

Jackson Heart Study Protocol
Manual 1
General Description and Study Management
Visit 1

Version 1.1

April 29, 2003

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FOREWORD

This manual is one of a series of protocols and manuals of operation for the Jackson Heart Study (JHS). The complexity of the JHS requires that a sizeable number of procedures be described, thus this rather extensive list of materials has been organized into the set of manuals listed below. Manual 1 provides the background, organization, and general objectives of the JHS Study. Manuals 2 and 10 describe the operation of the Cohort and Surveillance Components of the study. Detailed Manuals of Operation for specific procedures, including those of reading centers and central laboratories, make up Manuals 3 through 9 and 11.

JHS Study Protocols and Manuals of Operation

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1	General Description and Study Management
2	Cohort Component Procedures
3	Family Study
4	Blood Pressure
5	Electrocardiography
6	Echocardiography
7	Ultrasound Assessment
8	Pulmonary Function Assessment
9	Specimen Collection and Processing
10	Morbidity and Mortality Classification Manual
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1.0 INTRODUCTION

The Jackson Heart Study is a population-based study of cardiovascular disease in African-Americans sponsored by the National Heart, Lung, and Blood Institute and the National Center on Minority Health and Health Disparities (formerly known as the Office of Research on Minority Health) of the National Institutes of Health.

Rationale: Despite encouraging declines over the past three decades, cardiovascular disease (CVD) remains the number one cause of death in the U.S. A number of risk factors for coronary heart disease (CHD) and stroke have been identified; however, relatively few population-based studies have examined CVD in a large group of African-Americans. Existing evidence indicates that death rates for CVD in the U.S. are considerably higher among African-Americans. CVD death rates in Mississippi are the highest in the nation and particularly high among African-Americans. Between 1980 and 1995, the decline in CVD death rates has been the slowest among African-American men and women in Mississippi relative to other groups in the state and nation (Table 1).

Table 1. Age-adjusted Mortality Rates for Men and Women in the United States (US) and Mississippi (MS), 1997

Mortality ^{1,2}	Region	Black		White	
		Men	Women	Men	Women
All Causes	US	1,445	939	1,062	718
	MS	1,630	1,000	1,266	794
CVD	US	540	401	436	300
	MS	683	496	542	365
Hypertension	US	14	12	5	4
	MS	12	13	4	6
Heart Disease	US	414	295	347	223
	MS	548	385	448	285
Stroke	US	206	190	172	169
	MS	233	191	186	174

¹ Age-adjusted death rates to the total US population for year 2000; ages 35-84; annual rate per 100,000.

² ICD-9, International Classification of Diseases, Clinical Modification, 9th Edition for causes of death listed are:
 Cardiovascular Disease (CVD) 390-459
 Hypertension with or without Renal Disease 401, 403
 Heart Disease 390-398, 402, 404-429
 Stroke or Cerebrovascular Disease 430-438
Source: CDC Wonder Internet Web site (<http://wonder.cdc.gov>)

Objectives: The primary objective of the Jackson Heart Study (JHS) is to investigate the causes of CVD in African-Americans to learn how to best prevent this group of diseases in the future. More specific objectives include:

Identification of factors, which influence the development, and worsening of CVD in African-Americans, with an emphasis on manifestations related to high blood pressure (such as enlargement of the left ventricle of the heart, coronary artery disease, heart failure, stroke and disorders affecting the blood vessels of the kidney).

Building research capabilities in minority institutions at the undergraduate and graduate level by developing partnerships between minority and majority institutions and enhancing participation of minority investigators in large-scale epidemiologic studies.

Attracting minority students to and preparing them for careers in public health and epidemiology.

Study Description: The Jackson Heart Study (JHS) is a single-site prospective epidemiologic investigation of cardiovascular disease (CVD) among African-Americans from the Jackson, Mississippi metropolitan area. This study represents an expansion of one of the sites of the Atherosclerosis Risk in Communities (ARIC) Study, which included four geographically diverse communities in the U.S. (Northwestern suburbs of Minneapolis, Minnesota; Washington County, Maryland; Forsyth County, North Carolina; and the city of Jackson, Mississippi). The ARIC Study included a comprehensive baseline examination (1987-1989) and three subsequent follow-up examinations occurring at approximately three-year intervals (1990-1992, 1993-1995, and 1996-1999). A total of 15,792 individuals between 45 and 64 years of age were initially examined and 3,732 were from the Jackson ARIC cohort.

The JHS includes up to 6,500 African-American men and women between the ages of 35 and 84 and will invite all previous ARIC participants along with men and women from a larger geographic area. Non-ARIC participants are randomly selected from the African-American residents of Hinds, Madison and Rankin counties surrounding Jackson, Mississippi. Family members are included in order to permit future studies of familial and genetic contributions to CVD. The extensive examination includes a series of questionnaires, physical assessment, and laboratory measurements (Table 2). The information collected in this study includes both conventional risk factors and new or emerging factors that may be related to CVD. Some of the newer areas of focus include early indicators of disease, genetics, socio-cultural influences such as socioeconomic status and discrimination, and physiological relations between common disorders such as high blood pressure, obesity and diabetes and their influence on CVD. The initial examination phase of the study began in the fall of 2000 and will take approximately three years to complete. The study progresses in the following steps: definition of sampling frames, enumeration of households to determine study eligibility, interview in the household of all study eligibles, recruitment, clinical examination, interview of participant annually to determine health status, contact of health care providers and family members and review of medical records of participants. The timetable for the JHS is shown in Figure 1.

The JHS is sponsored by the National Heart, Lung, and Blood Institute (NHLBI) and the National Center on Minority Health and Health Disparities (formerly known as the Office of Minority Health at the National Institutes of Health in partnership with three Jackson, Mississippi institutions: Jackson State University, the University of Mississippi Medical Center, and Tougaloo College. The JHS offices and clinic facility are located in the main concourse of the Jackson Medical Mall, which is a remodeled mall now serving as a centralized location for high quality, efficient health care delivery for the underserved community.

Table 2. The JHS Study Component Schedule: Interview and Procedures by Visit

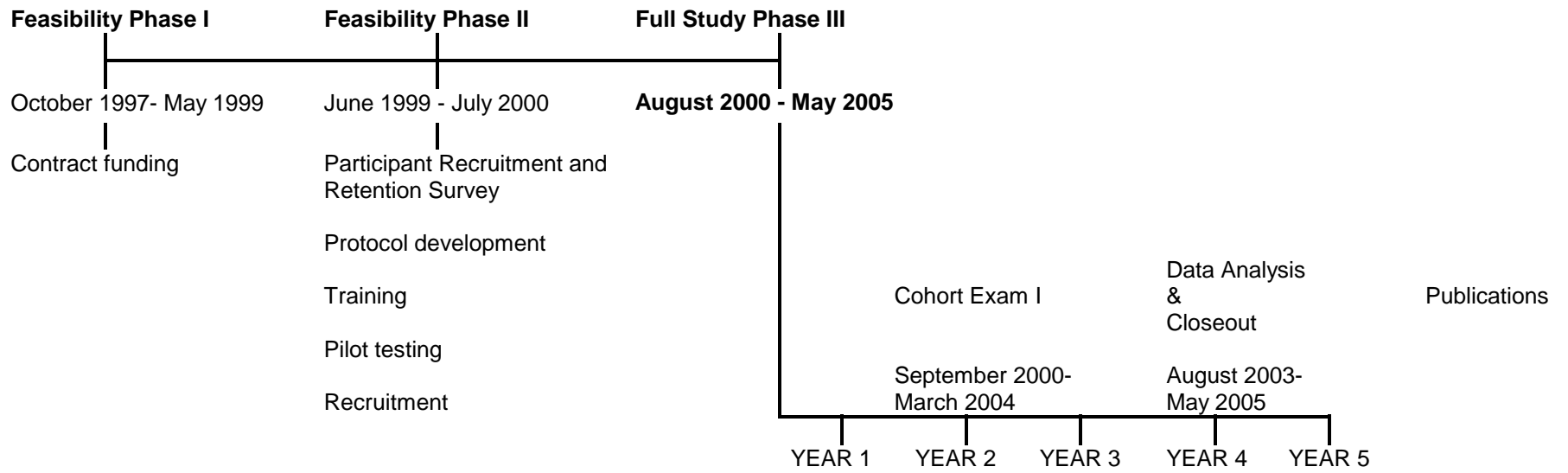
PROCEDURES	ARIC				JHS
	Visit 1 1987-89	Visit 2 1990-92	Visit 3 1993-95	Visit 4 1996-98	EXAM I 2000-03
ANTHROPOMETRY					
HEIGHT					
Sitting Height	X				
Standing Height	X		X	X	X
FRAME SIZE					
Elbow		X			
Wrist	X				
GIRTHS					
Calf	X				
Neck					X
Hip	X	X	X	X	
Waist	X	X	X	X	X
SKINFOLDS					
Subscapular	X	X			
Triceps	X	X			
WEIGHT	X	X	X	X	X
MALE BALDNESS				X	
BLOOD PRESSURE					
Sitting	X	X	X	X	X
Supine	X		S	S	X
Standing	X		S	S	
Ankle	X			S	X
Ambulatory					X
ECHOCARDIOGRAPHY			X		X
ELECTROCARDIOGRAPHY					
2-minute Rhythm Strip	X		X		X
12-Lead	X	X	X	X	X
Heart Rate Variability	S			A	
GLYCEMIC LOAD				X	
INTERVIEWS					
Anger (CHOSt, Anger In & Out)					X
Annual Follow-up	X	X	X	X	X
Blood Transfusion				X	
CHD Events/Procedures	X	X	X	X	X
CES-D					X
Cognitive Function		X	S	X	
Coping Inventory					X
Dietary Intake	X	S	X	S	X
Family History of CHD		X			X

PROCEDURES	ARIC				JHS
	Visit 1 1987-89	Visit 2 1990-92	Visit 3 1993-95	Visit 4 1996-98	EXAM I 2000-03
Global Stress					X
Health History	X	X	X	X	X
Home Interview	X				X
Inflammation				X	X
Informed Consent	X	X	X	X	X
Medication Survey	X	X	X	X	X
Personal History (Smoking, Alcohol, Access)	X	X	X	X	X
Physical Activity	X		X		X
Racism & Discrimination					X
Religion					X
Reproductive History	X	X	X	X	X
Respiratory Symptoms	X	X			X
Social Support		X			X
Socio-economic Status	X	X	X	X	X
Stress					X
TIA/Stroke	X	X	X	X	X
TIA/Stroke Summary	X	X			X
Tracking	X	X	X	X	X
Trait Anger		X		X	X
Violence					X
Vital Exhaustion		X			
Vitamin Survey			X		X
MEDICAL DATA REVIEW	X	X	X	X	X
MRI, CEREBRAL			X		
PERIODONTAL EXAMINATION				A	
PHYSICAL ACTIVITY MONITOR					X
PHYSICAL EXAMINATION					
Neck	X	X			
Cardio/pulmonary	X	X			
Lower Extremities	X	X			
PULMONARY FUNCTION					
FEV1.0	X				X
FVC	X	X			X
Max. Inspir. Pressure		X			X
RETINAL PHOTOGRAPHY			X		
ULTRASOUND, B-MODE					
Carotid Arteries	X	X	S	S	X
Distensibility	X	X			
Popliteal Artery	X				

PROCEDURES	ARIC				JHS
	Visit 1 1987-89	Visit 2 1990-92	Visit 3 1993-95	Visit 4 1996-98	EXAM I 2000-03
Urine Collection 24 Hour					X
VENIPUNCTURE					
Chemistries	X	X	X	X	X
Hematology	X	X	O	O	X
Hemostasis	X	X	X	X	X
Lipids	X	X	X	X	X

S=Sample; **A**=Ancillary study mechanism; **O**=Optional

Figure 1. JHS: Timetable



The Coordinating Center

Jackson State University developed a Coordinating Center (CC) where all data collected during the study is managed, analysis of the data is performed and community involvement is coordinated.

The JHS CC operates an Office of Partnership for Community Awareness and Health Education (PCAHE). The goal of PCAHE is to create an environment of trust and long-term support of the JHS by providing opportunities for substantive community involvement in all phases of the study development, conducting health promotion/education activities, and linking participants to needed services. The PCAHE Steering Committee serves as an independent body of community representatives, including political, medical, social, civic, business, health-related government agencies, and grassroots organizations, in order to provide ongoing input into the development and implementation of community mobilization activities.

