

MINUTES
Observational Study Monitoring Board
for the Jackson Heart Study, April 25-26, 2010 Meeting
Jackson, Mississippi

PARTICIPANTS:

OSMB Members Present: Gary Bennett, Trudy Burns, Mark Espeland, Paula Johnson (via phone), Shiriki Kumanyika (Chair), Warren Manning, Philip Wolf, Jackson Wright

OSMB Member Absent: Elizabeth Ofili

Jackson Heart Study Investigators: E. Meggie Akyzbekova, Michael Griswold, Francis Henderson, Solomon Musani, Asoka Srinivasan, Mario Sims, Solomon Musani Daniel Sarpong, Herman Taylor (Principal Investigator)

NHLBI Staff: Jane Harman, Cheryl Nelson (Project Officer), Lorraine Silsbee (Executive Secretary), Evelyn Walker

NCMHD Staff: Irene Dankwa-Mullan

STUDY DESCRIPTION: The Jackson Heart Study (JHS) is an investigation of causes of CVD in a population of African-American men and women from Jackson, MS. It was established in 1998 by the NHLBI with co-funding from the National Center on Minority Health and Health Disparities (NCMHD), building upon the success of the ARIC study's Jackson, MS, Field Center, in place since 1985. A cohort of 5,301 participants completed the baseline Exam in 2000-04 and Exam 3 is now in progress. The JHS is a collaboration between Jackson State University, Tougaloo College, the University of Mississippi Medical Center, and an NHLBI field site collaborating with the Jackson-area institutions.

MEETING LOCATION: This meeting was held in Jackson, MS to provide the OSMB an opportunity to briefly tour Jackson State University, Tougaloo College, the University of Mississippi Medical Center's MRI data acquisition site, and the JHS clinical exam center the morning of April 26, 2010.

CLOSED SESSION: Dr. Kumanyika convened the closed session of this regularly scheduled annual meeting on April 25, 2010 at 7:00 p.m. The minutes from the April 27, 2009 meeting were approved. The Executive Secretary confirmed that OSMB members had no new conflict of interest issues to report. The Board reviewed the investigators' report to the OSMB and discussed deficiencies in its data management report and responses to recommendations. Immediately following the closed session, a request from the Board was relayed to the investigators that identified specific deficiencies to be addressed at the following day's open session.

The Project Officer, Cheryl Nelson, described the current status of the study. Significant improvements in scientific productivity and "journal impact factors" for 2009 publications were noted. The closed session adjourned at 8:45 p.m.

OPEN SESSION: The open session began at 12:30 p.m. on April 26, 2010.

RESPONSES TO 2009 RECOMMENDATIONS: Though a number of the 2009 recommendations were adequately addressed by the investigators, important questions remain as detailed in the recommendations below. For example, the Board commented that there were no power calculations to determine any effects weaker than that of gender difference on coronary artery calcium and visceral adiposity. There were questions related to quality control of laboratory specimens in light of poor repeatability between paired samples.

STUDY PROGRESS: Scientific progress includes 17 publications in 2009, which exceeded the set benchmark of 12 publications. Twelve abstracts were presented at the 2010 American Heart Association Conference on Epidemiology and Prevention. Visit 3, which began in late February 2009, has 1,223 exams completed through April, 2010. To meet the recruitment goal of 4,242 examinations (85% of surviving cohort), an average of 27 examinations per week is needed. The CT scan component was implemented during Exam 2 in May 2007 and ended during Exam 3 in February 2010. CT scans were completed on 2,928 (97%) of the revised target of 3,000 participants. During Exam 3, cardiac MRI scans are being performed on a random sample subset of 2,500 participants, with gadolinium contrast medium to identify silent myocardial infarctions in a subset of 650 participants. No MRI studies were done from December 2009 until mid-April 2010, due to a staffing shortage at the MRI Data Acquisition Center. To reach the goal of 2,500 completed scans by May 2010, 20 or more MRI studies per week need to be conducted. Because of delays, the Board expressed concern that the MRI component will not reach its goal.

The Board encouraged the investigators to finalize the subcontract for heart failure adjudication with UNC Chapel Hill as soon as possible. An estimated 6 months will be required to complete the backlog of abstracted inpatient heart failure events once the contract is in place.

The Tougaloo Education and Training Center reported that 47 students are participating in JHS Scholars program out of 48 funded slots. The past predominantly female enrollment has been balanced out with an increase of male students this year. A very successful math enhancement program has helped retain students; through collaboration with Brown University, a dual degree undergraduate/MPH program has recently been established.

PRESENTATIONS: There were three scientific presentations: 1) *Advancing the hypothesis that place contributes to health*; 2) *Triglyceride-HDL cholesterol ratio fails to predict insulin resistance in African American women*; and 3) *Pericardial adipose tissue and CVD risk*.

RECOMMENDATIONS: The Board convened in closed session with NHLBI Staff at 4:45 p.m. on April 26, 2010 and adjourned at 5:15 p.m. The Board unanimously agreed the study has made important progress and should continue. The members complimented the investigators on the increase in scientific productivity and continued success of the JHS Scholars Program. The Board expressed concern regarding the Data Management and Quality Control reports and lack of confidence in the adequacy of the study's application of standard procedures for overseeing data quality. Recommendations follow and specific details regarding these recommendations will be provided to the Jackson Heart Study by the NHLBI Project Office.

