Jackson Heart Study Monitoring Board
Minutes of the Meeting of May 20, 2003
Marriott Suites Hotel (Democracy Blvd.)
Bethesda, Maryland

Members present: Drs. Shiriki Kumanyika (Chair), Trudy Burns, T. B. Ellis, Mark Espeland, Paula Johnson, and Philip Wolf

Members absent: Drs. Sherman James and George Mensah

Staff present: Drs. Diane Bild (Executive Secretary), Cashell Jaquish, Teri Manolio, and Evelyn Walker (Field Officer), and Ms. Cheryl Nelson (Project Officer) and Ms. Lisa O'Neill (Contracting Officer)

Investigators present: Drs. Bobby Clark, Robert Garrison, Daniel Sarpong, Asoka Srinivasan, Herman Taylor, James Wilson, and Sharon Wyatt

Executive Session

Dr. Kumanyika called the meeting to order, and the minutes from the December 2002 conference call of the Board were approved.

Project Office Report:

Ms. Nelson noted that recruitment is at 3,800, 78% of goal as of week 137. The average weekly number of clinic examinations was 33 in December, reached 43 in January, and was 40 in April 2003. She reviewed three areas of concern for the Board to consider: the apparently increasing rate of partial consent for DNA and timeliness of inputting this information into the Data Management System; the need to retrain and recertify clinic staff periodically who demonstrate poor performance; and timeliness of participant results reporting. The Board should also consider the acceptability of the investigators' proposal to reduce the target for the whole cohort to 5,500.

Dr. Manolio remarked on the draft report that was recently sent to the Board summarizing the recommendations of an Advisory Panel that met to discuss the scientific priorities that might be addressed in a renewal of the study. She reminded the Board that the contract ends in May 2005. The Advisory Panel was the first step in a series that would lead towards a contract renewal, including a presentation to the NHLBI Board of Extramural Advisors in September 2003, a proposal for the NHLB Advisory Council in October 2003, and issuance of an RFP in spring 2004. The JHS Advisory Panel generally recommended that renal disease, body composition, and congestive heart failure be given more emphasis, and that repeat echocardiography was not a high priority at this time.

The Board commented that it is important not to stretch the investigators too thin. They stated that cohort retention will be critical to the success of future exams. They also questioned whether overlap with and comparability to other cohorts would be considered in the renewal. They were concerned about the readability of the participant results, specifically in the use of symbols such as "<", rather than words ("less than"). They questioned why it appears that the consent for use of DNA is low. (Table 1.5.1 in Tab 9, page 20 showed that only 33.6% have consented to use of DNA with no restrictions.) They were also concerned, however, that the numbers didn't match across tables and with the errors in data entry mentioned in the report. They emphasized that DNA cannot be used until the investigators are sure that the informed consent directives have been recorded and applied accurately. The Board thought that the informed consent should be re-evaluated, particularly use of terms such as "cell lines" and "living tissue sample," which may mislead participants. They recommended conducting some type of qualitative assessment to determine why participants are refusing and approaching those who refused to make sure they understood the consent.

General Session

The investigators joined the Board at 9:15.

Steering Committee Report:

Dr. Taylor reviewed the participation of various subgroups, which is high for the ARIC members and household members (87%) but lower for family members. He briefly referred to the revised sample size calculations, which generally show that a final cohort of 5,500, rather than 6,500, is not greatly detrimental to statistical power to examine questions of interest. This new target appears to be attainable, since the clinic is seeing 7.5-8.0 participants per day. The investigators plan to stop contacting new potential participants in February, to allow a month for them to be examined. They predict that at the end of recruitment, there will be approximately 1,035 people who have had a household induction interview (HII) but no exam and have plans to either follow them for events, include them in cross sectional analyses, or enroll them in the second JHS exam.
The Board expressed some concern about the fact that the cohort is approximately 5 years younger, on average, than planned. This will reduce the number of events in the study and lower power. Event rates should be monitored in the study.

