

**Jackson Heart Study**  
Minutes of the Observational Study Monitoring Board  
Marriott Suites Hotel, Bethesda, Maryland  
April 21, 2006

Members present: Trudy Burns, Mark Espeland, Paula Johnson, Shiriki Kumanyika (chair), Elizabeth Ofili (via phone), Catherine Stoney, Philip Wolf

Member absent: T.B. Ellis

NHLBI staff: Jean Olson (Field Studies and Clinical Epidemiology SRG Leader), Cheryl Nelson (JHS Project Officer), Lorraine Silsbee (JHS OSMB Officer), Evelyn Walker (Director, Jackson Epidemiology Research Unit)

NCMHD staff: Jerome Wilson

Investigators: Ervin Fox, Daniel Sarpong, Asoka Srinivasan, Herman Taylor, Sharon Wyatt

**Closed Session**

Dr. Kumanyika called the meeting to order at 8:30 a.m. Introductions were made and the minutes from the May 16, 2005 OSMB meeting were approved.

Project Office Report

Ms. Nelson summarized the status of the Jackson Heart Study. Following renewal of the contract on June 1, 2005, the second examination of the cohort began on October 11, 2005. The renewal of the JHS is divided into two major phases corresponding to Exam 2 and Exam 3. Each examination phase includes protocol development, staff training, pilot testing, clinical data collection, follow-up, data close-out and analysis. Exam 2 is a 39 month cycle that will end in December, 2008. Exam 3 will begin in February 2009 and also has a duration of 39 months. Ms. Nelson distributed a handout of the examination components for the new contract period. The content of the renewal negotiated for the June, 2005 start was designed to fit the science within the funds available, to shorten the exams and to provide the investigators with some protected time for scientific productivity.

Ms. Nelson summarized a proposal NHLBI received from Dr. Taylor in December 2005 to consider additional Exam 2 components. The proposal was reviewed within DECA/EBP for scientific merit and participant burden and funded approval was granted for this additional work on March 1, 2006. Additional Exam 2 components include spot urine collection for albumin and creatinine, collection of fasting blood in the entire cohort for lipid panel (total cholesterol, triglycerides, HDL-cholesterol), C-reactive protein, Hemoglobin A1c, as well as an additional DNA collection from participants who did not have it isolated at Exam 1 and monocytes for cryopreservation from those who did not participate in the JHS Family study.

There were also two imaging components, cardiac MRI and chest CT, added to the Exam 2 protocol. MRI for measurement of cardiac structure and function under the direction of a Reading center was moved from Exam 3 into Exam 2. MRI measurements will include systolic and diastolic septal and posterior wall thickness and internal dimension (with derived LV mass and fractional shortening) and left atrial dimension. An Exam 3 follow-up cardiac MRI in a subset of 2000 participants from Exam 2 will be selected based upon Exam 2 MRI evidence of left ventricular dysfunction. CT was added to the Exam 2 protocol to measure coronary artery/aortic calcium and abdominal visceral fat under the direction of a Reading Center, using similar scanning and reading protocols as those used in other NHLBI observational studies to facilitate comparisons and [pooling of](#) data across cohorts. CT will be implemented on the full cohort, with exclusions to include pregnancy and weight over 350 pounds. In addition, to minimize radiation exposure, imaging for assessment of body composition only (i.e., no imaging for coronary plaque) will be obtained in men less than 35 years and women less than 40 years (those age subgroups highly likely to have CAC scores of 0).

Ms. Nelson noted there were delays in the start-up of Exam 2 due to Hurricane Katrina and the lapse in IRB approval last fall. Dr. Walker noted that it took longer than expected to make the community aware that the JHS was starting up again. To alleviate the effects of the delays, the investigators are scheduling Saturday appointments, expanding the [visit retention](#) window, and adjusting the window to contact participants earlier to schedule appointments. It was noted that some start-up delays were similar to Exam 1 such as updating the Manual of Procedures, preparing the data entry screens, and pilot testing.

Ms. Nelson indicated [that](#) the investigators are expecting a retention rate of 85 percent. The Board questioned whether this was overly optimistic based on return rates from other large population studies. It was explained that the return rate for ARIC, CHS, and MESA were at least 90%, so 85 percent seems reasonable.

Ms. Nelson also noted that there has been minimal scientific productivity since Exam 1. Of the 25 manuscripts published in FY 2005, there were 9 methods papers, ~~and m~~Most of the other papers were joint ARIC/JHS papers. Some problems exist with the Exam 1 data set, including delays in transmitting data from reading centers, inconsistent data entry for measurements, and the methodology used for handling outlying data. To date, 90 manuscripts have been proposed, but they are on hold until the data cleaning problems identified with the Exam 1 data set are resolved. The Board expressed concern that the robust quality control system previously presented to the Board was not implemented as expected.

