Jackson Heart Study Protocol

Manual 1

General Description and Study Management

Exam 2

Version 2.0

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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 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. The other Manuals describe the operations of the Clinic and Surveillance Components of the study. Detailed Manuals of Operation for specific procedures are contained in the other Manuals listed.

JHS Study Protocols and Manuals of Operation

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1	General Description and Study Management
2	Blood Pressure
3	Specimen Collection and Processing
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5	Quality Control
6	Data Management System
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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 for Minority Health and Health Disparities of the National Institutes of Health.

1.1 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

		Black		White	
Mortality[1,2]	**Region**	**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)

1.2 Study 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:

(1) 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 remodeling of the left ventricle of the heart, coronary artery disease, heart failure, stroke and disorders affecting the blood vessels of the kidney).

(2) 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.

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

1.3 Study Description

The JHS is a single-site prospective epidemiologic investigation of cardiovascular disease (CVD) among African-Americans from the Jackson, Mississippi metropolitan statistical 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 5,302 African-American men and women between the ages of 35 and 84 which includes 1,626 of continuing ARIC participants from Jackson along with men and women from a larger tri-county geographic area than the prior study. Non-ARIC participants were selected from the African-American residents of Hinds, Madison and Rankin counties surrounding Jackson, Mississippi. This is an area larger than either Rhode Island or Delaware in square miles. Family members were included in order to permit studies of familial and genetic contributions to CVD. The extensive examination in Exam 1 included a series of questionnaires, physical assessment, and laboratory measurements. Table 2 compares these components with those from the prior ARIC examinations.. Table 3 contains the components of Exams 2 and 3. The information collected included both conventional risk factors and new or emerging factors that may be related to CVD. Some of the newer areas of focus included 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 was conducted over 3.5 years beginning in the fall of 2000 and concluding in the spring of 2004. This phase of the JHS will include Exam 2 , 2005-2008 and Exam 3, 2009-2012; however, this Manual covers only Exam 2.

The JHS is sponsored by the National Heart, Lung, and Blood Institute (NHLBI) and the National Center for Minority Health and Health Disparities 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. Jackson State University developed a coordinating Center (CC) where all data collected during the study is managed, analysis of data is performed and community involvement is coordinated. Tougaloo college operates an Under graduate 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 University of Mississippi Medical Center developed an Exam Center (EC) which is responsible for conducting the examinations and retaining the cohort. The JHS offices and clinic facility are located in the main concourse of the Jackson

Medical Mall, which is serving as a centralized location for high quality, efficient health care delivery for the underserved community.

Table 2. The ARIC Study and JHS Exam 1 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 2000-04
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	4
Supine	X		S	S	X
Standing	X		S	S	
Ankle	X		S	S	X

PROCEDURES	ARIC				JHS
	Visit 1 1987-89	Visit 2 1990-92	Visit 3 1993-95	Visit 4 1996-98	EXAM I 2000-04
Ambulatory					X
ECHOCARDIOGRAPHY			X		X
ELECTROCARDIOGRAPHY					
2-minute Rhythm Strip	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	X
Coping Inventory					X
Dietary Intake	X	S	X	S	X
Family History of CHD		X			X
Fasting Status	X	X	X	X	X
Genogram					X
Global Stress					X
Health History	X	X	X	X	X
Home Interview	X				X
Inflammation				X	
Informed Consent	X	X	X	X	X

	ARIC				JHS
PROCEDURES	**Visit 1 1987-89**	**Visit 2 1990-92**	**Visit 3 1993-95**	**Visit 4 1996-98**	**EXAM 1 2000-04**
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**
Socioeconomic 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**

PROCEDURES	ARIC				JHS
	Visit 1 1987-89	Visit 2 1990-92	Visit 3 1993-95	Visit 4 1996-98	EXAM I 2000-04
PHYSICAL EXAMINATION					
Neck	**X**	**X**			
Cardio/pulmonary	**X**	**X**			
Lower Extremities	**X**	**X**			
PULMONARY FUNCTION					
FEV1.0	**X**	**X**			**X**
FVC	**X**	**X**			**X**
Max. Inspir. Pressure		**X**			
RETINAL PHOTOGRAPHY			**X**		
ULTRASOUND, B-MODE					
Carotid Arteries	**X**	**X**	**S**	**S**	**X**
Distensibility	**X**	**X**			
Popliteal Artery	**X**				
URINE COLLECTION 24-Hour					**X**
Spot Urine					**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

Table 3. The JHS Study Component Schedule: Interview and Procedures by Visit

PROCEDURES	JACKSON HEART STUDY		
		Proposed for	
	EXAM I 2000-04	EXAM 2 2005-08	EXAM 3 2009-12
Sitting	X	X	X
ABI	X		X
Ambulatory (24 hour)	X		
CT			
Coronary artery and aortic calcium		X	
Abdominal (visceral fat)		X	
MRI			
Cardiac (structure/function)		X	X subset
ECHOCARDIOGRAPHY	X		
ELECTROCARDIOGRAPHY			
12-Lead	X		X
INTERVIEWS			
Anger (CHOST, Anger In & Out)	X		
Annual Follow-up	X	X	X
CHD Events/Procedures	X	X	X
CES-D	X		
Coping Inventory	X		
Dietary Intake	X		
Family History of CHD	X		X
Fasting Status	X	X	X
Global Stress	X		
Health History	X	X	X
Home Interview	X		
Informed Consent	X	X	X
Medication Survey	X	X	X
Personal History (Smoking, Alcohol, Access)	X		X
Physical Activity	X		X
Racism & Discrimination	X		
Religion	X		
Reproductive History	X		
Respiratory Symptoms	X		

PROCEDURES	JACKSON HEART STUDY		
		Proposed for	
	EXAM I 2000-04	EXAM 2 2005-08	EXAM 3 2009-12
Sleep Quality	X		X
Social Support	X		
Socio-economic Status	X		X
Stress	X		
TIA/Stroke	X	X	X
TIA/Stroke Summary	X	X	X
Tracking	X	X	X
Trait Anger	X		
Violence	X		
MEDICAL DATA REVIEW	X	X	X
PHYSICAL ACTIVITY MONITOR	X		
PULMONARY FUNCTION			
FEV1	X		
FVC	X		
RESULTS/REFERRAL	X	X	X
SMBP DEVICES (distribute)		X	
ULTRASOUND, B-MODE Carotid Arteries	X		
URINE COLLECTION			
24 hour	X		
Spot	X	X	X
VENIPUNCTURE			
Electrolytes/Chemistries	X	X	X
BUN	x		x
Na/ K / Cl	x		
Creatinine	x		x
Glucose	x	x	x
Uric Acid	x		
Hematology	X	X	
Hemoglobin	x		
Hematocrit	x		
Hemoglobin A1c	x	x	

PROCEDURES	JACKSON HEART STUDY		
		Proposed for	
	EXAM I 2000-04	EXAM 2 2005-08	EXAM 3 2009-12
B12	x		
Folate	x		
GENETICS			
NON-FAMILY COMPONENT			
Cryopreservation		X	
FAMILY COMPONENT			
Family structure	X		
DNA, isolation and purification	X	X	
Cryopreservation	X		
DNA, transformed cell lines	X		
Candidate genes	X	X	X
Genome-wide scan (families)		X	

1.4 Study Centers

1.4.1 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 the Office of Community Partnership. The goal of the Community Partnership 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 Partnership for Community Awareness and Health Education 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 outreach and health education 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 JHS and its committees (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.

