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

February 1, 2010

The Peer Review Advisory Committee (PRAC) convened at 8:15 a.m. on Monday, February 1, 2010, at the Bethesda North Marriott Hotel in Bethesda, Maryland. The entire meeting was held in open session. Drs. Antonio Scarpa and Story Landis presided as co-chairs.

Members

Story Landis, Ph.D., co-chair
Toni Scarpa, M.D., Ph.D. co-chair
Dean Brenner, M.D.
Jill Buyon, M.D.
R. Lorraine Collins, Ph.D.
Garret FitzGerald, M.D.
Paulette Gray, Ph.D.

Ann Hagan, Ph.D.
Heidi Hamm, Ph.D.
Leslie Leinwand, Ph.D.
Peter R. MacLeish, Ph.D.
Sally Rockey, Ph.D.
Louise Ramm, Ph.D.
Jane Steinberg, Ph.D.

Cheryl A. Kitt, Ph.D., was the executive secretary for the meeting.

I. Welcome and Introductions

Dr. Cheryl Kitt welcomed attendees to the meeting and recognized new PRAC member Dr. Peter MacLeish, Professor of anatomy and neuroscience at the Neuroscience Institute at Morehouse College of Medicine. Dr. Landis, PRAC co-chair, added her welcome and said that PRAC helps NIH fulfill a critical piece of its mission to fund the best science in the most expeditious and appropriate fashion. Dr. Scarpa, PRAC co-chair, transmitted regards from NIH Director Francis Collins, who is overseas and could not attend the meeting.

Dr. Kitt asked PRAC members for comments or changes to the June 8, 2009, minutes. With no comments or changes, the committee unanimously approved the minutes.

II. CSR Peer Review Updates

Dr. Scarpa updated PRAC on recent CSR initiatives, changes that came from the trans-NIH Enhancing Peer Review effort, and future plans.

Recent CSR Initiatives

- **Reorganizing CSR:** The reorganization is complete, with five science-based review divisions. Three divisions have newly recruited directors, and about half of the Integrated Review Groups (IRGs) also have new leadership.
- **Improving study section alignment:** CSR receives community input and conducts internal reviews to consider potential changes to study sections to keep up with changing science and to balance workloads. CSR staff will present several suggested changes later in the meeting.
- **Shortening review time:** In 2005, about 5.5 months elapsed between submitting an application to posting its critique. By 2009, the average was less than three months.
- **Advancing additional review platforms:** Electronic review platforms help recruit reviewers who cannot travel. A survey of those involved in internet-assisted reviews showed a large majority are very or somewhat satisfied. A pilot for a multisite meeting will take place shortly. Other review platforms include editorial board reviews for very complex applications. Finally, several thousand, very distinguished scientists have agreed to be part of the new College of CSR Reviewers.
- **Recruiting the best reviewers:** Data show most CSR reviewers are full professors, followed by associate professors; fewer than 10 percent are assistant professors. Application load per reviewer has risen slightly to 7.5, up from 6 in 2005 but far below the average of 12 per reviewer 10 years ago. A smaller load means more reviewers are needed. Strategies to recruit top reviewers include moving some meetings to the West Coast; eliminating submission deadlines for chartered members, Council members, and frequent reviewers as an incentive to serve; and providing reviewers more flexible terms of service.
- **Reviewing highly transformative research:** The Transformative R01 program completed its first year, with an eight-page application and editorial-board type review. Of 720 applications submitted, 42 received funding. (CSR staff polled applicants and reviewers about the process and presented findings later in the meeting.)
- **Implementing other changes:** Dr. Scarpa touched on other changes: sun setting CDs in favor of secure downloads; consolidating the rosters of small special emphasis panels within IRGs to protect reviewer identities; offering “anytime submissions” to more reviewers to advance reviewer recruitment; and posting study section discussion schedules online in real-time for program officers so they can more easily hear their assigned applications discussed.

