

MINUTES
Observational Study Monitoring Board
for the Jackson Heart Study, April 28, 2008 Meeting

PARTICIPANTS:

OSMB Members Present: Shiriki Kumanyika (chair), Trudy Burns, Mark Espeland, Paula Johnson, Elizabeth Ofili (via telephone), Catherine Stoney, Philip Wolf, Jackson Wright

OSMB Members Absent: None.

Investigators: Francis Henderson, Herman Taylor (PI, University of Mississippi, Exam Center); Daniel Sarpong (Jackson State Coordinating Center), Asoka Srinivasan (Touglao College Undergraduate Training Program)

Guest Presenters Ana Diez Roux and Jennifer Robinson, University of Michigan

NHLBI Staff: Lorraine Silsbee (Executive Secretary), Jane Harman, Cheryl Nelson (Project Officer), Jean Olson, Paul McFarland, Austin Sachs, Paul Sorlie, Evelyn Walker

NCMHD Staff: Kyu Rhee

CALL TO ORDER: Dr. Kumanyika convened this regularly scheduled annual meeting at 8:30 am. The minutes from the April 23, 2007 meeting were approved. The Executive Secretary confirmed that Board Members had no new conflict of interest issues to report subsequent to their annual filing. The Board was informed that to avoid potential conflict of interest, Dr. Mark Espeland, Wake Forest University, will recuse himself from discussions related to the performance of the Wake Forest CT subcontract and any subsequent subcontracts awarded to Wake Forest. This arrangement has been approved by NHLBI. The Project Office Report described the current status of the study including Exam 2 recruitment, the status of annual follow-up, plans for the upcoming MRI pilot in Exam 2 and full implementation of that component in Exam 3, issues surrounding the type and quality of data included in the OSMB background reports, and an update on scientific productivity. The Project Officer also distributed the Report of the Genetics Site Visit conducted on Friday, April 18, 2008.

STUDY DESCRIPTION: The Jackson Heart Study (JHS) is an investigation of causes of CVD in an African-American population, involving approximately 5,300 men and women from Jackson, MS. Recruitment began in September, 2000 and was completed March 31, 2004. Follow-up is conducted annually by telephone and about every 4 to 5 years in person. The study is investigating CVD risk factors, including manifestations related to hypertension such as coronary artery disease, heart failure, stroke, peripheral arterial disease, and renal disease. Baseline examinations (Exam 1) included demographics, psychosocial inventories, medical history, anthropometry, resting and ambulatory blood pressure, phlebotomy and 24-hour urine collection, ECG, carotid ultrasonography, echocardiography, and pulmonary function. The first round of follow-up examinations (Exam 2) began in October, 2005 and is expected to end by December, 2008. The second round of follow-up examinations (Exam 3) will begin in February, 2009. Exam 2 includes some repeated components of baseline Exam 1 with several new measures, including distribution of self-monitoring blood pressure devices, a blood draw for additional lab assays and DNA collection, CT for coronary artery calcium and abdominal fat and cardiac MRI.

The JHS is in the 11th fiscal year of funding. The current contract funding period is scheduled to end on May 31, 2013.

RESPONSES TO 2007 RECOMMENDATIONS: The investigators presented their responses to the OSMB's April 2007 recommendations, which the OSMB generally accepted. The investigators described the new organizational structure of the JHS and indicated that it is working fairly well. The JHS investigators implemented a "social marketing" campaign to improve recruitment efforts and convened focus groups to evaluate whether the low annual follow-up telephone interview (AFU) response rates were due to excessive participant burden. The investigators decided to retain the AFU telephone questions during Exam 2 data collection because the burden was determined not to be excessive and to maintain consistency with the ARIC- JHS cohort. Modifications of the AFU questions will be considered for Exam 3. The investigators have targeted several high profile journals for scientific publications, with 2 published and 2 in press since the last OSMB meeting. Ancillary study guidelines were revised to indicate that ancillary studies not funded within two years of approval must be resubmitted. A lab committee was formed to review use of non-renewable study resources. A system of informing participants of incidental CT findings was developed. The quality assurance data in the OSMB report was clearer; however, the Board had expected more comprehensive data on quality assurance issues, with more interpretation.

