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NATIONAL HEART, LUNG, AND BLOOD ADVISORY COUNCIL

DEPARTMENT OF HEALTH AND HUMAN SERVICES NATIONAL INSTITUTES OF HEALTH NATIONAL HEART, LUNG, AND BLOOD ADVISORY COUNCIL

MEETING SUMMARY OF THE NATIONAL HEART, LUNG, AND BLOOD ADVISORY COUNCIL

October 22, 2013

The 253rd meeting of the National Heart, Lung, and Blood Advisory Council (NHLBAC) was convened at 12:30 p.m. on Tuesday, October 22, 2013, in Conference Room 10, C Wing, Building 31, National Institutes of Health (NIH), Bethesda, Maryland. The meeting was open to the public until 1:37 p.m. The closed session began at 1:43 p.m. and adjourned at 2:46 p.m. Dr. Gary H. Gibbons, Director of the National Heart, Lung, and Blood Institute (NHLBI), presided as Chair.

Council members attending via teleconference:

Mr. Jonathan R. Alger
 Dr. Ivor J. Benjamin
 Dr. George O. Daley
 Dr. Pamela S. Douglas
 Dr. Jonathan A. Epstein
 Dr. Lanetta B. Jordan
 Dr. Ron G. King
 Dr. Talmadge E. King
 Dr. Barbara A. Konkle
 Dr. Naomi L.C. Luban
 Dr. Polly E. Parsons
 Dr. Bruce M. Psaty
 Dr. Veronique Lee Roger
 Dr. Leslee J. Shaw
 Dr. Anna Maria Siega-Riz
 Dr. Gilbert C. White
 Dr. Jeffrey A. Whitsett

Council members absent:

Dr. Coletta C. Barrett
 Dr. Robert L. Jesse (ex officio)

Members of the public present:

Ms. Virginia Mechan, Northwestern University
 Ms. Karen Mowrer, Lewis Burke Associates
 Ms. Nancy Moy, SRI International
 Ms. Emily Smith, RTI International
 Mr. Victor Zulkosky, Social and Scientific Systems

CSR Employees present:

Dr. Lawrence Boerboom
 Dr. Kathy Malinda
 Dr. Ai-Ping Zou

NHLBI employees present:

Some NHLBI staff were in attendance or were able to listen to the meeting via teleconference.

I. CALL TO ORDER

Dr. Gary H. Gibbons, Director of the National Heart, Lung, and Blood Institute (NHLBI), called the 253rd meeting of the National Heart, Lung, and Blood Advisory Council (NHLBAC) to order. All Council members attended via teleconference. Dr. Gibbons updated members on NHLBI actions during the 16-day Government shutdown and startup activities. He also thanked staff for

their role in ensuring that the meeting occurred three days after the shutdown ended. He talked about the current Continuing Resolution that is in place until January 15, 2014. The NHLBI will use a 90 percent-level ?hold back? until the budget picture is more settled and it will use similar governing principles of the past year ? shared sacrifice, preserve the number of R01s, and protect Early Stage Investigators. He mentioned upcoming fiscal challenges and the potential of more sequester cuts, but expressed an optimistic goal of a payline at the 10-12 percentile. Because this was an abbreviated meeting due to the shutdown, Dr. Gibbons highlighted the February 2014 draft agenda that will include an update on BEECom, the role of Council in the Institute?s Strategic Visioning and Planning, a presentation by a Division of Intramural Research investigator, and a discussion of the Enhancing Reproducibility Initiative.

II. ADMINISTRATIVE ANNOUNCEMENTS

Dr. Stephen C. Mockrin, Director of the Division of Extramural Research Activities, updated members on the status of operations following the Government shutdown (October 1-16). He stressed that things continue to be very fluid. October application receipt dates have all been rescheduled to November so applicants have access to NIH staff and electronic systems. Applicants who have already made their submissions have the opportunity to replace the original application with a ?refreshed? one, without it being counted as a resubmission. NHLBI canceled 11 peer review meetings during the shutdown. All will be held, as planned or rescheduled in time to go to February Council. Overall, the shutdown forced the Center for Scientific Review to cancel more than 200 peer review meetings, affecting more than 11,000 applications. Those will be rescheduled for review in February and March, and will be reassigned to the May/June Council round. Despite this announced timeline, CSR is looking into completing reviews by mid-December so they can be assigned to the January/February round of Council meetings. The NIH will adjust the Early Stage Investigator status for applicants whose status changed during the shutdown. There is no information about timelines for the NIH Pathway to Independence Award Program (K99/R00). Adjustments to eligibility status will be made, as appropriate.

