NATIONAL HEART, LUNG, AND BLOOD ADVISORY COUNCIL

MEETING MINUTES
June 15, 2011

I. CALL TO ORDER AND OPENING REMARKS - Dr. Susan B. Shurin

Dr. Susan B. Shurin, Acting Director of the National Heart, Lung, and Blood Institute (NHLBI), welcomed members to the 242nd meeting of the National Heart, Lung, and Blood Advisory Council (NHLBAC).

Council Updates:

Dr. Shurin welcomed six new Council members:

• Jonathan Alger, J.D., Senior Vice President and General Counsel, Rutgers, The State University of New Jersey
• Coletta Barrett, R.N., Vice President of the Mission for Our Lady of the Lake Regional Medical Center, Baton Rouge, LA
• Ivor Benjamin, M.D., Professor of Medicine and Biochemistry, University of Utah School of Medicine
• Naomi Luban, M.D., Chief of the Division of Laboratory Medicine and Pathology, and Director of the Transfusion Medicine/Donor Center, Children's National Medical Center, Washington, D.C.

• Polly Parsons, M.D., Professor of Medicine and Chair of the Department of Medicine, University of Vermont, and Director of the Pulmonary and Critical Care Medicine Unit at the Vermont Lung Center
• Gilbert White, M.D., Executive Vice President for Research and Director of the Blood Research Institute, Blood Center of Wisconsin

NIH Updates:

Dr. Shurin updated the Council on NIH leadership appointments and vacancies:

• Dr. Martha J. Somerman has been appointed Director of the National Institute of Dental and Craniofacial Research (NIDCR).
• The search is ongoing for Director of the NHLBI; Director of the National Institute of General Medical Sciences (NIGMS); and Director of the proposed National Center for Advancing Translational Sciences (NCATS).

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II. REVIEW OF CONFIDENTIALITY AND CONFLICT OF INTEREST - Dr. Susan B. Shurin

The Council was reminded that under Public Law 92-463, the Federal Advisory Committee Act, a portion of the meeting would be closed to the public, for the consideration of grant applications. Dr. Shurin also reminded the Council members that they are Special Government Employees and are subject to Departmental conduct regulations.

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III. REPORT OF THE ACTING DIRECTOR – Dr. Susan B. Shurin

Budget Update:

Dr. Shurin reported that the NHLBI budget is about 1 percent lower than last year. After adjusting for inflation, we are operating with approximately the same purchasing power we had in 2000-2001. Under the FY 2011 Continuing Resolution, the NHLBI budget is only $132.1 million more than in FY 2008, and the proposed FY 2012 President's Budget for NHLBI is only about $210.3 million more than our FY 2008 actual budget. NHLBI FY 2011 funding paylines are the same as last year (R01/R21 A0: 16.0 percentile; R01/R21 A1: 12.0 percentile; R01/R21 A2: 10.0 percentile; Early Stage Investigator R01: 26.0 percentile). The Institute continues to emphasize support of investigator-initiated research as much as possible.

On April 8, 2011, Secretary Kathleen Sebelius, U.S. Department of Health and Human Services (DHHS), announced the HHS Initiative to Improve Care for Individuals with Sickle Cell Disease. The NIH and several other agencies are participating.

The NHLBI is also participating in the Medical Education Partnership Initiative, the goal of which is to develop and strengthen models of medical education and build research and clinical capacity in Sub-Saharan Africa.
Dr. Shurin updated the Council on two NIH-level organizational changes in progress. The formation of the National Center for Advancing Translational Sciences (NCATS), focused on accelerating the development and delivery of new, more effective therapeutics; and formation of an addiction Institute, comprising addiction components of the National Institute on Alcohol Abuse and Alcoholism (NIAAA), National Institute on Drug Abuse (NIDA) and National Cancer Institute (NCI).

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IV. A NEW NHGRI STRATEGIC PLAN: CHARTING A COURSE FOR GENOMIC MEDICINE - Dr. Eric Green

Dr. Eric Green, Director of the National Human Genome Research Institute (NHGRI), NIH, described progress in genomics research that has occurred since the completion of the sequencing of the human genome, and summarized the new NHGRI strategic plan for the future of human genome research in the article, “Charting a Course for Genomic Medicine from Base Pairs to Bedside”, which was published in Nature magazine on February 10, 2011. Dr. Green emphasized the importance of clinical applications of genomics. The term "genomic medicine" (also known as personalized medicine) refers to clinical care based on genomic information.

