U.S. Department of Health & Human Services

NIH Center for Scientific Review

CSR Advisory Council Update

September 2019

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

Welcome…

to our newest member!

Elizabeth Villa, Ph.D.

09/15/2019 – 12/31/2022

Assistant Professor
Division of Biological Sciences
University of California, San Diego

and our ad hocs!

Michelle C. Janelsins, Ph.D.

Ad Hoc

Associate Professor
Department of Surgery, Neuroscience, and Radiation Oncology
University of Rochester, Medical Center

Sara L. Zimmer, Ph.D.

Ad Hoc

Associate Professor
Department of Biomedical Sciences
University of Minnesota, Medical School

CSR's Mission

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 of Review Operations

247
Scientific Review Officers

>18,000
Distinct Reviewers

>200
Chartered or Recurring Study Sections

>1,450
Annual Review Meetings

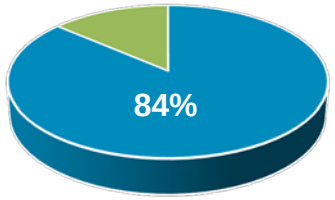
~75%
NIH Applications (62,000 of 82,600)

FY19 Applications

Scope of Review Operations

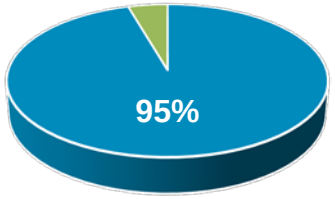
CSR Reviews a Majority of R01s, SBIRs & Fs for NIH…

RPGs



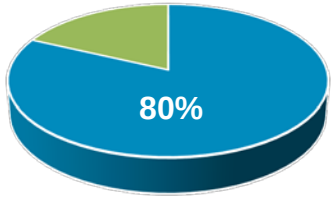
49,833

SBIRs/STTRs



6,189

Fellowships



4,702

Plus…

A Variety of Special Initiatives, Inter-agency and International Collaborations

- Common Fund
- ORIP
- INCLUDE
- ORWH Score Centers
- All of Us/Other Transaction Authority
- All FIC
- DA/MH HEAL initiatives (e.g. bBCD, SCORCH)
- Many Alzheimer's initiatives
- CA Moonshot
- GM MIRA
- CC U01s
- AI Antimicrobial Resistance Challenge Prize
- BRAIN
- NLM
- GACD
- US-China
- US-Brazil
- Expanded NIAID international programs, e.g. South Africa
- FDA/Tobacco

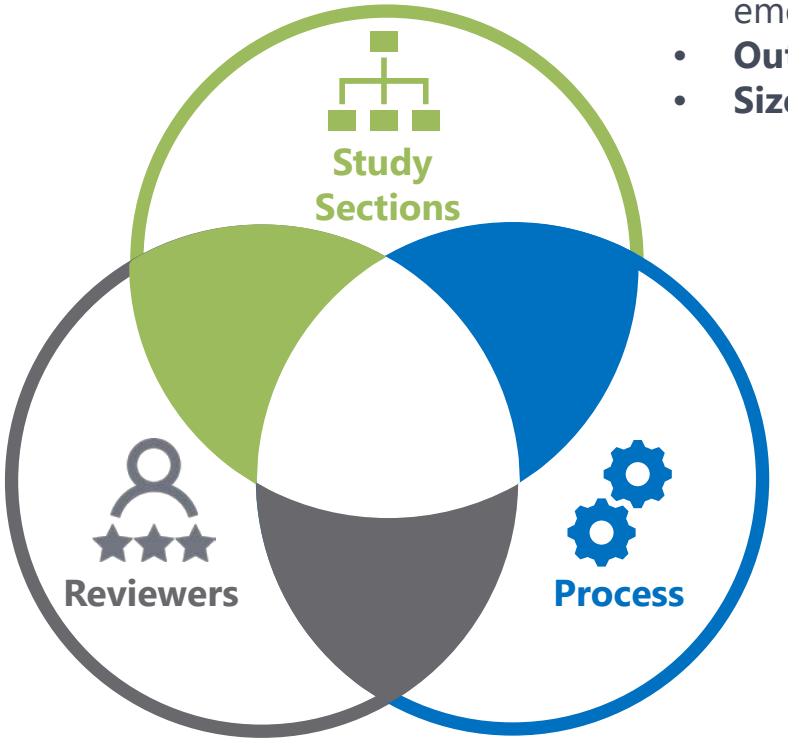
…and many more PARs, RFAs

Less than 0.4% of the $39.3B NIH budget

A Data-Driven Framework to Ensure Quality of Peer Review

Study Sections

- **Scientific boundaries** - relevance, adapting to emerging areas, perpetuating stale science
- **Output data** - identification of meritorious science
- **Size** – appropriate for competition and breadth?



