

Jackson Heart Study

Manual 2

Cohort Procedures

Version 1.0

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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 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, 3 and 10 describe the operation of the Cohort Procedures, Family Study and Surveillance Components of the study. Detailed Manuals of Operation for specific procedures, including those of reading centers and central laboratories, make up Manuals 4 through 9. The Data Management System is described in Manual 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	Cohort Surveillance
11	Data Management System



## Manual 2 Cohort Procedures

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## INTRODUCTION

The JHS cohort will be comprised of African-American males and females ages 35-84 living in the metropolitan Jackson, Mississippi area.

Chapter 1 of this manual describes the procedures for determining participant eligibility (Section 1.1), for scheduling and conducting the recruitment and Home Induction Interview (Sections 1.2 - 1.3) and for scheduling the participant's baseline clinical examination (Sections 1.4 - 1.6).

The first portion of Chapter 2 provides an overview of the design, objectives and content of the first clinical examination (baseline exam) and describes the logistics for setting up the clinical examination (Sections 2.1 - 2.2). The training and certification required to administer the forms as well as the quality assurance activities for all baseline interviews are described in the next section (Section 2.3). It then provides the background, rationale and description of each interview, the training and certification required to administer the form, the quality assurance activities, and the data collection instruments and procedures.

Chapter 3 provides similar information for the procedures performed during baseline exam.

Chapter 4 addresses the same information for the 24-hour monitoring measures of blood pressure, urine, as well as the participant take-home questionnaire.

Chapter 5 describes the rationale and procedures of the medical data review performed before the participant leaves the Examination Center.

Chapter 6 covers the study's referral and review guidelines.

Chapter 7 describes the procedures associated with the review of the clinically relevant study results by the JHS physician prior to release to JHS participants.

Chapter 8 describes the activities associated with reporting results to participants and her/his health care providers.

Chapter 9 outlines the procedures at the Examination Center to ensure participant safety.

Chapter 10 describes procedures for annual telephone follow-up of the cohort.

Chapter 11 describes the components of the physical activity and diet subgroup studies.

Chapter 12 overviews the procedures for surveillance and monitoring events of the cohort.



## **1.0 SAMPLING, RECRUITMENT, HOME INDUCTION INTERVIEW, AND RECRUITMENT MANAGEMENT**

### **1.1 Introduction**

The JHS cohort sampling plan is designed to identify a representative sample of participants for this longitudinal study. Over a three year period 6,500 men and women aged 35-84 are selected for the baseline examination. Annually, thereafter, participants are re-contacted by telephone in order to maintain correct addresses and to ascertain interim medical and socio-cultural events. An outline of the procedures employed follows:

#### **A. Sampling and Recruitment:**

1. Create sampling frame for Jackson MSA from a list purchased from Accudata
2. Random sampling selecting age-eligible individuals from sampling frame
3. Create listing by anniversary date of all ARIC study participants
4. Sample selected persons by year of study induction to ARIC and month of ARIC Annual-Follow-Up
5. Household enumeration for eligibility determination
6. Home interview with each age-eligible household or family member
7. Invitation to baseline clinic examination
8. Clinic examination
9. Pedigree for determination of family sample eligibility
10. 24-hour examination

#### **B. Follow-up**

1. Annual contacts by telephone (or home visit)
2. Birth certificate abstraction for birth weight
3. Record abstraction for hospitalized events
4. Death certificate abstraction and mortality investigation for cohort deaths

### **1.2 Sample Inclusion and Exclusion Criteria**

Explicit inclusion criteria for the cohort study are established and uniformly applied across Hinds, Madison, and Rankin counties, Mississippi. The criteria discussed below are applied during the sampling and recruitment phases of operation. The reference population for the JHS cohort study is all noninstitutionalized African-American persons currently living in those areas who, by the time they are enumerated, are 35-84 years of age.

Application of the study's eligibility criteria first occurs during sample selection. Area and list frames from which the Examination Center samples are drawn are confined to the boundaries of the following three Mississippi counties as recognized at the time that the initial cohort sample is drawn.

1. Hinds County, Mississippi
2. Rankin County, Mississippi
3. Madison County, Mississippi

Within these three geographic areas, only those people living in residential units are included. The following definition from the 1990 Census has been adopted:

Housing Unit – A house, apartment, mobile home or trailer, group of rooms or single room occupied or intended for occupancy as separate living quarters. Separate living quarters are those in which the occupants do not live and eat with any person in the structure and which have direct access from the outside of the building or through a common hall. The occupants may be a single family, one person living alone, two or more families living together, or any group of related or unrelated persons who share living arrangements (except as described by the definition of group quarters). For vacant units, the criteria of separateness and direct access are applied to the intended occupants whenever possible. If the information cannot be obtained, the criteria are applied to the previous occupants.

Explicitly excluded from the cohort study are all persons who live in residences called group quarters, in which relatively large groups of unrelated people live and share habitation together. Group quarters were defined as follows for the 1990 Census:

Group Quarters – Living arrangements other than households. Includes institutions such as mental hospitals, homes for the aged, prisons, etc., plus other quarters containing ten (10) or more persons where 9 or more are unrelated to the persons in charge. Such quarters are commonly found in dormitories, military barracks, etc., but may also be in a house or apartment used as a rooming house or occupied on a partnership basis.

The time marker for establishing a person's age eligibility is September 1, 2000. Individuals born after September 1, 1916 and before September 1, 1965 will be age eligible for the random component of the sample. Age eligibility for the family component of the sample will also be a birth date between September 1, 1916 and September 1, 1965 with exceptions noted in the family sampling protocol (Manual 3).

A number of other explicit exclusions from the study population are established. First, the sample excludes persons who indicate that her/his permanent residence is somewhere outside the study areas. Second, the study excludes persons who, in the judgment of the interviewer, would be physically or mentally incapable of full participation in the study. Third, persons currently living in the study area, but who indicate a definite relocation outside of the study area within the following twelve months are excluded, since follow-up of these persons would be difficult and incomplete.

There are several groups of people which will receive special enumeration, recruitment and scheduling efforts to ensure they are included in the cohort. The first group is all women who are in their third trimester of pregnancy or less than three months postpartum. Because of the infeasibility of certain measurements just prior to delivery, the examinations for these women are rescheduled for a later time when obtaining their measurements is more appropriate. A second group included is persons with language difficulties. Here, efforts are made to obtain an interview from the person, but with another family member or friend acting as an interpreter. Persons with language difficulties but with no available interpreters are treated as eligible nonrespondents and dropped from the study. A third group not excluded is persons who are temporarily away from home (e.g., on vacation or incarcerated for a time-limited duration within the study recruitment dates). As with the late pregnancies, examinations for this group are rescheduled for a more convenient time after they return.

To establish eligibility for the study, information can be obtained from any of the following sources:

1. Data available on the frame;
2. A knowledgeable adult member or the selected housing unit during enumeration; or
3. A knowledgeable adult neighbor to the selected housing unit.

Gaining information by proxy under the third alternative is allowed only as a last resort (i.e., after all required call attempts have been made).

**Table 1. Enumeration rules for the JHS cohort: persons staying in housing unit at the time of enumeration**

<b>Type of person including members of family, lodgers, servants, visitors, etc.</b>	<b>Include in roster</b>
1. Ordinarily stay here all the time (sleep here)	Yes
2. Here temporarily - no living quarters held for person elsewhere	Yes
3. Here temporarily - living quarters held for person elsewhere, but person spends (or expects to spend) largest part of the calendar year in this household.	Yes
4. Regularly sleep greater part of the week in another locality	Yes
5. Regularly sleep greater part of week in this household	Yes
6. Domestic servant who "lives in"	Yes
7. Student attending college in this locality - living in this household	See Table 3
8. Students away attending college - here only temporarily or on vacation	Yes
9. In Armed Forces - stationed at nearby installation, living in this household	No
10. In Armed Forces - temporarily here on leave - stationed elsewhere	Yes
11. Citizen of foreign countries - studying or working in the U.S. and living in this household	No
12. Citizen of foreign countries - temporarily traveling or visiting in the U.S.	Yes

**Table 2. Enumeration rules for the JHS cohort for absent persons who would normally reside in this housing unit**

Type of person including members of family, lodgers, servants, visitors, etc.	Include in roster
Person in institution where people normally stay for shorter periods of time (e.g., general or VA hospitals, short-stay jails, etc)	Yes
Person temporarily absent on a visit or vacation	Yes
Person temporarily absent on business trip or in connection with job (e.g., traveling salesman, bus driver, railroad man)	Yes
Person temporarily absent because of incarceration which will end prior to termination of recruitment	Yes
In Armed Forces- currently stationed elsewhere or assigned to naval vessel	No
Away attending school - living in a college dorm	Yes
Away attending school - living in a housing unit other than a college dorm	No
American citizen abroad :	
1. Temporarily on vacation or away in connection with work	Yes
2. Employed by U.S. Government with place of duty abroad	No
3. Any other American working or living abroad for extended period of time	No



**Table 3. ZIP Code listing for the Jackson, Mississippi Metropolitan Statistical Area\***

<b>City</b>	<b>County</b>	<b>ZIP Codes</b>	
Jackson	Hinds	39201	39202
		39203	39204
		39206	39209
		39211	39212
		39213	39216
Clinton	Hinds	39056	
Bolton	Hinds	29041	
Edwards	Hinds	39066	
Raymond	Hinds	39154	
Terry	Hinds	39170	
Tougaloo	Hinds	39174	
Utica	Hinds	39175	
Camden	Madison	39045	
Canton	Madison	39046	
Flora	Madison	39071	
Madison	Madison	39110	
Ridgeland	Madison	39157	
Sharon	Madison	39163	
Jackson/Pearl	Rankin	39208	39218
Brandon	Rankin	39042	
Florence	Rankin	39073	
Pelahatchie	Rankin	39145	

\*U.S. Census Bureau Map Service

### **1.3 Sampling Procedures for Initial Cohort Selection**

The Jackson Heart Study (JHS) sample will consist of 6,500 individuals including the Atherosclerosis Risk in Communities (ARIC) Study participants who agree to return for a fifth exam (approximately 2,000) along with age eligible individuals living in ARIC households (fewer than 100 total expected), the family sample (2,000 including approximately 100 informants from ARIC and 100 informants from the random cohort), and a random sample of about 2,500 not counting the family sample informants.

A certain proportion of informants (200) for the family sample will be selected from the random sample and from ARIC. This will result in a total of 6,500 participants when the three components are counted together and about 2,600 for the random component counted separately from ARIC along with approximately 2,100 returning ARIC participants and eligible household members counted separately from the family sample (with 1,800 non informant family sample participants).

The sampling plan will include drawing randomly from the Accudata commercial list for the Jackson MSA. The random selection will be used to generate a random list of households identified by householders. Initially a household will be potentially eligible if the householder from the sampling list is living in the household or deceased with spouse living in the household. From the list of potential eligible households, pre-screening will be performed to identify households with at least one age and race eligible individual and then all age and race eligible household members will be enumerated as potential study participants. Exceptions and special cases for eligibility include household for which the householder is temporarily away, including incarceration and potential eligible participants considered physically or mentally unable to participate in the study. The details of eligibility determination are discussed in the sections on study eligibility determination.

For areas in the Jackson MSA that are 80% or greater African-American based on census information and for households where phone numbers are not available the eligibility screening will be done when recruiters visit the household. Randomly selected households that are from less than 80% African-American and have phone numbers available on the sampling frame will be pre-screened with a quick phone contact to determine eligibility.

Any household that is drawn in this way will be considered a part of the random cross sectional sample. This will hold whether or not individual will eventually be the informant for a family sample unit. Individuals who are both selected randomly and also happen to be members of the ARIC cohort or are recruited for the family sample will also be considered members of the random cross sectional sample. In other words random selection by the sampling method described above will be the condition for membership in the random cross sectional sample without respect to concomitant ARIC participant status or incidental inclusion in the family sample.

#### **1.3.1. Population Sampled**

The population to be studied by the Jackson Heart Study consists of all African-Americans ages 35-84 living within the Jackson MSA which is defined by the county boundaries of Hinds, Madison and Rankin counties. Census statistics are given for the Jackson MSA.

At the time of the 1990 census there were 167,899 African-Americans living in the Jackson MSA of which 56,610 were between the ages 35 and 84. The most recent census projections for 1997 result in an expected age eligible African-American population of 68170.

Analyses of the Accudata list to be used as the sampling frame contains 123,403 households in the Jackson MSA with householders aged 35 and older. The Accudata list was selected from among several other commercially available lists based on coverage of high density African-American areas in the Jackson MSA and good coverage of age and socioeconomic status. Crude estimates for year 2000 based on census projections for the Jackson MSA yield roughly 120,000 households with householders aged 35 and older. About 39,000 of these households have African-American

householders aged 35 and older. Roughly 60.5% or 23,595 of these households are estimated to be from neighborhoods that were 80% -100% African-American for 1990 census data .

The Accudata list contains a total of 26,516 households for householders aged 35 and older from the 80% - 100% African-American census areas indicating that the JHS sampling frame does not undercount either the total number of households in the Jackson MSA or the total number of households in higher density African-American census areas.

### 1.3.2 Design Summary

The sample design for the JHS incorporates three sub-samples to achieve a total size of 6,500:

1. Community random sample
2. ARIC cohort and eligible household members
3. Family sample

Table 4 summarizes the sampling rates and sample sizes expected to obtain the completed cohort.

**Table 4. Sampling rates and sample sizes needed to obtain 6500 JHS cohort study participants.**

Sample Source	Sample Size
Random households	2676
Home interviews (estimated 1.6 eligibles per housing unit and 80% participation)	3425
Clinic exams from random households (estimated 73% participation)	2500
Clinic exams from family sample	2000
Clinic exams from ARIC cohort	2000

#### 1.3.2.1 Community Random Sample Design

The random sampling frame for participants aged 35-84 consists of the commercial list of residential households provided by Accudata America. The information furnished includes householder name, address, zip code, and phone number if available. Other useful information includes percent white from 1990 census data and age group in decades. The sample list includes household with householders aged 35 and older. In order to create the sampling frame list will be sorted in random order and households drawn from the top down until the initial cohort selection is complete. A new updated list will be obtained annually on September 1.

Recent changes in federal privacy regulations have prohibited the availability of lists with individual information on race/ethnicity and date of birth. Because of this there is no sampling frame available with individual information regarding self described ethnicity. Methods for dealing with sampling frames that contain elements that may not be members of the population of interest include a brief screening to screen out elements not belonging to the population of interest (blank listings) after the random sample is generated. This is generally done by selecting a random sample that is known to be smaller than that needed to complete the study and then screening for blank listings. Subsequent random sample can then be obtained with knowledge of the proportion of blank listings based on previous samples. Arranging the sampling frame in random order and proceeding to draw households from the top down avoids potential selection bias from correlation between the density of listings in any part of the frame and the content of those listings (Kish, 1995, pp, 384-387).

### **1.3.2.2 ARIC/JHS Sample Design and Selection**

Approximately 2000 to 2300 persons in the ARIC cohort along with age eligible household members are expected to participate in the JHS baseline visit. All remaining ARIC participants (all living individuals who had an ARIC baseline visit) and age eligible household members are eligible for participation in the JHS.

### **1.3.2.3 Family Sample Design**

The sampling frame for the family sample consists of persons selected from either the random community sample or the ARIC/JHS cohort sample who complete the baseline visit for the JHS, have two siblings and identify 9 or more first-degree relatives living in the sampling area. A full description of the Family Sample Design can be found in Manual 3: Family Study.

## **1.3.3 Sample Selection**

### **1.3.3.1 Community Random Sample Selection**

Sample lists will be generated every 3-6 months and sorted by zip code, name, age, and address for efficiency during recruiting efforts. Each list will be required to be exhausted before a new list is provided to recruiters to maintain the random nature of the sample. The last list of the three year baseline recruiting period will be adjusted based on actual response rates to be approximately exhausted by the end of the recruitment phase of the study. Generation of 3-6 months worth of potential participants and sorting by zip code, name and address will facilitate focused efforts in community awareness and health education and subsequent recruiting without compromising the random nature of the sample.

Each 3-6 month sample list will be divided into several sub-lists based on several criteria as follows:

1. Households in greater than 80% African-American areas based on the sampling frame census information. This information is coded in the frame as a character string that indicates "percent white" from the 1990 census. For operational purposes this will be inverted to obtain approximate percent African-American for the area in which each household resides.
2. Households not in greater than 80% African-American census areas for which phone numbers are available on the Accudata list.
3. Households not in greater than 80% African-American census areas for which phone numbers are not available on the Accudata list.

The sample records in item 1 above will be sent directly to the recruiters. Item 2 will be forwarded to the subcontractor for phone screening according to the phone screening protocol and the records from item 3 will be forwarded to the Undergraduate Training Center for phone number search. Once item 3 records are returned to the CC then records with phone numbers will be included in the next regular transmission of sample records to the phone screening subcontractor. All other records for item 3 for which phone numbers have not been located will then be sent to the recruiters.

Data records that are returned from the phone screening subcontractor will have screened ineligible records removed and archived and the remaining eligible and eligibility status unknown records will be forwarded to the recruiters.

Prior to recruiting, the sample list will be searched for households of ARIC participants who were present at ARIC exam 1 by comparing names and addresses to the ARIC database. These households will be removed from the recruiters list to avoid repeat contacts. This information will be archived for reporting rates of ARIC households re-sampled in the random household sample. Also

any ARIC participants found on the sampling list during recruiting or located in random household enumeration or family sampling will be noted and information archived.

### 1.3.3.2 ARIC Cohort Sample Selection

Sampling lists from the Jackson ARIC Field Center participant tracking database will be created every two months based on the sequential schedule outlined in Table 5. Entry into the JHS recruitment process will follow the ARIC annual follow up call in a coordinated manner so that all contact information will be as current as possible. ARIC participants whose baseline examination was in Year 1 of ARIC and are due for annual follow-up in August 2000 will be contacted for a Home Induction Interview and subsequent JHS clinic examination beginning with September 2000 recruitment. The selection process will continue in like manner with the following examination year and annual follow-up months in sequence.

**Table 5. Jackson Heart Study ARIC participants recruiting schedule, with expected total available for recruitment.**

<b>Date of ARIC data release</b>	<b>Month and Year for ARIC baseline visit</b>	<b>Expected Total</b>
September 10, 2000	July 1987, Aug. 1987, Sept. 1987	215
November 10, 2000	Oct. 1987, Nov. 1987, Dec. 1986	187
January 10, 2001	Dec. 1987, Jan. 1988, Jan. 1987	179
March 10, 2001	Feb. 1988, Mar. 1988, Feb. 1987, Mar. 1987	281
May 10, 2001	April 1988, May 1988, April 1987, May 1987	230
July 10, 2001	June 1988, July 1988, June 1987	244
September 10, 2001	Aug. 1988, Sept. 1988	187
November 10, 2001	Oct. 1988, Nov. 1988	183
January 10, 2002	Dec. 1988, Jan. 1989	228
March 10, 2002	Feb. 1989, Mar. 1989	180
May 10, 2002	April, 1989, May 1989	260
July 10, 2002	June 1989, July 1989	262
September 10, 2002	Aug. 1989, Sept. 1989	241
November 10, 2002	Oct. 1989, Nov. 1989	256
January 10, 2003	Dec. 1989, Jan. 1990, Feb. 1990, Mar. 1990	266
March 10, 2003	ARIC Finished	0
May 10, 2003	ARIC finished	0
July 10, 2003	ARIC finished	0
September 10, 2003	ARIC finished	0

Note: The expected totals are based on present ARIC annual follow-up information. This information is accurate for the next few months. There are presently about 70 deaths per year or about 6 per month. This will potentially reduce the monthly counts by as much 6 per month one year out and 12 per month two years out and 18 per month by the end of this schedule.

### **1.3.3.3 Family Sample Selection**

Each JHS participant meeting the minimum family size eligibility requirement will be a potential informant for the family study. The final sample for the family study will include approximately 2000 individuals. Thus the informant will meet recruitment criteria (age 35-84 years, living in the Jackson tri-county area and African-American). Families of an informant will be eligible for the JHS family study if the informant has 2 full siblings meeting JHS recruitment requirements and a minimum of nine first degree relatives among them who live in the Jackson recruitment area or elsewhere and are willing to travel to Jackson to participate in the clinic visit. The first-degree relatives do not necessarily need to meet the other recruitment requirements. It may be necessary to sample outside of the age range to obtain families of sufficient size. However, we would restrict the lower bound of age to 21 years of age and make all efforts to stay within the 35-84 year age range. In addition, efforts will be made to recruit the largest families available with a minimum family size of twelve (outlined above). In order to assure the most informative and largest families are selected, an algorithmic flagging system will alert the clinic to generate a graphical pedigree on each eligible informant. Graphical pedigrees will be reviewed quarterly by the Genetics Committee for final selection of potential families (see Manual 3: Family Study).

It is expected that approximately 140 ARIC participants will be selected incidental to drawing the random community sample. Based on the ARIC exam 4 schedule there should be from 42-96 existing ARIC participants per month leaving 85-139 participants from the family sample and random samples per month in order to attain the 180-181 participants per month required for a total of 6,500 participants over three years. As family study participants are located they will be scheduled for clinic visits along with participants from households selected in the random sample.

## **1.4 Sample Replication**

To facilitate quality control of the laboratory methods used during the three-year examination period, samples from the examination are randomized so that the individuals examined during any one-month period are a random subset of the full sample and, therefore, a representative sampling of the study population. This sample replication serves to remove the effect of inherent differences in the observed sample through time. Sample replication is done by selecting a new sample each quarter.

Departures from the initial replicate assignments occur in those cases where the actual examination cannot be conducted in the assigned month due to scheduling conflicts on the part of the participant. These departures are not expected to alter significantly the original intent of the replication, however individuals examined each month are still a reasonably representative sampling of the study population.

## **1.5 Household Enumeration**

Selectees chosen from the lists are first contacted by JHS using a letter sent to the selected individual at the listed address (Appendix). This letter serves to invite participation by introducing and explaining the purpose of the study and to assure confidentiality. The field interviewers are given the selected individuals' names and addressees, grouped geographically to minimize travel. The household containing the selected individual is found and the entire household enumerated for eligibility. If the address listed for the participant is incorrect, s/he is traced using phone directories, contacts with neighbors, etc. If the selectee still lives in the study community, the enumeration is completed; if the selectee lives outside the community boundaries, s/he is considered ineligible.

Interviewers are instructed to make her/his initial visit to a sample household in the late afternoon or early evening on a weekday or on Saturday, since the chance of finding an eligible enumeration respondent (a knowledgeable household member aged 16 or older) is enhanced at these times. If no eligible enumeration respondent is at home on the first attempt, the interviewer attempts to learn from other household members (e.g., under age 16) or neighbors when an eligible household member is

expected to be at home. If no contact is made, a door hanger is left to alert the sample household that a JHS recruiter has attempted to reach them. If a suggested time cannot be obtained, the interviewer is required to make the second attempt between 5:30-9:00 p.m. on a weekday or during the morning of the following Saturday. At this second call-back, if no contact is made, a second door hanger and a small welcoming incentive is left. Additional call backs are made, as necessary, with the interviewer continuing her/his efforts to learn from secondary sources when and how to contact an eligible enumeration respondent. In the absence of better information, successive attempts are made at varying time/day intervals in order to increase the probability of finding an adult at home. After three unsuccessful attempts, recruiter/interviewer will supplement household visits with telephone contact.

