

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

**Meeting Minutes
September 18, 2023**

The Center for Scientific Review Advisory Council (CSRAC) convened at 9:30 a.m., Monday, September 18, 2023.

Members Present

Anton M. Bennett, Ph.D.
Leopoldo J. Cabassa, MSW, Ph.D.
Matthew Carpenter, Ph.D.
Jonathan Epstein, M.D.
Christine P. Hendon, Ph.D.
Michelle C. Janelins-Benton, Ph.D.
Narasimhan Rajaram, Ph.D.
Elizabeth Villa, Ph.D.
Lynn Yee, M.D., M.P.H.

Ad-Hoc Participants

Rodney Kiplin Guy, Ph.D.
Daniel Woo, M.D.

Executive Secretary

Bruce Reed, Ph.D.

Ex Officio

Noni Byrnes, Ph.D.

CSR/NIH/HHS Employees and Members of the Public Present

The meeting was held in-person; one council member attended via Zoom (Lynn Yee, M.D., M.P.H.) and one council member was absent (Karen Anderson, M.D., Ph.D.). A small number of observers attended in person. All other observers, members of the public and CSR staff, attended virtually via NIH videocast.

Welcome and Introductions

Dr. Reed welcomed CSRAC members, ad-hoc participants, and attendees to the 26th CSRAC meeting. Each person introduced themselves along with their institutional affiliations and respective areas of science.

CSR Updates

Dr. Byrnes provided the following CSR updates:

Welcome ([NIH Videocast: 00:04:06](#))

Dr. Byrnes thanked all members for attendance and welcomed continuing council members, congratulated Lynn Yee on her endowed professorship and introduced newest council member Jonathan Epstein and ad-hocs Rodney Kiplin Guy and Daniel Woo. Lastly, a goodbye and thank you were extended to Dr. Elizabeth Villa, on the occasion of her final council meeting.

CSR News ([NIH Videocast: 00:08:56](#))

Dr. Byrnes provided an introduction to the CSR senior leadership team and congratulated Dipak Bhattacharyya for his commendation from the Secretary of the Department of Health and Human Services in recognition of his exceptional service and leadership during the COVID-19 pandemic. She also presented the newly CSR developed infographic that targets outreach to Offices of Sponsored Research and investigators at institutions with limited NIH engagement.

NIH News ([NIH Videocast: 00:12:45](#))

Senior leadership transitions at NIH Institutes, Centers and Offices: Jeanne MARRAZZO was appointed director of NIAID; Karina Walters was appointed director of the Tribal Health Research Office; and Jane Simoni was appointed as associate director for Behavioral and Social Sciences Research at OBSSR. Patricia Brennan of the National Library of Medicine is retiring as director. Monica Bertagnolli was nominated to be the 17th director of the NIH and a senate confirmation hearing is expected in October.

Budget ([NIH Videocast: 00:14:35](#))

NIH's appropriations will likely be essentially flat in FY 2024 compared to FY 2023. NIH is preparing for the likelihood of tight funding in FY 2024. Dr. Byrnes noted that CSR's budget is not appropriated by Congress and is a very small fraction of NIH's extramural budget (under one half percent). At present CSR's expectation is that we will be able to continue to further our major priorities.

RFI on updating the NIH mission statement ([NIH Videocast: 00:17:59](#))

Dr. Byrnes highlighted the August 25, 2023, release of a [Request for Information](#) (RFI) that invites comments and suggestions on updating the NIH mission statement. The request is in response to a report that was issued by the Subgroup on Individuals with Disabilities of the Advisory Committee to the Director Working Group on Diversity. The RFI closes November 24, 2023.

Guide Notices ([NIH Videocast: 00:18:54](#))

Dr. Byrnes reported on two recent NIH Guide Notices: [NOT-OD-23-149](#) - Use of Generative Artificial Intelligence Technologies Is Prohibited for the NIH Peer Review Process and [NOT-OD-23-156](#) - Review Integrity and Bias Awareness Training Will Be Required for NIH Reviewers Effective May 2024 Council Round.