III. REPORT OF THE BOARD OF EXTERNAL EXPERTS AND INITIATIVE CONCEPTS

NHLBI staff presented eight initiatives and renewals, which were reviewed in September by the Board of External Experts (BEE). Initiative development at the NHLBI is a two-cycle process. First, staff within each extramural division develops ideas and potential initiatives, which they present to the trans-NHLBI Idea Forum. Sufficiently developed initiatives are subsequently considered by the BEE, which ranks them and provides accompanying advice. The Council was mostly supportive of the initiatives presented, but made a number of specific recommendations for consideration prior to their release. The Director, NHLBI, will consider the recommendations of the BEE and the Council and other budgetary and programmatic issues in determining which of the proposed initiatives, if any, to implement.

INITIATIVES: SBIR/STTR

Initiative: Cardiovascular Development Consortium (U01)

Purpose: To create and share with the larger investigative community comprehensive knowledge of developmental cardiovascular networks, and to identify the series of mechanistic events that give rise to complex anatomic abnormalities in individuals with congenital heart disease (CHD).

Initiative: Pediatric Cardiac Genomics Consortium (U01)

Purpose: To improve the mechanistic understanding of how a genetic variant is temporally and spatially translated into an anatomic abnormality; To understand how genetic variants may impact key clinical outcomes, such as arrhythmias, impaired neurodevelopment, pulmonary vascular disease, and thrombotic complications; To increase the cadre of researchers and resources to sustain multidisciplinary, integrated research in congenital heart disease (CHD) pathogenesis.

Initiative: Women's Health Initiative (WHI) Renewal (N01)

Purpose: To 1) expand knowledge about the determinants of cardiovascular disease in older women (and conversely determinants of successful aging with absence of cardiovascular disease); 2) expand the study as a scientific resource for the research community; 3) mentor young investigators; and 4) facilitate a new generation of large simple prevention trials.

Initiative: Chronological Animal Models for Diseases of Heart, Lung, Blood, or Sleep (Type 3, Competitive Revision) (R01)

Purpose: To encourage researchers to interrogate the variable time in the pathogenesis of chronic diseases by using rodents or other animals of disease-critical age in a targeted set of experiments within the general scope of previously awarded NHLBI-funded R01s. It would allow researchers to interrogate a system that may more closely correspond to the human chronic diseases within the frame of their ongoing research.

Initiative: : Enriching the Hematology Research Workforce through Short-term Training in Emerging Science (R25)

Purpose: To maximize the scientific value of established research resources by providing them with a mentoring and training component that offers junior investigators the opportunities to acquire advanced targeted scientific tools with which to establish or enhance a blood research career.

Initiative: Sickle Cell Disease in Sub-Saharan Africa (U01)

Purpose: To establish a sustainable sickle cell disease (SCD) investigative network in sub-Saharan Africa. Such capacity building is intended to advance future SCD related epidemiologic, clinical, and implementation research.

CLOSED PORTION

This portion of the meeting was closed to the public in accordance with the determination that it concerned matters exempt from mandatory disclosure under Sections 552b(c)(4) and 552b(c)(6), Title 5, U.S. Code and Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. appendix 2).

IV. REVIEW OF INTRAMURAL RESEARCH

Reports prepared by the Board of Scientific Counselors (BSC), NHLBI, on the NHLBI intramural laboratories reviewed during FY 2013 were presented to the Council by Dr. Robert Balaban, Director, Division of Intramural Research, NHLBI, and Dr. Douglas Wallace (BSC Chair), Children's Hospital of Philadelphia.

V. REVIEW OF APPLICATIONS

The session included a discussion of procedures and policies regarding voting and confidentiality of application materials, committee discussions and recommendations. Members absented themselves from the meeting during discussion of and voting on applications from their own institutions, or other applications in which there was a potential conflict of interest, real or apparent. Members were asked to sign a statement to this effect. The Council considered and approved 1,004 applications requesting \$1,405,451,027 in total direct costs.

ADJOURNMENT

The meeting was adjourned at 2:46 p.m.

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