The CC provides centralized administration, planning, and management for many components of the JHS. The core operational and scientific coordinated functions include 1) Database Management; 2) Protocol development; 3) Quality assurance; 4) Biostatistical analysis; 5) Maintenance of phone system, local area networks, e-mail, intranet, and World Wide Web JHS Home Page; 6) Equipment purchasing and maintenance; and 7) Administrative support for the Project Office and the chairman of the Steering Committee (such as convening meetings, documenting decisions and action items, preparing and distributing meeting minutes and coordinating the work of the various subcommittees). The CC provides technical support for the installation, use and maintenance of local computer equipment and CC staff provides software. The CC serves as the official repository for all JHS Steering Committee records, manuals of operations, data collection instruments, research data and publications.

During the initial phases of the study, CC staff participate in activities of the Steering Committee, and all subcommittees providing technical assistance in the study design; data collection, processing and analysis; training and certification; quality assurance; pilot testing and evaluation; and study implementation. Once the study collects data, the CC supports the Events Monitoring Subcommittee in monitoring the status of each study endpoint, preparing documentation of events to be verified and creating a final diagnosis file.

The CC's responsibility for the centralized management of the study includes the provision and tracking of training and certification; monitoring protocol adherence in the EC and reading centers; the design, implementation and monitoring of quality assurance programs in the EC and reading centers; and data management, including the development of a computerized data collection system, on-site and centralized data processing and data analysis. Training and certification, protocol adherence and quality control are discussed in each of the manuals. The specific procedures for the distributed data management systems and data analysis are described in the following section of this manual. The CC also supports the design, management, and analysis of case-control studies and the publication of results of collaborative studies.

In order to obtain assistance needed to adequately address short-term development and intermediate-term implementation demands, the JHS CC has collaborated with an experienced coordinating center: The University of North Carolina School of Public Health, Department of Biostatistics' Collaborative Studies Coordinating Center (CSCC) in Chapel Hill, North Carolina. The CSCC supports the development of the JHS CC by providing training and technical support in the development of the study protocol, manuals of operations and data collection programs, and data management systems. The CSCC role includes 1) developing the manuals of operations, data collection instruments and question-by-question instructions, 2) coordinating initial exam center staff training and certification, 3) developing the data management system for the first JHS clinic visit, and 4) designing quality assurance procedures. The CSCC serves as a resource to the JHS CC for guidance in establishing procedures for

collecting, editing, storing, and analyzing data generated by the field center and reading centers, and in preparing the OMB packet for the study. The CSCC is responsible for preparing the JHS CC to assume full responsibilities of a coordinating center by the end of the second year of the cohort examination.

The National Human Genome Center at Howard University (NHGC) was contracted to partner with the JHS to contribute to the successful organization of a large well-characterized population-based cohort of African American pedigrees and to build capacity within the JHS to perform large family studies. Investigators at the NHGC will provide expertise in the following areas of genetics: family study design; protocol development; community mobilization and involvement in genome research; ethical issues in biomedical research including the development of culturally sensitive informed consent; data management, database development, data analysis and interpretation; manuscript development; and training JHS investigators, students, field and clinic staff. The long-term goals of this partnership are that NHGC investigators will provide genetic epidemiology to increase the number of minority investigators with skills to ensure adequate representation in genomic research. This collaboration between Historically Black Colleges and Universities (HBCU) will facilitate bridge building in several areas including student exchange programs in epidemiology, statistics, genetics, molecular techniques, research design and ethical issues in biomedical research. Expertise in community mobilization and interpretation of research findings will also be shared. Finally, this historic partnership promises to contribute at the federal and state levels to increased community participation in biomedical research and in the long run should help to reduce health disparities that currently exist in ethnic minority groups in the U.S.

The Examination Center

The University of Mississippi Medical Center developed an Exam Center (EC), which is responsible for recruiting participants and conducting the examinations. The EC is also responsible for the developing, pilot testing, and conducting surveillance for morbidity and mortality outcomes (events) of all participants examined in the Full Scale Study, to include: a) annual telephone or mail contacts as part of morbidity and mortality follow-up for the entire cohort to ascertain: (1) occurrence of cardiovascular events (including coronary heart disease, cerebrovascular disease, and congestive heart failure), other illnesses, and hospitalizations, including information from participants, personal informants, hospitals and physicians, according to a standard protocol; (2) dates and recorded causes of all deaths, using local vital statistics sources, obituaries, the National Death Index, and other sources; and; (3) circumstances surrounding death, through interview of family members, physicians and review of coroners' and other records; (4) participate in classification of cardiovascular events and conditions, using a standard protocol.

The Undergraduate Training Center

Tougaloo College created an Undergraduate Training Center (UTC) where selected students are given the opportunity to take course work in public health and epidemiology and gain practical experience in health research to help prepare them for potential careers in these fields.

The specific goals of the UTC are to 1) create a pool of well-trained high school students who upon entering college, can successfully complete undergraduate, graduate or professional degrees in health professions and public health; and 2) introduce a program of college courses to prepare students to pursue advanced studies towards public health and epidemiology, 3) recruit faculty to teach JHS related courses and do collaborative research with other institutions; and 4) participate on various JHS committees. The UTC accomplishes these goals by introducing Outreach to High School students to courses in Mathematics, Life Sciences, and Pre-college courses. The UTC also implemented a JHS training Plan where JHS scholars (freshmen or sophomore undergraduates) act as mentors and tutors to the Outreach high school students, take courses in Public Health , Epidemiology, Biostatistics, and Research Methods, attend Tougaloo College colloquia, and the Summer Epidemiology course, and receive didactic academic experience through involvement in the

practicum. The UTC collaborates with the JHS CC and EC and other local institutions to provide students with hands-on experiences to create interest in public health careers.

2.0 STUDY DESIGN

2.2 Cohort Design

The cohort design is divided into 7 operational sections: (1) sampling, (2) enumeration, (3) home interview, (4) recruitment, (5) first exam, (6) annual follow-up, and (7) clinical review and diagnostic classification. Sampling, enumeration and recruitment began in August 2000. The first cohort exam is scheduled for 2000-2003. Annual follow-up contact is done within a month of the anniversary date of the original visit.

2.1.1 Sampling

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 a all African-American population (ages 35-84), including genetic components. The JHS sample consists of 6,500 individuals including the ARIC Study participants who agree to return for a fifth exam (approximately 2,000), the family sample (2,000) and a community cohort of about 2,500 (includes 1,250 volunteers). Thus, the respondent universe begins by building on the existing Jackson ARIC cohort (n=2,000), originally sampled from the Jackson city limits only and limited to those aged 45-64. In order to increase the representativeness of the sample, the JHS universe was expanded geographically and age wise. The universe includes all African-American men and women, aged 35-84 who reside in the tri-county (Hinds, Madison, and Rankin) area of Jackson, MS. The 1990 population, social and economic characteristics of the Jackson metropolitan statistical area (MSA) are summarized in the Table 3.

Table 3. Population, Social and Economic Characteristics, Jackson, MS, 1990

Total	% Black	% Urban	%Education 12+ Years	Median Income	Blacks Aged 35-84
395,396*	42.0	76.0	74.0	31,575	56,610

* Source: 1990 Census of Population Characteristics, Table 1, June 1992; 1990 Census of Population: Social and Economic Characteristics: Tables 57, 59, 148. September, 1993; Jackson MSA.

The sampling list was provided by Accudata and consists of a list compiled by combining information from several sources including white page telephone directories, motor vehicle data, county assessor data, door to door canvassing, 1990 census data and various other secondary sources. In general the names and addresses for this list are 93% accurate and coverage of household counts and older individuals are very close to census projections for the Jackson MSA. The sampling plan includes drawing randomly from the Accudata list for a three-county area (Hinds, Madison and Rankin) that is nearly identical to the Jackson, MS MSA but is based on a list of ZIP codes provided by the United States Census Bureau. The Accudata list is the entire sampling frame of individuals aged 35-84. An ongoing analysis of the Accudata list will be conducted to guarantee individuals aged 65-84 are adequately represented. If older individuals are not sufficiently represented then the HCFA list of Medicare beneficiaries will serve to supplement the Accudata sampling frame.

2.1.2 Enumeration Procedures

Interviewers locate the designated sample individuals in the Jackson Mississippi metropolitan community area to determine eligibility status. When contact is made with an occupant of a designated household, the interviewer introduces him/herself, shows the respondent his/her credentials, briefly describes the purpose of the visit, and proceeds with enumeration. Enumeration is the process of completing a household roster needed to select the sample member(s). All members of the designated households ages 35-84 are asked to participate in the cohort study.

The enumerator lists all the persons at least 18 years old who reside in the sample household. Persons who indicate that their permanent residence is outside the study area are excluded, as are individuals who would be physically or mentally incapable of full participation in the study.

2.1.3 Home Interview

After enumeration, the interviewer conducts a home interview with each eligible respondent. The home interview has 6 sections: Health Status and Risk Factors, Family Medical History, Smoking, Employment, Education, Income and Wealth, Occupation, and Home Interview Debriefing. The purpose of each section is described in Table 4.

Table 4. The Home Interview in the JHS Cohort Component

Section	Purpose
Informed Consent	Obtain informed consent
Health Status	Obtain general Knowledge of the participant's health status; determine prior hospitalizations with the past year;
Risk Factors	Determine selected risk factors for cardiovascular disease (CVD)
Family Medical History	Obtain general knowledge of the participant's family health status; determine past history of cause of death due to CVD, cancer or diabetes
Smoking	Determine smoking status and amount
Employment	Determine the participant's current employment status.
Education	Determine the participant's level of education
Income and Wealth	Determine the participants individual and family income and wealth
Occupation	Determine the participants occupation
Home Interview Debriefing	Assess the participant's cooperation during the interview; assess the quality of the interview; assess the participant's literacy comprehension; verify contact information

2.1.4 Recruitment and Scheduling for the Clinic Examination

During the home interview, eligible cohort members are given a written and verbal description of the study. They are asked to participate in the complete study, which includes a clinical examination and the annual telephone follow-up.

The cohort member is scheduled for the clinical examination at the Jackson Medical Mall. The participant is asked to come to the clinic after a 12 hour fast and to bring all medications (prescription and nonprescription), which he/she has used in the last two weeks.

2.1.5 Clinic Examination

The clinic examination takes approximately 5 hours. The sequence of the exam is flexible so that up to four participants can be examined concurrently, in accordance with the available personnel and workstation configuration. The following sequencing restraints are necessary: (1) Fasting and abstinence from smoking and alcohol are required prior to venipuncture and blood pressure measurements, (2) Sitting blood pressure must be measured before venipuncture, (3) Interviewing and Examination must precede the Medical Review, (4) Venipuncture is done after at least 20 minutes in the supine position. Participants must fast and abstain from alcohol and tobacco for not less than one hour. A snack, however, is provided during the exam. Table 5 identifies and describes the components of the examination.

Table 5. Components of the JHS Examination I

Procedure	Description
Reception	Greet the participant; determine fasting status; obtain tracking data; collect medications.
Informed Consent	Obtain informed consent.
Blood Pressure	Obtain sitting blood pressure, ankle and arm.
Anthropometry	Measure weight, height, neck and waist.
Venipuncture	Obtain blood samples for lipid, hemostasis, hematology, chemistry measurements, and storage.
Snack	Provide a nutritious snack containing no caffeine or stimulants.
ECG	Obtain a resting 12 lead electrocardiogram
Interview	Collect medical/health history (medication survey, medical history, stroke symptoms, reproductive history, family structure, diet food frequency), and sociocultural history (discrimination and alcohol/drugs).
Echocardiographic Exam	Obtain 2-D Doppler images of the heart and great vessels to assess cardiac structure and function.
Ultrasound	Obtain B-mode scan for wall measurements in carotid. Measure supine brachial and ankle blood pressure.
Pulmonary Function	Obtain digitized spirometric measurements of timed pulmonary function (FVC, FEV1.0).
Medical Data Review	Ascertain the completeness of the exam, and verify abnormal results. Review results of the medical history and exam with the participant. Refer participant for diagnosis or treatment elsewhere if appropriate.
Exit Interview	Provide clinic summary report and return medications. Provide instructions on 48-hr urine collection, 24-hr exam procedures (urine collection, ambulatory blood pressure monitoring), substudies (diet and physical activity) and take home (Hassels and Mood Inventory- WSI, CED-D, CHOST, STAXI). Thank participant.

2.1.6 Follow-Up

Annual follow-up of the JHS cohort is used to maintain contact, to correct address information of cohort participants and to ascertain medical events between three-year comprehensive examinations.