CSRs scope, strategic framework, and operating principles ([NIH Videocast: 00:21:46](#))

Dr. Byrnes reviewed the mission and scope of CSR, which reviews approximately 60,000 applications with ~19,000 reviewers across ~1,200 meetings. She spoke of the 161 special initiatives reviewed by CSR and reminded Council of CSR's strategic framework, which seeks to optimize peer review by focusing on key components of peer review—reviewers, study sections, and review processes. Dr. Byrnes reviewed CSR's operating principles of transparency, data-driven decision-making, involvement/engagement of stakeholders, and staff engagement, training, and development.

ENQUIRE Overview ([NIH Videocast: 00:27:48](#))

This is a two-stage, systematic, data-driven, and continuous process to evaluate study sections. The process is overseen by CSR's scientific division directors. The process includes 3 phases: an external scientific evaluation panel, internal NIH process evaluation panel, and CSR Advisory Council approval. Following CSRAC approval, CSR staff further evaluate feasibility of the recommendations with mock sorts, finalize study section guidelines, and publish and implement the changes. ENQUIRE takes about 12-18 months from initiation to implementation of new or restructured study sections.

Format of Study Section Meetings ([NIH Videocast: 00:30:52](#))

In-person study section meetings resumed in FY 2023 (Fall 2022). CSR set the goal of holding 1 of 3 meetings per year as in-person for study sections with standing/recurring membership (~220 meetings per year). CSR held 76 in-person review meetings in Oct/Nov 2022, 57 in Feb/March 2023, 88 in June/July 2023, and ~78 in Oct/Nov 2023. CSR has completed an analysis of in-person versus virtual study sections for Fall 2022 meetings, including reviewer survey data, a roster analysis, and a scoring analysis. Dr. Byrnes noted that this report, which allowed comparison of in-person and virtual meetings within the same round, represents only one review round of experience and that it would be premature to draw firm conclusions. CSR is continuing to gather and evaluate data and will issue later this fall a report based on meetings run in the spring and summer of 2023.

The full detailed data/analyses report can be found here: [CSR Analysis of Fall 2022 In-Person and Virtual Peer Review](#)

Dr. Byrnes outlined the current piloting of hybrid review meetings. She briefly described promising results for the hybrid format from an analysis performed on the 2023 meeting (in-person, hybrid, virtual) experiences of reviewers. The full report is expected by October 2023. CSR will focus on increasing the number of hybrid review meetings with the goal of making hybrids a seamless and integrated experience for all attendees, regardless of how they attend.

Engaging CSR's Advisory Council ([NIH Videocast: 00:57:44](#))

In 2019, an expanded role and resources were introduced for CSR's Advisory Council, most significantly a series of advisory council working groups. Three working groups were convened in 2019: CSRAC Review Integrity Working Group, CSRAC Early Career Reviewer Working Group, and CSRAC Simplifying Review Working Group (non-clinical trials). In 2020, a second CSRAC Simplifying Review Working Group was formed, this one with a focus on clinical trials review. In

2021, the CSRAC Bias Awareness Working Group and the CSRAC Fellowship Working Group were convened. All have had a significant impact. Dr. Byrnes reported that two new CSRAC working groups will launch in October 2023: one on Reviewer Evaluation and the other on Reviewer Recognition. Both are linked to CSR's framework for optimizing review and recognizing the central importance of having a broad pool of well-trained reviewers.