Enhancing Peer Review

Dr. Scarpa discussed implementation of the trans-NIH Enhancing Peer Review initiative. Changes that began in July 2009 included the 1–9 scoring system, new critique templates, and

clustering of applications for consideration within a meeting. Researchers will use shorter applications beginning in 2010. He summarized how some of the changes are going:

- **Enhanced review criteria** are still a bit misunderstood. NIH will issue a new guideline to explain overall impact and significance more clearly.
- **Template-based critiques** that provide applicants with more feedback about their proposals are going well. CSR is working to ensure that all critiques effectively convey the information needed. Examples of good and bad bulleted critiques have been developed to help reviewers.
- **The simplified 1-9 scoring scale and clustered discussion** are also working well. CSR study section discussions now consider applications with the best average preliminary scores first. Clustering addresses the concern about potential scoring variations during different times of a meeting.
- **Training for CSR and Institute and Center (IC) study section chairs** help improve execution of these changes.

Final Thoughts

- **Applications are on the rise.** In 2009, they rose above 100,000, including a large number of applications for American Recovery and Reinvestment Act (ARRA) funds. These rising numbers adversely affect paylines and pose challenges for reviewers and staff. December 2009 saw a record number of applications received, and the staff was working almost 24/7.
- **Staff and reviewers performed heroically.** Dr. Scarpa expressed his gratitude.
- **The 2009 Marcy Speer Outstanding CSR Reviewer Award was given to Dr. John Raymond,** provost and vice president at the Medical University of South Carolina. He thanked his mentors, the Scientific Review Officers (SROs) with whom he has worked, and his family for their support.

Discussion Highlights

- **Has there been feedback yet on shorter applications?** Dr. Scarpa said applicants have asked about the review process for these applications. Reviewers will need to understand that applications will not contain as much detail as in longer applications. The Challenge Grants had a shorter application, which worked well.
- **How will the College of CSR Reviewers work and will it have an impact on IC reviewers?** Dr. Scarpa said these reviewers will have limited assignments, perhaps a few hours a month.
- **Will study sections shift to more electronic meetings?** Dr. Scarpa said such meetings are used when necessary to recruit reviewers who otherwise could not participate. Face-to-face meetings remain dynamic and invaluable ways to review applications, and NIH will continue to use them.

Has NIH considered a two-phase application used by some foundations? With very low paylines, such an application could ease the burden on both applicants and reviewers. Dr. Sally Rockey noted regulations dictate scoring all applications; a negative reaction to a letter of intent cannot exclude applicants from submitting applications. PRAC members suggested setting up a

pilot in which applicants submit abstracts in a first phase. Applicants would not be prohibited from submitting full applications but would have a more realistic sense of their chances of funding. Providing feedback before writing an entire application could ease a huge burden on applicants and their institutions. Dr. Scarpa said he would discuss with Dr. Rockey and others the possibility of developing a pilot to evaluate a two-phase application process.

- ***Is only one resubmission workable for applications that are just missing out on funding?*** Dr. Landis said Bridge Awards in some ICs tide researchers over until they receive new funding. In addition, ICs set program priorities and may fund high-priority applications very close to the payline. She noted that funding has not kept pace with scientific opportunities, and the scientific community may want to do more to educate the public about NIH's role in advancing public health, scientific discovery, and the economy.

III. Early Stage Investigator Policy: The First Year

Dr. Walter Schaffer, Senior Scientific Advisor for Extramural Research in the Office of Extramural Research (OER), and Dr. Suzanne Fisher, Director of the CSR Division of Receipt and Referral, summarized the new policies to support Early Stage Investigators (ESI). ESIs are applicants who have received their terminal scientific degree or completed their residency within the last 10 years. They are a subset of applicants NIH regards as New Investigators—researchers who have not yet competed successfully for a substantial, competing NIH research grant.