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.

1.4.2 The Examination Center

The University of Mississippi Medical Center developed an Examination Center (EC), which is responsible for 1) protocol development; 2) conducting the examinations, annual follow-up, and retention of participants; and 3) developing, pilot testing, and conducting surveillance for morbidity and mortality outcomes (events) of all participants. Surveillance includes annual telephone or mail contacts as part of morbidity and mortality follow-up for the entire cohort to ascertain: (a) 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; (b) dates and recorded causes of all deaths, using local vital statistics sources, obituaries, the National Death Index, and other sources; and; (c) circumstances surrounding death, through interview of family members, physicians and review of coroners' and other records; (d) participate in classification of cardiovascular events and conditions, using a standard protocol.

1.4.3 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 Science, Language and Mathematics (SLAM) inclusive of 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. A modular system for scholar education and associated JHS practica was initiated for Exam 2. The UTC collaborates with the JHS CC and EC and other local and international institutions to provide students with hands-on experiences to create interest in public health careers.

1.5 Clinic Examination

The clinic examination for Exam 2 takes approximately 3 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 work station configuration. The following sequencing restraints are necessary: (1) Fasting and abstinence from smoking and alcohol is required for not less than 12 hours prior to the venipuncture, spot urine and blood pressure measurements, (2) The venipuncture and spot urine should be done before the sitting blood pressure, (3) Sitting blood pressure must be measured before the body composition (4) Computed Tomography should be done before the snack. (5) Interviewing will precede the distribution of the home blood pressure monitor and related teaching, (6) Medical Data Review must be done prior to the exit

interview. Since participants must fast for not less than 12 hours prior to the examination, a snack is provided during the exam sequence. Table 4 identifies and describes the components of the Examination 2.

Table 4. Components of the JHS Examination 2

Procedure	Description
Reception	Greet the participant; determine fasting status; obtain tracking data; collect medications
Informed Consent Spot Urine Venipuncture	Obtain informed consent Obtain urine specimen Obtain blood specimens for fasting blood glucose, hemoglobin A1c,lipids, C-reactive protein, and DNA
Blood Pressure	Obtain sitting blood pressure
Body Composition Computed Tomography	Measure weight and height . Measure waist., neck and hip circumference. Measure % body fat Accompany participant to site for heart x-ray
Snack	Provide a nutritious snack containing no caffeine or stimulants
Interview	Collect medical/health history (medication survey, medical history, health history, renal disease, stroke symptoms)
Self-Monitored Blood Pressure	Distribute home blood pressure monitor. Teach participants to measure blood pressure at home using provided equipment.
Medical Data Review	Ascertain the completeness of the exam and verify abnormal results. Review the 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 and thank participant.

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—adjusted for a three-year exam cycle rather than the 3 ½ year cycle used in Exam 1. Contact letters are on JHS stationery and inform the addressee that s/he 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.

1.7 Clinical Review and Diagnostic Classification

During the follow-up contact, the cohort participant may indicate that he or she had 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 cardiac 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 and with each subsequent clinic visit, 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.

1.8 Reading Centers

1.8.1 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 (Bio-safety 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 (MOO) 7. The MOO 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.

2.0 DATA MANAGEMENT

2.1 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 prompts further investigation. In addition to collecting and editing the data, the system permits 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.

2.2 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 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.

The JHS data management system is centrally operated through a local area network that connects 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 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.

2.3 Data Security and Confidentiality

All investigators maintain data security and confidentiality in accordance with their Institutional Review Board agreement. The Principal Investigator and Center Directors/Co-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.

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.

2.3.1 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.

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.

2.3.2 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.

2.3.3 Central Laboratory and Specimen Repository Data Management

Aliquots of plasma and serum and tubes of whole blood per subject are stored at 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.

During Exam 1, inventory records listing participant ID numbers for blood specimens were sent weekly from the EC to the CC. Data backup at the EC included electronic copies of the inventory records of specimens sent. The study elected not to draw extra blood specimens as backup in case of loss or damage during processing or shipping. The CC stored all data received from the CL/SR in the collaborative database and sent a floppy disk to the EC containing study results of its participants in order to update the local databases each week.

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

For the first 12 months of Exam 2, no specimens were stored or shipped. Finger stick samples were analyzed at the point of contact using the Cholestech LDX system. This system uses reflectance photometry (the amount of light reflected from a solid surface) to measure the amount of substances in the blood. The analyzer measures color changes of the 4 reagent pads that is then converted to mg/dL or U/L and displayed on the Liquid Crystal Display (LCD) screen. Data from the display screen was recorded directly into the data management system.

Beginning in October 2006 (approximately), blood specimens will be collected via venipuncture. All blood specimens will be processed, packaged and shipped to CL, in accordance with CL instructions. Sample collection, processing, storage and analysis are monitored using an internal and external quality control program 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 sub-samples of the JHS cohort. Laboratory technicians are trained in proper venipuncture and processing methods and are certified and periodically recertified by the chief technologist.

2.3.4 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.

3.0 STUDY MANAGEMENT

3.1 Introduction

The JHS Study is funded by the National Heart, Lung, and Blood Institute and the National Center for Minority Health and Health Disparities of the National Institutes of Health, and directed by the Epidemiology and Biometry Program of the Division of Epidemiology and Clinical Applications. The Principal Investigator, Center Directors/Co-Principal Investigators, 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 Investigator of the overall JHS, Director/Co-Principal Investigators or two representatives of the EC, CC, UTC, and the NHLBI Project and Field Officers as shown in the organizational chart in Appendix 2.

