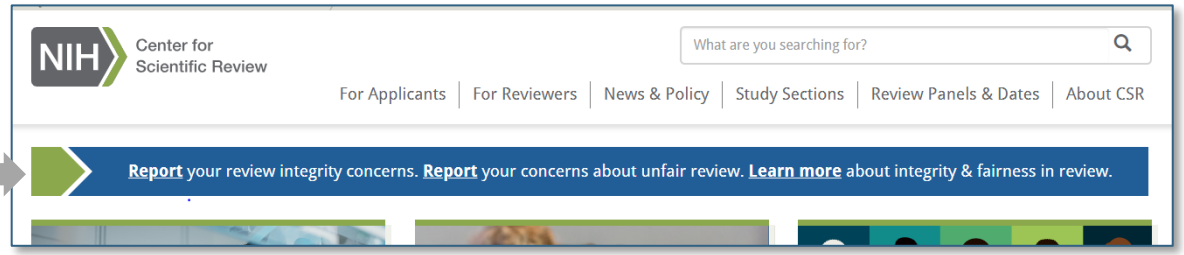
- Every allegation is carefully investigated by CSR senior management
- If we agree re: biased/flawed review – CSR will re-review application in same council round.
- If we don't agree, the official NIH appeals process through IC council remains available to all investigators.
- Follow-up with reviewer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

We publicize the reporting avenue in many ways

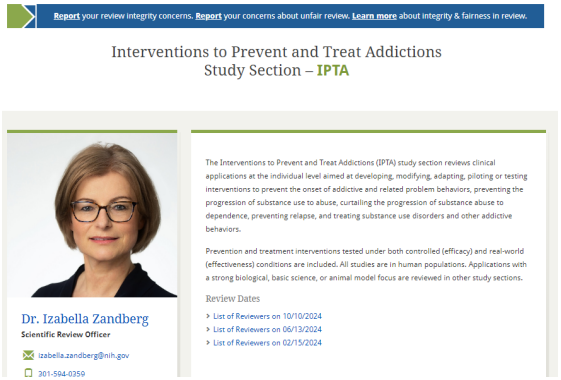
Prominent banner on CSR web landing page and highly-trafficked individual study section pages

Report your review integrity concerns. **Report** your concerns about unfair review. **Learn more** about integrity & fairness in review.

CSR internet home page



Study section description pages



In every outreach presentation by CSR SROs

Included in email signature of all CSR staff

Fairness matters. Say something! For possible violations of peer review integrity, contact your Scientific Review Officer (SRO), the CSR Review Integrity Officer at csrrio@mail.nih.gov or the NIH Review Policy Officer at reviewpolicyofficer@mail.nih.gov. For issues related to respectful interactions, bias or anything else that could affect the fairness of the review process, contact your SRO or send a message to reportbias@csr.nih.gov.

The data – are complaints increasing?

1) There's **no comparison available**. Prior to 2020, there was no reporting avenue, no tracking of complaints, and very few re-reviews by CSR.

2) For the last three years, CSR has had an established and highly-publicized reporting avenue reportbias@csr.nih.gov and clear process for redress/re-review without the delay of an appeal.

3) The numbers: In the last fiscal year:
   - CSR SROs identified, checked qualifications, recruited, trained and worked with **>19,000 expert reviewers**
   - CSR SROs screened **>200,000 reviewer critiques**
   - CSR SROs managed the entire peer review process for nearly **67,000 applications**
   - Approximate # of complaints received by CSR (includes formal appeals, bias box or direct complaints to CSR staff or leadership) were **>6.7 (0.01%), <67 (0.1%).**

Generalized complaints are not helpful.
CSR welcomes notification of specific concerns as soon as possible to allow us to take corrective action.

Some recent examples of CSR's response to specific complaints

From: *[CSR Scientific Division Director]*
Sent: Friday, September 20, 2024 3:16 PM
To: *[Applicant]*
Subject: RE: Formal complaint about a reviewer critique

Dear Dr. *[Applic*

Thank you for c
summary stater
second reviewe
should be done
review of the ap
application (Gra

If, in the future,
soon as you ide

From: *[CSR Scientific Review Division Director]*
Sent: Wednesday, February 28, 2024 10:19 AM
To: *[Applicant]*
Cc: CSR Report Bias <reportbias@csr.nih.gov>
Subject: RE: Concern
reviewer bias
Importance: High

Dear Dr. *[Applicant]*

Thank you for reachi
application. We've t
concerns. We do not
working with a progr
your resubmission ar

From: *[CSR Scientific Division Director]*
Sent: Wednesday, March 13, 2024 10:10 AM
To: *[Applicant]*
Subject: Follow Up: Concerns of reviewer bias

Dear Dr. *[Applicant]*
First I want to thank you for reporting your concerns about the fairness of the review of the application at the meeting you recently attended. I have spoken to the branch chief of the MCST review branch and the Scientific Review Officer about your concerns. There was agreement among all staff who were involved that the text you identified from Reviewer 3 suggesting English not being the applicant's first language was not appropriate and cannot be a basis for assessing the application. CSR views the review of this application as having been flawed and we will take appropriate actions to correct that.