Policies that Cover ESIs

- ***Funding appropriate numbers of New and Early Stage Investigators:*** NIH has committed itself to fund R01 grant applications from these investigators at the same rate as it funds new R01 applications submitted by established investigators.
- ***Determining eligibility:*** Applicant information submitted to the Commons system is used to determine ESI status; investigators are encouraged to ensure their profiles are correct and up to date.
- ***Making reasonable exceptions:*** Using a simple on-line system, investigators can request extensions if their careers were interrupted for various reasons, including family needs, further training, military service and others. These requests are considered—usually within 1 to 2 weeks—by the ESI Extension Committee, which includes senior NIH extramural staff and is coordinated by CSR and OER.

Status Report on the Extension Process

- ***Family considerations and clinical training*** are the most common reasons for extension requests.
- ***Seventy-two percent of the 665 requests received in the first year of this effort were granted based on committee consideration.*** An additional 12 percent needed administrative action to correct the individuals profile and establish ESI status. Reasons for denial include pursuing alternate degrees (e.g., an MBA), a prolonged period of childcare, or work in industry.

- *FAQs are constantly evolving* to address questions and clarifications about allowable reasons and the overall process.
- *Future evaluations will assess the extension process*, particularly the impact of extensions on the funding of ESIs.

III. Update: Electronic Submission of Grant Applications

Ms. Megan Columbus, Program Manager for the Electronic Receipt of Grant Applications in the Office of Extramural Research, said the move to electronic submission of applications through Grants.gov is moving ahead. She highlighted recent changes and challenges:

- *Transition to electronic submission has continued*, with career development (K), fellowship (F), and, as of January 25, 2010, training (T&D) applications moving online fairly smoothly.
- *The move to new application forms was more complex than expected*. Language in almost 600 funding opportunities had to match language in the new applications, and new forms had to replace the old ones. Her office spread the word about the new forms through direct e-mail, IC communications, the Enhancing Peer Review Web site, and other means.
- *Large, complex multiproject grant applications are still submitted on paper*. Grants.gov cannot currently handle them electronically. Non-competing forms, such as administrative supplements, also cannot be submitted via Grants.gov. Discussions on how to handle the next generation of grants with Grants.gov staff are underway.

IV. Electronic Research Administration (eRA) and a New Business Model for Receipt and Referral of Grant Applications

Dr. Pete Morton, eRA Program Manager, and Dr. Paul Sheehy, Associate Director for Extramural Activities in the National Institute of General Medical Sciences, discussed eRA re-engineering.

- *The situation*: The IMPAC II system for tracking grant applications and grants is 20 years old and the needs for improvement surpass its limitations.
- *The way forward*: NIH will use new technologies and business processes to evolve the old system into a new one. The new system will be designed to meet the needs of grants management.
- *The first step*: CSR's receipt and referral sections of the new system are being developed first.

The IT Refreshment Strategy

- *Building a new hardware infrastructure*: eRA moved to new servers, which were necessary to handle the influx in ARRA applications in May 2009.
- *Developing a new software infrastructure*: This ongoing effort is focused on upgrading the system's underlying IT applications and data tables.

- ***Taking a business process reengineering (BPR) approach:*** NIH will sequentially examine each business area and provide the support to “refresh” it. By the time all areas of grant management are covered, it will be time to start the cycle again. This process is known as “evergreening.” One important outcome is a less interdependent system, so IT-related problems in one area do not affect others.

BPR Pilot for the Division of Receipt and Referral

- ***Receipt and referral areas targeted first:*** The division’s work comes at the beginning of the grants management process and is somewhat self-contained.
- ***Six BPR processing steps identified:*** validating the current business process models, establishing metrics, identifying areas of challenge, performing root cause analysis on these areas, reviewing potential solutions, and developing a new business process model.
- ***Significant improvements identified*** by focusing on the 20 percent of applications that cannot be processed within one day.
- ***Many IT-mediated changes were identified,*** including immediate-, medium-, and long-term changes

Future Directions for Evergreening eRA

- ***Move on to the review module,*** which will be more complicated and involve more parts of NIH.
- ***Recruit for governance and subject matter experts*** to contribute to the effort.
- ***Ensure any potential changes have broad review*** by trans-NIH senior staff and functional areas.