1. **Follow-up Metrics and Event Rates**
 - a. Implement measures of follow-up and event rates.

2. **Data Management and Quality Control**
 - a. Strengthen/clarify the quality control process by establishing schedules for generation and review of quality control data and reports by August 15, 2010.
 - b. Conduct an external review of quality control operations by an individual suggested by NHLBI and provide a report to the OSMB by August 15, 2010.
 - c. Develop a set of standardized table shells for QC reports by August 15, 2010.
3. **Data Reports and Data Distribution (August 15, except item a)**
 - a. Within six months, propose a set of standardized table shells for reports provided to the OSMB. Tables will include tracking numbers of missed annual interview and true lost to follow-up
 - b. Develop a description of informed consent tiers and provide the number of individuals in each tier, and description of the participants in each tier.
 - c. Provide notation within the data files to flag protocol deviations or other considerations that might enter into analyses.
 - d. For primary outcome papers, develop a plan for data verification and documentation of final analyses prior to publication.
4. **Adverse Events (August 15, 2010)**
 - a. Provide a report of adverse events for Visit 3 to the OSMB within 3 months.
5. **Genetic Data Update (August 15, 2010)**
 - a. Provide a summary of the following: 1) status of microsatellite data cleaning and availability to internal and external investigators for use in analyzing Exam 1 data; and 2) status of identity by descent (IBD) data for family members and availability to internal and external investigators for use in analyzing Exam 1 data.
6. **Cognitive Function Test (August 15, 2010)**
 - a. Provide a plan to identify ways to reduce refusals on the Montreal Cognitive Assessment (MOCA), including a reassessment of clinic flow and exam component order.
7. **Criteria to Establish Priority Order for Use of Samples (November 1, 2010)**
 - a. Clarify the decision-making process for use of lab samples.
 - b. Complete the development of the Specimen Tracking table and implement in six months.
8. **MRI and Clinic Visits (August 15, 2010)**
 - a. Provide a plan to assure that clinic staff is aware of appropriate examination and MRI goals to ensure that component targets are met.
9. **Blood Pressure Referral (August 15, 2010)**
 - a. Revise guidelines for blood pressure referral as recommended by the OSMB.
10. **Study Description (August 15, 2010)**
 - a. Revise the standard description of the Jackson Heart Study for use in publications and ancillary study proposals with particular attention to descriptions of the study population, family study, and family statistics.

11. Follow-Up

- a. Provide an update of progress on these recommendations during a conference call to be scheduled with the OSMB in six months.
- b. Share OSMB recommendations with the Presidents of the three JHS Institutions.

NEXT MEETING: A conference call will be scheduled in November, 2010 and the next in-person meeting is expected to be scheduled in April, 2011.


SIGNATURES

Respectfully submitted,

/Signed/ 5/10/2010
Shiriki Kumanyika, Ph.D
Chair,
Jackson Heart Study OSMB

/Signed 5/10/2010
Lorraine Silsbee, M.H.S.
Executive Secretary
Jackson Heart Study OSMB

APPROVAL DISAPPROVAL



Acting Director, NHLBI

May 10, 2010

Date

MINUTES
Observational Study Monitoring Board
for the Jackson Heart Study, May 4, 2011
Bethesda, Maryland

PARTICIPANTS:

OSMB Members: Gary Bennett, Trudy Burns, Mark Espeland, Paula Johnson, Shiriki Kumanyika (Chair), Warren Manning, Philip Wolf, Jackson Wright

Jackson Heart Study Investigators: Ervin Fox, Michael Griswold, Francis Henderson, DeMarc Hickson, Donna Antoine-LaVigne, Solomon Musani, Asoka Srinivasan, Herman Taylor (Principal Investigator), Karen Winters

NHLBI Staff: Carmen Edghill, Jane Harman, Stanley Knight, Cheryl Nelson (Project Officer), Michelle Olive, Jean Olson, Austin Sachs, Lorraine Silsbee (Executive Secretary), Paul Sorlie, Evelyn Walker

Other: James Hurley, Organizational Consultant

STUDY DESCRIPTION: The Jackson Heart Study (JHS) is an investigation of causes of CVD in a population of African-American men and women from Jackson, MS. It was established in 1998 by the NHLBI with co-funding from the National Center on Minority Health and Health Disparities (NCMHD), building upon the success of the ARIC study's Jackson, MS, Field Center, in place since 1985. A cohort of 5,301 participants completed the baseline Exam in 2000-04, with two follow-up exams in the current contract period; Exam 2 ended in 2009 and Exam 3, now in progress, will end in 2012. The JHS is a collaboration between Jackson State University, Tougaloo College, the University of Mississippi Medical Center, and an NHLBI field site.

CLOSED SESSION: Dr. Kumanyika convened the closed session of this regularly scheduled annual meeting at 8:00 a.m. The minutes from the April 25-26, 2010 meeting and November 29, 2010 conference call were approved. The Executive Secretary confirmed that OSMB members had no new conflicts of interest to report.

The Project Officer, Cheryl Nelson, described the current status of the study. She also reported that this summer, Dr. Evelyn Walker, the NHLBI Field Officer located in Jackson, Mississippi, will enter a one-year health policy fellowship program. This program requires Dr. Walker to leave the NHLBI JHS Field Office.