3.1 JHS Director

The JHS Director actively participates in Monitoring Board, Steering Committee and appropriate subcommittee meetings to develop and implement a coordinated plan to achieve study objectives. The JHS Director acts as chair of the JHS Steering Committee. The Steering Committee is comprised two representatives each from the CC, the EC, the UTC, and the NHLBI Project Officer, the NHLBI Field Site Medical Director and a community representative. The JHS Director has the primary responsibility for planning and facilitating the conduct of the study, responding to issues raised by the Monitoring Board, e.g. protocol design, participant safety, and feasibility, and determining the content and implementation of the study. The JHS Director enlists appropriate senior personnel, either as staff, consultants, or subcontractors, with expertise in cardiovascular epidemiology, behavioral medicine, medical sociology, cardiovascular and renal physiology, medical genetics, clinical cardiovascular disease, noninvasive imaging, laboratory measurements, statistics, and longitudinal studies management to develop the study. The JHS Director fosters an atmosphere among the JHS investigators to work cooperatively with each other and the NHLBI Field Site and Project Office. The JHS Director actively promotes the JHS to the scientific community and the general public.

The Directors' Council (DC) comprising the Center Directors, the NHLBI Field Office Director and the Sr. Operations Manager forms the equivalent of an Executive Committee which meets fortnightly or more frequently if deemed necessary by JHS Director to discuss issues relating to the overall operations and performance of the study.

In view of the emphasis in Exams 2 and 3 on scientific productivity and cohort retention, a small administrative unit has been formed to provide administrative and scientific support to assist the Director in achieving the scientific and operational goals of the JHS through 2013. The JHS Director's Office staff is directly accountable to the JHS Director and is to be specifically responsible for the scientific productivity of the JHS and the oversight of the administrative and fiscal operations of the three JHS Centers. The creation and funding of the Office as a distinct administrative entity within the EC provides the resources to assure scientific productivity through such activities as Invited Collaborators, conferences and convening of an Emerging Science Committee of external experts. Web-based conferences, off-site regional locations and national scientific meeting linkage will be utilized as well as conferences held in Jackson. In addition to accomplishing this plan for scientific productivity, the Office staff will provide the infrastructure and create opportunities to train minority investigators. Ancillary Study instigation and

monitoring will also be a major responsibility of the Office leadership, with these instigation efforts often made in conjunction with the aforementioned Invited Collaborators conferences. Finally, the Office staff will provide essential across center administrative, infrastructure and fiscal coordination. Included among the numerous such responsibilities will be the consistent deliverable content and schedule compliance for all centers.

3.3 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 Append 3**.** The committees are: the Scientific Directions; Ancillary Studies; Genetics; Clinic Operations and Results Reporting; Events Monitoring; Community Partnership; Retention; Statistics, and Sampling; Academic; Research Training Appointments; and IRB Adherence.

3.4 Communications

3.4.1 Periodic Reports

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

3.4.2 Newsletters

The CC prepares and distributes a newsletter to facilitate communication among JHS participants. In general, each edition includes (1) reports from the Project Office, the EC, CC and UTC 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 participant follow-up rates and preliminary study results and abstracts.

3.4.3 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.

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

3.5 Publication and Presentation Policy

3.5.1 Overview

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, the JHS Director's office, community representatives, and recognized outside scientists. Meetings occur on a regular basis as necessary (e.g. monthly). Abstract approval between meetings takes place by e-mail or fax as necessary to facilitate scientific productivity.

3.5.2 Publications Data Base

A series of tracking tables and data bases maintained by the CC for the PPS are 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) is updated quarterly and maintained on the JHS web site (http://ccaix.jsums.edu/~jhs/) with subject and author-based search capability. This is true for Ancillary Studies and Genetics Studies as well.

3.5.3 Preparation and Approval Process for Manuscripts, Abstracts and Presentations

3.5.3.1a. Manuscript proposals. 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 would 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.

3.5.3.1b. 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 are 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.

3.5.3.1c. 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.

3.5.3.1d. Distribution of manuscript proposals to Steering Committee. After approval by the PPS, manuscript proposals are sent to the JHS Steering Committee for ratification and any additional recommendations that they may wish to make. The Steering Committee meets monthly.

3.5.4 Data analysis. The writing group prepares and communicates a detailed plan for data analysis containing computational specifications to the CC, or it prepares statistical computations using the data set distributed by the CC when local analytic assistance is available. In some cases analyses may be done outside the CC (e.g. biostatistical consultants). The CC 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 CC performs the specified statistical computations according to priorities set by the PPS.

3.5.3 Authorship. 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. S/he 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.

3.5.4 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-two weeks). In cases where ARIC approval is required, simultaneous submission is made to the ARIC Publications Committee (see section 3.4.7, 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.

3.5.5. 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 CC 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.

3.5.6 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 is made to the ARIC Publications Committee (see section 3.4.7, Coordination with ARIC).

3.5.7 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/cscc/ARIC/). If other standard criteria are met, approval by ARIC will generally be granted unless a substantially similar manuscript proposal was 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).

3.5.8 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.

3.5.9 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,

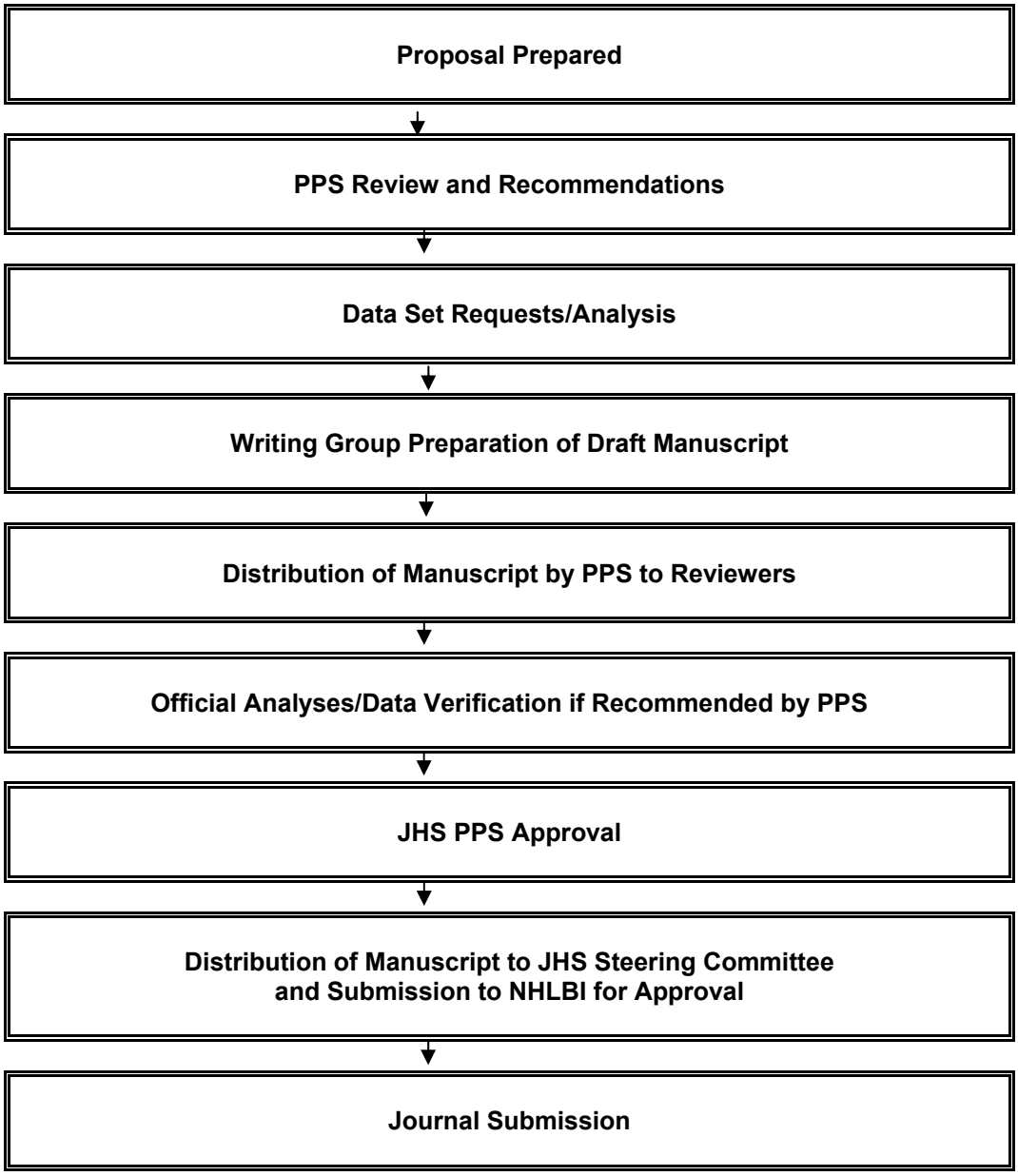
date and location. In the case of lectures and other informal presentations no formal approval is required assuming initial release of JHS results is not involved.