STUDY PROGRESS: There have been several interactions between members of the OSMB, NHLBI and Jackson Heart Study staff over the past year, including the July 2007 site visit, meetings and conference calls with NHLBI staff, and a recent site visit by a Genetics Team. As result of these discussions, the Board noted there has been substantial progress in study management and scientific productivity over the past year, though they strongly encourage that efforts in these areas continue.

The investigators described the shortfall in annual follow-up telephone calls and, consequently, a shortfall in subsequent clinic visits triggered by those calls during a 3-4 month period in the late Summer and early Fall of 2007. They were able to identify the contributing problems and implement a variety of strategies to increase clinic visits since that time. The Board requested the investigators provide a cumulative Annual Follow-Up report in person years as well as a tracking of participants with any contact per year (either phone or in person) in addition one that describes those efforts on a yearly basis.

Implementation of a formal quality control system was discussed. The investigators reported that a data team convenes weekly, but the formal quality control committee meets every other month and occasionally those meetings are cancelled. The Board suggested a more formalized QC system and more formal communication of QC issues to the clinic staff for immediate resolution. Consistent with this, the Board suggested the investigators develop a regular schedule for recertification of the Master Trainers for clinic technicians using a trainer outside of the study. The comprehensiveness and focus of the quality control approach were also of concern to the Board. External or NIH advice as to what QC issues are being tracked and how, was recommended to ensure that the balance of attention to issues such as digit preference, technician certification, equipment certification, and other aspects of data quality is appropriate.

All hospital abstractions are completed for years through 2007. Abstracted hospital medical records are sent to the Surveillance/Events reading center, the ARIC Coordinating Center at the University of North Carolina. The Board indicated they would like to see details or a summary of reading center reports. Additionally, event rates in the past were lower than expected for heart

failure. The Board requested a report on event rates for MI, heart failure, stroke, etc. and a description of how those rates were developed, including how they arrived at the denominator.

The Ethics Advisory Board (EAB) meets ad hoc to advise the Steering Committee on considerations related to genetic research. The Board would like clarification on what issues, other than genetics, the Ethics Advisory Board would want to have input on. The Board suggested a meeting schedule be established to allow the EAB to provide input to the JHS on a more regular basis.

The investigators described their efforts and progress in conducting CT scans. At the current rate, a target of approximately 4,000 CTs will be completed by December, 2009.

The investigators indicated that the echocardiography data was re-read by Dr. Liebson (University of Chicago) after the initial reading by Dr. Samdarshi (UMC Reading Center). There was approximately a 60 – 70% correlation for the different readings and investigators noted that readers may have read different axes (short vs. long) or different frames. The OSMB would like to understand reasons for the differences in echo readings and requested the echo report be forwarded to the Board by July 30, 2008.

The investigators described their activities to optimize scientific output through collaborations with other Institutions, ancillary studies, subcontracts and other studies including the Framingham Heart Study. Though the investigators are showing some progress in publishing study results, the Board requested that the investigators reduce the timeframe in which inactive manuscripts may be reassigned to other investigators and develop a system for actively reassigning them. The Board also clarified that the prior recommendation to emphasize high impact journals is in no way intended to discourage publication in respective specialty journals appropriate to the subject matter. The point is to increase the visibility, credibility, dissemination, and impact of JHS findings in the relevant scientific and policy domains. Targeting journals that are compatible with this goal would be appropriate. The Board also requested that lists of manuscripts and publications include all authors to highlight the range of expertise and effort involved in each manuscript.