When contact is made with an eligible enumeration respondent, the interviewer introduces her/himself, briefly describes the purpose of the visit, shows the respondent her/his credentials, and proceeds with enumeration. Enumeration is the process of completing a household roster to select the sample member(s). To be eligible to be a cohort member for a selected household, the person must be a member of the sample household and be ages 35 through 84, as of September 1, 2000. Identification of the cohort sample participants is done by the interviewer. To assure proper selection, the enumeration respondent is asked to list all the persons 18 years of age or older who reside in the sample unit. From this listing, the number of eligibles per household is determined. As described previously, all eligible members of a household are selected for the cohort sample.

To assure that comparable efforts are made in obtaining participation for the study, a set of criteria for enumeration and clinic recruitment has been established. Unless early attempts indicate that further efforts are fruitless (e.g., an unequivocal refusal), field staff are not allowed to consider a selected housing unit as a final non-contact until at least five (5) call attempts have been made, with at least one attempt made during a weekday, during a weeknight, and on a weekend (legitimate exceptions allowed). Initial non-respondents not giving an unequivocal refusal are re-contacted for possible clinic recruitment. The Examination Center is allowed to try to reschedule eligible persons for a period of up to six months after the month in which the person was initially assigned. If rescheduling is required for reasons such as illness or travel, this time period can be extended up to nine months.

## **1.6 The Home Induction Interview**

The Home Induction Interview is administered to all age 35-84 eligibles (self-identified African-American ethnicity) within a sampled housing unit. After identifying those eligible to participate, the JHS is explained and those who are eligible are asked to take part in it. The Home Induction Interview is also designed to obtain certain demographic, sociocultural, and medical information from the participant. Any questions the participant has about her/his clinic visit or about the study in general are clarified.

### **1.6.1 Home Induction Interview Procedures**

As eligible sample members (respondents) are identified through the enumeration process, the interviewer attempts to secure the home interview for all respondents on the same visit to the household whenever possible. When contacting an eligible respondent, the interviewer repeats the JHS introduction (assuming the sample respondent is a different person from the enumeration respondent) and explains in somewhat more depth the purpose and importance of this study. A brochure and letter explaining the purpose of the study and the examination are used for recruitment. The voluntary nature of the study and the confidentiality of the collected data are stressed. If a sample respondent is not at home at the time of enumeration, call backs are made as necessary, to secure the household interview and schedule the clinic appointment.

### **1.6.2 Contacts with Participants**

The first contact from the JHS is by a letter sent to the selected individual at the listed address. When the address is a P.O. Box, a postage paid card is included to request street address. The purpose of

the letter is to introduce and explain the purpose of the study and to describe confidentiality assurances.

The JHS interviewer, wearing an identification badge and uniform clothing, visits the selected household, enumerates the household to determine eligibility, and recruits eligibles to the study. The JHS enumeration protocol and forms, as well as the eligibility requirements are described below.

### **1.6.3 Recruiter/Interviewer Training, Certification and Quality Assurance**

#### **1.6.3.1 Training**

Interviewers are centrally trained to use a standardized procedure for administering the Home Induction Interview. Training includes an overview of the JHS and its precursor, ARIC; an overview of epidemiological cohort research methods; instructions in research interviewing techniques: communication, respecting cultural diversity, and in completing the forms, including:

1. a thorough review of the forms, instructions and protocol to promote adherence to the protocol
2. practice in the use of nonjudgmental attitude
3. practice with the degree and nature of prompting permitted
4. dealing with problem interview situations
5. use of response cards
6. practice handling participants' comments and recording relevant information on the note logs
7. review of post-interview responsibility for the data

More extensive detail of the training component for completing paper forms and interview techniques are included in the Appendix.

#### **1.6.3.2 Certification**

Interviewers are certified by the Central Trainer at the successful completion of training. New staff are trained and certified using the same format.

#### **1.6.3.3 Quality Assurance**

To promote consistency and accuracy in data collection and to minimize inter- and intra-interviewing differences, the Director of Recruitment monitors 5% of the interviews done by each recruiter/interviewer. Technique and adherence to protocol are also monitored at least semi-annually by Coordinating Center monitors. In addition, a brief written worksheet/quiz on recruiting, and interviewing problems is completed by each interviewer every 6 months. This worksheet/quiz is distributed by the JHS Coordinating Center and reviewed by the JHS Cohort Operations Committee.

### **1.6.4 Home Induction Interview (HII)**

The Home Induction Interview (HII) is a part of the core data collection instruments for the first cohort examination. The HII is actually a composite of forms to elicit participant eligibility and, once confirmed, to enumerate the sample respondent's household identifying all age-eligible JHS potential participants. The interview covers information regarding personal and family health history, global stress, tobacco use, physical activity, social support as well as personal and socioeconomic data. Upon completion of the HII, a clinic appointment is scheduled to complete the baseline examination.



#### **1.6.4.1 Rationale**

The HII serves several purposes. It provides an initial contact with the JHS in a comfortable and known environment. It serves to introduce the participant to the clinic examination and the collection procedures to ascertain baseline data concerning a number of core variables for the JHS. Information on each of the composite forms is included below.

#### **1.6.4.2 Administration**

The HII is divided into three major sections:

1. Eligibility and enumeration
2. Interview
3. Schedule clinic appointment

Question by question instructions (QxQ's) are located in the Forms Appendix, immediately following each form. The interviewer determines and records whether the sample respondent meets eligibility requirements for the JHS. Once eligibility is verified and consent to proceed with questions is obtained, the interviewer then enumerates all persons living in the household and ascertains willingness of eligible household members to complete the interview. The HII is then conducted with each eligible respondent. Specific instructions for administration of each component of the HII follow below in each sub-section. Instructions for scheduling the clinic visit follow in section 1.6.5.

#### **1.6.4.3 Data Collection**

All forms which comprise the HII are paper forms which are designed to be interviewer-administered. Data are entered using pencil directly onto the paper form and are subsequently entered into the data entry system (DES).

#### **1.6.4.4 Household Enumeration (HEF) and Household Enumeration Supplement (HES)**

The Household Enumeration (HEF) and Household Enumeration Supplement (HES) forms are intended to confirm the address of the sample individual and gather baseline information on all persons living in the household of the identified sample individual. This form was adapted from ARIC and gathers the name, date of birth, ethnicity, gender, and marital status of each person who considers the identified address as their residence. As the only form that obtains ethnicity, the HEF also serves to confirm eligibility of the identified sample person as a self-identified African-American. Other household residents will be considered eligible for inclusion in JHS if they are within the 35-84 age range and self-identity as African-American. The ethnicity eligibility requirement is void for participants in the Family Study based on the household sampling unit.

##### **1.6.4.4.1 Rationale**

The HEF provides the information necessary for completing the household sampling unit used for the JHS. By identifying each person residing in the identified sample individual's residence, individuals eligible for participation in the JHS are identified. Further, the HEF provides the opportunity for confirmation of self-reported African-American ethnicity. The HEF is used to assign both Household ID and Participant ID numbers for each potential household eligible.

##### **1.6.4.4.2 Administration**

The HEF is administered by a trained recruiter/interviewer to all identified sample persons (or another household resident 18 years of age or older if the identified sample person is not at home) as part of the HII. Detailed instructions for administering each question are contained in the QxQ instructions. If there is insufficient space on the HEF to enumerate all the residents of the household, the

interviewer is to proceed to the Household Enumeration Supplement (HES), which provides additional space for listing more than 5 household members.

#### **1.6.4.5 Household (HER) and Participant Record of Calls (IRC) and Tracing (TRC) and Household Induction Record of Calls (IRC)**

Several forms provide an ongoing tracking system which documents efforts to contact the sample household to complete enumeration and subsequently complete the Home Induction Interview with each enumerated eligible. The Household Enumeration Record of Calls (HER) documents each attempted contact with the sample household. The Tracing form (TRC) is implemented when the identified sample person no longer resides at the address provided from the sampling frame. Tracing is initiated to locate the identified sample at another address in order to complete the enumeration process. Upon completion of the HER, and, if needed, the TRC, the Household Induction Record of Calls (IRC) provides documentation of all attempts required to complete the Home Induction Interview (HII). Each of these forms are modifications of similar ARIC forms.

##### **1.6.4.5.1 Rationale**

Maintaining documentation of the effort required to contact household and individual sample eligibles is necessary to determine the response rate for the sample selection process. Final Results Codes will document the number of completed and incomplete HII as well as the number of and reasons for refusals. Information documented on these forms provides the basis for routine reports on recruitment and allows adjustment of sampling efforts and workload allocation for the recruiter/interviewer staff.

##### **1.6.4.5.2 Administration**

The HER is completed as a study tracking form by trained recruiter/interviewers on all participants as part of the HII. It is completed as the first form in the HII forms packet. A Household Identification number is assigned and the identified sample person's name is listed at the top of the form. The day of the week, date and time of initial and all subsequent household contacts are recorded on separate lines. A Result Code is assigned for each contact and notes are entered as needed to further explain the code. Detailed instructions for completing the HER are included in the Forms Appendix.

The TRC is completed only on those participants who are no longer living at the address provided by the sample frame by a trained recruiter/interviewer as part of the HII. This form is initiated based upon a Result Code, "Tracing Required," entered on the HER. For each tracing step attempted, the date and information obtained is recorded according to the QxQ instructions.

The IRC is completed on all participants by a trained recruiter/interviewer as a study tracking form. A separate IRC is initiated for the identified sample person and for each enumerated household eligible. Both the person's name and the Participant Identification number as assigned from the HER are recorded at the top of the form. The day of the week, date and time of initial and all subsequent HII contacts are recorded on separate lines. A Result Code is assigned for each contact and notes are entered as needed to further explain the code. Detailed instructions for completing the IRC are included in the Forms Appendix.

##### **1.6.4.6 Eligibility (ELG)**

The Eligibility (ELG) form is intended to assure that each identified sample person and enumerated household member are eligible for participation in the JHS according to the sample criteria discussed in Section 1. Further, it ascertains eligibility for participation in the Family Study by identifying the number of living first degree relatives who reside in the study locale, or are willing to travel to participate in the JHS. Finally, the ELG identifies the respondent's level of awareness about the JHS and factors important to their participation or non-participation. The ELG is based on a similar ARIC form, but has significant modifications to meet the unique requirements of the JHS.

#### **1.6.4.6.1 Rationale**

Confirmation of eligibility is essential to assure that the final sample indeed meets the residence, age and ethnicity criteria identified for inclusion in the JHS. Additionally, it is important to recruitment and ongoing retention to understand the level of community awareness and issues surrounding participation.

#### **1.6.4.6.2 Administration**

The ELG form is administered to all participants at the initiation of the HII by a trained recruiter/interviewer. Detailed instructions for administering each question are contained in the QxQ instructions.

#### **1.6.4.7 Personal and Family Health History (PFH)**

The Personal and Family Health History (PFH) is intended to gather baseline information on the personal and family health background of each respondent. This form was adapted from the ARIC Personal History form and additional questions on the health history of full brothers and sisters and natural children were added to assure that a wide range of essential family health data can be captured. Likewise, this data provides important baseline information for the family component of the JHS.

##### **1.6.4.7.1 Background, Rationale, and Hypotheses**

An extensive, well-accepted body of data supports the relationship between health history and risk for development of CVD. Self-perceived health status has likewise been positively correlated with disease likelihood. We hypothesize that these strong relationships will continue with the JHS. That is, the more extensive the history of CVD and other metabolic conditions, the more likely the person is to develop CVD over her/his lifetime. Further, this relationship will be moderated by a variety of socioeconomic and psychosocial variables, e.g., discrimination, stress, social support, coping, SES, health care access, and so forth.

##### **1.6.4.7.2 Administration**

The PFH is administered to all participants during the HII by a trained recruiter/interviewer. Detailed instructions for administering each question are contained in the QxQ instructions. The initial question requires the respondent to rate her/his health status. Subsequent questions seek specific information on self-reported history of hypertension, hyperlipidemia, heart attack, stroke or diabetes among the respondent and her/his parents, siblings and children.

#### **1.6.4.8 Physical Activity (PAC)**

The JHS Physical Activity Survey (PAC) is an interviewer-administered instrument designed to obtain information about respondents' physical activity habits. The survey contains 30 items in 4 sections. The participant responds to a series of 7 questions about usual level of participation in her/his daily routine (active living), 8 questions about occupational activity, and 7 questions about activities in the home, yard, and garden. For the sports/exercise section, respondents are also asked to identify the frequency and duration for the three most frequent sports/exercise activities performed in the past year.

##### **1.6.4.8.1 Background, Rationale, and Hypotheses**

Physical activity is widely recognized as an important and independent risk factor for many chronic diseases, including CHD, hypertension, and diabetes (Pate, et al., 1995; U. S. Department of Health and Human Services, 1996). The effect of a sedentary lifestyle on CHD is now recognized as almost

as great as smoking and hypertension (Kriska & Caspersen, 1997). Epidemiologic surveys consistently show that prevalence of sedentary lifestyles is greater in minority, lower education, and lower income populations (Pate, et al., 1995), although the reasons for the observed differences are not yet understood (King, et al., 1992).

#### Method of Assessment of Physical Activity and Results to Date from ARIC.

For public health surveys, the most frequent choice for physical activity assessment has been interviews or questionnaires. These are favored because they: 1) do not alter the behavior of the person being surveyed; 2) are practical in terms of cost of administration and participant convenience and, 3) can be adapted to the population being assessed (Kriska & Caspersen, 1997). The physical activity instrument used in the ARIC study was a modified version of a self-report questionnaire developed for a study of Dutch men and women (Baeccke, et al., 1982): the instrument yields 3 scores assessing activity at work, in sport and at leisure. Researchers (Richardson, et al., 1995) reported additional gender-specific reliability and validity data for the ARIC instrument, and concluded the instrument is simple and easy to administer, is reliable and assesses heavy activity quite well. Its weaknesses were the relative inability to accurately assess moderate level activity and the absence of items involving child care and household activity. These weaknesses were shared by most of the instruments available at the time.

Folsom and others (1994) have examined the physical activity data from ARIC in relation to CHD and risk factors. Work physical activity scores from ARIC showed an inverse dose-response relationship with carotid wall thickness in black and white men and women, independent of other risk factors, including body mass index (BMI). In a second study, an association between CHD and the sports and leisure scores was observed in white men and women, but no association was observed in the black participants (Folsom, et al., 1997). In this study, the investigators noted that the black participants had lower levels of activity than whites and fewer (5% vs. 15%) reported any vigorous activity. This restricted range could have obscured an association between physical activity and CHD. In a more recent study, Pereira, Folsom, et al., (Pereira, Folsom, et al; ARIC manuscript #422), examined physical activity in relation to hypertension. Blacks reported more walking and standing and less sitting at work than did whites, and blacks were less likely to report often or very often playing a sport or exercising during leisure time compared with whites (47% vs. 72%). Neither the sports nor the work index were associated with reduced odds of hypertension in blacks, but the lack of graded inverse association between BMI and waist-hip ratio with physical activity scores once again suggested measurement problems.

The positive features of the ARIC methods for assessing physical activity that have been retained in the JHS instrument include: 1) evidence that it is a valid and reliable measure of vigorous activity; 2) ability to assess activity in different domains (work, sport/leisure); 3) brevity and ease of administration. The ARIC instrument has important limitations and may have not worked as well in blacks as in whites. Fortunately, a modification of the ARIC instrument, known as the Kaiser Physical Activity Survey, has recently been validated in a multi-ethnic sample of women (Sternfeld, et al., 1999; Ainsworth, et al., in press). Sternfeld's (1999) study of the modified ARIC instrument with 2,635 ethnically diverse women ages 20-65 found associations between level of activity and lower BMI, not having young children in the home, social support for exercise, and motivation to exercise, and age, but these demographic and psychosocial correlates of physical activity differed by domain. Ainsworth and others (under review) compared the summary indices from the modified instrument with Caltrac accelerometers and participant physical activity diaries and with fitness and percent body fat measures. One month test-retest reliability correlations were high for all the indices ( $r=.79$  to  $.91$ ,  $p<.01$ ). Age-adjusted Spearman rho correlations between the sports/exercise index and the active living index were moderate for VOCpeak ( $r=.34$  to  $.76$ ,  $p<.01$ ) and percent body fat ( $r=.30$  to  $-.59$ ,  $p<.05$ ). Correlations between similar activities for the instrument and participant's physical activity diaries ranged from  $r=.03$  to  $.64$ . These findings show good reliability and validity for the modified ARIC instrument and that, at least in women, it works well across ethnic groups. Some additional minor modifications were made to adapt a few items for male respondents for the JHS (Personal communication, Barbara Ainsworth, July 31, 1999).

### Physical Activity Hypotheses for the JHS

Physical activity will be examined in the JHS in order to examine its impact as an independent heart disease risk factor in male and female African-Americans and to understand its interaction with both established and nontraditional risk factors. Questions of interest include:

1. Is physical activity protective against heart disease and cardiovascular disease in African-Americans? At what levels of intensity and/or energy expenditure can a protective effect be observed?
2. What is the relationship of physical activity to weight and body composition in the adult African-American population?
3. Does physical activity in different settings (occupational, household, leisure/recreational) contribute similarly to protection against heart disease in African-Americans?
4. What sociocultural variables are associated with differing levels of physical activity in the JHS population in different age-sex groups?
5. Can environmental variables such as community crime and violence rates be related to activity levels of men and women at different ages and with varying employment and home/child care responsibilities? Can perceptions of discrimination be related to lower levels of physical activity?
6. What are the most frequent intensities and types of activities in various age-sex subgroups of African-Americans in the JHS?

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#### **1.6.4.8.3 Administration**

The PAC form is administered by trained interviewers as part of the HII in the participant's home. The form contains 30 items and 4 sections, "Active Living," "Occupational Activities," "Home, Family, Yard and Garden," and "Sports and Exercise." Participants are asked to identify the frequency and duration for these activities. Each of these activities is coded based on the effort typically required to perform that type of activity. Detailed instructions for administering each item are found in the QxQ instructions.

#### 1.6.4.8.4 Coding and Scoring

Activity indices are created for each domain of activity by summing the domain-specific responses and dividing by the number of items, giving an average value that ranges from 1 to 5. The coding and scoring are adapted from Ainsworth, Sternfeld, et al. (in press). For each item, response A=1, B=2, C=3, D=4 and E=5.

The ACTIVE LIVING INDEX is calculated as the sum of [Q1,Q3, Q4, (6-Q6) divided by 4.

The OCCUPATIONAL INDEX is calculated as the sum of [Q9, Q10, (6-Q11a), Q11b-e, occupational intensity code]/8. The occupational intensity code comes from the physical demands of the occupation of 1=low, 3=medium, and 5=high from the Department of Labor Occupational Codes.

The HOME, FAMILY, YARD, AND GARDEN index will be calculated as the sum of [Q12, Q13, Q14, Q15, Q16, Q17, Q18]/7.

The SPORT INDEX calculation requires several steps. The specific activities are coded by intensity and multiplied by hours and months. The resulting score is mapped to an ordinal scale from 1 to 5 and used as a fourth sports and exercise item.

1. First, each of the activities reported by the participant must be scored by intensity as < 4 METs/4-6 METs/>6 METs. This is done by computer matching the code number for the activity with intensity values for each code (Q21,Q25 and Q28).

<b>METS</b>	<b>Intensity</b>
<4	0.76
4-6	1.26
>6	1.76

2. Then the months per year must be converted to a proportion of the year (0.5,1.3, 2.5, 3.5, 4.5). This is also done by computer (Q22, Q25 and Q28).

<b>Months per Year</b>	<b>Proportion</b>
<1	0.5
1-3	1.3
4-6	2.5
7-9	3.5
>9	4.5

3. The time for each activity is then converted to a proportion: (Q23, Q26 and Q29)

<b>Hours per Week</b>	<b>Time</b>
<1	0.04

At least 1 but < 2	0.17
At least 2 but < 3	0.42
At least 3 but < 4	0.67
4 or more	0.92

4. The simple sport score is calculated as the product of intensity by proportion by time for each specified activity and summing over the number of activities (Q22, Q25, Q28).
5. The simple sport score will take the value of 1-2-3-4-5 corresponding to the resulting values of 0; 0.01-<4; 4<8; 8-<12; >12. If no activities were specified, the sum will be 0.
6. The index can now be calculated as the sum of [Q30, simple sport score] /4.

#### **1.6.4.9 Tobacco Use (TOB)**

The Tobacco Use (TOB) form is administered as part of the HII to document current and past tobacco use. Questions cover all types of tobacco (cigarettes, pipes, cigars, chewing tobacco, and dip / snuff). Additional questions include an estimate of environmental tobacco smoke (ETS) exposure, as well as an assessment of nicotine dependence for cigarette smokers (Fagerström Test for Nicotine Dependence [FTND], items 4 – 9).

##### **1.6.4.9.1 Background, Rationale and Hypotheses**

Tobacco use has been firmly established as a significant, modifiable risk factor for a wide range of medical disorders. The association between the use of tobacco and the development and severity of coronary heart disease and cerebrovascular disease is well accepted (USDHHS, 1983, 1998a). Evidence attests to its influence on accelerating the progression of atherosclerosis, as well as its role as a proximal cause for significant cardiovascular events, including myocardial infarction and cerebrovascular accidents.

The detrimental effects of tobacco use on the cardiovascular system are associated with both direct and indirect effects of (primarily) nicotine and carbon monoxide, including greater hemodynamic stress, increased output of lipids, catecholamines, fibrinogen and thromboxane, and increased platelet adhesiveness (Bolinder & de Faire, 1995). Smoking has been shown to interact with other cardiovascular risk factors, often yielding synergistic effects on health beyond the additive influence of individual factors (USDHHS, 1983). Finally, considerable evidence exists attesting to the benefits of quitting smoking, with substantial reductions in cardiovascular risk becoming evident once abstinence has been attained (USDHHS, 1990).

Several studies have previously reported that African-American smokers produce measurably higher levels of cotinine, a primary metabolite of nicotine, than whites (e.g., Wagenknecht, et al., 1990). Cotinine levels are a marker for degree of nicotine dependence. Our own research conducted in Jackson is consistent with these data, demonstrating higher scores on the Fagerström Test for Nicotine Dependence (FTND: Heatherton, Kozlowski, Frecker, & Fagerström, 1991), a well accepted self-report measure of nicotine dependence, for black smokers vs. white smokers (Payne, et al., 1997). Recent evidence suggests that blacks absorb more nicotine from smoking, and that cotinine may be detected in body fluids of black smokers for a longer duration than for white smokers (Caraballo, et al., 1998; Perez-Stable, Herrera, Jacob, & Benowitz, 1998). These findings may provide at least a partial explanation as to why African-American smokers suffer from a disproportionately higher rate of tobacco-related diseases, as well as experience greater difficulty achieving abstinence (Orleans, et al., 1989).



Another recent finding which has important implications for the JHS concerns the role of environmental tobacco smoke (ETS) exposure. Howard, et al. (1998) examined the relationship between cigarette smoking and the progression of atherosclerosis in the ARIC population, as indexed by intimal-medial thickening in the carotid artery. The authors noted a relationship with smoking, but also that ETS exposure was an independent risk factor, as demonstrated by carotid wall changes in individuals who were either past or never smokers. Thus, greater specificity in the degree and nature of ETS exposure seems warranted.

Other lines of research have identified additional issues of interest with respect to the goals of the JHS. For example, a growing literature attests to smokeless tobacco use as a contributor to the development of cardiovascular disease (Bolinder, Ahlborg, & Lindell, 1992; Squires, et al., 1984; USDHHS, 1998a; Westman, 1995). Cigar smoking has increased dramatically since 1993 and, in more recent years, the greatest increase has occurred within the premium cigar market (USDHHS, 1998b). As with many of the previous issues, these issues are understudied, and particularly so for the African-American population.

