Minutes from the Working Group on Future Research Opportunities in the Multi-Ethnic Study of Atherosclerosis (MESA) can be accessed by going to the following website: http://www.nhlbi.nih.gov/meetings/workshops/mesawg.htm

Working Group on Future Research Opportunities in Multi-Ethnic Study of Atherosclerosis (MESA)

Hyatt Regency Bethesda
March 5, 2007

Welcome and Charge

Dr. Newman stated that the charge was to recommend areas of research that MESA can uniquely address during a continuation, based on knowledge of the field and an understanding of the resource that MESA has created and to provide some level of ranking of research ideas presented.

Background information about MESA

Dr. Bild presented a brief overview of the study, referring to the binder of materials that had been distributed, including the following:

- Original MESA Objective – To identify determinants of progression of subclinical to clinical cardiovascular disease (CVD)
- Cohort characteristics – age, gender, and ethnicity distribution and no prevalent CVD at baseline
- Subclinical CVD measures, including measures available to analyze progression
- Ancillary studies – 48 funded, many pending, in a wide range of disciplines
- Resources created -- a large data set and repository of blood and urine samples and DNA
- Publications – listing and selected reprints

NHLBI Strategic Plan

Dr. Bild reviewed the NHLBI Strategic Plan, including the process that led to the penultimate plan that was presented to the NHBL Advisory Council in February. She gave an overview of the three major goals and eight strategies in the plan and highlighted language relevant to goals and opportunities in MESA. These include:

- Delineate normal and pathologic mechanisms (e.g., identify biomarkers and characterize role)
- Enhance transmission of knowledge between basic and clinical arenas
- Identify key genetic variants, integrate phenotype and genotype data, and identify gene-environment interactions
- Study disease across the life span
- Develop approaches for risk stratification and their application and identify possible prevention strategies
- Advance personalized medicine, including provide environmental context
- Develop more precise measures of environmental exposures and more robust definitions of phenotypes
- Identify cost-effective approaches to prevention, diagnosis, and treatment
- Enhance understanding of the contributions of individual and societal factors in health disparities
- Support data-sharing

Strategies outlined in the Strategic Plan that align with MESA's strategies include:

- Enhance interdisciplinary work
- Increase the return from NHLBI population-based and outcomes research
- Support multi-disciplinary teams
- Develop and retain human capital – particularly by serving as a training ground for young investigators

Investigator Presentations

Dr. Burke -- Predictive value of subclinical CVD measures. He presented data on the predictive value of MR-measured LV mass for heart failure and coronary calcium for coronary heart disease events, on predictors of progression of coronary calcium, and on changes in risk factors observed in the cohort. He emphasized the opportunities that would be made available by the accrual of more clinical events, including the conduct of subgroup analyses, identification of risk factors and subclinical disease measures that could be further investigated for their potential to prevent onset of clinical disease, identification of strategies to better identify intermediate risk groups, and the observation of whether there are differences across age, gender, and ethnic groups.

Dr. Lima -- Cardiac MRI measures of LV structure and function in MESA. He acknowledged his many collaborators, including trainees and junior investigators from the departments of Radiology, Cardiology, and School of Hygiene. He described the methods for measuring regional wall function, which is now considered the gold standard. In MESA, approximately 5000 participants had traditional MRI measures of LV mass, volume, and function. Approximately 2000 participants underwent an MRI tagging study using HARP methodology to quantify regional myocardial function. The primary measure of function analyzed is circumferential strain, though many other measures are also available. He reviewed several MESA findings, including associations of strain with smoking, blood pressure, carotid IMT, ethnicity (worse in African Americans than other groups), and gender (worse in men than women). After 4 years of follow-up, heart failure events in MESA (n=78) mimic the pattern by ethnicity observed for circumferential strain: most events occurred in African Americans and fewest in Chinese. Finally, he showed preliminary data indicating that diabetes is associated with worsening function over time.