Reviewers

- **Training** reviewers/chairs – consistent, transparent
- **Broadening pool** of reviewers - overuse vs. broadening pool, incentivizing service
- **Evaluating reviewer performance** – qualifications/expertise, scoring patterns, critiques

Process

- Confidentiality/**Integrity** in review
- **Bias** in review
- Assignment/**Referral** of Applications
- Review **Criteria** - Simplification
- **Scoring** system

Core Operational Principles

Transparent, data-driven decision-making

Involvement/engagement of **stakeholders**

Open, multi-directional **communication** strategies

A number of recent changes driven by data and/or stakeholder input

CSR Update

Leadership and Management Transitions

Executive Officer
Bonnie Ellis

Associate Director for Diversity & Workforce Development
Gabriel Fosu

AIDS and Related Research (AARR) IRG Chief
John Pugh

SRO Handbook & Policy Coordinator
Gary Hunnicutt

Senior Advisor for Communications & Outreach (on Detail)
Kristin Kramer

New Referral Officers

Antonello Pileggi

Aiping Zhao

Aruna Behera

Upcoming Retirements....

Lawrence Boerboom
Director
Division of Physiological & Pathological Sciences (DPPS)

Patrick Lai
Chief
Immunology (IMM) IRG

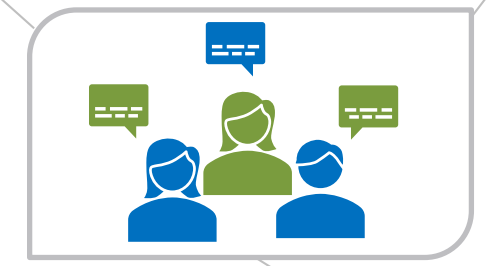
A New CSR Office of Communications and Outreach
(within CSR Office of the Director)

Planning

- Proactive communication plan
- Incorporate CSR's operational principles

Target Audiences

- External scientific community
- Special focus on under-represented populations
- NIH Extramural programs
- CSR staff



Increase Engagement

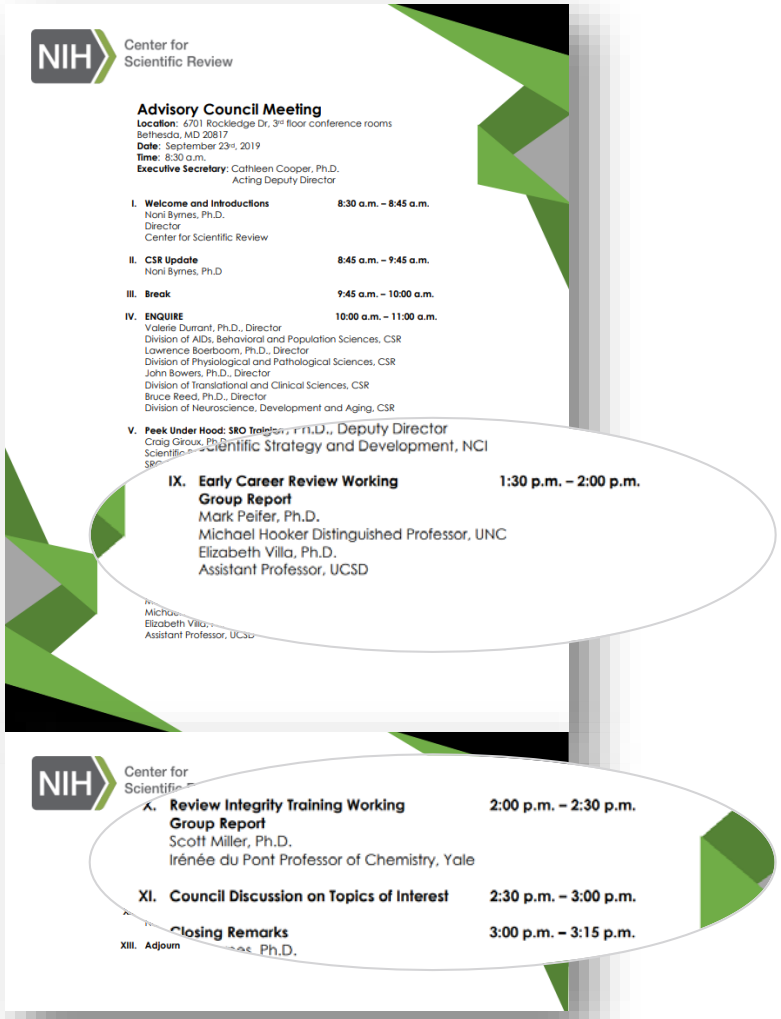
- Ensure transparency in peer review
- Capitalize on the diversity to get broader perspective
- Tools – increase collaboration between ICs, scientific societies and CSR

