

**NATIONAL HEART LUNG AND BLOOD INSTITUTE
ADVISORY COUNCIL**

**MEETING MINUTES
October 21, 2008**

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I. CALL TO ORDER AND OPENING REMARKS - Dr. Elizabeth G. Nabel

Dr. Elizabeth G. Nabel, Director of the National Heart, Lung, and Blood Institute, welcomed members to the 232nd meeting of the National Heart, Lung, and Blood Advisory Council (NHLBAC).

Member Updates:

Dr. Nabel recognized five Council members who are retiring:

- Dr. Charles Esmon
- Dr. Katherine High
- Ms. J. Hoxi Jones
- Dr. Jeffrey McCullough
- Dr. Patricia Wahl

New Staff:

Dr. Nabel also announced two upcoming changes in NHLBI personnel:

- Dr. Marvin Konstam, Senior Advisor to the Director for Cardiovascular Diseases, is returning to Tufts University to serve as Chief Physician Executive at the new Tufts Medical Center Cardiovascular Center. While at the NHLBI, Dr. Konstam provided invaluable advice and strategic guidance for the Institute's national research programs on the causes, prevention, and treatment of cardiovascular diseases.

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- Dr. Keith Hoots will join the Institute in January as the Director of the Division of Blood Diseases and Resources. Dr. Hoots is currently Professor of Pediatrics and Division Head, Pediatric Hematology, The University of Texas Medical School at Houston; Section Head, Pediatric Hematology, The University of Texas M.D. Anderson Cancer Center; and Medical Director, Gulf State Hemophilia and Thrombophilia Treatment Center.

Dr. Nabel acknowledged the extraordinary efforts of Dr. Susan Shurin, Deputy Director, NHLBI, who has been serving as Acting Director of the Division of Blood Diseases and Resources.

Invited Guests:

Dr. Nabel welcomed representatives of two NHLBI Advisory Committees:

- Dr. Robert Wise, representing the Heart, Lung, and Blood Program Project Review Committee
- Dr. Pamela Ouyang, representing the Clinical Trials Review Committee

Dr. Nabel also welcomed the two invited speakers:

- Dr. Jeremy Nicholson, Head of the Department of Biomolecular Medicine, Imperial College, London.
- Dr. Keji Zhao, Senior Investigator, Laboratory of Molecular Immunology, NHLBI Division of Intramural Research

II. REVIEW OF CONFIDENTIALITY AND CONFLICT OF INTEREST - Dr. Elizabeth G. Nabel

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 and the review of intramural programs. A notice of this meeting was published in the Federal Register. Dr. Nabel also reminded the Council members that they are Special Government Employees and are subject to Departmental conduct regulations.

III. REPORT OF THE DIRECTOR - Dr. Elizabeth G. Nabel

Dr. Nabel announced two changes at the NIH:

- The NIH became a [tobacco-free campus](#) on October 1st.

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- Dr. Elias Zerhouni, Director of the NIH for the past 6 years, will be leaving the NIH at the end of October. A tribute to him will be held on October 30th. Dr. Zerhouni brought important reforms to the NIH during challenging times. Dr. Raynard Kington, currently Deputy Director of the NIH, will assume the duties of Acting Director.

Budget Report:

The NIH is currently operating under a Continuing Resolution, in effect through March 6, 2009. Consequently, the NHLBI must operate at its FY 2008 budget level, which was \$2,922,654,000 (not including the \$15 million end-of-year supplement received in FY 2008). Dr. Nabel cautioned that the NIH may have to operate under the Continuing Resolution for the entire fiscal year, but assured Council that the Institute will do its best to continue its support of research project grants as well as other innovative programs.

Updates:

New and Early Stage Investigators

New Investigator : A principal investigator (PI) is considered a New Investigator if he/she has not yet competed successfully as a PI for a significant NIH independent research award.

Early Stage Investigator: An individual who is classified as a New or First-Time Investigator and is within 10 years of completing his/her terminal research degree or is within 10 years of completing medical residency (or the equivalent) is considered an Early Stage Investigator.

