Department of Health and Human Services
National Institutes of Health (NIH)
Office of the Director (OD)
Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI)

Council of Councils Meeting
August 17, 2010
Via Teleconference

Meeting Minutes of Open Session*

I. WELCOME

Lawrence Tabak, D.D.S., Ph.D., Council of Councils (CoC) Chair, and Acting Director, DPCPSI, opened the teleconference shortly after 11:00 a.m. and welcomed participants, NIH staff members, and members of the public to the sixth meeting of the Council of Councils (CoC). He said that the purpose of the meeting was to have a discussion about the Roadmap Transformative R01 Program (TR01) and the review process that was established to handle the large number of applications received. Following the open session, the CoC would reconvene in closed session to conduct a second-level review of grant applications submitted in response to RFA RM-09-022, "Roadmap Transformative R01 Program."

A. Attendance

1) Council Members Present

Chair: LAWRENCE A. TABAK, D.D.S., Ph.D., Acting Director, DPCPSI, OD, NIH
Executive Secretary: ROBIN I. KAWAZOE, DPCPSI, OD, NIH
RONALD L. ARENSON, M.D., University of California, San Francisco
STEPHEN L. BARNES, Ph.D., University of Alabama at Birmingham, Birmingham, Alabama
ENRIQUETA C. BOND, Ph.D., Burroughs-Wellcome Fund, Marshall, Virginia
DONNA BATES BOUCHER, Bates Group, Inc., Denver, Colorado
DAVID W. CRABB, M.D., Indiana University School of Medicine, Indianapolis, Indiana
CECILE A. FELDMAN, D.M.D., M.B.A., University of Medicine and Dentistry of New Jersey, Newark, New Jersey
EDWIN FLORES, Ph.D., J.D., Chalker Flores, LLP, Dallas, Texas
DANIEL H. GESCHWIND, M.D., Ph.D., University of California, Los Angeles
MAE O. GORDON, Ph.D., Washington University School of Medicine, St. Louis, Missouri
JOSEPH H. GRAZIANO, PH.D., Columbia University, New York, New York
MARY J.C. HENDRIX, Ph.D., Northwestern University Feinberg School of Medicine Chicago, Illinois
ARTHUR M. KLEINMAN, M.D., M.A., Harvard University Medical School, Cambridge, Massachusetts

*The Council also conducted business in closed session.

JOSEPH LOSCALZO, M.D., Ph.D., Harvard University Medical School, Cambridge, Massachusetts
JEAN MCSWEENEY, Ph.D., R.N., F.A.H.A., F.A.A.N., University of Arkansas Medical Science College of Nursing, Little Rock, Arkansas
ORIEN REID, M.S.W., Consumer Connection, Laverock, Pennsylvania
MARTIN ROSENBERG, Ph.D., Promega Corporation, Madison, Wisconsin
DAVID VALLE, M.D. Johns Hopkins University School of Medicine, Institute of Genetic Medicine, Baltimore, Maryland
JOHN WALSH, Alpha-1 Foundation, Miami, Florida
GARY L. WESTBROOK, M.D., Oregon Health and Science University, Portland, Oregon
LUTHER WILLIAMS, Ph.D., Tuskegee University, Tuskegee, Alabama
MARINA E. WOLF, Ph.D. Rosalind Franklin University of Medicine and Science, North Chicago, Illinois

2) Council Members Absent
ELIZABETH B. CONCORDIA, M.A.S., University of Pittsburgh Medical Center, Pittsburgh, Pennsylvania
CECILE A. FELDMAN, D.M.D., M.B.A., University of Medicine and Dentistry of New Jersey, Newark, New Jersey
EDWIN FLORES, Ph.D., J.D**.,** Chalker Flores, LLP, Dallas, Texas
BEVRA H. HAHN, M.D., University of California, Los Angeles
JUANITA L. MERCHANT, M.D., Ph.D., University of Michigan, Ann Arbor
DARIA MOCHLY-ROSEN, Ph.D. Stanford University School of Medicine, Palo Alto, California
RICHARD A. RUDICK, M.D., Cleveland Clinic Foundation, Cleveland, Ohio

3) Presenters in Attendance
ELIZABETH L. WILDER, Ph.D., DPCPSI
JOHN BOWERS, Ph.D., Center for Scientific Review

4) NIH Staff and Guests
In addition to Council members and presenters, others in attendance included NIH staff and interested members of the public.

B. Introductions and Plans for the Meeting

Robin I. Kawazoe, Executive Secretary, CoC, took a roll call, and reviewed the following:

- Each Council participant has completed and submitted a conflict of interest statement as a Federal requirement for membership on individual IC advisory councils.
- CoC members should not speak on behalf of the Council.
- The public is invited to submit comments after the meeting.
- A meeting summary will be posted on the DPCPSI website (http://dpcpsi.nih.gov).