OPEN SESSION: The open session began at 8:45 a.m.

RESPONSES TO 2010 RECOMMENDATIONS:

Overall, the Board was pleased with the responses to the recommendations from the April, 2010 meeting and November, 2010 follow-up conference call. Significant improvements were noted in the areas of data management, quality control, data reporting, and data distribution, particularly in the development of standardized report tables, event rate reporting, participant tracking, and documentation of adverse events. Improvements in the standard description of the Family Study sample design and staff receptivity to administering cognitive function testing were also acknowledged.

STUDY PROGRESS: Scientific progress includes 16 publications in 2011, to date. Exam 3 is approximately two-thirds complete with 2,740 clinical examinations conducted. This represents

65 percent of the retention goal of approximately 4,240 of the 5,000 surviving participants. The number of participants seen per week has been steadily increasing in recent months. If this continues, it is anticipated that the target retention goal will be surpassed.

Clinical events adjudication in JHS is accomplished through a subcontract with UNC Chapel Hill. There is still a backlog of JHS events to be adjudicated, but the investigators have been assured they will receive all adjudicated JHS events data through 2008 for MI, in-patient heart failure and stroke by June 30, 2011.

To date, 969 Exam 3 MRIs have been completed including 111 MRIs with gadolinium. It is projected that approximately 1,400 MRIs will be completed by the end of Exam 3. The Board encouraged the investigators to explore ways to increase participation in the MRI exam including follow-up calls to ensure appointments are kept and making additional slots available to allow for equipment failure or for when equipment is not available.

Investigators described recent efforts to increase collaborations with outside investigators through working groups and writers workshops designed to provide feedback for work in progress and to explore alternative methods for data analysis. Twelve Vanguard Data Collaborative Centers were established to offer a mechanism for sharing current JHS data, to foster collaborations and increase scientific productivity.

The Tougaloo Education and Training Center (ETC) has filled all 12 of its freshman JHS Scholars slots for the upcoming year with a total of 47 out of 48 program slots currently filled. The attrition rate of students is declining, which is attributed to early programs to enhance math and reading skills. The ETC continues efforts to track the educational and professional paths of the Scholars after they leave the program. As of 2010, 69 students have completed the JHS Scholars Program; of these, 39 students have entered graduate school in biomedical and related research fields. The Board strongly encouraged that the success of the Tougaloo ETC be documented in a publication.

The wide array of community outreach efforts and activities was described including local health fairs, partnerships with local health coalitions and community advisors, and connections with the media. Plans to evaluate the success of these collaborations were also described.

The JHS held a successful 10th anniversary Scientific Conference in September, 2010 attended by scientists, young investigators, practitioners, students, Tougaloo ETC alumni, JHS participants, and community members.

The Project Office briefly described plans for renewal of the JHS. The current contract ends May 31, 2013. The emphasis of the proposed renewal would be on increasing scientific productivity utilizing resources collected in the JHS through the end of Exam 3. A new exam will not be proposed in order to provide time to analyze previously collected data.

PRESENTATIONS: There were two scientific presentations: 1) *The relation of obesity to circulation B-type natriuretic peptide concentrations in African Americans: The Jackson Heart Study* 2) *Pericardial fat and cardiac-pulmonary risk: The Jackson Heart Study*.

RECOMMENDATIONS: The Board convened in closed session with NHLBI Staff at 3:00 p.m. and adjourned at 3:30 p.m. The Board unanimously agreed the study has made important progress and should continue, particularly noting improvements in data presentation, study infrastructure and study cohesiveness. The members complimented the investigators on the increase in scientific productivity as well as the continued success of the JHS Scholars Program. Specific recommendations follow:

1. Expand the present manuscript tracking system to include benchmarks such as completion of drafts, submission to journals and final publication.
2. Compare lost to follow-up rates across subgroups to determine if strategies to reduce potential biases associated with missing data are required.
3. In future quality control reports from replicate lab samples, feature coefficients of variation and inter-replicate correlations for individual analytes rather than t-test p-values.
4. Review missing data for ankle-brachial index and other procedures/measurements with high rates of missingness; break out reasons for lower completion rates, differentiating those related to ineligibility for a procedure from other reasons
5. Continue to explore ways to increase participation in the MRI exam.
6. In annual follow-up contacts, consider offering a definite time window for the interview in the advance letter or in a separate preceding phone call.
7. Consider consulting with specialists in geriatrics (e.g., geriatric social workers) for advice about helping older participants understand and navigate the study.
8. Publish the experiences of both the Training Program at Tougaloo College and the Community Outreach program at JSU to document their achievements and serve as models for development of similar programs elsewhere.
9. Use consistent definitions and terminology for issues such as 'refusal' throughout the OSMB Report tables and within the study process.
10. Define and track protocol deviations, particularly those that may impact participant health and safety (for example, those concerning alert value notifications).
11. For the 4,052 unrelated JHS participants, describe how many have microsatellite marker data, genome-wide SNP data, and genotype data from the IBC chip, and include consent tiers as in Table 7.25 (pg. 62 of the OSMB book) for the Family Study component.
12. By August 1, 2011, update the Board on whether the adjudicated clinical events data through 2008, expected by June 30, are received by the JHS as scheduled.

NEXT MEETING: An in-person meeting will be scheduled in April – May, 2012.


