Center for Scientific Review Advisory Council Meeting National Institutes of Health U.S. Department of Health and Human Services

March 30, 2020

The Center for Scientific Review Advisory Council (CSRAC) convened at 1:00 p.m., Monday, March 30, 2020, via an online video meeting due to the COVID-19 public health emergency. Noni Byrnes, Ph.D., presided as chair.

Members Present

Noni Byrnes, Ph.D. Jinming Gao, Ph.D. Alfred L. George, M.D. Yasmin Hurd, Ph.D. Deanna L. Kroetz, Ph.D. José López, M.D. Scott J. Miller, Ph.D. Tonya Palermo, Ph.D. Mark A. Peifer, Ph.D. Julie C. Price, Ph.D. Elizabeth Villa, Ph.D.

Ad-Hoc Participants

Vinay Aakalu, M.D. Michelle Janelsins-Benton, Ph.D. Betty Sue Pace, M.D.

Bruce Reed, Ph.D., was the executive secretary for the meeting.

CSR/NIH/HHS Employees Present

Sally Amero, Ph.D. Dipak Bhattacharyya, Ph.D. John Bowers, Ph.D. Cathleen Cooper, Ph.D. Valerie Durrant, Ph.D. Ray Jacobson, Ph.D. Kristin Kramer, Ph.D. Ross Shonat, Ph.D.

Members of the Public and Other HHS Employees Present

The entire meeting was held using CSR's video meeting service and all observers, including members of the public, were able to view the meeting via the NIH videocast web site.

Welcome and Introductions (NIH Videocast: 09:04)

Dr. Reed welcomed CSRAC members, ad-hoc participants, and attendees to the 19th CSRAC meeting. After the members introduced themselves, they approved the minutes from their September 23, 2019 meeting.

CSR Updates

After welcoming CSRAC members and ad-hoc participants, Dr. Byrnes provided updates on recent activities.

COVID-19 (NIH Videocast: 10:50)

Dr. Byrnes gave a timeline on how CSR and NIH adjusted peer reviews in response to the COVID-19 pandemic: On March 9, CSR converted all outstanding review meetings for May councils into virtual meetings. Soon after, all nonessential staff began teleworking. All in-person meetings for the fall council round were converted to virtual meetings. NIH extended late application due dates to May 1. Dr. Byrnes thanked staff for their extraordinary efforts to implement these changes.

Other Updates

Dr. Byrnes discussed staffing changes and vacancies before giving an overview of the framework of CSR's efforts to enhance peer review. They specifically focus on characteristics of reviewers, study sections, and the peer review process.

ENQUIRE: Evaluating Panel Quality in Review (NIH Videocast 18:56)

CSR uses a two-step process to evaluate scientific clusters of its study sections. First, a working group of external scientists focuses on whether changes in scientific scope of study sections are needed to better identify high impact science. Second, a working group composed of internal NIH stakeholders focuses on issues related to the review process. After describing how these groups work, Dr. Byrnes focused on recent ENQUIRE evaluations.

She noted that the Healthcare Delivery/Patient Outcomes reorganization plan (cluster 16; approved by Council at the September 2019 meeting) was completed. For the remaining three clusters, CSR developed guidelines for the proposed study sections and conducted mock applications sorts. CSR requested approval of the recommendations given to Council for ENQUIRE clusters 6, 9, and 11. These three clusters were approved by CSRAC. Dr. Byrnes noted that implementation of changes for all four clusters would be delayed until October receipt deadlines due to the pandemic.

GI, Renal, Endocrine Systems (cluster 9): The external panel recommended separate panels for diabetes, obesity, and metabolic disease. But the internal group and CSRAC suggested cross-cutting disease/physiology study sections in a continuum from basic to clinical. CSR's plan to follow the modifications recommended by the internal panel was endorsed by CSRAC after a discussion of how CSR deals with oversubscription and undersubscription to study sections.

Cardiac, Vascular and Hematologic Sciences (cluster 6): The internal group and CSRAC previously endorsed the plan proposed by the external group. Members

discussed the distribution of basic, translational and clinical research among the study sections. They then unanimously endorsed the plan.

Functional/Cognitive Neuroscience (cluster 11): CSR's mock sorts raised issues with respect to three study sections:

- The Neuroscience of Interoception and Chemosensation, and the Sensory-Motor Neuroscience study sections barely had enough applications to be viable. CSR proposed to implement the suggested changes with the understanding that CSR monitor the study sections closely and restructure the study sections if application numbers prove too low.
- The Behavioral Neuroendocrinology, Neuroimmunology, Rhythms, and Sleep study section: External and internal groups disagreed on whether to put behavioral neuroendocrinology and neuroimmunology in this study section. The mock sort showed clearly that without these areas, there were not enough applications to review to make the study section viable. CSRAC unanimously endorsed the proposed study sections with this change.

Action Item: Dr. Byrnes noted that CSR will make adjustments as needed. She then said that CSR is developing a plan for monitoring study section performance and that she would share it with CSRAC at its next meeting.