Discussion Highlights

- ***What is the trigger to these changes, besides that the system needs updating?*** Dr. Landis said the Extramural Activities Working Group, which she and Dr. Rockey co-chair, had to decide whether to start with a new system or use this stepwise approach, and chose the latter. Dr. Rockey said that making the modules more independent is a primary goal: when one part of the system now has a problem, the whole system has to be shut down to fix it. The larger goal is to support the business processes of NIH, internally and externally.
- ***What is PRAC’s role?*** Staff asked PRAC to weigh in if members think this is the correct approach. A Commons working group of grantee institution representatives regularly meets and has made valuable contributions.

V. Evaluation of Peer Review Initiatives

Dr. Andrea Kopstein, Director of CSR’s Office of Planning, Analysis and Evaluation, presented results of evaluations related to ARRA grant application reviews, pilots on the order of review and clustering during study section meetings, and the review of Transformative R01 grant applications.

American Recovery & Reinvestment Act

Both CSR and the ICs saw huge increases in applications and reviewers needed in June 2009 compared to June 2008, in part because of ARRA funding. CSR was responsible for reviewing ARRA Challenge grant applications, which involved a two-stage review process and a 12-page application. Dr. Kopstein sent evaluations to the more than 14,000 reviewers involved, with a response rate of about 52 percent: about 6,500 mail reviewers and 1,100 in-person reviewers.

Key Findings

- ***The distribution of reviewers' institutions was about the same for mail and in-person reviewers***, dispelling the perception that the composition differs between the two groups. More than 70 percent of both groups work at universities, followed by hospitals and medical centers.
- ***Academic rank and seniority were about the same*** among different reviewer groups—by-mail ARRA reviewers, in-person ARRA reviewers, and non-ARRA reviewers. In-person reviewers were somewhat more likely to be senior-level (full professor).
- ***A majority of reviewers felt the 12-page application contained enough information*** for them to thoroughly assess all five core review criteria.
- ***A majority of reviewers found the shorter application was less or somewhat less of a burden to review.***
- ***A majority of reviewers liked the 1–9 scoring scale***, although some expressed concern about whether applicants would understand the reviews as presented in bulleted form.

Order of Review/Clustering Pilot

As discussed earlier, CSR conducted a pilot to evaluate the practice of reviewing grant applications based on their preliminary impact scores (“best to worst”) and also grouped “like” applications together for discussion, such as clinical applications and New/Early Stage Investigator R01 applications. Dr. Kopstein invited 663 reviewers and 29 SROs to provide feedback about their experience; 63 percent of reviewers and 86 percent of SROs responded.

Key Findings

- ***A majority of both reviewers and SROs were satisfied with reviewing applications in preliminary score order***, with an additional 22 percent neutral and only 14.5 percent unsatisfied.
- ***A majority of reviewers and SROs were somewhat or very satisfied with clustering of applications***, with about 11 percent somewhat or very unsatisfied.
- ***A majority of reviewers and SROs felt that clustering was fair to new investigators and ESIs***, because the method helped focus reviewer attention on these groups.

Transformative R01

The Transformative R01 Initiative used a three-stage review process: The first and third stages involved a group of 11 esteemed investigators with broad perspectives. In the second stage, mail

reviewers provided critiques on specific aspects of the applications. Dr. Kopstein sent surveys to 700 applicants (with 62 percent responding) and to the 11 “generalist” reviewers (63 percent responding).

Key Findings: Applicants

- ***Ethnic, gender, and age breakdowns*** indicated a large majority were Caucasian and non-Hispanic, were men, and were aged 35 to 65.
- ***Almost all had received previous NIH funding***, indicating they were not new to the NIH system.
- ***When asked about their proposals***, 80 percent said the concepts significantly departed from their usual research, with molecular, cellular, and chemical biologists, and clinical/translational research as the two most commonly occurring categories.
- ***Most said it was very or somewhat unlikely they would receive funding from other sources*** for these projects.

