Attachment 3

National Heart Lung and Blood Advisory Council Minutes

National Heart, Lung, and Blood Advisory Council

This is a brief summary of the June 10, 2009, meeting of the National Heart, Lung, and Blood Advisory Council (NHLBAC). It will be replaced by the full minutes of the meeting when they become available.

[To Top]

OPENING REMARKS AND REPORT OF THE DIRECTOR

Dr. Elizabeth Nabel, Director of the National Heart, Lung, and Blood Institute (NHLBI), welcomed members to the 234th meeting of the National Heart, Lung, and Blood Advisory Council (NHLBAC).

Dr. Nabel announced two Institute changes:

- The Division of Cardiovascular Diseases and the Division of Prevention and Population Sciences will be merged into the Division of Cardiovascular Sciences to align the Institute's administrative structure with the its cardiovascular programs which now effectively span basic, clinical, and population research. Dr. Michael Lauer, currently Director of the Division of Prevention and Population Sciences, will serve as Director of the new Division, and Dr. Sonia Skarlatos, currently Acting Director of the Division of Cardiovascular Diseases, will serve as Deputy Director.
- The Institute is seeking a Director (application closing date June 23) for its new Office of Global Health. The Institute has initiated several global health activities this year. In June, it awarded contracts to establish nine global health Centers of Excellence (a joint project with UnitedHealth Group's Chronic Disease Initiative). Each Center will be led by a research institution in a developing country paired with at least one partnering academic institution in a developed country. This worldwide network of research and training centers will build institutional and community capacity to prevent and control chronic diseases.

Dr. Nabel announced two changes in NHLBI leadership:

- Dr. Gregory Morosco, who served as Director of the Division of Application of Research Discoveries, retired recently after more than 25 years with the Institute. Dr. Morosco played an instrumental role in the Institute's educational and outreach programs for health professionals, patients, and the public. Dr. Rob Fulwood is serving as Acting Director.
- Mr. Donald Christoferson, NHLBI's Executive Officer, will retire in July after 37 years with the NIH. Mr. Christoferson was recently awarded the Presidential Rank Award of Meritorious Executive. Mr. Timothy Wheeles will serve as Acting Executive Officer.

[To Top]

Budget Update

Dr. Nabel reviewed the Institute's FY 2010 President's Budget, which totals $3,050,356,000, a 1.1 percent increase over the FY 2009 Conference budget. No major changes have been made in any of the budget categories since FY 2009. Total research project grants (noncompeting and competing) are $2,051,848,000, a 1.0 percent increase over FY 2009.

Currently, the Institute's payline is at the 15.0 percentile for traditional research project grants (R01s) and exploratory/developmental research grants (R21s); at the 20.0 percentile for new R01 investigators; and at the 25.0 percentile for early stage investigators (if expedited administrative review resolves summary statement comments). (See discussion below regarding payline expansion with ARRA funds.)

[To Top]

American Recovery and Reinvestment Act (ARRA) Update

The ARRA was signed into law by President Obama on February 17, 2009. It provides $10.4 billion to the NIH (available for 2 years—through September 2010) to support programs to stimulate the economy, create and preserve jobs, and advance

biomedical research. The NHLBI is grateful for the opportunity to join the NIH in helping to improve the Nation's health and economy.

Dr. Nabel summarized the NIH scientific research and funding approach to ARRA, and described NHLBI ARRA funding plans in more detail.

Using existing mechanisms as well as new programs, the NIH plans to spend ARRA monies as follows: $8.2 billion for extramural scientific research ($7.4 billion of which will be transferred to the Institutes/Centers (ICs), using a percentage-based formula); $1.3 billion for extramural repair, improvements, and construction; $0.5 billion for intramural repair, improvements, and construction; and $0.4 billion for comparative effectiveness research (CER).

The NHLBI will receive about 10 percent of the $7.4 billion provided to NIH ICs for scientific research. It plans to accelerate implementation of the NHLBI Strategic Plan, fund programs that will demonstrate significant advances in 2 years, and create or preserve jobs (with emphasis on supporting new and early-stage investigators). The Institute will participate in the following NIH-wide ARRA programs:

- Payline Expansion—to increase the number of R01s and R21s awarded by expanding FY 2008 and FY 2009 paylines.
- Administrative Supplements—to provide an increment in funding to support research that is within the original scope of an active research grant. The NHLBI plans to award administrative supplements to support:
  - research employment opportunities on R01s and R21s for new full-time-equivalent employees who are pre-doctoral students, postdoctoral trainees or fellows, or recent college or master's degree graduates. Priority will be given to applications submitted by principal investigators who were qualified to receive their current awards as Early Stage Investigators or New Investigators.
  - summer research experiences for students and science educators.
  - diversity in health-related research.
  - re-entry into biomedical and behavioral research careers.
- Challenge Grants—to support high-impact research in topic areas that address specific scientific and health research challenges in biomedical and behavioral research that would benefit from significant 2-year jumpstart funds.
- Grand Opportunity (GO) Grants—to support high-impact, large-scale research on well-defined, priority topics that would benefit from a significant amount of 2-year funds. Research supported by "GO" grants should provide a high short-term return and offer a high likelihood of enabling growth and investment in biomedical research and development, public health, and health care delivery.
- New Faculty Recruitment to Enhance Research Capacity program—to enable U.S. academic institutions to augment or expand their biomedical research efforts by hiring newly-independent investigators and providing them with appropriate start-up packages and the resources needed to develop pilot research projects.
- Summer Jobs in Research for Students and Teachers program—to engage students and educators in scientific research; funded with NIH OD ARRA funds.
- Small Business Programs:
  - Small Business Catalyst Awards for Accelerating Innovative Research—to accelerate innovation through high-risk, high-reward research with commercial potential; to attract new small businesses to the Phase I Small Business Innovation Research (SBIR) program and encourage pursuit of fresh research perspectives.
  - Biomedical Research, Development, and Growth to Spur the Acceleration of New Technologies Pilot Program—to address the funding gap between promising research and development (R&D) and commercialization by fostering "later stage" research activities and partnerships among a variety of R&D collaborators.
- Comparative Effectiveness Research—to support CER programs. The Federal Coordinating Council for Comparative Effectiveness Research was authorized by ARRA legislation to help coordinate research and guide investments in CER funded by ARRA.

To provide accountability and transparency, the NHLBI has tailored standard operating procedures to ensure that ARRA goals and requirements are met. In addition, grantees will be required to provide detailed quarterly budget reports (to be made publicly available at Recovery.gov) listing all ARRA-supported projects or activities with estimates of the number of jobs created or retained.

The NHLBI ARRA Web site provides additional information, guidelines for grantees, FAQs, and links to additional ARRA resources.

[To Top]

Council Nominations for Center for Scientific Review (CSR) Study Sections and NHLBI Review Committees

In response to a Council request in February 2009, the NHLBI developed the following proposed process to facilitate Council nominations of peer reviewers:

> **Nominations for NIH CSR study sections**: Prior to each Council meeting, Council members will be able to complete reviewer nomination forms via the Electronic Council Book. Forms will be downloaded and distributed to Institute staff. When CSR requests nominations, staff will forward recommendations to the Director, NHLBI, for submission to CSR.
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> **Nominations for the three NHLBI Chartered Review Committees (NHLBI Clinical Trials Review Committee; NHLBI Institutional Training Mechanism Review Committee; Heart, Lung, and Blood Program Project Review Committee):** Once a year, Council members will be able to complete reviewer nomination forms via the Electronic Council Book. Forms will be downloaded and distributed to committee Executive Secretaries, with subsequent decision by the Director, NHLBI. The NHLBI will apprise Council yearly as to which reviewers were selected.

Council concurred with the proposed process. Nomination forms will be available on the Electronic Council Book for the next Council meeting.

[To Top]

MERIT Award Program

The NHLBI Method To Extend Research in Time (MERIT) Award (R37) is intended to provide long-term research grant support to investigators whose research competency and productivity are distinctly superior and thus are likely to continue to perform in an outstanding manner. Investigators may not apply for a MERIT award; instead, they are selected by the NHLBI on the basis of their current grant applications and their present and past grant support. MERIT awards are made for up to 5 years, with the possibility of a 5-year extension.

Council members expressed concern about the process for selecting individuals for MERIT awards. To ensure selection of the most productive researchers, Council suggested initially screening a larger pool of candidates (by adjusting the percentile cut-off for eligibility) and providing for a Council review of all eligible candidates. The decision was made to provide Council a list of all eligible MERIT award nominees for FY 2009 (investigators with current applications within the 10th percentile would be considered) for review during closed session of the September 2009 Council meeting.

Because the process is under revision, no new MERIT nominations have been made as yet for FY 2009. However, FY 2009 MERIT extensions will be awarded under the existing review procedure.

[To Top]

NHLBI PUBLIC INTEREST ORGANIZATION (PIO) MEETING

Ms. Paula Polite, Council member and Manager of Quality Programs, Division of General Services, Memphis, Tennessee, reported on the 10th annual NHLBI PIO

meeting held June 8-9, 2009. She thanked the NHLBI and reported that participants continue to find the content of the meetings and opportunities for networking and meeting with NHLBI staff to be very beneficial. Ms. Polite noted that participants find the "Meet the NHLBI Staff" portion of the meeting especially helpful.

Dr. Nabel emphasized the importance of this event to the Institute and thanked Dr. Carl Roth, Associate Director for Scientific Program Operation, and his staff for organizing the meeting each year.