SIGNATURES

Respectfully submitted,

/s/ 5/13/2011
 Shiriki Kumanyika, Ph.D
 Chair,
 Jackson Heart Study OSMB

/s/ 5/13/2011
 Lorraine Silsbee, M.H.S.
 Executive Secretary
 Jackson Heart Study OSMB

APPROVAL DISAPPROVAL



 Acting Director, NHLBI

May 20, 2011

 Date

NATIONAL HEART, LUNG, AND BLOOD ADVISORY COUNCIL

MEETING MINUTES October 18, 2011

- I. CALL TO ORDER AND OPENING REMARKS - Dr. Susan B. Shurin
- II. REVIEW OF CONFIDENTIALITY AND CONFLICT OF INTEREST - Dr. Susan B. Shurin
- III. REPORT OF THE ACTING DIRECTOR - Dr. Susan B. Shurin
- IV. MOVING COMPLEX CELL THERAPIES FROM THE BENCH TO THE BEDSIDE: HEMATOPOIETIC STEM CELLS AS A PARADIGM – Dr. Cynthia Dunbar
- V. DIVISION OF INTRAMURAL RESEARCH UPDATE: PROGRESS IN CLINICAL RESEARCH – Dr. Robert S. Balaban
- VI. UPDATE FROM THE NIH PRINCIPAL DEPUTY DIRECTOR – Dr. Lawrence A. Tabak
- VII. PATHWAYS TO INDEPENDENCE AWARD (K99/R00) – Dr. Susan B. Shurin
- VIII. REPORT OF THE BOARD OF EXTERNAL EXPERTS AND INITIATIVE CONCEPTS FOR FISCAL YEARS 2012 AND BEYOND – Dr. Susan B. Shurin
- IX. INTRAMURAL REVIEW
- X. REVIEW OF APPLICATIONS

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 244th meeting of the National Heart, Lung, and Blood Advisory Council (NHLBAC).

Council Updates:

Dr. Shurin recognized three Council members who are retiring:

- Dr. C. Noel Bairey-Merz
- Dr. Andrew Marks
- Dr. Marlene Rabinovitch

Three new Council members are expected to participate at the next Council meeting:

- Dr. Ron King, President and Chief Scientific Officer, BioAccel, who was able to attend the meeting
- Dr. Pamela Douglas, Professor of Research in Cardiovascular Diseases, Duke University School of Medicine
- Dr. Barbara Konkle, Director, Translational Research, Puget Sound Blood Center

Advisory Committees Updates:

Dr. Shurin welcomed representatives of three NHLBI Advisory Committees:

- Dr. Sairam Parthasarathy, representing the Sleep Disorders Research Advisory Board
- Dr. David Pinsky, representing the Heart, Lung, and Blood Program Project Review Committee
- Dr. Amy Shapiro, representing the Clinical Trials Review Committee

Dr. C. William Balke of the NHLBI Institutional Training Mechanism Review Committee and Dr. Edward Benz of the Sickle Cell Disease Advisory Committee were unable to attend.

NHLBI Updates:

Dr. Shurin introduced Ms. Kate O'Sullivan, the new NHLBI Executive Officer. Dr. Shurin thanked Mr. Tim Wheelles for his devoted and wonderful service as the Acting Executive Officer for 25 months.

The search for the new Director of the NHLBI is ongoing.

NIH Updates:

Dr. Shurin noted with sadness the recent deaths of two important leaders of NHLBI activities:

- Dr. Bernadine Healy, a former NIH Director, who launched the Women's Health Initiative in 1991.
- Dr. William Kannel, a former Director of the Framingham Heart Study.

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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:

The NHLBI is very concerned about the impact of current budget constraints on the future of biomedical research. The NIH received a one percent cut in its budget for FY 2011 and is preparing for budget decreases again this year and next. The Institute plans to continue its policy of making strategic cuts as necessary, rather than across-the-board cuts. It will continue to look closely at potential investments. The Institute will begin FY 2012 with a research project grant (R01) payline at the 10th percentile and plans to have one payline for both new applications (A0s) and resubmissions (A1s).

HHS Updates:

Dr. Shurin summarized the Department of Health and Human Services (HHS) Sickle Cell Disease Initiative. The HHS has charged six agencies (NIH, CDC, HRSA, FDA, AHRQ, and CMS) and the Offices of Minority Health and Planning and Evaluation to improve the health of people with sickle cell disease. Each agency is taking action to:

- Enhance implementation of research advances.
- Provide evidence-based guidelines to families, health care providers, and payers.
- Facilitate new drug development.
- Provide public health data to impact both the health care delivery and research agendas.

Dr. Shurin noted two HHS policy issues:

- An HHS Advance Notice of Proposed Rulemaking (ANPRM) on Human Subject Research Protection was published on July 26, 2011. See ANPR Revisions to the Common Rule.
- HHS financial conflict of interest regulations have been revised.

Dr. Shurin offered Council members an opportunity to discuss their concerns about the effects of the new NIH policy to allow only one resubmission grant application (i.e., no A2s). Dr. Shurin offered to raise the issue with NIH leadership and to convey the concerns and suggestions of Council members.