Finally, other data being collected on participants of the JHS will permit a more in-depth examination of issues related to tobacco use in African-Americans. Several psychosocial factors that are related to tobacco use will be subject to a more intensive investigation. For example, higher levels of distress (depression, anger) and exposure to environmental stressors are related to tobacco use and difficulty in achieving cessation, whereas social support and knowledge of tobacco's detrimental effects on health are associated with a greater likelihood of successful cessation (USDHHS, 1988, 1990, 1998a). This study will provide a unique opportunity to examine the complex interactions among these variables in a large sample of African-Americans.

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#### **1.6.4.9.3 Administration**

The TOB is administered by a trained interviewer in the participant's home. Detailed instructions for administering each item are provided in the QxQ's. The form systematically gathers information on historical and current use of each form of tobacco. Responses vary from question to question, ranging from open-ended questions that are subsequently recorded or coded, to specific ratings of frequency, amount, etc.

#### **1.6.4.10 Health Care Access and Utilization (HCA)**

The Health Care Access and Utilization (HCA) Form is administered as part of the HII to collect baseline information about the access to, use of, and payment for health care services. Items on this form were derived from the Detroit Area Study (DAS), the National Survey of Black Americans (NSBA), and other standardized instruments that have been used to measure the availability, accommodation, acceptability, and affordability of health care services.

##### **1.6.4.10.1 Background, Rationale and Hypotheses**

Access to health care implies that an individual has a place to go as well as the financial means of obtaining care (Aday, 1993). Excess cardiovascular disease (CVD) mortality and morbidity in African-Americans has been linked to inequities in access to primary and secondary health services as well as to a number of sociocultural factors such as socioeconomic status, health practices, health beliefs, stress, violence, and racism (Andersen, 1978; Berk & Schur, 1997; Blustein & Weitzman, 1995;

Broadhead, et al., 1983; Carlisle, Leake, Brook, & Shapiro, 1996; Carlisle, Leake, & Shapiro, 1995; Carlisle, Leake, & Shapiro, 1997; Ford & Cooper, 1995; Gornick et al., 1996; Hannan, Kilburn, O'Donnell, Lukacik, & Shields, 1991; Horner, Oddone, & Matchar, 1995; Lee, Gehlbach, Hosmer, Reti, & Baker, 1997; Mitchell & Khandker, 1995; Raczynski, et al., 1994; Sedlis, et al., 1997; Seipel, 1998; Strogatz, 1990; Wenneker & Epstein, 1989; Whittle, Conigliaro, Good, & Lofgren, 1993). The conceptualization of access in the JHS was derived from the models developed by Aday and Anderson (Aday & Andersen, 1974; Anderson, McCutcheon, Aday, Chui, & Bell, 1983; Andersen & Davidson, 1996; Berk & Schur, 1997) which suggest that characteristics of the health care delivery system and of the population at risk influence the utilization of health services and the satisfaction with that service.

Characteristics of the population include predisposing, enabling, and need factors of individuals which influence health-seeking behaviors. Data regarding predisposing characteristics such as demographic factors, social structure, and health beliefs will be gathered in other aspects of the JHS. HCA will also collect data regarding enabling factors such as the availability of health insurance and a regular or a usual source of care. Having insurance and a usual source of care are measures that are used consistently in research regarding access to health care. These two measures have been shown to greatly influence the utilization of other health services as well as health status, morbidity, and mortality in African-Americans. HCA will collect data regarding the utilization of preventive services by asking participants about the use of dental and primary health care services over that past year. The use of preventive services is seen as a gatekeeper to the use of secondary services such as hospitalization, and interventional procedures such as angioplasty, PTCA, CABG, and thrombolytic therapy. HCA will also collect data regarding accommodation by asking participants about difficulty they may have experienced when obtaining health services in relation to a perceived need. Difficulties related to transportation, getting an appointment, or getting time off work may present barriers that decrease the utilization of health services by African-Americans. Finally, HCA will collect data regarding the satisfaction with health services by asking about satisfaction with the health provider.

Specific hypotheses which will be tested include the following:

1. Having a usual source of care decreases the risk of experiencing CVD mortality and morbidity independently of racism, socioeconomic status, and health practices in African-Americans in Jackson.
2. The availability of health insurance decreases the risk of experiencing CVD mortality and morbidity in African-Americans in Jackson.
3. The use of preventive services is related to the risk of experiencing CVD mortality and morbidity in African-Americans in Jackson.
4. The use of dental services is related to the risk of experiencing CVD mortality and morbidity in African-Americans in Jackson.
5. Trust in the health care provider is related to the use of health services in African-Americans in Jackson.
6. Satisfaction with health services is related to the use of health services in African-Americans in Jackson.

#### **1.6.4.10.2 References**

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#### **1.6.4.10.3 Administration**

HCA is administered to all participants during the HII by a trained recruiter/interviewer. Detailed instructions for administering each question are provided in the QxQ instructions following the form in the Forms Appendix. The first question asks if the participant has a place to go when feeling sick. Additional questions get more specific information regarding the place, the use of professional services, the ease of access, and the availability of private health insurance. All participants are asked about the use of government-sponsored insurance such as Medicare, Medicaid, and Champus, and about her/his satisfaction with her/his regular health professional.

#### **1.6.4.11 Global Stress (STS)**

STS also known as the Global Perceived Stress Scale, is an 8-item, self-report measure of perceived chronic stress. The STS will be administered to all participants as part of the HII. The STS was newly created for use in the JHS. It assesses perceived stress across 8 broad domains derived from subscale factors underlying lengthier measures specific to each content domain (e.g., Family Environment Scale, Occupational Stress Inventory, Work Environment Scale, etc.). Rather than assessing discrete episodic stressful event occurrences (major or minor), the STS assesses global perceptions of stressors associated with ongoing or enduring stressful conditions, such as work, marriage, caregiving, etc.

##### **1.6.4.11.1 Background, Rationale and Hypotheses**

Exposure to stress, both acute events and chronic burden, has been related to CHD risk (Lepore, 1995). The frequency and types of stressors experienced by an individual may be influenced by broad societal factors operating on a given segment of the population. Stress exposure has been related to social class and to a lesser extent ethnicity and thus may contribute to SES or ethnic differences in CHD risk. In the JHS, 3 types of stress exposure will be assessed: major life events (at annual follow-up), minor life events, and chronic stress.

Chronic stressors are stressful events or conditions that tend to persist over time (Lepore, 1995). Examples of chronic stressors include environmental (e.g., neighborhood crime), economic (e.g.,

work, financial), or role stressors (e.g., marital, caregiver). Minor stressors and chronic stressors, in contrast to more time-limited and episodic major life events, may provide a more plausible theoretical link to the development of diseases that have a gradual long-term onset, such as CHD.

Hypotheses include:

1. High stress will be associated with an increased risk of hypertension and CHD events independent of the contribution of traditional CHD risk factors.
2. The relationship observed between stress, hypertension, and CHD events will be moderated by social support, coping style, SES, and education.

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#### **1.6.4.11.3 Administration**

The STS will be administered by a trained recruiter/interviewer to all participants in the participant's home as part of the HII. The interviewer will read the statement explaining the general rationale for the stress questions: "We are interested in the amount of stress that you have experienced over the past 12 months." Each question begins with the phrase "Over the past 12 months, how much stress did you experience," followed by a specific question. Each question contains several examples to help the participant appreciate the scope of each question. Detailed instructions for the STS are provided in the QXQ instructions located in the Forms Appendix.

#### **1.6.4.11.4 Scoring/Coding**

The STS yields a single total score. The total score is calculated as the sum of the stress ratings across items.

#### **1.6.4.12 Social Support (SOC)**

The Social Support form (SOC) is one of two measures of social support used in the JHS. The emphasis in the SOC is on the structural component of support, as well as negative functional aspects.

##### **1.6.4.12.1 Background, Rationale and Hypotheses**

Although the primary assessment of social support will be accomplished via the administration of the Interpersonal Social Support Evaluation List (ISL) (see section 1.6.7.1.1), a number of important structural and functional aspects are not evaluated by the ISL. Considerable evidence points to the importance of structural components of social support. In addition, more recent data indicate that negative aspects of support may in fact be a very important and relatively overlooked aspect of this dimension. The SOC was constructed using items from other standardized instruments to allow for a more comprehensive evaluation of the social support construct. Most of the questions were taken from the Berkman Social Network Index, and address structural components of support (type and frequency of contacts). Other items have been drawn from the East Side Village Study to assess negative aspects of social support. The remainder simply request general information. The greater breadth of assessment made possible by the inclusion of this instrument allows for a more accurate evaluation of the relationship between social support and health variables, as well as the indirect, moderator functions predicted.

#### **1.6.4.12.2 References:**

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#### **1.6.4.12.3 Administration**

The SOC is to be administered as part of the HII by a trained interviewer in the participant's home. Detailed instructions for the SOC are provided in the QxQ instructions, located in the Forms Appendix. Response formats include open-ended questions that are subsequently coded to ratings utilizing Likert-type scales.

#### **1.6.4.13 Personal Data and Socioeconomic Status (PDS)**

The Personal Data and Socioeconomic Form (PDS) is the first of several data collection instruments spaced over the baseline Home Induction and Annual Follow-up Interviews. Taken together, the data obtained will allow tracking of the participant's socioeconomic status at different stages of the life course. In the baseline HII, data is obtained on place of birth, marital status, employment or retirement status, first full-time job as well as information on personal and spousal education, income and occupation, and household wealth; job latitudinal satisfaction (adopted from the Karasek), and several measures of thwarted aspirations and relative deprivation. In subsequent annual follow-up interviews additional data is obtained regarding childhood, parental and neighborhood SES factors.

##### **1.6.4.13.1 Background, Rationale and Hypotheses**

The direct relationship between socioeconomic status (SES) and health is firmly established. This relationship holds for most of the identified risk factors for CVD including smoking, obesity, physical activity, hemostatic factors, diabetes, hypertension as well as access and quality of health care, particularly preventive care. Further, the social class gradient in CVD incidence and survival accounts for much of the black disadvantage (Cooper, 1993; Schoenbaum & Waidmann, 1997). Multiple mechanisms of socio-cultural effects on health and CVD are hypothesized. Included are early life experiences (Elo & Preston, 1992; Smith et al., 1997), disproportionate exposure to ecologic stressors (Harburg, et al., 1973; Karasek, et al., 1981; Markowe, et al., 1985; Meade, et al., 1986), harmful materials or vectors of disease (Schell, 1997), poor health practices (Adler & Folkman, 1993; Kumanyika, 1987; Lynch, et al., 1996; Sobal & Stankard, 1989; Strogatz, et al., 1991; USDHSS, 1985), and variations in health enhancing personality characteristics (Mirowsky & Ross, 1989; Williams, 1990). The JHS provides opportunity for the additional research needed to understand the ways in which salutogenesis and pathogenesis is shaped by the larger social context.

The comparatively low SES of blacks to whites makes this a plausible explanation for the excess CVD morbidity and mortality in blacks. Clarifying what it is about low SES that influences susceptibility to CVD in black Americans remains one of the most important challenges for health research (James, 1984) and high priority for the JHS. Based on current literature, priority was given to comprehensive measures which: 1) capture the multiple dimensions of individual, family, and neighborhood or community variations of social stratification; 2) address the differential social advantage offered African-Americans by equivalent levels of education, income and occupation; and 3) capture variation in SES over a lifetime, including specific measures of early life SES conditions. Traditional individual measures of income, education and occupation as well as measures of wealth/assets, dominant member approach family/ household social status, and parental occupation/education are included. Direct measures of neighborhood context which may serve as stressors (neighborhood violence and disorder) or buffers (social cohesion and resources) for the development of CVD are also included (Sampson, et al., 1997; Diez-Roux, 1997, 1999). Geo-coded census block information will be appended to each participant record for later determination of neighborhood/community measures; e.g. neighborhood class will be determined by grouping census block-coded occupational and educational data to create a meaningful measure of neighborhood

social class according to techniques described by Krieger (Krieger, 1992). Also, specific measures of individual, family/household, and neighborhood/community income, education, occupation, wealth/assets, poverty/deprivation, and socioeconomic/prestige ratings across all three levels and time will be developed from census data. Inclusion of individual and group level measures on the same traits will allow use of contextual regression analysis (Blalock, 1984; Boyd & Iverson, 1979) to determine whether the effects of individual SES are modified by household and neighborhood conditions. These comprehensive measures and analytic approaches during the first five years of the study will assure avoidance of either the individualistic or ecological fallacy in accounting for SES differences in CVD outcome over the course of the JHS.

Measures of early life SES conditions will be sought as indicators of deprived economic status when growing up; for example, parental education and occupation, subjective perceptions of comparative economic position. Class mobility will be assessed by a combination of measures of first job and subjective assessment of social class. Further, global assessments of relative deprivation (Adler, 1993) and thwarted aspirations (Williams, et al., Detroit Area Study) will be obtained.

Hypotheses include:

1. Family/household social status, including wealth, will be related to risk factors, hypertension, subclinical disease and CVD independent of individual level SES.
2. Neighborhood environment will be related to risk factors, hypertension, subclinical disease and CVD independent of individual level SES.
3. The relationship between race and CVD risk factors and outcomes will be modified by all levels of SES.
4. Measures of social status will interact with identified genetic factors to modify the occurrence of subclinical disease and the progression to clinical events.

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#### **1.6.4.13.3 Administration**

The PDS form is administered to all participants as part of the HII. Detailed instructions for administering each question are provided by the Q x Q instructions. The first question asks about place of birth and then continues with an assessment of participant standing in her/his community. Potentially sensitive questions on personal and household income, and wealth conclude the HII. Care must be exercised to administer this section in a nonjudgmental fashion.

#### **1.6.4.13.4 Instructions for Coding of Occupation**

Two certified coders will assign occupational codes. All field interviewers are trained to ensure proper recording of occupational data for coders. Training includes probing for full and accurate responses.

##### **1.6.4.13.4.1 The Alphabetical Index of Industries and Occupations**

The basic resource for coding occupation is the Alphabetical Index of Industries and Occupations. 1990 Census of Population. Final Edition. November 1992. The document is available from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402, or from any U.S. Department of Commerce District Office. (Prepayment is required if ordering by mail. Check price before ordering. For information call GPO, Washington, D.C. 202-783-3238.)

A companion volume, the Classified Index of Industries and Occupations (PHC 80-R4) is available from the same source.

Both indexes list some 20,00 industry and 29,000 occupation titles. The Alphabetical Index lists titles in alphabetical order, the Classified Index lists them in numerical order. The Alphabetical Index is the basic resource to use in identifying the appropriate occupational code. The Classified Index helps the user understand how the titles fit into the classification structure. This volume is also useful when dividing between two or more categories. It gives a broad picture of all the titles included within a category.

Both indexes are divided into two sections: the “white pages” list the industry codes; the “yellow pages” list the occupation categories. Each industry and occupation title has a 3-digit number or a letter which can be translated into a 3-digit number. The coder’s task is to identify the 3-digit occupational code which best fits the respondent’s answers to the occupation questions. The procedure is similar to looking words up in a dictionary. Once the coder is familiar with the index, the 3-digit code is relatively simple to assign for most cases. Few problems are expected with the cases and a mechanism is set up for resolving problem cases. If not, the Industry “white pages” has a section SELF-EMPLOYED with an extensive listing.

The coder uses the description given by the respondent to identify the occupational code in the “yellow pages.” In those cases where specific industries are associated with an occupational title, the coder uses the industry information to select the appropriate code. If industry information happens to be incomplete, use the most general or “not elsewhere specified” category. The use of the 3-digit Census occupational codes provides maximum analytic flexibility. The codes can be aggregated into a common system across centers or into a system tailored to particular research objectives.

The Occupational Classification System developed by the Census contains 503 separate categories which include the 29,000 titles. The categories are contained in six summary groups and 13 major groups. This system, expanded to 15 major groups by separating out “writers, artists and athletes” and “farm operators and managers,” is shown in Table 6.

**Table 6. Occupational Classification System: 1990 Census, Fifteen Major Groups in Six Summary Groupings<sup>1</sup>**

<b>Occupational Summary Groups</b>	<b>Occupational Codes</b>
<b>I. Managerial and Professional Specialty Occupations</b>	<b>(003-199)</b>
1. Executive, Administrative, and Managerial Occupations	Codes 003-037
2. Professional Specialty Occupations	Codes 043-179
3. Writers, Artists, Entertainers, and Athletes	Codes 183-199
<b>II. Technical, Sales, and Administrative Support Occupations</b>	<b>(203-389)</b>
4. Technicians and Related Support Occupations	Codes 203-235
5. Sales Occupations	Codes 243-285
6. Administrative Support Occupations, Including Clerical	Codes 303-389
<b>III. Service Occupations</b>	<b>(403-469)</b>
7. Private Household Occupations	Codes 403-407
8. Protective Service Occupations	Codes 413-427
9. Service Occupations, Except Protective and Private Household	Codes 433-469
<b>IV. Farming, Forestry, and Fishing Occupations</b>	<b>(473-499)</b>
10. Farm Operators and Managers	Codes 473-476
11. Other Farming, Forestry and Fishing Occupations	Codes 477-499
<b>V. Precision Production, Craft, and Repair Occupations</b>	<b>(503-699)</b>
12. Mechanics and Repairers, Construction Trades, Extractive Occupations, Precision Production Occupations	Codes 503-699
<b>VI. Operators, Fabricators, and Laborers</b>	<b>(703-889)</b>
13. Machine Operators, Assemblers, and Inspectors	Codes 703-799
14. Transportation and Material Moving Occupations	Codes 803-859
15. Handlers, Equipment Cleaners, Helpers and Laborers	Codes 863-889

<sup>1</sup> See Appendix for the detailed Bureau of the Census Occupational Classification System.

#### 1.6.4.13.4.2 Special Codes

The Bureau of the Census system includes occupation codes for persons in the labor force only. Other codes may be developed independently or special codes developed by the Census for other studies may be used. The following list of special cases (Table 7) is a combination of both. This list is updated from time to time.

**Table 7. Occupational Codes for Selected Special Cases**

Employment Status	If No Occupation Information is Given, Code as Follows	If Occupation Information is Given, Code as Follows
Armed Services:	For: Military rank Military branch Military occupation (gunner, pilot, etc.)  Code 905	For: Occupations that could be civilian or military, such as clerk, etc.  Code according to regular instructions.
National Guard:	Not considered part of Armed Services.	Code occupation according to regular instructions.
Retired:	Code 913	Code occupation before retirement if information is given.
Disabled:	Code 917	Code occupation before disabled if information is given.
<b>Other</b>		<b>Codes Assigned</b>
Homemaker or Housewife, Not in Labor Force:		Code <u>997</u>
Never Worked:		Code <u>998</u>
No Codable Information, or No Answer:		Code <u>999</u>

#### 1.6.4.13.4.3 Specific Rules for Coding

##### 1.6.4.13.4.3.1 Coding “Down”

When there is uncertainty or ambiguity in the responses to the occupation questions, code conservatively. There is apparently a tendency for people to inflate responses. When there is a choice in the selection of a code, follow the principle of “coding down” rather than “coding up.”

Please note that “coding down” results in a higher 3-digit number not in a lower one. In the Occupational Coding system, lower 3-digit numbers describe more professional occupations than the higher numbers. For example, “Managerial and Professional Specialty Occupations” range in codes from (003-199), whereas “Operators, Fabricators, and Laborers” range from (703-889).

#### **1.6.4.13.4.3.2 Self-Employed**

Note that the industry “white pages” include a section on SELF-EMPLOYED with an extensive listing of occupations. The listing starts on page I-140 of the Alphabetical Index. 1990 Census, and continues through the middle of page I-142.

In assigning an occupation code for a self-employed individual, first check the Self-Employed section, but do not limit search to these pages. If the appropriate code is not found in the SELF-EMPLOYED section, use the regular “yellow pages” to identify the appropriate occupation code.

#### **1.6.4.13.4.3.3 Multiple Jobs**

The interviewer probes for the main job if the respondent has more than one. The main job is defined as the job that which the person spends the most hours. If the hours are equal, the main job is the one the person considered the most important. If the person does not consider one job more important than the others, focus on the first job mentioned, making the assumption that the first job mentioned is the most salient one.

The Census Occupational Classification System includes a “homemaker” title, code T (407) under the heading “Private household cleaners and servants,” which refers to work in someone else’s home. The JHS uses a special code, 997, for the unpaid homemaker or housewife who works in her own home.

#### **1.6.4.13.4.3.4 Quality Control**

At the start of the JHS Cohort study, the first 100 cases assigned are reviewed by a second person. Where there is disagreement, the cases are referred to the Cohort Operations Committee.

### **1.6.5 Making the Clinic Appointment**

At the end of the HII, the clinic visit is described to the participant and a request made for an appointment. The interviewer inquires about several items to assist in scheduling the appointment:

1. any medical conditions (e.g., diabetes, dietary restrictions) which might affect the physical examination and/or type of snack provided
2. need for assistance in mobilization
3. preferred time and date of examination
4. desire for contact by JHS Council of Elders

The interviewer schedules appointments for the examination during the 30 days following this household visit, using the Clinic Appointment Form (CLA). Detailed QxQ instructions are specified in the Forms Appendix. The interviewer calls the clinic scheduler while at the home of the respondent to set an appointment day and time. The appointment is recorded on a reminder sheet, which is left for the participant. Participants are scheduled for appointments at her/his convenience, dependent upon clinic schedule. Whenever possible, eligible members of a single household are scheduled for examination on the same day. This makes the examination visit more attractive to the participants.

When examination arrangements have been made, the interviewer provides the participant with the JHS information videotape and/or consent brochure (see Appendix) if not already given, and a Participant Information Sheet, PART, (see Forms Appendix). The interviewer thoroughly reviews the consent brochure with the participant. Information provided in the brochure and information sheet includes the following: study overview, fasting requirements, description of the examination procedures, location of the clinic and so forth. Participants are asked to complete a form containing

her/his identifying information, as well as the names, addresses, and phone numbers of contact persons. Once participants have signed the informed consent at the Examination Center the information collected on this form is verified, and added to the database. At the conclusion of the interview, the sample respondent is thanked for her/his participation.

### **1.6.6 Participant Instructions for the Baseline Clinic Examination**

The instructions for the clinic visit are specified on the Participant Information Sheet, PART, and the Medication Information Sheet, MIN.

The instructions include:

1. Appointment date and time
2. Directions to the clinic (a map) and to parking facilities (JHS provides free parking and reimbursements)
3. Preparations:
  - a. 12 hour fast
  - b. No tobacco or vigorous activity
  - c. Clothing to wear for the visit
4. Things to bring:
  - a. Eyeglasses for reading
  - b. Name and address of health care provider and clinic
  - c. Names, address, and phone number of contact persons
  - d. Medications  
A script describing the need for medication information is on the home interview form and is read to the participant. The reminder sheet also indicates which medications should be brought. A bag is provided in which to carry the medications.
  - e. Completed Approach to Life Form (see 1.6.7.1)
5. Clinic Operation
  - a. A snack is provided after the initial part of the exam
  - b. Clinic hours and phone number
6. Transportation
  - a. The JHS will provide transportation and arrange for participant pick-up for those participants who need this service
  - b. Those who drive are asked to record mileage for reimbursement
7. Optional contact by JHS Council of Elders for additional information about participation

### **1.6.7 Contact Form (CON)**

The Contact form (CON) provides information on multiple ways to contact an individual participant. This form was modified from ARIC CON with the addition of electronic and cellular methods of contacting the participant, as well as information to contact the participant's health care provider.

