Jackson Heart Study
Minutes of the Observational Study Monitoring Board
Marriott Suites Hotel, Bethesda, Maryland
May 16, 2005

Members present:	Trudy Burns, T.B. Ellis, Mark Espeland (acting chair), Paula Johnson, Elizabeth Ofili (via phone), Catherine Stoney, Philip Wolf
Member absent:	Shiriki Kumanyika
NHLBI staff:	Kristi Cooper, Gwennifer Epps, Teri Manolio, Jean Olson, Cheryl Nelson Lorraine Silsbee, Pat Smith, Evelyn Walker
NCMHD staff:	Derek Tabor, Mary Rory, Jerome Wilson
Investigators:	Daniel Sarpong, Asoka Srinivasan, Herman Taylor, Wendy White Sharon Wyatt

Executive Session
Dr. Espeland called the meeting to order at 8:30 a.m., introductions were made and the minutes from the May 25, 2004 OSMB meeting were approved.

Project Office Report
Ms. Nelson summarized the current status of the Jackson Heart Study and provided an orientation to the materials that were distributed. Since the May, 2004 OSMB meeting, baseline examinations were completed and exam data close-out is currently underway at the Coordinating Center. The Office of Management and Budget (OMB) has approved annual follow-up data collection about participants from physicians and participant proxies until May 31, 2007. The current Certificate of Confidentiality will expire in June, 2005. The Interim Clinic Plan (ICP) activities are ongoing at the Exam Center and the investigators have begun preliminary preparations for Exam 2 which is scheduled to begin in September, 2005. The ICP is providing follow-up on reported participant results with attention focused on participants who have had alert findings. It also provides educational sessions to the cohort on improving heart disease risk factor awareness and promoting healthy behaviors. The ICP is scheduled to end July, 2005. The NHLBI Project Office projects that by the end of the ICP on July 1, 3660 participants will have completed the ICP telephone survey (70%); 2051 participants will have been scheduled for a "Know Your Numbers (KYN)" educational session (40%); and 884 will have attended the KYN educational session (17%).

Ms. Nelson reminded the Board that the NHLBI Project Office is in the midst of negotiating the Jackson Heart Study contract renewal and that some of the examination components outlined by the Exam Center may be modified or cut as we try to fit the science within the available budget.

Ms. Nelson requested that the Board provide recommendations and/or guidance on ways to increase manuscript productivity on the baseline methods papers. She noted that the moratorium

on ancillary studies was lifted in December, 2003. Since that time the Data and Materials Distribution Agreement was approved by the Institute. The Ancillary Studies subcommittee has been very active and will likely recommend approval of two ancillary study proposals by the Steering Committee in a few weeks. These are: "Genetic susceptibility to dilated cardiodmyopathy (Dr. Olson, Mayo Clinic); and "The Broad-Novartis diabetes initiative: the Jackson Heart Study Component (Dr. Altshuler – Harvard).

One challenging issue related to ancillary studies is the unfunded demand put on the Coordinating Center and/or Exam Center to support collaborations for external ancillary studies. Some of our epidemiology studies have been more successful than others in managing these demands for support. The NHLBI policy that ancillary studies be fully supported by their own funds is part of the JHS Ancillary Studies Guidelines. Similar funding language is also part of the Jackson Ancillary Study Instructions to Applicants. Ms. Nelson requested recommendations about how the JHS should begin to manage this potential demand as the number of ancillary study requests begins to increase.

Related to the renewal of the JHS contract, Dr. Espeland inquired whether the Board needs to approve the final protocol. The Board does not approve the protocol; however, NHLBI will send the Board the negotiated components of Exam 2 for comment.

General Session

Following introductions, Dr. Espeland welcomed everyone to the meeting on behalf of Dr. Kumanyika who was unable to attend. Dr. Taylor noted that this was the 6th meeting of the Board and thanked the Board members for their efforts over the years.