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IV. MOVING COMPLEX CELL THERAPIES FROM THE BENCH TO THE BEDSIDE: HEMATOPOIETIC STEM CELLS AS A PARADIGM –

Dr. Cynthia Dunbar

Dr. Cynthia Dunbar, Hematology Branch, NHLBI Division of Intramural Research, discussed three areas of research involving cell therapy in which lab has been involved:

- Hematopoietic stem cell gene therapy --- insights from the non-human primate model.
- Stem cell-niche interactions --- research on improving mobilization, homing, and engraftment for transplant and gene therapy.
- Reprogrammed stem cells (iPSC) --- studies of iPSC and their utility as regenerative medicine models and their suitability for preclinical development.

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V. DIVISION OF INTRAMURAL RESEARCH UPDATE: PROGRESS IN CLINICAL RESEARCH – Dr. Robert S. Balaban

Dr. Robert S. Balaban, Scientific Director, NHLBI Division of Intramural Research, summarized NHLBI collaborative activities with the new NIH for Regenerative Medicine. The Center, supported by the NIH Common Fund and located within the NIH Intramural Research Program, was established to accelerate the development of cell-based therapies for repairing or replacing tissue damaged by disease or injury. Several NHLBI intramural research projects are being funded by the Center, and the NHLBI iPSC Core Facility has been established to serve as the main research site focusing on the applications of iPSC for NHLBI mission-oriented projects.

Dr. Balaban discussed the success of the NIH Stadtman Tenure-Track Investigator Program to recruit outstanding tenure-track scientists and the La Clinical Research Scholars Program to help increase the pool of talented clinical/translational researchers. Dr. Balaban also mentioned the Intramural Division's new Clinical Research Strategic Plan, developed to:

- Support investigator-initiated research.
- Support small first-in-human trials, especially with respect to safety, reporting, and regulatory standards.
- Develop and maintain infrastructure for clinical research at all levels: FDA interaction, protocol development, research nurse support, data management and analysis.
- Partner with regional clinical programs (e.g., partnerships with Johns Hopkins University/Suburban Hospital and Children's National Medical Center extramural/intramural partnerships; and the NIH Center for Human Immunology and Inflammation).
- Hire, train, and mentor the next generation of physician-scientist leaders

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VI. UPDATE FROM THE NIH PRINCIPAL DEPUTY DIRECTOR – Dr. Lawrence A. Tabak

Dr. Lawrence A. Tabak, Principal Deputy Director, NIH, discussed the continuing efforts of the NIH to improve the diversity of the NIH funded scientific workforce. Dr. Tabak reported that despite efforts spanning 30 years, the NIH has had a less than impressive impact on the diversity of the NIH-funded workforce. As part of an ongoing effort to examine and improve the situation, the NIH has commissioned several recent studies, one of which (published in Science, August 19, 2011) provides data on the differences in success rates for NIH research project grants (R01s) experienced by white and underrepresented minority applicants.

Dr. Tabak and Dr. Francis S. Collins, NIH Director, responded in the same edition of Science, emphasizing NIH's commitment to a diverse biomedical workforce and discussing the steps it is taking to address the situation.

Dr. Tabak reiterated that the NIH takes these data seriously and is determined to discern the causes of differential success rates and to undertake

interventions to reduce them. NIH actions include:

- The NIH is engaged in vigorous communication outreach to all stakeholders.
- Because review experience correlates with application success, the NIH has recently established an "Early Career Reviewers" program to increase exposure of investigators from diverse institutions to the review process (and to increase diversity of review panels).
- The NIH will conduct experiments on the review process to determine if bias exists.
- The NIH will work with academic institutions to encourage creation or strengthening of pre-application mentoring programs for junior faculty.
- The NIH has funded several extramural grants, including the NIH Pathfinder Award, designed to study different interventions to strengthen the pipeline in a manner that will help improve workforce diversity.
- The NIH Director formed two high level groups to recommend actions to help the Agency increase the diversity of its workforce and create a sustained environment that supports diversity.
- o NIH Diversity Task Force (Part of the NIH Director's Steering Committee) --- internal group of NIH leaders.
- o Advisory Committee to the Director Working Group on Diversity in the Biomedical Research Workforce --- provides an external perspective and

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VII. PATHWAYS TO INDEPENDENCE AWARD (K99/R00) – Dr. Susan B. Shurin

Dr. Shurin discussed the possibility of using the K99/R00 mechanism to support Early Stage Investigators (ESIs) who do not have much preliminary. She reminded Council members that the Institute recently decided it will no longer participate in the Parent Announcement for the NIH Exploratory Developmental Research Grant Program (R21). The Institute determined that the R21 mechanism was not affecting its research grant portfolio in the manner for which it was originally intended. Moreover, although the R21 mechanism may have seemed an attractive opportunity for ESIs, it provided insufficient time for them to obtain results needed to support an R01 grant.

NHLBI analysis provided information on the Institute's recent use of the K99/R00 program. It found that the success rate for K99 applications has been reasonable over the past several years, ranging from about 25 to 45 percent annually. Of the 118 K99 NHLBI awardees from FY 2007-2010, most had PhD degrees. Most K99 applicants with a PhD or MD/PhD degree received their K99 award much sooner after receiving their degree (within about 1 year) than MD applicants, while MD applicants transitioned more quickly to the R00 award than PhDs and MD/PhDs.

Data show that ESI MD applicants seem to be transitioning smoothly to the R01 mechanism. The K99/R00 mechanism will probably be most useful

PhD and MD/PhD applicants.

