U.S. Department of Health & Human Services



## **Center for Scientific Review Update** NICHD Advisory Council January 2020

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

## **NIH Institutes and Centers**





## **CSR's Mission**





Center for Scientific Review To ensure that NIH grant applications receive fair, independent, expert, and timely reviews - free from inappropriate influences - so NIH can fund the most promising research.



### **Scope of Review Operations**



FY19 Applications



### **Scope of Review Operations**

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



#### *Less than 0.4% of the \$39.3B NIH budget*







## **Quality of Peer Review**

# **Study Sections Reviewers Process**

### **Study Sections**

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

### Reviewers

- Training reviewers/Chairs consistent, transparent
- Review Service Overuse vs. broadening pool, incentivizing service
- Evaluating reviewers qualifications/expertise, scoring patterns, critiques



#### **Process**

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

## **Underlying Principles**





# Transparent, data-driven decision-making

Involvement/engagement of stakeholders Open, multi-directional communication strategies



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





## **CSR Advisory Council**

University of Washington

José López, M.D.

Scott Miller, Ph.D.

Tonya Palermo, Ph.D.

University of Washington

Anesthesiology and Pain Medicine

Hematology

Chemistry

Yale University



Jinming Gao, Ph.D. Pharmacology and Otolaryngology University of Texas Southwestern Medical Center



Alfred George, M.D. Department of Pharmacology Northwestern University



Yasmin Hurd, Ph.D. Psychiatry, Neuroscience, Pharmacology and System Therapeutics Mount Sinai School of Medicine



Deanna Kroetz, Ph.D. Bioengineering and Therapeutic Sciences University of California, San Francisco









Mark Peifer, Ph.D. (Ad-hoc) Biology University of North Carolina



Julie Price, Ph.D. Radiology and Biomedical Imaging Harvard Medical School



Elizabeth Villa, Ph.D. Biological Sciences University of California, San Diego



Jennifer West, Ph.D. Biomedical Engineering Duke University



Denise Wilfley, Ph.D. Psychiatry, Pediatrics, Psychological and Brain Sciences Washington University



## **CSR Advisory Council Working Groups**

- **Revamping the Early Career Reviewer Program** *launched Dec. 2019*
- Development of a Reviewer Integrity Training Module with case-studies – piloting in Feb/Mar meetings with ~30 study sections, launch for all CSR reviewers planned Jun/July meetings
- Up Next: **Simplification of Peer Review Criteria** to refocus on scientific assessment/reduce reviewer burden *ongoing, interim report by working group at Mar 2020 full CSRAC meeting*

#### **Review Matters**

#### Revitalizing the Early Career Reviewer Program

Noni Byrnes Director November 15, 2018

In June Twoste that we intended to re-evaluate our Lafry Career Reviewer (ECI) Program. Thanka to the work and ideas of many people, including some dyso. La reproved by our Man Jungkins. In July: Latomena et CSR Advosty Ocean Utwoing Group, comprising two members of the CSR Advisory Council (Drs., Mark Pefer and Elizabeth Villa, two CSR SROC (Drs., Kistin Kismer and Adronello Pilogg), and four sensets the interesting served as ECI (Dr. Vinay Adata). University of Timosa Cickage: Drs. Stephanie Cook, Teervirk University: Dr. Las Jones, University of Marginatis, and Dr. Mannel Llano, University of Timosa Lickage: Drs. Stephanie Cook Teervirk University: Dr. Las Jones, University of Marginatis, and Dry. Mannel Llano, University of Timosa Lickage: Dr. Stephanie Advintas, Stephanies of this voirking group for their their Integration, which were informed by the members with had direct experience as ECRs, as well as by CCR survey results and input from the broader scientific community of early career scientists, such as all tervity Eliad community.

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## **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 launch: Jan 2020 receipt date for MIRA (summer 2020 meetings)
- Refinement, plans for broader rollout for all CSR reviewers and SROs in late 2020/early 2021

### Understand and Mitigate Potential Biases Maximizing Investigators' Research Award (MIRA)

SCIENCE WORKFORCE DIVERSITY, NIH OFFICE OF THE DIRECTOR NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES CENTER FOR SCIENTIFIC REVIEW





### **Redesigned CSR Internet**



Acknowledgment: Web Team and Kristin Kramer



## All 175+ Study Section Descriptions Updated

#### Pregnancy and Neonatology Study Section – PN

The Pregnancy and Neonatology Study Section [PN] reviews applications related to the physiology of pregnancy and placental development, parturition, clinical obstetrics, maternal/ fetal medicine, and fetal/neonatal development utilizing molecular/genetic, cellular, whole-organ/animal model/human subject, and/or biochemical methodologies. Emphasis is on basic and/or clinical models to understand pregnancy progression and its disorders.



- Placental development and maintenance: trophoblast invasion and differentiation; endocrinology; transport; the development of utero-placental blood flow; maternal/fetal immune-tolerance mechanisms; hypoxia; epigenetics; application of novel technologies or approaches to assess placenta development/function across pregnancy.
- Parturition: cervical ripening; myometrial contractility; production of factors leading to labor; obstructive labor; clinical obstetrics.
- Complications of pregnancy: preeclampsia; gestational diabetes; maternal metabolic changes and obesity; fetal origins of disease involving fetal/neonatal/maternal endpoints; spontaneous abortion; pre-term labor; recurrent pregnancy loss; diabetic embryopathy; intrauterine growth restriction.
- Fetal biology: growth, development, and metabolism; fetal physiology, pharmacology, toxicology, and neurobiology; fetal diseases; in utero infection; maternalfetal interactions; fetal microchimerism.
- Neonatology: transition to extra-uterine life; neonatal physiology, endocrinology, and pathophysiology; jaundice; complications of low birth weight; SIDS



## All 175+ Study Sections Added Scientific Overlap Statements

Shared Interests and Overlaps

There are shared interests with <u>Cellular</u>, <u>Molecular and Integrative Reproduction [CMIR]</u> in the investigation of factors that modulate early embryo implantation. Grant applications that focus on post-implantation and trophoblast invasion may be reviewed in PN. Applications focused on preimplantation embryo development up to implantation may be review in CMIR.