An update on the activities of the Undergraduate Training Center was provided. The students are making excellent progress and an increasing number of students are giving presentations based on their research. Evaluation of the effects of the program on the College as a whole would be useful to more fully ascertain the program's impact and potential as a national model.

The investigators described the Jackson Heart Study's participation in the CARE pilot study. Concern was expressed that due to sensitivities associated with reporting genetic results in minority populations, there should be scientific review of the manuscripts by study representatives and NHLBI prior to publication.

PRESENTATIONS: Dr. Ana Diez Roux presented the collaboration of the Jackson Heart Study with the University of Michigan Center for Integrative Approaches to Health Disparities, which is funded by the National Center for Minority Health and Health Disparities at NIH. Dr. Herman Taylor gave a presentation, entitled, "Do relations between clinically relevant categories of BMI and CVD risk factors differ by race: comparison between the Jackson Heart Study and Framingham Heart Study." Dr. Jennifer Robinson of the University of Michigan gave a presentation entitled, "The impact of neighborhood in determining physical activity in African Americans in the Jackson Heart Study."

RECOMMENDATIONS: The Board unanimously agreed that the study should continue. It commended the investigators on the progress they have made in the staff reorganization, operations, overall management of the study and collaborations with outside individuals and groups. The OSMB also commended the continued success of the Scholars Program at Tougaloo College. There were several areas for which the Board made recommendations, which are presented below. Unless otherwise noted, updates should be provided in the next OSMB report.

- Develop a plan for timely availability of the Exam 2 data set to investigators/collaborators for analysis and manuscript publications. Review data to ensure that difficulties encountered with the prior data set are resolved.
- Provide a report on the surveillance process with respect to event classification, review, and adjudication procedures.
- Provide a report on success rates and timeliness in obtaining records to investigate for potential events. Provide a report on JHS event rates e.g. MI, stroke, heart failure and indicate how these rates are developed, including methods used for determining the denominators.
- Provide an Annual Follow-Up report utilizing a cumulative (or person years) model as well as a report clarifying how many people have had direct in person or telephone contact during the year.
- Describe the protocol for reading echocardiography reports and address reasons for 0.6 to 0.7 inter-reader correlation. Provide the echo report to the OSMB by **July 30, 2008**.
- Provide a formal description of the Master Trainer and technician re-certification process and the process for minimizing intra and inter-rater variability of clinical measurements. Develop a plan for formal re-certification of Master Trainers and technicians.
- Describe the focal points for quality control (QC), how missing data are handled, the frequency of QC assessments, and the QC alerts that trigger action; describe the lines of communication and responsibility for resolving QC issues. Seek external advice with respect to the scope and balance of a comprehensive QC program.
- Reduce the time period of 3 years after which unpublished manuscripts are withdrawn and become available for other investigators to pursue. Develop a process for active reassignment of unpublished manuscripts. Concentrate on publishing study results, even if not in one of the highest impact journals. In the OSMB report, list all authors to show the range of expertise involved in each manuscript.
- Consider engaging an outside facilitator without ties to the Jackson Heart Study for a Study-wide retreat to focus on management and other non-scientific issues within the study.
- Review the procedures that are in place for handling emergent CT incidental findings to clarify and, adjust, if necessary, the follow-up being provided by the study and the mechanisms or resources external to the study that are in place to ensure that JHS participants benefit or are at least not harmed by the process. Report to the Board on this issue.

- Develop guidelines for comparing JHS data with other cohort studies with regard to baseline disease and risk factor levels.

NEXT MEETING: The OSMB meeting adjourned at 3:40m. The next meeting is expected to take place in April or May 2009.

Respectfully submitted,

IApproved 5/04/08

Shiriki Kumanyika, Ph.D.
Chair, JHS OSMB

/s/ 5/04/08

Lorraine Silsbee, M.H.S.
Executive Secretary, JHS OSMB

___ Approve

___ Disapprove

Deputy Director, NHLBI