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VIII. REPORT OF THE BOARD OF EXTERNAL EXPERTS AND INITIATIVE CONCEPTS FOR FISCAL YEARS 2012 AND BEYOND – Dr. Susan B. Shurin

Council considered seven new initiatives, seven renewals, and one request by another IC for secondary support, all of which had been reviewed in September by the Board of External Experts (BEE). Initiative development at the NHLBI is a two-cycle process. First, staff within each extramural Division 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 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

Career Development Program in Omics of Lung Diseases (K12; renewal), RFA

To develop multidisciplinary career development programs that will equip new investigators with the knowledge and skills to apply pan-omics and integrated approaches to elucidate genomic and molecular bases of lung disease heterogeneity, key gene regulatory networks, and relevant disease biomarkers in order to increase understanding of lung disease pathobiology and lung disease personalized medicine.

Council recommended this initiative.

Career Enhancement Award for NHLBI Selected Topics (K18; renewal), PA

To renew the parent program announcement for the K18 mechanism. The current NHLBI K18 program supports training in stem cell research; this initiative will broaden the scope to include training in other areas where a retraining mechanism would be useful to help retool investigators to be a

pursue new and innovative areas of research.

Council recommended this initiative.

NHLBI Systems Biology Collaborations (R01; renewal), PAR

To support high impact, collaborative systems biology research projects to advance understanding of normal physiology and perturbations associated with heart, lung, and blood diseases and disorders.

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

Clinical Studies Using Health Information Technology for Pediatric Pulmonary Vascular Disease (U01), RFA

To create a virtual cohort of children with pulmonary arterial hypertension, by using electronic health information, a bioinformatics infrastructure, and computational science that will allow the elucidation of phenotypes and longitudinal outcomes, queries on therapy and the responses, and investigate other research questions.

Council recommended this initiative.

Coronary Artery Risk Development in Young Adults (CARDIA) Study Renewal (N01; renewal), RFP

To leverage the NHLBI's long-term investment in CARDIA and its 25 years worth of clinical, psychosocial, environmental, and genotypic data and findings to focus primarily on early-onset heart failure.

Council recommended this initiative.

Engine for Fast Execution of Clinical Trials (N01), RFP

To establish a virtual network involving a large number of sites to conduct a clinical trial of triple therapy ICS/LABA/LAMA combination for COPD exacerbations in an inpatient setting and immediate post-discharge period. Additional task orders will be issued to support additional peer-reviewer

in the same inpatient setting, depending on the success of the first trial.

Council recommended this initiative.

Pregnancy as a Window to Future Cardiovascular Health: Adverse Pregnancy Outcomes as Predictors of Increased Risk Factors for Cardiovascular Disease (U10), RFA

To leverage the NICHD-sponsored study entitled "Nulliparous Pregnancy Outcomes Study: Monitoring Mothers-to-be" to test the hypothesis that women who experience preeclampsia and other adverse pregnancy outcomes in their first pregnancy have elevated cardiovascular risk profiles at approximately two years postpartum compared to women who do not experience an adverse pregnancy outcome in their first pregnancy.

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

Cardiothoracic Surgical Trials Network (UM1; renewal), RFA

To continue the Cardiothoracic Surgical Trials Network in order to maintain an environment and infrastructure that promotes the advancement of cardiothoracic surgical research through the use of evidence-based medicine.

Council recommended this initiative.

Cardiovascular Risk Reduction in Underserved Rural Communities (R01), RFA

To build the evidence base and accelerate the implementation and translation of evidence- or practice-based interventions into practice in rural communities by planning and conducting well-designed controlled trials.

Council recommended this initiative.

National Health and Nutrition Examination Survey (NHANES), Cardiovascular and Sleep Component (Y01; renewal), IAA

To support the continued collection of data in children and adults, including measures of blood pressure, total cholesterol, triglycerides, HDL-cholesterol, and fasting glucose.

and Apo(B); results of DEXA scans and accelerometry measures; and responses to questions about weight loss and sleep disorders. In addition, a urine collection subsample will be added to measure urinary sodium excretion, a biomarker for sodium intake.

Council recommended this initiative.

NHLBI SBIR Phase IIB Bridge Awards to Accelerate the Commercialization of Technologies for Heart, Lung, Blood, and Sleep Disorders Diseases (R44), RFA

To provide support to enable promising SBIR Phase II projects to pursue the next appropriate milestone(s) toward commercialization.

Council recommended this initiative.

Summer Institute for Training in Biostatistics II (T15; renewal), RFA

To support up to eight universities to teach summer courses in biomedical statistics for advanced undergraduates and beginning graduate students to encourage them to pursue careers in the area.

Council recommended this initiative.

Transcatheter Cerclage Mitral Valve Annuloplasty for Secondary Mitral Regurgitation (N43/N44), RFP

To translate an NHLBI intramural research program invention into a commercial solution for catheter-based non-surgical treatment of secondary ("functional") mitral valve regurgitation.

Council recommended this initiative.

Transitions in Care of NHLBI Diseases (R01), PAR

To test the effectiveness of various approaches to improve transitional care, especially for the transition from hospital acute care to the outpatient setting in order to improve post-acute-care outcomes, such as unplanned hospital re-admissions, in adults and children with cardiovascular, pulmonary, or blood diseases and conditions.