New NIH policies:

- Clustering at Review — Review committees will cluster applications from New and Early Stage Investigators, thereby permitting committees to develop score metrics based on applicants at the same stage in their careers.
- Encouraging Traditional Research Project Grant (R01) Applications — New Investigators will be discouraged from submitting Exploratory/Developmental Grant (R21) applications. The NHLBI is already doing this.
- Setting Targets for New and Early Stage Investigators
- Success rates for Early Stage Investigators will be equivalent to success rates on Type 1 (i.e., new) R01 applications from established investigators.
- NIH Institutes/Centers will use this approach to make R01 awards to approximately 1,650 New Investigators in FY 2009.
- At least 60 percent of the New Investigator pool will be Early Stage Investigators (proportion will increase to 75 percent over future years).

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The NHLBI will begin implementing the new policy on success rate targets and composition of the New Investigator pool immediately. Based on an analysis of applications considered at a recent Council round, the success rate of Early Stage Investigators was already slightly higher than that of Established Investigators on Type 1 R01 applications under existing NHLBI [New Investigator policies](#).

Dr. Nabel requested input from Council on the new policies. The Institute will analyze data from this Council round (October 2008) and report to Council.

New NIH Policy Regarding Amended Applications

Beginning with the January 2009 application receipt date, all original (i.e., unamended) new applications and competing renewal applications will be permitted only a single amendment (A1). The [new policy](#) (resulting from the recent review of the NIH peer review system) was established to facilitate earlier funding of high-quality applications and improve efficiencies in the peer review system.

Dr. Nabel updated the Council on progress in implementing recommended actions resulting from the recent NIH-led [study of the NIH peer review system](#). First-rate peer review is a cornerstone of the NIH, but new challenges for peer review have been created by the increasing breadth, complexity, and interdisciplinary nature of biomedical science and exacerbated by tight budgetary times. Recommendations and plans for implementation can be found at [Enhancing Peer Review at NIH](#). The study identified four priority areas:

- Priority Area 1: Engage the best reviewers
- Priority Area 2: Improve the quality and transparency of review
- Priority Area 3: Ensure balanced and fair reviews across scientific fields and career stages, and reduce administrative burden
- Priority Area 4: Ensure continuous review of Peer Review.

IV. REBALANCING SUCCESS RATES – Dr. Carl Roth

Dr. Carl Roth, Associate Director for Scientific Program Operation, NHLBI, presented a potential funding policy which was developed by an NHLBI committee charged with developing policies and procedures to restructure success rates among submissions—initial applications (A0s), first amendments (A1s), and second amendments (A2s)—in order to reduce the number of resubmissions necessary to receive an award, and thereby improve the efficiency of the peer review system and reduce the associated burdens on applicants, reviewers, and NIH staff.

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Based on its analysis of recent NHLBI funding, the Committee concurred with the NIH decision to eliminate A2s. (Note: The Committee commenced its work prior to the NIH decision.) NHLBI funding data from the post-doubling era (FY 2004 - FY 2007) show that a large proportion of applications with an A0 percentile score fairly far down the percentile ranking were eventually funded, often as A1s or A2s. For example, about 80 percent of applications from established investigators (85 percent from new investigators) with an A0 score at the 20th percentile were eventually funded. The data also indicate a marked shift toward A2s and away from A0s. Furthermore, the data show substantial improvement in percentile scores between A0 applications and their A1s, and likewise between A1 applications and their A2s, for new investigators as well as established investigators. Based on these data, the Committee recommended eliminating A2s.

Next, the Committee considered percentiling A0s separately from A1s. FY 2007 data show this policy would have substantially lowered the percentile scores of A0s and substantially raised the scores of A1s. A retrospective model that re-percentiled NHLBI R01s and R21s by amendment status (and excluded A2s) showed that 267 resubmissions could have been avoided in FY 2007, 199 resubmissions avoided in FY 2006, and 31 resubmissions avoided in 2005. Therefore, the Committee proposed the following funding policy for consideration by Council:

For applications funded starting in FY 2010 (received January 2009 and thereafter):

- o Re-percentile by:
 - Amendment status (A0, A1)
 - Investigator status (Early Stage Investigator, Established Investigator)
- o Pay by new percentile to equivalent success rates

The Council enthusiastically supported the proposed policy.

V. UNDERSTANDING SUPERORGANISM BIOCHEMISTRY IN HEALTH AND DISEASE – Dr. Jeremy Nicholson

Dr. Jeremy Nicholson, Head of the Department of Biomolecular Medicine, Imperial College, London, and author of many articles and patents on the development and application of new spectroscopic and chemometric approaches to studying disturbed metabolic processes in complex organisms, described some of his extensive research.