He provided a summary of the JHS responses to the Board's recommendations from the May 25, 2004 meeting as follows:

Investigators should bring human subject and safety concerns related to the ancillary studies to the attention of the Board and provide a periodic update of these issues.
Dr. Taylor noted that the Ancillary Studies Guidelines include procedures for review and approval of all ancillary studies by the Board. Initial review of human subject and safety concerns will be obtained by principal investigators from their own Institutional Review Boards and provide documentation to the Jackson Heart Study which will also be forwarded to the JHS IRBs. Semi-annual reports will be required from each ancillary study which will include information on any issues arising from the conduct of the study. These issues will immediately be brought to the attention of the OSMB and the Jackson IRBs. Also, an annual update of all ancillary studies, including human subject and safety concerns, will be submitted as part of the OSMB reporting process.

Investigators are encouraged to continue and expand community involvement in the research and dissemination process with reference to models such as the one developed by the Strong Heart Study.
Dr. Taylor noted that there is a process for community involvement via the JHS Translating Research into Practice and Prevention (TRIPP) Subcommittee. This purpose of this committee is to assist in translating information and findings to the community. This committee is aware of

the Strong Heart Study activities related to community involvement. The initiative of translating research into practice has two audiences: 1) the lay public and 2) practicing physicians and other health care providers. The JHS Steering Committee also has two community representatives and is adding two representatives to the Publications and Presentations Subcommittee.

Investigators are encouraged to document and publish, as soon as possible, the early recruitment history including original recruitment goals, and how the recruitment process evolved.
This paper, along with a set of 7 other papers, is in the final stages of preparation for submission as a supplement to *Ethnicity and Disease.* It will include the history of the recruitment process including key decision points, modification of recruitment targets, inclusion of the volunteer sample, and other historical details. This is expected to be published in the Fall 2005.

The Coordinating Center (CC) should request sufficient support for data management, analysis, and distribution. The CC is encouraged to fill positions they are seeking as soon as possible.
The Coordinating Center is actively recruiting additional staff for data management, analysis and distribution. The positions are Senior Research Scientist and Research Statistician. An Applications Programmer was recently hired. A SAS programmer has been identified and the CC is pursuing this individual.

The investigators should prioritize updating of clinic forms to include differentiation between data that are missing, not applicable to the respondent, not applicable because of skip patterns, or refused.
This recommendation was implemented. All data collection instruments used in the Interim Clinic Plan have appropriate codes and the forms are set up for direct key entry. This is also being implemented in the forms being developed for Exam 2.

The Undergraduate Training Center is encouraged to take full advantage of resources of the Young Epidemiology Scholars (YES) Program in developing curricula for their program.
YES Program exercises and concepts have been incorporated into the high school SLAM Program. Students have also analyzed the winning YES abstracts and discussed project ideas. No Jackson student has entered the YES competition, but one student is working on a project with an eye toward entering the YES competition next year.

Investigators should consider obtaining an in-house coordinator/contractor to assist with analysis of genetic data and to develop infrastructure associated with management of genetic data.
The genetic biostatistician position remains open. Dr. Jim Wilson continues to provide strong genetics support at the local level and efforts continue to seek a qualified in-house coordinator. Until then, collaborations with outside experts will continue. The CC has acquired a server dedicated to genetic data which will provide capabilities to manage and analyze data locally. It is expected the server will be fully functional on May 31, 2005.

Comments by the Board: After hearing updates on the various aspects of the Study, the Board provided comments. Dr. Espeland suggested standardizing forms and procedures for processing ancillary study requests and for reporting adverse events. Dr. Wyatt indicated that the JHS will

adopt and use existing IRB forms for this purpose. Requestors will need to meet with Drs. Wyatt and Sarpong to ensure there is enough funding for specific ancillary study requests.

In response to Dr. Espeland's question about whether community involvement has influenced the publications process, Dr. Taylor indicated that the publications proposed to date have not been controversial. They cover methodology and prevalence of disease and thus far no change in direction has been suggested. He indicated this might change as publications delve more into genetic and social/cultural issues.

