**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 Teleconference**
**August 15, 2013**

**Meeting Minutes**

## I. WELCOME

James M. Anderson, M.D., Ph.D., Chair, welcomed participants, NIH staff members, and members of the public to the open conference call of the Council of Councils. The call opened at 1:00 p.m. on Thursday, August 15, 2013.

### A. Attendance

#### 1) Council Members Present

Chair: JAMES M. ANDERSON, M.D., PH.D., Director, DPCPSI, OD, NIH
Executive Secretary: ROBIN I. KAWAZOE, DPCPSI, OD, NIH
EMERY N. BROWN, M.D., PH.D., Massachusetts Institute of Technology, Harvard Medical School, Massachusetts General Hospital, Cambridge, MA
LAVARNE A. BURTON, M.A., American Kidney Fund, Rockville, MD
CARLOS D. BUSTAMANTE, PH.D., Stanford University School of Medicine, Stanford, CA
F. XAVIER CASTELLANOS, M.D., New York University of School of Medicine, New York, NY
JANICE E. CLEMENTS, PH.D., The Johns Hopkins University School of Medicine, Baltimore, MD
STEVEN T. DEKOSKY, M.D., University of Virginia, Charlottesville, VA
RICHARD L. EHMAN, M.D., Mayo Clinic College of Medicine, Rochester, MN
RICHARD M. GREENWALD, PH.D., Simbex, iWalk, Thayer School of Engineering, Lebanon, NH
NANCY L. HAIGWOOD, PH.D., Oregon Health & Science University, Beaverton, OR
PETER J. HOTEZ, M.D., PH.D., Baylor College of Medicine, Houston, TX
JEFFREY A. KAUFMAN, M.B.A., Adenoid Cystic Carcinoma Research Foundation, Needham, MA
MARK O. LIVELY, PH.D., Wake Forest University School of Medicine, Winston-Salem, NC
K.C. KENT LLOYD, D.V.M., PH.D., University of California, Davis, Davis, CA
JOYCE A. MITCHELL, PH.D., F.A.C.M.G., F.A.C.M.I, University of Utah, Salt Lake City, UT
REGINA RABINOVICH, M.D., M.P.H., Global Health Consultant, Seattle, WA
JAMES E. SCHWOB, M.D., PH.D., Tufts University School of Medicine, Boston, MA

GILBERT C. WHITE, II, M.D., Blood Research Institute, BloodCenter of Wisconsin, Milwaukee, WI

**2) Council Members Absent**

JACK A. ELIAS, M.D., Yale University School of Medicine, New Haven, CT
SUSAN F. GOEKLER, PH.D., M.C.H.E.S., Directors of Health Promotion and Education, Washington, DC
BARBARA J. GUTHRIE, R.N., PH.D., F.A.A.N., Yale University, New Haven, CT
GRACE LEMASTERS, PH.D., University of Cincinnati College of Medicine, Cincinnati, OH
H. KIM LYERLY, M.D., Duke University School of Medicine, Durham, NC
CRAIG J. MCCLAIN, M.D., University of Louisville School of Medicine, Louisville, KY
ROBERT F. MURPHY, PH.D., Carnegie Mellon University, Pittsburgh, PA
REGIS J. O'KEEFE, M.D., PH.D., University of Rochester Medical Center, Rochester, NY
TERRIE FOX WETLE, PH.D., Brown University Medical School, Providence, RI

**3) NIH Staff and Guests**

In addition to Council members and Directors, others in attendance included NIH staff and interested members of the public.

**B. Meeting Procedures**

- Following introductions and the following announcements from Robin I. Kawazoe, Executive Secretary for the Councils of Councils, Dr. Anderson reviewed the day's agenda.