Drs. Arnett and Divers -- Ancestral informative markers (AIMs) and self-reported ethnicity and LV mass. LVH phenotype varies among ethnicities, including size and remodeling. There is strong evidence from previous studies that there is a genetic component, with heritabilities of 30-60%. Principal component analysis of AIMs shows a distinct cluster for Chinese, less homogeneous clusters for whites and African Americans, and the greatest heterogeneity among Hispanics, with substantial overlap with the white and African American groups. Self-reported ethnicity and assigned ethnicity agreed well for African Americans and whites, but there was poor agreement among Hispanics. The principal component analysis removes the genetic background effect on LV mass and LV ejection fraction in epidemiologic and genetic studies. This method provides results that are similar to what we observe when the ancestry proportion estimates are used as control variables.

The investigators departed, with thanks from the Working Group members and NHLBI Project Office.

Plans for Renewal (MESA II)

Dr. Bild presented the plans for study renewal, including the general framework – cohort surveillance through 2014-15 and an Exam 5 in 2010-11. The cohort is projected to include 5,200 participants (90% of surviving participants), with an age range 54-93, and with a slightly altered ethnic composition based on current drop-out experience (43% white, 26% African American, 20% Hispanic, and 11% Chinese).

She presented the four proposed "anchoring" objectives, as well as other possible research areas, and invited the

Working Group to provide feedback and additional suggestions. The four objectives include

1. To identify factors related to progression of subclinical to clinical CVD
2. To identify predictors of decline in ventricular function
3. To provide a platform for in-depth studies in CVD and other areas
4. To determine the basis for racial/ethnic differences in CVD

Noting that large observational cohort studies are able to address many objectives simultaneously, she provided a list of other research areas that could be addressed, including the following:

- Unrecognized MI
- Diabetes and glucose intolerance
- Renal function (estimates of glomerular filtration and albuminuria)
- Cognitive function
- Sleep disorders
- Right ventricular function
- Pulmonary function
- Carotid atheroma
- Coronary disease (CT angiography)
- Peripheral vascular disease
- Genetics and gene X environment interactions
- Proteomics
- Metabolomics (using fresh blood)
- Changes in diet, physical activity, and environmental factors
- Retinal vessels and disease

She presented data that address the feasibility of observing meaningful change in LV function over time, including cross-sectional data that show measurable differences in regional strain measures associated with risk factors and the projected number of expected new clinical heart failure cases: 300 by 2010. If regional dysfunction precedes clinical heart failure and represents the tip of the iceberg, then many more cases of significant dysfunction will be able to be identified. She also referred back to Dr. Lima's presentation, which demonstrated measurable changes in strain over 4 years.

She presented the proposed timeline and noted that MESA Air is planning to repeat coronary calcium and carotid IMT measures in half the cohort in 2010 in conjunction with a MESA Exam 5. Finally, she described the process for further review of the MESA initiative by the NHLB Advisory Council, and the subsequent review and acquisition process, if the initiative is approved. RFPs specify the statement of work, while the researchers' proposals provide details about how the work would be performed, along with all relevant technical information. There is a period of protocol development after awards are made.

Discussion by Working Group

The Working Group acknowledged that MESA is unique because of its multiple ethnic groups and precise characterization of subclinical CVD. The Group endorsed the four main objectives as presented, including continued evaluation of the predictive value of subclinical CVD and other measures and studying the natural history and predictors of change in left ventricular function and development of heart failure. They also stated that providing a platform for additional in-depth studies and evaluating variation by race/ethnicity were important features of MESA. The Working Group discussed the proposed research areas and suggested others. While there was not enough time for a detailed discussion of all possible components and priorities the following feedback and approximate priorities were provided.

Highest priority:

- Continue surveillance for clinical CVD events in order to take advantage of the data that have been collected and allow research questions related to progression of and predictive value of subclinical disease measures and other measures in important subgroups, including age, ethnicity, and gender, to be addressed.