Blog, webinars, social media

Twitter: @CSRpeerreview
Facebook: CSRpeerreview
Blog: https://www.csr.nih.gov/reviewmatters

Expanding the Role/Visibility of CSR's Advisory Council

Council Working Groups



Center for Scientific Review

Advisory Council Meeting
Location: 6701 Rockledge Dr, 3rd floor conference rooms
Bethesda, MD 20817
Date: September 23rd, 2019
Time: 8:30 a.m.
Executive Secretary: Cathleen Cooper, Ph.D.
Acting Deputy Director

I. **Welcome and Introductions** — 8:30 a.m. – 8:45 a.m.
Noni Byrnes, Ph.D.
Director
Center for Scientific Review

II. **CSR Update** — 8:45 a.m. – 9:45 a.m.
Noni Byrnes, Ph.D

III. **Break** — 9:45 a.m. – 10:00 a.m.

IV. **ENQUIRE** — 10:00 a.m. – 11:00 a.m.
Valerie Durrant, Ph.D., Director
Division of AIDs, Behavioral and Population Sciences, CSR
Lawrence Boerboom, Ph.D., Director
Division of Physiological and Pathological Sciences, CSR
John Bowers, Ph.D., Director
Division of Translational and Clinical Sciences, CSR
Bruce Reed, Ph.D., Director
Division of Neuroscience, Development and Aging, CSR

V. **Peek Under Hood: SRO Trainin**, Ph.D., Deputy Director
Craig Giroux, Ph
Scientific Strategy and Development, NCI
Ser

IX. **Early Career Review Working Group Report** — 1:30 p.m. – 2:00 p.m.
Mark Peifer, Ph.D.
Michael Hooker Distinguished Professor, UNC
Elizabeth Villa, Ph.D.
Assistant Professor, UCSD

Michae
Elizabeth Villa,
Assistant Professor, UCSD

Center for
Scientific

X. **Review Integrity Training Working Group Report** — 2:00 p.m. – 2:30 p.m.
Scott Miller, Ph.D.
Irénée du Pont Professor of Chemistry, Yale

XI. **Council Discussion on Topics of Interest** — 2:30 p.m. – 3:00 p.m.

Closing Remarks — 3:00 p.m. – 3:15 p.m.

XIII. Adjourn
Ph.D.

Council Announcements/Videocast on Social Media

Center for Scientific Review @CSRpeerreview · Sep 17
Watch our Sept 23 meeting on NIH Videocast videocast.nih.gov to learn about how we decide foci for study sections, proposed changes to the ECR program, reviewer integrity training, and more.
2 2

New Council Website

Council Input on Strategic Planning….

Incoming Study Section Chair Orientations (Summer 2019)

88

Incoming chairs

9

Separate Sessions

9-10 chairs per session
Livestreamed

Completely redesigned and restructured orientations by a small group of creative CSR staff

- ***15 min overview –*** chair as a role-model, what chairs can do to ensure a culture of integrity/confidentiality, and how chairs can address conservatism in peer review (getting at "significance").
- ***15 min nuts-and-bolts of chairing*** – pre-, at- and post-meeting expectations, role of chair versus SRO, practical tips.
- ***1.5 hours of interactive discussion*** using a vignette-based framework – facilitated by 2 CSR SROs.

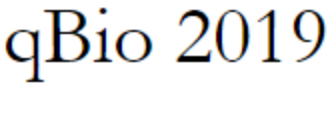
Videos Available Online

> Well done. Appropriate. both administrative input and comments from prior chairs useful.

> Excellent session- particularly the case vignettes.