Council recommended this initiative

Request for Secondary Support

Paul D. Wellstone Muscular Dystrophy Cooperative Research Center and Multisite Clinical Studies (U54 or UMI; renewal) [NIAMS, NINDS and NICHD], RFA

To encourage clinical research directed at the cardiac morbidities suffered by patients with muscular dystrophy.

Council recommended this initiative.

IX. INTRAMURAL REVIEW

Reports prepared by the Board of Scientific Counselors (BSC), NHLBI, on the NHLBI intramural laboratories reviewed during FY 2011 were presented to the Council by Dr. Robert Balaban, Director, Division of Intramural Research, NHLBI and Dr. Michael I. Kotlikoff, (BSC Chair), Cornell University.

X. REVIEW OF APPLICATIONS

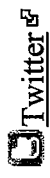
The session included a discussion of procedures and policies regarding voting and confidentiality of application materials, committee discussions and recommendations. Members absented themselves from the meeting during discussion of and voting on applications from their own institutions, or applications in which there was a potential conflict of interest, real or apparent. Members were asked to sign a statement to this effect.

The Council considered 2,039 applications requesting \$2,667,283,274 in total direct costs. The Council recommended 2,039 applications with total costs of \$2,667,283,274.

ADJOURNMENT

The meeting was adjourned at 2:45 p.m. October 18, 2011.

Last Updated September 2011



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MINUTES
Observational Study Monitoring Board
for the Jackson Heart Study, May 2, 2012
Bethesda, Maryland

PARTICIPANTS:

OSMB Members: Gary Bennett, Trudy Burns, Mark Espeland, Paula Johnson, Shiriki Kumanyika (Chair), Warren Manning, Wendy Post, Jackson Wright

Jackson Heart Study Investigators: Adolfo Correa, Michael Griswold, DeMarc Hickson, Donna Antoine-LaVigne, Solomon Musani, Asoka Srinivasan, Herman Taylor (Principal Investigator), Karen Winters

NHLBI Staff: Carmen Edghill, William Etti, Jane Harman, Lucy Hsu, Cheryl Jennings, Cheryl Nelson (Project Officer), Jean Olson, Austin Sachs, Lorraine Silsbee (Executive Secretary), Catherine VanCise

STUDY DESCRIPTION: The Jackson Heart Study (JHS) is an investigation of causes of CVD in a population of African-American men and women in Jackson, MS. It was established in 1998 by the NHLBI with co-funding from the National Center on Minority Health and Health Disparities (NCMHD), building upon the success of the ARIC study's Jackson, MS, Field Center, in place since 1985. A cohort of 5,301 participants completed the baseline Exam in 2000-04, with two follow-up exams in the current contract period; Exam 2 ended in 2009 and Exam 3, now in progress, will end later this year. The JHS is a collaboration between Jackson State University, Tougaloo College, the University of Mississippi Medical Center, and an NHLBI field site.

CLOSED SESSION: Dr. Kumanyika convened the closed session of this regularly scheduled annual meeting at 8:00 a.m. The minutes from the May 4, 2011 meeting were approved. The Executive Secretary confirmed that OSMB members had no new conflicts of interest to report.

The Project Officer, Cheryl Nelson, described the current status of the study. Dr. Evelyn Walker, the former NHLBI Field Officer located in Jackson, Mississippi, has taken a position as Medical Director of Health Promotion and Health Disparities Elimination at the Mississippi Department of Health. A search for her replacement is in progress.

OPEN SESSION: The open session began at 9:15 a.m.

The Board was pleased with the responses to the recommendations from the May 2011 meeting. In particular, the Board noted the study's cutting edge leadership in the area of information and systems management. Continued improvements since the last meeting were noted in the areas of data management, addressing missing data and lost-to-follow-up concerns, quality control, data reporting, and data distribution. The investigators reported on strategies implemented to increase participation in the clinic and MRI exams.

STUDY PROGRESS: Scientific progress included 29 publications in 2011 with an average journal impact factor of 7.9. Exam 3 is almost complete with clinical examinations scheduled to end May 31, 2012. The MRI examinations will continue through December 2012. The Exam 3 retention goal is 85% of the approximately 5,000 surviving participants. To date, 3573 clinical exams have been completed and it is projected that 3,675 exams (74%) will be completed by the scheduled end of Exam 3. The investigators have launched an active retention campaign to improve exam attendance through the end of the exam period. The Board suggested exploring

ways to increase exam attendance further by conducting abbreviated exams to obtain blood and vital signs and to administer questionnaires.

Approximately 61% of the cardiac MRIs have been completed, with lower participation rates for scans with gadolinium contrast. It is anticipated that, at the current rate, the number of gadolinium scans will fall significantly short of the goal of 500 - 600. It was noted that, within the field at large, liver disease is no longer considered to be a contraindication for gadolinium, although this exclusion is still a part of the JHS protocol. The investigators may wish to explore revising their protocol to remove this exclusion criterion. The Board encouraged the investigators to obtain as many gadolinium MRI scans as possible for meaningful analysis.