Please don't hesitate to reach out to me if you have any questions. Thank you again for alerting us to this.

Challenges remain in getting the word out about recent changes in NIH peer review

- Countering misinformation or outdated perceptions of peer review
  - Often from well-meaning senior faculty who last served years ago (“pink sheet”)
  - Advice based on old information, perpetuates outdated practices, and personal experience from years past inadvertently suppresses applications
- Getting people’s attention about the changing landscape of NIH peer review
- Encouraging those who feel they got an unfair review to reach out to reportbias@csr.nih.gov – as soon as possible to allow us to re-review if needed

Internally at CSR, the pace of change has been rapid, requiring major shifts in both organizational structure and culture

- **ENQUIRE study section restructuring** *to ensure maximum competition, incorporation of emerging science*
- **Simplified Review Framework (Research Project Grants)** *to reduce burden and distraction of administrative compliance, better focus on the science and identify the most promising research projects without undue influence of institutional reputation or investigator pedigree.*
- **Revised Review Criteria (Fellowships)** *to reduce biases in the review process, allowing identification of the most promising research scientists of the next generation, sponsored by scientists across all career stages, from a broad range of institutions.*
- **Bias Awareness & Mitigation Training** *to enable all reviewers to identify bias in the peer review process, and provide tools for intervention, allowing the best science to emerge*
- **Review Integrity Training** *to ensure that all reviewers learn how violation of confidentiality or inappropriate influence seriously undermines the ability of peer review to identify the best scientific ideas, and provide them with reporting tools*
- **Broadening the reviewer pool**
- **Direct Bias/Unfair Review Reporting mailbox**

Our SROs are part of the broader scientific community, and their active engagement was critical for changing internal practices

From a 2020 presentation

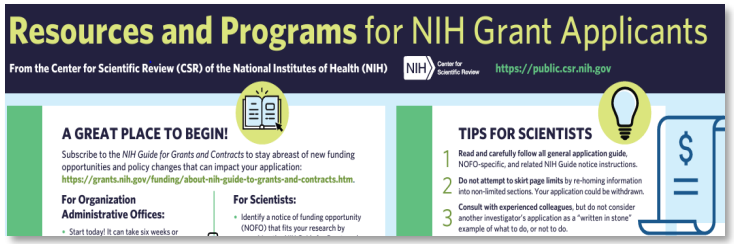
CSR SROs are now on the leading edge of culture change across extramural NIH

- Have a nuanced understanding of diversity and balance – appreciate the importance and multidimensional nature of diversity, can communicate this out and push back against false dichotomies (diversity versus quality) that persist among some in the broader community
- Have heightened awareness, good gut instincts, and strong training to promote integrity and confidentiality in the review process
- Are welcoming of transparency and accountability – examine the review process objectively, with an acknowledge/fix/learn approach regarding errors vs. a “must avoid appeals” mindset
- Participate in all-SRO forums (like M&M in medicine) during the post-meeting period each council round – to openly share specific issues with each other and disseminate lessons learned, with a goal of continuous improvement

Many of the changes in NIH peer review are a direct result of the tremendous work of our SROs

Building foundational capacity in communications, training, data analytics played a critical role in the development/implementation of new initiatives

Office of Communications & Outreach [2020]



Fostering engagement, transparency, easier access to information *for the scientific community*

Division of Planning, Analysis and Information Management [2021]

Centralized operation to provide ***analytics, tools to support data-driven decision-making***

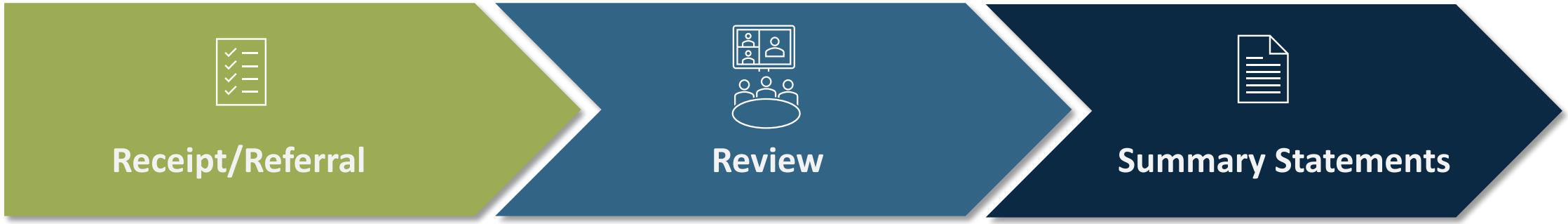
Office of Training & Development [2022]

Centralized, multimedia ***training resources for study section chairs, reviewers, SROs***

Accomplishment of CSR's important peer review mission requires a multi-faceted team with expertise in a broad range of functional areas

Ethics | Administrative Services | Committee Management | IT/Desktop Services

Budget Management | Review Support | Informatics, Data Analytics | Communications | Management Analysis



Project Control | Media Production | Web Services | Human Resources | Business Automation

SREA (hotels/reviewer travel, reimbursements) | Events Management | Training | Data Security

Special Acknowledgment: CSR's Scientific Review Branch Chiefs

CSR's outstanding team of scientific, administrative and technical professionals

Discussion