3.5.10 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.

3.5.11 Contact Information

PPS Administrative Coordinator:	Brenda Campbell Jenkins, brenda.w.campbell@jsums.edu Jackson Heart Study Coordinating Center Jackson Medical Mall, Suite 701 350 W. Woodrow Wilson Dr. Jackson, MS 39213 (601) 368-4631 Fax: (601) 982-5421
PPS Chair:	Herman A. Taylor, MD, MPH, htaylor@medicine.umsmed.edu Jackson Heart Study Jackson Medical Mall, Suite 701 350 Woodrow Wilson Drive Jackson, MS 39213 (601) 368-4644 Fax: (601) 982-5421
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:	Debbie Rubin Willaims, uccdrw@mail.cscc.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) 962-3246 Fax: (919) 966-3804

Figure 1. Jackson Heart Study Proposals and Manuscripts



4.0 ANCILLARY STUDIES

4.1 Objectives

An ancillary study is an investigation, which is not part of the Jackson Heart Study (JHS) protocol but uses all or a subgroup of the JHS cohort, 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 Sub-Committee (ASSC) 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 Guidelines is to stimulate scientific productivity of the JHS and to stimulate interest in the JHS by a diverse group of investigators.

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

4.2 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 Sub-Committee (ASSC) in care of the JHS Coordinating Center. The ASSC will review the proposal to ascertain that it is completed satisfactorily. If the proposal is incomplete, the Principal Investigator (PI) of the ancillary proposal will be notified within five (5) working days after receipt by the JHS Coordinating Center. The ancillary study proposal form and guidelines are 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) 982-1133; Fax: (601) 982-0006.

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@jsums.edu and inquiries about ancillary studies may be directed to the -chair of the ASSC: Dr. James Perkins at James.Perkins@jsums.edu

C. ASSC Review

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

1. <u>Proposals with New Participant Burden</u>

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

2. <u>Proposals Requiring Specimen Collection</u>

If the ancillary study proposal indicates blood use of any kind, the proposal will be sent to the COC for review. The COC will review the proposal within 10 working days and return it to the ASSC 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 ASSC 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). ASSC and COC 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 Paul Solis, Acting Director, Division of Epidemiology and Clinical Applications.

4.3 Procedures

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 CC or EC resources are to be used, arrangements must be made with the Center

Directors/Co-Principal Investigators. 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. Proposal, Data Request, and Funding Source Changes
Following approval of an ancillary study by the Steering Committee, there can be no substantial changes in the proposal 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 proposal. Also, if a previously approved ancillary study is to be submitted to a different organization for funding, a revised proposal must be submitted for approval.

D. Time Requirement for Review of Ancillary Studies

Ancillary study proposals 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 Proposal Form

The proposal form must be fully completed by the PI of the proposed ancillary study. The body of the ancillary study proposal must include the following information: 1) investigator information; 2) project sponsoring information; 3) design and methods; 4) assurances that data used by ancillary study PI will be given back to JHS to incorporate into larger JHS data set; 5) data management of the ancillary study project; 6) genetic/family studies information (if applicable); and 7) "other information" regarding the ancillary study. Each section is elaborated in detail on the proposal form which is found on the JHS web site (http://www.jsums.edu/~jhs). The completed proposal should not exceed five (5) pages (excluding literature citations and appended questionnaires and forms).

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 Observational Studies Monitoring Board for review, comment and approval.

The ASSC 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 Chairperson(s) of the ASSC 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 ASSC. 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:

1. The ancillary study investigator will submit a formal manuscript proposal to the JHS Publications and Presentations Sub-Committee (PPS), which consists of a title, proposed writing group, introduction and rationale, analysis plan, conclusion, and references.

2. The PPS 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.

3. When the writing group has been finalized, and a memo from the PSS has confirmed the final writing group, the manuscript can be started.

4. The PPS requests that the writing process involves the whole writing group, i.e.; drafts should be circulated regularly to the writing group.

5. The PPS should review the last draft of the manuscript arising from an ancillary study.

6. When approved by the PPS , this draft will be submitted to the JHS Steering Committee and NHLBI for final review.

7. 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.

8. The Chair of the writing group for the paper will be responsible for reporting to the PPS on the paper's progress.

9. A reprint of the final published article must be sent to the JHS CC.

10. 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 PPS:

    (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 and approved by the PPS); 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 PPS Chair.