High priority:

- Perform repeat cardiac MRI on the entire available cohort, including tagging to measure regional dysfunction, to allow the study of change over time. Tagging would also allow excellent study of diastolic function.
- Perform gadolinium enhancement to identify unrecognized myocardial infarction.
- Perform echocardiography in a subset to compare its clinical utility with MRI.
- Measure serum brain natriuretic peptide (BNP) as a predictor of HF.
- Perform studies to characterize sleep, including actigraphy (to measure sleep duration), oximetry (to measure blood oxygen desaturation), and sleep-disordered breathing. MESA could fill in gaps not addressed by the Sleep Heart Health Study, including evaluating sleep and nocturnal hypoxemia in relation to heart failure.
- Measure physical functioning as it relates subclinical cardiovascular disease.
- Perform brain MRI to identify lacunar strokes, white matter disease, and other abnormalities as objective measures of brain pathology as related to subclinical cardiovascular disease. It was noted that vascular disease of the brain is as important as vascular disease of the heart in elderly people.
- Assess cognitive function (a 30-minute assessment was recommended) to relate cross-sectionally or retrospectively to other data and as a baseline for possible future measures. Include an assessment of depression and executive functioning. Test performance may be influenced by culture or education; attention should be paid to this when selecting tests. The most useful design is to obtain change over time in individuals.
- Re-evaluate diet, physical activity, and other environmental factors.

Enthusiasm also expressed:

- Repeat coronary calcium measurement in the entire cohort.
- In conjunction with coronary calcium measurement, CT angiography in a subset (perhaps 50%) to identify and quantify non-calcified plaque. Coronary calcium measurement may be particularly valuable in women, who develop it later than men. Consider comparing participants who undergo CTA to those who do not to gain an understanding of the clinical impact of the measurement itself. There was much discussion about CTA with a wide range of level of enthusiasm and caution expressed about the risk of iodine-contrast agent-induced renal failure and anaphylaxis, difficulty handling clinically significant findings (without some relevant guidelines being in place), and interfering with the natural history of atherosclerosis.
- Measure visceral adiposity and liver fat from CT or MRI of the abdomen.
- Re-evaluate carotid plaque characteristics with MRI.
- Measure hemodynamics, such as vascular compliance or stiffness.
- Perform electrocardiogram.
- Measure ankle-brachial index.
- Include provocative testing, such as with a simple exercise test.
- Evaluate renal function.

Other comments:

- Study whether further evaluation of the “intermediate risk” group can enhance risk prediction.
- Determine which tests for subclinical disease assessment might be useful clinically.
- Gadolinium used for carotid MR imaging has had good acceptance in the MESA substudy and in an ancillary study and in the Icelandic Heart Study. However, there are recent reports of dermopathy in renal failure patients.
- Speed up events investigations to take better advantage of these data.
- Prepare for changes in CT (e.g., 128- and 256-slice scanners) and MRI technology (e.g., 3 Tesla magnets).
- Genetics is a currently active area in MESA and will continue to be so; additional phenotyping will enhance the value of the genetics studies.
- Ascertainment and definitions of heart failure should be carefully considered.
- Consider PET scanning in a substudy (though concern was expressed about radiation).
- Future MRI may be able to assess non-ischemic fibrosis in heart failure without gadolinium.
- Getting good measures of diastolic dysfunction will allow the study of questions of why some people with diastolic dysfunction become symptomatic and some do not.
- MR of the head could include upper airway images.
- Include costs in the renewal for sharing of images.
- Perform whole genome amplification to assure an abundant supply of DNA.
- Consider the value of follow-up after Exam 5 to evaluate how Exam 5 measures relate to subsequent outcomes and change, particularly in cognition. (The current plan for renewal has 3 years of surveillance after Exam 5.)

Drs. Newman and Bild thanked the Working Group members for their valuable time and contributions.

Working Group Members:

- Anne Newman, MD, MPH (Chair)
- Andrew Arai, MD
- Richard Devereux, MD
- Zahi Fayad, PhD
- Robert Hart, MD

- Ray Hershberger, MD
- Lenore Launer, PhD
- Barrie Massie, MD
- Christopher O'Donnell, MD
- Stuart Quan, MD
- George Mensah, MD

NHLBI Staff:

- Diane Bild, MD, MPH
- Paul Einhorn, MD
- Lawrence Fine, MD
- Jane Harman, DVM, PhD
- Hanyu Ni, PhD
- Jean Olson, MD, MPH
- Charlotte Pratt, PhD
- Jacques Rossouw, MD
- Peter Savage, MD
- Denise Simons-Morton, MD, PhD
- Paul Sorlie, PhD
- Gina Wei, MD
- Colin Wu, PhD

MESA Investigators:

- Donna Arnett, PhD
- Gregory Burke, MD, MS
- Jasmin Divers, PhD
- João Lima, MD

NATIONAL HEART, LUNG, AND BLOOD ADVISORY COUNCIL

MEETING MINUTES
June 5, 2007

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

Dr. Elizabeth G. Nabel, Director of the National Heart, Lung, and Blood Institute (NHLBI), welcomed members to the 226th meeting of the National Heart, Lung, and Blood Advisory Council (NHLBAC).