II. DISCUSSION OF ROADMAP TRANSFORMATIVE RO1 PROGRAM

Elizabeth L. Wilder, Ph.D., DPCPSI, described the Roadmap Transformative Research Projects Program (T-R01). The program was specifically created in 2008 under the NIH Roadmap for Medical Research to support innovative, high-risk, original research projects that have the potential to transform fundamental paradigms. Awards were first made in 2009. The T-R01 is part of the High-Risk, High-Reward Programs in the NIH Common Fund. In comparison to the NIH Director's Pioneer and New Innovator Programs, the primary emphasis of the Roadmap Transformative Research Projects Program is on *creative ideas*—projects of any size with the potential to transform a field of science and to provide adequate support for the work—rather than on *creative individuals* who have already proven to be innovative researchers. The program also lacks a budget cap and has flexibility for investigators to assemble groups and conduct any type of research. Projects can be as large as needed to accomplish the scientific goals. The average requested budget this year is slightly greater than that of last year. In both years, about two-thirds of the submitted applications have a first year, direct cost request of less than $500,000; however, this year there were some requests of more than $1 million.

The RFA issued in the first year of the program articulated and highlighted research needs based on wide-scale community input. However, feedback following that cycle revealed that some potential applicants working outside these areas did not apply because of the perceived targeting of certain areas of interest. Dr. Wilder said that this year's RFA did not include highlighted areas; the program was open to any area of science in the NIH mission. She said that the applicants in both years have been strongly biased toward basic science, despite the focus of the program across the spectrum from basic to translational to clinical research. For FY 2011, program staff has tried to strengthen language in the RFA to encourage translational and clinical applications. Dr. Wilder recognized Dr. Kristin Abraham, from NIDDK, who volunteers her time to work with DPCPSI on this program.

Discussion Highlights:

- There was frustration among applicants after the 2009 grants cycle about not receiving information about why some applications did not move from the first stage of the initial review process (review by the editorial board) to the second stage (mail reviews from outside experts). Discussion on that issue was deferred to follow Dr. John Bower's presentation on the review process.

III. DISCUSSION OF REVIEW PROCESS

Dr. John Bowers, Center for Scientific Review, described the three-stage review process for the 557 compliant applications received. In the first stage, a 12-member editorial board reviewed the applications to determine which should be discussed. Five editors were assigned to each application and asked to provide a preliminary score and the arguments used to determine that score. After this stage, the field was narrowed from 557 applications to 76, which were then sent forward for second-level review.

In the second stage, three subject matter experts conducted a mail review for each application. They did not provide scores, just their impressions, as the program does not want reviewers to

treat these applications like traditional RO1s. These reviews then went back to the editorial board for final review.

In the third stage of review, the editors convened for one day to discuss all applications (76) and make funding recommendations. Following the review, applicants who made it to the final review round received a summary statement which included a priority score, a resume of the editorial board's discussion of that application, and the mail reviews. Those that did not make it to the second stage of review received a summary statement which included only a statement that the application failed to proceed to the second stage, along with a description of the review process.

Discussion Highlights:

- The model used to review these relies on a small group of reviewers. The only way to manage this system is to not require each reviewer to write critiques for an unreasonably large number of applications, which is why everyone does not receive comprehensive feedback. Although preliminary scores are available for all applicants, NIH as a practice does not release preliminary scores.

- NIH should review the reviewers—that is, review the nondiscussed applications to see if there is a reviewer bias against particular fields, e.g., behavioral and social sciences. The review process was assessed post-hoc to determine whether there bias against human subjects research and none was found. A similar process could be conducted to assess other potential areas of bias.

- The RFP was clearly written.

- NIH should review the correlation between initial scores and final scores to assess how well the triage process (first stage of the initial review) is working.

- There was a wide distribution in scores, raising the question of whether the triage process allowed weak applications into the final stage of reviews. However, it was explained that reviewers were instructed to use the entire range of scores and the scores are relative to each other, not the entire cohort.

IV. NEXT STEPS AND CLOSING REMARKS

Dr. Tabak closed the open meeting by thank those who participated in the session. At that point, the open session was adjourned, and the closed session convened. He again encouraged all public comments per the notice that appeared in the Federal Register notice of July 21, 2010.

V. CERTIFICATION

I hereby certify that, to the best of my knowledge, the foregoing summary minutes are accurate and complete.

Robin I. Kawazoe
Executive Secretary, NIH Council of Councils
Deputy Director, Division of Program Coordination,
Planning, and Strategic Initiatives
Office of the Director
National Institutes of Health