Recruitment and Participation Rates:

Dr. Wyatt noted that the JHS cohort mirrors the community in its demographics, including 65% women. There are approximately 55 clinic exams per 100 household contacts, and 74 exams per 100 HIIs completed. Fluctuations in recruitment have occurred because of holidays, staffing changes, and some recent negative publicity about UMMC.

Clinic Operations:

Completeness for performing components is generally >85%. Echocardiography completeness has improved greatly with 93% of studies being completed in one clinic visit. Participation in the 24-hour studies has not improved. The urine collection protocol was changed to include a spot urine collection on all participants, but few participate in the 24 hour study. The Diet and Physical Activity substudy (n=250) is going well and is collecting 24-hour urines on all participants. The expectation is that there will be approximately 1,000 participants with 24-hour urine and 1,000 with 24-hour ambulatory BP studies completed at the end of Exam 1.

Timeliness in reporting participant results has improved; results from December are now being distributed. Annual follow-up is going well with 98% completeness for those whose windows have closed for the first follow-up and 99% completeness for the second follow-up. A summary of current challenges for the Exam Center include glitches in the tracking software, which is being worked on now; staffing turnover; results reporting; and data entry.

Events monitoring:

Dr. Sarpong provided a brief update on the status of the surveillance system, which is jointly performed by JHS staff and University of North Carolina at Chapel Hill. The JHS identifies events in the Jackson cohort and abstracts data from the medical records. This information, along with ECG codes from the hospital ECGs, is sent to UNC for data processing and event classification, using ARIC methods. The first batch of data was sent to UNC in April.

There have been 25 deaths among JHS members. Death certificates have been obtained on 19 thus far, and 13 of the deaths are CVD-related. Of the 25, 18 are from the ARIC cohort.

Quality Control:

Dr. Sarpong described the procedures for data checking and cleaning, including the automatic flagging of out-of-range values by ClinTrial, as well as the QC runs performed periodically to identify data errors. Other quality control procedures include comparing technician measurements and reading center data over time while adjusting for covariates to detect differences and trends. He described the procedure for sending phantom sets of tubes of blood to the laboratory for blind replicate analysis. It can require 2-3 days to create a complete set, which introduces some additional time before sending the set to the laboratories. Digit preference in the measurement of blood pressure and weight has been identified for several technicians. They have been retrained and their performance will be monitored. Missing data are investigated and corrected, if possible. Completeness of data in the data base once obtained in the clinic is generally 99-100% except for forms the participant brings in, for which the data are ~92% complete.

One of the current challenges includes generating operational reports from ClinTrial. Dr. Sarpong has implemented a Visual Basic interface to do this, and it seems to work well, but it is time-consuming. The Coordinating Center has limited statistical computing personnel.

However, they are recruiting a full-time statistical geneticist and have hired a statistician who is being trained in genetics.

Undergraduate Training Center:

Dr. Srinivasan reported that the first class of JHS Scholars will graduate this spring, and they expect 11 to graduate next year. They tend to be the top students at Tougaloo. The first year Scholars have no difficulty finding interesting summer internships. The UTC would like to implement a plan in the fall for the seniors to perform hands-on clinic work and research projects in the JHS. One continuing problem is the lack of men in the program. For example, of the 10 Freshmen, only one is a man. The Board remarked that this is an area of concern in programs for minority students generally and is also reflected somewhat in non-minority programs. The Board encouraged the investigators to publicize the success of the program. It was noted that there is a "methods" manuscript underway that describes it.

Family Study:

Dr. Wilson presented the numbers in the Family Study as of April 24: 1,103 HIIs had been conducted, resulting in 935 clinic visits, for a rate of approximately 90 per month. If this is maintained, 1,800 family study participants will be included. Recruitment is resulting in approximately 48% clinic visits per HII. The average family size is 7-8. Greater than 90% of the families have 5 members or more, although the size is expected to decrease as relatedness of individuals is determined genetically and spouses with no biological children are removed from pedigrees. The Genetics Committee is working on a data sharing policy. They are planning a submission to the Mammalian Genotyping Service in the Spring of 2004 to perform a genome scan which will provide a map with a density of ~5 cM.