Member Updates:

Dr. Nabel introduced the new Council members:

- Joe Garcia, M.D., Professor and Chair, Department of Medicine, University of Chicago
- Rao Musunuru, M.D., President of Bayonet Point/Hudson Cardiology Associates, Hudson, Florida
- Jeanine Arden Ornt, J.D., Vice President and General Counsel, Case Western Reserve University
- Paula Polite, Manager of Quality Programs for the City of Memphis, Tennessee; and Founder and Past President of the Sarcoidosis Research Institute
- Steven Shapiro, M.D., Jack D. Myers Professor and Chair, Department of Medicine, University of Pittsburgh
- Shaun Coughlin, M.D., Ph.D., Director, Cardiovascular Research Institute, University of California, San Francisco (not in attendance)

New Staff:

Dr. Nabel welcomed Dr. Michael S. Lauer, who has accepted the position of Director of the Institute's Division of Prevention and Population Sciences (DPPS), effective July 1, 2007. Dr. Lauer is currently Director of the Cleveland Clinic Foundation Exercise Laboratory; Vice-Chair of the Clinic's Institutional Review Board; Professor of Medicine, Epidemiology, and Biostatistics at the Cleveland Clinic Lerner College of Medicine of Case Western Reserve University; and a Contributing Editor of the Journal of the American Medical Association. A leader in the cardiovascular community, Dr. Lauer has an exceptionally strong background in cardiovascular epidemiology and medical research.

Dr. Nabel announced several other changes in personnel:

- Dr. Diane Bild has accepted the position of Deputy Director of DPPS. (She is currently the Acting Deputy Director.) In addition to her new duties, Dr. Bild will continue to manage the Multi-Ethnic Study of Atherosclerosis (MESA).
- Dr. Denise Simons-Morton has accepted the position of Senior Scientific Advisor to the Director of DPPS. (She is currently Chief of the Clinical Applications and Prevention Branch in DPPS.) In her new position, Dr. Simons-Morton will focus on the development of clinical trials to identify practical, effective disease prevention methods; cross-cutting obesity research issues; and the translation of research results into practice.
- Dr. Peter Savage, currently Acting Director of DPPS, will join the Office of the Director, NHLBI, as the Special Assistant for Clinical Research. Dr. Savage will work with the Institute's leadership to strengthen oversight and support of the Institute's clinical research program.

Dr. Nabel also announced two departures from the Institute:

- Dr. Charles Friedman, who established the Institute's Center for Research Informatics and Information Technology, has joined the Office of the Secretary, DHHS. Mr. Ralph Van Wey is currently serving as Acting Director of the Center.
- Dr. Carol Vreim, Deputy Director of the Division of Lung Diseases since 1995, will be retiring in August. Dr. Vreim has been an outstanding role model of scientific and administrative excellence since joining the Institute in 1976.

Invited Guests:

Dr. Nabel introduced Mr. Marc Smolonsky, Associate Director for Legislative Policy and Analysis, NIH

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

The Council was reminded that according to Public Law 92-463, the Federal Advisory Committee Act, the meeting of the NHLBAC would be open to the public except during consideration of grant applications. A notice of this meeting was

published in the *Federal Register* indicating that it would start at 8:30 a.m. and remain open until approximately 12:00 p.m. Dr. Nabel 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 DIRECTOR - Dr. Elizabeth G. Nabel

Budget Report:

Dr. Nabel reviewed the Institute's budget. The FY 2008 President's Budget is $2,925,413,000, an increase of only $6,605,000 (0.23 percent) over the FY 2007 Continuing Resolution (upon which the FY 2008 President's Budget was built). The extramural portion of the Institute's FY 2008 President's Budget comprises: research project grants (74.8 percent); contracts (11.2 percent); centers (5.4 percent); career grants (2.9 percent); training grants (3.4 percent); other (2.2 percent).