To address the Exam 1 data set issues and to spark scientific productivity, the NHLBI Project Office arranged a two-day Data Symposium in Jackson in early December. This included a review of data entry procedures, coding, and organizing data on the first day, and a discussion of analytic considerations for selected manuscripts in preparation on the second day. The symposium included experienced investigators from the MESA and Framingham studies. NHLBI also plans to hire a biostatistician in the Bethesda office to spend 75 percent time on the Jackson Heart Study, working closely with the investigators. It is expected that an individual will be on board this summer. The Board was pleased to hear about the additional NHLBI staff

position, but expressed concern about building capacity within the JHS itself. The Board indicated that in addition to the staff to be hired, constructive site visits might be a helpful way to provide guidance and improve data quality.

The Undergraduate Training Center at Tougaloo continues to do very well, enrolling 12 scholars per year, 90 SLAM students per summer, and providing summer internship opportunities for the Scholars at various U.S. and international institutions. The ~~community service~~ [Translating Research Into Practice and Prevention \(TRIPP\) Subcommittee](#) was established. ~~Filling t~~ [The community service positions of Social Worker, Community Outreach Education, and Community Outreach Coordinator are underway. Plans for staffing and scheduling meeting dates for the and staff and events for the](#) Community Monitoring Board are underway. The annual JHS birthday celebration was held as scheduled this past year.

## **General Session**

### Responses to OSMB Recommendations

Following introductions, Dr. Kumanyika welcomed the Board and the JHS investigators. Dr. Herman Taylor provided a summary of the JHS responses to the Board's recommendations from the May 16, 2005 as follows:

*Aggressively pursue filling vacancies for statistical positions and an in-house genetics coordinator.* A recently graduated Ph.D. biostatistician and a statistical geneticist with post-doctoral experience have been identified to fill these roles and are expected to begin this summer.

*Use cohort size of 5,302 in publications.*

The recommendation has been adopted and used in the preparation of the analysis data set.

*Present data by rates using survival curves and person-years.*

This recommendation has been adopted.

*Convene groups of experts to review the echocardiography and ultrasound data.*

A review group was convened, problems were identified and are being addressed.

*Prior to the next exam, perform quality control procedures during the pilot phase.*

Extensive quality assurance and control procedures were used during the pre-pilot and pilot phases of Exam 2.

*Encourage events adjudication as quickly and efficiently as possible.*

The investigators have implemented a process similar to the one used in ARIC. They have two fully trained adjudicators and three trained reviewers who review cases that are not automatically classified by computer algorithm.

*Limit number of abstracts presented per author until manuscripts are published.*

The JHS Guidelines for Publications and Presentations have been modified to indicate that publication of scientific findings is a goal of the publications process, but limit the number of approved abstracts to three per person until previously approved manuscripts are published.

*Develop alert criteria for assessment of depression for feedback to participants.*

Measurement of depression is not included in [the](#) Exam 2 protocol, so this item was not addressed. If it is added to the Exam 3 protocol, alert criteria will be developed.

*Acknowledge funding contributions of the National Center on Minority Health and Health Disparities in publications.* This is being done and authors are reminded at the time of manuscript approval.

Dr. Taylor gave an overview of 2005-06 highlights including organizational improvements, the consultant and planning retreat, success of the Undergraduate Training Center and reinstatement of the short course on epidemiology. He also reviewed the impact Hurricane Katrina had on the start of the second examination. The Board inquired whether JHS could incorporate psychosocial questions to measure the effects of the hurricane in the JHS examination. It is not possible to do that for Exam 2, but could be considered for Exam 3 [or for the interim telephone survey.](#)—

#### Undergraduate Training Center

Dr. Srinivasan reported that requirements for students at the UTC were becoming more stringent. To remain in the program, students are required to maintain a GPA of 3.0 and juniors and seniors are directly involved in research and required to give presentations. Though the Fall Semester started late due to Hurricane Katrina, the modules were revised to ensure the students are caught up by the 2006 Spring Term. The Board inquired about data preparation for the students' research. Dr. Srinivasan indicated that data for the students is coordinated and prepared by Dr. Fahmy at the UTC who acts as a liaison to Dr. Sarpong at the Coordinating Center. This helps to reduce the burden on the Coordinating Center and is also a security precaution. Dr. Srinivasan also reported that one student placed in the State semi-finals for the Young Epidemiology Scholars (YES) competition and received a monetary prize. Overall, the UTC is doing extremely well training students and engaging them in research related to the Jackson Heart Study. Recent graduates have gone on to professional schools in medicine and dentistry, and one is enrolled in a computational medicine program at Jackson State.