Dr. Johnson cautioned the investigators that committee members from the community sometimes can become acculturated to the study and eventually adopt views of the scientific community. She suggested that participating community members be rotated to prevent this phenomenon. Dr. Taylor indicated that some investigators feel that the community involvement can slow down the publications process, but also recognize its importance and value.

In response to Dr. Wilson's inquiry about whether the community has been educated about the study, Dr. Taylor indicated that there have been many efforts including town hall style meetings, annual meetings with the community, and presentations from genetics experts including Dr. Kittles and Dr. Royal, a genetics ethicist. Dr. Wilson also suggested that the investigators consult with Dr. Vince Barnum from the Genome Institute.

Study Operations Report: Dr. Taylor provided a summary of the study's progress to date. The response to the RFP for exams 2 and 3 was submitted, Exam 1 data closeout is complete, and key study outcome derived variables have been identified. A summary of the progress of the Undergraduate Training Center indicated that 25 JHS Scholars have graduated from Tougaloo, with 2 medical school students returning for the summer on minority supplements; 1 student is returning to teach in the SLAM program. There are currently 33 JHS scholars (12 new slots per year); and approximately 200 health professionals have completed an annual summer short course in epidemiology. Scientific productivity since the last OSMB meeting includes 3 JHS publications and 7 Jackson-ARIC publications, and approximately 60 manuscript proposals have been approved. A Methods supplement will be published this fall in *Ethnicity and Disease*, which will include 8-9 Jackson-related papers. Two JHS abstracts are being submitted for the upcoming AHA November meetings. There are currently 8 ancillary studies in various stages of review and approval.

Dr. Burns asked the investigators to describe the process for manuscript approval. Dr. Taylor indicated that the process is almost identical to that established for the ARIC Study with more information requested on rationale and methods -- writing groups are formed, a draft proposal is submitted, the proposals are listed on the website, and decisions about the proposals are made at monthly publications meetings. Moving a manuscript from proposal to press may take as long as three years, the major bottleneck being obtaining statistical support. Proposals are not required to include table shells, but variables for analysis are listed. When a proposal is approved, the Coordinating Center and lead author put together an analysis plan. Regardless of who does the analysis, the analysis plan is used as a guide. Dr. Sarpong indicated that the Coordinating Center performs the analyses for approximately 85% of the manuscripts proposals.

Dr. Espeland suggested that publications might be moved along by asking for table shells at the time the proposal is submitted. It would be very helpful even if those tables ultimately were not included in the final paper. Dr. Wolf indicated that while it is not difficult to put together abstracts, it is important to complete full manuscripts on a timely basis. He suggested limiting the number of abstracts per author until the manuscripts pertaining to the existing abstracts have been completed. Also, to move the publications process along, Dr. Manolio noted that heritability data are publishable by themselves. Dr. Burns indicated that monographs could certainly be written.

In response the report on the Undergraduate Training Center, Dr. Wilson encouraged the program to steer the students toward a research career (epidemiology and biostatistics) to the extent possible. Dr. Srinivasan indicated that many of the students are interested in medical careers, but they are encouraging the students toward research.

Dr. Sarpong explained rationale for the proposed final data set size of 5,302 including a detailed description of the Jackson Heart Study cohort. The mean age of the cohort is 54.8 years; mean age of the women is 55.2 years and the mean age of the men is 53.9 years. Approximately 22% of the cohort had less than a high school education; 22.5% had a high school education; approximately 55% achieved more than a high school education. He reviewed other characteristics of the cohort including BMI, lipid and glucose levels, and blood pressure by gender.

Dr. Wolf suggested that the investigators look at why people did not complete all exam components. Some unpopular components of the exam included the "bring to clinic" forms, 24 hour urine, and ambulatory blood pressure monitoring. In the future all forms will be completed at the clinic and assistance will be offered to ensure greater completion rates and modifications were made to the other procedures to facilitate collection of these data. The Board also suggested that quality control procedures be tested during the pilot phase before the next examination.