The FY 2007 Joint Resolution (the amount the NHLBI actually received) is $2,919,980,000 — $1,172,000 more than the Continuing Resolution. In addition, the NHLBI had another $35 million to work with since it was no longer required to contribute to the Common Fund (i.e., NIH Roadmap activities) from its own appropriation. (The overall FY 2007 Joint Resolution provided funds specifically for the support of the Common Fund so that individual Institutes/Centers were no longer required to contribute from their own appropriations.)

Dr. Nabel assured the Council that the Institute intends to maintain its commitment to investigator-initiated research and to its training programs during these tight budgetary times, and will continue to seek the advice of Council on such matters.

Updates:

Dr. Nabel updated the Council on two programs:

- The NHLBI is establishing a Registry of Angioplasty Registries (ROAR) to increase understanding about the rate of subacute thrombosis for both drug-eluting and bare metal stents, the predisposing factors for the thrombotic events, and ways to reduce the risks of them. The program has been announced in the Federal Business Opportunities, and the Request for Proposals (RFP) is expected to be released soon.
- The NHLBI is planning to co-sponsor, with the National Cancer Institute, part of the NIH Genes, Environment, and Health Initiative that was announced in February 2006.

NHLBI Stragetic Plan:

The NHLBI Strategic Plan — a version for scientific audiences, as well as a summary brochure for public audiences — is being printed. The plan will be distributed widely to scientific groups, professional organizations, public interest groups, and the Congress.

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IV. NIH REAUTHORIZATION – Mr. Mark Smolonsky

Mr. Marc Smolonsky, Associate Director for Legislative Policy and Analysis, NIH, discussed the NIH Reform Act of 2006 that reauthorized the NIH. The Act includes several provisions to enhance management of the NIH, including establishment of a new Division of Program Coordination, Planning, and Strategic Initiatives within the NIH Office of the Director to identify and report on areas that would benefit from trans-NIH research. It also establishes a Common Fund to pay for such research. The Act requires establishing "... an electronic system to uniformly code research grants and activities ..." (The NIH Research, Condition, and Disease Categorization system, described below, responds to this requirement.) The Act also establishes a scientific process for recommending and making future organizational changes at the NIH.

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V. NIH RESEARCH, CONDITION, AND DISEASE CATEGORIZATION (RCDC) – Dr. Carl Roth

Dr. Carl Roth, Director of the Office of Science Technology, NHLBI, described the NIH RCDC initiative, an NIH-wide effort to improve access to, and reporting on, the NIH research portfolio. Each year the NIH reports to the Congress and the public on how much it spends in approximately 360 research and disease areas. The NIH reports are obtained by aggregating the reports of the individual Institutes/Centers (ICs), even though the ICs currently use inconsistent reporting methodologies.

In the RCDC system, an area to be reported on is summarized in a category "fingerprint" - a list of relevant concepts (with weights to reflect their relative importance) that have been selected by NIH scientific experts to define a research category. Similarly constructed project fingerprints are compared (using an algorithm) with the category fingerprints to determine which individual projects are reported within a category.

The RCDC system is expected to provide consistency, transparency, and efficiency to the NIH reporting process. Recognizing that there is no such thing as "100 percent accuracy," the system represents a significant improvement over the status quo. Reports using the RCDC system will begin in FY 2008 and will almost certainly produce different total dollar amounts for categories than previously reported by the NIH.

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

The Board of External Experts (BEE) is a newly constituted advisory working group to the NHLBI Council. It is charged with implementing the NHLBI Strategic Plan, discussing and prioritizing program ideas and potential initiatives, serving as an incubator for new ideas and recommendations, recommending improvements in the Institute's business operations, and providing advice on a program's effectiveness.

The BEE met on June 1, 2007 and discussed implementation of the NHLBI Strategic Plan. Dr. Nabel summarized the BEE's recommendations and Council members offered additional ideas.

The BEE also discussed the future of the Institute's Specialized Centers of Clinically Oriented Research (SCCORs) and Clinical Research Networks (CRNs). Noting opportunities for synergy, the BEE suggested redesigning SCCORs to support early translational research that could feed into CRNs. Dr. Nabel noted that the Institute plans to further discuss this along with other related ideas with the Council.