Dr. Nicholson described his model of the complex human biological system, which comprises several components including genetics, environment, diet, and the microbiome (i.e., the entire set of microbes living in a person's body). These components interact in complicated ways that affect human metabolism and ultimately influence health and disease. The model provides a

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new paradigm for personalizing medicine. Dr. Nicholson studies microbial metabolic factors (i.e., the metabolic activity of the microbes found in a person's body) as well as human metabolic factors. He proposed the idea (and presented supportive data) that various diseases (e.g., hypertension and obesity) could be, in part, related to activity of the human microbiome. Dr. Nicholson's research suggests that the human microbiome is a potential new target for drugs (in addition to the genetic targets being sought via genome-wide association studies).

VI. CHARACTERIZATION OF HUMAN EPIGENOMES – Dr. Keji Zhao

Dr. Keji Zhao, Senior Investigator, Laboratory of Molecular Immunology, NHLBI Division of Intramural Research, discussed his research. Dr. Zhao's productivity at the NIH illustrates the opportunities inherent in supporting young investigators with exciting, new ideas.

Dr. Zhao's research is in the area of epigenomics—a field that involves the study of changes in the regulation of gene activity and expression that are not dependent on gene DNA sequence. Epigenetic mechanisms are affected by factors such as development *in utero* and in childhood, environmental chemicals, drugs and pharmaceuticals, aging, and diet, and they are thought to sometimes affect people's health, possibly resulting in illnesses such as cancer, autoimmune disease, mental disorders, and diabetes. (See [NIH Roadmap for Medical Research](#) for more information on epigenomics.)

Dr. Zhao presented results from his research, which focuses on how the chromatin structure (chromatin is the complex combination of DNA and proteins that makes up chromosomes) of eukaryotic DNA (i.e., DNA in organisms like the human body in which the cells have membrane-bound nuclei) is modified during cellular development and how those changes determine the expression potential of a specific genomic locus.

VII. MEETING OF THE BOARD OF EXTERNAL EXPERTS – Dr. Elizabeth G. Nabel

NHLBI staff presented 7 new initiatives and 8 renewals, 2 ideas, and 2 requests by other ICs for secondary support, all of which had been reviewed in October 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 provides recommendations to Council. The BEE also considers ideas that are not developed to the level of an initiative.

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

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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.

VIII. PRESENTATION OF INITIATIVES – Dr. Elizabeth G. Nabel

Initiatives and Ideas Related to 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

Exploratory and Developmental NHLBI Systems Biology Collaborations (R21; renewal), PAR

To foster the adoption of integrative systems biology approaches in the NHLBI research domain, through the support of new collaborations or new research directions within existing collaborations. The program supports exploratory and developmental collaborative research projects by multidisciplinary teams that combine computational and experimental expertise. This R21 program is a companion to the proposed PAR entitled "NHLBI Systems Biology Collaborations (R01)."

Council recommended this initiative.

NHLBI Systems Biology Collaborations (R01; renewal), PAR

To advance understanding of normal physiology and perturbations associated with heart, lung, blood, and sleep diseases and disorders, by supporting collaborative research projects by multidisciplinary teams that combine computational and experimental approaches.

Council recommended this initiative.

NHLBI Research Centers at Minority-serving Institutions (UH1 and R25; renewal), RFA

To establish research centers at minority institutions to augment and strengthen their research capabilities and resources in order to perform biomedical and/or behavioral research related to heart, lung, blood, and sleep diseases and disorders.

Council recommended this initiative.

Strategies to Control Adverse Myocardial Extracellular Matrix Remodeling (R01), RFA

To identify and characterize key molecules and pathways that regulate myocardial extracellular

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matrix homeostasis and adverse cardiac remodeling in order to advance the development of new diagnostic and therapeutic strategies for heart diseases.

Council recommended this initiative.

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

Action to Control Cardiovascular Risk in Diabetes (ACCORD) Follow-up Study (contract; renewal), RFP

To support a post-trial follow-up study after termination of trial-assigned treatments in the ACCORD trial. The follow-up study will determine whether differences identified during the trial in mortality, cardiovascular disease events, and microvascular diseases persist or change over time, and whether other differences emerge.

