

Request for OMB Approval of Revision of the

Jackson Heart Study

Supporting Statement Part B

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Cheryl Nelson

6701 Rockledge Drive MSC 7934

Bethesda, MD 20892

Phone: 301-435-0451

FAX: 301-480-1667

E-Mail: NelsonC@NHLBI.NIH.GOV

Table of Contents

B. Collections of Information Employing Statistical Methods	
1. Respondent Universe and Sampling Methods.....	3
2. Procedures for the Collection of Information.....	4
3. Methods to Maximize Response Rates and Deal with Nonresponse.....	7
4. Tests of Procedures or Methods to be Undertaken.....	8
5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data.....	8

B. Collections of Information Employing Statistical Methods

B.1. Respondent Universe and Sampling Methods

B.1.a. Design Summary

The JHS is a single-site prospective investigation of CVD among African-Americans from the Jackson, Mississippi metropolitan area. The JHS was designed to collect data in a single site, consisting of an all African-American geographically defined community. The goals of the JHS are to study CVD in an all African-American population (ages 35-84), including genetic components. 5,302 participants completed the baseline clinical Exam 1, including 1,601 Jackson ARIC Study participants, 2,228 new Jackson participants (924 randomly selected residents from three Jackson counties and 1304 volunteer participants who met demographic criteria) and 1,473 Jackson family member (from 200 probands). Eighty percent (80%) of the surviving JHS participant (N=4203) completed Exam 2; projected retention for Exam 3 is eighty-six percent (86%) (N=4082).

B.1.b. Respondent Universe

In the Surveillance component, data will be examined based on specific diagnostic codes. The study will obtain information from hospitals, physicians and relatives on all fatal and non-fatal cases of CVD in the cohort. The cohort mortality rate is expected to be similar to rates found in the Jackson cohort of ARIC of 11% - resulting in approximately 300 deaths annually. The expected

response rate for data collection from the respondent universe (physicians and next of kin) is 85%.

The communities selected for investigation in the JHS will provide information on the occurrence and trends in CVD in a unique environmental setting. The cohort samples will permit inferences to be made about risk factors and disease relationships from the population. The JHS will permit evaluation of the consistency of any observed association. It was important to select a community in which identification, repeated examinations, and surveillance of a cohort of individuals would be possible and linkage between CVD occurring in the community and in the cohort could be made.

Community Health Advisor Networks (CHANs) comprise another component of the Study. CHANs address CVD prevention through health education programs in five Mississippi communities, as most Mississippians have at least one risk factor associated with CVD. Community Health Advisors (CHAs) are trained and certified to organize and implement various programs in their communities. Forty five CHAs have conducted over 1,000 outreach events.

B.2. Procedures for Information Collection

The next of kin will be contacted by letter requesting permission for an interview about the participant's existing medical situation at the time of death. A copy of the consent form will be attached. These informants will later be contacted

by telephone to gather information about events surrounding the death of the participant.

Physicians, familiar with the medical history or with the events preceding the death of a JHS participant, will be contacted by letter to help classify the death of the participant. They will be mailed a self-administered questionnaire to ascertain whether the deaths of the JHS participants, which occurred out of hospital emergency room or prior to arrival at hospital (DOA's) are due to cardiovascular disease.

Information is also collected for the Community Health Advisors Networks (CHAN). The CHANs meet monthly from September through June. Before implementing health education sessions, community members are administered pre-tests to assess their knowledge about cardiovascular disease and risk factors. Post-tests are administered after the completion of health education sessions to ensure that the community has a greater understanding and knowledge of the topics covered during the training.

B.2.a. Community Surveillance Component Design

Surveillance of the JHS cohort will be used to ascertain medical events between each contact. The study will obtain a complete enumeration and valid diagnostic classification of the fatal CVD and hospitalized incidences of participants. Surveillance data gathering procedures will be based on a review of

hospital records of all participants with either a diagnosis of cardiovascular disease or one of several screening diagnoses who were discharged from any of the acute care hospitals in the area. The JHS surveillance staff will conduct review and abstraction of hospital records.

The surveillance of CVD deaths in the cohort is accomplished by the review and abstraction of all age and residence eligible death certificates with various manifestations of CVD coded as the underlying cause of death during the study period. Sources of validation for out-of-hospital death, and dead-on-arrivals will include interviews with the next-of-kin, and personal physician, coroner or medical examiner reports, and hospital records. Deaths occurring in the hospital are classified by abstracting information from the medical record. All CVD deaths which cannot be positively classified by the diagnostic algorithm will undergo review by a classification panel. The information on hospitalizations and deaths will be reviewed and a determination of the occurrence of CVD and stroke will be made according to defined criteria. Cause of death will also be determined.

The death certificate will be obtained from the Vital Statistics registrars and the place of death determined. For in-hospital deaths, the hospital record is reviewed as indicated above. For out-of-hospital deaths and decedents admitted without a pulse rate or blood pressure, the participant=s family and physician will

be contacted to provide information on the circumstances surrounding the death, if the participant gave prior consent.

B.3. Methods to Maximize Response Rates and Deal With Non-response

The procedures to maximize responses will focus on maintaining high-response rates to the surveillance questionnaires from the relatives and physicians of the participants. To maintain a high response rate to the surveillance phase of the JHS, the following procedures will be implemented:

- A letter will be sent to the next-of-kin of the participants indicating that the participant had given permission to contact a relative for information; a copy of the consent form is enclosed with the letter. The relative will also be informed that a JHS staff will make contact to ask medical questions relating to the participant to prepare the relative so that he or she may have information available for the JHS staff. A letter will also be sent thanking the relative for participating in the process.
- A letter will be sent to the participant's physician requesting assistance in classifying the participant's death in terms of heart disease and requesting completion of the Physician Questionnaire.
- If the information for the surveillance component cannot be obtained, then an interviewer will call or visit the household or the physician to obtain the information.

B.4. Test of Procedures or Methods to be Undertaken

The procedures and methods of data collection have all been defined previously in the JHS to minimize burden and improve utility. Data collection related to the training of community members by Community Health Advisors is the only new component to the study.

B.5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

The following individuals were consulted on statistical aspects:

Michael Andrew, Ph.D. Center for Disease Control and Prevention
Morgantown, West Virginia
(301) 285-6189

George Howard, Ph.D. Department of Biostatistics
University of Alabama, Birmingham
(205) 934-4905

James Hosking, Ph.D. Department of Biostatistics
University of North Carolina, Chapel Hill
(919) 962-3085

The following individuals are responsible for data collection:

Herman A. Taylor, M.D. Director and Principal Investigator
Jackson Heart Study

University of MS Medical Center,
Department of Medicine/Cardiology
(601) 368-4644

Frances Henderson, Ph D. Co-Director and Investigator

Jackson Heart Study Examination Center
Jackson Heart Study Exam Center
(601) 368-7317

Ervin Fox, M.D.

Co-Director and Investigator
Jackson Heart Study Examination Center
University of MS Medical Center
(601) 815-5050

The following individuals are responsible for data analysis:

Daniel F. Sarpong, Ph.D. Director and Investigator

Jackson Heart Study Coordinating Center
Jackson State University
(601) 368-4648