Follow-up contacts are targeted to occur within a month of the anniversary date of the original visit. Contact letters are on JHS stationery and inform the addressee that he/she will receive a telephone call from JHS asking about interim health problems.

A telephone interview is conducted to ask participants about hospitalizations for illness or surgery, diagnoses and symptoms. If the participant cannot be reached by telephone, a home interview is attempted. The questionnaire queries information on hospitalizations for illness or surgery, diagnoses, medical care and symptoms. The participant is asked the standard Rose questionnaire for angina, possible MI and intermittent claudication, vital status, hospitalizations, and a variety of socio-cultural topics that will change each year. Verification of address and phone number is made along with an update of the other information used to contact the participant. Every attempt is made to identify cohort participants who have died in advance of the annual contact through regular review of obituaries and death certificates.

2.1.7 Clinical Review and Diagnostic Classification

During the initial home interview, the examination or the follow-up contact, the cohort participant may indicate that he or she has been hospitalized. Records are obtained for all hospitalizations, which occur after the Exam I visit. Abstracters record all discharge diagnoses and clinical information related to coronary or cerebrovascular diseases. The participant will have signed a medical release form allowing the study to access medical records.

Similarly, during the obituary review or a follow-up contact, it may be determined that the participant has died. In these cases, the death certificate is obtained and the place of death is determined. For in-hospital deaths, the hospital record is reviewed. For out-of-hospital deaths and decedents admitted without vital signs, the participant's family and physician are contacted to provide information on the circumstances surrounding the death. At entry to the study, the participant will have given consent to contact family members and physicians in the event of his or her death.

A special Events Monitoring Subcommittee reviews the information on hospitalizations and provides the study diagnosis for coronary heart disease or cerebral vascular disease according to defined criteria. The Events Monitoring Subcommittee also provides a classification of cause of death.

2.2 Reading Centers

The JHS includes reading centers. The protocols for the procedures performed by each of these reading centers are contained in separate manuals: Electrocardiography (Manual 5), Echocardiography (Manual 6), Ultrasound (Manual 7), Pulmonary Function (Manual 8), and Central Laboratory and Specimen Repository (Manual 9). The roles of these reading centers are summarized in this section.

The reading center investigators are encouraged to collaborate with other JHS investigators in the analysis of study data, presentation of abstracts, and preparation and submission manuscripts. All publications concerning JHS data are governed by the JHS publications policy (Section 4.4). Reading center investigators may not publish any data from the JHS without prior review and approval by the JHS Steering Committee (SC).

2.2.1 Electrocardiography Reading Center

The Electrocardiographic Reading Center (ECGRC) is located at the University of Minnesota, School of Public Health, and Division of Epidemiology. The ECGRC is responsible for the development and implementation of methods to permit central evaluation and analysis of all ECGs obtained as part of the JHS protocol. The ECG examination will be conducted in the JHS Clinic facility by trained technicians.

The ECGRC is responsible for preparing an Electrocardiography Manual of Operations (MOP), detailing all ECGRC procedures, including procedures for 1) performing, collecting, and transmitting standard ECGs obtained at the JHS Clinic; 2) collecting and transmitting Ancillary ECGs (A-ECGs) recorded outside the JHS clinic; 3) coding and storing received ECGs; 4) transmission of resulting data to the CC; and 5) quality assurance and quality control of ECG collection and coding.

Two categories of resting ECGs are collected: 1) at baseline, for all JHS participants, a standard 12-lead ECG will be recorded digitally and 2) Ancillary ECGs (A-ECGs) for participants having ECG recorded outside the clinic and including ECGs recorded in-hospital and local medical facilities. Any subsequent tests can determine changing ECG status.

The ECGRC is responsible for providing reliable ECG measurements from digital and paper ECGs which are to be used to identify prevalent coronary disease (CHD) and new CHD events such as unrecognized myocardial infarction (MI) and in-hospital acute MI. The ECGRC provides ECG documentation of 1) Prevalent ECG findings reflecting cardiac diseases; such as MI, left ventricular

hypertrophy (LVH), bundle block, cardiac arrhythmias and other major or minor ECG findings, 2) other prevalent ECG risk indicators such as low heart rate variability, prolongation of the heart rate QT interval (QTc), 3) Incident myocardial infarction, symptomatic or asymptomatic, and 4) estimated left ventricular mass.

2.2.2 Echocardiography Reading Center

The Echocardiography Reading Center (ERC) is the University of Mississippi Medical Center Cardiovascular Division. The ERC is responsible for the development and implementation of methods to permit central evaluation and analysis of all echocardiograms obtained as part of the JHS protocol. The echocardiographic examination will be conducted in the JHS Clinic facilities at the Jackson Medical Mall. Trained cardiac sonographers will perform the echo studies. The EC and ERC staff will train these technicians in the specific protocol for the JHS studies.

The ERC prepares an Echocardiography Manual of Operations (MOP), detailing all ERC procedures, these include procedures for 1) performing, collecting, and transmitting echocardiograms obtained at the JHS Clinic; 2) transmission of resulting data to the CC; and 3) quality assurance and quality control of echocardiogram collection and coding.

The echocardiographic study will 1) characterize a variety of cardiac structural and functional parameters in the JHS cohort and 2) examine these data for relationships with traditional and non-traditional risk factors for CVD, prevalent of CVD, and CVD incidence, adding to similar information collected in other important population-based studies.

Participants in the JHS will have an echocardiographic examination as part of the Exam I clinic visit. A number of these individuals also participated in the Atherosclerosis Risk in Communities (ARIC) study, and may have had echocardiography as part of that study during the years 1993 to 1996. The echocardiography protocol will incorporate currently accepted standard echocardiographic techniques to enhance comparison with preceding and future studies. Structural parameters to be studied include left ventricular (LV) wall and chamber dimensions, and LV mass (calculated from dimensions). Cardiac function data will be derived from measurements of systolic performance such as fractional shortening, regional wall motion, and wall stress, and from Doppler data describing left ventricular diastolic filing.

Each echocardiogram is interpreted clinically by one of the ERC cardiologists with a few days of examination. Given the greater sensitivity and specificity of an echocardiographic measure it may serve as a surrogate measure of preclinical manifestations of cardiovascular disease and a prognostic indicator for future clinical events (i.e., hypertension, myocardial infarction, and/or stroke), abnormal echocardiographic findings are reported promptly to the EC PI. The echocardiography quality control program in place 1) provides quantitative documentation of the reproducibility of the scanning and reading procedures, and 2) assures the comparability of the JHS echo scanning and reading procedures with ARIC and other important echocardiography data sets.

2.2.3 Ultrasound Reading Center

The Ultrasound Reading Center is at Wake Forest University School of Medicine, Winston-Salem, North Carolina. The Ultrasound Reading Center is responsible for the development and implementation of methods to permit central evaluation and analysis of all carotid ultrasound measures obtained as part of the JHS protocol.

During the clinic exam, the carotid ultrasound examination attempts to obtain images at 3 defined segments (Common, Bifurcation, and Internal) of the right and left carotid arteries. The measurements at each site include mean and maximal far wall thickness, mean and maximal near wall thickness, and mean and minimum residual lumen. The Ultrasound Reading Center performs a centralized reading of the cohort ultrasound videotapes produced at the EC.

Each reader uses a reader station to evaluate the images. The reader station consists of a personal computer equipped with an image capture board, a sVHS VCR, 19" video and computer monitor, and desk and chair. Computer software and hardware controls reading of the scans. To initiate readings for each carotid segment, the reader reviews the 10 cardiac cycles identified as protocol quality images by the sonographers and selects a single systolic (widest diameter) frame for measurement based on the visualization of arterial interface. The reader then marks arterial interfaces by tracing the boundaries with a mouse using a series of straight lines connected by knots, or fixed points located by clicking on the mouse button. The computer checks the data for possible errors in wall thickness and the reader notes, the presence of lesions and acoustic shadowing. At the conclusion of the reading, the participant record for a given date includes the participant ID, date, reader and sonographer identification, and the boundary lengths and mean and maximum arterial dimensions for each arterial site. After completing the reading of all the sites for a given scan, the data are sent to the main database computer via Local Area Network (LAN).

2.2.4 Pulmonary Function Reading Center

The Pulmonary Function Reading Center (PFRC) is the Pulmonary Lab at LDS Hospital, Salt Lake City, Utah. The PFRC is responsible for the development and implementation of methods to permit central evaluation and analysis of all pulmonary function spirometry and pressure determinations obtained as part of the JHS protocol. Trained technicians will conduct pulmonary function testing (PFT), including spirometry and inspiratory/expiratory pressure testing, on all JHS participants as part of their clinic examination. The EC and PFRC staff will train these technicians in the specific protocol for the JHS studies. The Respiratory Sciences Center at the University of Arizona Health Sciences Center provides support for the training certification and quality assurance components.

The PFRC prepares a Pulmonary Function Manual of Operations (MOP), detailing all reading center procedures, these will include procedures for: 1) collecting and transmitting PFT data obtained at the JHS Clinic; 2) evaluating and storing received PFT data; 3) transmission of resulting data to the CC; and 4) quality assurance and quality control of PFT data collection and reading programs. All PFTs will be evaluated for quality using flow and volume grades assigned based on specific criteria. Results will be communicated to each pulmonary function technician on a regular basis (e.g., monthly), recommendations will be provided and re-training will be conducted when indicated.

2.2.5 Central and Local Laboratories

The Central Laboratory (CL) and Local Laboratory (LL) are responsible for the development and implementation of methods to permit evaluation and analysis of blood and urine samples obtained as part of the JHS protocol. The Central Laboratory is at the University of Minnesota Department of Laboratory Medicine and Pathology and the Fairview-University Medical Center. The Local Laboratory is at the University of Mississippi Medical Center.

The CL and LL collaborates with the SC in the development of the study protocol, and other documentation, providing expertise in the collection and selection of analytes relevant to cardiovascular risk factors (established, novel or putative) and clinical and subclinical endpoints. The methods are as technically compatible for collecting blood with those in ARIC as possible.

Sample collection, processing, storage and analysis are monitored using an internal and external quality control program and through the analysis of blind duplicates. An added check on drift or shifts in laboratory performance is provided by analysis of blood from monthly random subsamples of the JHS cohort. Laboratory technicians were trained in proper venipuncture and processing methods and are certified and periodically recertified by the chief technologist.

The proposed analytes are listed in Table 6. The type of analysis to be performed upon procurement of the specimens in the JHS are for glycemia (fasting glucose, fasting insulin, HbA1c); basic chemistry and hematology (hematology panel, Na, K, and Cl, creatinine, and uric acid); lipid profile (total cholesterol, triglycerides, HDL cholesterol and LDL cholesterol); inflammation and endothelial

cell damage (fibrinogen, tissue plasminogen activator [tPA], plasminogen activator inhibitor [PAI-1], C-reactive protein, p-selectin, e-selectin); endocrinology (ACTH, cortisol); renal (aldosterone, renin activity, angiotensinogen); and other cardiac risk factors (homocysteine, folate). Additional, newer measurements are to be made on selected cases and controls, using stored plasma.

Table 6. Blood/Plasma/Serum Measurements Performed at the JHS Laboratories

Central Laboratory	Local Laboratory (UMMC)
Adrenocorticotrophic Hormone (ACTH)	Blood Complete Blood Count with Platelets Chloride Creatinine Glucose Potassium Sodium Uric Acid Urine 24-hour Collection Albumin Chloride Creatinine Potassium Sodium 48-hour Collection (10% of total cohort) Albumin Chloride Creatinine Potassium Sodium
Aldosterone	
C-reactive protein	
Chlamydia antibody	
Cholesterol (HDL; Total)	
Cortisol	
Endothelin	
Fibrinogen	
Folate	
HbA1C	
Homocysteine	
Insulin	
Leptin	
Lp(a)	
PAI-1	
Plasma Renin Activity	
tPA	
Triglycerides	
uPA	
Vitamin B6	
Vitamin B12	
DNA extraction	
Lymphocyte immortalization	

2.2.6 Specimen Repository

The Specimen Repository (SR) provides facilities and equipment to receive, store, aliquot, and distribute urine, white blood cells, DNA and /or transformed white blood cells from JHS participants. The facilities provide aseptic and/or sterile conditions as appropriate (Biosafety Level 2 Containment). The SR, like the CL, is at the University of Minnesota Department of Laboratory Medicine and Pathology and the Fairview-University Medical Center. The SR has laboratory facilities and personnel for developing and monitoring the inventory of specimens. The JHS Ancillary Studies Committee reviews all requests for samples.