Key Findings: Reviewers

- ***First/third-stage reviewers found the second stage reviewers helped***: They felt these mail reviewers always or often had the appropriate technical expertise to review the proposals.
- ***Both sets of reviewers felt that the applicant pool was strong***: They felt 50 percent of the applicants understood the project goals and 25 percent were capable of carrying out the transformative research they proposed.

Discussion Highlights

- ***What is the gender breakdown of the 42 applicants who received Transformative R01 grants?*** CSR staff will provide PRAC with the gender breakdown for recipients of Transformative R01 grants.
- ***Can you evaluate what happened when applicants received a poor score but without significant weaknesses identified?*** The next cycle of ARRA might afford this opportunity. Drs. Kitt and Landis also said various NIH groups, including the Peer Review Oversight Committee, are looking at how to address potential discrepancies between scores and the strengths or weaknesses identified.
- ***The three-stage process for the Transformative R01s worked well.*** A PRAC member who served as a reviewer noted it was not a major reviewing burden and was fair. Other PRAC members said the process suggests the need to involve reviewers beyond the two assigned to review initial submissions, perhaps by providing abstracts to the whole group.
- ***In discussing applications by preliminary scores, what happens when the two scores greatly diverge?*** Dr. Kopstein explained the rank order discussion is based on an average, even when the two scores greatly diverge. Several PRAC members suggested that CSR examine the discussions that take place when reviewers discuss applications with very disparate scores.

VI. Update on CSR Realignment

Dr. Don Schneider, Director of the Division of Basic and Integrative Biological Sciences, reported on recent efforts to align study sections to stay current with science. He noted study sections can become too large or too small over time.

Basic Oncology and Bioengineering IRGs

Dr. Schneider summarized the background about proposed realignments and the process that resulted in the proposed changes he presented:

- ***Within the Oncology 1 – Basic Translational IRG:*** Move applications related to telomeres and epigenomics from the Cancer Molecular Pathology to the Cancer Genetics study sections, and move some epigenomics applications from Cancer Etiology to Cancer Genetics.
- ***Within the Bioengineering IRG:*** Options are to allow the presently low-volume Microscopic Imaging and Spectroscopy study section more time for growth or merge it with the Enabling Bioanalytical and Biophysical Technologies study section, which would then move to the Interdisciplinary Molecular Sciences and Training IRG.

PRAC members agreed with the Oncology recommendation. As to Bioengineering, members saw the value of maintaining a home for basic imaging and appreciated that the Microscopic Imaging and Spectroscopy is too small. They suggested that CSR go back to the working group for discussion of a merger solution.

Vascular and Hematology IRG

Dr. Joy Gibson, Director of the Division of Translational and Clinical Sciences, summarized the background for the proposed realignments in this IRG and the process that resulted in the proposed changes she presented:

- ***Merge the rosters of Erythrocyte and Leukocyte (ELB) and Hematopoiesis (HP) study sections,*** ensuring a strong chair and study section members with appreciation of both communities. This move is needed due to the continuous decline in the number of applications received for review in the ELB Study Section.
- ***Convene the new Molecular and Cellular Hematology Study Section in June 2010*** with submission of the first nomination slate of members in 2011.

PRAC members agreed with these changes, noting that leukemias and stem cell-related research might increase in the future.

Healthcare Delivery and Methodologies IRG

Dr. Kate Bent, Chief of the Healthcare Delivery and Methodologies IRG, summarized the background about proposed realignments and the process that resulted in the proposed changes she presented:

- **Create three new study sections:** Clinical and Research Ethics, Health Disparities and Equity Promotion, and Dissemination and Implementation Research in Health. These new study sections will relieve pressures on study sections that have grown too large: Nursing Science: Adults and Older Adults; Community-Level Health Promotion; Health Services Organization and Delivery; and Community Influences on Health Behavior. In addition, the new study sections will address emerging high-priority science areas and will provide long-term opportunities to consolidate similar science in special emphasis panels in other IRGs.
- **Create a new Nursing and Related Clinical Science study section:** This group would merge two Nursing Science study sections currently split by age of subjects. The size of the study section would be monitored for future growth and possible division, which would occur along conceptual, rather than age, lines.
- **Monitor Biomedical Computing and Healthcare Informatics and Biostatistics Methods and Research Design:** These study sections had been shrinking but saw a recent spike in applications; thus, she presented no recommended changes at present.