- Ms. Kawazoe reminded Council members that the open session of the call was being recorded and that members of the public might be present. She also acknowledged public comments that had been received and invited members of the public to submit any other comments to her in writing; instructions are available on the DPCPSI Web site and in the *Federal Register.*

- Ms. Kawazoe noted that Council members had signed financial disclosure forms and conflict-of-interest statements as a Federal requirement on advisory councils, and she reminded the Council not to speak individually on the Council's behalf or on activities not yet cleared by the Council. The approved meeting minutes will be posted on the DPCPSI Web site.

## II. ESTABLISHMENT OF THE CHIMPANZEE RESEARCH USE PANEL

Dr. Anderson referred the members and public attendees to the document entitled "Establishment of Chimpanzee Research Use Panel and Discussion," which was posted on the DPCPSI web site prior to this meeting. He reminded all attendees that in January

of this year the Council had provided to Dr. Francis Collins, NIH Director, recommendations regarding the use of chimpanzees in NIH-supported research. The recommendations were developed in response to a report by the Institute of Medicine (IOM) and the subsequent review by a Council working group. Following submission of the Council's recommendations to the NIH, in January 2013 the NIH dissolved the Working Group on the Use of Chimpanzees in NIH-Supported Research and issued a Request for Information from the public, which yielded over 12,500 responses. Based on all input, Dr. Collins reviewed and accepted all but one of the Council's recommendations in June 2013.

Among the recommendations was the suggestion that NIH establish a review process, independent of standard peer review, to address whether applications proposing to use chimpanzees in research comply with IOM principles and criteria. In response, DPCPSI proposes the establishment of a Chimpanzee Research Use Panel (CRUP) –a Working Group of the Council of Councils – to serve in an advisory role and, specifically, to review whether proposals for grants, contracts, or intramural projects that intend to use chimpanzees adhere to the principles and criteria outlined by IOM. The proposed CRUP will provide its recommendations to the Council of Councils, which will deliberate and provide final recommendations to the Institute or Center (IC) Director deciding on the research proposal.

**Composition of the Chimpanzee Research Use Panel**

The CRUP members will bring scientific, biomedical, and behavioral expertise and include scientific experts, veterinarians with experience in the care of chimpanzees and other non-human primates, primatologists, bioethicists or individuals with experience in bioethics, statisticians, and public representatives. *Ad hoc* members can be appointed during each review cycle, depending on the specific scientific areas requiring review. The CRUP will replace the Interagency Animal Models Committee's role in this area and will be independent. Therefore, no Federal members will be part of the Panel. However, NIH officials will be available to advise on process, information, and logistics.

**Requirement for Supplemental Information**

Unless the proposed research is exempt, as defined by the Council and by IOM principles and criteria, investigators proposing to use chimpanzees in research will be required to complete a form and provide supplemental information specifically addressing these principles. Exempt research includes projects that involve no contact with chimpanzees, including observational or non-interventional studies, studies using samples, or studies involving noninvasive sample collection (hair, feces).

**Review Process**

The CRUP review will be separate from the standard NIH peer-review process, and it will focus specifically on the IOM principles and criteria for the use of chimpanzees in research. Thus evaluation will be based on the supplemental information provided by applicants. All proposals for NIH grants, contracts, or intramural projects, as well as

third-party use of NIH-owned chimpanzees, will undergo CRUP review following the standard first and second level reviews.

It is anticipated that CRUP will meet three times a year, following the IC Advisory Council meetings, and provide its recommendations for consideration at the Council of Councils meetings. Thus CRUP will review only applications that the IC Advisory Councils have recommended for funding.

**Discussion Highlights**

- This is a new process and will likely be a work-in-progress for the first year.

- The NIH Office for Laboratory Animal Welfare (OLAW) will determine whether proposals are exempt from CRUP review.

- Public representatives on CRUP must be able to assess adherence to IOM principles and criteria without bias. Thus DPCPSI proposes that such representatives be drawn from the NIH Council of Public Representatives. This council comprises individuals who are recognized for their public work and have already been vetted for conflicts of interest.

- Any use of NIH support for chimpanzee research, as well as any use of NIH-owned chimpanzees, will be reviewed by CRUP.