The SR procedures are detailed in Manual of Operation (MOP) 9. The MOP includes 1) a description of the procedures to be followed for processing, inventory control and delivering samples; 2) procedures for training personnel; 3) a detailed description of computer system and data entry system; and 4) a detailed protocol for long term storage.

3.0 DATA MANAGEMENT

This section describes the distributed data management systems used for the collection, processing and distribution of data and materials among the various JHS study components. The data management system has three major components: a Computer Assisted Data Collection (CADC) system, a local data base management system (LDMS) and the collaborative DMS. The CADC system uses PC and compatible lap top microcomputer workstations for data collection, editing and correction during the cohort examination, for record abstraction, and for entering data collected on paper forms. The EC has a PC for local data base management, ad hoc retrieval and reporting, scheduling and other study management functions, and communication with the CC. The collaborative DMS is maintained at the CC and is used to store, update, and access the data from the EC and reading centers. Section 3.1 briefly outlines the flow of data and materials such as blood samples, ultrasound tapes and ECG tracings through the various study reading centers and EC. Subsequent sections provide a more detailed description of the EC's and reading center's data management system. Additional information on specific operational procedures is documented in each chapter of the Manual of Operations.

3.1 Overview of JHS Data Flow

The data and materials flow for the JHS Study can be grouped into three main categories: 1) the study data and materials collected and processed by the various study components; 2) inventory and study management information used to monitor the study data and materials and to schedule various study activities; and 3) various types of reports on performance and quality control. A large portion of the study data is collected and processed using the microcomputers described elsewhere in this document. These data, as well as some of the inventory information and reports, are transferred between centers by mailing floppy diskettes or by telecommunications. Study materials, including blood samples, tapes and tracings from the various examination procedures are transferred to the appropriate centers by mail or other carrier as described in specific sections of the protocol.

As shown in Figure 2, the flow of study data begins with the selection. Next, participants are recruited and scheduled for the base line interview and examination. At this visit interview and examination data are recorded for each subject, either directly into the microcomputer using the CADC system or by completing paper forms that are entered into the CADC system at some later time. These data are then transferred to the CC by mail on a regular schedule.

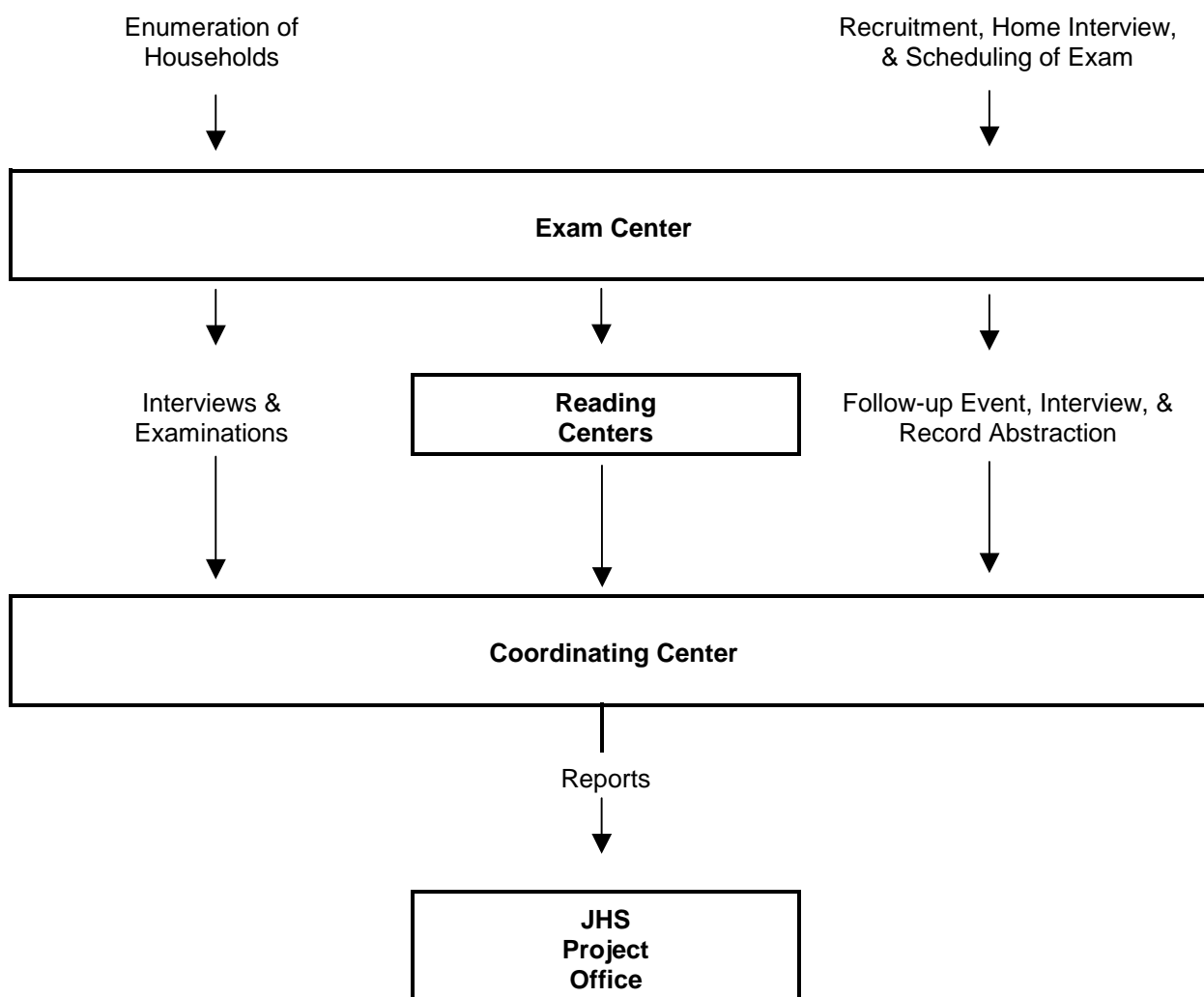
Blood samples are shipped to the CL, ultrasound tapes to the Ultrasound Reading Center, ECG data to the ECG Reading Center and pulmonary function data to the Pulmonary Function Reading Center. Echocardiography results are read locally at the Echo Reading Center. After the reading centers have made their respective determinations, the results are sent to the CC where they are added to the collaborative database. The data collected during the interview and examination are used to identify existing cardiovascular disease and other diagnoses of interest. In addition, the participant is contacted annually to ascertain his or her health status. Data collected during the annual follow-up precipitate the collection of additional data from medical records, abstractions and interviews with doctors or next-of-kin. These data are sent to the CC and added to the database. Potential events are classified with the appropriate diagnostic criteria by applying standardized algorithms.

In addition to the data and materials transferred among the study components, inventory identification and study management information is also required. This information, in general, follows the same direction as the flow of data shown in Figure 2. The results of recruitment and the scheduling of visits are stored in the EC database. Identification information accompanies the materials sent to the reading centers in order to verify that all materials shipped are received. This information may be a paper shipping list or a floppy diskette, depending on the requirements of the specific reading center. Inventory information pertaining to these materials is also sent to the CC. After a suitable time delay, this inventory information is compared with the reading center results received at the CC and any discrepancies resolved. A similar system ensures that reading center results are returned to the EC. Schedules for data transfer and a system of acknowledgements is used to monitor all transfers and

shipments. When a shipment is received by a study component, an appropriate acknowledgement is returned to the sending component. These acknowledgements flow in the opposite direction of the arrows in Figure 2. If either the expected shipment or the acknowledgement is not received, action is taken to trace the problem.

Routine performance and quality control reports are generated by the CC and distributed to the other study components. Exception reports are generated when problems are identified and immediate action is required. A sample of pulmonary function tracings and results is sent to the Pulmonary Function Reading Center for quality control purposes. Similarly, ECG data are sent for interpretation to the ECG Reading Center. The results of these readings and quality control samples are sent to the EC and the CC. Reading Center alert values constitute another important group of exception reports. These results are communicated to the EC and relayed to the participant as expeditiously as possible.

Figure 2. JHS Cohort Data Collection and Data Flow



3.2 Coordinating Center Data Management System

The JHS uses state-of-the-art CADC systems during the collection of examination and annual follow-up, in order to maximize data accuracy. A centralized data management system with direct data

entry was developed using the software ClinTrial4. This type of system displays screens that resemble paper forms, and eliminates the burden of data entry and editing, reduces data entry turnaround time, and improves the quality of data analysis while minimizing respondent burden. The data collector reads the items from the screen, performs the measurement or queries the participant, and keys the response into the computer. As data for the EC are entered, they are edited by the system. Values failing the edit checks cause an error message to be displayed and prevents further investigation. In addition to collecting and editing the data, the system permit users to enter text into an electronic "post-it note". This computer assistance rapidly directs the interviewer to the relevant sections of the interview for the particular respondent and provides for very rapid interviewer action, thus lessening the respondent burden.

The home induction interviews are collected using paper and pencil questionnaire methodology since ClinTrial4 does not currently support a remote (lap top) version. All interview forms are designed using structured questions in order to minimize interviewer error and thus reduce respondent burden. All items have been pretested on groups of 9 or fewer participants from the surrounding African American communities outside the target geographic area in order to demonstrate ease of understanding and accuracy of response skip patterns. Pretesting enhanced future interviewer training and further reduced respondent burden. In the event of equipment failure of the centralized database, all clinic examination, and follow-up forms are available in paper form as back-up. Clinic interviewers are trained to record the responses on paper and key enters the data once the equipment is functional. Electro-cardiographic, pulmonary function, ultrasound and echocardiography data are collected electronically on separate, procedure-dedicated computers.

Completed paper forms from the Home Interviews are entered into the CADC system by the recruiters with double entry. All questionnaire forms are stored in locked file cabinets in the "secure data room". All data entered are stored electronically in the computer network server residing at the CC and each component data files are linked only by study identification numbers. Data undergo further cleaning, reduction and analysis using PC SAS®

3.3 Examination Center Data Management System

The EC is responsible for managing the data collected during the cohort examinations and event abstractions. This includes the initial recording, keying, editing, correction, and transmission of data to the JHS CC. It also includes maintaining an inventory of data forms and other materials collected (e.g., blood, ultrasonography tapes) and sent to the JHS Reading Centers and CC.

The CADC workstation allows EC personnel to enter, edit and correct data values directly eliminating the need for paper forms, except as a back up. During the cohort examination, the CADC system is used to collect, interview and enumerate data in this manner. The portable lap top computers use the same system to abstract, cohort data from medical records library in the study hospitals. In those situations where use of CADC is not desirable or possible, the same system can be used to enter data from completed paper forms.

The JHS data management system is centrally operated through a local area network that will connect workstation microcomputers to a local database computer. The network eliminates the need for individual participant diskettes since the local database is updated from each workstation as participant information is entered. Data records corresponding to each form are written to multiple hard disk files as the data are collected. Thus, a system failure will only affect the current form being entered. In the event that the network is not functioning, participant information is written to the workstation hard disk and is used to update the local database once the network is operating properly. If for some reason, such as power failure, the data management system is not functioning, paper forms are available for data collection. These data can then be entered when the data management system becomes operational.

As participant information is entered at a workstation, the local database is updated and automatically encrypted. In addition, a copy of each participant record is written to an encrypted ASCII file on the

workstation hard disk. This file serves as a backup from which the local database can be restored, if necessary. If the network is not functioning, this file can be used to update the local database once the network is functioning.

3.4 Data Security and Confidentiality

3.4.1 Coordinating Center

Since this is a single study site, the data are entered quickly after collection and do not leave the premises. Data are only made available to persons performing statistical analysis. If outside consultants or investigators with offices outside the study site need access to the data for publications, a data tape or CD-ROM is prepared with no personal identifiers included. All investigators maintain data security and confidentiality in accordance with their Institutional Review Board agreement. The Principal Investigators maintain data security and confidentiality in accordance with guidelines of the NIH.

All JHS staff is instructed in procedures for maintaining data confidentiality, and sign a form indicating their awareness of the necessity of maintaining confidentiality of data. Staff will be informed that any inappropriate use or disclosure of confidential data is cause for immediate termination of employment.

The JHS maintains a "secure data room" that is an interior room within the CC office suite. This room is designed so that it is environmentally controlled with Halon fire protection. This room is used to store original paper forms and data tapes. The room is locked at all times and only select members of the CC computing division have access to this room. The CC also has procedures for disposal of confidential data, as defined by any medium containing masked information or personal identifiers.

