

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

March 26, 2018

The Center for Scientific Review Advisory Council (CSRAC) convened at 8:30 a.m., Monday, March 26, 2018, at the Center for Scientific Review (CSR), 6107 Rockledge Drive, Bethesda, MD. The entire meeting was held in open session. Richard Nakamura, Ph.D., presided as chair.

Members Present

Jinming Goa, Ph.D. (<i>ad hoc</i>)	Scott Miller, Ph.D.
Alfred L. George, M.D.	Richard Nakamura, Ph.D.
Yasmin Hurd, Ph.D. (<i>ad hoc</i>)	Tonya Palermo, Ph.D. (<i>ad hoc</i>)
Deanna Kroetz, Ph.D. (<i>ad hoc; participating remotely</i>)	Julie C. Price, Ph.D.
José López, M.D. (<i>ad hoc</i>)	Jennifer West, Ph.D. (<i>participating remotely</i>)

Noni Byrnes, Ph.D., was the executive secretary for the meeting.

I. Welcome and Introductions

Dr. Nakamura, CSR Director, welcomed CSRAC ad hoc and regular members, CSR staff, and other attendees in person and via webcast to the 15th CSRAC meeting. He asked for a motion to approve the minutes from the September 25, 2017, meeting. CSRAC approved the minutes.

II. CSR Update

Dr. Nakamura gave an overview of CSR activities and budget; an analysis of the kinetics of reviewed applications; results of surveys of reviewers, program staff, and CSR staff; and updates on several pilot tests.

NIH Budget

For the third year, NIH's budget increased above the rate of inflation. The FY2018 budget is \$36.4 billion, an increase of \$3 billion. More than 80 percent supports extramural research.

In FY2017, 95,000 applications were received, of which CSR reviewed 61,000. Reviews involved 18,000 reviewers and 247 Scientific Review Officers (SROs) in more than 200 standing and recurring study sections.

It costs CSR about \$2,000 per application, considering travel, staff time, and all other expenses. Application numbers remain high, although unevenly distributed, with the May Council round receiving the highest number. CSR SROs handle more applications on average than Institutes and Centers (ICs) SROs and adapt to many different mechanisms. NIH policy changes have increased costs and SRO workloads, including the focus on rigor and transparency, shorter

timelines for Small Business Innovation Research (SBIR)/Small Business Technology Transfer (STTR) applications, and IC requests for more special emphasis panels (SEPs).

Kinetics of Applications

CSR studies the timeline of the review process. From submission to release of a summary statement, CSR averages about 150 days per application, compared to an average of about 200 days across ICs. AIDS-related applications are on a faster timeline.

Survey Results

CSR regularly conducts surveys to understand the value of its services. In a recent survey, a majority of reviewers said the quality of discussion is stronger in face-to-face meetings. POs' satisfaction with video-assisted and Internet-assisted meetings is improving, but they also greatly prefer in-person meetings.

In the 2017 NIH employee survey, CSR had the second highest response rate, at about 80 percent. While overall satisfaction is high, a small percentage expressed dissatisfaction. CSR scored high in terms of talent management opportunities and a results-oriented performance culture. Responses varied across Integrated Review Groups (IRGs) related to workload. CSR is now able to hire 20 new SROs, which may help ameliorate the workload issue.

Pilot Tests

One pilot has looked at an added half-point scoring approach. The current system shows peaks, rather than a smooth curve, in scoring. A pilot to add half-point increments showed a better distribution and differentiation between applications. Reviewers involved in the test felt it helped in prioritization and favored a policy change.

A second test looked at intra-IRG/cross study review group (SRG) ranking. The question it aimed to answer was whether high-quality applications tend to cluster in certain SRGs, which would result in higher competition. Dr. Nakamura explained the test and its conclusion that applications are reasonably distributed across SRGs.

Other studies underway are looking at reliability of scoring, investigation of preliminary scoring and bias, and anonymization.

Fairness of Review

The need to re-review 60 applications provided an opportunity to focus on fairness of review. Elements looked at included stage of career, gender, field, race/ethnicity, and reviewer status. While the reviews were generally deemed fair, differences in scoring seemed concentrated in preliminary scoring. This finding makes the anonymization study all the more important.