- Each review cycle, working with OLAW and the Center for Scientific Review (CSR), DPCPSI will identify and track applications that might come forward for CRUP review. The Panel will meet following the last IC Advisory Council that has an application involving chimpanzees.

- CSR has agreed to establish a process to remind peer reviewers that their responsibilities do not include a review of whether an application adheres to IOM principles. The CRUP review will remain separate and independent from the first and second level reviews.

- CRUP recommendations for approval will require a majority "yes" or "no" vote. The Panel and its Co-Chairs will have to determine how to proceed for applications for which the Panel is clearly divided.

- The CRUP will simply provide recommendations to the Council, which in turn will provide recommendations to IC Directors. Final funding decisions lie with the IC Director.

- This additional review will add a lot of time to the overall review process, which can affect when investigators can resubmit.

**Motion to Establish CRUP**

A motion to establish the Chimpanzee Research Use Panel was forwarded and seconded. The motion passed unanimously.

## III. NIH DIRECTOR'S EARLY INDEPENDENCE AWARDS OVERVIEW

Dr. Elizabeth Wilder provided an overview of the NIH Director's Early Independence Awards program (EIA), which was developed in 2010 to address concerns about the older age—on average, 42 years—at which investigators secure their first faculty appointments and R01s. Although NIH continues to view postdoctoral training as important, it has implemented EIA with the idea that a small pool of exceptional researchers will be ready to embark upon their careers immediately after the end of their terminal research degrees or clinical residencies. For this small group of clearly stellar researchers, a postdoctoral period might actually impede their careers.

Candidates for EIA must apply 1 year before or after they complete their terminal research degree or clinical residency. Host institutions can submit no more than two applications in response to an EIA solicitation. Review and selection emphasize the quality of the applicant, his or her research vision, and the amount of support (including protected time) provided by the host institution for the candidate to establish a project and research program. Review follows a two-step model, in which mail-reviewers assess the scientific and technical aspects of the proposal and an editorial board assesses the exceptionality of the applicant, the resources and support provided by the host institution, and the potential for the project to grow into a sustained research program with a substantial impact on the field. Following selection by the editorial board, finalists meet with the editorial board, make presentations, and undergo interviews.

Dr. Wilder noted that of 84 compliant applications from 65 different institutions, 31 have been recommended for funding. The Council will provide a second-level review in which it assesses the appropriateness of the initial review process. The Common Fund expects to award $4 million in total costs, and the Common Fund High-Risk-High-Reward Working Group will serve as a resource in developing a funding plan for each proposal, to be approved by Dr. Anderson and the IC Director.

## IV. REVIEW OF GRANT APPLICATIONS

This portion of the meeting was closed to the public, in accordance with the provisions set forth in Sections 552(b)(c)(4) and 552(b)(c)(6), Title 5, U.S. Code and Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix).[1] Members were instructed to exit the call if they deemed that their participation in the deliberation of any matter before the Council would represent a real or perceived conflict of interest. Members were asked to sign a conflict-of-interest/confidentiality certification to this effect. The *en bloc* vote for concurrence with the initial review recommendations was

[1] For the record, it is noted that members absented themselves from the meeting when the Council discussed applications (a) from their respective institutions or (b) in which a conflict of interest may have occurred. This procedure applied only to applications that were discussed individually, not to "en bloc" actions.

affirmed by all Council members present. During the closed session, the Council concurred with the review of 84 Common Fund applications with total direct costs of $20,460,363.

## V. ADJOURNMENT

Dr. Anderson adjourned the open session of the conference call at 1:42 p.m.

## VI. CERTIFICATION

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

James M. Anderson, M.D., Ph.D. — Date: 9-8-13
Chair, NIH Council of Councils
Director, Division of Program Coordination,
Planning, and Strategic Initiatives (DPCPSI)
Office of the Director
National Institutes of Health

Robin I. Kawazoe — Date: 9/6/2013
Executive Secretary, NIH Council of Councils
Deputy Director, DPCPSI
OD, NIH