The NHGRI strategic plan is built around five domains of genomics research:

- Understanding the structure of genomes
- Understanding the biology of genomes
- Understanding the biology of disease
- Advancing the science of medicine
- Improving the effectiveness of healthcare

The NHGRI strategic plan identifies several "imperatives for genomic medicine." Although the NHGRI plans to facilitate future genomics activities as much as possible, Dr. Green emphasized that implementing the strategic plan will require the efforts of genome scientists from around the world.

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V. EXPLORATORY/DEVELOPMENTAL RESEARCH GRANT AWARDS (R21) – Dr. Carl Roth

Dr. Carl Roth, Acting Deputy Director of the NHLBI and Associate Director for Scientific Program Operation, presented results of an analysis of recent NHLBI participation in the R21 program. The R21 mechanism provides 2 years of funding for exploratory research projects. Of concern is that New Investigators (NIs) appear to believe that R21 awards facilitate success in

applying for research project (R01) awards. The NHLBI payline policy currently gives Early Stage Investigators (ESIs)—and previously, all NIs—up to a 10 percentile point advantage on R01 applications compared with Established Investigators (EIs).

Dr. Roth presented NHLBI data that address two questions:

Do NIs/ESIs obtain R21 grants more easily than R01 grants?

The data indicate:

- R21 NI ultimate award rate < R21 EI ultimate award rate.
- R01 NI ultimate award rate is about the same as R01 EI ultimate award rate.
    - NHLBI NI payline policy was initiated in FY 2005.
    - NHLBI ESI payline policy was initiated in FY 2010.
- NI ultimate award rate for R01s > NI ultimate award rate for R21s.

Do R21 grants prime NIs/ESIs for future R01 grants?

The data indicate:

- NIs with R21 awards have a slightly higher R01 award rate than NIs without prior R21 awards.
- The vast majority of NI R01 awardees do not have a previous R21 award.

Dr. Shurin proposed the following NHLBI R21 policy for Council consideration:

- NHLBI will stop participating in the parent NIH R21 program.
- ESIs, if appropriate and eligible, will be encouraged to explore opportunities to be mentored, such as the NIH Pathway to Independence Award (parent K99/R00).
- The NHLBI will issue highly targeted RFAs for R21s when scientific opportunities arise. (Note: Only established investigators [e.g., investigators with more than two R01-equivalents] will be eligible for these R21s and only if the application represents a substantial departure from previous research directions.)

Council members discussed the proposal and expressed their support.

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VI. METHOD TO EXTEND RESEARCH IN TIME (MERIT) AWARDS – Dr. Susan B. Shurin

Dr. Shurin reviewed the goal of the MERIT program, which is to afford productive investigators who have demonstrated exceptional talent and imagination and a record of preeminent scientific achievements the opportunity to continue making fundamental contributions of lasting scientific value.

The main elements of the MERIT program include:

• Investigators may not apply for a MERIT award.
• NHLBI staff nominate and Council members select MERIT PIs from eligible R01 applicants whose applications are within the R01 payline.
• The benefit for the awardee is a simplified renewal process for an additional award term.

Dr. Shurin summarized recent criticisms of the MERIT program:

• The program supports productive, steadily funded investigators (i.e., those who would be funded anyway).
• Much of the work funded by the MERIT program, while highly meritorious, has not been especially "high impact."
• It is difficult to establish and implement criteria for the award other than priority scores, publications, and continuity of NIH grant support; hence, most who are eligible are nominated for (and receive) MERITs.
• In the current funding environment, it is difficult to justify non-competitive renewal awards.

Dr. Shurin proposed the following NHLBI MERIT policy for Council consideration:

• NHLBI will stop participating in the MERIT award program. (No new MERIT awards will be made, but existing MERIT awards will be extended if eligible.)
• NHLBI will emphasize participation in existing innovative NIH programs, including the Transformative R01 and EUREKA awards (which are being combined); the Pioneer award; and the New Innovator award.

Council members discussed the proposal and expressed their support.