#### **1.6.7.1 Background and Rationale**

Having multiple reliable means of contacting study participants over the duration of the JHS is essential to ongoing retention. Similar longitudinal studies have verified the importance of gathering at least two additional methods of getting in touch with each participant. Maintaining current health care provider contact information is required for sending study results, if requested.

### **1.6.7.2 Administration**

The CON is administered to all participants during the HII by a trained recruiter/interviewer. Detailed instructions for completing each item are contained in the QxQ instructions. The initial item obtains complete contact information on the individual participant, including home, work, electronic and cellular contact data. Additional items gather similar information on family, friends, work colleagues, neighbors or others who can serve as a means of contacting the participant should s/he not be reached via their primary contact. At least two contacts are requested of all participants.

## **1.6.8 Participant “Bring to Clinic” Forms**

### **1.6.8.1 Approach to Life**

The Approach to Life form is a self-administered questionnaire completed by participants following the home interview and brought with them to the baseline examination clinic visit. It is designed to obtain additional information on aspects of how participants approach and cope with life stressors. This form is comprised of three separate standardized measures designed to capture information on social support, coping and religion/religious coping.

#### **1.6.8.1.1 Approach to Life A: Interpersonal Support Evaluation List (ISL)**

The Approach to Life Interpersonal Support Evaluation List (ISL) (Cohen & Hoberman, 1983) is administered as part of the Approach to Life Form in the Bring to Clinic section. It will be employed as a primary measure of the functional components of social support. Considerable evidence supports the validity and reliability of this instrument. The 16-item version to be employed in the JHS is comprised of four subscales, which assess the following dimensions: (a) emotional support (Appraisal), (b) others with whom one can interact (Belonging), (c) material aid (Tangible), and (d) others with whom one believes she/he compares favorably (Self-Esteem). These factors have previously been found relevant to health-related outcomes.

##### **1.6.8.1.1.1 Background, Rationale and Hypotheses**

Considerable literature has established the importance of social support as a moderator of morbidity and mortality rates across a variety of diseases. Stressful life events are considered to have a deleterious impact on particular physiological processes, which in turn contribute to the likelihood of poor health outcomes. Social support is generally considered to function as a buffer against the effects of stressors. Despite the breadth of this construct, and the many ways in which it has been measured (e.g., perceived emotional or tangible support from family / friends / co-workers / etc., community involvement, marital status, number of friends, frequency of social contacts), research has consistently supported its beneficial effects. In addition to the positive health-related outcomes, much research suggests underlying mechanisms of action, including changes in cardiovascular, immune, and endocrine systems (Uchino, Cacioppo, & Kiecolt-Glaser, 1996).

As expected, social support has been found to moderate the relationship between psychological variables and health outcome, as well as physiological functions considered to contribute to health outcome. Lepore, Mata Allen, and Evans (1993) demonstrated that the effects of an acute laboratory stressor on blood pressure (BP) was moderated by social support (experimental manipulation of the supportiveness of a confederate). In a follow-up study, Lepore (1995) observed once again that individuals under a high relative to low social support condition produced smaller BP increases to laboratory stressors. The findings, however, held only for individuals low in cynicism; BP responses were not moderated for high cynicism participants. Brownley, Light, and Anderson (1996) observed differential effects of cynicism on ambulatory BP in whites as compared to blacks across three sites: home, work, and clinic. In this study, higher level of appraisal support was related to lower overall BP across race and gender. Of interest was the association between low hostility and higher blood pressure in black males. The authors noted that this finding was best understood in the context of low hostility scores coupled with high levels of anger, suggesting the suppression of hostility is an

important consideration. Other findings were more complex, with high hostile black men who reported greater levels of tangible support showing lower BP, whereas white women with higher scores on belonging support showing lower BP overall. This representative group of findings underscores the importance of understanding the complex interactions that various components of social support may have with factors known to contribute to health risk status.

In a review of the literature on the role of social networks and support, Berkman, Vaccarino, and Seeman (1993) concluded that both low support (particularly emotional) and social isolation have been consistently related to all-cause mortality and cardiovascular death for men and women. Currently, the data appear more consistent for men, and there is evidence that men are at greater risk for death following the death of a spouse than visa versa. Despite these findings, the authors acknowledge numerous shortcomings and methodological problems with the studies cited, including limited range and delineation of social support factors assessed, and differential risk status of men compared with women. Finally, whereas data addressing the relationship to mortality are limited but sufficient to draw preliminary conclusions, morbidity data are far less available. Orth-Gomer, Rosengren, and Wilhelmsen (1993) reported one of the few studies predicting CHD based on a measure of social integration. Holahan, Moos, Holahan and Brennan (1995) found that for individuals with cardiac illnesses, social support was negatively related to number of depressive symptoms.

Thus, the JHS will permit the investigation of several factors relevant to social support that have as yet received insufficient attention. An accurate characterization of various support dimensions in a large African-American sample of men and women across a broad age range comprises one excellent opportunity. Second, an extension of prior work considering the nature of social support interactions with other cardiovascular risk factors will be possible. Finally, beyond the relationship to long-term mortality outcome, there will be the ability to examine the relationship between social support and morbidity, as well as proximal physiological measures purported to have a relationship with ultimate risk, such as ambulatory blood pressure, cortisol measurements, and other vital sign data collected at regular visits.

#### **1.6.8.1.1.2      References**

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Cohen, S., & Hoberman, H.M. (1983). Positive events and social supports as buffers of life change stress. Journal of Applied Social Psychology, 13, 99-125.

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Lepore, S.J. (1995). Cynicism, social support, and cardiovascular reactivity. Health Psychology, 14, 210-216.

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Orth-Gomer, K., Rosengren, A., & Wilhelmsen, L. (1993). Lack of social support and the incidence of coronary heart disease in middle-aged Swedish men. *Psychosomatic Medicine*, 55, 37-43.

Uchino, B.N., Cacioppo, J.T., & Kiecolt-Glaser, J.K. (1996). The relationship between social support and physiological processes: A review with emphasis on underlying mechanisms and implications for health. *Psychological Bulletin*, 119, 488-531.

#### **1.6.8.1.1.3 Administration**

The ISL will be handed to the participant at the conclusion of the HII as part of the Approach to Life booklet. The participant will be instructed to complete this form and bring it with them to the clinic exam visit. Although instructions will be located at the beginning of this form, the interviewer will review the instructions and answer any questions that arise to assure the participant's clear understanding of the manner in which to complete the form. If the participant requests to complete this form at the conclusion of the interview, the interviewer will facilitate this. Specific instructions are included in the QXQ instructions. It is important that no questions be left blank. Clinic staff will review forms for completeness at the baseline clinic examination and assist the participant to complete the form if needed.

#### **1.6.8.1.1.4 Scoring for the Interpersonal Support Evaluation List (ISL)**

Each item is rated on a 4-point scale: Definitely True (1), Probably True (2), Probably False (3) and Definitely False (4). The instrument is scored by summing all items within each of the four subscales: Appraisal, Belonging, Tangible Support, and Self-Esteem.

Minimum score for a subscale is 4, and the maximum is 16. The four subscales are also summed to yield a total score. The specific item assignment is as follows:

<b>Subscale</b>	<b>Items</b>
Appraisal:	5, 8, 12, 15
Belonging:	2, 3, 4, 9
Tangible Support:	6, 7, 11, 14
Self-Esteem:	1, 10, 13, 16

#### **1.6.8.1.2 Approach to Life B: Coping Strategies Inventory (CSI)**

The Approach to Life B: Coping Strategies Inventory (CSI) (Tobin, Holroyd, Reynolds, & Wigal, 1989) is administered as part of the Approach to Life booklet in the Bring to Clinic section. It will be used to assess a variety of coping dimensions organized within a hierarchical structure. The two primary dimensions include problem-focused versus emotion-focused coping style. This factor is considered in the context of the second dimension, approach versus avoidance coping. Although the original scale is 85 items in length, a substantially shorter 16-item version has been developed for the JHS, based on data collected on research samples in Jackson, Mississippi, including headache sufferers, patients with coronary heart disease, and caregivers of Alzheimer's patients.

#### **1.6.8.1.2.1 Background, Rationale and Hypotheses**

The manner in which one copes with environmental stressors is purported to moderate physiological responses that influence health outcome. Coping refers to individuals' cognitive and behavioral responses to stressful life circumstances in an attempt to mitigate the effects of those experiences (cf.

Lazarus & Folkman, 1984). The ultimate impact of these actions is considered to be a function of a variety of factors, including the specific coping behavior performed, stimulus qualities of the stressor and response characteristics of the individual.

A number of efforts have been made to understand the organizational structure of coping. Two approaches are more or less accepted. The first is the approach-avoidance scheme. Approach-based coping includes behaviors that involve direct actions to manipulate the environmental stressor. Avoidance-based coping, on the other hand, is comprised of behaviors that attempt to reduce stress via reduction in exposure to the stressor. The second approach emphasizes the type of effect sought. Problem-focused coping emphasizes management of the stressor, whereas the goal of emotion-focused coping is the regulation of one's affective response.

A small but growing literature addresses the impact of different coping efforts in the context of the particular outcome of interest. Earlier efforts demonstrated the effects of denial on recovery from a myocardial infarction (Levine, et al., 1987). In this study, it was shown that denial had a positive impact in the short term (e.g., earlier release from hospital), but poorer long-term health outcome. Several investigations have examined the role of measures of defensiveness in modifying the relationship between hostility and physiological function. Helmers, et al. (1995) demonstrated that defensive-hostile (high hostility, high defensiveness) patients with CAD showed increased ischemia (laboratory and ambulatory monitoring) and perfusion defects. Larsen and Langer (1997) similarly demonstrated increased reactivity for these individuals. Holahan, et al. (1995) assessed approach and avoidance coping (represented as percentage approach coping) in individuals with cardiac illness. Fewer depressive symptoms were evident for those individuals having higher scores. These data also provide support for the conceptualization of social support as exerting its positive influence via its influence on coping (cf. Lazarus & Folkman, 1984).

It would thus appear that coping serves an important moderator role in the relationship between environmental stressors and psychological CV risk variables on the one hand, and detrimental physiological responses and poor health outcomes on the other. Assessment of both approach and avoidance-based coping appears important. Recently, in a study examining stress and coping in medical students, Mosley, et al. (1994) similarly demonstrated the positive impact of approach (engagement) and negative impact of avoidance (disengagement) coping on depressive symptoms. They used the original, full-version CSI (CSI; Tobin, Holroyd, Reynolds & Wigal, 1989), which has been demonstrated as useful in identifying stress coping patterns in various populations (e.g., headache).

#### **1.6.8.1.2.2      References**

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Tobin, D.L., Holroyd, K.A., Reynolds, R.V., & Wigal, J.K. (1989). The hierarchical factor structure of the of the Coping Strategies Inventory. Cognitive Therapy and Research, 13, 343-361

#### **1.6.8.1.2.3 Administration**

The CSI will be given to the participant at the conclusion of the HII as part of the Approach to Life booklet in the Bring to Clinic section. The participant will be instructed to complete this form and bring it with them to the clinic exam visit. Although instructions will be located at the beginning of this form, the interviewer will review the instructions and answer any questions that arise to assure the participant's clear understanding and the manner in which s/he may complete the form. Detailed QxQ instructions are specified in the Forms Appendix. If the participant requests to complete this form at the conclusion of the interview, the interviewer will facilitate this. It is important that no questions are left blank. Clinic staff will review forms for completeness at the baseline clinic examination and assist the participant in completing the form if needed.

#### **1.6.8.1.2.4 Scoring for the Coping Strategies Inventory**

Each item is rated on a 5-point Likert-type scale from Never (1), to Seldom (2) to Sometimes (3) to Often (4) to Almost Always (5). The instrument is scored by summing the responses to items within each of the four subscales. Minimum score for a subscale is 4 and the maximum is 20. The specific item assignment is as follows:

<b>Dimension</b>	<b>Items</b>
Problem-focused Approach	1,2,8,9
Problem-focused Avoidance	4,7,12,14
Emotion-focused Approach	5,6,11,13
Emotion-focused Avoidance	3,10,15,16

#### **1.6.8.1.3 Approach to Life C: Religion/Religious Coping (RCP)**

The Approach to Life C: Religion and Religious Coping (RCP) is administered as part of the Approach to Life booklet in the "Bring to Clinic" section of the HII. It will be employed as a primary measure of religious coping. The form was modified from several standardized measures of religious coping currently in testing by the MacArthur Group and included in the General Social Survey.

##### **1.6.8.1.3.1 Background, Rationale and Hypotheses**

Studies of religious coping indicate that religion provides solace in confronting physical illness and disability (Jenkins & Pargament, 1988; Pargament & Hahn, 1986) as well as other acute and chronic threats (Bulman & Wortman, 1977; Kotarba, 1983; Maton, 1989). Religious coping may be more effective than other strategies in reducing negative affective states accompanying physical health-related stressors (Mattlin, Wethington, & Kessler, 1990). Religion and its associated rituals assist in the process of adjustment to difficult life situations, especially those over which there is little direct control. The few studies of religious coping in black samples show that, on average, black Americans are more likely to use religious coping strategies than are whites (Conway, 1985-86; Gibson, 1986). Systematic data is lacking, however anecdotal evidence suggests that religious cognitions are employed by blacks in confronting health conditions as well as poverty and racism (Neighbors, Jackson, Broman, & Thompson, 1996). The potential for protection against the development of CVD may be direct in that it has stress- reducing effects mediated through lowered cortisol secretion from the pituitary-adreno-cortical pathway via catecholamine secretion from the sympathetic-adreno-

medullary pathway. Alternatively, it may be indirect through the association between religion/spirituality and healthy diet or other health practices or improved social support. Religion/spirituality is a multidimensional concept and three dimensions are selected for inclusion in JHS: organizational religiousness, private religiousness, and daily spirituality.

Regular church attendance has been associated with lower rates of CHD (Comstock, 1972; Medalie, 1973) and mortality (House, 1982; Berkman, 1979; Seeman, 1987; Strawbridge, 1977; Schoenback, 1986; Bryant, 1992). Private religiousness (non-organizational, informal or non-institutional) has been associated with lowered blood pressure (Levin, 1989; Chesney, 1987; Caudill, 1987) and reduced mortality following cardiac surgery (Oxman, 1995). Spirituality is intended to go beyond religious boundaries and focus on the internalization of religious principles in daily life. The measures chosen for each of these dimensions are state of the art instruments currently being used in the General Social Survey and are being studied for psychometric properties.

Hypotheses include:

1. Religiousness/spirituality is associated with hypertension and sub-clinical disease independently of diet and social support.
2. The higher the religiousness/spirituality the less the effects of negative emotions and chronic stress on hypertension, sub-clinical disease and progression to events.

#### **1.6.8.1.3.2 References**

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Levin JS, Vanderpool HY. (1987). Is frequent religious attendance really conducive to better health: Toward an epidemiology of religion. Social Science and Medicine.;24:589-600.

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#### **1.6.8.1.3.3 Administration**

The RCP given will be given to the participant at the conclusion of the HII as part of the Approach to Life booklet. The participant will be instructed to complete this form and bring it to the baseline examination clinic visit. Although instructions will be located at the beginning of this form, the interviewer will review the instructions and answer any questions that arise to assure the participant's clear understanding and the manner in which she/he may complete the form. Detailed instructions for the RCP are described in the QxQ instructions. If the participant requests to complete this form at the conclusion of the interview, the interviewer will facilitate this. Clinic staff will review forms for completeness at the baseline clinic examination and assist the participant with completing the form if needed.

#### **1.6.9 Interviewer Observations Form (OBS)**

The Interviewer Observations Form (OBS) provides a context for the HII as well as additional information to plan for the subsequent clinic examination and future follow-up calls. The OBS was modified from similar instruments used in several studies of African-Americans including the Detroit Area Study and the Eastside Village Study. It is intended to gather subjective information regarding the success of the interview as well as pertinent observations about the participant, which will assist with retention across the study duration.

##### **1.6.9.1 Background and Rationale**

The initial contact with JHS participants occurs in their home. This contact allows for a natural interview setting for the participant, thus providing important information on the participant's likes and dislikes and life situation. Such information is important to personalizing subsequent contacts with the participant. Likewise, information which rates the overall quality of the interview is important as a context or background for the data obtained. Such information will facilitate ongoing evaluations of the quality of the data obtained in the field setting.

##### **1.6.9.2 Administration**

The OBS is completed by the trained interviewer/recruiter following the completion of the HII. It is completed after the interviewer/recruiter has left the home, but within 24 hours of completing the

interview. Detailed instructions for completing each item are contained in the QxQ instructions. The initial item provides a rating of the interviewer's estimate of the participant's cooperation in completing the HII. Additional items record observations about degree of talkativeness or engagement in the interview, as well as any auditory, visual or physical impairment or any language or comprehension issues for this respondent. Finally, the interviewer rates the overall quality and personal satisfaction with this interview.

#### **1.6.10 Clinic Examination Appointments Schedule System**

The interviewer delivers all materials from the HII to the supervisor at the Examination Center (EC) prior to the scheduled clinic appointment. The material is reviewed by office staff and entered into the data base on a regular basis. Sufficient appointments are scheduled each day for Tuesday through Saturday, to meet the requirement of 45 appointments per week. The database is updated on a regular basis. The EC maintains:

1. Assignment record of labels for the clinics.
2. A listing of telephone numbers and dates and times to conduct the telephone reminder calls.
3. Daily appointment schedule with participant name, ID number, appointment time, and special considerations such as health restrictions or child care requests. This schedule is used to structure that day's appointments and to check in participants as they arrive for her/his examination.
4. Clinic schedules are maintained by clinic schedulers and/or an answering service. When an answering service is used following clinic hours to schedule appointments, duplicate appointment books are kept and updated on a daily basis to avoid conflicts in schedules. When conflicts arise due to overbooking of an appointment, they are resolved by clinic personnel.

### **1.7 Recruitment for Baseline Clinic Examination**

#### **1.7.1 Introduction**

The projected clinic response rates (ranging from 60 to 80 percent) are dependent upon the ability to recruit eligible participants and to maintain clinic attendance. Every effort is made to make the clinic visit as pleasant and burden free as possible. Additionally, the following features are part of the effort to maximize participation: (1) Qualified interviewers, (2) Pre-appointment contacts, (3) No show procedures, (4) Reimbursement, (5) Community awareness and health education activities and (6) Supervision.

#### **1.7.2 Qualified Interviewers**

Standard survey procedures assist in maximizing the rate of participation. Experienced, well-qualified and sensitive interviewers are employed to conduct data collection activities. They generally live in or near the area in which they are working.

Interviewers are thoroughly trained to overcome objections and concerns. The training includes two to three months of classes covering issues of cultural sensitivity, interviewing practices, details of the JHS, the extent of the interviewer probing and overcoming participant objections and/or concerns.

Interviewers make initial contact with households at optimal times (i.e., late afternoons, evenings, or weekends), and schedule appointments for interviews as needed. Additionally, interviewers make call backs as necessary, at varying times of day and week. No unlocateable code may be entered until a minimum of five contacts have been made.

### **1.7.3 Pre-appointment Contacts**

To increase respondent participation following recruitment by an interviewer, a pre-appointment postcard is mailed prior to the scheduled appointment. This card reviews the fasting requirements, and the examination date and time.

Reminder calls are made to each participant one or two days prior to the examination. At this time, the information concerning the fasting requirements, medications bags, and other details is reviewed with the participant. Participants are asked if they have any special needs and every effort is made to answer their questions.

When appropriate, a letter is sent to the participant's employer explaining the JHS (see Appendix). Additionally, participants may be contacted by other JHS cohort members through the JHS Council of Elders to reinforce participation.

### **1.7.4 Contacts for No Shows**

Eligible participants who fail to arrive for a scheduled appointment or who cancel her/his appointments are contacted by telephone to reschedule the appointment. At that time, the scheduler attempts to address any concerns or fears that the participant may still have.

Each no-show case is individually reviewed by the recruiter/interviewer and when necessary by the supervisory staff. Conversion efforts include a combination of telephone contacts, in-person visits, and/or conversion letters. A participant is considered a refusal following six broken appointments.

### **1.7.5 Reimbursement**

The JHS EC provides for or reimburses transportation. Parking is free at the Jackson Medical Mall site of the JHS clinic. For those who are reimbursed, detailed records are maintained for accounting purposes according to OMB and the UMMC guidelines.

### **1.7.6 Partnerships for Community Awareness and Health Education**

To enhance participation the Coordinating Center Partnerships for Community Awareness and Health Education (PCAHE) office maintains close contact with the media, churches, businesses, health organizations and professionals, school systems, sponsors and other community sources of information. Information and updates on the study are provided on a regular basis to enhance community support. Community education and provision of heart health information are regular components of PCAHE to assure wide community benefit from the study. The "Friends of the Jackson Heart Study" volunteer program provides and encourages ongoing community information and involvement.

In addition to the community-wide efforts, PCAHE will target specific local areas approximately two weeks prior to recruiters entering that locale in order to increase awareness. The PCAHE plan contains a full description of PCAHE activities.

### **1.7.7 Supervision**

Throughout the entire process, from initial interview to final interview/examination or refusal, close supervision helps maximize the response rate. Supervisors record reasons for non-response, and examine performance trends by interviewer and by area. When deemed appropriate, supervisors initiate re-contact with refusing participants to attempt her/his conversion. Detailed records of all contacts are maintained.





## **2.0 INTERVIEWS IN THE BASELINE CLINIC EXAMINATION VISIT**

### **2.1 Introduction**

Upon completion of the HII, eligible participants are invited to take part in the baseline examination at the JHS Exam Center. Nine or more participants are scheduled daily, Tuesday through Saturday.

Chapter 2, Interviews in the Baseline Clinic Examination Visit, is one of two chapters that present an overview of the examination components, interviews and procedures. This chapter focuses on the interviews to be conducted during the baseline visit while Chapter 3 will detail the baseline examination procedures. Tables 8, 9, and 10 summarize all the core components of the JHS beginning with the HII and continuing through annual follow-up and surveillance. Each of these components are likewise detailed in separate chapters of this manual.

To orient the reader to the overall clinic flow, information on the sequence of flow for both interviews and procedures precedes detailed information on training, quality assurance, and specific interview forms included in the baseline clinic visit.