#### Exam Center

Dr. Taylor presented the exam components and rationale for Exams 2 and 3. The duration of the exams has been reduced from 4 hours to approximately 2 hours. However, recognizing the importance of evaluating subclinical disease and its progression, additional components were proposed to the Institute and now Exam 2 includes an expansion of the laboratory analytes and CT to measure coronary artery and aortic calcium and visceral fat. The CT exam will begin in November, 2006. The equipment is already located at the Medical Mall where the rest of the JHS exam takes place. Participants who have already been seen for Exam 2 will need to return for this imaging component. The Board concurred that conducting the imaging at a different time from the exam and blood draw would not compromise the results. The CT protocol will be identical [to](#)as that used in MESA. Two sites are under consideration for the CT Reading Center. Both have had extensive prior experience with NHLBI –supported studies and the intent is to have comparable data to the other NHLBI –supported studies [that are](#) conducting this imaging. Exam 2 will also include MRI for cardiac structure and function. It has not yet been determined

where the MRI equipment will be located, but investigators are pursuing its location at the Medical Mall as well. Having the MRI done at the mall would be preferable from the perspective of assuring a consistent and positive interface for JHS participants. - MRI imaging is expected to start in January, 2007. Approximately 4,500 participants are currently considered eligible, but that number may decline after exclusion criteria are considered. Echocardiography will not be repeated in Exam 2 or 3.

In reducing the length of the Exam 2, many questionnaires were not repeated from Exam 1 including psychosocial measures. The Board indicated that psychosocial measures, especially depression, should be included in one more exam to assess potential changes over time and also to allow study of the ~~the effects of stress on the~~ interaction between biological and socio-environmental factors. The Board felt it important to have this measured at two points in time. The investigators will look into reinstating some of these measures in Exam 3. The Board also supports incorporating questions to assess the effects of Hurricane Katrina and other sources of stress on long-term psychosocial outcomes.

Start-up delays due to the hurricane are being alleviated through increasing the number of participants seen per week and offering Saturday clinic times. For the past four weeks the clinic has been averaging 36 participants per week.

#### Coordinating Center Report

Dr. Sarpong provided a detailed update on activities at the Coordinating Center. He reviewed the quality assurance checks of the data management system (DMS), staffing issues, and problems with data quality from Exam 1. He also reviewed changes to the DMS based on lessons learned from Exam 1. The data set was sent to NHLBI for review. Some of the problems encountered with the Exam 1 data set include outlying data or unexpected values. He cited problems with the physical activity data where responses were outside the allowable range. Those values were set to "missing" in the data set. Issues also arose with inconsistencies for height/weight measurements. Data were entered using both the metric and English systems. After the conversions were done, it was not always possible to determine which system was used for which data. This had an effect on derived variables such as BMI.

Problems in reading the echo and ultrasound data were described. The echo QC data indicated a significantly lower than expected computation of LVH and significant reader differences, with one reader overestimating the internal diameter measurement and underestimating the posterior wall thickness. The carotid ultrasound data requires adjustment to correct for outliers/extreme values ( $\pm 4$  SE), non-randomness of missing data, and reader differences. Investigators have brought in an outside consultant and are working with the reading centers to resolve issues surrounding imaging data.

To prevent similar problems in Exam 2, Dr. Sarpong described additional quality control checks which include requiring all fields of the data entry system to have designated codes, obtaining expert opinions in setting validation ranges and flagging data that falls outside of those ranges, and using customized Personal Digital Assistant (PDA) devices to collect and verify times and completion of examination components.

Quality assurance activities include additional staff training and performance monitoring, discussion at weekly meetings ~~to discuss issues~~ that are attended by investigators as well as clinic staff, and weekly visits to the clinics to assure that log books are maintained.

The addition of the biostatistician and statistical geneticist will provide added oversight to the data issues. Dr. Sarpong indicated that one of those people will also serve as an overall Project Manager. He indicated that his staffing is “bottom-lite” with a shortage of programmers. One person working on web design is scheduled to move into a programming position this summer when the web applications are completed.

Given these problems, the Board expressed concern that Dr. Sarpong was stretched too thin in his role as Coordinating Center PI. The Board felt strongly that a dedicated Project Manager to oversee the day to day issues associated with data collection and management is needed.

Dr. Sarpong described the management reports developed for the Jackson Heart Study. To ensure “turn-key” operations of the Examination center and reduce reporting burden for the Coordinating Center, data reports and a web-based query system were developed. The Crystal Reports ensure that lab data are correctly entered and that all participants are entered in the data base. It includes an inventory to determine if participants have returned all forms and a medication check to ensure that medications were entered correctly including spelling and concentration, and that the number of medications is accurately reflected. In addition several other quality control reports are run to verify clinic appointments, consent, alerts, deaths, and follow-up.