Appendix 1 JHS Principal Investigators and Directors

Herman A. Taylor Jr., M.D., M.P.H. JHS Director and Principal Investigator
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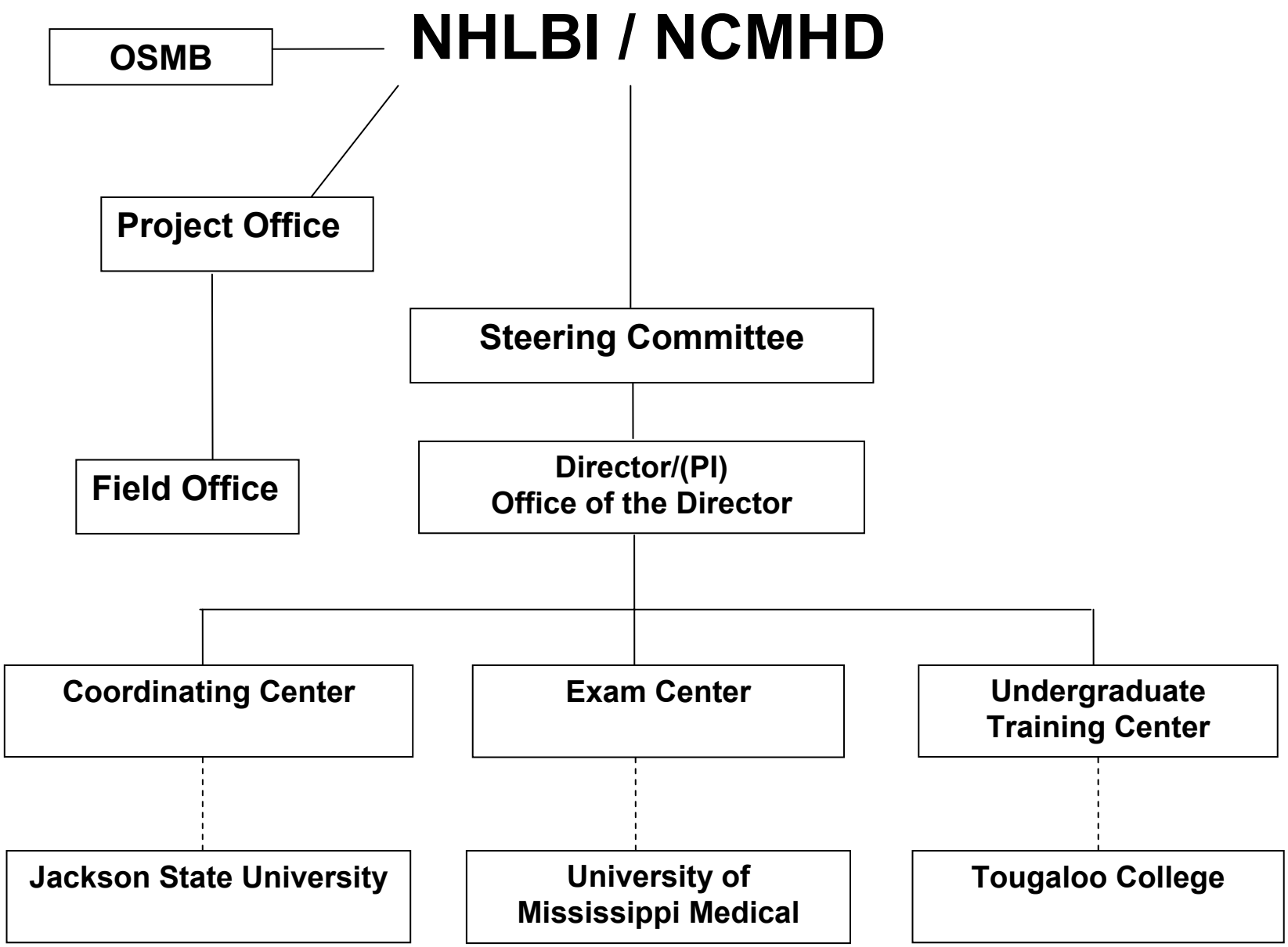
Michael Steffes, M.D., Ph.D	Principal Investigator Jackson Heart Study Central Laboratory Reading Center and Specimen Repository Reading Center University of Minnesota Medical School Department of Laboratory Medicine & Pathology 420 Delaware Street, SE Minneapolis, MN 55455-0391 (612) 624-8164 Michael.w.Steffes-1@tc.umn.edu
Evelyn Walker, M.D.	Director, NHLBI JHS Field Site Jackson Heart Study Jackson State University 350 W. Woodrow Wilson Drive ewalker@ccaix.jsums.edu
Cheryl R. Nelson, M.S.P.H.	NHLBI JHS Project Officer NHLBI 6701 Rockledge Drive Bethesda, MD 20892-7934, nelsonc@nhlbi.nih.gov
Paul Solis, PhD	Director, Epidemiology and Biometrics Program, DECA 6701 Rockledge Drive Bethesda, MD 20892-7934, manoliot@nhlbi.nih.gov
Jennifer Jennings	NHLBI JHS Contracting Officer NHLBI 6701 Rockledge Drive Bethesda, MD 20892-7934 [Jenningsj@nhlbi.nih.gov]
Austin Sachs	NHLBI JHS Contracting Specialist NHLBI 6701 Rockledge Drive Bethesda, MD 20892-7934 Sachs, Austin (NIH/NHLBI) [E] [sachsa@nhlbi.nih.gov]