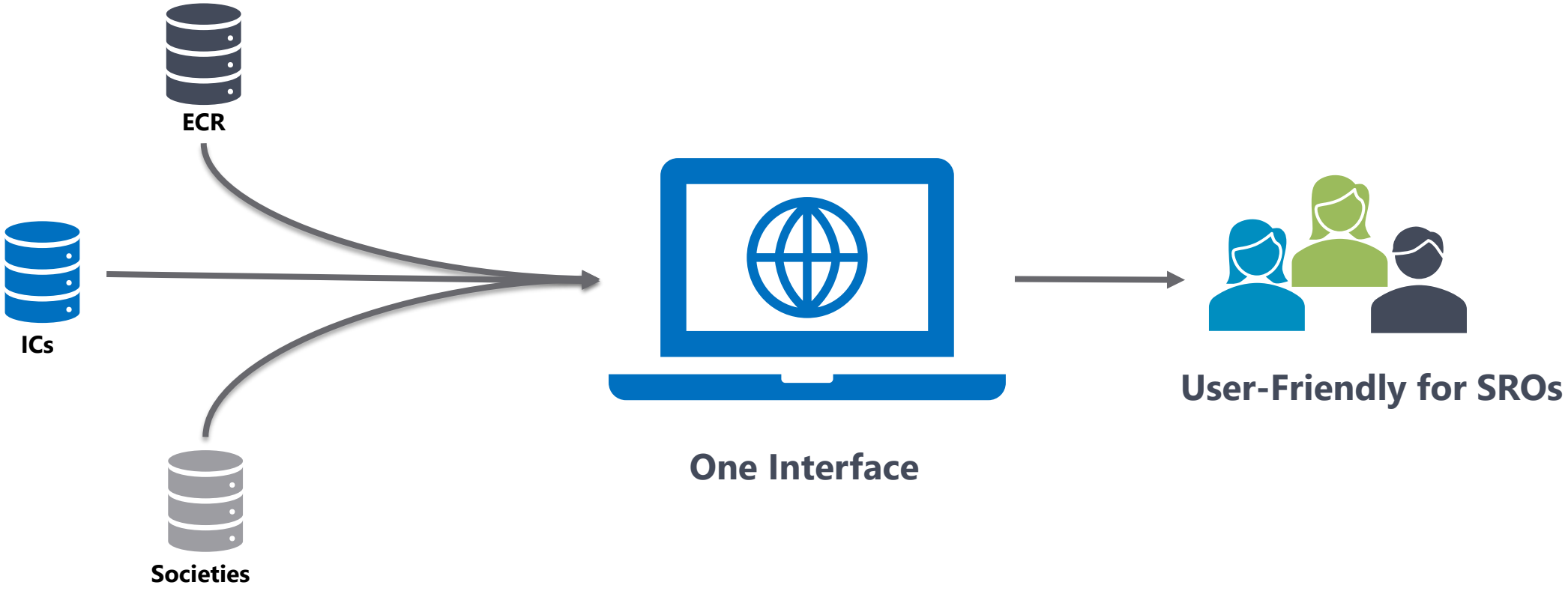
Received uniformly positive reviews from our new chairs, and from SROs!

CSR Staff Outreach at Scientific Societies



Actively Seeking Qualified Reviewer Recommendations

IC Program, Scientific Societies, Early-Career Reviewer (ECR)



Changes to Peer Review Practices – Randomized Discussion Order

2009: Move from randomized discussion order → preliminary score-based discussion order

- CSR-only, not NIH-wide
- Reasoning: focus on strong applications first, compare apples-to-apples (i.e. grey area comparisons), recalibrate in real-time, natural stop (not-discuss line) once applications become weak

Sounds great! Why change it?

- **Integrity:** Back on our radar due to two recent incidents involving peer review integrity – discussion order yielded information about poor outcomes prior to the meeting (to reviewer in conflict who confronted another reviewer; to applicant who withdrew an A1 prior to the meeting) - broader NIH effort to restrict information access (need-to-know basis)
- **Fairness:**
  - Significant decrease in reviewer engagement as meeting goes on
  - Pre-determined placement bias without real, committee-wide calibration/discussion
  - Score calibration in "real-time" elusive (calibrating a weaker 1,1,2 at 8:45 am, versus a stronger 2,2,3 at 10:15 am) – *rewards fields with generous reviewers; hurts fields with reviewers who spread scores*

Randomization alone will not address all problems with integrity or fairness or calibration - it's one of many strategies to tackle these critical issues

Stakeholder Feedback: Since implementation, consistent feedback that it's not working as planned - from chairs, reviewers, ICs

"The problem is that once the high scoring grants are discussed, there appears to be reduced interest in the remaining grants." – Reviewer Survey 2015

"Some reviewers are more lenient and some are more stringent. Randomizing would mitigate some of the bias due to review order" – Reviewer Survey 2015

"I dislike the idea of discussing applications in the order based on preliminary scores. This has the strong potential of influencing the impressions of applications that were initially not scored as favorably." – Reviewer Survey 2017