A breach of conduct within a study section necessitated the re-review. Breaches of review integrity are rare but very serious. Dr. Nakamura asked CSRAC for suggestions about how to enforce review integrity.

Monitored for the Future

Dr. Nakamura concluded with items to monitor for the future, including growth in applications, complexity of reviews, and increases in other transactions (OT) that involve new partners and processes. He announced his plans to retire in the next few months.

Discussion Highlights

- **Review integrity:** Julie Price, Ph.D., stressed the role of the SRG chair in leading by example. Scott Miller, Ph.D., suggested an online “Reviewer Lab” course, citing one conducted by the American Chemical Society as an example. He noted incomplete conflict of interest (COI) certifications are a big problem and suggested CSR work with university vice-presidents for research to improve certification. Albert George, M.D., suggested clearly stating the consequences of a breach. Dr. Price suggested training early in the process, while reviewer vetting takes place. Yasmin Hurd, Ph.D., noted reviewers do not realize that some practices constitute a breach. José López, Ph.D., commented a culture of “everyone is doing it” could affect some practices. Dr. Jinming Gao, Ph.D., suggested a CSR-wide mechanism, rather than have training fall on individual SROs. Dr. Nakamura said NIH is planning a curriculum.
- **Kinetics of applications:** Dr. George asked about AIDS versus non-AIDS applications. Dr. Nakamura said slices of time are taken out of each phase in an AIDS review, but that results in less time to make reviewer assignments and read applications. When people push for a quicker process, they look at CRS first without looking at where the slowdown takes place. Noni Byrnes, Ph.D., noted the time lag often come after the review itself.

III. CSR Special Reviews

Dr. Byrnes introduced a series of five special initiatives reviewed wholly or partially through CSR. The review landscape has been changing over the last two decades, with CSR now handling many more complex reviews in addition to the more standard business of R01 reviews in standing study sections.

NIH Director’s Pioneer Award

James Mack, Ph.D., SRO in the Division of Basic and Integrative Sciences, said the Pioneer Award supports high-risk, high-reward research conducted by exceptionally creative scientists. He explained the application and award features. A reduced criterion set, with a focus on impact, seeks potential breakthroughs. Applicants are reviewed in two stages. Stage 1 reviewers have in-depth experience in one of nine scientific areas. Stage 2 reviewers have a wide purview of subject-matter and leadership experience. In stage 2, finalists present their ideas in person. Compared to R01s, Pioneer Awards have a more emergent premise. The overall mindset favors plausibility, rather than feasibility, even if the premise seems a very risky or novel pursuit.

Discussion Highlights

- **Preliminary data:** In response to Dr. George, Dr. Mack said finalists often have some data by their interview. He acknowledged a fine line to ensure the plan is not implausible.

Maximizing Investigators’ Research Award (MIRA)

Maqsood Wani, Ph.D., Chief of the Cell Biology IRG, discussed CSR’s role in reviewing the MIRA award, or the R35, sponsored by the National Institute of General Medical Sciences

(NIGMS). Four other ICs have R35s under different titles, but they review the applications themselves. The purpose is to fund programs (a collection of projects) rather than projects. NIGMS issues four MIRA Funding Opportunity Announcements (FOAs) for early-stage and established investigators. To review 1,120 applications, 287 reviewers participated. They have broad expertise to meet the intent of each FOA. CSR conducts training and has modified critique templates to respond to MIRA. Critiques are pre-screened and feedback provided to meet the MIRA criteria. Because the program is fairly new, the potential impact of the MIRA program on R01 application numbers is not known.

Discussion Highlights

- ***SRO involvement:*** In response to Dr. George and Dr. López, Dr. Wani said SROs tailor training and feedback for MIRA reviewers. Long-term impact is stressed.