[To Top]

NHLBI CARDIOVASCULAR DISEASE (CVD) RISK FACTOR GUIDELINES: NEW DIRECTIONS

Dr. Sidney C. Smith, Jr., Professor of Medicine, University of North Carolina, and Senior Advisor for Cardiovascular Research Translation and Application, NHLBI, reported on progress in developing new NHLBI clinical guidelines for cardiovascular risk reduction. The activity addresses Challenge 3.3 of the Institute's Strategic Plan:

> "To promote the development and implementation of *evidence-based guidelines* in participation with individuals, professional and patient communities, and health care systems and to communicate research advances effectively to the public."

Current NHLBI CVD clinical guidelines focus on one specific risk factor (i.e., individual guidelines for hypertension, high blood cholesterol, and overweight/obesity). Based on stakeholder recommendations, the NHLBI decided to maintain and update its risk factor-specific guidelines, but also to develop new integrated CVD risk reduction guidelines to address more closely the "real world" clinical scenarios faced by individuals and clinicians.

The new NHLBI model for developing clinical guidelines:

- emphasizes user-identified needs (targeting stakeholders, especially primary care clinicians and patients/consumers in addition to cardiovascular specialists; being user-friendly; and providing concise, focused messages).
- considers implementation issues throughout the process.
- incorporates innovative informatics approaches and tools in guidelines development, knowledge gap analysis, implementation, and dissemination.
- fosters communities of practice, national and international, including the joint development and sharing of tools and resources.

Dr. Smith explained the guidelines development process, described the underlying IT infrastructure, and noted how the new Web-based approach is supporting collaboration. He emphasized the need for additional scientific evidence upon which to base clinical guidelines. See recent article co-authored by Dr. Smith (*JAMA*. 2009; 301:831-841).

The adult integrated CVD risk reduction guidelines are expected to be completed in 2011; the pediatric integrated cardiovascular risk reduction guidelines in 2009; and the individual risk factor guideline updates in 2010.

[To Top]

REPORT OF THE BOARD OF EXTERNAL EXPERTS AND INITIATIVES FOR FISCAL YEARS 2010 AND BEYOND

NHLBI staff presented 12 new initiatives, 7 renewals, and 3 requests by other ICs 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 BEE also considers ideas that are not developed to the level of an initiative, but does not rank them.

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 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

Initiative	Purpose
Advancing Glycosciences in Heart, Lung, and Blood Research with Resource Services, Training, and Career Development (U01), RFA	To provide critical research resources and services to advance the emerging discipline of glycosciences; and to build capacity through multidisciplinary training, creating a cadre of "scientifically-bilingual" investigators fluent in glycan chemistry and biology.
Cellular and Molecular Mechanisms of Arterial Stiffening and Its Relationship to Development of Hypertension (R01), RFA	To stimulate basic physiological, cellular, and molecular investigations to elucidate the underlying mechanisms that lead to arterial stiffening; to determine the relationship between arterial stiffening and the development of hypertension in animal models; and to identify new targets for therapeutic intervention to prevent or reverse arterial stiffening.
Directed Stem Cell Differentiation for Cell-Based Therapies for Heart, Lung, and Blood Diseases (R21, SBIR [R43/R44], STTR [R41/R42]; renewal), PA	To support research on the factors and mechanisms that control the differentiation of embryonic or adult stem or progenitor cells *in vitro* or *in vivo*.
Lung Tissue Research Consortium (renewal), RFP	To facilitate studies of pulmonary diseases by continuing the Lung Tissue Research Consortium, an NHLBI program for the standardized processing, storage, and distribution of lung tissues and associated clinical data.
Nutrition and Diet in the Causation, Prevention, and Management of Heart Failure (R01 and R21; renewal), PA	To stimulate research on the role of nutrition and diet in the causation, prevention, and treatment of cardiomyopathies and heart failure. The overall goal is to develop a satisfactory science base for nutritional management of patients in various stages of heart failure and development of preventive approaches for high-risk individuals.
Systems Biology Approach to the	To investigate the mechanisms of latency and the reactivation of tuberculosis in the host using

Mechanisms of Tuberculosis Latency and Reactivation (R01), **RFA**	collaborative systems biology approaches based primarily on human studies.
Next Generation Association Studies (U01), **RFA**	To support technology development and implementation with the goal of adding a functional dimension to genome-wide association studies by combining cellular reprogramming strategies with molecular profiling, followed by integrating the resultant information with existing genotypic data to determine how naturally occurring human genetic variation influences the activities of biological networks in cell-based models of disease.