Slates: How CSR Selects Members of Standing Study Sections (Dr. Bruce Reed) ([NIH Videocast: 01:13:18](#))

Dr. Reed gave an overview on the nomination process and how standing study section members are selected to serve on panels. Panels play a central role in the model of review that NIH uses—all review outcomes are panel decisions. Dr. Reed discussed the slate journey, beginning with the primary requirements. Slates require scientific expertise, multidimensional diversity, credible rosters, and members who are good reviewers, as well as who are fair minded and who possess professional integrity. Also, all members must be authorized per the Federal Advisory Committee Act (FACA). Scientific review officers complete a substantial amount of foundational work in the selection process, from recruiting, observing, and training possible members, to defining membership needs—all must be concluded prior to drafting a slate package. The slate package is digital and includes substantial data; when compilation is complete, the package is submitted for a diligent, multilevel review process that incorporates external feedback prior to final approval. External feedback and slate guidelines drive study section membership, but so do other CSR policies and practices. In the past few years, CSR and NIH have taken multiple steps to strengthen study sections by improving diversity. Nominees are not selected individually, but rather as a set to form a panel that will provide fair and effective review of scientific merit.

Council raised a few questions regarding the representation and engagement within standing study sections. It was discussed that CSR tracks all groups and their involvement in study sections, and the approval of appropriate diversity on each panel is expected. It was noted that diversity will fluctuate across different dimensions, and CSR does not work with specific numerical targets. The topic of allowing more clinicians the opportunity of extended service was raised. CSR does not provide this option broadly because appointed members are expected to be present and are the core of the study sections. Members were enthused by the fact that reviewer recruitment is focused on selecting those with the most appropriate scientific expertise and of diverse backgrounds.

ENQUIRE Report: Immunology and Respiratory Systems (Dr. Ross Shonat) ([NIH Videocast: 02:01:56](#))

Dr. Ross Shonat gave an overview of the ENQUIRE cluster 13 process and recommendations. ENQUIRE cluster 13 is a group of 10 standing study sections that can be organized into three subgroups; three study sections within basic immunology, four related to applied immunology, and three study sections related to respiratory systems. Recommendations from external workgroup members were presented, as well as input on these recommendations provided by an internal panel of NIH stakeholders. Recommendations were to charter 13 new study sections – five related to basic immunology, four restructured panels in applied immunology, and four in the area of respiratory systems.

Council was generally in favor of the proposed restructuring. A question was raised regarding whether each of the 13 panels will have high enough application numbers to function well. With the mock-sort, CSR will evaluate whether there is likely to be adequate application numbers in each, while taking into consideration overlaps with existing and other study sections. The set is still subject to modification.

A Council motion to approve CSR's final recommended set of study sections (with the proviso that adjustments may be needed based on mock-sort results) carried unanimously. A tentative timeline for implementation is late 2024.

Implementing Changes to NIH Peer Review Criteria

Simplified Review Framework for Research Project Grants (Drs. Mark Caprara and Brian Hoshaw) ([NIH Videocast: 02:35:45](#))

Drs. Hoshaw and Caprara reported on the Simplified Review Framework for Research Project Grants. The framework will reorganize the five statutory criteria; Significance, Investigators, Innovation, Approach, and Environment into three

factors; Factor 1: Importance of the Research (Significance and Innovation, scored 1-9), Factor 2: Rigor and Feasibility (Approach, scored 1-9), and Factor 3: Expertise and Resources (Investigators and Environment, considered in overall impact, no individual score). The implementation of the revised framework began in December 2022 with a Request for Information. The RFI consisted of 800 responses from individuals, scientific societies and academic institutions. The majority of the respondents were supportive of the proposed changes. To facilitate a smooth and successful implementation process, NIH formed a Simplifying Review Framework Implementation Committee. Committee members have expertise across the many domains needed for implementation; in addition to the executive committee, three sub-groups were created to help execute the implementation. The three groups will be responsible for the following areas: Group 1: Communications, Group 2: Policy/Guide/eRA/Systems, Group 3: Training. Each institute/center/office has identified a central coordinator to facilitate implementation activities at their respective ICO. A Guide Notice is being prepared to be issued in Fall 2023, this will notify the public of the final SRF language and implementation date. Post Guide Notice, there will be a vigorous socializing plan to inform the public of the existence of the Guide Notice and its contents. RPG funding announcements will need to be reissued to incorporate the new review framework. To make the reissue process as smooth as possible, a “soft launch” is planned to develop best practices for reissues. The new framework will be implemented on applications submitted for due dates on or after January 25, 2025; the applications will be reviewed in Summer 2025 for October 2025 Advisory Councils.