Community Awareness:

Dr. Garrison reported on the activities of the Partnership for Community Awareness and Health Education, which is headed by Donna LaVigne. Three Community Health Action Networks have been initiated, in Canton, Clinton, and Madison. He reviewed the turn-around in recruitment in Canton, which resulted in excellent participation and recruitment of 206 participants. Hinds is the current challenge in raising community awareness and recruitment.

Publications and Presentations:

Dr. Clark presented the plans for 6 types of papers, including review manuscripts, ARIC data analyses, JHS methods, JHS baseline data, JHS/ARIC longitudinal analyses, and JHS longitudinal analyses. Good progress has been made in the first three categories, with several publications and several in press. There are 6 ARIC data analyses in preparation. There are also two doctoral theses being written using JHS data.

Dr. Clark presented data on pulse pressure and cardiovascular disease from ARIC. Increased pulse pressure of 10 mmHg results in an approximate 45% increase in CHD mortality, independent of age, sex, race, and other CHD risk factors. The Board remarked that it is difficult to tease out the effects of pulse pressure from systolic and diastolic blood pressure.

Ancillary Studies:

Two draft ancillary study proposals were included in the report, for the Board's information. Dr. Taylor remarked that there is continued interest on the part of outside investigators to collaborate with the JHS. The Board stated that it would like the investigators to consider when and how to re-open this type of collaboration, without hindering continued efforts at recruitment.

Executive Session

The Board made the following comments and recommendations:

1. The Board complimented the investigators for their careful consideration of recruitment issues, progress in recruitment, increased quality control efforts, and the improved quality of the information presented in the report. They urged the investigators to be vigilant about maintaining these efforts though the end of recruitment. They requested receipt of monthly recruitment information.

2. The Board recommended approving the new target for the cohort of 5,500. They cautioned that on-study rates should be examined to determine the accuracy of estimates of event rates. Particular attention must also be paid to the improving the rate of recruitment of subjects in the low SES strata.

3. The Board recommended maintaining the moratorium on ancillary studies. They suggested that the investigators provide a rationale and plan for the Board before making any plans to resume ancillary studies. In particular, they cautioned against ancillary studies that would interfere with the study protocol and impose too much of a burden on the investigators and staff.

4. The Board expressed concern about losing the excellent trained staff towards the end of recruitment and urged the investigators to plan to retain staff as necessary and feasible and otherwise avoid the disruption caused by departure of staff.

5. The Board stated that a clear plan should be developed for the end of recruitment, including timing of cessation of HIIs. They felt that after several attempts had been made to bring in participants who had had an HII but no exam, success was unlikely and further recruitment efforts should be discontinued. The investigators might consider performing cross-sectional analyses, as proposed, on persons with HII but no exam data, but additional resources should not be devoted to collect more data in this group.

6. The Board was concerned about the high rate of restrictions on use the DNA and suggested re-evaluating the language on DNA in the informed consent and collecting some qualitative information on attitudes and understanding regarding genetic research as presented in the consent form. They suggested cautiously re-approaching refusers, particularly those who are key links in families. They also stated that the database on informed consent directives must be thoroughly evaluated for accuracy and corrected as necessary before any genotyping is performed. They would also like to request an update on the number of full sibling pairs, etc. for which DNA is available for genotyping.

7. The Board encouraged the investigators to provide continued active quality control feedback and follow-up. They encouraged regular re-training of staff and suggested that annual site visits of the Exam Center be performed to maintain quality.

8. The Board encouraged the investigators to report results to participants as close to within 3 months of their exam as possible.

The Board will hold a conference call on Tuesday, December 2, 2003, 10 am – 12 noon EDT and will have a meeting on Tuesday, May 25, 2004 in Bethesda, Maryland.

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Dr. Shiriki Kumanyika, Chair Date

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Dr. Diane Bild, Executive Secretary Date