

MINUTES
Observational Study Monitoring Board
for the Jackson Heart Study, April 23, 2007 Meeting

PARTICIPANTS:

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

OSMB Members Absent: None.

Investigators: Ervin Fox, Francis Henderson, Asoka Srinivasan, Herman Taylor, James Wilson.

Coordinating Center Staff: Daniel Sarpong

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

NCMHD Staff: Carl Hill, Derrick Tabor.

CALL TO ORDER: Dr. Kumanyika convened this regularly scheduled annual meeting at 8:30 am. The minutes from the April 21, 2006 meeting were approved. Ms. Silsbee confirmed that Board Members had no new conflict of interest issues to report subsequent to their annual filing. The Project Office Report described the current status of the study including recruitment, scientific productivity and the timetable for Exams 2 and 3.

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. It investigates CVD risk factors, including manifestations related to hypertension such as coronary artery disease, heart failure, stroke, peripheral arterial disease, and renal disease. Examinations include demographics, psychosocial inventories, medical history, anthropometry, resting and ambulatory blood pressure, phlebotomy and 24-hour urine collection, ECG, carotid ultrasonography, echocardiography, and pulmonary function. State-of-the-art physiologic and epidemiologic methods are incorporated in a stable population-based minority cohort to provide research experience and build research capabilities at minority institutions.

RESPONSES TO 2006 RECOMMENDATIONS: The investigators presented their responses to the OSMB's April 2006 recommendations, which the OSMB accepted. Quality control standards have been set for Exam 1 datasets. Issues related to carotid artery measurements were resolved. Issues surrounding echocardiography have not been completely resolved though progress on the resolution was provided. A revised system was implemented to improve tracking and retention of Exam 2 participants. Proposed psycho-social measurements will be added to Exam 3. Additional staff has been hired including a project manager, 2 statisticians, and two senior scientific officers who provide direction on manuscript preparation. An Ancillary Studies task force has been established to alleviate the backlog of ancillary study requests and to develop a streamlined approach to review and approval of ancillary studies. A summary report of DNA aliquot tracking has been developed. A query system has been implemented for editing Exam 2 data making use of Exam 1 data to assess consistency of key data over time. Also, investigators are blocking out time for publications, attempting to focus more on manuscripts than abstracts.

STUDY PROGRESS: The investigators presented the progress made in the past year in retention of the cohort, data cleaning, and online management of manuscript proposals.

For Exam 1 echocardiography readings, 300 out of 500 have been read. Comparison with echo images taken early in the ARIC study has proven difficult due to degradation of the images over time. Digital storage media are being used for current images.

Scientific productivity has been lagging. To date, there have been 24 JHS papers that do not involve ARIC investigators or the joint ARIC-Jackson cohort. Ten methodology papers were published in 2005; ten JHS data driven papers are near completion. The OSMB strongly encouraged the investigators to make publication of JHS data driven manuscripts a priority, particularly now that the data availability and quality issues that might have been hindrances have been largely resolved.

Annual follow-up (AFU) via a one-hour telephone call and recruitment for Exam 2 are underway. Newly added Exam 2 components include phlebotomy and a CT scan for coronary calcium. The pilot CT component is now underway and scanning is expected to be included as part of Exam 2 on May 1, 2007. Cardiac MRI will be incorporated into Exam 2 for all eligible participants and in Exam 3 for a selected subgroup. Identifying an affordable MR scanning center has been challenging, but the investigators hope to incorporate MRI into Exam 2 in October 2007. The AFU follow-up rate for contact year 4 is 65% and concern was raised about "participant fatigue" by having participants involved in a lengthy follow-up call as well as a callback examination. This problem may be exacerbated by the need to arrange for the Exam 2 CT and MRI exams for a large number of participants who have already completed the other parts of Exam 2. The Board expressed concern as to whether the "social marketing" strategies used to recruit participants for Exam 1 will be as effective in Exam 2.

Related to quality control, the Board requested that the OSMB report provide more information on the quality of the JHS dataset (e.g. completeness, timeliness) and less information on the process of data quality control. The Board also requested the report include results of technician recertification.

There was discussion of the importance of establishing a process for when and how to report CT incidental findings to participants and their primary care providers. This would go beyond sending the radiologist's report and a CD of the images, but ideally also include some information about the potential significance of the finding and appropriate follow-up. It was suggested that the local cancer center may be willing to provide consultation about appropriate evaluation of incidental findings.

The potential participation of the Jackson Heart Study in the NHLBI CARE and SHARe programs was described. Participation in these programs can provide a wider network of experienced investigators with which the JHS may collaborate. The Board, while recognizing the important opportunities provided by CARE and SHARe, also recognized the additional burden on the JHS operation associated with participation.

The Undergraduate Training Center provided an update on the JHS Scholars Program. Diagnostic testing for reading and math skills has been added to the Program. Additional instruction is provided as needed for students needing improvement in these areas. Data collected to date indicate that this is highly successful in improving math and reading skills among the Scholars.

The status of ancillary studies was reviewed. It was suggested that the investigators develop a policy to set time limits on the approval of JHS ancillary studies and require reapplication for those unfunded past the time limit.

The focus for the coming year will be on publication of manuscripts and Exam 2 recruitment and retention.

SCIENTIFIC PRESENTATIONS: Dr. Fox gave a presentation on "The Epidemiology and Heritability of C-Reactive Protein." Dr. Taylor gave a presentation on "Hypercholesterolemia Prevalence, Awareness, Treatment, and Control" 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 adding needed staff, organizing weekly meetings to discuss and resolve data collection issues, and the progress and innovation of the JHS Scholars Program at Tougaloo College. There were also several areas for which the Board made recommendations:

1. Develop a strategic plan to maximize participant return rate for Exams 2 and 3 by developing a "social marketing" campaign tailored to those examinations, stratifying recruitment efforts and using the qualitative data collected to develop telephone scripts to address refusal scenarios.
2. Make scientific productivity an extremely high priority with a focus on publication of primary papers based on data collected in JHS. Rather than focusing only on baseline descriptive papers, pursue more hypothesis-driven analyses. Consider mechanisms for increasing available scientific and scientific writing expertise to assist with publications, including linkages to postdoctoral training programs and editorial services.
3. Explore ways to reduce respondent burden on Annual Follow-up questionnaires.
4. Develop a policy for time limits on approvals of unfunded ancillary studies
5. Constitute an executive lab committee to set priorities for use of non-renewable study resources
6. Develop a process for quickly and effectively reporting incidental findings from the CT and MRI scans.
7. Provide more information in the 2008 report on the results of quality control analyses and less on the processes used to obtain those results. The report should also include technician recertification results.

NEXT MEETING: The OSMB meeting adjourned at 3:00m. The next meeting is anticipated to take place in April or May 2008.

Respectfully submitted,

/s/ 4/29/07 _____
Shiriki Kumanyika, Ph.D.
Chair, JHS OSMB

/s/ 4/30/07 _____
Lorraine Silsbee, M.H.S.
Executive Secretary, JHS OSMB

____ APPROVAL ____ DISAPPROVAL

Deputy Director, NHLBI

Date