Appendix 2 Jackson Heart Study Organizational Chart



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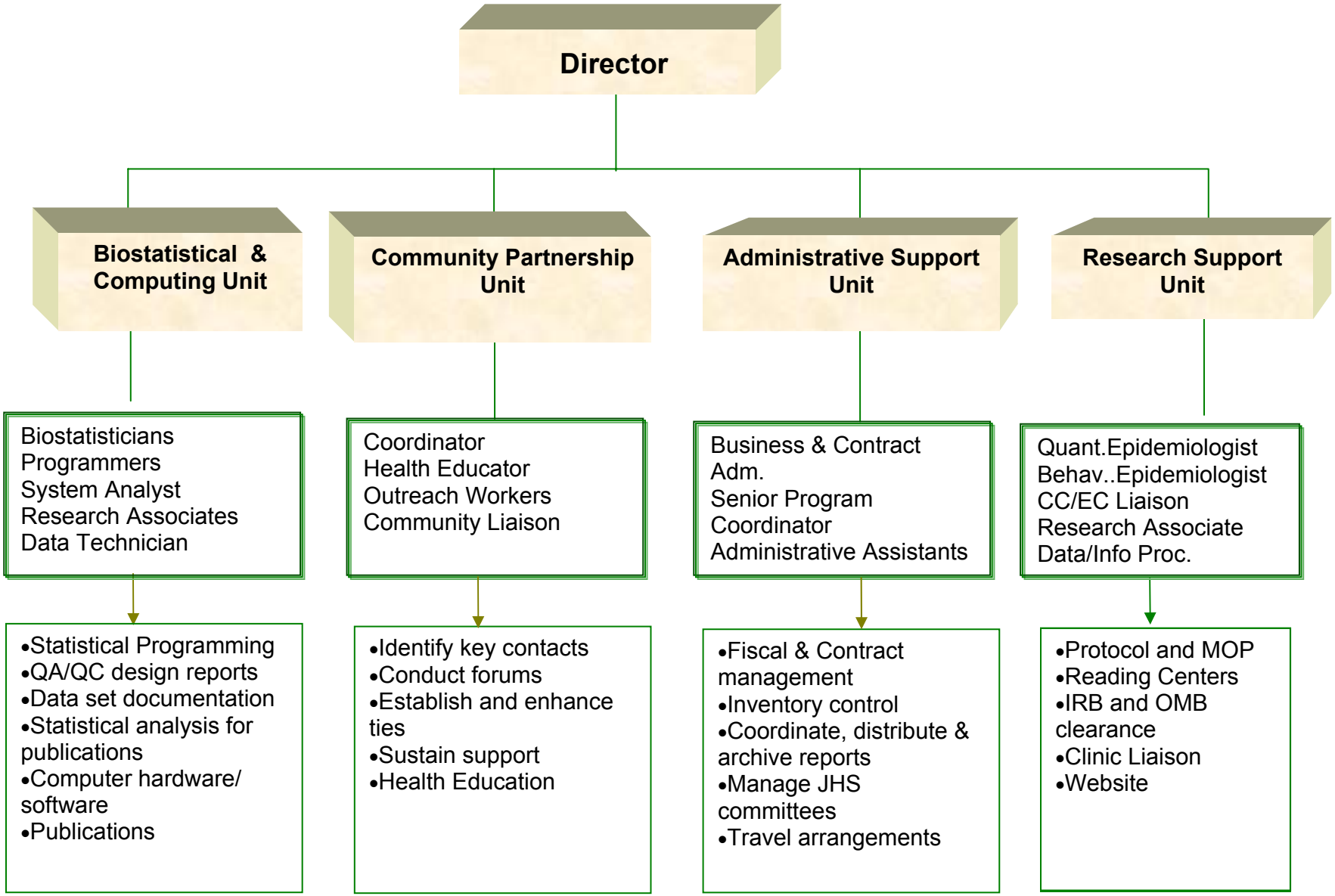
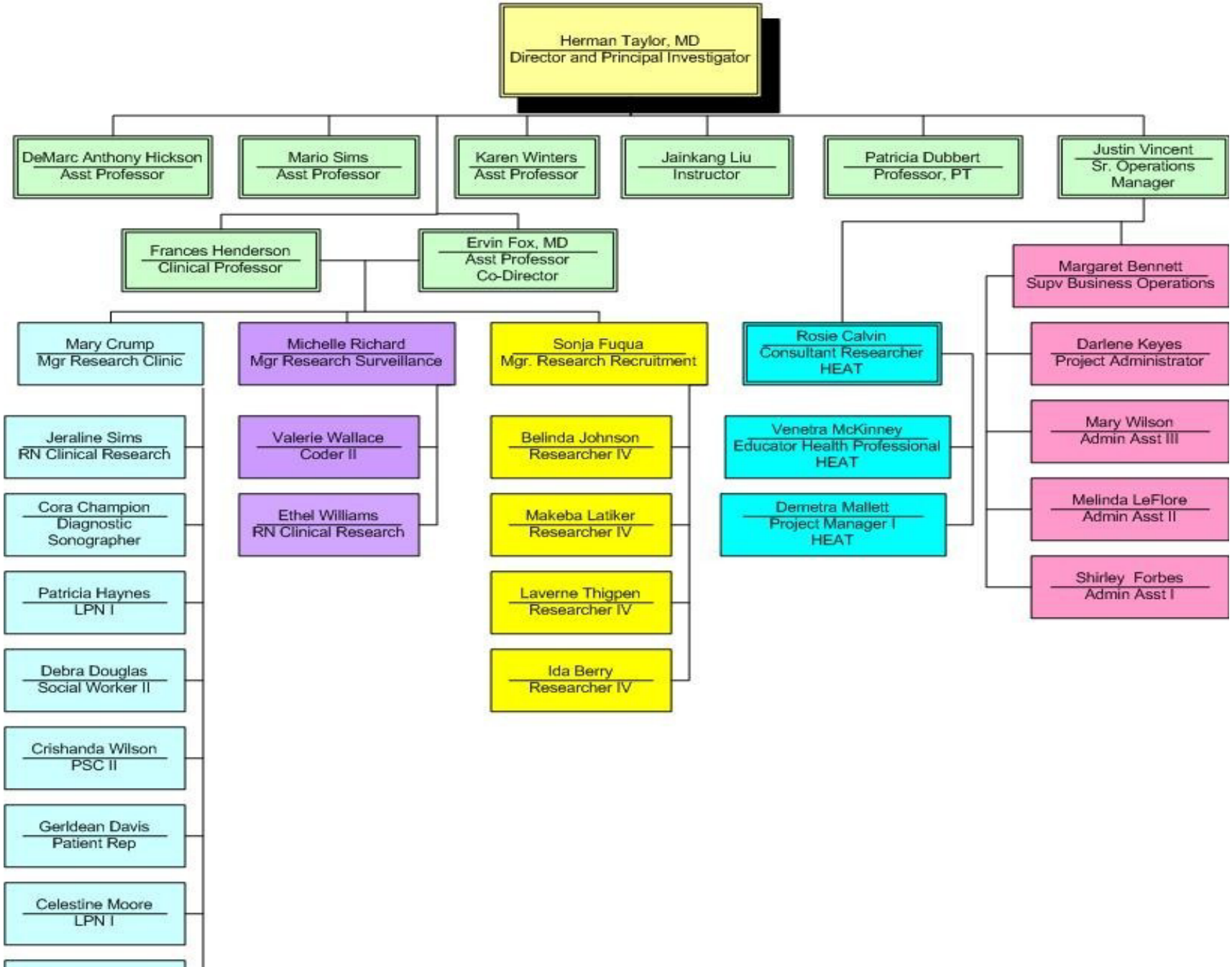
JHS Coordinating Center Organization Chart