Surveillance: The Jackson Heart Study began sending ECG readings to Minnesota in February, 2005 for review and adjudication of CHD events. Implementation of an annual follow-up form including congestive heart failure is also underway. The investigators will work closely with ARIC in CHF classification and adjudication.

The investigators described their records abstraction process. Based on ARIC data for CHD and stroke and on published data from other studies, approximately 2,483 record abstractions are anticipated over the next 9 years. Abstractions for the Year 2003 are expected to be completed in July, 2005. The investigators also described difficulties in abstracting 9 records from the Veteran's Administration and 14 records from a local hospital due to several changes in the hospital administration. Dr. Stoney questioned why there were more abstractions than events. Dr Wyatt responded that any hospitalization triggers an abstraction which may or may not lead to an eligible CVD event.

In response to the presentations, Dr. Espeland suggested that it would desirable to present data by rates using survival curves and person-years. He also asked why a two-year time period is

needed from occurrence of an event to adjudication. The investigators indicated that it takes a long time to obtain records and to verify deaths. They also indicated that they are tied to the ARIC process for adjudication and ARIC takes a long time due to its community surveillance component.

Interim Clinic Plan (ICP): This began approximately one year ago to assure continued involvement with the JHS cohort between examinations. It included phone surveys, targeted educational sessions (Know Your Numbers), and the opportunity for surveys about health behaviors. It will end in June, 2005. Some of the lessons learned from the ICP are that the cohort greatly appreciated the continued contact and that even though participation in KYN was lower than expected, people expressed their intent to return for Exam 2. Reduced participation did not necessarily indicate lack of interest but rather reflected limited time people have available. The investigators are now working on different interim plan approaches such as web-based participation.

Undergraduate Training Center: Dr. Srinivasan provided more details about the programs at Tougaloo and their success. There has been a 100% return rate in the high school SLAM program from SLAM 2 to SLAM 3 and 100% participation in a KYN program among high school students.

Dr. Johnson encouraged the UTC to engage students even if they are not enrolled in the Jackson Heart Study Scholars program. Dr. Srinivasan stated there is a luncheon for those students not accepted and they are still encouraged to pursue research careers. Dr. Tabor noted that a majority of the students are female, but urged the investigators not to sacrifice quality just to recruit male students. Dr. Srinivasan indicated that the program is reflective of the demographics of the Tougaloo student body which is approximately 60-70% female.

*Jackson Heart Study Data: D*r. Taylor described preliminary results of echocardiography and related issues about data quality. Although the overall quality of the data is very good, the LV mass measurements in JHS participants also in ARIC were lower than measurements obtained in ARIC for these same participants. The investigators agreed that since LV mass and LV hypertrophy are important phenotypes, the quality of the echo data is critical. Dr. Taylor noted that the wall thicknesses in the Jackson cohort were a little smaller and the diameters were a little larger – i.e. these results are similar to those in Framingham, rather than ARIC. Dr. Skelton reread 151 echos. After testing the equipment, it was determined these variations were not due to differences in equipment. They are also looking at reader differences. Temporal drift was also suggested as a possible explanation.

Dr. Ofili and others on the Board suggested that the studies be reviewed to determine if there are differences across technicians. The Board also suggested that JHS convene an outside group of experts to systematically review problems/discrepancies related to the echocardiography and possibly a separate group to review carotid ultrasound. A sample should be reviewed across time, age, and sex, and technicians. Dr. Johnson suggested the possible need for an echo quality control board or an imaging committee to look at these issues.

Coordinating Center Report: Dr. Sarpong described the organization of the Coordinating Center, automation of various functions, revised methods for data collection in Exam 2 including special codes to ensure data entry of all fields, and methods for reviewing and validating data. Several Web based applications are also being developed for the Health Awareness and Know Your Numbers Surveys, as well as for submitting ancillary study proposals. These systems will help to relieve the Coordinating Center burden and enable staff to devote more time to analyses.