NIH-FDA Tobacco Centers of Regulatory Science (TCORS)

Jasenka Borzan, Ph.D., SRO in the Division of Neuroscience, Development and Aging, said the Tobacco Regulatory Science Program is the central hub of an NIH-Food and Drug Administration (FDA) collaboration that coordinates an FDA-funded grant portfolio to implement the 2009 Family Smoking Prevention and Tobacco Control Act, or the U54. CSR coordinates center reviews, which have different research priorities than other NIH tobacco research. The grants focus on scientific inquiry to inform potential regulatory decisions and actions, and not on mechanisms or disease treatment. Applications are pre-screened for responsiveness to the grant criteria.

Challenges for peer review include finding reviewers without conflicts of interest but with the necessary expertise. The U54's significance and innovation criteria are slightly modified. At least five reviewers read each application, but they review only the sections within their expertise. Discussion on the entire application takes place in person. The reviews are highly complex.

Discussion Highlights

- ***Center review:*** In response to Dr. Gao, Dr. Borzon contrasted the U54 with a P01. Dr. Miller raised a cautionary note that no one person reviews an entire application.

Native American Research Centers for Health (NARCH)

Delia Olufokunbi Sam, Ph.D., Chief of the Population Sciences and Epidemiology IRG, explained the purpose and objectives of Native American Research Centers for Health, which focus on capacity building to do research. They are NIH–Indian Health Service (IHS) collaborations. Tribes, tribal organizations, and consortia are eligible, and are encouraged to partner with research-intensive institutions. Five types of projects receive funding. Applicants can submit for multiple components. An interdisciplinary panel reviews applications based on broad goals and specific expertise for the subprojects.

Key review challenges include:

- Priority to include American Indian and Alaska Native (AI/AN) reviewers, but a limited pool;

- High number of reviewer conflicts given the small community;
- Location of most reviewers in the west, which increases institutional dyads;
- Potential perception of tribal bias;
- Historical tension around research on AI/AN populations;
- Logistics of coordinating large, complex applications.

Discussion Highlights

- ***Broadening the reviewer pool:*** In response to a question from Dr. Price, Dr. Olufokunbi Sam acknowledged the difficulty in finding Native American, Alaskan Native, and Pacific Islander reviewers, but they have worked to broaden the pool over the 10 years the program has operated. Dr. Hurd suggested considering Canadian investigators to serve as reviewers.

Global Alliance for Chronic Diseases (GACD)

Seetha Bhagavan, Ph.D, SRO in the Division of Neuroscience, Development and Aging, coordinates joint peer review through the Global Alliance for Chronic Diseases. NIH, represented by the Fogarty Center, is a member of GACD, along with health-related agencies from 13 other countries. GACD sends out a joint call and conducts joint peer review on priority topics, but each agency funds research separately rather than pool resources.

The first joint funding call was on hypertension. Others have targeted Type 2 diabetes, lung diseases, and mental health and substance abuse. The usual NIH and GACD peer review processes have some, although not major differences; the scoring systems, however, do differ greatly. GACD agreed to the NIH system and to multistage reviews. In the 2017 mental health joint peer review, applications were clustered and ranked.

Discussion Highlights

Choice of topics: Dr. Price asked about the topics of the RFAs. Dr. Bhagavan said they rotate among the priority topics, but all focus on capacity building and implementation science in low-resource settings. Dr. Nakamura noted the GACD review set a precedent because representatives from other governments were present for an NIH review.

IV. Peer Review: The Foundation of NIAMS' Funding Decisions

Stephen Katz, M.D., Ph.D., director of the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), is one of NIH's longest-serving IC directors and has served as an advisor to many NIH directors. Dr. Katz focused on how NIAMS makes funding decisions and on new initiatives.

NIAMS stresses transparency. Funding plans are posted online, as are criteria used when a grant beyond the payline is funded, such as for early stage investigators. Decisions become more difficult when applications within the payline are not funded because they are deemed a low program priority. In these rare instances, the NIAMS Council discusses the application before Dr. Katz as director makes a final decision.

Funding Policies

A policy has evolved over the past few years in which planning grants need to precede NIAMS-funded interventional clinical trials. A special NIAMS review group looks at applications for clinical outcomes studies. CSR reviews applications for mechanistic clinical studies.