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

NHLBI staff presented 13 new initiatives, which were reviewed and ranked by the BEE. The Council was supportive of the initiatives, but made a number of specific recommendations for consideration prior to their release. Dr. Nabel 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.

Deep Vein Thrombosis and Venous Disease **, RFA**

To support basic and clinical research on venous thrombotic diseases, with emphasis on sharing resources to improve diagnosis, therapy, and prevention; and to collaborate with the Center for Disease Control and Prevention (CDC) and its ongoing Thrombosis and Hemostasis Program.

Council recommended this initiative.

Mechanisms and Management of Cardiovascular and Metabolic Complications of HIV/AIDS **, RFA**

To elucidate the underlying mechanisms of, and to identify treatment strategies and interventional approaches for, cardiovascular risk in individuals with HIV infection who are on Highly Active Antiretroviral Therapy (HAART).

Council recommended this initiative.

Metabolomics of the Respiratory System in Health and Disease **, RFA**

To apply metabolomics approaches to the study of the respiratory system.

Council considered this area of research to be very important, but suggested considering combining with the Molecular Phenotypes for Lung Diseases initiative.

Molecular Phenotypes for Lung Diseases **, RFA**

To re-define major categories of lung diseases using molecular phenotypes, a critical step toward the development of personalized and pre-emptive approaches to Pulmonary medicine.

Council recommended this initiative.

Pediatric Hydroxyurea Phase III Clinical Trial (BABY HUG) Follow-Up Study **, RFP**

To provide structured follow-up of the participants in the original BABY HUG treatment study, in order to characterize the long-term benefits and toxicities associated with initiation of hydroxyurea treatment at an early age.

Council recommended this initiative.

Pilot and Pre-Test of Acute Coronary Syndrome Module for the National Hospital Discharge Survey (Interagency Agreement) **,RFA**

To obtain improved national estimates of the annual incidence and in-hospital care patterns of acute coronary syndrome.

Council recommended this initiative.

Prevention of Atherosclerotic Cardiovascular Events Trial **, RFP**

To conduct a randomized clinical trial in older patients to assess the clinical benefit of enhanced low density lipoprotein cholesterol (LDL-C) lowering compared to current guideline-based therapy.

Council recommended this initiative.

Systolic Blood Pressure Intervention Trial (SPRINT) **, RFP**

To conduct a multicenter randomized trial to determine whether treating systolic blood pressure to a lower goal than currently recommended will reduce cardiovascular disease.

Council recommended this initiative and recommended a partnership with PhRMA.

Targeted Approaches to Weight Control for Young Adults **, RFA**

To support 4 to 5 studies to develop and test promising, innovative intervention approaches for weight loss and/or prevention of further weight gain in young adults.

Council recommended this initiative.

Biorepository and Limited Access Data Set Information Coordinating Center **, RFP**

To establish an Information Coordinating Center that will develop and maintain an administrative and data management infrastructure to facilitate access to two valuable NHLBI scientific resources, the Biological Specimen Repository and the Limited Access Data Set programs.

Council recommended this initiative.

Cardiovascular Health Study (CHS) - Transition Phase Renewal **, RFP**

To maintain the CHS infrastructure for continued access to study resources (including DNA) and expertise, and to support scientific collaborations and mentorship of early-career investigators.

Council recommended this initiative.

Coronary Artery Risk Development in Young Adults (CARDIA) Study - Renewal **, RFP**

CARDIA will capitalize upon two decades of study by conducting an examination of data and stored specimens collected throughout young adulthood to study the impact of traditional and novel risk factors on the development of subclinical abnormalities in mid-life.

Council recommended this initiative.

Multi-Ethnic Study of Atherosclerosis (MESA) - Renewal **, RFP**

To continue to study the MESA cohort to capitalize and expand upon the resources of data, samples, and infrastructure that have been developed over 10 years.

Council recommended this initiative.

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).

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.

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VIII. REVIEW OF APPLICATION

The Council considered 1,143 applications requesting $1,512,657,417 in total direct costs. The Council recommended 1,141 applications with total direct costs of $1,498,891,712. A summary of applications by activity code may be found in Attachment B.

ADJOURNMENT

The meeting was adjourned at 3:30 p.m. on June 5, 2007.