There are shared interests with <u>Integrative Nutrition and Metabolic Processes [INMP]</u> in the investigation of nutrient effects on maternal/fetal health. Grant applications focused on nutritional effects to maternal/fetal development may be reviewed by PN. Applications focused on nutritional regulation of maternal-fetal programing may be reviewed by INMP.

There are shared interests with <u>Clinical and Integrative Diabetes and Obesity Study Section [CIDO]</u> in the investigation of maternal obesity and diabetes. Grant appliations that focus on understanding complications to pregnancy, fetal development, or the neonate by gestational diabetes or obesity may be reviewed in PN. Applications that focus on maternal nutrition and gestational diabetes effects on childhood or adult obesity may be review by CIDO.

There are shared interest with <u>Integrative and Clinical Endocrinology and Reproduction [ICER]</u> in the investigation of reproductive toxicology. Applications that focus on endocrine or reproductive function may be reviewed by ICER. Applications focused on effects on pregnancy complications or fetal development may be reviewed in PN.

There are shared interests with <u>Cardiovascular Differentiation and Development [CDD]</u> in the investigation of neonatal physiology. Grant applications that focus on effects of pregnancy complications on fetal heart development may be reviewed in PN. Applications focused on development and differentiation of the heart may be reviewed by CDD.

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### **Incoming Study Section Chair Orientations (Summer 2019)**







### **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**



Center for

Scientific Review

NI



### Actively Seeking Qualified Reviewer Recommendations IC Program, Scientific Societies, Early-Career Reviewer (ECR)





### **Quality of Peer Review**

### **Reviewers**

- Training reviewers/Chairs consistent, transparent
- Review Service Overuse vs. broadening pool, incentivizing service
- Evaluating reviewers gualifications/expertise, scoring patterns, critiques



### **Study Sections**

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

#### **Process**

- Confidentiality/Integrity in review
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## **Study Sections**

### **Previous Study Section Evaluations at CSR (2003-2015)**

- By CSR's internal organizational/management groupings (IRG)
- Input from CSR management only (2004 2008)
- Input from chairs/selected reviewers (2008 2011)
- Input from blue-ribbon external scientific working group, given data re: application, workload, bibliometric, (2011 2015)

**Output:** Comments about use of surveys, exit interviews, ranking, H-indices, bibliometrics, should Chairs be used to recruit new members, % ND, private discussion with SROs assess IRG management, NIH A2 policy.

\*\* Only **scientific** changes recommended were endorsement of proposals made by the CSR IRG Chief during his/her presentation of the science

### **Problems:**

- 1) Reviews by study sections clustered by CSR organizational structure
- 2) Too much info, too broad a scope including both science and process

## **Study Sections**

### **Previous Study Section Evaluations at CSR (2015-2018)**

Reviewed in scientific, not organizational groupings

Input from blue-ribbon external scientific working group, given data re: applications, workload, bibliometric data, etc.

**Output: Significant scientific** changes recommended, study sections restructured, eliminated, formed, etc.



### **Problem:**

Addressed scientific <u>structure</u>, but not study section <u>function</u> that can affect quality of output – i.e. reviewers, assignments, scoring, discussions, etc.





## **Evaluating Panel Quality in Review (ENQUIRE)** A New, Systematic Evaluation Framework for CSR Study Sections



## **ENQUIRE STEP 1:** <u>Scientific</u> Evaluation

- Review by scientific clusters, not by management/organizational clusters or IRGs (10-20 SRGs)
- Assemble blue-ribbon **External Scientific Working Group** of scientifically broad, senior scientists (with interest in more than one SRG)
- Provide **enough information** for each study section in cluster (current scientific guidelines on web, sampling of titles/abstracts/specific aims, workload trends, bibliometric output of awarded grants, ESI submission and success rates)
- Provide enough **time and guidance** for meaningful evaluation and recommendations
- Ask 1 **question** designed to focus discussion on science, not process: "How well does the scientific scope of the study sections align with the current state of the science?"



### **Multiple Actions for Restructuring Study Sections**



Change in scientific guidelines





Create new study sections



### Eliminate study sections



Move an area of science from one study section to another/others



Add emerging areas of science



### **ENQUIRE STEP 2:** <u>Process</u> Evaluation

- **Assemble Process Working Group** of NIH (Institute and CSR) extramural scientists with broad perspective and interest in more than one SRG
- Provide process-related **information** (workloads, web guidelines, scoring trends, survey feedback from reviewers/POs, site-visit information on meeting function/dynamics)
- Provide External Scientific Working Group's report/recommendations for input
- Questions: Does the study section function support optimal identification of high-impact science?



### **ENQUIRE** Characteristics and Timeline

- **Systematic, data-driven, continuous** process about 20% of CSR study sections evaluated per year, every study section gets evaluated every 5 years
- Stakeholder input and involvement
- **Iterative** Approach: Continuous refinement/modification of process based on experience and feedback
- Critical to success matching referral of applications and reviewer expertise to redefined scientific content of study section





### Complex Operation, Critically Important Mission Needs Many Hands to Accomplish





## This is CSR











## For Same Dataset: IC R01 Award Rates Vary Considerably





(x) Variables

## Low to High "Reviewer Topic Preference" → Low to High IC Award Rates





(x) Variables

### **IC Funding Decisions**