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

Initiative	Purpose
Atherosclerosis Risk in Communities (ARIC) Study (contract; renewal), **RFP**	To expand upon the resources of data, specimens, and infrastructure developed over 20 years of ARIC by re-examining and continuing follow-up of the aging ARIC cohort; continuing community surveillance to support research on long-term trends in coronary heart disease and heart failure; enhancing both the cohort and community components with cardiovascular outcomes research to assess quality and outcomes of medical care for heart failure and heart failure risk factors; and providing a population laboratory platform for ancillary studies, training for new investigators, and data sharing.
Cross Organ Mechanism-Associated Phenotypes for Genetic Analyses of Heart, Lung, Blood, and Sleep Diseases (U01), **RFA**	To define an accumulating set of mechanism-associated traits that cross organ systems based upon evolving knowledge of biological and molecular networks to improve phenotyping of individuals for genetic research studies.
Functional Modeling of the Upper Airway (R01), **RFA**	To identify control points of airflow limitation over the course of normal and abnormal development of the upper airways.
In Vivo Detection of Atrial Fibrosis (R01), **RFA**	To develop non-invasive methods to detect, localize, and assess atrial fibrosis *in vivo* to facilitate advances in the prevention and treatment of atrial fibrillation.
Lung Transplantation: Planning Grants for Clinical Trials of Novel Therapies (R34), **RFA**	To foster development of cutting-edge clinical trials, establish information about available patient populations, and support investigator commitment to testing new efficacious interventions for reducing complications after allograft lung transplantation in patients with chronic respiratory disease.
National Registry of Genetically Triggered Thoracic Aortic Aneurysms and Other Cardiovascular Conditions (GenTAC) (renewal), **RFP**	To optimize the value and effectiveness of the NHLBI-supported GenTAC Registry. The renewal will enrich datasets by collecting longitudinal follow-up data; improve data quality by the addition of an Imaging Core; promote access and use of the Registry; and continue limited, new enrollment to enrich the cohort with subgroups of high scientific interest.
New Strategies for Growing 3D Tissues (R01/R21), **RFA**	To improve understanding of how cells respond to their environment and to develop accurate assays and methods that may instruct the creation of 3D engineered cellular aggregates. Multidisciplinary investigations are needed to demonstrate reproducible recapitulation in the laboratory for events such as differentiation, proliferation, and senescence for tissue repair and regeneration relevant to heart, lung, and blood diseases.
Summer Institute Program to Increase Diversity in Health-related Research (R25, renewal), **RFA**	To renew a highly successful Summer Institute Program to increase diversity in the study of heart, lung, blood, and sleep disorders; to improve the recruitment and retention of junior faculty from disabled and underrepresented minority groups.
Women's Health Initiative (WHI)(renewal), **RFP**	To use the large WHI cohort to launch the next generation of important cardiovascular research projects that target older women; to study heart failure, atrial fibrillation, venous thrombo-embolism, coronary heart disease, and stroke in African American, Hispanic, and white women.

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

Initiative	Purpose
Innovators in Hemoglobinopathies Care Career Development Award (K07), **RFA**	To build additional research investigator capacity by developing a new core group of clinical investigators for multicenter studies in hemoglobinopathies that can address important questions about patient management and translation of research results into practice through the use of multidisciplinary teams.
Reducing CVD Risk through Treatment of Obstructive Sleep Apnea (U34), **RFA**	To support two randomized controlled trials and a protocol review committee via the Clinical Trial Planning Grant Program Cooperative Agreement mechanism (U34) in order to acquire preliminary,

	critical information necessary for designing a Phase III clinical trial to test whether positive airway pressure treatment of obstructive sleep apnea reduces cardiovascular events.
Effectiveness Research on Smoking Cessation in Hospitalized Patients (R01, R18), **RFA**	To determine how to translate efficacious smoking cessation interventions into effective programs for implementation in routine clinical care, and to assess their cost effectiveness.

Requests for Secondary Support

Initiative	Purpose
VITamin D and OmegA-3 TriaL (VITAL) [NCI]	To determine whether daily supplements of vitamin D or marine omega-3 fatty acids (eicosapentaenoic acid [EPA] + docosahexaenoic acid [DHA]) supplements will prevent the development of cardiovascular disease in middle-age and elderly adults without clinical CVD. (The full trial will also test whether the interventions reduce the risk of cancer.)
Health Behaviors in School-Age Children – A Longitudinal Study [NICHD]	To collect longitudinal data on individuals in a nationally representative sample supported by the NICHD, in order to characterize the developmental changes in CVD-related risk factors and behaviors in older adolescents (15-18 years) as they become young adults; improve understanding of the etiology, determinants, and influences on adolescents' diets, physical activity, obesity, and CVD risk; and provide information to guide preventive programs.
The Testosterone Trial – Cardiovascular and Metabolic Risk Trial [NIA]	To test whether testosterone treatment for one year in elderly men with low serum testosterone concentration (100 -250 ng/dL) and signs and symptoms that could be due to low testosterone improves their cardiovascular risk profile more than placebo and results in a smaller increase in coronary artery plaque volume (as evaluated by coronary computed tomography angiography).