"Reviewers' initial scores can change substantially through discussion. As the order of discussion is significant to the final outcomes, I feel it would be best to randomize all applications that are initially rated 'high-impact'." – Reviewer Survey 2019 (ENQUIRE)

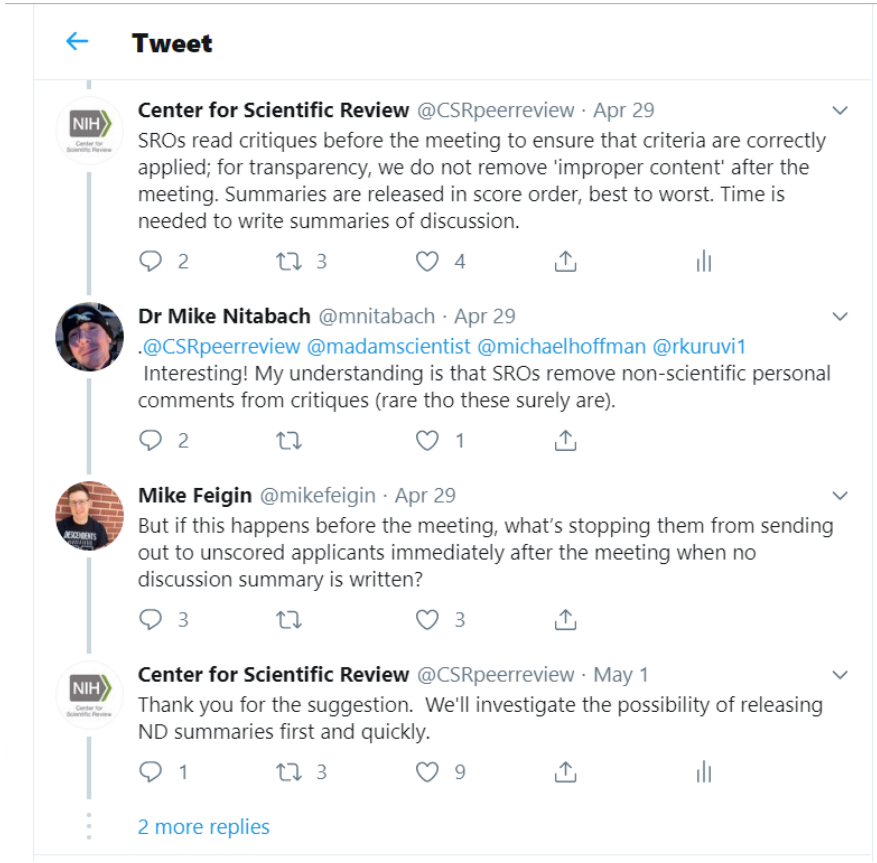
"Applications should be discussed randomly and NOT based on preliminary scores to avoid bias in the assignment of finals scores" – Early Career Reviewer Survey 2018

Response from 2019 incoming chairs (informed on 9/11/19) has been uniformly positive

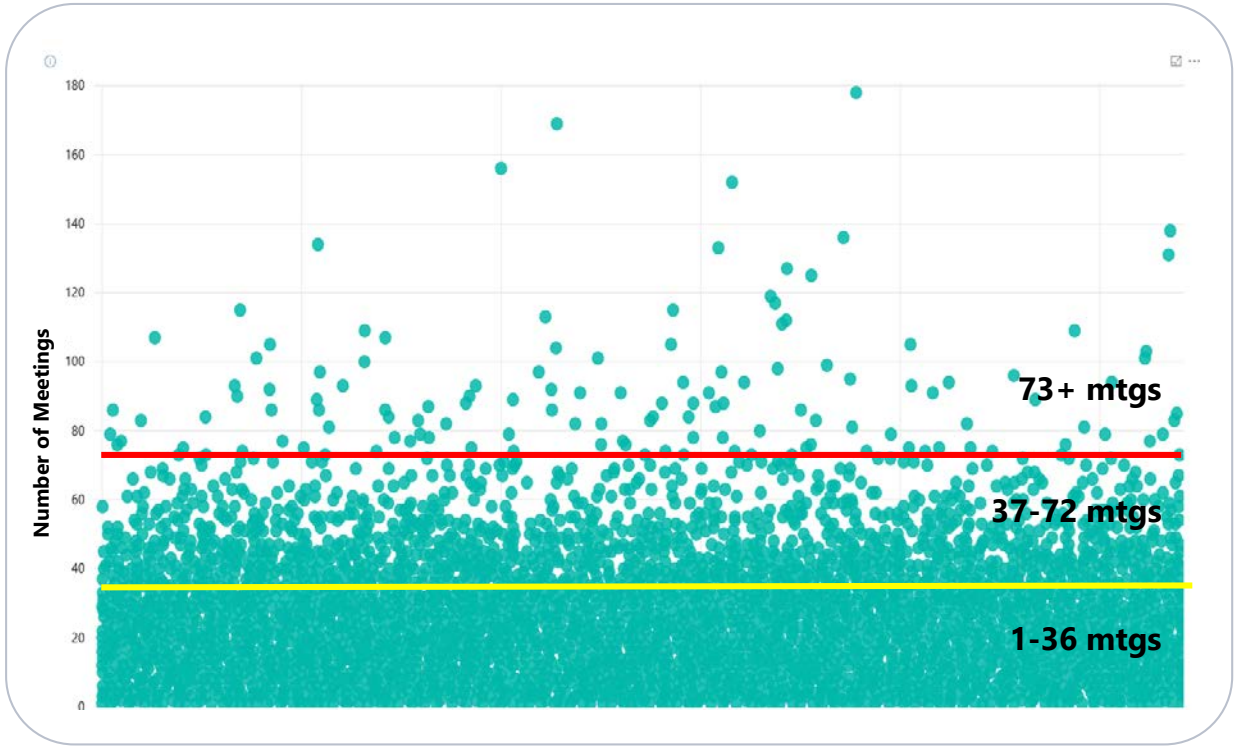
Changes to Review Practices – Release of Not Discussed Summary Statements