Council recommended this initiative.

Common Pathogenetic Mechanisms of Lung Cancer and COPD (R01), RFA

To identify the fundamental etiopathogenetic commonalities between lung cancer and chronic obstructive pulmonary disease (COPD) in order to characterize: a) the genotypic and phenotypic characteristics that determine individual susceptibility; and b) the shared biochemical and immunological pathways involved in the development and progression of the two diseases.

Council recommended this initiative.

NHLBI Programs of Excellence in Nanotechnology (U01; renewal), RFA

To promote the application of nanotechnology to the diagnosis and treatment of heart, lung, and blood diseases.

Council recommended this initiative.

NHLBI Proteomics Initiative (renewal), RFP

To build upon the foundation developed by the NHLBI Proteomics Centers and the NHLBI Clinical Proteomic Program; to enhance the translation of innovative proteomic approaches and technologies to clinical utility, and to develop greater understanding of physiological pathways, molecular interactions, and regulatory signals related to heart, lung, blood, and sleep diseases

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and disorders.

Council recommended this initiative.

Nutrition and Physical Activity Research to Promote Cardiovascular and Pulmonary Health (R01), PAS

To support research on the roles of nutrition and physical activity in the development, prevention, and management of cardiovascular diseases or pulmonary diseases; specifically, 1) to improve knowledge of the contribution of diet and physical activity to cardiovascular and pulmonary conditions, and the influences of sleep on these relationships, 2) to increase the evidence base for refining public health recommendations and clinical guidelines regarding these lifestyle behaviors, and 3) to develop and test strategies to improve the adoption of the recommendations.

Council recommended this initiative.

Prematurity and Respiratory Outcomes Program (U01), RFA

To identify predictors of chronic respiratory morbidity in premature infants. Council recommended this initiative.

Initiatives Related to 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

Recipient Epidemiology and Donor Evaluation Study-III (REDS-III) (contract; renewal), RFP

To assure safe and effective blood banking and transfusion medicine practices through a comprehensive, multi-targeted strategy involving basic, translational, and clinical research to improve the benefits of transfusion while reducing its risks. The proposed program builds upon the many successes that the REDS-II program has realized over the years, while remaining responsive to changing research and clinical needs, and adapting to emerging priorities.

Council recommended this initiative.

Examining Effects of Community Programs to Reduce Childhood Obesity (U01 or contract), RFA or RFP

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To examine outcomes associated with community programs to reduce childhood obesity through policy, environmental, and educational activities addressing energy balance through diet and physical activity. One research unit will be funded to serve as a study coordinating center to work with the National Collaborative on Childhood Obesity Research (NIH, Robert Wood Johnson Foundation, and Centers for Disease Control and Prevention [CDC]) to design and implement the research.

Council recommended this initiative.

Feasibility Study of Early Intervention with Mechanical Circulatory Support Therapy for Heart Failure Patients (contract), RFP

To explore the potential benefit of ventricular assist device therapy in advanced heart failure patients who have significant functional impairment but who have not yet developed serious consequences such as malnourishment, end-organ damage, or immobility. The feasibility study will serve to inform a pivotal clinical trial.

Council recommended this initiative.

NHLBI Cardiovascular Outcomes Research Centers (U01), RFA

To support observational and quasi-experimental cardiovascular research focused on the end results, or outcomes, of healthcare and the determinants of these outcomes. The program is designed to run in parallel with a similar program administered by the American Heart Association.

Council recommended this initiative.

Resuscitation Outcomes Consortium (U01; renewal), RFA

To leverage 5 years of out-of-hospital research and infrastructure development to improve patient survival from cardiac arrest or life-threatening trauma.

Council recommended this initiative.

Requests for Secondary Support

Centers for Population Health and Health Disparities (P50) [NCI], RFA

To create specialized centers of transdisciplinary research that will evaluate the multilevel

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determinants of health disparities, and develop interventions to reduce them. The Centers concept addresses two dominant aspects of health disparities: their persistence and multi-factorial etiology.

Council recommended this initiative.