Four years ago, NIAMS launched the Research Innovations for Scientific Knowledge (RISK) award to support highly innovative and significant ideas in their infancy, with an emphasis on novel applications that may not fare well otherwise in peer review. RISK employs a two-stage review process that takes place anonymously. A survey after the first round showed almost all reviewers thought anonymity had been achieved. Further suggestions and comments included the following:

- Lack of information on research strategy makes evaluating innovation and significance a challenge;
- Grantsmanship is important in the success of an application;
- Variability in how applicants provide details makes comparisons a challenge;
- A standardized template will facilitate review;
- Reviewers saw no need to cite references to review the applications.

Five of the 60 respondents did not like the X02 mechanism or anonymous review, but most supported it. RISK does require more outreach to increase awareness of the opportunity.

Other Council Activities

The NIAMS Council has made many recommendations in addition to those above. For example, the Supplement to Advance Research (STAR) from Projects to Programs, or PA-15-109, has proven popular. It helps early established investigators facilitate the transition from a single research project to a program. NIAMS notifies applicants eligible to apply. The selection process includes a four-page essay and a recommendation from department chairs.

Discussion Highlights

- **RISK X02 success:** In response to a question from Dr. Hurd about the anonymous reviews, Dr. Katz said when their identities were later revealed, about 75 percent were researchers generally successful in obtaining grants. He noted the importance of grant-writing ability in their success.
- **High-risk research:** Dr. Miller asked whether the scientific community should stress submitting more high-risk proposals within professional societies and universities. Dr. Katz said with success rates so low, an unsuccessful applicant might blame riskiness as the reason for lack of funding. For this reason, several ICs, including his, have introduced high-risk awards. Several funded RISK applications had earlier gone through other peer review channels unsuccessfully. Dr. Miller agreed a multiplicity of mechanisms helps investigators think differently about their projects.

V. **Imaging Reorganization and Somatosensory and Pain Sciences (SPS) Chartering**

Bruce Reed, Ph.D., Director of the Division of Neuroscience, Development, and Aging, briefed CSRAC and requested approval to restructure two sets of study sections.

Biomedical Imaging Science Reorganization

Five SRGs currently review developmental biomedical imaging science. Issues these SRGs arose in 2015, and CSR made some changes. Implementation issues and large numbers of applications prompted a re-evaluation of the changes in 2017. A strong external panel recommended six reorganized SRGs. Three would have an engineering emphasis and cover technology development from creation to clinical or research use. Two would review contextually linked imaging science across a wide continuum of development. The sixth would focus on applications to bring the technology into the clinic. A mock sort of applications showed the numbers of applications would distribute relatively evenly across the six SRGs. After the sorting exercise, staff revised guidelines and drafted overlap statements.

As a result, CSR views the six SRGS as a good structure to handle applications related to biomedical imaging basic and clinical research.

Discussion Highlights

- ***Ophthalmology imaging:*** In answer to a question from Dr. Hurd, Dr. Reed said the location of this type of applications must still be determined.
- ***Motivation for review:*** Dr. Gao praised the process but asked whether application numbers drive these types of reviews. Dr. Reed said both science and workload are taken into account. Dr. Nakamura said restructuring aims to accomplish workload, coherent science, and overlap issues.

Council Action: CSRAC unanimously recommended that CSR create the six biomedical imaging study sections as proposed: **Imaging Technology Development (ITD); Emerging Imaging Technology Applications (EIA); Clinical Transitional Imaging (CTI); Image Guided Interventions and Surgeries (IGIS); Emerging Imaging Technologies in Neuroscience (EITN); and Imaging Probe and Contrast Agents (IPCA).**

Recurring SEP for Somatosensory and Pain Science

Dr. Reed's second proposal related to dividing the current Somatosensory and Chemosensory Systems SRG into two: a Somatosensory and Pain System (SPS) chartered study section and Chemosensory System (CSS) recurring Special Emphasis Panel (SEP). In 2003, SPS was formed under the belief the two fields were related enough for a successful SPG. However, both fields say the science does not mesh and, in any event, workload has increased beyond one study section. In 2017, an external scientific review indicated a division would provide competitive breadth. Program officers and the scientific community have provided positive feedback.