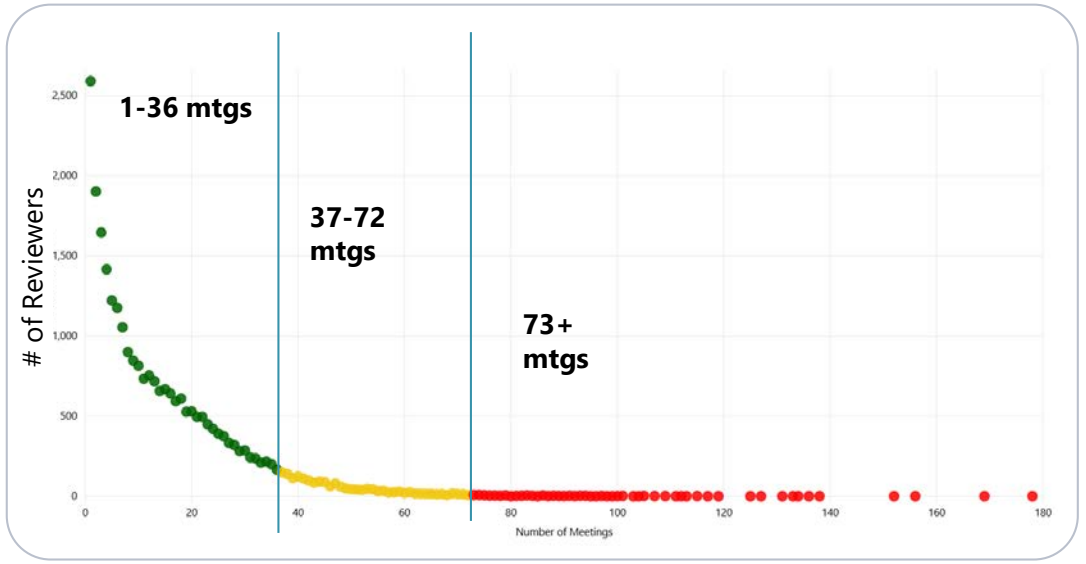
- SROs prepare resumes for scored applications (time-consuming), do minimal editing of critiques for ND applications (quick).
- Old: Summaries released from best to worst by score, followed by ND, all within 30 days of meeting, at least 30 days before council
- Resulted in SROs editing NDs while preparing resumes but holding them until the end (e.g. ND ready on day 7 may be held to release on day 28 or 30)
- **New:** Summaries released in any order, NDs released as prepared – do not hold until end
- No change: ESI/NIs still released before established, all still released within 30 days of meeting, at least 30 days before council

Entirely driven by community



Change to Review Practices: Active Management of Undue Influence





- Majority of reviewers have served in just 1-5 meetings in 12 years
- CSR SROs actively checking review service records carefully prior to inviting reviewers
- Recognized by NIH as critical issue (NIH-wide guidance being developed)

Continuous Submission Program

"Continuous Submission" Policy as review incentive – can send in application any time (council date cutoffs)