**Table 8. Core Components of the JHS Baseline Induction and Examination**

<b>COMPONENT</b>	<b>DESCRIPTON</b>	<b>MANUAL</b>
Interviews: Home Induction	Administer instruments: Household Enumeration; Eligibility; Personal & Family Health History; Health Practice: Tobacco Use and Physical Activity; Stress; Social Support; Personal Data/SES; Clinic appointment; Contact Information; Medications Instructions; Participant Information Form; Interviewer Observations.	2
Interviews: Self Administered	At home induction interview provide the following instruments for participant to complete and return at clinic visit: Approach to Life: ISEL, CSI, Religion/Coping forms and Health Care Provider Contact Information.	2
Reception	Informed consent for interviews, examination and procedures, DNA collection, medical records, release of data, ancillary studies. Administer Fasting form and update Contact form.	2
Anthropometry	Weight, height, waist and neck girth	2
Blood Pressure: Resting, Ankle/Arm	Assess sitting blood pressure, using random zero sphygmomanometer. Assess ankle and arm blood pressure using doppler.	4
Electrocardiogram: 12-lead	Obtain resting 12-lead electrocardiogram.	5
Echocardiography	Use ultrasonography to examine the heart and great vessels to diagnose cardiovascular lesions.	6
Ultrasonography	Obtain b-mode scan of extracranial carotid arteries. Record heart rate and blood pressure changes.	7
Venipuncture	Obtain blood samples for laboratory tests and storage of specimens.	2, 9
Pulmonary Function Test	Obtain measure of air volume and exhalation rate from the lungs using a volume displacement spirometer.	8
Snack	After venipuncture, participants will be given a nutritious snack.	2
Interviews: Medical/Health	Administer instruments: Medication Survey, Medical History, Stroke Symptoms, Reproductive History, Diet-FFQ (food frequency), Family Structure and Parental Identification (Family Study, only).	2
Interviews: Sociocultural	Administer instruments: Discrimination, Alcohol and Drugs.	2

Interviews: Take Home	Provide the following forms to be completed at home and picked up with 24-hr study data/equipment: Hassles and Mood Inventory (WSI, CES, CHO, STX), Family Contact Form (Family Study only).	2
Interview: Exit	Ascertain completeness of exam, verify abnormal results, provide clinic summary report, return medication, provide instructions on 24-hr /48-hr urine collection, ambulatory blood pressure measurements, and physical activity measurements. Instructions on substudies and ancillary studies. Provide information on results reporting.	2
24-hour Exam Procedures	24-Hour Tracking Ambulatory Blood Pressure: Pre ABPM, Post ABPM, Return Monitor 24-Hour Urine and 48-Hour Urine: Pre-24 Hour Urine, Post-24 Hour Urine, 24 Hour Urine Return, Second 24 Hour Urine Return, 24-Hour Physical Activity: Pre- Physical Activity, Post Physical Activity, Return Physical Activity	2
Medical Data Review	Participant's responses to standardized questions in the interviews and exams with potential medical impact or participant safety implications are reviewed by Examination Center clinical staff.	2
Referrals and Review Guidelines	Guidelines for referring participants for further medical care are based on responses to questions with cardiovascular disease implications.	2
Clinician Reviews	Procedures for second level of medical data review by Exam Center medical staff	2
Participant Safety	Guidelines for the safety and welfare of the JHS participants.	2

**Table 9. Core Components of Annual Follow-up and Surveillance**

<b>COMPONENT</b>	<b>DESCRIPTION</b>	<b>MANUAL</b>
Annual follow-up ID Information	Update Contact form	2
Annual follow up interview	Annual call to ascertain 1) correct contact information; 2) update tracing information on 3 contact persons; 3) ascertain participants vital status; 4) document medical events, life events and functional status	2
Additional Questions	Additional questions to be administered in Yr 1, Yr 2, and Yr 3. [John Henryism, Lifecourse SES, Optimism, Major Life Event Stress, and Neighborhood SES instruments]	2
Surveillance: In hospital and Out of Hospital	Forms: Birth Certificate; Death Certificate; Hospital Record Abstraction; Informant Interview; Physician Questionnaire; Coroner/Medical Examiner; Cohort Event Eligibility; Cohort Stroke Abstraction; Cohort Stroke Supplement	10

**Table 10. Core Components of Baseline Visit Substudies**

<b>COMPONENT</b>	<b>DESCRIPTION</b>	<b>MANUAL</b>
Diet Sub-study	Monitor and record food intake for a 24-hour period.	2
Physical Activity Sub-study	Monitor physical activity for a 3- or 7-day period with ergonometric equipment	2

## **2.2 Participant Flow**

The flow of participants will follow a common plan. This plan is aimed at minimizing the participant time burden and reducing variability in the various baseline measurements. The schedule is divided into fixed and non-fixed sequences to accommodate legal requirements, scientific constraints regarding the order of measurements, the daily fluctuations in Exam Center staffing patterns and unforeseen number of participants who keep scheduled appointments, the configuration of the Exam Center's physical layout, equipment availability and function, the integration of ancillary studies, and so forth. Participant flow and the approximate time associated with each workstation are outlined in Table 11.

### **2.2.1 Rationale**

The fixed components of scheduling participant flow reflect the requirement to initiate the examination with the administration of informed consent, the scientific constraints which establish the grouping of procedures which require fasting, and the logistical necessity of conducting medical data reviews after all other procedures have been completed. The flexible components reflect the advantages of conducting the majority of the interviews and examinations in accordance with the physical layout and the scheduling patterns of the Exam Center. This approach is intended to minimize participant burden to approximately 4.5 hours and reduce variability in study measurements.

### **2.2.2 Fixed Sequence**

The fixed sequence of participant flow reflects the following requisites: signed informed consent prior to any examination; participant time is to be kept to approximately 4.5 hours (excepting Family Study participants); twelve hours of fasting and one hour of abstinence from smoking are required for venipuncture and measurement of sitting blood pressure; sitting blood pressure and anthropometry to be measured before venipuncture; 20 minutes in a supine position is required before venipuncture; and both the interviews and the physical examination are to be completed prior to the medical data review.

After the participant has been welcomed and has signed the consent form, s/he is asked to change into a surgical scrub suit, provided by the Exam Center. The Exam Center provides a safe place to store clothing and valuables for the duration of the visit. Table 11 details anticipated clinic flow. After changing, anthropometry and sitting blood pressure are measured, and either EKG, Echo or ultrasound are completed prior to venipuncture. Following venipuncture, the participant is shown to the snack area and provided with a caffeine-free, low fat snack.

**Table 11. Clinic Flow: Jackson Heart Study Baseline Visit**

Participant Flow	Group 1 4 participants	Group 2 4 participants	Group 3 4 participants	Group 4** 4 participants		
8:00 a.m.	Reception	Reception				
8:15	Echo & Ultrasound	Interview				
8:30					Reception	Reception
8:45						Anthro
9:00		Interview	Interview			
9:15						
9:30	Snack				Snack	
9:45	Anthropometry	Echo	Anthro		Anthro	
10:00				Snack		
10:15			Anthro	Interview		
10:30	Interviews		Echo			
10:45			Echo			
11:00		Anthro	Echo	Interview		
11:15						
11:30	Interview	Anthro		Wait		
11:45	Exit	Exit		Wait		
12:00 p.m.		Exit	Exit	Wait		
12:15	4.50 hrs	4.50 hrs	4.50 hrs	Echo		
12:30						
12:45						
1:00				Echo		
1:15						
1:30						
2:00						
2:15						

Echo & Ultrasound Includes Echo and Ultrasound, Phlebotomy done. Time 75 minutes.

Interviews Personal/Family, Genogram, Contact, Reproductive, Stroke, meds, diet, smoking and discrim. Time: 73 minutes. Phlebotomy done. Interview rooms will require a chair that allows the participant to be supine.

Anthropometry Anthrometrics, PB, ankle/brachial BP, EKG, PFTs. 30 minutes added for phlebotomy. 75 minutes

Exit Interview 24-hour urine and ambulatory BP, results reporting and exit interview. 30 minutes

\*\* Exam data will be collected to the extent possible

## **2.3 Training**

The Exam Center staff is trained before the baseline exam to use a standardized technique for administering all baseline interviews. Training includes an overview of the JHS and its precursor, ARIC; an overview of epidemiological cohort research methods; instructions in research interviewing techniques: communication, respecting cultural diversity and in specific forms completion including:

1. a thorough review of the forms, instructions and protocol to promote adherence to the protocol
2. practice in the use of non-judgmental attitude
3. practice with the degree and nature of prompting permitted dealing with problem interview situations
4. use of response cards
5. practice handling participants' comments and recording relevant information on the note logs
6. review of post interview responsibility for the data

The Clinic Manager and interviewer team leader are responsible for training new staff based on standardized interview techniques (see Appendix), QxQ instructions for each form, practice scripts and role playing.

## **2.4 Certification**

Tables 12,13, and 14 summarize certification and re-certification criteria for all elements of the baseline visit; interviews and procedures. Interviewers are certified by the interviewer trainer at the successful completion of training. Certification is achieved by the demonstration of adequate technique on five taped interviews, reviewed and approved by the Clinic Manager or interviewer team leader. Re-certification is completed annually and requires the successful completion of one taped interview. With participant approval, all interviews are taped for quality control. All tapes are included in the round robin and are reviewed by the interviewer supervisors selected to monitor each year's round robin. Special certification criteria beyond these tape reviews are described below with the appropriate exam component.

## **2.5 Quality Assurance**

With participant approval, most interviewer-administered forms are taped for quality control. A non-systematic sample of forms are reviewed by the Clinic Manager and interviewer team leader monthly. Routine quality assurance is provided through observation by the Clinic Manager. Protocol adherence and interviewing techniques are reviewed at least biannually by Coordinating Center examination monitors. Deviations from protocols and possible remedial actions are discussed with the Clinic Manager and staff at that time. Major deviations are brought to the attention of the JHS Cohort Operations Committee. Data quality is monitored by the Quality Control Committee semi-annually.

**Table 12. Certification Criteria: Baseline Visit Cohort Exam Procedures and Interviews**

<b>COMPONENT</b>	<b>CERTIFICATION REQUIREMENT</b>	<b>CERTIFIER OR REVIEWER</b>	<b>RECERTIFICATION REQUIREMENTS</b>	<b>RECERTIFIER OR REVIEWER</b>
Interviews: Home Induction	Adequate technique on 5 taped interviews	Supervisor or Interviewer team leader/CC Central Trainer	Annually, 1 taped participant interview	Supervisor or Interviewer team leader
Interviews: Self-administered	Adequate explanation on 5 taped introductions to participants	Supervisor or interviewer team leader/CC Central Trainer	Annual review	Supervisor or Interviewer team leader
Reception Interviews	Adequate technique on 5 taped interviews	Supervisor or Interviewer team leader/CC Central Trainer	Annually, 1 taped participant interview	Supervisor or Interviewer team leader
Anthropometry	Lead technician 1 cm of trainer agreement w/ trainer Equipment Calibration on Log	Clinic manager	Biannually for technicians Annually for Lead Technician	Lead Technician
Blood Pressure: Resting, Ankle/Arm	Lead technician training	Central trainer or Lead Technician	Biannually. Annual re-certification for Lead technician	Lead technician
Electrocardiogram: 12-lead	Adequate technique on 5 ECG tracings	ECG Reading Center reviews ECG quality	Monitored continuously w/ quarterly reports	ECG reading center
Echocardiography	Central training by ERC staff Submit 10 acceptable scans	ERC/Chief sonographer	Monitored continuously at ERC Biannual QC review	ERC and QC committee
Ultrasonography	Central training by URC staff Submit 10 acceptable B-mode scans	URC/Chief sonographer	Monitored continuously at URC Biannual QC review	URC and QC committee
Pulmonary Function Test	Central training by PFRF staff Submit 5 acceptable PFTs	Chief spirometrist	Monitored continuously at PFRF Biannual QC review	PFRF and QC committee
Venipuncture	Lead technician training, Pass written and practical exams, 2 acceptable draws/processing	Lead technician	Biannually @ Exam Center	Lead Technician



<b>COMPONENT</b>	<b>CERTIFICATION REQUIREMENT</b>	<b>CERTIFIER OR REVIEWER</b>	<b>RECERTIFICATION REQUIREMENTS</b>	<b>RECERTIFIER OR REVIEWER</b>
Interviews: Medical/Health	Adequate technique on 5 taped interviews	Supervisor or Interviewer team leader	Annually, 1 taped participant interview	Supervisor or Interviewer team leader
Interviews: Socio-cultural	Adequate technique on 5 taped interviews	Supervisor or Interviewer team leader	Annually, 1 taped participant interview	Supervisor or Interviewer team leader
Interviews: Take Home	Adequate explanation on 5 taped introductions to participants	Supervisor or interviewer team leader	Annual review	Supervisor or Interviewer team leader
Interview: Exit	Adequate technique on 5 taped interviews	Supervisor or Interviewer team leader	Annually, 1 taped participant interview	Supervisor or Interviewer team leader
Medical Data Review	Local approval	Supervisor or PI	Methods reviewed annually during CC monitoring	Supervisor or Interviewer Team Leader
Results Reporting	Adequate technique on 5 reports	Committee Chair or Interviewer team leader	Annually, 1 complete review	Committee Chair or Interviewer team leader
Referrals and Review Guidelines	Adequate technique on 5 referrals	Committee Chair or Interviewer team leader	Annually, 1 complete review	Committee Chair or Interviewer team leader
Physician Reviews	Adequate technique on 5 reviews	Exam Investigator	Annually, 1 complete review	Exam Investigator
Participant Safety	Local review of safety procedures	Supervisor	Annual safety review	Supervisor
Follow-up: Annual Follow-up Interview	Local review of AFU procedures	Supervisor or Interviewer team leader	Annual rose Questionnaire Exercises annually	Supervisor or Interviewer team leader
Follow-up: Surveillance	Local review of surveillance procedures	Supervisor or Lead Records Administrator	Excercises annually	Supervisor or Lead Records Administrator

**Table 13. Certification Criteria: Baseline Visit 24-hour Exam Procedures**

24-Hour Tracking	Adequate completion of 5 tracking forms	Central Trainer or supervisor	Annually, 1 completed tracking	Central or Supervisor
Ambulatory Blood Pressure	Lead technician training Adequate explanation and cuff placement on 5 exams	Central trainer or Lead Technician	Biannually. Annual re-certification for Lead technician	Lead technician
24-Hour Urine	Lead technician training Adequate completion on 5 forms	Lead technician	Biannually @ Exam Center	Lead Technician
48-Hour Urine	Lead technician training Adequate completion on 5 forms	Lead technician	Biannually @ Exam Center	Lead Technician

**Table 14. Certification Criteria: Baseline Visit Sub-study Procedures**

Physical Activity Sub-study	5 Completed instructions to participants, monitor application and data download	JHS PA Study Investigator	2 Adequate annual completed cycles	JHS PA Study Investigator
Diet Sub-study	Completion of 2-day Delta NIRS training. Completion of 7 NDS 24-hour recall w/ final 2 taped with <6% error.	JHS Diet Study Investigator	Monthly quality assurance review with recertification exercises if fall below desired accuracy	JHS Diet Study Investigator

## 2.6 Reception

The reception workstation welcomes the participant to the clinic and initiates the baseline exam interviews and clinical measurements at the Exam Center. Prior to the participant's arrival, a baseline exam folder is assembled which contains labeled data collection forms: the Record of Calls and Scheduling (IRC) forms (these may also be filed in a separate, recruitment folder at the discretion of the Exam Center, but are available for use during the JHS exam), the Participant Itinerary Sheet (PIN), and blank copies of the JHS Baseline exam forms, the Fasting/Tracking (FTR) form and the Venipuncture (VEN) (data are collected on paper for delayed data entry) and the Medical History (MHX). Additionally, the Hassles and Moods is included for participant self-administration between work stations, if time allows. Folders also contain Report and Referral forms and ALERT/REFERRAL logs for use in baseline exam. The PIN is attached to the outside of the clinic visit folder.

On arriving at the Exam Center, the participant is greeted and welcomed. Travel reimbursement and participant payment information is obtained. Approach to Life and Health Care Provider Contact forms are collected and checked for completion. If incomplete, assistance is offered.

Informed Consent for the full JHS exam (see Appendix) is obtained before administering any other JHS interviews. Participant questions are answered. Demographic and tracking information (CON Form) are updated. Fasting status (Fasting/Tracking form) is determined. Consent to tape interviews for quality assurance assessment is requested and documented on the Itinerary sheet (see Forms Appendix). The Informed Consent Tracking form is completed either during or after the participant has left the reception workstation. Medication bags are logged and labeled.

General instructions on how to administer each interview are given in the text of Chapter 2 under the name of the data collection form. Specific instructions for completing each item on the data collection form are given in the question by question (QxQ) instructions that follow each individual form in the Forms Appendix.

The schedule for reporting the participant's study results can be reviewed with the participant at the reception workstation. The interviewer explains that some of the study results are reported at the conclusion of the exam before the participant leaves the Exam Center. Results of all studies done during the visit are reviewed by the JHS clinician after the participant has left the Exam Center (see Appendix). A final summary report is mailed to the participant and her/his health care provider (with her/his permission) 6 - 8 weeks after the clinic visit date, as described in Chapter 8 (RESULTS REPORTING). Letters are mailed to participants and her/his health care providers in conjunction with her/his final summary report when all study results are available, or prior to that when study results are found to be an alert value (Chapter 8, and Appendix).

When Informed Consent and the Fasting forms have been administered, the participant is shown where to change into an examination gown/robe, asked to remove all jewelry, and to place clothing and valuables in a secured locker.

Staff are trained for the reception workstation at central training and by the Clinic Manager at the Exam Center. Certification requirements include the successful completion of training on general interviewing techniques, Informed Consent, the Fasting/Tracking form, Direct Data Entry System. Although no formal certification schedule has been established, interviewers working at the reception workstation are observed by the Clinic Manager for quality assurance and standardization.

## 2.7 Informed Consent

Administration of Informed Consent precedes all other activities at the Exam Center. The core content and consent options of the baseline exam informed consent documents comply with the National Institutes of Health and the National Heart, Lung, and Blood Institute guidelines on the protection of human subjects, the American Society of Human Genetics' statement on informed

consent for genetic research and the approval of the JHS Steering Committee. The Institutional Review Boards of Jackson State University, Tougaloo College and the University of Mississippi Medical Center have approved the study protocol and informed consent procedures, maintaining annual review.

### **2.7.1 Rationale**

The primary objective of administering the baseline exam informed consent is to affirm that the participant understands (1) the purpose of the research; (2) what data collection procedures are used; (3) the risks and benefits of participation; (4) alternatives to participation (5) what procedures are in place to protect confidentiality; (6) that s/he is free to participate, refuse any procedure or answer any question, and to withdraw at any time; (7) and that withdrawing carries no penalties. The informed consent has a record of the project director and a contact person. Signing permits the participant to indicate her/his current preference for the use and disposition of study data, including genetic materials, and to change her/his preference at a future date; affirms permission to release clinically relevant study data to the health care provider of her/his choice, and gives the participant's permission to abstract her/his medical records in the event of hospitalization or death.

### **2.7.2 Administration**

The Informed Consent is administered as the first component of the baseline exam. The goals of JHS at the baseline exam are reviewed with the participant prior to the administration of any other data collection instrument. Consent to participate in the regular JHS examination (baseline exam) is documented on the informed consent forms (see Forms Appendix). Written, audio and visual consent forms are available. Time is allowed for the person to read and ask questions about the informed consent documents in a confidential setting. If the participant is visually handicapped or otherwise incapable of reading the study description and informed consent page, the narrative portion is read to her/him and then the person is asked to sign the document. The original Informed Consent documents are filed in the participant's JHS study folder. A copy of the informed consent and signature page is given to the participant.

### **2.7.3 Training**

Interviewers are centrally trained in general interviewing techniques and the goals and objectives of informed consent. The Clinic Manager or interviewer team leaders are responsible for providing staff training for new staff.

### **2.7.4 Certification**

Although there is no formal certification schedule, interviewers who administer informed consent are observed by the Clinic Manager or interviewer supervisor.

### **2.7.5 Quality Assurance**

Routine quality assurance is provided at the Exam Center by means of observation by the Clinic Manager. Administrative techniques and adherence to protocol are also monitored at least semi-annually by Coordinating Center monitors; frequency distributions of consent preferences recorded on the Informed Consent Tracking form (ICT) are monitored by the Quality Control Committee on a semi-annual basis.

### **2.7.6 Data Collection**

Descriptions of the study and the signature pages acknowledging informed consent for the baseline exam are paper forms. The participant receives a copy of the full informed consent document and the signed consent statement. In all cases, the original signature page must be kept at the Exam Center and stored in the participant's JHS study folder.

## **2.8 Informed Consent Tracking (ICT)**

The Informed Consent Tracking (ICT) form is an internal form that applies to the consent given by cohort members to participate in the regular JHS study. It tracks each participant's type of consent (full or partial), restrictions on use or storage of DNA (yes or no), type of restrictions on DNA use or storage (CVD research, JHS only, no use/storage of DNA, other), other restrictions on procedures or use of study data (yes or no), type of restrictions on procedures or use of study data (CVD research, JHS only, other), restrictions on release of results to participant's health care provider and permission to access medical records and birth certificate. The form is completed by JHS staff, and NOT administered to participants.

### **2.8.1 Rationale**

The purpose of the form is to document and track in the JHS central database the initial level of, and subsequent (if any) changes to, participants' restrictions on the use of her/his study data, including DNA, by JHS investigators.

### **2.8.2 Administration**

Items 1 - 10 on the ICT form are completed by an interviewer at the reception workstation after participants have read and signed the baseline exam Informed Consent form. Items 11 through 16 are completed when a participant notifies the study of a desire to either change her/his type of consent or access to medical records, or to withdraw from the study. QxQ instructions are provided in the Forms Appendix.

## **2.9 Fasting Tracking (FTR)**

The Fasting Tracking (FTR) form is a core data collection form which confirms the participant has had nothing to eat or drink for 12 hours before the baseline visit. The form is administered at reception and documents the participant's fasting status and establishes the participant's official visit date for the baseline exam.

### **2.9.1 Rationale**

The participant's fasting status affects the measurement of glucose, and the lipid and hemostatic profiles. To standardize measurements, participants are requested to take nothing by mouth except water for 12 hours prior to arriving at the Exam Center.

### **2.9.2 Administration**

The FTR is completed for all participants during the reception for the baseline exam. QxQ instructions for administering the FTR form are provided in the Forms Appendix. The participant's fasting status is verified. Strict fasting is defined as nothing taken by mouth, except water, for the preceding 12 hours. However, for purposes of results reporting of the clinical chemistries, participants can be considered fasting if they have fasted for at least 10 hours or if they have ingested no more than one cup of black, unsweetened coffee/tea within the past 10 hours. Ingestion of more substantive liquids or solids constitutes breaking the fast. The participant's fasting status is recorded in number of hours on the FTR form, but the consumption of coffee/tea is recorded in a note log.

Blood samples are drawn on all participants, regardless of fasting status. If the participant has not fasted for 10 hours, the participant is also offered the opportunity to repeat blood drawing in the fasting state at a later date. The FTR is completed; the non-fasting state and rescheduled date of venipuncture are noted on the Participant Itinerary Form. When the participant returns in the fasting state for venipuncture, the questions concerning fasting status and recent blood donation on the FTR

form are updated, and the Lipid and Hemostasis laboratories are notified that replacement samples are being shipped (See Manual 10, Specimen Collection and Processing).

The FTR form also documents whether the participant has given blood within the last 7 days. It is assumed that very few cohort members will have donated blood within the last week as they are reminded during both the scheduling calls not to do so, or to reschedule her/his clinic visit if they have had to give blood. Recent donors are not rescheduled once they come for baseline exam; the response to question 5 on the Fasting/Tracking form is recorded to reflect the recent blood donation and the individual is sent to the venipuncture workstation.

## **2.10 Family Structure Form (FST)**

See Manual 3: Family Study. The Family Structure Form (FST) is included in the Forms Appendix with QxQ instructions.

## **2.11 Medication Survey (MSR)**

The Medication Survey (MSR) is part of the core data collection instruments and is administered to all participants during the baseline exam. The survey covers the use of any prescribed or over-the-counter medications, including vitamins, mineral supplements or other herbals or home remedies, used within the two weeks prior to the participant's interview as well as the current and regular use of aspirin and non-steroidal anti-inflammatory drugs in the JHS population. It also queries usual medication – taking practices of participants.

### **2.11.1 Rationale**

The goal of the MSR is to ascertain medication usage by coding prescription and nonprescription drugs, home or folk remedies, used by the respondent within the two weeks preceding the interview. This information assists in measuring patterns of medication use in the study communities, temporal changes in medical care practice, diagnostic classification of cardiovascular diseases, interpretation of laboratory results, and predictors of study end points. A second goal is to document individual medication-taking practices to assist in determining adherence to prescribed regimes.