CSR Advisory Council Workgroups (NIH Videocast 56:41)

Dr. Byrnes gave updates on the activities of three CSR Advisory Council Workgroups:

Revamping the Early Career Reviewer Program: After CSRAC discussed workgroup recommendations at its last meeting, CSR revamped the Early Career Reviewer (ECR) database; increased to two the ECRs on standing committees and added 1-2 ECRs to special emphasis panels; formed a committee to consistently vet ECRs; and developed best practices for engaging and working with ECRs. The numbers of ECRs used Feb./Mar. 2020 jumped to 375 from 185 last year.

Members

- CSRAC: Drs. Peifer and Villa
- Ad Hoc (ECRs): Drs. Vinay Aakalu, Stephanie Cook, Lisa Jones, and Manuel Llano
- CSR Staff: Drs. Kristin Kramer and Antonello Pileggi

Development of a Review Integrity Training Module: After CSRAC discussed it at its last meeting, CSR did a soft launch with ~30 study sections and shared it with SROs and NIH leadership. CSR is analyzing reviewer and SRO surveys and hopes to fully implement the training in summer or fall 2020.

Members

CSRAC: Drs. Miller, Gao, Kroetz, Palermo, and Wilfley

CSR Staff: Drs. Kathryn Koeller, Miriam Mintzer, and Raul Rojas

Simplification of Peer Review Criteria: Drs. Reed and Palermo provided an update later in the meeting.

Efforts to Address Bias (NIH Videocast 1:01:01)

CSR Anonymization Study: CSR's study of 1,200 previously reviewed applications in full and redacted forms showed that anonymization does not appear to affect the scores of African-American applicants. However, redaction slightly but significantly appeared to worsen scores of White applicants. CSR hopes to post the results on a preprint server by May 1.

Pilot Bias Training for SROs, Reviewers, and Program Officers (POs): CSR worked with the National Institute of General Medical Science and the NIH Chief Officer for Scientific Workforce Diversity to develop bias awareness training for SROs, reviewers, and POs involved in reviews of applications for the Maximizing Investigator's Research Award program. CSR hopes to further develop the training and roll it out for all CSR reviewers and SROs in early 2021.

Pilot Multi-Stage Anonymized Review: CSR is working with NIH Common Fund officials to conduct a multistage review of applications received in September 2020 for NIH Director's Transformative Research awards. An editorial board will review the specific aims and subject matter experts will review the specific aims, abstract, and research strategy using applications anonymized by the applicants. The editorial board then will review the top candidates by examining the full applications.

Review Criteria: Interim Report of CSRAC Workgroup

(NIH Videocast <u>1:11:47</u>)

Dr. Reed explained that this workgroup was charged to recommend changes to research project grant review criteria that will improve review outcomes and reduce reviewer burden. He said the group would initially focus on R01 and R21 non-clinical trial reviews before tackling other NIH funding mechanisms.

Members

- CSRAC: Drs. Gao, George, Hurd, Kroetz, López, Palermo
- Ad Hocs: Drs. Kevin Corbett, Michelle Janelsins, and Brooks King-Casas
- NIH Staff: Drs. Sally Amero and Bruce Reed

The workgroup met together and in three smaller groups to review the current criteria, identify concerns and propose solutions. The group also received suggestions from the scientific community that were solicited by CSR's Review Matters blog. The workgroup integrated this input with their own to produce an interim report to CSRAC.

Interim Recommendations (NIH Videocast <u>1:21:10</u>)

Dr. Palermo presented the workgroup's six interim recommendations:

- **1.** *Reorganize review criteria to focus (and score) key questions:* Should it be done? Can it be done well? and Will it be done?
- 2. Define each criterion and factor conceptually
- 3. Alter templates to focus reviewer attention on score driving factors
- **4.** *Clarify reviewer responsibility for evaluating the budget:* reviewers would simply judge whether the budget is appropriate, excessive or inadequate with comments optional.
- 5. Relieve reviewers of responsibility for most "additional review" considerations.
- 6. Convene an additional workgroup for review criteria for clinical trials applications and other mechanisms.

She then provided sample guidance on assessing the importance of the science and definitions for Significance, Innovation, and Overall Impact.

Next Steps (NIH Videocast 1:28:57)

Dr. Reed continued by summarizing next steps:

- Obtain further CSRAC advice
- Continue to consider community comments
- Solicit input from key NIH components
- Evaluate other funding mechanisms

Discussion (NIH Videocast: 1:30:22)

Members expressed much support for the approach described in the interim report. All of the recommendations received support. Council comments reflected the view that some of the changes had the potential to make major improvements in how grant applications are reviewed. The recommendations to simplify reviewer evaluation of the budget and to relieve peer review of certain additional review considerations were well received.

Some members noted that reviewers at times offer valuable scientific insights when evaluating certain administrative issues such as biohazards and authentication. CSRAC then discussed the possibility of giving reviewers the option to comment on administrative issues.

CSRAC members also discussed the value of getting reviewers to focus less on the institution per se and more on whether the resources and proposed team could ensure success.

Closing Remarks (NIH Videocast 2:03:36)

Dr. Byrnes thanked the workgroups and CSR staff for their valuable contributions. She then said she hoped to meet face to face next time to further address their interests and concerns.

The meeting adjourned at 3:10 p.m. We do hereby certify that, to the best of our knowledge, the foregoing minutes of the March September 30, 2020, CSRAC meeting are accurate and complete.

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

Bruce Reed, Ph.D. Executive Secretary Center for Scientific Review Advisory Council