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 15, 2011
Via Teleconference

Meeting Minutes

I. WELCOME

James M. Anderson, M.D., Ph.D., Director DPCPSI, Chair, Council of Councils, opened the teleconference at 1:00 pm and welcomed all participants, NIH staff, and members of the public to the council meeting. The open session of the meeting was convened to address three items: concept clearance of the proposed initiates of the National Center for Regenerative Medicine (CRM), the followup discussion to the concept clearance of H3Africa proposed initiatives, and a discussion of the NIH Director's Early Independence Award program and review process.

A. Attendance

1) Council Members Present

Chair: JAMES M. ANDERSON, M.D., Ph.D., Director, DPCPSI, OD, NIH
Executive Secretary: ROBIN KAWAZOE, Deputy Director, DPCPSI, OD, NIH
STEPHEN L. BARNES, PH.D., University of Alabama at Birmingham
DONNA BATES BOUCHER, Bates Group, Inc. Denver, CO
JORDAN COHEN, M.D., The George Washington University, Washington, DC
ELIZABETH B. CONCORDIA, M.A.S., University of Pittsburgh Medical Center, Pittsburgh, PA
DAVID W. CRABB, M.D., Indiana University School of Medicine, Indianapolis, IN
CECILE A. FELDMAN, D.M.D., M.B.A., University of Medicine and Dentistry of New Jersey, Newark, NJ
GARRET A. FITZGERALD, M.D., University of Pennsylvania, Philadelphia, PA
DANIEL H. GERSCHWIND, M.D., PH.D., David Geffen School of Medicine, University of California, Los Angeles, CA
JOSEPH H. GRAZIANO, PH.D., Columbia University, New York, NY
PETER J. HOTEZ, M.D., PH.D., Baylor College of Medicine, Houston, TX
MARK O. LIVELY, PH.D., Wake Forest University School of Medicine, Winston-Salem, NC
JEAN MCSWEENEY, PH.D., R.N., F.A.H.A., F.A.A.N., University of Arkansas Medical Sciences, Little Rock, AR
REGIS O'KEEFE, M.D., PH.D., University of Rochester School of Medicine and Dentistry, Rochester, NY
REGINA RABINOVICH, M.D., Bill & Melinda Gates Foundation, Seattle, WA
DAVID VALLE, M.D., Johns Hopkins University School of Medicine, Baltimore, MD

JOHN W. WALSH, Alpha-1 Foundation, Miami, FL
GARY L. WESTBROOK, M.D., Oregon Health and Science University, Portland, OR
TERRIE FOX WETLE, PH.D., Brown University Medical School, Providence, RI
LUTHER WILLIAMS, PH.D., Tuskegee University, Tuskegee, AL
MARINA E. WOLF, PH.D., Rosalind Franklin University of Medicine and Science, North Chicago, IL

2) Council Members Absent

ENRIQUETA C. BOND, PH.D., Burroughs-Wellcome Fund, Research Triangle Park, NC
RICHARD L. EHMAN, M.D., Mayo Clinic College of Medicine, Rochester, MN
JACK A. ELIAS, M.D., Yale University School of Medicine, New Haven, CT
EDWIN FLORES, PH.D., J.D., Chalker Flores, LLP, Dallas, TX
MAE O. GORDON, PH.D., Washington University School of Medicine, St. Louis, MO
HERBERT KIM LYERLY, M.D., Duke University Medical Center, Durham, NC
JUANITA L. MERCHANT, M.D., PH.D., University of Michigan, Ann Arbor, MI

3) Ad Hoc Representatives

ELIZABETH L. WILDER, PH.D., Director, Office of Strategic Coordination, DPCPSI, OD

4) Presenters in Attendance

STORY LANDIS, PH.D., Director, National Institute of Neurological Disorders and Stroke
MARK GUYER, PH.D., Director, Division of Extramural Research, National Human Genome Research Institute and Co-Chair, Common Fund H3Africa Working Group
ELIZABETH L. WILDER, PH.D., Director, Office of Strategic Coordination, DPCPSI, OD

5) 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 Announcements

Robin Kawazoe, Executive Secretary of the Council, completed a roll call, and reviewed the following topics:

Each Council member has completed and submitted a conflict of interest statement as part of the Federal requirement for membership on individual IC advisory councils.

A summary of both the June 29, 2011, and this meeting will be posted on the DPCPSI website at http://dpcpsi.nih.gov.

Members of the public are free to submit comments after the meeting through the website.