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VII. REPORT OF THE BOARD OF EXTERNAL EXPERTS AND INITIATIVE CONCEPTS FOR FISCAL YEARS 2012 AND BEYOND

NHLBI staff presented 15 new initiatives, 2 renewals, and 1 request for secondary support, all of which had been reviewed in May by the Board of External Experts (BEE). Initiative development at the NHLBI is a two-cycle process. First, staff within each extramural Division develop ideas and potential initiatives, which they present to the trans-NHLBI Idea Forum. Sufficiently developed initiatives are subsequently considered by the BEE, which ranks each 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 Acting 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.

Strategic Plan Goal I: To improve understanding of the molecular and physiological basis of health and disease, and to use that understanding to develop improved approaches to disease diagnosis, treatment, and prevention

Clinical Trials Network for the Prevention and Treatment of Acute Lung Injury (N01), RFP

To evaluate therapies and new approaches for preventing and treating acute lung injury via a multidisciplinary clinical trial research network. The initiative will build upon the strengths and experience of the NHLBI Acute Respiratory Distress Syndrome Clinical Trial Network (ARDSnet) and focus on earlier intervention, multidisciplinary collaborations, new partnerships, new approaches, and prevention.

Council recommended this initiative.

Early CF Lung Disease Studies in Humans (R01), RFA

To characterize pre-symptomatic cystic fibrosis lung disease in infants and young children, with the intent of leading to early interventions to mitigate or ameliorate disease progression.

Council recommended this initiative.

Identifying Heart, Lung, and Blood Disease-Causing Variants and Genes (R01), PAR

To identify heart, lung, and blood disease-causing rare genetic variants using the extensive exome data generated by the ARRA Grand Opportunity Exome Sequencing Project (GO ESP) and other genotyping efforts.

Council recommended this initiative.

Integrative Genomics Research Consortium for Lung Diseases (U01), RFA

To support a program of integrative genomics studies for discovery of molecular determinants and biomarkers that will improve diagnosis and treatment of lung diseases.

Council recommended this initiative.

Molecular Imaging of the Lung (R01), RFA

To facilitate discovery of novel in vivo imaging reagents and technologies such as molecular probes that target pathways or cells involved in development and pathobiology of pulmonary diseases. The long-term goal is to facilitate early detection and diagnosis of lung disease, enable noninvasive monitoring of lung disease progression and prognosis, and accelerate progress in cell-specific drug delivery and therapies.

Council recommended this initiative.

Understanding Mechanisms of Terminal Erythroid Maturation (R01), RFA

To improve understanding of the molecular mechanisms that regulate the late stages of erythroid maturation. The investigations are intended to lead to the identification of new therapeutic targets for erythropoietin-resistant anemias characterized by defects in late-stage erythroid maturation.

Council recommended this initiative.

Strategic Plan Goal II: To improve understanding of the clinical mechanisms of disease and thereby enable better prevention, diagnosis, and treatment

Early Translation of Technologies in Cardiothoracic Surgery Research (R01), PAR

To leverage existing technologies and develop new approaches for overcoming current challenges in cardiothoracic surgery by promoting collaborations between cardiothoracic surgeons and researchers in diverse areas such as cell and tissue engineering, imaging, multi-scale modeling, and biomaterial development.

Council recommended this initiative.

Excellence in Hemoglobinopathy Research Awards (R01 or U01), RFA

To accelerate multi-disciplinary basic and translational research in the hemoglobinopathies and to facilitate collaboration among basic and translational scientists in relevant biomedical disciplines and clinical hematologists located throughout the world.

Council recommended this initiative.

Hispanic Community Health Study – Study of Latinos (N01; Renewal), RFP

To: 1) investigate further the apparent paradox of high socioeconomic adversity and substantial cardiovascular and pulmonary disease (CVPD) risk factor burden, and low CVPD prevalence and mortality in Hispanics; 2) identify putative causes for diseases and conditions highly prevalent in Hispanics (e.g. diabetes, asthma, chronic obstructive pulmonary disease, left ventricular hypertrophy, and gestational diabetes mellitus); 3) describe the transformation of health-related risk and protective factors related to migration, acculturation, and length of time living in the U.S.; 4) assess the impact of socioeconomic factors, cultural values, risk behaviors, and access to medical care on health in Hispanics; and 5) investigate genetic effects, gene-gene interactions, and gene-environment interactions in relation to measured phenotypes in this uniquely admixed population.

Council recommended this initiative.