### **2.11.2 Administration**

The MSR is divided into five major sections. QxQ instructions are located in the Forms Appendix. During reception, the interviewer determines and records in Part A of the form whether the participant has brought in all medications taken within the last two weeks. Identification labels are placed on the participant's medication bag and MSR form. If the participant has not brought in any (all) medications, inquiries are made to differentiate between non-compliance with pre-visit instructions or non-use of medications in the prior two weeks. In case of inadvertent omissions, arrangements are made for obtaining the information, usually by telephone interview. The deliberate omission to bring medications to the Exam Center is recorded on the MSR and on the Participant Itinerary Sheet (Forms Appendix) and conversion is attempted later with the participant during the review of medical data. Subsequent parts of the MSR can be administered during reception (if the area affords the opportunity for maintaining confidentiality) or later, by trained interviewers or the JHS nurse/clinician in areas in the Exam Center usually designated for conducting interviews.

Before starting Part B of the MSR, the name on the medication bag is checked against the name on the MSR. Medication containers are removed from the participant's medication bag and the medication name and concentration are transcribed into column (a) of Section B on the form. Medications that are not in a container are examined only in front of the participant, with her/his permission. When there are more than 26 medications, recording the name and concentration is continued on the back of the page if a paper form is used. If the Medication Survey DES form is used and more than 26 medications need to be entered, the name and concentration of the additional medications are written on a piece of paper labeled with the participant's ID, and filed in the

participant's folder for future coding. See below for coding instructions. If the name of the medication exceeds the number of fields in the DES, the name is abbreviated on the screen.

When more than 26 medications have been recorded, the priority algorithm for data entry and coding of the medications is as follows: prescription medications first; aspirin and aspirin-containing medications (aspirin, Alka Seltzer, headache powders, cold medications, medication for arthritis, etc.); anti-inflammatory drugs (ibuprofen, Motrin, Nuprin, etc.); then over-the-counter-medications, followed by vitamins and food supplements.

To administer Parts B and C, a trained interviewer or the JHS nurse/clinician shows each container of medication to the participant, transcribes its name in column (a) of Section B (MEDICATION RECORDS), records medication's concentration in column (b), and asks and records in column (d) whether the medication was used within the last 24 hours.

When preparing to ask the participant about each medication, the interviewer removes all containers from the bag and sets them in front of the participant. As each medication is reviewed, it is shown to the participant while keeping the other medications in view. After the participant answers the questions for each medication, its container is placed back in the carrying bag to minimize confusion and to assure that all medications are returned.

The interviewer verifies the transcription of medication names and makes corrections on the paper (or DES) form as required. Use the American Drug Index and Physician's Desk Reference for unknown and incomplete names.

Part C of the MSR ascertains (1) whether any of the participant-reported medications were used to treat cardiovascular diseases or symptoms (high blood pressure; high blood cholesterol; angina; arrhythmia; heart failure; blood thinning; diabetes; stroke; intermittent claudication) or (2) whether aspirin or aspirin-containing medications were used in the last two weeks and the reason for her/his use; current, regular use (at least once per week for several months) of aspirin or other non-steroidal anti-inflammatory drugs.

Part D of the MSR ascertains any reasons the participant may have for not taking her/his prescription medications as prescribed. It also requests information on the participants current or regular use of either aspirin or non-steroidal inflammatory agents.

Part E asks the participant to identify any folk medicine, herbals, roots or teas that they may have used for medicinal purposes in the last two weeks. A separate question ascertains whether such remedies have ever been used and for what health-related reason.

### **2.11.3 Certification**

Certification to administer the MSR is achieved by the demonstration of adequate technique on 5 taped interviews, reviewed and approved by the supervisor or interviewer team leader. Re-certification is required annually, and requires the successful completion of one taped interview of an actual participant. This tape is included in the round robin that is reviewed by the four interviewer supervisors selected to monitor each year's round robin tapes.

Separate certification is required for medication coding, based on a minimum of 80% correct responses on the certification test provided by the Coordinating Center and administered at central training. Re-certification for medication coding is also required annually. For the Medication-Coding Specialist, this includes coding a set of selected medication names circulated for this purpose and adequate performance on blinded re-coding of medications recorded during the previous year. Re-certification criteria for medication coders require meeting minimum standards of coding repeatability (by interviewer/transcriptionist) and a review at the Coordinating Center of the accumulated performance on quality control repeat medication coding.

#### **2.11.4 Quality Assurance**

For each person certified to code medications a ten percent sample of medication coding records is identified by the Coordinating Center for blinded repeat coding at the Exam Center.

#### **2.11.5 Data Collection**

The six digits medication code numbers are listed in a hard copy or DES version of the Medication Coding Dictionary. The Medispan code in part (c) can be matched to the drug name while transcribing the name of the drug in part (a) into the DES screens, or can be ascertained later. Drug names are listed alphabetically. The medication code of a drug not listed in the dictionary is left blank, and its status code is always set to "Q" (questionable) so that the pharmacist at the Coordinating Center can develop a code number and update the dictionary. Detailed instructions for coding medications are provided in the QxQ instructions for the MSR.

### **2.12 Medical History (MHX)**

The Medical History (MHX) form is a core data collection form, administered during the flexible component of the baseline exam. In the baseline examination it serves to assess potential sleep apnea or other sleep disturbance as well as a number of specific cardiovascular symptoms. Chest pain, possible infarction, intermittent claudication (peripheral vascular disease), and congestive heart failure are each detailed. The occurrence of the participant-reported chest pain is confirmed as positive angina and/or myocardial infarction by London School of Hygiene criteria. The questionnaire also documents the occurrence of procedures to diagnose or treat cardiovascular disease as well as current or ever renal dialysis.

#### **2.12.1 Rationale**

A major objective of the JHS is the assessment of CHD in the study population at each clinical examination and across time from the baseline examination. This is done, in part, by the documentation of the symptoms of heart disease and exposure to diagnostic and therapeutic procedures of each participant at each visit and annual follow-up call. Another objective is a similar assessment of peripheral vascular disease (PVD). Questions on claudication provide baseline information on PVD symptoms. Another major contributor to CHD is sleep apnea. Data also suggest a relationship between sleep quality irrespective of sleep apnea, as a correlation with CHD.

#### **2.12.2 Administration**

The MHX form is administered by trained and certified interviewers with an understanding of the medical terms and diagnostic procedures referred to in this instrument. The frame of reference for questions in section A (chest pain on effort) and sections B and C (invasive/non-invasive diagnostic and therapeutic cardiovascular procedures) is the time period prior to the JHS baseline. Detailed procedures for administering the form are provided in the QxQ instructions immediately following the form in the Forms Appendix.

### **2.13 Respiratory Symptoms (RSF)**

The Respiratory Symptoms form (RSF) is one of the core data collection instruments to assess symptoms of cough, wheezing, breathlessness and asthma administered during the flexible component of the baseline exam. The instrument was adapted from the Adult Respiratory Symptoms Questionnaire and is a condensed version of the questions on respiratory symptoms asked in the Respiratory Symptoms/Physical Activity form during ARIC Visit 1.



### **2.13.1 Rationale**

Relevant questions on respiratory symptoms are necessary for the analysis of the pulmonary function tests.

### **2.13.2 Administration**

The RSF form is administered by certified interviewers. Questions are taken directly from the Adult Respiratory Symptoms questionnaire. Interviewers are instructed to read each question as printed and accept unequivocal answers as provided by the respondent. The wording of the questions and the instructions by the interviewer before starting the interview lead to simple “yes” or “no” answers. Probing is limited to repetition of the question when possible, and equivocal answers are recorded as “no.” Detailed QxQ instructions are specified in the Forms Appendix.

## **2.14 Stroke (SSF)**

The Stroke Symptoms Form (SSF) is one of the core data collection instruments to assess the symptoms of stroke and transient ischemic attack. The interview is administered during the flexible component of the JHS exam.

### **2.14.1 Rationale**

Stroke and transient ischemic attack (TIA) are identified as end points in the JHS study. A baseline history of stroke symptoms will be collected during baseline exam.

### **2.14.2 Administration**

The SSF administered by certified interviewers. Positive symptoms are recorded during the standardized interview along with her/his speed of onset, duration, and co-morbid manifestations. QxQ instructions are in the Forms Appendix. Section A of the form documents the participant's medical history of a stroke. The subsequent sections cover six neurologic symptoms which are associated with strokes and TIAs and are administered in a standardized format. Descriptors of the neurologic symptoms (earliest, longest and worst) often require probing, but the definitions are left to the respondent.

## **2.15 Reproductive History (RHX)**

The Reproductive History form (RHX) is administered to female cohort members during the flexible component of the exam. The objective of this questionnaire is to determine the menopausal status, the use of exogenous gonadal hormones and to obtain her history of gynecological surgery.

### **2.15.1 Rationale**

The questions on menstrual patterns and hormone use have been developed to help establish with more certainty whether menopause has taken place. Questions addressing exogenous gonadal hormone exposure are used because of the belief that they may play a role in the development of atherosclerosis.

### **2.15.2 Administration**

The RHX is administered by certified interviewers within the flexible sequence of the participant examination. Detailed instructions for administering each question are provided in the QxQ instructions. Questions on menstrual history and the use of female hormones may be considered sensitive by participants and care must be exercised to administer each section in a nonjudgmental format.

The questionnaire is divided into 3 sections: (1) recent menstrual history and onset of menopause; (2) the use of exogenous hormones, and (3) a history of gynecological surgery.

Item 1 is not read aloud. The response category is based on information printed on menopausal status on the PIN sheet. The majority of the questions on the form are closed-ended or pre-coded questions designed for direct entry into the computer by the interviewer. Open-ended questions are to obtain names of female hormones being used, age, or some other concept of time.

The exact wording and order of the questions is followed to ensure standardization. Questions are not skipped unless indicated by the skip pattern.

## **2.16 Delta Nutrition Intervention Research Initiative Food Frequency Questionnaire**

The Delta Nutrition Intervention Research Initiative (NIRI) Food Frequency Questionnaire (FFQ) will be administered during the baseline examination during the flexible sequence. This questionnaire will measure an individual's usual dietary intake over a six month time period.

The original FFQ was developed by the Delta NIRI staff and is in the process of being validated within the Delta region. It was critically reviewed by the JHS Diet Workgroup and is thought to be a robust diet instrument with significant potential for increased accuracy in the assessment of African-Americans. After extensive research (outlined in previous documents) the JHS Diet Workgroup voted to adopt the Delta NIRI (FFQ). At the request of the JHS diet workgroup Delta NIRI agreed to modify the original DELTA NIRI FFQ to accommodate the JHS participant burden requirement of 20 minutes to allow its use for assessment of diet patterns for the entire 6,500 member JHS cohort.

### **2.16.1 Background, Rationale and Hypotheses**

International variations of cardiovascular diseases (CVD) suggest that dietary and environmental influences can explain the CVD differences in Americans, rather than genetics (Fumo, et al., 1992; Cappuccio, 1997; Cooper, et al., 1997; Cooper & Rotimi, 1994; Cooper, 1993). The role of diet, particularly electrolyte cations in modulating hypertension, stroke, and cardiovascular diseases especially in African-Americans has led to a significant body of scientific investigation (Watson, et al., 1980; Kagan, et al., 1985; Sasaki, et al., 1995; Khaw & Barrett-Connor, 1987; Alderman, et al., 1995; Law, et al., 1991; Schmider, et al., 1988; Liu, et al., 1979; Grim, et al., 1980; Marmot, 1994; Law, et al., 1994; Gillum, 1979; Falkner, 1987; Grim, et al., 1980; Falkner, 1987).

Most past surveys failed to capture black-white differences in added fat or in fat food sources. As Cooper and Rotimi (1994) noted, many of these studies are driven by contrast of race and gene rather than public health concern. Kumanyika (1991) pointed out the conceptual and methodological pitfalls in the poor use and interpretation of the health differentials within the races.

In the Boston Validity Study, the Willett FFQ (62 items) was validated against four 1-week dietary records among 173 women in the Boston area. A moderate correlation was found in most nutrients (0.36 for Vit. A to 0.75 for Vit. C.) between these methods. Only a small percentage of this sample was African-American. Past studies demonstrated that regardless of race and sex, high educational attainment is associated with recommended dietary intake patterns. Intake differences could not be separated from race to assess if differences were due to racial or regional influences.

Urban and international studies (Vaughan and Miall, 1979; Bunker, et al., 1992; Mufunda, et al., 1993; Adams-Campbell, 1993; Kaufman & Barkey, 1993; Hackland, 1982) reported that rates of hypertension were attributed to stress in urban life or high dietary sodium.

Although an absolute "gold standard" does not exist, and even with documented flaws (Ness, et al., 1997), FFQs are commonly used in epidemiologic research on diet and disease to assess the usual food or nutrient intakes of individuals. There is substantial variation among the few African-American focused studies that exist which raises questions about the ability to draw comparisons across

populations (Stampfer & Rimm, 1996). To be effective in addressing the “epidemic” of high blood pressure a population approach addressing lifestyle factors such as diet and nutrition is critical (Frishman & Sonnenblick, 1992). The dietary assessment method selected for study of a population must be sensitive to the culture being investigated (Traber & Packer, 1995; Boushey, et al., 1995).

Specific areas needing further investigation include (1) diet determinants for obesity (Kumanyika, 1992; Kumanyika, et al., 1992 & 1993; Kumanyika, et al., 1995; Kumanyika, 1993 & 1987; Kumanyika & Charleston, 1992), (2) the relationship between obesity and cardiovascular disease risk (Grim, et al., 1980; Jones 1998), (3) the etiology of obesity-associated hypertension, (4) the variation in the influence of sodium in hypertension (Liu, et al., 1979; Hixson, 1990; Simmons, et al., 1983; Carvalho, et al., 1989; Naiker, 1998; Miller, et al., 1983; Witteman, et al., 1989; Sower, et al., 1988; Falkner & Kushner (1990); Sower, et al., 1988; Lever, et al., 1981), (5) the effects of free radicals versus antioxidants and homocysteine relationships.

Over the past year, the Lower Mississippi NIRI Food Frequency Working Group has developed a specialized food frequency questionnaire for use in the assessment of “usual intake” of the participants (Nutrition Assessment Survey) NAS Part II. The FOODS data set was analyzed at the Tufts Human Nutrition Research Center (HNRC) to identify the major food contributors to intake of each nutrient and to document the distribution of portion sizes. Based on this information, a form was drafted by a model used previously at Tufts HNRC for a FFQ for use with Hispanics (Puerto Rican Study) that was originally modeled on the Block FFQ. This draft form was reviewed, evaluated and revised by the Delta NIRI FFQ Working Group, where specific names of foods, portion size assumptions and cooking adjustment questions were adapted to cover the likely food intakes in the Delta.

The Delta pilot data used to produce and verify the food list resulted from telephone-administered 24-hour recalls from adults in the Delta (including Mississippi). This pilot revealed the need for portion size adjustments for some items (especially snacks and soft drinks). Open-ended techniques are being considered for some items with highly variable portion sizes. The desire of the Delta group to automate the FFQ and the additional administration and processing time that will be required to accommodate open-ended components are all being considered. Many items will retain the original small, medium and large approach for portion estimation. Items heavily used with a wide variation in portion sizes will have up to 4 more specific choices.

Because the food list and average portion sizes were actually developed with Mississippi Delta participants, it was felt to be the most “robust” instrument with the greatest outcome potential. A shortened version of this instrument was developed for use and validation in the JHS.

The following research questions will be considered for investigation:

#### 1. Classic “diet-heart” hypothesis

Does high intake of saturated fats and cholesterol and low intake of polyunsaturated fats increase the level of serum cholesterol, lead to the development of CVD?

Do dietary intake behaviors of African-Americans within the JHS differ significantly by age, gender, educational level or socioeconomic status?

#### 2. Role of Dietary Sodium and Potassium in Cardiovascular Disease:

What is the role of increased dietary sodium and decreased dietary potassium in hypertension and target organ injury in African-American?

Is the relationship between stroke and sodium intake explained by high blood pressure?

Is the relationship between left ventricular mass and sodium intake explained by high blood pressure?

Does dietary or supplemental potassium intake correlate with blood pressure control in African-Americans with hypertension?

### 3. Diet Determinants of Obesity:

Is there a gender-specific association between energy and macronutrient intake with levels of obesity in the JHS cohort?

Are there diet intake behaviors that are associated with increasing levels of obesity in JHS participants?

### 4. Role of Fiber Consumption in Coronary Heart Disease Risk:

What are typical fiber consumption practices of African-Americans?

Do African-Americans consume fiber at levels recommended to decrease her/his risk for CHD?

What effects on plasma lipids or plasma glucose levels are documented at various levels or with different forms of fiber intake?

### 5. Positive Impact of Folic Acid in Reduction of Homocysteine Levels and Reduced CHD Risk:

Do levels of folic acid and other B vitamins consumed by JHS participants correlate with individual plasma homocysteine levels?

Is there a relationship between consumption of folic acid and socioeconomic status in JHS participants?

### 6. Role of Antioxidants in Decreasing CVD and CHD Risks:

Are intakes of antioxidants (Vitamins C & E, carotenoids) associated with the development of CVD or CHD risk factors?

If so, are these associations due to antioxidant intakes from diet or supplements?

### 7. Investigation of the impact of socioeconomic status on dietary practices:

Do dietary intake behaviors of African-Americans within the JHS differ significantly by age, gender, educational level or socioeconomic status?

Is there a significant association between dietary or supplemental intake of antioxidants (Vitamins A, C, E) and socioeconomic status of JHS participants?

## **2.16.2 Administration**

This first page of the FFQ consists of demographic information that will be completed prior to the interview by JHS staff. Participants will be asked to provide information on both the frequency and portion of her/his usual intake of food items listed on the FFQ. Cue cards with frequency measures and standard portions will be used during the interview to prompt and remind participants of her/his choices. Selected food models will also be available to provide additional support for portion estimations. Detailed instructions for administering questions on this FFQ can be found in the QxQ instructions (see Forms Appendix).

## **2.16.3 Quality Assurance**

1. 5-10% random data checks will be done for the original FFQ forms. Checks for missing data and for unusual portion sizes will be made.
2. Checks of the dataset will be made by batch for outliers, with nutrient totals, gram weights, frequency and serving sizes for both the recalls and FFQ.
3. Comparison of mean intakes from the recall and the FFQ will be done every 6 months.

#### Transfer nutrient analysis to Jackson Heart Study

Every 6 months a SAS transport file will be generated by Tufts, which will include daily totals of the recalls and FFQ. This will be sent to JHS Coordinating Center electronically.

#### **2.16.4 Data Collection**

The Delta NIRI FFQ will be administered by JHS interviewers who have completed a required training program. The Delta FFQ will be completed as a paper form. At the completion of each interview, the interviewer will review the form for completeness and clarify any areas of concern. Dietary data will be grouped into batches. Each batch should include completed FFQ on 50 participants. A name should be given to each batch and each record should have a unique identifier designed to identify the participant and the encounter. For example: the first batch would be batch "01" and so on. A data management roster should keep track of the batch names and what participants are in each batch. This will be done in Microsoft Access according to guidelines provided by Tufts.

Once the interviewer completes her/his review, the FFQ will be placed in the batch file for an additional quality assurance check by the nutrition monitor. Once approved by the nutrition monitor, questionnaires will be sent for scanning to Tufts University. A quarterly mailing will be sent to Tufts where each will be scanned and the diet data collection stored in a SAS data set for future analysis.

##### 1. Checking Data (before sending to Tufts)

All FFQ will be reviewed for missing data, bends, rips, folds, stray marks, or incomplete erasures before sending to Tufts. If there are missing data in the FFQ, JHS staff should contact the participant for complete data. If the participant is unable to answer or can not be contacted then the missing data should be recorded as "never eaten" and specific notes to this effect kept for future reference. Please note: all data must be filled in to get a complete FFQ analysis.

##### 2. Sending Dietary Data to Tufts

JHS staff should send batches of 50 completed FFQs to Tufts on a quarterly basis. Up to 12 batches (600 FFQs) can be sent at one time.

#### **2.17 Alcohol and Drug Form (ADR)**

The Alcohol and Drug Form (ADR) is a core data collection form administered during the flexible component of the baseline exam to document alcohol and drug abuse. It uses questions from ARIC and several other large epidemiologic studies to provide general information about whether the participant has ever used alcohol and several other substances. Information obtained about alcohol will allow classification of participants into lifetime abstainers, ever users, and users during the past 12 months. It will assess preferred beverage, history of heavy use (yes/no), and provide quantity-frequency information about alcohol intake during the past 12 months. The information about drug use will allow classification into lifetime abstainers, ever users of cocaine or other drugs and provide an estimate of total number of cocaine uses. This form is not designed to be sufficient to allow for assessment of dependence or history of dependence for alcohol or other substances and will not provide lifetime quantitative data about total alcohol or drug exposure.

The sources for each item are shown in Table 15 below.

**Table 15. Sources for each item in the Alcohol and Drug Form**

ITEM	SOURCE
Alcohol Item 1	ARIC
Alcohol Item 2	ARIC, 18b. from PHXB
Alcohol Item 3	NHANES3
Alcohol Item 4	ARIC
Alcohol Item 5	NHANES3
Drug Item 6	NHANES3
Drug Item 7	NHANES3
Drug Item 8	NHANES3

### **2.17.1 Background, Rationale, and Hypotheses**

The association of alcohol to CVD risk has been examined in many studies, but some of the findings remain controversial (Hanna, 1997). The lowest CVD death rates appear to occur with light to moderate alcohol intake (about 1 drink per day). Higher death rates are observed in nondrinkers (individuals who have never consumed alcohol as well as those who quit drinking) and individuals consuming more than 2 or 3 drinks per day (Fuchs, et al., 1995; Klatsky, Armstrong, & Friedman, 1992; Klatsky, Armstrong, & Friedman, 1997); Thun, et al., 1997). Plausible mechanisms for the beneficial effects of light to moderate drinking, including increased HDL cholesterol and an antithrombotic effect, have been proposed and are supported by epidemiologic data. Yet many investigators remain concerned about the potential bias (i.e., the confounding of nondrinking controls with people who quit drinking after becoming ill and of subgroups with light-moderate intake with relatively affluent, well-educated adults with healthier lifestyles). Despite all the attention to the “beverage effect” in the popular media, the evidence that wine (and particularly red wine) is more cardioprotective than other beverages is not consistent or strong when total ethanol and other factors are controlled (Klatsky, et al., 1997).

A number of epidemiologic studies have confirmed an association between alcohol and hypertension risk when the level of drinking exceeds 1 or 2 drinks per day. A large prospective study found rates of death from all CVD were 30 to 40 percent lower among men and women reporting at least one drink daily than among nondrinkers, with little relation to amount of alcohol consumed. An earlier study of 72,000 Kaiser Permanente health plan participants which included 30% Blacks found no differences by race in the U-shaped relation of alcohol use to coronary disease (Klatsky, et al., 1992). This group (Klatsky, et al., 1997) also reported on a prospective case-cohort study of risk for CAD hospitalization almost 129,000 members of a northern California health plan; about 20% of the participants were African-American. Each beverage type showed evidence of CAD protection, but these investigators concluded there may be some additional benefits from beer and red or white wine.

About 20 to 30% of cardiomyopathy cases are attributable to chronic alcohol use (Secretary of Health and Human Services, 1994). Cardiac arrhythmias are frequently associated with acute alcohol intoxication and/or prolonged drinking at the level of 6 or more drinks per day (Regan, 1990), and may at least in part explain the increased risk of sudden death associated with heavy drinking. Compared to healthy controls, alcoholic men presenting for outpatient treatment had significantly

lower mean ejection fraction, dilation of the left ventricle, and increased left ventricular mass (Urbano-Masquez, et al., 1989). Cardiac dysfunction has been demonstrated, even in the absence of malnutrition or severe social consequences, in a third of asymptomatic alcoholic men (Regan, 1990).