PRAC agreed with this approach. Dr. Scarpa also recognized Dr. Bent and her IRG for their work on the Challenge Grants. This one IRG reviewed 12 percent of the 20,000 applications.

VII. Comparison of Preliminary and Final Score in Grant Applications

Dr. Michael Martin, Senior Scientific Advisor to the CSR Director, reported on an analysis that compared preliminary and final priority scores of R01s in standing study sections.

Scope of the Analysis

- **Applications reviewed in the fall 2008** before the new 1 to 9 scoring scale and other subsequent changes.
- **172 randomly selected study sections** that reviewed 7,503 R01 applications in this period.
- **1,395 applications** of the 7,503 R01 applications reviewed were used in this study.
- **Reviewer load averaged 7.2 applications**, with 80 percent reviewing six or more applications.

Findings

- **Impact of study section discussions on final scores was statistically significant.** Changes from average preliminary to final priority scores varied: 45 percent had better scores than average pre-meeting score, 51 percent had worse scores, and only 4 percent had no change.
- **Most final scores fell within the range of the preliminary scores given by the individual assigned reviewers, but 19 percent did not:** Just over 80.2 percent of final scores were within the preliminary scores, but 7.3 percent fared better than any preliminary score, and 12.5 percent fared worse.

- ***Even small differences in scores could correspond to large differences in scoring percentiles:*** For example, a 1.45 score approximates the 12 percentile, while a 1.60 approximates the 19th percentile.
- ***Preliminary scores are useful as a reference for the start of the discussion:*** however, they do not dictate a specific final outcome of the study section.

Discussion Highlights

- ***How did applications fare when the assigned reviewers had very different preliminary scores?*** Dr. Martin will mine the data to see what can be learned.
- ***Did this analysis take place for discussions organized by preliminary score?*** They did not. Dr. Martin suggested undertaking an analysis when the new voting system has stabilized.
- ***What is the effect of the interplay among reviewers on a final score?*** Interpreting the reactions of other reviewers may affect scores. The preliminary scores used in this study were the independent evaluations of the individual reviewers before any interaction. Dr. Martin suggested one way to address this issue is to compare score changes in Internet-assisted versus face-to-face meetings. However, the number of R01s reviewed by Internet-assisted methods in the October 2008 reviews were too small to provide a useful analysis.

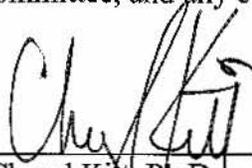
VIII. General Discussion/Future Agenda Items

Dr. Kitt opened the meeting to any final comments or questions from PRAC.

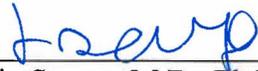
- ***What is the effect of flexible service periods for reviewers on Council member nominations?*** Dr. Scarpa said the Enhancing Peer Review working groups, as well as other outside stakeholders strongly recommended this change. Dr. Landis observed that reviewers invited to serve on a Council tend to leave study sections, especially if they have served on a study section for a while.
- ***Can program directors serve as reviewers?*** Dr. Rockey clarified the policy: NIH Intramural researchers may serve on peer review panels as long as the panel does not fall within their Institute. Extramural employees cannot.

With no further comments or questions, the meeting adjourned at 2:16 p.m.

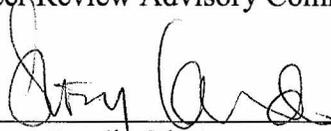
We do hereby certify that, to the best of our knowledge, the foregoing minutes of the February 1, 2010, meeting of PRAC are accurate and complete. The minutes will be considered at the next meeting of the Advisory Committee, and any corrections or comments will be made at that time.



 Cheryl Kitt, Ph.D.
 Executive Secretary
 Peer Review Advisory Committee



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