II. CONCEPT CLEARANCE: NATIONAL CENTER FOR REGENERATIVE MEDICINE - PROPOSED INITIATIVES

Story Landis, Ph.D., Director, National Institute of Neurological Disorders and Stroke, stated that the study and development of stem cell technology was set as a priority by Dr. Francis Collins shortly after his appointment as the Director of the NIH. Stem cell technology, including the development of induced pluripotent (iPS) stem cells, holds the potential to transform medicine and the treatment of patients. In January 2010, a workshop was convened to explore potential avenues that utilize the unique resources of the NIH to develop iPS stem cell technology and enable further progress. This meeting led to the development of the National Center for Regenerative Medicine (CRM).

The mission of the CRM is to establish a 'hub of excellence' within the NIH for the development and use of iPS cells in the new therapeutic strategies and the treatment of patients. By leveraging the significant resources of the NIH, including the NIH Clinical Center and the National Chemical Genomics Center (NCGC) high throughput (HT) screening facility, the CRM can coordinate resources to facilitate collaborative projects that involve both intramural and extramural investigators to conduct transformative stem cell research.

Under the guidance of the new director, Dr. Mahendra Rao, the CRM proposes to develop resources for stem cell research, including establishing cell lines and a repository to store and distribute cells, developing controls and standards, addressing procedural and policy issues including coordination with other agencies such as the Food and Drug Administration (FDA), and establishing intramural and extramural collaborative efforts. Efforts towards these goals began in FY11 when a director was selected and seed money for pilot intramural programs was provided. In FY12, focus will be applied to the generation of iPS cells and in determining which genotypes will be selected for the development of iPS cells. During this time, proposals for innovative investigator-initiated, collaborative projects will be solicited. The development of community standards and banking of iPS cells will be established in FY13. During FY14-16, policy issues will be addressed, production and distribution of GMP-grade iPS cells will be increased, and collaborative projects will be established.

Through extensive collaborative efforts between NIH-centered resources including the NIH Clinical Center and the NCGC HT center, intramural and extramural investigators, outside agencies such as the FDA, and the scientific community at large, the CRM can provide exceptional resources to develop and implement the clinical use of iPS stem cell technology. This holds the potential to produce transformative results in the treatment of disease. After this funding period is complete, individual ICs may fund these projects.

Discussion Highlights:

CRM and the new director may not wish to wait until FY13 to establish community standards.

The CRM will build a resource that benefits both the NIH and the greater scientific community and will allow for investigator-initiated research to occur.

Neither the CRM nor the proposed initiatives are redundant with other NIH Centers or projects including the proposed National Center for the Advancing Translational Sciences (NCATS) or the Clinical and Translational Science Awards (CTSA).

It is important to support research across a broad range of diseases and projects to prevent one cell or disease state from dominating the field. One approach to broad support could be to determine the top 10 disorders and compare this list to the top translational projects that are ready to move forward.

Along with funding research projects and infrastructure development, the ethics of stem cell research should be addressed simultaneously.

iPS stem cell therapy holds the potential for great benefit to limiting health disparities, for example sickle cell anemia.

A motion to approve the Concept as presented was passed unanimously by the Council.

III. FOLLOWUP TO CONCEPT CLEARANCE DISCUSSION OF H3AFRICA PROPOSED INITIATIVES

Dr. Anderson provided a brief recap of the H3Africa Proposal Initiative, which had been discussed at the Council of Councils meeting on June 29, 2011. At that time, the Council had voted to approve with further clarification of the proposal, especially concerning sustainability of the project. On July 25, additional materials were made available to Council members and discussed through an online forum.

The members were reminded that the H3Africa Project has already been approved by Dr. Collins. The role of the Council is to provide input on the proposed initiatives.

Discussion Highlights:

Currently, the bioinformatics/biorepository infrastructure component of H3Africa is under development coordinately with the research component. Some Council of Council members suggested that it might be beneficial to delay the implementation of research programs until after the infrastructure pieces are established. In response, however, it was pointed out that, if this were done, it would limit the ability of the research projects to help shape and grow the infrastructure components to meet their needs.

To obtain more information to assist in development of the infrastructure program, t he NIH issued Requests for Information (RFIs) to gather details regarding the status of bioinformatics and biorepositories in Africa. Information provided in response to these requests demonstrated that some collaborative efforts between institutions have actually already been established to begin the process of building the necessary informatics infrastructure. Planning grants for biorepository developments should be considered.

The concern of several members that this project will consume a large portion of the Common Fund budget was addressed. It was explained that the proposed budget for H3Africa was quite small, as a proportion of the Common Fund. It was also noted that the Wellcome Trust is a committed financial partner in the project. Other governmental and non-governmental organizations, such as Grand Challenges Canada, are also considering the possibility of providing resources some time in the future. There is support for building biological research in Africa from organizations within and outside Africa. The members stated that the new information answered their concerns.