Web-based applications were developed to increase efficiency and processing of requests for data by the Coordinating Center. The goal of these reports is to automate simple, recurrent requests to aid in manuscript preparation and to minimize the burden such requests place on the Coordinating Center. Some of the features include manuscripts, publications, and ancillary studies tracking systems. The Board was impressed with this system and encouraged its further development and implementation.

#### Ancillary Studies

To date, nineteen ancillary studies have been proposed and nine have been approved for submission for funding. The investigators indicated that the ancillary study proposal review process is extremely time consuming. To alleviate the time burden of reviewing ancillary study proposals, the investigators have implemented a step-wise pre-proposal stage that requires completion of a table of participant burden, sample size, number of analytes requested and a consultation with members of the Ancillary Study Committee. The Board encouraged the investigators to set priorities, ~~and~~ to develop a more restrictive pre-approval process for ancillary studies, and to select ancillary studies particularly relevant to the JHS and most likely to be successful in obtaining funding. The Board also suggested that ancillary studies not be considered if they do not provide for “capacity building” through minority supplements or involvement of minority investigators.

Dr. Sarpong indicated that, for ancillary studies, the Coordinating Center is collaborating with the repository at the University of Minnesota to track availability of specimens. The

Coordinating Center will ensure that all specimens released by the repository are approved by the Coordinating Center.

### Publications

It has been two years since the end of Exam 1. Of the twenty-five JHS publications, 9 are methods papers and the remainder are joint ARIC/JHS publications. Dr. Taylor noted that joint ARIC/JHS papers are mandated by NHLBI and while these papers are attributed to JHS investigators, they are not using JHS data. JHS investigators are anxious to promote publications, but the Board expressed concern about conducting analyses before problems with the Exam 1 data set are resolved.

The Board emphasized the importance of setting aside protected time for investigators to work on manuscripts. It was noted that staffing is the root problem in scientific productivity. Once this is alleviated, it is expected that productivity will improve.

### Scientific Presentations

Dr. Wyatt gave a presentation entitled, “Prevalence, Awareness and Control of Hypertension at Baseline in the Jackson Heart Study.” She concluded that age-specific data demonstrate lower levels of control among men and those aged 60+, and poor control among diabetic hypertensives.

Dr. Sarpong presented an abstract entitled, “Diabetes Prevalence, Awareness, and Control at Baseline in African Americans in the Jackson Heart Study.” It suggests that there is a high prevalence of diabetes mellitus with sub-optimal control in a significant fraction of the population within the Jackson Heart Study population.

Dr. Fox presented, “Epidemiology of C-Reactive Protein in a Community-Based Cohort of Middle-Aged African Americans: The Jackson Heart Study.” He concluded that in the middle-aged community based cohort of African Americans, CRP levels are higher by age and gender distribution than those reported for other population-based cohorts; however levels remain closely associated with traditional cardiovascular risk factors.

### Closed Session

The Board was impressed with progress in the development of web-based applications for the Jackson Heart Study and with the successes of the Undergraduate Training Center at Tougaloo. The Board expressed concerns about the following challenges facing the study:

- Proper cleaning of variables from the Exam 1 data set, including physical activity, echo and ultrasound data, is needed before data [for these variables](#) are released for further analyses.
- Coordinating Center staff is stretched thin; staffing pattern does not allow for sufficient or experienced oversight of data collection and preparation of data sets.
- Current pre-submission review procedures for ancillary study proposals are overly time consuming for staff. [Particularly given that not all of these proposals will be viable for funding.](#)

- NHLBI should consider bringing in an outside consultant to provide guidance on building data sets; consider more site visits or outside audit to review data management and provide guidance.

Recommendations:

- The Coordinating Center should develop a means for identifying successive editions of Exam 1 data, which should be updated only periodically (e.g. for use in ancillary studies) so that the source of data are identifiable and results within a particular edition are consistent.
- Within 4 months provide the OSMB with an update on resolution of carotid artery and echocardiography measurement issues.
- A better tracking of Exam 2 retention is needed to identify early issues and delays.
- Include psycho-social measures in Exam 3.
- Hire a Coordinating Center project manager to oversee study management and data collection and quality.
- Develop a more restrictive pre-submission ancillary study policy. Select ancillary studies particularly relevant to the main hypotheses of the JHS and most likely to be successful ~~in~~ acquiring funding.
- Develop an aliquot allocation report for DNA and plasma/serum samples, with the DNA tracking table to accompany the genetic ancillary studies provided to the Board.
- Queries for editing Exam 2 data should make use of Exam 1 data, e.g. to assess the consistency of key data over time.
- The investigators are encouraged to block out and prioritize time each week for completing JHS manuscripts.

Respectfully submitted,

---

Shiriki Kumanyika, Ph.D.  
Chair

---

Lorraine Silsbee, M.H.S.  
Executive Secretary