3.4.2 Examination Center

The local area network adds a level of confidentiality since a user must have a special ID and password to log onto the network in order to gain access to the data management system. In addition, another level of security is function-specific, so that interviewers only be allowed to access the specific interviews they were assigned, and staff performing editing, analysis, etc., have another function-specific ID and password. Data is backed-up after each interview is completed, and daily back-ups are performed to the network server to minimize data loss.

Disclosure to the participants regarding confidentiality of their data is completed during reception. The consent form states that information provided by the participant is kept confidential and is only used for scientific research purposes without revealing their name. Individuals are informed that participation in JHS is voluntary, and that they may withdraw from the study at any time. Individuals are informed that the purpose of the survey is to collect information to aid in the understanding of the mechanisms of disease of the heart, lung, and blood vessels, and help physicians treat patients by recommending preventive measures against future disease among healthy individuals.

Individuals are informed that they may refuse to answer any questions or to participate in any of the tests. Refusal to participate or answer any of the questions does not result in any loss of benefits to which they might otherwise be entitled, nor does it adversely affect their medical care. In publications, the individual identities of participants are not disclosed, and data are reported only in aggregate. Abnormal findings are relayed to the participant and his or her physician as agreed to by the participant. EC staff is trained in procedures for insuring confidentiality of participant information.

Certifying Institutional Review Board approvals by each collaborating institution are included in accordance with 45 CFR 46. Participant data are collected and stored by two methods. In addition to the computerized data management system, data may be collected on paper forms or audiotape for quality control, and then stored in locked file cabinets, stored in locked rooms. Since this is a single study center, original data does not leave the premises, and electronic back up of the data is made on a regular basis.

3.5 Electrocardiography Reading Center Data Management

Twelve lead ECG tracings are electronically recorded in EC clinic and transmitted daily from the ECG machine at the EC (approximately 6 ECGs per day). ECGs for all participants at baseline are sent by phone modem to be analyzed by computer at the ECGRC. Continuous computer measurements are made on the ECG wave forms (including the Minnesota Code and additional indices of electrocardiographic findings). Every week/month the ECGRC sends data for the ECGs received to the JHS on diskette. The ECGRC uses an automated system for identifying, logging, tracking, and inventory of received ECGs. Paper copies are made of all transmitted ECGs. These are read daily for alert ECG findings and any ECG with such specified finding is communicated to the JHS clinic site via e-mail. All ECGs with Minnesota Codes suggesting ischemia, MI or severe arrhythmias are visually read by the PI. The ECGRC generates a list of processed ECGs on a monthly basis together with a quality score for each transmitted ECGs.

ECGs of hospitalized cohort members are photocopied locally and coded manually by the ECGRC. Technicians read each ECG independently, and the ECG supervisor and/or an electrocardiographer at the reading center adjudicate unresolved disagreements. Serial change rules are used for suspected MI. All readings are made without knowledge of clinical or laboratory findings for the subject. At periodic intervals, a subsample of hospital and clinic examination ECGs are resubmitted for masked reading to monitor the ECGRC performance.

Inventory records listing ID numbers of subjects tested are sent weekly from the EC to the CC. Data backup at the EC includes paper ECG tracings, which can be read by the ECGRC if necessary. The CC stores all data received from the ECGRC in order to update the database.

3.6 Echocardiography Reading Center Data Management

The data acquisition, archival and transmission components of the ERC will be at both the JHS clinic site as well as on the main campus of the University of Mississippi Medical Center. The design of the echo examination as well as the reading process is based on an integrated digital imaging network with acquisition nodes attached to each echo machine, a server computer with additional software for permanent archival, and workstation nodes on the network where images are reviewed and analyzed.

Technicians record image and Doppler data as digital images, which are stored on a digital image server's hard disks. These disk arrays are configured with hardware redundancy so that hardware failure will not result in data loss. In addition, the completed studies are automatically archived, as a background task, to permanent storage media. The data are stored in a format to provide the broadest versatility for data exchange and future compatibility.

The ERC maintains a computer database for storage of the entire data relevant to the echo studies. Participant identification and qualitative observations made at the examination are entered from written data on the technician worksheets. Qualitative data generated by the ERC review are also entered from written worksheets. Quantitative results of measurements on the analysis workstation are directly imported into the database without keyboard data entry. This process not only duplicates other written and electronic records of this information but also consolidates data for local analysis and for ease of archiving the results onto the UMMC network servers.

Data on all network servers are back up daily by the UMC Department of Information Systems (UMC DIS). Data security and confidentiality are ensured by the network and application level login requirements. Access rights are determined by the data "owners" (in this case JHS through its EC and ERC) and are implemented by UMC DIS network managers. All data required for analysis are transmitted to the CC where the official analysis files are maintained.

3.7 Ultrasound Reading Center Data Management

B scan ultrasonography is performed on each subject with results sent every two weeks to the Ultrasound Reading Center on sVHS videotape. The videotape images are digitized; wall and lumen area calculations are then made for each carotid segment and stored in a relational database. Completed results for all ultrasound measurements are sent monthly from the Ultrasound Reading Center to the CC using a secure file transfer protocol for transfer into the main study database. An ongoing quality assurance program assesses intra- and inter-technician repeatability and temporal drift, and includes visual review of suspect arterial dimensions.

3.8 Pulmonary Function (PF) Reading Center Data Management

After spirometry is done on each cohort participant, initial calculations are performed on the PC locally at the EC. Results are sent weekly on floppy disks to the Pulmonary Function Reading Center for further calculations and the University of Arizona for quality control. Completed pulmonary function test results are sent weekly from the Pulmonary Function Reading Center to the CC on floppy disks for transfer into the main study database.

Inventory records listing ID numbers of subjects tested are sent weekly from the EC to the CC. Data backup at the EC includes electronic copies of raw data. The CC stores all data received from the Pulmonary Function Reading Center in the collaborative database and sends weekly to the EC a floppy disk containing study results of its participants to update the local databases.

3.9 Central Laboratory and Specimen Repository Data Management

Aliquots of plasma and serum and tubes of whole blood per subject are sent in daily or weekly batches from the EC to the CL/SR. An inventory record on paper accompanies each batch of specimens. Specimen analyses are performed on many different instruments with software written for each machine permitting transmittal of results directly to the central computer for the clinical laboratory. Results are then sent from the CL/SR to the CC via file transfer protocol (FTP) for transfer into the main study database.

Inventory records listing participant ID numbers for blood specimens are sent weekly from the EC to the CC. Data backup at the EC includes electronic copies of the inventory records of specimens sent. The study has elected not to draw extra blood specimens as backup in case of loss or damage during processing or shipping. The CC stores all data received from the CL/SR in the collaborative database and sends weekly to the EC a floppy disk containing study results of its participants in order to update the local databases.

Additional tests are run on selected cases and controls. These results are transmitted from the laboratory's computer via FTP the CC.

3.10 Collaborative Database

The collaborative portion of the database management system is used to store, update, and access the data from the EC and the reading centers. Since each data item is edited, corrected, and verified at the data collection site, editing by the collaborative system largely consists of record level "data base closure" checks, such as ensuring the receipt of all expected records from each exam, contact, hospitalization, and death. The focus of the collaborative DMS is retrieval for analyses. The LDMS directly generates analysis files in SAS data set, BMD save file, and SPSS save file formats. It includes a relational query language, a programming language, and a full-screen forms-oriented retrieval facility. It includes comprehensive security and confidentiality facilities including passwords, encryption, and audit trails. Given the size of the collaborative database, it is maintained on the University's mainframe computer.

4.0 STUDY MANAGEMENT

4.1 Introduction

The JHS Study is funded by the National Heart, Lung, and Blood Institute and the Office of Research on Minority Health of the National Institutes of Health, and directed by the Epidemiology and Biometry Program of the Division of Epidemiology and Clinical Applications. Principal investigators, directors, and their affiliations are listed in Appendix 1. The operations of the study are directed by the JHS Study Steering Committee whose members are the Principal Investigators of the overall JHS, EC, CC, UTC, and the NHLBI Project and Field Officers as shown in the organizational chart in Appendix 2.

4.2.1 JHS Study Subcommittee and Charges

Subcommittees responsible for the details of study design and implementation support the Steering Committee. These committees report and make recommendations to the Steering Committee. The subcommittees and their charges are listed in Appendix 3. The composition of each committee is: 1) the Scientific Output & Directions Committee (Publications & Presentations Subcommittee, Scientific Directions Subcommittee, Ancillary Studies Subcommittee, Genetics Subcommittee); 2) the Examination and Operations Committee (Events Monitoring, Participants Examination Results, Exam and Questionnaire Related Working Groups), 3) The Community and Cohort Committee (Partnership for Community Awareness and Health Education, Recruitment and Retention, Statistics, and Sampling), and 4) The Education Committee (Academic and Research Training Appointments).

4.3.1 Communications

4.3.2 Periodic Reports

The EC and reading centers prepare routine periodic reports to the JHS Study Project Office, which document the progress to date in each major activity, administrative matters, staffing changes, and current or anticipated problems. The CC also provides reports on the data collection at the Exam and Reading Centers, quality control findings on examinations, re-abstracted records, re-certification, laboratory determinations, and protocol adherence. Status reports on recruitment and data collection prepared for the Project Officer are also sent to the EC. Quality control reports are likewise sent to the reading centers.

4.3.3 Newsletters

The CC prepares and distributes a newsletter to facilitate communication among JHS Study staff. In general, each edition includes (1) reports from the Project Office, the EC, CC and UTC, the reading centers, and the Steering Committee, (2) a description of the facilities and staff (3) general information on data management and (4) a calendar of events. The newsletter also provides reports on issues such as recruitment and participant follow-up rates, the development and the use of new ECG, laboratory, pulmonary function, or ultrasound methods and equipment, and preliminary study results and abstracts.

4.3.4 Electronic Mail

The EC, reading centers, the CC, some UTC staff, NHLBI Field and Project Office are linked by electronic mail using microcomputers at each center. The electronic mail network is used to facilitate rapid and efficient communication among centers for messages such as announcements, meeting agendas, abstracts for clearance and acknowledgements of receipt of data.

4.3.5 Site Visits

Project Office staff conduct periodic monitoring visits to the JHS Centers as needed to (1) maintain channels of communication with investigators and staff, (2) solve participant recruitment or follow-up

problems, (3) monitor adherence to the protocol and (4) provide technical support for activities such as data management and quality control.

4.4 Publication and Presentation Policy

The Publications and Presentations Subcommittee (PPS) is responsible for overseeing all aspects of study publications and presentations, from the formation of writing groups and approval of manuscript proposals through the final approval of JHS manuscripts prior to journal submission. An overview of the process is shown in Figure 1.

The goal of the PPS is to encourage the preparation of manuscripts and abstracts while providing oversight for their scientific quality and content. The PPS will establish, disseminate and oversee policies for the use of JHS data in abstracts, presentations and publications, and help maintain the publications database at the Coordinating Center. The PPS is composed of members from the three Jackson institutions, the National Heart, Lung, and Blood Institute (NHLBI) field site and the JHS Director's office. A process will be developed to enable community representatives to serve on the PPS, participate in the review of proposals and manuscripts, and potentially become members of a writing group when possible and relevant to the topic. Meetings will occur on a regular basis as necessary (e.g. monthly or bimonthly). Abstract approval between meetings can take place by e-mail or fax when necessary.

Publications Data Base - A series of tracking tables and data bases maintained by the JSU Coordinating Center for the PPS will be used to monitor the approval and status of new proposals, presentations, abstracts and manuscript publications. A separate listing of all JHS manuscript proposals, abstracts and presentations and JHS publications (including those in press) will be updated quarterly and maintained on the JHS web site (<http://ccaix.jsums.edu/~jhs/>) with subject and author-based search capability.