In comparison to alcohol use, there are as yet few studies of the association between cocaine and other "street" drugs with CVD. Cocaine use is associated with increased acute CVD risk, but limited evidence suggests it may not be an independent predictor of hypertension or renal disease (Braun, et al., 1997; Brecklin, et al., 1998). Illegal drug use may be related to personality characteristics and psychological states which are known to adversely affect CVD risk.

### Early Findings from ARIC

Folsom and others (Folsom, et al., 1991) examined ethanol intake in relation to plasma fibrinogen and factor VII in the ARIC cohort. An inverse association of Factor VII with ethanol intake was observed. Patsch, et al., found that alcohol consumption was associated with higher HDL cholesterol levels, with one drink per day associated with HDL increases of approximately 2.5 mg/dl in men and 7.5 mg/dl in women. These associations were essentially unchanged after adjustment for BMI, physical activity, smoking, and age. Demirovic, et al. (1993) reported the overall level of alcohol consumption in ARIC was low, with age-adjusted means for grams of ethanol per week 72.0 for white and 74.3 for nonwhite men and 24.8 for white and 11.2 for nonwhite women. After adjustment for age, artery depth, education, BMI, physical activity, smoking, LDL, and diabetes, the only race-sex group in which an hypothesized relationship between alcohol consumption and carotid wall thickness and distensibility was observed was in white women; however the significance was borderline. Duncan, et al. (1995) examined beverage-specific effects of alcohol on waist to hip ratio in the ARIC cohort. They found a reasonably graded increase in the waist-hip ratio with increased proportion of ethanol intake from beer or liquor (versus wine), which was most pronounced in individuals with BMI < 25. The findings were similar across race-gender categories. The authors noted that very few modifiable factors have been found which impact waist-hip ratio, and suggested that the observed effect may be one of the mechanisms mediating the cardioprotective effect of wine. However, they also acknowledged the likelihood of differences in diet, drinking pattern (e.g., slowly, with meals), and other factors between wine and nonwine drinkers.

### Method of Alcohol Use Assessment in ARIC

Information on alcohol use was obtained at each visit by trained interviewers. 10 items queried whether the participant had ever used alcohol; whether s/he currently used alcohol (if not, how much time had elapsed since the most recent use); the current weekly intake of 4 oz. glasses of wine, 12 oz. cans of beer, and/or 1.5 oz shots of liquor in total drinks; and number of days each week when liquor was consumed. This would allow evaluation of effects of 1) total ethanol consumed 2) the pattern of drinking and 3) type of beverage. Several ARIC items have been retained for JHS Alcohol and Drug Form. Drug use was not assessed in ARIC.

Hypotheses include:

1. There will be a J- or U-shaped association of alcohol intake and CVD with abstainers having greater risk than minimal drinkers, and increased risk beginning with the average of 3-5 or more drinks per day.
2. Greater alcohol intake will be associated with other indications of inadequate coping and/or high levels of perceived stress and more dysfunctional psychological status.
3. Association of alcohol intake with CVD will be moderated by type of preferred beverage.
4. A history of heavy drinking during the 12 months preceding the examination (more than 2-3 drinks/day) will be associated with greater CVD risk.

5. Cocaine and other drug use will be associated with increased CVD risk.  
Number of times of crack or cocaine use will be associated with demographic and sociocultural CVD risk factors.

## 2.17.2 References

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### 2.17.3 Administration

The ADR is administered to all participants during the baseline examination immediately following the food frequency assessment. There are 5 questions about alcohol use, followed by 3 items on drug use. The participant must have sufficient privacy to feel comfortable talking honestly about her/his substance use. Response cards with photographs of commonly used alcoholic beverages and “street” names for drugs will help participants understand the types of substance use we want to know about. Interviewers must be knowledgeable about different quantities and types of alcoholic beverages (for example, a “fifth” of whiskey) to accurately assess amounts reported. It is important not to make assumptions. If the participant says, “one half a beer,” ask questions until you are certain of the size of the bottle or can s/he was referring to. Detailed instructions are included in the QxQ instructions following the ADR form in the Forms Appendix.

## 2.18 Discrimination (DIS)

The Discrimination Form (DIS) is a core data collection form administered during the flexible part of the baseline examination to document racial discrimination experiences. This includes the participant’s attributions, day-to-day experiences, major life events, and coping/responses to racial discrimination. Jackson, et al. (1996) concluded key dimensions include racism as major and minor stressors, perceptions of racism, responses to racism, and indicators of institutional racism. No single instrument assesses the multiple dimensions. A multidimensional measure of racism that captured these key elements has been adapted from the Discrimination Scale (Kreiger, 1990), the Everyday Racial Discrimination Questionnaire (Williams, 1997), and the Perceived Racism Scale (McNeilly, et al., 1996).

### 2.18.1 Background, Rationale, and Hypotheses

Several studies have found that exposure to racist provocation in the laboratory setting leads to increased cardiovascular and psychological reactivity (Anderson, et al., 1989; Armestead, et al., 1989). There is some evidence from epidemiologic and other studies that perceived discrimination may adversely affect health as well as blood pressure (Dressler, 1990; James, 1984; Thompson, 1996; Williams, 1997; Krieger, 1990; Krieger & Stanley, 1996), while others found no association with hypertension and cardiovascular disease (Broman, 1996). The inclusion of a measure of discrimination in the JHS will allow for further investigation of whether discrimination, as a source of psychosocial stress, contributes (directly or in interaction with other sociocultural measures) to the development of hypertension, CVD and subclinical markers of LVH, carotid wall thickness, etc. If perceived discrimination proves to be related to the development and progression of CVD, it may be relevant to understanding race and SES discrepancies observed.

Development of discrimination measures is in its infancy though a number of measures have been developed over the past several years. In particular, measurement issues have included attention to the acute, every day, and lifetime measures. Both major life domains as well as explicit exemplars (dimensions) have been offered. Three major measures were considered for the JHS: Krieger's questionnaire (used in CARDIA), Williams, et al. (1997) measure of everyday discrimination, and Mac Neilly's (1996) Perceived Racism Scale. By adapting these three measures, JHS captures information on acute, episodic, daily and lifetime discrimination. In addition, because some limited research suggests that coping strategies may modify the relation of discrimination to outcomes, a question on response to discriminatory situations is included.

Hypotheses include:

1. Perceived discrimination is associated with risk factors, sub-clinical and overt cardiovascular disease at baseline.

2. Among persons with similar degrees of sub-clinical and overt disease at baseline, those with higher levels of perceived discrimination will be at greater risk for subsequent CVD events over the course of follow up.
3. Perceived discrimination interacts with SES to modify the effects of other social stressors.

### 2.18.2 References

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### 2.18.3 Administration

The DIS is administered by certified interviewers during the flexible component of the baseline exam. Detailed instructions for administering each question are provided in the QxQ Instructions. The first portion of the DIS ascertains information on the participant's day-to-day experiences. The subsequent section gathers information on the participant's lifetime experiences, frequency of those experiences and the last time for the experience. The DIS consists of 20 multiple choice, yes/no, and fill-in-the-blank type questions.

The exact wording and order of the questions are followed to ensure standardization. Questions are skipped only when indicated by the skip pattern instructions. Because of the number of skip pattern instruction in this form, the interviewer needs to memorize the flow of the questions. Items in PARENTHESES, SHADED BOXES and/or CAPITAL BOLD LETTERS are instructions to the interviewer and are not read to the participant. The questions are read clearly using the exact wording on the form. The nature of the discrimination questions may be considered sensitive and care must be taken to ask the questions and to record the responses in a nonjudgmental manner.



### **3.0 PROCEDURES IN THE BASELINE EXAM CLINICAL EXAM**

#### **3.1 Introduction**

Chapter three presents a detailed description of the baseline examination components, and a reference to the pertinent manuals of the protocol for those examination procedures not covered in detail in Manual 2. Separate protocol manuals are available for baseline examination components that require lengthy description and technical specification, or are of intrinsic substantive interest as stand-alone documents.

#### **3.2 Ankle/Brachial Blood Pressure (ABB)**

See Manual 4, Blood Pressure. The Ankle Brachial Blood Pressure (ABB) is found in the Forms Appendix with QxQ instructions.

#### **3.3 Anthropometry (ANT)**

Height, weight and body size are measured during baseline exam. All measurements are recorded on the Anthropometry form (ANT) (see Forms Appendix). Procedures for measuring the height, weight and waist and neck girths are provided below. Separate instructions for completing the data collection form are provided in the ANT QxQ instructions (Forms Appendix). At the option of the Exam Center, the circumference of the right upper arm (to determine blood pressure cuff size) can also be measured at this workstation and recorded on the sitting blood pressure form.

##### **3.3.1 Rationale**

Obesity is a risk factor for cardiovascular disease. Height, weight, body mass index, and girth measures provide easily attained indicators for obesity and body fat distribution.

##### **3.3.2 Procedures**

Anthropometry is performed before the clinic snack and after the participant has changed into a scrub suit or examination gown and been given the opportunity to empty her/his bladder. All measurements are made with the participant wearing light-weight, non-constricting underwear. Participants wearing nylon hose or other forms of constricting undergarments are instructed to remove them. Weight and height are measured without shoes. Technicians complete the procedures on every participant by following the general checklist for performing anthropometric measurements (Forms Appendix).

All anthropometric measurements are taken by either a team of two persons (one serving as observer; the other as recorder) or by one technician using a full length mirror to aid in the appropriate placement of the tape measure to record the girths. Using the team approach, the observer calls out the name of the next measurement, takes the measurement, and keeps the measuring instrument in place until the recorder repeats the number. The recorder checks the position of the examinee and verifies the horizontal placement of the measuring instrument during each procedure, and records the result. When a single technician performs the measurements, s/he verifies the horizontal placement of the measuring instrument (using the mirror when appropriate) for each measurement and records each measurement immediately after it is taken.

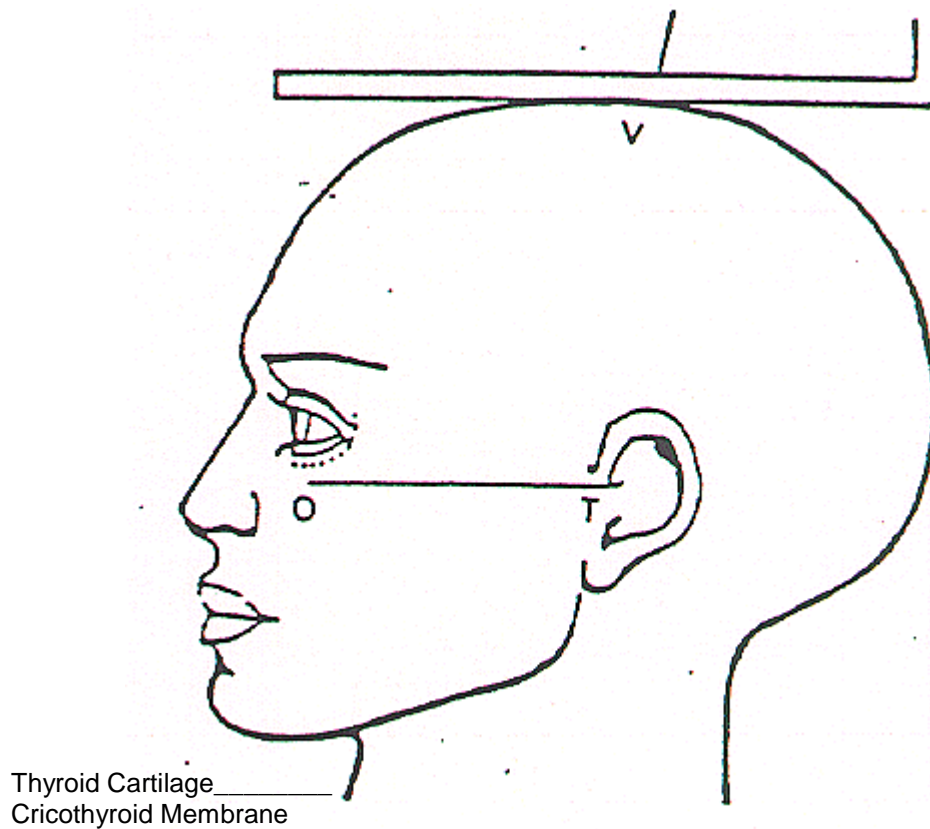
##### **3.3.2.1 Standing Height**

The participant stands erect on the floor or the horizontal platform with her/his back against the vertical metal centimeter ruler mounted on the wall. The heels are placed together and positioned against the vertical ruler. The participant is instructed to stand as straight as possible, but with feet flat on the floor. The participant looks straight ahead with her/his head in the Frankfort horizontal

plane (i.e., the horizontal plane which includes the lower margin of the bony orbit -- the bony socket containing the eye -- and the most forward point in the supratragal notch -- the notch just above the anterior cartilaginous projection of the external ear) (Figure 1). The right angle is brought down snugly, but not tightly, on the top of the head. A footstool is used if the examiner is shorter than the participant, such that the examiner's view is level with the point of measurement on the head of the participant. The certified technician follows a checklist for height measurement (Forms Appendix) which outlines the procedures for checking the equipment and measuring the participant's height and enters study data on the Anthropometry form. The participant's height is recorded to the centimeter. The conversion chart in Table 16 is provided to assist in the converting to and from metric measures. A chart converting centimeters to inches is available for use in informing the participant of her/his height in inches (Table 17).

The height rule is observed weekly to see that it (a) touches the hard-surfaced floor or platform on which measurements are done, and (b) is perpendicular to the floor. This weekly check is recorded on the Anthropometry Equipment Calibration Log (see Appendix).

**Figure 1. Frankfort Plane for Measuring Body Height**



ORBITALE: Lower margin of eye socket

TRAGION: Notch above tragus of ear or at upper margin of zygomatic bone at that point

FRANKFORT PLANE: Orbitale-tragion line horizontal

THYROID CARTILAGE: Firm, cartilaginous prominence on neck

CRICOTHYROID MEMBRANE: Below thyroid cartilage

### **3.3.2.2 Body Weight**

Before a participant is weighed, the scale is balanced so that the indicator is at zero when no weight is on the scale. The scale must be level and on a firm surface (not a carpet). The participant is instructed to stand in the middle of the platform of the balance scale (Detector, model #437) with head erect and eyes looking straight ahead. Weight is adjusted on the indicator until it is balanced. Results are recorded to the nearest kilogram. A chart converting kilograms to pounds is available for use in informing the participant of her/his weight in pounds (Table 17).

To maintain accuracy, the scale is zero balanced daily and calibrated with a known weight (50 lbs) every week or whenever the scale is moved. The daily zero balance and the weekly scale calibration are documented on the Anthropometry Equipment Calibration Log (see Appendix). The scale is professionally calibrated and serviced annually. The certified technician follows a checklist for weight measurement (Forms Appendix) which outlines the procedures for checking the equipment and measuring the participant's weight and enters study data on the ANT.

### **3.3.2.3 Abdominal Girth**

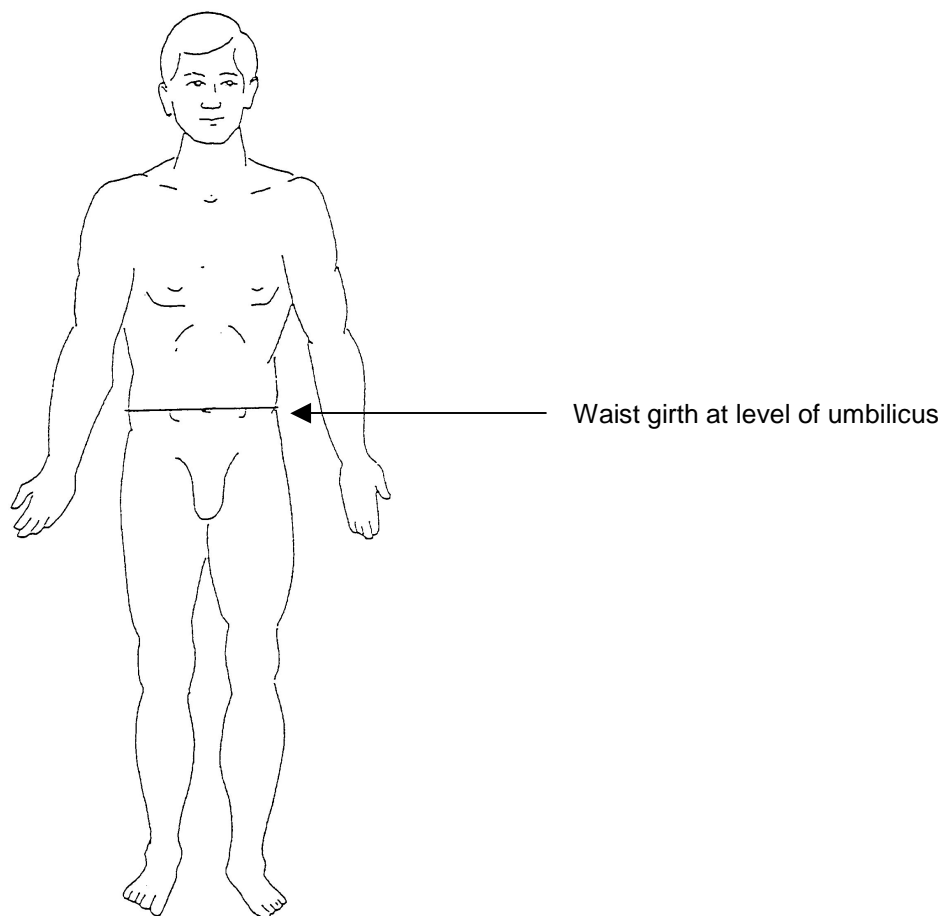
The participant is instructed to stand erect and relaxed with the feet approximately 6 inches apart and the weight equally distributed on both feet. The participant is asked to lift the scrub suit top just high enough to make the area visible (hands must not go above waist level). An anthropometric tape is applied at the level of the umbilicus (navel) and the participant is instructed to breathe quietly. The tape should be snug, but not so tight as to compress tissue (Figure 2). The full length mirror or recorder verify that the participant is standing erect and that the tape is horizontal. The measurement is recorded to the nearest centimeter at the point of relaxation end exhalation. The technician follows a checklist for the measurement of the maximal abdominal girth (Forms Appendix).

### **3.3.2.4 Neck Circumference**

The participant stands erect, looking straight ahead with the head in the Frankfort horizontal plane as described in sections 3.3.2.1 and illustrated in Figure 1. The examiner stands at the side of the participant on a footstool, if necessary, so that the examiner's view is at the level of the point of measurement. The examiner places the index and middle finger on the thyroid cartilage, commonly known as the "Adam's apple." The index finger should be at the point of greatest prominence of the thyroid cartilage. The tape is placed below the middle finger, approximating the level of the cricothyroid membrane. The tape is wrapped snugly at this level and is recorded to the nearest centimeter.



**Figure 2. Location of Waist Girth Measurement**



### **3.3.5 Quality Assurance**

In addition to annual recertification, protocol adherence in the performance of each procedure is reviewed at least annually by the by Coordinating Center monitors. Deviations from protocol and possible remedial actions are discussed with the Clinic Manager and staff at that time. Quality control observations of technicians by an observer are also performed biannually by Exam Center staff in January and July of each year and documented on the Report on Use of Observation and Equipment Checklist (see Appendix). These are sent to the JHS Coordinating Center for review. Major deviations from the protocol are brought to the attention of the Cohort Operations Committee.

Anthropometry equipment is calibrated frequently and results are recorded on an Anthropometry Equipment Calibration Log (see Appendix). Scales are zero balanced daily and calibrated weekly, or when moved. Measuring tapes are checked monthly and replaced as needed. The number of above measurements are recorded on the Report on Use of Observation and Equipment Checklist (see Appendix) and sent to the Coordinating Center biannually.

Digit preference, systematic differences in location statistics, completion of checklists/logs according to schedule are analyzed by the Coordinating Center. Important quality assurance/control measures analyzed include training/certification, instrument checks, random repeatability studies and biannual observations of technicians by other technicians and Coordinating Center monitors are monitored and reviewed by the Quality Control Committee.

### **3.3.6 Data Collection**

The ANT is collected by either the technician (observer) or recorder by direct data entry on a data entry screen or on a paper form (see Forms Appendix) for delayed data entry according to QxQ instructions.

**Table 16. Converting To and From Metric Measures****Conversion from Metric Measures**

Symbol	When you Know	Multiply by	To Find	Symbol
<b>Height</b>				
Cm	Centimeters	0.3937	inches	in
<b>Weight</b>				
Kg	Kilograms	2.2046	pounds	lb

**Conversion to Metric Measures**

Symbol	When you Know	Multiply by	To Find	Symbol
<b>Height</b>				
In	Inches	2.54	centimeters	cm
Ft	Feet	30.7	centimeters	cm
<b>Weight</b>				
Lb	Pounds	0.454	kilograms	kg

**Table 17. Body Size Measurements: Body Height in Centimeters and Inches**

Centimeters	Inches		Centimeters	Inches
122	48.0		165	65.0
123	48.4		166	65.4
124	48.8		167	65.7
125	49.2		168	66.1
126	49.6		169	66.5
127	50.0		170	66.9
128	50.4		171	67.3
129	50.8		172	67.7
130	51.2		173	68.1
131	51.6		174	68.5
132	52.0		175	68.9
133	52.4		176	69.3
134	52.8		177	69.7
135	53.1		178	70.1
136	53.5		179	70.5
137	53.9		180	70.9
138	54.3		181	71.3
139	54.7		182	71.7
140	55.1		183	72.0
141	55.5		184	72.4
142	55.9		185	72.8
143	56.3		186	73.2
144	56.7		187	73.6
145	57.1		188	74.0
146	57.5		189	74.4
147	57.9		190	74.8
148	58.3		191	75.2
149	58.7		192	75.6
150	59.1		193	76.6
151	59.4		194	76.4
152	59.8		195	76.8
153	60.2		196	77.2
154	60.6		197	77.6
155	61.0		198	78.0
156	61.4		199	78.3
157	61.8		200	78.7
158	62.2		201	79.1
159	62.6		202	79.5
160	63.0		203	79.9
161	63.4		204	80.3
162	63.8		205	80.7
163	64.2		206	81.1
164	64.6		207	81.5

**Table 18. Body Size Measurements: Body Weight in Kilograms and Pounds**

Kilograms	Pounds		Kilograms	Pounds
48	105.8		81	178.6
49	108.0		82	180.8
50	110.2		83	183.0
51	112.4		84	185.2
52	114.6		85	187.4
53	116.8		86	189.6
54	119.0		87	191.8
55	121.3		88	194.0
56	123.5		89	196.2
57	125.7		90	198.4
58	127.9		91	200.6
59	130.1		92	202.8
60	132.3		93	205.0
61	134.5		94	207.2
62	136.7		95	209.4
63	138.9		96	211.6
64	141.1		97	213.8
65	143.3		98	216.1
66	145.5		99	218.3
67	147.7		100	220.5
68	149.9		101	222.7
69	152.1		102	224.9
70	154.3		103	227.1
71	156.5		104	229.3
72	158.7		105	231.5
73	160.9		106	233.7
74	163.1		107	235.9
75	165.3		108	238.1
76	167.6		109	240.3
77	168.8		110	242.5
78	172.0		111	244.7
79	174.2		112	246.9
80	176.4		113	249.1

### **3.4 Echo**

See Manual 6, Echocardiography

### **3.5 Electrocardiogram**

See Manual 5, Electrocardiography

### **3.6 Sitting Blood Pressure**

See Manual 4, Blood Pressure. See Forms Appendix for Sitting Blood Pressure (SBP) form and QxQ instructions.