Jackson Heart Study Renewal (N01 and R01; Renewal), RFP and RFA

To leverage the NIH investment in the Jackson Heart Study (JHS) to support the JHS goal of describing and addressing the biological, behavioral, and psychosocial factors that account for the high burden of cardiovascular disease in African-Americans; and to continue and expand JHS research workforce development and community outreach and education efforts.

Council recommended this initiative.

Management of HIV-related Lung Disease and Cardiovascular Co-morbidity – Planning Grants for Clinical Trials on Treatment Optimization (R34; AIDS funds), RFA

To support the initial organization, protocol development, and necessary preliminary studies critical for the design of robust phase II and III clinical trials in HIV-infected populations with lung disease alone or with cardiovascular co-morbidity. The focus of the clinical trials will be on optimizing intervention strategies to reduce morbidity and mortality associated with HIV-related lung disease, with or without co-morbid cardiovascular disease.

Council recommended this initiative.

Mentored Scientific and Career Enhancement Award in Sleep and Circadian Health and Biology (K18), RFA

To improve the capacity of established investigators to develop trans-disciplinary research programs that integrate the latest concepts in sleep and circadian biology.

Council recommended this initiative.

Personal and Residential Interventions that Reduce Cardiovascular Risk in High-Risk Individuals from Fine Particulate Air Pollution (R01), PAR

To test whether personal and residential interventions that limit exposure to fine particulate matter air pollution would reduce cardiovascular risk or surrogate markers of cardiovascular disease (CVD) in individuals at high risk for CVD.

Council recommended this initiative.

Sudden Cardiac Death in the Young: Population-Based Studies (Y01 and U01), RFA and Other

To estimate the incidence of sudden cardiac death (SCD) in infants, children, and young adults; determine the etiologies of, and risk factors for, SCD in these populations; and establish a resource for investigation into SCD in the young.

Council recommended this initiative.

Vascular Interventions/Innovations and Therapeutic Advances Program (N01), BAA

To accelerate the development of promising diagnostic and therapeutic modalities for vascular diseases. This translational program is specifically designed to address the "Valley of Death" in product development by providing support for research that is beyond the hypothesis-driven stage and is ready for hypothesis testing and clinical development.

Council recommended this initiative.

Strategic Plan Goal III: To generate an improved understanding of the processes involved in translating research into practice and use that understanding to enable improvements in public health and to stimulate further scientific discovery

Asthma Empowerment Partnerships to Reduce Childhood Asthma Disparities (U01), RFA

To test whether new models for integrated asthma management programs in community settings will create improvements in asthma outcomes that can lead to substantial reductions in asthma disparities. The integrated programs will address individual, home, medical care, and community sectors that affect asthma outcomes, and will target those children in identified communities who experience the highest rates of adverse asthma outcomes.

Council recommended this initiative.

NHLBI Centers for Accelerated Innovations (U54), RFA

To nurture the development of high-priority, early-stage technologies within the NHLBI's mission in a manner consistent with business case development and regulatory requirements by: 1) providing funding for feasibility, prototype development, or proof-of-concept studies; 2) providing unified, coordinated expertise in areas required for early technology development, including scientific, regulatory, business, legal, and project management; 3) leveraging existing NIH resources, such as Science Moving Rapidly Towards Translation (SMARTT) and the Clinical and Translational Science Awards (CTSAs); 4) establishing new partnerships and strengthening existing alliances between stakeholders, including public, private, non-profit, and academic sectors; 5) providing investigators with training and hands-on experience in entrepreneurship, and 6) creating cultural and systemic changes by providing the necessary resources to move more quickly from breakthrough innovations to products that will have health, economic, and societal effect.

Council recommended this initiative.

Request for Secondary Support

Data Resource for Analyzing Blood and Marrow Transplants (U24; NCI is lead Institute), RFA

To continue collection of research-grade clinical outcomes data from patients receiving hematopoietic stem cell transplants; provide investigators access to a contemporary outcomes database; and promote research within the mission of NHLBI using these data.

Council recommended this initiative.

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).

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VIII. REVIEW OF APPLICATIONS

The Council considered 1,522 applications requesting $2,174,414,143 in total direct costs. The Council recommended 1,522 applications with total direct costs $2,174,414,143.

ADJOURNMENT

The meeting was adjourned at 4:00 p.m. on June 15, 2011.

Last Updated March 2011