4.4.1 Preparation and Approval Process for Manuscripts, Abstracts and Presentations

- a. **Manuscript proposal.** Manuscript proposals most commonly arise from JHS investigators. A JHS investigator includes Principal Investigators, Co-Principal Investigators and academic staff from the three partner institutions, the JHS Director's office, participating NHLBI staff (field site and project office) and JHS subcontractors. The PPS and the JHS Steering Committee may also designate a topic, select a writing group, and identify its chairperson (lead author). The proposal must include a clear statement of the nature of the publication, its rationale, the hypotheses to be addressed, the analytic approach to be used (types of statistical computations or summarization of data likely to be required) and pertinent references (see Appendix for manuscript proposal form). The lead author initiates the manuscript proposal draft, prepares a list of co-authors, and obtains any suggestions for the proposal. For locally generated proposals, the lead author should in principle strive to include investigators from all local institutions involved in the JHS based on their potential interest and areas of expertise. The writing group should be composed of both interested collaborators and experienced investigators. Interested JHS investigators should have an opportunity to participate. For proposals developed by non-JHS investigators, at least one JHS investigator must be included.
- b. **Format and submission.** The JHS has a standardized form (attached and available electronically on the JHS web site) that is used for proposal submission. Proposals should be submitted electronically to the PPS chair and Administrative Coordinator (see contact information at end) who will arrange distribution to the members and maintain appropriate databases.
- c. **PPS Proposal Approval.** The manuscript proposal, including the list of proposed authors, is submitted to the PPS for approval. Review will include assessment of scientific content, potential overlap with previously approved manuscript proposals, priority, and recommendations for members of the writing group.

- d. Distribution of manuscript proposals to Steering Committee.** After approval by the PPS, manuscript proposals are distributed to the JHS Steering Committee for any additional recommendations that they may wish to provide. The Steering Committee meets monthly.

The writing group prepares and communicates a detailed plan for data analysis containing computational specifications to the Coordinating Center, or it prepares statistical computations using the data set distributed by the Coordinating Center when local analytic assistance is available. In some cases analyses may be done outside the Coordinating Center (e.g. biostatistical consultants). The Coordinating Center has representation on the writing group in most cases and this person serves as the liaison to the writing group, both for communications about computing issues and for providing or obtaining appropriate statistical input. The Coordinating Center performs the specified statistical computations according to priorities set by the PPS.

The initiator of a manuscript proposal generally assumes first authorship. The PPS will assist in resolving any conflicts or confusion that occurs with respect to appropriate recognition of authorship. The lead author should elicit involvement in the manuscript from the co-authors, circulate drafts for co-author input and coordinate revisions. He/she should determine the order of authorship. Selection of the journal for initial submission is delegated to the writing group with input from the PPS and JHS Steering Committee.

4.4.2 Review and Approval Procedures

- a. Abstract approval.** Abstracts should be submitted electronically to the PPS chair and Administrative Coordinator for approval at least 2 weeks prior to the submission deadline. Abstracts will be circulated to PPS members for review and recommendations. After approval by the PPS and incorporation of any revisions, the abstract will be sent by the Administrative Coordinator to NHLBI (ebpdocs@nhlbi.nih.gov) for rapid review and response (usually takes approximately one week). In cases where ARIC approval is required, simultaneous submission will occur to the ARIC Publications Committee (see section 7, Coordination with ARIC). Following communication of these approvals (sent by the Administrative Coordinator) the writing group chair may submit the abstract. A copy of the final abstract, notification of acceptance and, if published, its citation, should be sent to the PPS Administrative Coordinator.
- b. PPS review of completed manuscripts.** The writing group prepares reviews internally, and submits the completed manuscript to the PPS for review and approval. Two JHS reviewers are assigned by the PPS chair to review the manuscript. Ad hoc reviewers with special expertise may be assigned by the chair. Under exceptional circumstances this review may be waived by the PPS with a majority vote. A detailed critique is expected from the reviewers within two weeks. Upon receiving the critiques, two courses of action are possible: (1) if the PPS deems the reviewer suggestions to be mainly editorial in nature, it may approve the manuscript and request that the authors incorporate suggested changes to the final version, or submit in writing reasons for not doing so. No further action is needed from the PPS; or (2) if, in the PPS's judgment, the critiques entail substantive changes, a revised manuscript must be further reviewed by the primary reviewers, before PPS approval is granted. The PPS may recommend data verification by the Coordinating Center based on reviewer comments and prior experience with JHS data analysis, although this will not be required in all instances. Members of the JHS Steering Committee receive copies of approved manuscripts. Manuscripts should include the phrase: "the Jackson Heart Study" in the title whenever possible and acknowledgement of funding sources for the JHS contract. In the case of genetic or family studies no pedigrees will be published.
- c. NHLBI review.** NHLBI review of completed manuscripts occurs following PPS approval. The PPS Administrative Coordinator will send the manuscript to NHLBI (see contact information) once the lead author has incorporated any recommended revisions based on the PPS review. Manuscript review may take 2-4 weeks. In cases where ARIC approval

is required, simultaneous submission will occur to the ARIC Publications Committee (see section 7, Coordination with ARIC).

- d. **Coordination with ARIC.** Manuscript proposals that involve data from any or all of the four ARIC centers, including Jackson alone, will follow existing ARIC publication policies (<http://www.bios.unc.edu/csc/ARIC/>). If other standard criteria are met, approval by ARIC will generally be granted unless a substantially similar manuscript proposal were already approved by ARIC, in which case modification or withdrawal of the new proposal would be necessary. Approval, along with other comments from the ARIC Publications Committee, will be conveyed to the JHS investigators. In the particular case where proposals include both ARIC and JHS data (e.g. longitudinal designs that include the first JHS exam), formal ARIC consideration will not be required; instead only JHS PPS approval will be necessary. Thus, an exemption from the ARIC review process would be in effect when the manuscript proposal requires JHS data for analysis. The ARIC Steering Committee will send copies of approved proposals and manuscripts to the JHS PPS to facilitate awareness and minimize potential overlap for new proposals. The JHS PPS Administrative Coordinator will submit requests for approval of proposals, abstracts and completed manuscripts involving ARIC data to the designated person at the ARIC Coordinating Center (see contact information).

4.4.3 Journal Submissions

- a. **Journal submission of manuscript.** After approval and incorporation of recommended revisions, the manuscript is formally submitted to a journal for consideration. The lead author must notify the PPS when the manuscript is submitted, which journal was selected and whether the manuscript was approved or rejected by the journal (e.g. a copy of paper and cover letter will suffice). Once published, a reprint or copy of the manuscript should be sent to the PPS Administrative Coordinator.
- b. **Presentations.** A formal slide or poster presentation at a national or regional scientific meeting can be reviewed by the PPS if desired by the lead author. However, notification of a JHS presentation must be sent to the PPS Administrative Coordinator for tracking purposes and should include the title, authors, name of the meeting, date and location. In the case of lectures and other informal presentations no formal approval is required assuming initial release of JHS results is not involved.
- c. **Interviews and press releases.** Discussions with the media and press releases should not be used as a forum to release new information, but may be used to clarify scientific findings for the lay public. In general, scientific findings from the JHS made available to the media will involve those findings presented at scientific meetings and published in the literature. Investigators are requested to keep the NHLBI Project Office informed of contacts with representatives of the major national media and of major national media coverage of information that they have supplied. Release of general descriptive information about the JHS for local use (such as a local newspaper, university newsletter or state medical society journal) does not require prior approval. Use of centrally prepared materials for such purposes is encouraged and can be obtained from JHS investigators associated with the partnering institutions, published journal articles, previous abstracts or presentations, and other JHS published materials. A copy of the resultant article should be sent to the Project Office.

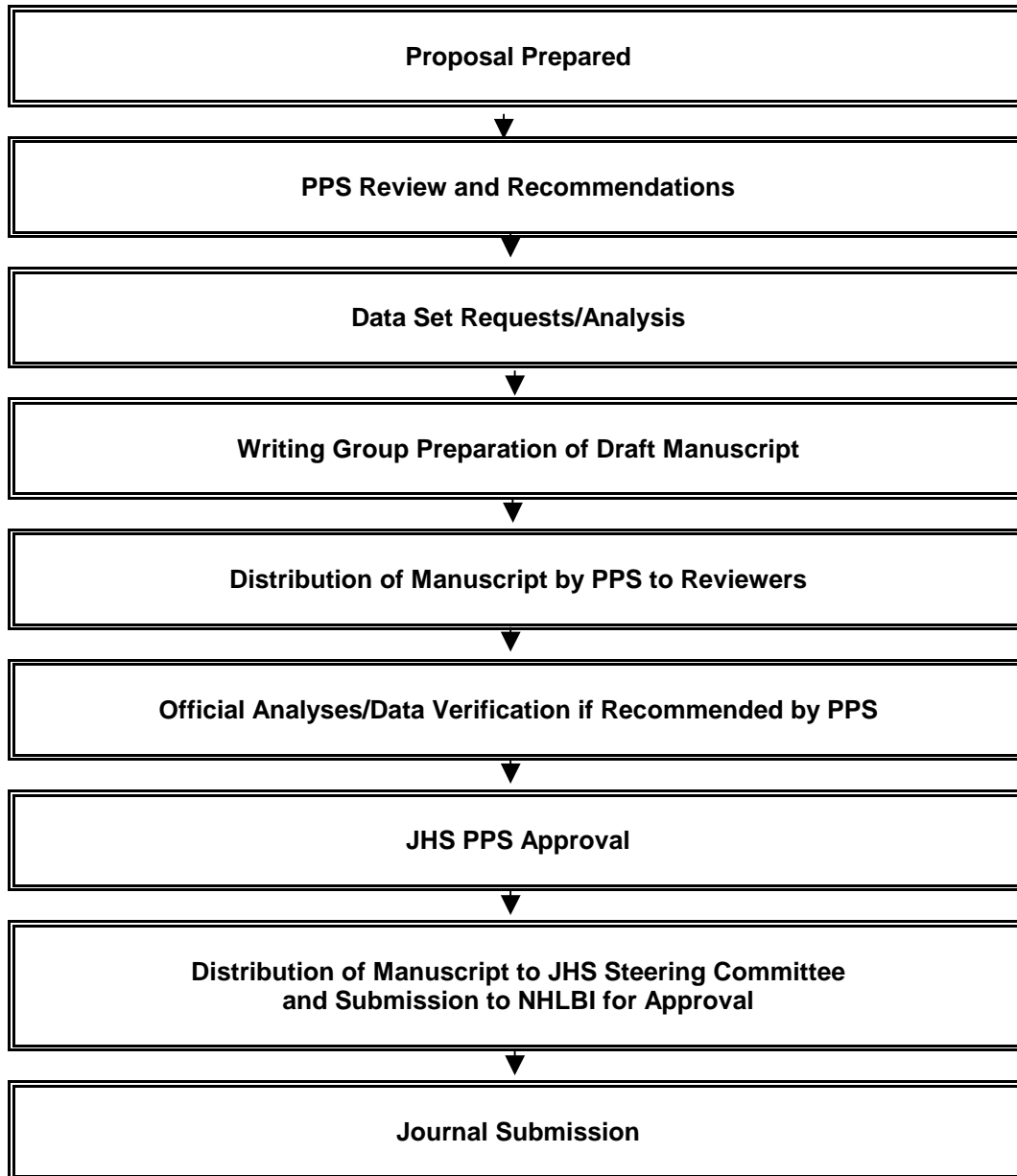
Contact Information

PPS Administrative Coordinator: Brenda Campbell, bcampbel@ccaix.jsums.edu
Jackson Heart Study Coordinating Center
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1400 John R. Lynch Street
Jackson, MS 39217
(601) 979-5840 Fax: (601) 979-3664

PPS Chair: Bobby Clark, Ph.D, Bclark@medicine.usmed.edu
NHLBI Field Site
Jackson Heart Study
Jackson Medical Mall, Suite 701
350 W. Woodrow Wilson Dr.
Jackson, MS 39213
(601) 368-4641 Fax: (601) 368-4651

NHLBI: Shirley Arnold, arnolds@nhlbi.nih.gov
Epidemiology & Biometry Program
NIH / NHLBI / DECA
II Rockledge Centre, Room 8170A
6701 Rockledge Dr., MSC 7934
Bethesda, MD 20892
(301) 435-0445 Fax: (301) 480-1455

ARIC Coordinating Center: Pat Penland, pat_penland@unc.edu
University of North Carolina, Biostatistics Department
Collaborative Studies Coordinating Center
Bank of America Center, CB#8030
137 E. Franklin Street, Suite 203
Chapel Hill, NC 27514
(919) 962-2073 Fax: (919) 962-3265

Figure 3. Jackson Heart Study Proposals and Manuscripts

5.0 ANCILLARY STUDIES

5.1 Objectives

An ancillary study is an investigation, which is not part of the Jackson Heart Study (JHS) protocol but uses JHS participants, samples, or data collected by JHS. In most cases, an ancillary study will involve acquisition of additional data, which are not compiled as part of the standard JHS data set.