Discussion among Council raised several issues, among them how multiple PIs would be evaluated, whether new content would be required for clinical trials applications, the scoring of Factor 3, plans for evaluation of the new framework, and how to effect the culture change needed to successfully implement these changes.

Revisions to NRSA Fellowship Review (Drs. Ericka Boone, Alison Gammie, and Bruce Reed) ([NIH Videocast: 03:12:37](#))

The group briefly reviewed the background and components of a set of revisions to fellowship review, which grew out of a CSR Advisory Council working group. The review criteria will be restructured from five to three; 1) The scientific potential and preparedness of the fellowship candidate, 2) the scientific project or research training project, and 3) training plan and training resources. “Sponsor” and “Institutional Environment” are eliminated as distinct criteria. In April 2023, an RFI was issued to seek recommendations for improving on NRSA fellowship review. Significant outreach targeting schools that submit few Fs and/or MSIs regarding the RFI was done. 147 responses were received. The feedback received from the public consisted of a strong support for the proposed restructuring of the application, and suggestions to further clarify and provide additional guidance for specific criterion processes. The fellowship application will be changed to better align with the new review criteria. To guide and execute the implementation, NIH has formed a NRSA Fellowship Review Implementation Committee. The committee consists of multidimensional domain expertise, drawing from the Executive Committee, four sub-groups were developed to carry out the revision. The four groups will focus on the following areas: Group 1: NOFO/SF424, Group 2: eRA/Business Systems, Group 3: Targeted Outreach & Communications, Group 4: Reviewer Orientation & NIH Staff Training. Over the next year, the application instructions will be refined and approval from the Office of Management and Budget will be obtained, required system changes will be implemented and additional resources and training will be created to enhance awareness. In late 2024/early 2025, funding opportunities will be updated and public webinars providing an early overview of changes will be held. CSR anticipates that the first NRSA submissions under the revised framework will occur in 2025.

Most of the discussion focused on how we could intentionally engage with the institutions that submit few NRSA applications and the strategic outreach that is being led to increase their participation. A concern was raised that the enhancement/changes being made may not be enough to get the smaller institutions over the barrier due not having the time and adequate resources to apply.

A Framework for Evaluating Reviewers (Drs. Lambratu Rahman Sesay, Joseph Rudolph, and Elena Smirnova)

([NIH Videocast: 03:46:53](#))

Dr. Smirnova presented on behalf of CSR’s internal working group, and emphasized the important role of reviewers, noting that Objective 2.3 of [CSR’s Strategic Plan](#) is to propose the development of a formal process for reviewer

performance assessment and feedback with the ultimate goal of improving reviewer performance and the quality of review. She reviewed the approaches other major scientific peer review organizations take to evaluate reviewers. She noted that a fundamental task of evaluation was to first define the characteristics of a good reviewer. The conceptual framework presented by the group defines a high-quality reviewer as one who is fair, one who adheres to the review criteria, using only information presented in the application, and one who is open-minded, not limited to preconceived ideas, and free of bias. A good reviewer will be knowledgeable, one who applies their scientific expertise and experience to evaluating applications, while being able to communicate that very assessment in critiques and presentations. Ultimately, a quality reviewer will be evaluative, will have the ability to distinguish between applications by scientific merit, and their assessment will be supported by evidence based declarative statements of strengths and weaknesses.

Council members stated that the defined, expected behaviors during a review are the most practical and concise that they've seen. Part of the discussion focused on methods used by other major scientific peer review organizations and how they do or do not coincide with our new processes. The discussion also touched on ideas for how the working group will need to complete tasks related to this framework.

The meeting adjourned at 3:26 p.m.

We hereby certify that, to the best of our knowledge, the foregoing minutes of the September 18, 2023, CSRAC meeting are accurate and complete.

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

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