On the broader issue, NIH staff stated that the cost of the project is not a deciding factor for the Council. It was acknowledged that these proposals are complex and may require greater depth of information to be provided so Council members can make an informed decision. DPCPSI is addressing this issue.

Following their receipt of the additional materials and the clarification of the resources and infrastructure that currently exists in regions of Africa, members of the Council expressed support for the project. The additional information provided by the H3Africa Working group was sufficient to satisfy the concerns of the Council Members, and no vote was needed for this informational item.

IV. DISCUSSION OF NIH DIRECTOR'S EARLY INDEPENDENCE AWARD PROGRAM AND REVEIW PROCESS

Elizabeth L. Wilder, Ph.D., DPCPSI, stated that the NIH Director's Early Independence Award (EIA) Program was established by Dr. Collins to provide a mechanism for exceptional, early career scientists to proceed directly to an independent research position after graduate school without the need for additional training as a postdoctoral fellow. Exceptional young scientists who are within a year of completing or have completed graduate school or a residency program are eligible for this award. Awards of $250,000 per year (direct costs) for 5 years will be provided. In response to RFA-RM-10-019, applications were limited to two per institution, with 10 awards anticipated.

The initial review process included two tiers. Tier-one was a scientific review conducted by qualified experts in the field of each project. In this tier, the science came first. If selected, the proposals proceeded to a second-tier review. This entailed a formal interview process where the candidate was evaluated for maturity and feasibility of managing an independent lab.

An evaluation of the EIA program by the NIH was conducted while the process was ongoing. Overall, this award mechanism met with mixed responses. During this process, several challenges and preliminary findings were highlighted. Reviewers felt the two-tier process

worked well, although they sought clarification on how to weigh institutional support and letters of reference in rating the proposals. Most junior scientists who applied were currently in post-doctoral fellowship or junior faculty positions and applications were tied to the current institution. Although it was thought that institutions would like this award mechanism and could use it as a recruitment vehicle, institutions expressed difficulty understanding the eligibility requirement of the applicants. There was also difficulty integrating potential candidates into existing positions within the institution. Junior scientists expressed concern with the timeline from the release of the RFA to submission of the application. Due to challenges and lengthy delays in obtaining institutional support, the application deadline was deemed too short. This was also complicated by the limitation of two applicants per institution. Applicants also expressed difficulty obtaining collaborator support, generating preliminary data (although this was not a requirement), and understanding the requirements of the proposal. Many junior scientists felt this award could be detrimental to their career. No clear definition of "exceptional" candidate was provided.

Through the evaluation, the following recommendations were made:

Operationalize the qualifications of "exceptional."

Increase awareness of the program and identify contacts within institutions to promote this mechanism.

Create a centralized database of interested institutions.

Increase the timeline between the release of the RFA and the application deadline.

Calibrate the scores among reviewers.

Provide questions to be addressed by referees to standardize letters of recommendation.

Conduct tier-two interviews in a room conducive to interviews.

Provide information to finalists with prep questions for the interview.

Increase the number of awards.

Discussion Highlights:

This mechanism should be a good vehicle for institutions to recruit scientists.

The review process could be simplified to a review of student past achievement and the research plan.

As awardees are selected, their profiles can be used as examples of what constitutes an exceptional junior scientist.

An indicator of "exceptional" is whether the individual has gone beyond the normal trajectory of his or her lab.

This mechanism selects for the rare individual whose research career will actually benefit from bypassing the usual postdoctoral experience. The EIA could harm individuals who are not ready for early independence.

At times, it is difficult to determine how much influence and independence a student has from his or her mentor. Independence is important for this award mechanism, therefore awards to students who will still be highly influenced by a mentor should be avoided. How to determine if this is the case prior to awarding the project is difficult. Program management by NIH can help clarify how independent an awardee is after the establishment of the new lab.

Although this is an independent award, the institution must provide a good/productive environment for the new faculty member. This includes good mentorship at the institution.

V. CLOSING REMARKS

Dr. Anderson thanked all participants and the open-session of the teleconference was adjourned at 2:30 p.m., and the closed session followed immediately thereafter.

VI. CERTIFICATION

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

1-11-2012

JAMES M. ANDERSON, M.D., Ph.D. (Date)
Chair, NIH Council of Councils
Director, Division of Program Coordination,
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Office of the Director (OD), NIH

1/10/2012

ROBIN I. KAWAZOE (Date)
Executive Secretary, NIH Council of Councils
Deputy Director, DPCPSI, OD, NIH
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