The JHS Steering Committee encourages investigators to propose and conduct ancillary studies. Such studies enhance the value of JHS and ensure the continued interest of the diverse group of investigators who are critical to the successes of the study as a whole. They provide an exceptional opportunity for investigators, either within or outside of JHS, to conduct additional projects within an already existing participant cohort. In general, ancillary studies will require outside (non-JHS) funding.

The objectives of the JHS Ancillary Studies Committee (ASC) is to assure the protection of human research subjects as it relates to the JHS, and to assure the integrity of the main goals of the JHS. The aim of the Ancillary Studies protocol is to stimulate scientific productivity of the JHS and to stimulate interest in the JHS by a diverse group of investigators.

This document describes the procedures for application, submission, review, approval or rejection of ancillary studies, as well as guidelines for publications and presentations resulting from ancillary studies.

5.2 Review Process

In order to protect the integrity of JHS, all ancillary studies must be reviewed and approved before access to JHS data or participants is permitted. The review process is as follows:

A. Application

New ancillary study proposals should be sent to the Ancillary Studies Committee (ASC) in care of the JHS Coordinating Center. The ASC will review the proposal to ascertain that the application form is completed satisfactorily and establish a file. If the form is incomplete, the Principal Investigator of the ancillary proposal will be notified within five (5) working days after receipt by the JHS Coordinating Center. The Ancillary study application form is also available on the Jackson Heart Study Web site (<http://www.jsums.edu/~jhs>) or can be obtained by contacting the JHS Coordinating Center (Phone: (601) 368-4050; Fax: (601) 368-4651).

B. Submission

Electronic inquiries and submission of applications are encouraged. The ancillary study application should be submitted to Ms. Brenda Campbell, Research Associate at brenda.w.campbell@ccaix.jsums.edu and inquiries about ancillary studies may be directed to Dr. Mary Lou Gutierrez-Mohamed at mary.lou.mohamed@ccaix.jsums.edu.

C. ASC Review

The ASC Chair will review the ancillary study to determine if items 1, 2, or 3 below apply. If not the recommendation of the ASC will be sent directly to the JHS Director for Steering Committee review.

1. Proposals with New Participant Burden

If the ancillary study proposal indicates participant burden, the proposal will be sent to the Examination/Operations Committee (EOC) for review. The EOC will review the proposal within 10 working days and return it to the ASC Chair with their comments and recommendations.

2. Proposals Requiring Specimen Collection

If the ancillary study proposal indicates blood use of any kind, the proposal will be sent to the EOC for review. The EOC will review the proposal within 10 working days and return it to the ASC Chair with their comments and recommendations.

3. Proposals Involving the JHS Family or Genetics Studies

If the ancillary study proposal indicates the use of family relationship information or the use of genetic material (DNA), the proposal will be sent to the Genetics Subcommittee for review. The Genetics Subcommittee will review the proposal within 10 working days and return it to the ASC with their comments and recommendations.

D. Steering Committee Review

The Steering Committee will review whether the proposed study duplicates existing JHS research, whether it is feasible, and whether the impact of the proposed study on JHS operations and resources is justified by its scientific merit (see below for further discussion of review guidelines). ASC and EOC review comments will be attached to the ancillary study proposal before the proposal is submitted to the Steering Committee. Approval/disapproval will be made by the Steering Committee.

E. National Heart, Lung, and Blood Institute Project Office Review

The approved ancillary study proposal will be sent to the National Heart, Lung, and Blood Institute Project Office for review by the JHS Monitoring Board. In the situation where anticipated direct costs exceed \$500,000 in a given year, additional instructions as specified on the National Heart, Lung, and Blood Institute web site (www.nhlbi.nih.gov/funding/policies/500web.htm) should be followed with submission directed to Peter Savage, M.D., Acting Director, Division of Epidemiology and Clinical Applications.

5.3 Guidelines

A. Informed Consent and Institutional Review Board Approval

If separate informed consent is necessary, this must be obtained from all participants of the ancillary study. This should clearly identify the ancillary study as one being performed in addition to the main study and inform subjects that their participation in the ancillary study is not necessary for them to continue in the JHS. Institutional Review Board (IRB) approval for the ancillary study is the responsibility of the principal investigator of the ancillary study and must be obtained prior to initiation of the study.

B. Inclusion of JHS Investigators in Ancillary Studies

A JHS investigator must be included as a co-investigator in every ancillary study proposal. If the Coordinating Center or Examination Center resources are to be used, arrangements must be made with the Center Directors. Separate funding will usually be required for ancillary study related expenses, such as space rent and support staff. In order to avoid

misunderstandings, all communication regarding resources with the JHS Coordinating Center and Examination Center must take place between the senior JHS investigator involved in the ancillary study and the Center liaisons.

C. Protocol, Data Request, and Funding Source Changes

Following approval of an ancillary study by the Steering Committee there can be no substantial changes in the protocol or type or amount of data requested from the Coordinating Center. If major changes are made, the ancillary study must be reconsidered as a revised application. Also, if a previously approved Ancillary Study is to be submitted to a different organization for funding, a revised application must be submitted for approval.

D. Time Requirement for Review of Ancillary Studies

Ancillary studies should be submitted for review at least 60 days prior to the deadline for the funding application. This will provide time for circulation to appropriate committees, JHS Steering Committee recommendation and NHLBI approval prior to submission to a funding agency. Additional time is required if direct costs exceed \$500,000 in a given year.

E. Ancillary Study Application

A proposal for an ancillary study will require a formal application. This application should be completed for all new and revised JHS Ancillary Studies. Investigators should provide a synopsis of the proposed study, including project sponsoring information, design and methods, and data management issues. This synopsis should not exceed three pages.

1. Project Sponsoring Information
 - a. Initiating investigators, collaborators, sites involved
 - b. Planned starting date, conclusion date
 - c. Estimated cost, funding organization, source or agency, and current status
2. Design and Methods
 - a. Brief background, rationale, and significance of the study
 - b. Study questions or hypothesis, specific aims
 - c. Sample size, justification, proposed exclusions
 - d. Methods, data to be collected, analytic approach
 - e. Burden on JHS participants
 - f. Impact on the JHS facilities and operations
3. Data Management
 - a. Schedule for delivery of data from ancillary study to JHS
 - b. Schedule for delivery of data edit specifications to JHS CC
 - c. Data needed from the core JHS study for analysis of ancillary study

F. Criteria Used to Assess Priority of Ancillary Studies

The JHS Steering Committee will use the ancillary study application to assign priority of the proposed study in relation to the JHS objectives and, most importantly, determine its potential impact on the JHS facilities and operations.

Highest priority will be given to studies which:

- do not interfere with or duplicate the JHS research objectives;
- have the highest scientific merit;
- produce the least burden on JHS participants and the least demand on JHS resources such as blood samples;
- have objectives closest to those of JHS; and
- require the unique characteristics of the JHS cohort.

The Steering Committee will review the proposal primarily to determine that it will not compromise, complicate, or jeopardize the conduct of the JHS. Review of proposed ancillary studies for scientific merit is not the primary responsibility of this review process, but is a necessary consideration for allocating access to scarce JHS resources. All ancillary study proposals approved by the Steering Committee will also be sent to the NHLBI Project Office and the JHS Monitoring Board for review, comment and approval.

The ASC will record the progress of approved ancillary studies since the composite impact of the total number of active studies will be difficult to assess without central monitoring. Investigators with approved ancillary studies will report to the Chairman of the ASC every six months regarding the status of study funding, initiation and termination dates, success of data collection, and any presentations and publications derived from the ancillary study. A written progress report on ancillary studies will be made twice a year at the request of the ASC. This written report will be submitted to the Steering Committee.

G. Guidelines for Publications and Presentations from Ancillary Studies

Potential manuscripts from ancillary studies will follow the same procedures as JHS publications and presentations and must adhere to the following guidelines:

- The ancillary study investigator will submit a formal manuscript proposal to the Publication Committee, which consists of a title, proposed writing group, introduction and rationale, analysis plan, conclusion, and references.
- The Publications Committee will submit the proposal to the Steering Committee requesting nominations for the writing group from the JHS investigators who have special expertise in the subject of the manuscript.
- When the writing group has been finalized, and a memo from the Publications Committee has confirmed the final writing group, the manuscript can be started.
- The Publications Committee requests that the writing process involves the whole writing group, i.e.; drafts should be circulated regularly to the writing group.
- The Publications Committee should review the last draft of the manuscript arising from an ancillary study.
- When approved by the Publications Committee, this draft will be submitted to the JHS Steering Committee and NHLBI for final review.
- If the data analysis for the ancillary study was not conducted at the JHS CC the analysis may be verified by the CC before submission to a journal.
- The Chair of the writing group for the paper will be responsible for reporting to the Publications Committee on the paper's progress.

- A reprint of the final published article must be sent to the JHS CC.
- Abstracts generated from ancillary studies must follow the same guidelines for all JHS abstracts. The proposed abstract must be sent to the Chair of the Publications Committee:
 - (a) two weeks prior to the deadline for the abstract's submission if data from a JHS paper in progress is used (e.g. abstract is based on paper already reviewed by Publications Committee; and
 - (b) four weeks in advance if the project has not already been reviewed by the Publications Committee. The proposal should be approved by all co-authors before it is sent to the Publications Committee Chair.

APPENDICES

Appendix 1 JHS Principal Investigators and Directors

- Herman A. Taylor Jr., M.D. Overall Director and Principal Investigator
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Division of Hypertension
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National Heart, Lung, and Blood Institute (NHLBI) Project Office

Jackson, MS (field site)

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Director, NHLBI Field Site, JHS
ewalker@jusms.edu

TBA
Medical Officer, NHLBI Field Site, JHS

Bethesda, MD Site

Cheryl R. Nelson, M.S.P.H.
NHLBI Project Officer, JHS
Cn80n@nih.gov

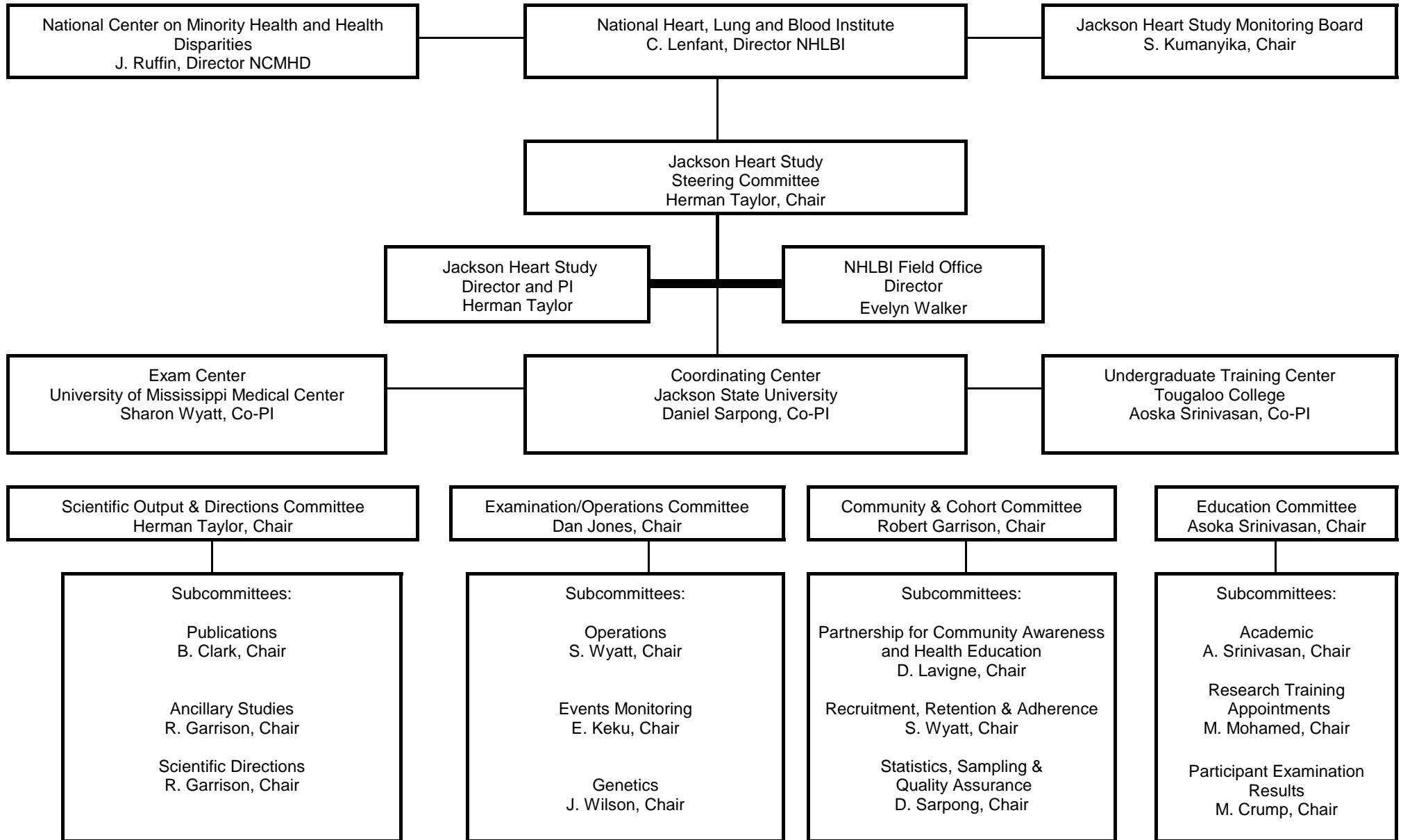
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Lisa O'Neill
NHLBI Contracting Officer, JHS
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Appendix 2 Jackson Heart Study Organizational Chart