CSR believes chartering SPS and redefining CSS will result in two study sections with appropriate scientific scope, reasonable workload, and support in the scientific community.

Discussion Highlights

- **Community reaction:** Dr. Hurd commented colleagues in pain science did not like the existing system. In response to a question from Dr. George, Dr. Reed said neurobiology of pain would fit within SPS. Dr. Nakamura asked the impact of the additional funding in the FY2018 budget for pain science on these SPGs. Dr. Reed responded other study sections also cover aspects of pain science; the one under discussion covers very basic science.

Council Action: CSRAC unanimously recommended restructuring of the Somatosensory and Chemosensory Systems SRG into two: a Somatosensory and Pain System (SPS) chartered study section and Chemosensory System (CSS) SEP, as proposed.

VI. AIDS and Nursing Study Sections Reorganization

Valerie Durrant, Ph.D., Director of the Division of AIDS, Behavioral and Population Sciences, provided an update on an IRG reorganization and introduced a proposal for the reorganization of one SRG within her division.

AIDS and Related Research (AARR) Study Sections

After an internal review, an external working group made initial recommendations in 2017. ICs provided input, and the CSRAC recommended approval of the proposed study sections at its September 2017 meeting. The reorganization plan called for six study sections spanning basic, translational, clinical and population contexts.

CSR has continued to refine the study section descriptions. The science has realigned in recent years, moving from AIDS to HIV, from bench to bedside, encompassing the comorbidities and other impacts of living with HIV, and emphasizing treatment as a form of prevention. The science has become more overlapping. The revised reorganization responds to these change and aligns with Office of AIDS Research priorities. If approved by NIH, reviewers would start with the changes in 2018, with full implementation for the 2019/01 Council round.

Approved study sections include:

- HIV Molecular, Virology, Cell Biology and Drug Development (HVCD);
- HIV Immunopathogenesis and Vaccine Development (HIVD);
- HIV Comorbidities and Clinical Studies (HCCS)
- HIV Coinfections and Associated Cancers (HCAC);
- HIV/AIDS Individual Level Determinants and Behavioral Interventions (HIBI)
- Epidemiologic, Population, and Public Health Approaches to HIV/AIDS (EPPH) (Note: This was changed to Population and Public Health Approaches to HIV/AIDS (PPAH) after the meeting).

Reorganization of the Nursing Related Clinical Sciences (NRCS) Study Section

This study section fits within the Healthcare Delivery & Methodologies IRG. Because of increasing workload, the proposal splits the section into two based on focus. NRCS would cover patient care and management in institutional settings, and NRCS II would cover them in home-based and community settings. Other options considered included two twin study sections or even three sections. Dr. Durrant further described the scientific scope of the two SRGS. [Note: the NRCS II study section was renamed the Clinical Management of Patients in Community-based Settings (CMPC) study section after the CSRAC meeting.]

Discussion Highlights

- **Nomenclature:** Dr. Price said she liked the distinction by setting. She asked about “nursing” in the title. Dr. Durrant said the applications cover a wide scope of clinical research beyond nursing.
- **Workload:** Dr. George asked about whether two study sections were sufficient to cover the workload. Dr. Durrant said the two sections can handle the number now, but there have been more applications in all aspects of service and care. She said a review based on workload might be necessary in the future should increases continue.

Council Action: CSRAC unanimously recommended that CSR restructure of the Nursing Related Clinical Sciences Study Section into two groups as proposed.

VII. Closing Remarks

Dr. Nakamura thanked CSRAC for their engagement and advice. He expressed his appreciation to CSR Council and staff for their contributions. Dr. Hurd thanked Dr. Nakamura, praising the hard work that goes into thinking through how to improve CSR.

We do hereby certify that, to the best of our knowledge, the foregoing minutes of the March 26, 2018, meeting of CSRAC are accurate and complete. The minutes will be considered at the next meeting of the Advisory Council, and any corrections or comments will be made at that time.

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

Richard Nakamura, Ph.D.
Chair
Center for Scientific Review Advisory Council