The Board questioned the procedures used for identifying and investigating potential clinical events. The investigators reported overall improvements in collecting medical records for event investigations from hospitals but continued difficulty in obtaining medical records at two hospitals. The Board suggested that the investigators collect records on all eligible hospitalizations when reported by the participants, rather than waiting for the annual comprehensive lists of hospitalized patients from the local hospitals. The Board requested more details about how many potential events have been reported by the participants, how many hospital records have been obtained and abstracted, and how many have been adjudicated. In addition, the Board would like to see the number of verified adjudicated events that meet criteria for MI, CHD death, stroke and cardiovascular procedures as separate numbers in addition to the combined counts.

The investigators reported on their continued collaborations with the Vanguard Centers. The Board noted the increasing publication record of the JHS and recommends that future publication reports identify separately publications that represent JHS data only and those from large consortia in which JHS data are included.

The Tougaloo Education and Training Center (ETC) has filled all 12 JHS Scholars slots for this year with a total of 46 slots filled. The high school SLAM (Science, Language Arts, Mathematics) program is still a highly competitive program with about twice as many applicants as openings. The 6-day summer epidemiology course also continues to be successful. As of May 2011, 80 students have completed the JHS scholars program. Out of these, 45 enrolled in graduate and professional schools and one enrolled in an MD/PhD program. In response to a previous recommendation from the OSMB, a manuscript profiling the ETC is expected to be published by the end of 2012. The Board suggested that the study also track the professional progress of junior faculty who use JHS data for their research but are based at schools outside of the Jackson area institutions.

The wide array of community outreach efforts and activities was described, including local health fairs, partnerships with local health coalitions and community advisors, and connections with the media. The evaluation team's efforts to analyze community outreach activities were described.

The Project Office briefly described plans for renewal of the JHS contracts. The current contracts end May 31, 2013. The emphasis of the planned renewal will be on increasing scientific productivity utilizing resources collected in the JHS through the end of Exam 3. Four contracts will be offered, separating the community relations component from the operation of the data coordination center. The renewal process will be competitive rather than sole source, as in prior contract periods, and the next contract period will not include a clinical examination.

OTHER

In response to a question from the investigators regarding distribution of the OSMB materials, the Board would like to receive the materials via hard copy as well as electronically.

PRESENTATIONS: There were two scientific presentations: 1) *Plasma B-type natriuretic peptide and longitudinal changes in blood pressure: findings from the Jackson Heart Study*; 2) *Prevalence of risk factors and CVD events in the Jackson Heart Study*.

RECOMMENDATIONS: The Board convened in closed session with NHLBI Staff at 2:10 p.m. and adjourned at 2:40 p.m. The Board unanimously agreed the study has made important progress and should continue. The Board complimented the investigators on their responsiveness to recommendations from the prior meeting, and noted a transformation from "catch-up" mode to a leadership role, particularly recognizing advances and leadership in study data presentation, systems improvements, scientific productivity, and the outstanding success of the ETC. Specific recommendations follow:

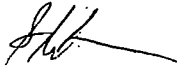
- 1) By August 1, 2012, provide more detail about the number of hospitalizations reported by the participants, the number of hospital records that have been obtained, and how many have been adjudicated for these events.
- 2) By August 1, 2012, provide more detail about problems identifying and obtaining medical records for potential clinical events and efforts to improve the process.
- 3) By August 1, 2012, provide the number of verified adjudicated events that meet criteria for MI, CHD death, stroke and cardiovascular procedures as separate numbers in addition to the combined counts.
- 4) By August 1, 2012, provide a description of how the gadolinium MRI procedure is presented to participants and how the anticipated small number of completed contrast MRIs will provide sufficient power for useful data analysis.
- 5) By August 1, 2012, provide comparison of event rates with other studies by age, gender and race. Report JHS event rates for both JHS-only and JHS-ARIC participants as well as overall.
- 6) Distinguish terminology for clinical alerts from flagged data outlier alerts.
- 7) Provide a report distinguishing which publications utilize JHS data only and which ones are consortia publications.
- 8) Provide information on the status of manuscripts in progress and published related to psychosocial aspects of the data, with emphasis on contextual variable, SES, behavior, neighborhood influences on CVD. Consider establishing one or more working groups to explore a broad range of psychosocial and environmental context variables. This might be facilitated with Vanguard Centers that have CTSA's and through linking GIS data to other databases such as those available through NCCOR.
- 9) Review the original specific aims of the JHS and evaluate the variety of publications and papers in progress to determine how well they address those aims. Provide detail on the status of event-driven manuscripts.
- 10) Explore expanding the community engagement effort beyond communication and education to engaging the community scientifically as well. Scientifically engage the communities by partnering the JHS Community Unit with CTSA Vanguard Centers.

- 11) If a suitable local candidate for the data manager position is not found, consider filling the position with a candidate who can serve in the position remotely.
- 12) NHLBI should consider extending Exam 3 beyond the current May 31, 2012 end date as feasibility and funding allow, including home visits and abbreviated exams to maximize engagement of participants otherwise unable or unwilling to participate.

NEXT MEETING: An in-person meeting will be scheduled in April – May, 2013.

Signatures

Respectfully Submitted,



5/11/2012
Shiriki Kumanyika, Ph.D
Chair
Jackson Heart Study OSMB

/s/ 5/14/2012
Lorraine Silsbee, M.H.S.
Executive Secretary
Jackson Heart Study OSMB

APPROVE

DISAPPROVE



Acting Director, NHLBI

May 16, 2012

Date