The Diabetes Prevention Program Outcomes Study (U01) [NIDDK], RFA

1) To determine the longer-term effects of the original Diabetes Prevention Program interventions on a) further development of diabetes (5-year goal), and b) development of microvascular, neurologic, and cardiovascular disease in people with impaired glucose tolerance and those who develop diabetes during the study period (10-year goal). 2) To study the epidemiology of pre-diabetes and new onset of Type 2 diabetes (with known time of diagnosis). 3) To examine all the outcomes in subgroups defined by age, sex, race/ethnicity, and baseline weight.

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).

This 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.

IX. INTRAMURAL REVIEW

The Council then reviewed reports prepared by the Board of Scientific Counselors, NHLBI, which reviewed the NHLBI intramural laboratories during FY 2008.

X. REVIEW OF APPLICATIONS

The Council considered 1,044 applications requesting \$1,294,152,628 in total direct costs. The Council recommended 1,042 applications with total direct costs of \$1,295,620,308.

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ADJOURNMENT

The meeting was adjourned at 3: 05 p.m. on October 21, 2008.

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Advisory Council Member Roster

As of April 15, 2011

CHAIRPERSON

Shurin, Susan B., M.D. (2010)
Acting Director
National Heart, Lung, and Blood Institute
National Institutes of Health
Bethesda, Maryland 20892
(Also an Ex Officio member)

MEMBERS

Arden Ornt, Jeanine, J.D. (2010)
Vice President and General Counsel
Case Western Reserve University
Cleveland, Ohio 44106

Bairey Merz, C. Noel, M.D. (2011)
Women's Guild Endowed Chair in Women's Health
Director, Women's Heart Center
Director, Preventive and Rehabilitative Cardiac Center
Cedars-Sinai Medical Center
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Borecki, Ingrid B., Ph.D. (2012)
Co-Director
Division of Statistical Genomics
Genome Sciences Center
School of Medicine
Washington University in St Louis
St. Louis, Missouri 63108

Coller, Barry S., M.D. (2012)
Vice President for Medical Affairs
The Rockefeller University
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Coughlin, Shaun R. M.D., Ph.D. (2010)
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Elias, Jack A., M.D. (2012)
Waldemar Von Zedwitz Professor of Medicine
Chair, Department of Internal Medicine
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New Haven, Connecticut 06520

Garcia, Joe G. N., M.D. (2010)
Vice Chancellor for Research
Professor of Medicine
University of Illinois at Chicago
Chicago, Illinois 60612

Gibbons, Gary H., M.D. (2013)
Director, Cardiovascular Research Institute
Morehouse School of Medicine
Atlanta, Georgia 30310

Hogan, Beverly W. (2012)
President
Tougaloo College
Tougaloo, Mississippi 39174

Jordan, Lanetta B., M.D., MPH (2013)
Director
Sickle Cell Services
Memorial Healthcare System
Hollywood, Florida 33021

King, Talmadge E., Jr., M.D. (2013)
Julius R. Krevans Distinguished Professor
Chair, Department of Medicine
University of California, San Francisco
San Francisco, California 94143

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Marks, Andrew R., M.D. (2011)
Professor and Chair
Department of Physiology and Cellular Biophysics
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Parmacek, Michael S., M.D. (2012)
Herbert C. Rorer Professor
Director, Cardiovascular Institute
University of Pennsylvania School of Medicine
Philadelphia, Pennsylvania 19104

Polite, Paula Y. (2010)
Compliance and Quality Coordinator
City of Memphis
Memphis, Tennessee 38106

Rabinovitch, Marlene, M.D. (2011)
Dwight and Vera Dunlevie Professor of Pediatrics
Director of Research
Vera Moulton Wall Center for Pulmonary Vascular Diseases
Stanford University School of Medicine
Stanford, California 94305

Shapiro, Steven D., M.D. (2010)
Jack D. Myers Professor and Chair
Department of Medicine
University of Pittsburgh
Pittsburgh, Pennsylvania 15261

Shaw, Leslee J., Ph.D. (2013)
Professor of Medicine
School of Medicine
Emory University
Atlanta, Georgia 30306

EX OFFICIO MEMBERS

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Jesse, Robert L., M.D., Ph.D.
Acting Principal Deputy Under Secretary for Health
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Mahon, Cdr. Richard T., MC, USNR
Head
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Sebelius, Kathleen, M.P.A.
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EXECUTIVE SECRETARY

Mockrin, Stephen C., Ph.D.
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