Jackson Heart Study



Appendix 3 JHS COMMITTEES AND SUBCOMMITTEES

COMMITTEES/SUBCOMMITTEES	CHARGE	CHAIRS & MEMBERS
1.1 **1.2 STEERING COMMITTEE** EXECUTIVE COMMITTEE DIRECTOR'S COUNCIL	**Overall planning and conduct of JHS.** **Development (through subcommittee 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 Directions.**	**1.3** 1.4 **Herman Taylor, Chair** (JHS Director) **Frances Henderson – EC** **Michael Winniford -- EC** **Emmanuel Keku -- CC** **Daniel Sarpong -- CC** **Asoka Srinivasan -- UTC** **Wendy White -- UTC** **Community Representative:** **Jermal Clark** **NHLBI Representatives:** **Cheryl Nelson (Project Officer)** **Evelyn Walker (Field Site Director)** Herman Taylor, Chair **(JHS Director)** **Ervin Fox, EC** **Frances Henderson, EC** **Daniel Sarpong, CC Director** **Asoka Srinavasan, UTC Director** **Justin Vincent, Sr. Operations Manager** **Evelyn Walker, Field Site Director**
JHS SUBCOMMITTEES IRB Adherence Subcommittee Publications and Presentations Subcommittee	**Set, disseminate and enforce policies for use of**	**1.17** **IRB Adherence Subcommittee** **Justin Vincent, Chair** **Mary Crump** **Brenda-Campbell Jenkins** **Melinda Leflore** **Daniel Sarpong** **Asoka Srinivasan or Designee**

	JHS data in abstracts, presentations, and publications. **Maintain updated file of all JHS manuscript proposals, publications, abstracts, presentations and ancillary or sub studies.** **Review all manuscript proposals and determine suitability and protect against overlap with other proposed projects and recommend priority for data analysis.** **Review abstracts and manuscripts prior to submission.**	**Publications and Presentations Subcommittee** **Nimr Fahmy, Chair** **Patricia Dubbert** **Joseph Maher** **Frances Henderson** **Gailan Marshall** **Neil Powe** **Daniel Sarpong** **Michael Steffes** **Ad Hoc:** **Clifton Addison** **Myra Carpenter** **Richard deShazo** **Ervin Fox** **Robert Garrison** **Emmanuel Keku** **Kent Kirchner** **Charles Rotimi** **Tandaw Samdarshi** **Asoko Srinivasan** **James Wilson** **Community Representative:** **Richard Sullivan** **NHLBI Representatives:** **Cheryl Nelson** **Evelyn Walker** **NCMHD Representative:** **Jerome Wilson** **JHS Coordinators:** **Lynette Ekunwe** **Brenda Campbell-Jenkins**
Scientific Directions Subcommittee And Emerging Science Scientific Directions Subcommittee And Emerging Science (Continued)	**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.**	Scientific Directions Subcommittee ,Chair **Ermekgul Akylbekova** **Teresa Carithers** **Ervin Fox** **Celso Gomez-Sanchez** **Elise Gomez-Sanchez**

			Frances Henderson **Robert Garrison** **Emmanuel Keku** **Abdul Mohamed** **Ana Diez-Roux** **Mario Sims** **David Williams** **James Wilson** **Ad Hoc:** **Michelle Albert** **Donna Arnett** **Gerado Heiss** **Rick Kittles** **Community Representative:** **John Bower** **Emerging Science I** Eric Boerwinkle David Herrington Rick Kittles Bruce Psaty Ellen Wijsman Ad Hoc: Robert Garrison Daniel Sarpong Michael Steffes James Wilson
	Ancillary Studies Subcommittee	**Review ancillary studies for compatibility with JHS goals and make appropriate recommendations to JHS Steering Committee.**	**Ancillary Studies Subcommittee** **James Perkins, Chair** **Emekgul Akylbekova** **Ervin Fox** **William Johnson** **Anthony Mawson** **Mario Sims** **William Woolverton** **Jiankang Liu** **Ad Hoc:** **Asoka Srinivasan or Designee**
1.4.1.1.1 **1.4.1.1.2** **1.4.1.1.3** **1.4.1.1.4**	Ancillary Studies Subcommittee **(Continued)**		

1.4.1.1.5 **1.4.1.1.6** **1.4.1.1.7** **1.4.1.1.8** **1.4.1.1.9** **Statistics and Quality Assurance Subcommittee**		**Community Representative:** **Charles Spann** **NHLBI Representative:** **Cheryl Nelson** **JHS Coordinator:** Brenda Campbell-Jenkins
	Establish standard methods for data collection; develop methods for technician monitoring; develop methods for data coding; establish quality control procedures; processing of Coordinating Center statistical requests; oversee quality control and quality assurance, data management systems, and analysis.	Statistics and Quality Assurance Subcommittee William Johnson, Chair **Clifton Addison** **Mary Crump** **Nimr Fahmy** **Daniel Sarpong** **Warren May** **Gregory Wilson** **Ad Hoc:** **NHLBI Representative:** **Sean Coady**
Genetics Subcommittee		1.17.1.1.1.1.1 1.17.1.1.1.1.2 Genetics Subcommittee
	Monitor genetic data collection protocols. **Assist in the development of genetics educational materials for the community.** **Assist in developing mechanisms for the community to become actively involved in genetics research and in decisions made regarding JHS genetics studies.** **Develop and monitor policies to ensure privacy and confidentiality of genetic information, including development of informed consent for genetics.**	Rick Kittles, Co-Chair James Wilson, Co-Chair **Ermekgul Akylbekova** **Errol Crook** **Joseph Maher** **Charles Rotimi** **Charmaine Royal** **Barbara Wilson** **Ad Hoc:** **Donna Arnett** **Sarah Buxbaum** **Jean MacCluer** **Asoka Srinivasan**
Genetics Subcommittee (Continued)	**Assist in the development of policies for sharing genetic information with participants and development of policies to assure access to**	**Community Representative:** Bruce Taylor Aneice McLemore