2008 appointed regular CSR and NIH study section members

2009 plus appointed NIH Advisory Council and BSC members

"Frequent Flyer" Program allows Continuous Submission for non-members who serve frequently

2010 Provides those with "Recent Substantial Service" aka Frequent Flyers" continuous submission privileges - (must have served 6 times in the last 18 months, i.e. 6 times in 5 council rounds)

Period of Service	Time of Eligibility
January 1, 2016 – June 30, 2017	August 1, 2017 – September 30, 2018

Changes to Peer Review Practices – Broaden the Pool Associate/Assistant Professors on Study Sections

- Brakes on the trend toward "rank" (full professor) as a primary driver for selection of reviewers
- Main driver for selection: scientific qualifications, scientific breadth, scientific credibility - publications and funding

- **Goal is BALANCE to achieve diversity and quality of perspectives**
  - A mix of senior, mid-career and junior, ECR
  - Needs careful assessment, not an easy, fixed metric to check, not a direct-proportion relationship – reviewer with 3 R01s isn't necessarily higher quality than one with 1 R01; having 95% full professors isn't better than having 40% full professors

ENQUIRE: Evaluating PaNel QUality In REview

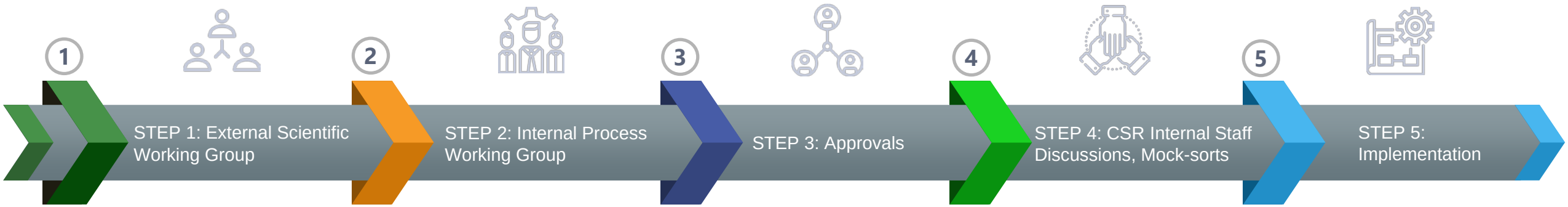
1. **Critical assessment of the output of CSR's study sections by scientific cluster**

and

2. **Recommendation of changes* to ensure that the scientific scope and function of study sections are optimized to identify high-impact science**

**changes = modify referral guidelines/boundaries, add emerging fields, create new study sections, disband study sections, merge, redistribute, modify expertise or qualifications of reviewers, changes in administration of study section*

ENQUIRE: Process and Timeline



Months 1 - 4	*Months 5 - 6*	*Months 7 - 8*	*Month 9 -10*	*Months 11 - 12*
External Scientific Working Group of scientifically broad, senior scientists (with interest in more than one SRG) –"Does the **scientific scope** support the identification of high-quality research?" • *Scientific guidelines* • *Workload trends* • *Random sample abstracts/specific aims* • *Publication/bibliometric output of study section*	**Internal Process Working Group** of senior-level IC and OD stakeholders, CSR leadership (with interest in more than one SRG) – "Does the **review process** support the identification of high-quality research?" • *External Scientific WG Report* • *Rosters* • *Scoring patterns* • *Reviewer surveys, PO surveys, Study section site visit reports re: discussions/culture* • *ESI application/award rates*	**Approvals** NIH Extramural Activities Working Group (high-level multi-IC policy group advisory to NIH Director) CSR Advisory Council	**CSR Internal Staff Discussions, Mock-sorts**	**Implementation**

Systematic, data-driven, continuous process – about 20% of CSR study sections evaluated per year

ENQUIRE Update: Four Clusters (42 study sections – 24%) Evaluated Nov 2018-Sept 2019

Healthcare Delivery/Patient Outcomes

9 study sections

- Behavioral Medicine: Interventions and Outcomes (BMIO)
- Biomedical Computing and Health Informatics (BCHI)
- Community-Level Health Promotion (CLHP)
- Clinical Management of Patients in Community-based Settings (CMPC)
- Dissemination and Implementation Research in Health (DIRH)
- Health Disparities and Equity Promotion (HDEP)
- Health Services Organization and Delivery (HSOD)
- Nursing and Related Clinical Sciences (NRCS)
- Psychosocial Risk and Disease Prevention (PRDP)