Examination Center Report: Cohort retention is considered to be the most challenging aspect of the next examination cycles. The study is continuing to implement community-driven strategies identified in the initial Participant Recruitment Study. The study is actively involving the community through family days, cards and a JHS newsletter. Layered informed consents and methods for tracking them have been developed and the cohort retention protocol is being revised to include letters and follow-up phone calls. Web-based applications are also being developed for participant use. The web-based applications (CDCWonder type) for the cohort and the community are intended to be supplementary, not the primary mode for disseminating information. The Board asked about participant access to computers and timely alert procedures. The investigators indicated that computers are widely available in libraries and some are slated to be available in the Medical Mall. Also they are considering placing kiosks in the medical library. Dr. Stoney suggested the investigators develop alert triggers for the depression screening questionnaires as this could have serious implications.

Ancillary Studies Update: Six to eight ancillary studies have been reviewed to date. The Coordinating Center is collaborating with the specimen repository at the University of Minnesota to track availability of specimens and to set priorities for their use. The Coordinating Center will ensure that all specimen requests are approved by the Steering Committee and if a specimen request is approved but samples haven't yet been sent, they will still be considered out of inventory. The Project Office suggested that in tracking specimens, the plasma category be tracked by components (EDTA, citrated). The Board inquired if unused samples will be returned to the repository. Dr. Taylor indicated that the study would like to retain as many samples as possible because unused samples may be useful in some manner.

Different options for funding ancillary study involvement were discussed. The main point stressed was that ancillary studies should not interfere with the conduct of the main Jackson Heart Study.

Plans to Stimulate Manuscripts: The investigators are "advertising" the fact that Jackson Heart Study data are available through presentations at national meetings. An Emerging Science Committee brings together experts to discuss scientific direction and the investigators are also engaging leading African American scientists. It was noted that one of the goals of the JHS was to build infrastructure and capacity at the Institutions involved. There are also close ties between University of Mississippi JHS and the EXPORT grant at Jackson State.

The Board noted that there are a considerable number of proposed publications and questioned what efforts are underway to keep them on track. Dr. Taylor responded that the early focus of the study was on recruitment, increasing participation and the mandate to work on ARIC

manuscripts. Now the investigators can turn their attention to JHS manuscripts and he anticipates that more progress will be made.

Scientific Presentations: Dr. Taylor gave a presentation on the Relation of Aortic Valve Sclerosis to Risk of Coronary Heart Disease in African-Americans. (Am. J Cardiology 2005;95-401-404. The analysis suggests that AVS is prevalent and of prognostic importance for coronary heart disease among a younger, African-American sample.

Dr. Wyatt presented "Participation on an Observational Study Alters Health Behaviors in African Americans: The Jackson Heart Study Baseline Exam." She concluded that participation in an epidemiology cohort study was positively associated with health behavior changes in African Americans.

Dr. Taylor thanked the Board for their contributions.

Executive Session

The Board complimented the efforts and progress the investigators have made on the Jackson Heart Study. No problems were identified that would impede the progress of the study. In particular, the Board praised the efforts of the Undergraduate Training Center at Tougaloo College. Dr. Tabor noted that the National Center on Minority Health and Health Disparities is partially funding the Jackson Heart Study and was not acknowledged under its current name in publications. Members discussed timeliness of alerts, adjudication of events and developing alerts (triggers) for assessments of depression.

Recommendations by the Board

- Aggressively pursue filling vacancies for statistical positions and an in-house genetics coordinator
- Use cohort size of 5,302 in publications
- Present data by rates using survival curves and person-years
- Convene groups of experts to review the echocardiography and ultrasound data
- Prior to the next exam, perform quality control procedures during the pilot phase
- Encourage events adjudication as quickly and efficiently as possible
- Limit number of abstracts presented per author until manuscripts are published
- Develop alert criteria for assessment of depression for feedback to participants.
- Acknowledge funding contributions of the National Center on Minority Health and Health Disparities in publications

The meeting adjourned at 2:45 p.m. The next meeting will be decided upon at a future date.

Respectfully submitted,

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Mark Espeland, Ph.D.	Lorraine Silsbee, M.H.S.
Acting Chair	Executive Secretary