1.4.1.1.10 **1.4.1.1.11** **1.4.1.1.12** **1.4.1.1.13** **1.4.1.1.14** **1.4.1.1.15** **1.4.1.1.16** **1.4.1.1.17** **1.4.1.1.18** **1.4.1.1.19** **1.4.1.1.20**	**Clinic Operations and Participant Results Subcommittee**	**genetic data by the scientific community while protecting participants' privacy.** Assist in the development of quality control of genetic data and samples. **Assist in further refinement of JHS genetics hypotheses and suggest directions for new genetics research.** **Participate in the review of proposals for new JHS genetics research.** **Assist with incorporating genetics into the educational aspects of the JHS, including genetic epidemiology into the summer Epidemiology Course and Scholars Program to ensure that scholars have the opportunity to apprentice in an area of genetics research.**	**<u>NHLBI Representative:</u>** **Ebony Bookman** <u>JHS Coordinator:</u> Lynette Ekunwe
1.5 **1.6** **1.7** **1.8** **1.9** **1.10** **1.11** **1.12** **1.13** **1.13.1.1.1** **1.13.1.1.2** **1.13.1.1.3** **1.13.1.1.4** **1.13.1.1.5** **1.13.1.1.6** **1.13.1.1.7** **1.13.1.1.8** **1.13.1.1.9** 1.14 **1.15** **1.16** **1.16.1.1.1**	**Events Monitoring Subcommittee**	**Monitor and manage operation of clinic and conduct of exams (tracking flow).** **Develop methods for data coding and transmission in concert with CC (Coordinating Center).** **Establish quality control procedures for clinic exam and its components in collaboration with Statistics and Quality Assurance Subcommittee.** **Establish and monitor examination "alert criteria".** **Develop methods for providing clinical information to participants and their health care providers.** **Interface with clinical subcontractors for CC.** **Develop scientific rationale and protocol for all Interviews, procedures and specimen collection in cooperation with PIs of the appropriate Reading Center, Repository or Laboratory.** **Ensure appropriate referral for participants requiring medical follow-up.**	**Clinic Operations and Participant Results Subcommittee** Daniel Sarpong, Chair **Clifton Addison** **Michelene Brock** **Mary Crump** **Patricia Dubbert** **Debra Douglas** **Frances Henderson** **Wendy White** **<u>Ad Hoc:</u>** **PIs of Central Agencies** **Sonja Fuqua** **William Rock, Local Lab Reading Center** **Michael Steffes, Central/Repository Reading Center** **Minta Uzodinma** **Justin Vincent** **Evelyn Walker** **Gregory Wilson** **<u>NHLBI Representative:</u>** **Cheryl Nelson** <u>Events Monitoring</u> Alan Penman, Chair **David Conwill** **Ervin Fox** **Sonja Fuqua**

Community Partnership Subcommittee Multiple working groups anticipated, focusing on various aspects of charge: media and government relations, student involvement, etc. **1.16.1.1.2** **1.16.1.1.3** **1.16.1.1.4** **1.16.1.1.5** **1.16.1.1.6** **1.16.1.1.7** **1.16.1.1.8** **1.16.1.1.9** **1.16.1.1.10 Translating Research into Practice and Prevention (TRIPP) Subcommittee** **1.16.1.1.11** **1.16.1.1.12** **1.16.1.1.13** **1.16.1.1.14** **1.16.1.1.15** **1.16.1.1.16** **1.16.1.1.17**	**Develop and monitor protocols for annual follow up, cohort morbidity and mortality assessment, and events ascertainment.** **Establish quality control procedures for events ascertainment in concert with Statistics and Quality Assurance Subcommittee.** **Enhance awareness of study among community health care providers/general community.** **Develop, implement and evaluate plan for community partnership.** **Facilitate community awareness and feedback regarding JHS (including ethical and genetics research issues).** **Translate research affiliated with JHS into**	**Emmanuel Keku** **Michael McMullan** **Michelle Richard** **Wayne Rosamond** **Cynthia Dorsey-Smith** **Ad Hoc:** **Ermekgul Akylbekova** **Robert Garrison** **NHLBI Representative:** **Evelyn Walker** Community Partnership Subcommittee Evelyn Walker, Chair **Clifton Addison** **Sonja Fuqua** **Donna Antoine-LaVigne** **Cynthia Dorsey-Smith** **Justin Vincent** **Ad Hoc:** **Mary Crump** **Wendy White** **Community Representative:** **Jermal Clark** **NHLBI Representative:** **Cheryl Nelson** **NCMHD Representative:** **Francisco Sy** Translating Research into Practice and Prevention Subcommittee Frances Henderson, Chair **Diane Beebe** **Kenneth Ray Butler** **Mary Crump** **Sonja Fuqua** **Donna Antoine-LaVigne** **Rob Rockhold** **Marjayua Lartey-Rowser**

1.16.1.1.18	**practice for health professionals and the lay public.** **Develop the raw materials for two major products: a lay-oriented lecture series and articles for local print media.** **Identify external funding sources for committee activities.**	**Cythia Dorsey-Smith** **Debra Sutton** **Justin Vincent** **<u>Community Representatives:</u>** **Jermal Clark** **Margie Cunningham** **<u>NHLBI Representative:</u>** **Evelyn Walker**
1.16.1.1.19 **1.16.1.1.20 Academic Subcommittee** **1.16.1.1.21** **1.16.1.1.22** **1.16.1.1.23** **1.16.1.1.24** **1.16.1.1.25** **1.16.1.1.26** **1.16.1.1.27** **1.16.1.1.28**	**Conduct major educational activities associated with the JHS.** **Establish cross-center collaboration for practicum development.** **Develop summer epidemiology course.**	**Academic Subcommittee** **1.18 Asoka Srinivasan, Chair** **Marilyn Houston-Coleman** **Mary Crump** **Barbara Dease** **Candace Jackson** **Emmanuel Keku** **Ernest Limbo** **Richard McGinnis** **Robin Rockhold** Ad Hoc **Nimr Fahmy** **Wendy White** **<u>Community Representatives:</u>** **Clyde Christopher** **Dorothy Williams**
1.16.1.1.29 Retention Subcommittee **1.16.1.1.30** **1.16.1.1.31** **1.16.1.1.32** **1.16.1.1.33** **1.16.1.1.34** **1.16.1.1.35** **1.16.1.1.36** **1.16.1.1.37**	**Develop seminar series for local investigators in collaboration with the Emerging Science Groups.** **Develop, update and implement guidelines for individuals seeking JHS appointments that provide skilled-based research training opportunities.** **Facilitate awareness and development of skilled-based placements within the JHS and among the larger community of educational institutions.**	**<u>NHLBI Representative:</u>** Evelyn Walker **Retention Subcommittee** _____,Chair **Clifton Addison** **Mary Crump** **Debra Douglas** **Sonja Fuqua** **Frances Henderson** **Donna Antoine-LaVigne** **Cynthia Dorsey-Smith** **Justin Vincent** **Wendy White**

1.16.1.1.38 Research Training (RT) Subcommittee	**Develop, implement, and evaluate JHS Retention Plan.** **Establish monitoring and quality control procedures concert with the Statistics and Quality Assurance Subcommittee.** **Monitor AFU productivity and completion rates.** **Provide continuous review of appointment applications and matching applicants with placement.** **Serve as a resource for information on training funding opportunities and liaison with other training programs that serve the same mission.**	**<u>Community Representative:</u>** **Margie Cunningham** **<u>NHLBI Representative:</u>** Evelyn Walker **Research Training Appointments Subcommittee** Paul Tchounwou, Chair **Clifton Addison** **Rosie Calvin** **Lynette Ekunwe** **Joey Granger** **Brenda Campbell-Jenkins** **Gloria Miller** **Linda Moore** **Wendy White** **<u>Community Representative:</u>** **<u>NCMHD Representative:</u>** **Derrick Tabor** **<u>Ad Hoc</u>** **Asoka Srinivasan**