GI, Renal, Endocrine Systems

11 study sections

- Kidney Molecular Biology and Genitourinary Organ Development (KMBD)
- Pathobiology of Kidney Disease (PBKD)
- Urology and Urogynecology (ZRG1 DKUS 90)
- Clinical, Integrative and Molecular Gastroenterology (CIMG)
- Gastrointestinal Mucosal Pathobiology (GMPB)
- Hepatobiliary Pathophysiology (HBPP)
- Cellular Aspects of Diabetes and Obesity (CADO)
- Clinical and Integrative Diabetes and Obesity (CIDO)
- Integrative Physiology of Obesity and Diabetes (IPOD)
- Integrative Nutrition and Metabolic Processes (INMP)
- Molecular and Cellular Endocrinology (MCE)

Cardiac, Vascular and Hematologic Sciences

10 study sections

- Atherosclerosis and Inflammation of the Cardiovascular System Study Section (AICS)
- Cardiac Contractility, Hypertrophy, and Failure Study Section (CCHF)
- Clinical and Integrative Cardiovascular Sciences Study Section (CICS)
- Electrical Signaling, Ion Transport, and Arrhythmias Study Section (ESTA)
- Hemostasis and Thrombosis Study Section (HT)
- Hypertension and Microcirculation Study Section (HM)
- Molecular and Cellular Hematology Study Section (MCH)
- Myocardial Ischemia and Metabolism Study Section (MIM)
- Vascular Cell and Molecular Biology Study Section (VCMB)
- Transfusion Medicine Sep (ZRG1 VH-D 55)

Functional/Cognitive Neuroscience

12 study sections

- Neuroendocrinology, Neuroimmunology, Rhythms and Sleep (NNRS)
- Neurobiology of Learning and Memory (LAM)
- Language and Communication (LCOM)
- Somatosensory and Pain Systems (SPS)
- Sensory Motor Integration (SMI)
- Ocular Surface, Cornea, Anterior Segment Glaucoma, and Refractive Error Special Emphasis Panel (ZRG1 BDCN-J 81)
- Cognition and Perception (CP)
- Mechanisms of Sensory, Perceptual, and Cognitive Processes (SPC)
- Auditory System (AUD)
- Biology of the Visual System (BVS)
- Diseases and Pathophysiology of the Visual System (DPVS)
- Chemosensory Systems (CSS)

Lessons Learned and Next Steps

Lessons Learned:

- Avoid single IC-captive cluster
- Avoid members with vested interest in one study section
- Blank canvas approach – discuss emerging fields
- Build in time at working group meeting to develop new descriptions/overlaps
- PARs, RFAs – can provide insight into emerging science

Next Steps – short hiatus to:

- Work with our staff and SROs to do mock sorts, develop new study section guidelines, membership transfers, etc., implement for Feb 2020 receipt dates (summer 2020 meetings)
- Standardize both external/internal processes, data, reporting and ongoing monitoring plans
- Refine scientific groupings/clusters
- Prioritize next 3-4 clusters
- **Fill Division Director vacancies!**

CSR Anonymization Study Update: Preliminary Findings

- Study by external contractor (SSI) completed in September 2019.
- 1200 previously-reviewed applications in both full and redacted forms
- Preview of results:
  - Redaction does not appear to make scores of African-American applicants better or worse
  - Redaction appears to slightly worsen the scores of White applicants
  - Small, significant difference, but effect size is very small
  - Over 20% of reviewers were able to identify the applicant correctly despite redaction
- CSR's next steps:
  - Get results peer reviewed and published
  - Make all the de-identified data from the study publicly available for further analyses

Pilot Implicit Bias Training for SROs, Reviewers (and POs)

- Using NIGMS MIRA program as a pilot – person-based, finite, small numbers of SROs, reviewers
- Collaboration between CSR, NIGMS, and NIH's Chief Officer for Scientific Workforce Diversity (COSWD)
- Background narrated slides, followed by case studies/scenarios specifically targeted to the audience
- Planned for Jan 2020 receipt date for MIRA (summer 2020 meetings)

Up Next: Simplify Peer Review Criteria

- Review criteria length and complexity
- Administrative questions for scientific peer reviewers
- Reviewer burden – time spent before and at meeting on answering all disparate questions, fatigue, disenchantment with process, disincentive to review
- Plan a CSR AC Working Group, with external scientific community participants, CSR and OER representatives – goal: develop plan to simplify peer review criteria to refocus on scientific assessment and reduce reviewer burden

Staff Acknowledgment

Complex Operation, Critically Important Mission Needs Many Hands to Accomplish

This is CSR