Appendix 3 JHS Committees and Subcommittee Members

COMMITTEE	CHARGE	CHAIR & MEMBERS	
<p align="center">Steering Committee</p>	<p>Overall planning and conduct of JHS Development (through sub-committee mechanism) and approval of all aspects of study protocol Respond to issues raised by the Monitoring Board Review reports of all major Committees Review recommendations for Ancillary Studies from Scientific Output and Direction</p>	<p>H. Taylor – Chair (JHS Director) C. Nelson – NHLBI (Project Officer) R. Garrison – CC D. Sarpong– CC D. Jones – EC S. Wyatt – EC A. Srinivasan – UTC W. White - UTC</p>	<p>M. Carpenter - UNC-CC E. Walker - NHLBI TBN– NHLBI Field Center <u>Community Representatives</u> Sophia Leggett Johnnell Smith</p>
<p align="center">Scientific Output And Directions Committee</p> <p align="center"><u>Subcommittees:</u></p> <p align="center">Publications & Presentations</p> <p align="center">Scientific Directions</p>	<p>Set, disseminate and enforce policies for use of JHS data in abstracts, presentations, and publications</p> <p>Maintain updated file of all JHS manuscript proposals, publications, abstracts, presentations and ancillary or sub-studies</p> <p>Review all manuscript proposals and determine suitability, protect against overlap with other proposed projects and recommend priority for data analysis</p> <p>Continuous review of scientific directions for the JHS, to insure innovative scientific hypotheses are addressed, and to insure that the most productive approaches are used to test these hypotheses.</p>	<p>Publications & Presentation H. Taylor, serves on all committees</p> <p>TBA, Chair R, Garrison <u>Community Representative(s)</u> E. Walker Gerri Cannon D. Sarpong Richard Middleton A. Srinivasan S. Wyatt B. Campbell TBA - NHLBI Field Site Medical Examiner</p> <hr/> <p>Scientific Directions R. Garrison, Chair D. Jones B. Clark S. Wyatt E. Fox D. Bild J Hall M.Mohammed</p> <p>E. Walker E. Keku D. Sarpong T. Samdarshi J. Wilson TBA - NHLBI Field Site Medical Examiner</p>	

Appendix 3 JHS COMMITTEES and SUBCOMMITTEE MEMBERS (continued)

COMMITTEE	CHARGES	CHAIR & MEMBERS	
Ancillary Studies	Review ancillary studies for compatibility with JHS goals and make appropriate recommendations to Steering Committee	<u>Ancillary Studies</u> R. Garrison, Chair J. Hall D. Bild C. Nelson M. Mohamed B. Campbell	
Statistics, Sampling and Quality Assurance	Statistics Establish standard methods for data collections; develop methods for technician monitoring; develop methods for data coding; establish Quality Control procedures; processing of Coordinating Center statistical requests; oversight Quality Control and Quality Assurance, data management systems, and analysis Sampling Establish sampling methods: determine data to be collected on non-participants; characterize non-respondents from sampling frame	<u>Statistics, Sampling and Quality Assurance</u> D. Sarpong (Chair) C. Addison C. Jacquish N. Fahmy B. Clark E. Walker M. Crump TBA - NHLBI Field Site Medical Examiner <u>Ad Hoc</u> M. Carpenter S. Coady J. He P. Sorlie C. Nelson	
Genetics	To develop and implement genetic data collection protocols (Family Study Manual of Operations). Development of forms and instructions for collection of family information and genetic samples. Assist in the development of educational materials regarding genetics for the community, assist in developing mechanisms for the community to become actively involved in genetics studies in the JHS	<u>Genetics</u> J. Wilson, Interim Chair C. Jaquish, Co-Chair S. Wyatt M. Carpenter D. Antoine-Lavigne E. Walker C. Rotimi J. Maher E. Keku B. Clark E. Crook	C. Nelson C. Royal D. Sarpong <u>Consultant(s)</u> J. MacCluer D. Arnett <u>Ad. Hoc</u> A. Srinivasan <u>Community Representative(s)</u> Anniece McLemore

Appendix 3 JHS COMMITTEES and SUBCOMMITTEE MEMBERS (continued)

COMMITTEE	CHARGES	CHAIR & MEMBERS
<p>Genetics (Continued)</p>	<p>Development of policies to ensure privacy and confidentiality with regard to genetic information.</p> <p>Assist in the development of quality control of genetic data and samples. Assist in the future refinement of genetic hypotheses in the JHS and suggest directions for new genetics research</p> <p>Development of Policies to ensure privacy and confidentiality with regard to genetic information, including development of informed consent with regard to genetics, assist in the development of policies for sharing genetics, assist in the development of policies for sharing genetic information with participants and development of policies to assure access to genetic data by the scientific community while protecting participants privacy.</p> <p>Assist in the development of quality control of genetic data and samples including, clinic and laboratory procedures, decisions regarding collection of individual pedigree members or pedigrees, protocols, for assessing quality of pedigree data and correcting errors, and protocols for assessing quality of genotyping data and correcting errors.</p> <p>Assist in the further refinement of genetics hypotheses in the JHS and suggest directions for new genetics research. Participate in review of proposals for new genetics research in the JHS.</p> <p>Assist with incorporating genetics into educational aspects of the JHS including, incorporating genetic Epidemiology into summer Epidemiology Course and scholars program and ensuring scholars have the opportunity to apprentice in an area of genetics research</p>	

Appendix 3 JHS COMMITTEES and SUBCOMMITTEE MEMBERS (continued)

COMMITTEE	CHARGES	CHAIR & MEMBERS
<p>Examination/Operation Committee</p> <p><u>Subcommittees:</u></p> <p>Operations</p>	<p>Monitor and manage operation of clinic and conduct of exams (tracking flow)</p> <p>Develop methods for data coding and transmission in concert with CC (Coordinating Center)</p> <p>Establish Quality Control procedures for clinic exam and its components in collaboration with CC</p> <p>Establish "alert criteria"</p> <p>Develop methods for providing clinical information to participants and their physicians</p> <p>Interface with clinical subcontractors for CC</p> <p>Scientific rationale and protocol development for all laboratory measurements made from blood or urine in cooperation with PI's of the appropriate Reading Center, Repository or Laboratory</p>	<p>Clinic Operations</p> <p>S. Wyatt, (Chair)</p> <p>C. Nelson D. Sarpong P. Dubbert M. Carpenter T. Carithers M. Crump M. Steffes, Central/Repository Reading Center G. Evans, Ultrasound R. Crow, Echocardiogram C. Rotimi, Genetics K. Klischer, Ambulatory R. Jensen, Pulmonary W. Rock, Local Lab T. Skelton, Electrocardiogram Reading Center A. Srinivasan E. Walker K. Tucker</p> <p>Ad Hoc</p> <p>W. White</p>
<p>Events Monitoring</p> <p>Annual follow-up, cohort morbidity and mortality</p>	<p>Scientific rationale and protocol development for ultrasound, echo and other imaging techniques incorporated in the exam in cooperation with PI's of the appropriate Reading Center, Repository or Laboratory</p>	<p>Events Monitoring</p> <p>E. Keku, Chair</p> <p>S. Wyatt M. McMullan P. Miller W. Rosamond E. Walker E. Fox C. Smith</p>

Appendix 3 JHS COMMITTEES and SUBCOMMITTEE MEMBERS (continued)

COMMITTEE	CHARGES	CHAIR & MEMBERS
<p>Participants Examination Results</p>	<p>Ensure appropriate referral for participants requiring medical follow-up</p>	<p><u>Participants Examination Results</u> M. Crump, Chair E. Walker R. Smith H.D. Sullivan D. Sarpong M. Brook (Ad Hoc) J. Robinson D. Douglas H. Al-Fadhli</p>
<p>Community and Cohort Committee</p> <p>Subcommittees:</p> <p>Partnership for Community Awareness and Health Education Enhance awareness of study among community health care providers/general community</p> <p>Multiple working groups anticipated, focusing on various aspects of charge: media and government relations, student involvement, etc.</p>	<p>Develop overall methods for establishing and maintaining the population-based sample of African American, Jackson residents' central to the JHS.</p> <p>Develop and implement plan for community mobilization</p> <p>Facilitate community awareness and feedback regarding JHS (including ethical and genetics research issues)</p> <p>Develop and conduct appropriate surveys; apply survey results to recruitment, retention and adherence efforts</p>	<p><u>Partnership for Community Awareness and Health Education</u> D. Lavigne (Chair) B. Clark C. Smith E. Walker S. Fuqua R. Calvint TBA - NHLBI Field Site Director</p> <p>Community Representative Sophia Leggett</p> <p><u>Ad Hoc</u> W. White</p>

Appendix 3 JHS COMMITTEES and SUBCOMMITTEE MEMBERS (continued)

COMMITTEE	CHARGES	CHAIR & MEMBERS	
<p>Recruitment and Retention</p>	<p>Develop and conduct recruitment survey: facilitate Community Mobilization and Recruitment and Retention efforts with results of survey</p> <p>Develop and implement recruiting plan; monitor success of recruiting goals; develop and implement strategies for retaining participant involvement over course of study</p>	<p><u>Recruitment, Retention and Adherence</u> S. Fuqua (Chair) S. Wyatt J. Wilson E. Walker H. Al-Fadhli D. Lavigne M. Mohamed D. Antoine-Lavigne</p>	<p>B. Clark R. Calvin C. Addison L. Frith TBA - NHLBI Site Director</p> <p>Community Representative John Morris Margie Cunningham</p> <p><u>Ad Hoc</u> J. Wilson</p>
<p>Education Committee</p> <p>Academic</p>	<p>To conduct major educational activities associated with the JHS.</p> <p>To establish cross-center collaboration for practicum development.</p> <p>To develop summer Epidemiology course</p> <p>To develop seminar series for local investigators in collaboration with Scientific Output and Direction Committee</p>	<p><u>Academic</u> A. Srinivasan, Chair M. Mohamed E. Walker I. Perkins H. Al-Fadhli N. Fahmy R. Rockhold TBA - NHLBI Field Site Medical Examiner</p> <p><u>Ad Hoc</u> D. Sarpong W. White</p>	<p><u>Community Representatives</u> Cyde Christopher</p>

Appendix 3 JHS COMMITTEES and SUBCOMMITTEE MEMBERS (continued)

COMMITTEE	CHARGES	CHAIR & MEMBERS
<p>Research Training Appointments</p>	<p>Develop, update and implement guidelines for individuals seeking JHS appointments that provide skilled-based research training opportunities</p> <p>Facilitate awareness and development of skilled based placements within the JHS and among the larger community of educational institutions</p> <p>Provide continuous review of appointment applications and matching applicants with placement.</p> <p>Serve as a resource for information on training funding opportunities and liaison with other training programs that serve the same mission.</p>	<p><u>Research Training Appointments</u> M. Mohamed, Chair M. Wofford R. Calvin H. Al-Fadhli M. Hill N. Horton P. Banks C. Addison T. Samdarski B. Campbell E. Walker</p>

NOTE: The process for adding members to committees is subject to JHS Steering Committee approval, candidate must seek permission of Committee Chair and JHS Director. After permission is granted, attendance at committee meetings will be on an "AdHoc" basis until Steering Committee can vote final approval.