### **3.7 Spirometry/Pulmonary Function**

See Manual 8, Pulmonary Function Assessment

### **3.8 Ultrasound**

See Manual 7, Ultrasound

### **3.9 Venipuncture**

See Manual 9, Specimen Collection and Processing. See Forms Appendix for the Venipuncture (VEN) form and QxQ instructions. Exam Center (CXI) and Sample Shipping (SMP) Inventory forms are located in Forms Appendix.

### **3.10 Snack**

A light snack is scheduled as soon as possible after venipuncture. Caffeine-free refreshments are provided, including decaffeinated coffee and tea, fruit juices and reduced fat or skim milk. Menus are determined by the Exam Center staff, but will include heart-healthy alternatives.

## **4.0 24 HOUR MONITORING AND TAKE HOME QUESTIONNAIRE**

The final component of the baseline examination is a 24-hour post-examination monitoring of participant's ambulatory blood pressure and routine physical activity. Also included is collecting a 24-hour urine specimen and responding to a self-administered questionnaire to assess daily hassles and moods. Participants consenting to this 24-hour component of the examination will be fitted with a blood pressure cuff and waist-belt monitor, and a fanny-pack accelerometer and step counter. These monitoring devices will be initialized in the clinic and careful instructions provided to participants.

When possible, 24-hour urine collections will be initiated at the conclusion of the baseline examination before the participant leaves the clinic. Instructions for collecting urine until the same item on the following day will be provided. Individual arrangements will be made for participants who desire to delay the onset of these 24-hour measures. All participants will complete a set of take-home questionnaire to assess daily hassles, minor stressors and moods. All 24-hour measures will be picked up at a place that is convenient for the participant. If desired, participants may return monitors, samples, and questionnaires to the JHS clinic.

### **4.1 Ambulatory Blood Pressure Monitoring**

See Manual 4, Blood Pressure.

### **4.2 24-Hour Urine Collection**

See Manual 7, Specimen Collection and Processing.

### **4.3 24-Hour Physical Activity Monitoring**

Concurrent 24-hour physical activity monitoring (PAM) and ambulatory blood pressure monitoring (ABPM) will provide an objective measure of physical activity that, in the absence of participant diaries with information about activity preceding and during the cuff inflation, will aid in interpreting the blood pressure and heart rate data. Few studies have attempted such concurrent measurement, thus data from JHS will make a significant contribution to understanding the correlations between daily physical activity and blood pressure.

#### **4.3.1 Background, Rationale, Hypotheses**

See sections 1.6.4.8 and 11 for a full discussion of the background, rationale and hypotheses for physical activity questions and monitoring.

#### **4.3.2 Data Collection**

Data will be collected on all participants who agree to participate in the 24-hour ABPM. Participants will be instructed on the PAM equipment and will be fitted with (1) a CSA (Computer Science Applications, Inc, Shalimar FL) activity monitor (accelerometer) in its protective pouch and (2) a Digiwalker step counter, which are worn secured by a belt at the waist. The CSA monitor and step counter will be picked up 24 hours later by the JHS Sample Coordinator.

##### **4.3.2.1 Initializing Measurement Instruments, Collection and Downloading of Activity Monitor Data**

###### **4.3.2.1.1 CSA Monitor**

Prior to fitting the participant, the CSA monitor is initialized by connecting it to its host computer at the Exam Center and running the CSA software program for initialization. The instructions are pasted near the computer and activity monitor interface. The study staff member responds to queries to set

the date and time for beginning data collection and checks for the signal that the unit has been successfully activated. The monitor will then collect and store data at the intervals specified until it receives signals to download via the host computer interface. Data will be downloaded on return of the instrument to the Exam Center. To download, the CSA monitor is connected to its host computer using the interface equipment and the stored information is retrieved using the appropriate CSA software. The data file is given a unique name to allow linking of the data to the individual participant who wore the monitor. Detailed instructions for use of the accelerometer (CSA monitor), including initializing files and downloading data files using the computer interface, can be found in the CSA Monitor Manual supplied by the vendor and kept in the Exam Center. The PAM data will be stored on a dedicated computer with the CSA interface system and software, with the data backed up at least weekly on a zip disk and transferred at least every three months to the JHS CC.

To facilitate interpretation of the ABPM and CSA monitor data, the time on the ABPM should be set to match the time on the host computer for the CSA monitors. This will be done by setting the date and time on both computers to a designated Exam Center clock. Time synchronization will be checked weekly. Software developed by the manufacturer will be used to interpret the data collected during the monitoring period.

#### **4.3.2.1.2 Step Counter**

The step counter is initialized by setting the step counter to "0" just before fitting it to the participant. The participant will be instructed not to re-set the counter during the monitoring period. The total steps will be recorded when the step counter is retrieved by the Sample Coordinator.

#### **4.3.2.2 Participant Instructions and Fitting of Monitor**

Both the CSA monitor and step counter are worn on a belt fitted to the participant. The CSA monitor is worn to the right side and the step counter is worn to the left. The CSA monitor and step counter should be worn while awake except while bathing or swimming. To protect the electronics, the equipment should not be immersed in water and should be protected from excess heat and sunlight. The accelerometer (CSA monitor) will be programmed to record activity at one minute intervals. The participant will be unaware of the CSA monitoring as the instrument operates silently and there is no display to provide feedback. The step counter may click softly as the participant moves about, and the cumulative step count is visible when the case is opened. Participants will not be given feedback about the meaning of the step counts, such as what is a "good" number of steps to achieve. If they ask, they should be told that the purpose of the study is to help get answers to this question. Experts have not determined how many steps are related to healthy activity in women and men of different ages and body types.

Prior to leaving the Exam Center with the CSA monitor and step counter, the participant will be given an additional opportunity to ask questions or express concerns. S/he will be given a one-page 24-Hour Physical Activity Monitor Instructions sheet (see Appendix) summarizing information about when and how to wear the monitor and providing a contact number if needed. The participant can remove the step counter and CSA monitor to bathe and sleep or if necessary for other reasons by simply unfastening the belt clasp. No other action is required except placing the belt and monitors in a safe place where they will not be dropped, stepped on, or misplaced. The CSA monitor data will reveal quiescent periods when the monitor was not moved, so removal of the monitor can often be inferred from the data. The step counter data will be most valuable if participants can recall when they removed it and when they put it back on so that the cumulative step count can be adjusted for hours worn. Participants will be instructed not to take the CSA monitor out of its pouch. It is especially important that participants do not try to open the monitors because the electronics are easily damaged.

Arrangements will be made for the return (pickup) of the activity monitor the following day. Information documenting the explanation, participant agreement to wear the monitors, CSA and step counter monitor ID numbers initialization and time synchronization with the ABPM and the start time of PAM



are recorded on the Pre 24-Hour Activity Monitoring Form (BPA) (see Forms Appendix). Details for completing this form are contained in the QxQ instructions in the Forms Appendix.

#### **4.3.2.3 Monitor Retrieval**

A Sample Coordinator will pick up the accelerometer and step counter approximately 24-hours after fitting in the clinic. The Post 24-Hour Physical Activity Monitoring form (PPA) (see Forms Appendix) is completed to record the date and time of pick-up, any time the participant did not wear the CSA and step counter monitors, and any difficulties encountered. Detailed instructions for completing each item are included in the QxQ instructions in the Forms Appendix. The monitors are returned to the Exam Center for subsequent data downloading. Upon return of the instrument to the Exam Center, a trained staff or research associate will transfer the information to the host computer using the downloading procedure. Additional information will be entered on the PPA form at this time.

#### **4.3.3 Data Management**

Upon return of the instrument to the Exam Center, a study staff member will transfer the information from the CSA monitor to the host computer and name the data file so that it can be linked to the appropriate participant(s). This file name is entered on the PPA form. These individual participant CSA files will be named using the participant's JHS identification number as follows C[7 digit JHS participant number].dat.

Data from the CSA monitors will be initially stored and checked on the dedicated PAM computer. The investigator or a trained study assistant will do initial data screening. Downloaded data from the CSA accelerometer monitoring will consist of time markings associated with activity/motion readings. Software is also provided to calculate estimates of kilocalorie expenditure per unit of time while the monitor is worn. The CSA files will be read into Microsoft Excel for further analysis. The original and derived data files will be backed up at least weekly on zip disks and sent to the CC on a quarterly basis for merging with other JHS data.

An expert consultant experienced in the use of activity monitors in field trials will provide training to the individuals responsible for implementing the CSA PAM. Thereafter, the major investigator for this component of the study will direct the data reduction, oversee training for study staff who assist in this work, and certify their competency in these activities. Valid activity counts per time period will be examined in relation to other variables.

#### **4.3.4 Quality Control**

Following training, study staff will give return demonstrations of the procedure for the activity monitoring. The PAM principal investigator will certify them after 5 successful demonstrations. Thereafter the investigator will request unannounced demonstrations of the procedures at least every 6 months with re-certification to occur annually. One adequate complete execution of PAM will be required for re-certification. The investigator will review the CSA monitor data files on a regular basis to check the quality of the data. The software for the CSA instruments assists in filtering out data points that are incompatible with human motion.

The outer surface of the step counters will be wiped clean with isopropyl alcohol wipes between use by different participants. When necessary, the CSA monitors may be wiped clean with a soft cloth moistened in soap and water, or their surfaces can be sanitized using isopropyl alcohol wipes. They should not be immersed in liquid or subjected to corrosive substances. When necessary, the belts and protective pouches can be washed in cool water with a mild detergent and air-dried. Demonstration of procedures for maintaining equipment will be observed on a monthly basis by the Clinic Manager and reviewed annually as part of the re-certification requirements.

The CSA monitors will require battery replacement, typically after 9 to 10 hours of continued use. Lithium coin cell batteries designated in the industry as CR2430 must be used. Several acceptable

brands have been identified in the manual supplied by the vendor. Estimated battery life remaining is displayed each time the instrument is initialized. Battery life will be significantly shorter if the monitors are used for 3 days or more continuously without downloading data. Battery replacement must be done carefully to avoid damaging the electronics and will be done only by staff approved by the investigator for the PAM.

#### **4.4 Hassles and Mood Inventory**

The Hassles and Mood Inventory is a participant self-administered questionnaire to assess daily hassles and minor stress, mood and strong emotions such as anger and hostility. The Hassles and Mood Inventory is comprised of four standardized measures of weekly stress, depression, anger and hostility.

Training, certification and quality assurance for the Hassles and Mood Inventory are described in sections 2.3, 2.4 and 2.5.

##### **4.4.1 Hassles and Moods A: Minor Stress (WSI)**

Minor stressful life events will be assessed using the Hassles and Moods A: Weekly Stress Inventory (WSI) (see Forms Appendix), an 87-item checklist of minor stressors (Mosley, et al., 1996). Participants are asked to indicate whether an event occurred during the past week, and if so, to rate the amount of stress that the event caused on a 7-point Likert-type scale (1 = not stressful; 7 = extremely stressful). The WSI is a standardized questionnaire and will be administered to all participants in the Take Home Questionnaires following the baseline exam, as one of the measures making up the Hassles and Mood Inventory. The undesirable stressful events on the WSI were derived from the stress-monitoring of a large sample of community adults and from selected items modified from other established minor life event inventories. The WSI has been validated in a sample of CHD patients in Mississippi (Mosley, et al., 1996).

##### **4.4.1.1 Background, Rationale and Hypotheses**

Exposure to stress, both acute events and chronic burden, has been related to CHD risk (Lepore, 1995). The frequency and types of stressors experienced by an individual may be influenced by broad societal factors operating on a given segment of the population. Stress exposure has been related to social class and, to a lesser extent, ethnicity and thus may contribute to SES or ethnic differences in CHD risk. In the JHS, we will assess 3 types of stress exposure: major life events (at annual follow-up), minor life events, and chronic stress (as part of the HII).

Minor life events differ from major life events in that they occur more frequently and individually have a less severe negative impact upon the individual (Brantley, et al., 1997). Minor stressors and chronic stressors, in contrast to more time-limited and episodic major life events, may provide a more plausible theoretical link to the development of diseases that have a gradual long-term onset, such as CHD.

Hypotheses include:

1. High stress will be associated with an increased risk of hypertension and CHD events independent of the contribution of traditional CHD risk factors.
2. The relationship observed between stress, hypertension, and CHD events will be moderated by social support, coping style, SES, and education.

##### **4.4.1.2 References**

Mosley, T. H., Jr., Payne, T. J., Plaud, J. J., Johnson, C. A., Wittrock, D. A., Seville, J. L., Penzien, D. B., & Rodriguez, G. (1996). Psychometric properties of the Weekly Stress Inventory (WSI):

Extension to a patient sample with coronary heart disease. *Journal of Behavioral Medicine*, 19, 273-287.

Lepore, S. J. (1995). Measurement of chronic stressors. In S. Cohen, R. C. Kessler, & L. U. Gordon (Eds.). *Measuring stress: A guide for health and social scientists* (pp. 102-120). New York, NY: Oxford University Press.

Brantley, P. J., Waggoner, C. D., Jones, G. N., & Rappaport, N. B. (1987). A daily stress inventory: Development, reliability and validity. *Journal of Behavioral Medicine*, 10, 61-74.

#### **4.4.1.3 Administration**

The WSI will be administered to all participants, as a paper-and-pencil questionnaire, as one of the four measures making up the Hassles and Mood Inventory. Following the JHS baseline exam, participants will be provided with the Hassles and Mood Inventory. Participants will be asked to complete the packet of questionnaires at home. Participants will be read a general statement explaining the instructions for completing the packet of questionnaires and briefly explaining the rationale (see Appendix). The completed questionnaires will be picked up from the participant's home by the Sample Coordinator. When picking up the Hassles and Mood Inventory, Sample Coordinator will check the questionnaires for completeness and will offer assistance to those who may have had difficulty completing the questionnaires (e.g., due to illiteracy, visual deficit, etc.). Detailed instructions for the WSI are provided in the QXQ instructions (see Forms Appendix).

#### **4.4.1.4 Data Collection**

The WSI will be completed on paper, self-administered in the participant's home. When necessary, interviewer assistance will be available. Subsequently, the WSI data will be entered into the data entry system by clinic staff.

#### **4.4.1.5 Scoring/Coding**

The WSI yields two summary scores: (a) the number of stressful events endorsed (WSI-Event), and (b) the sum of the subjective ratings assigned to the endorsed events (WSI-Impact).

#### **4.4.2 Hassles and Moods B: Depression (CES-D)**

The Hassles and Moods B: Center for Epidemiologic Studies Depression Scale (CES-D) (see Forms Appendix) will be used to assess depressive symptoms. The CES-D is a standardized, 20 item, self-report instrument developed by the National Institute of Mental Health to measure the frequency of recently experienced depressive symptoms (Radloff, 1977). Participants are asked about her/his mood over the past week, responding to each item as to how often they felt "this way." Item ratings range from rarely or none of the time, to most or all of the time. The CES-D will be administered to all participants in the Take Home Questionnaires following the baseline exam, as one of the measures making up the Hassles and Mood Inventory. In addition to four subscale factors, a total score may be calculated with recommended cut offs suggestive of clinical depression (Radloff, 1977).

#### **4.4.2.1 Background, Rationale and Hypotheses**

Depression has been linked to CHD in several studies (Booth-Kewley, 1987; King, 1997). To date, most of the studies on depression have focused on its relationship with morbidity or mortality following a coronary event (Frasure-Smith, et al., 1993; 1995). A literature is accumulating, however, that depression also increases risk of incident myocardial infarction and related CHD events in community samples (Anda, et al., 1993; Barefoot & Schroll, 1996; Pratt, et al., 1996; Hippersly-Cox, et al., 1998; Sesso, et al., 1998; Mendes de Leon, et al., 1998; Whooley, et al., 1998).

Hypotheses include:

1. Negative emotions will be associated with an increased risk of hypertension, CHD events, and mortality independent of the contribution of traditional CHD risk factors.
2. The relationship observed between negative emotions, hypertension, and CHD events will be moderated by social support, coping style, SES, and education.

#### 4.4.2.2 References

Radloff, L.S. (1977). The CES-D scale: A self-report depression scale for research in the general population. Applied Psychological Measurement, 1, 385-401.

Booth-Kewley, S., & Friedman, H.S. (1987). Psychological predictors of heart disease: A quantitative review. Psychological Bulletin, 101, 343-362.

King, K. B. (1997). Psychologic and social aspects of cardiovascular disease. Annals of Behavioral Medicine, 19, 264-270.

Frasure-Smith, N., Lesperance, F., & Talajic, M. (1993). Depression following myocardial infarction: Impact on 6-month survival. JAMA, 270, 1819.

Frasure-Smith, N., Lesperance, F., & Talajic, M. (1995). Depression and 18-month prognosis following myocardial infarction. Circulation, 91, 999.

Anda, R., Williamson, D., Jones, D., et al. (1993). Depressed affect, hopelessness, and the risk of ischemic heart disease in a cohort of U. S. adults. Epidemiology, 4, 285-294.

Barefoot JC, Schroll M. (1996). Symptoms of depression, acute myocardial infarction, and total mortality in a community sample. Circulation, 93, 1976-1980.

Pratt LA, Ford DE, Crum RM, et al. (1996). Depression, psychotropic medication, and risk of myocardial infarction: Prospective data from the Baltimore ECA follow-up. Circulation, 94, 3123-3129.

Hippisley-Cox J, Fielding K, Pringle M. (1998). Depression as a risk factor for ischaemic heart disease in men: Population based case-control study. BMJ, 316, 1714-1719.

Sesso HD, Kawachi I, Vokonas PS, et al. (1998). Depression and the risk of coronary heart disease in the Normative Aging Study. Am J Cardiol, 82, 51-56.

Mendes de Leon CF, Krumholz HM, Seeman TS, et al. (1998). Depression and risk of coronary disease in elderly men and women. Arch Intern Med, 158, 2341-2348.

Whooley MA, Browner WS for the Study of Osteoporotic Fractures Research Group. (1998). Association between depressive symptoms and mortality in older women. Arch Intern Med. 158:2129-2135.

#### 4.4.2.3 Administration

The CES-D will be administered to all participants, as a paper-and-pencil questionnaire, as one of the four measures making up the Hassles and Mood Inventory. Following the JHS baseline exam, participants will be provided with the Hassles and Mood Inventory. Participants will be asked to complete the packet of questionnaires at home. Participants will be read a general statement explaining the instructions for completing the packet of questionnaires and briefly explaining the rationale (see Appendix). The completed questionnaires will be picked up from the participant's

home by the Sample Coordinator. When picking up the Hassles and Mood Inventory, the Sample Coordinator will check the questionnaires for completeness and will offer assistance to those who may have had difficulty completing the questionnaires (e.g., due to illiteracy, visual deficit, etc.). Detailed instructions for the CES-D are provided in the QXQ instructions (see Forms Appendix).

#### **4.4.2.4 Data Collection**

The CES-D will be completed on paper, self-administered in the participant's home. When needed interviewer assistance will be available. Subsequently, the CES-D data will be entered into the data entry system by clinic staff.

#### **4.4.2.5 Scoring/Coding**

The CES-D yields a total score as well as 4 possible subscale factors. Total scores range from 0 to 60, with higher scores indicating greater frequency of depressive symptoms. The total score is computed as the sum of the items, with items scored from 0 to 3 (0 = rarely, 3 = most). Items 4, 8, 12, and 16 are reverse-scored (rarely = 3, most = 0).

#### **4.4.3 Hassles and Moods C: Hostility (CHO)**

Hostility will be assessed using the Hassles and Moods C: CHOST (CHO) (see Forms Appendix), a 27-item, true-false, self-report questionnaire (Barefoot, et al., 1989). The CHO is a standardized questionnaire derived from the Cook-Medley Hostility Scale and assesses experiential hostility, that is an attitude of cynicism, suspiciousness, mistrust, or resentful feelings towards others. The CHO will be administered to all participants in the Take Home Questionnaires following the baseline exam, as one of the measures making up the Hassles and Mood Inventory. The Composite Hostility Score (CHO) has been found to be a better predictor of mortality (Barefoot, et al., 1989), myocardial ischemia, (Helmert, et al., 1993) and of cardiovascular responses (Suarez, et al., 1993) compared with the total score from the longer Cook-Medley Hostility Scale.

##### **4.4.3.1 Background, Rationale and Hypotheses**

Several negative emotions have been identified as possible risk factors for coronary heart disease (CHD) (Booth-Kewley, et al., 1987). The negative or "coronary-prone" emotions have been found to influence the incidence, symptom expression, morbidity and mortality associated with CHD.

Chronic anger and hostility have emerged as the primary (toxic) components thought to underlie associations between Type A personality and CHD. Several epidemiologic studies have found that chronic anger and/or maladaptive anger coping styles are associated with an increased risk of CHD-related morbidity and mortality (Barefoot, et al., 1989; Barefoot, et al., 1983; Haynes, et al., 1980). Anger has also been associated with all-cause mortality in a number of studies (Miller, et al., 1996). Anger is not a unitary construct. The measures of anger selected for use in the JHS assess key components of this multidimensional construct, i.e., cynicism and anger expression.

Hypotheses include:

1. Anger will be associated with an increased risk of hypertension, CHD events, and mortality independent of the contribution of traditional CHD risk factors.
2. The relationship observed between anger, hypertension, and CHD events will be moderated by social support, coping style, SES, and education.

#### 4.4.3.2 References

- Barefoot, J.C., Dodge, K.A., Peterson, B.L., Dahlstrom, W.G., & Williams, R.B. (1989). The Cook-Medley Hostility Scale: Item content and ability to predict survival. Psychosomatic Medicine, 51, 46-57.
- Helmers, K. F., Krantz, D. S., Howell, R., Klein, J., Bairey, N., & Rozanski, A. (1993). Hostility and myocardial ischemia in coronary artery disease patients: Evaluation by gender and ischemic index. Psychosomatic Medicine, 55, 29-36.
- Suarez, E. C., & Williams, R. B. (1989). Situational determinants of cardiovascular and emotional reactivity in high and low hostile men. Psychosomatic Medicine, 51, 404-418.
- Booth-Kewley, S., & Friedman, H.S. (1987). Psychological predictors of heart disease: A quantitative review. Psychological Bulletin, 101, 343-362.
- Barefoot, J.C., Dahlstrom, W.G., & Williams, R.B. Jr. (1983). Hostility, CHD incidence and total mortality: A 25-year follow-up study of 255 physicians. Psychosomatic Medicine, 45, 59-63.
- Barefoot, J.C., Larsen, S., von der Lieth, L., et al. (1995). Hostility, incidence of acute myocardial infarction, and mortality in a sample of older Danish men and women. Am J Epidemiol, 142, 477-84.
- Dembroski, T.M., MacDougall, J.M., Costa, P.T. Jr., & Grandits, G.A. (1989). Components of hostility as predictors of sudden death and myocardial infarction in the Multiple Risk Factor Intervention Trial. Psychosomatic Medicine, 51, 514-522.
- Everson, S.A., Kauhanen, J., Kaplan, G.A., Goldberg, D.E., Julkunen, J., Tuomilehto, J., & Salonen, J.T. (1997). Hostility and increased risk of mortality and acute myocardial infarction: The mediating role of behavioral risk factors. American Journal of Epidemiology, 146, 142-152.
- Kawachi, I., Sparrow, D., Spirro, A. III, Vokonas, P., Weiss, S.T. (1996). A prospective study of anger and coronary heart disease: The Normative Aging Study. Circulation, 94, 2090-2095.
- Haynes S.G., Feinleib M., Kannel W.B. (1980). The relationship of psychological factors to coronary heart disease in the Framingham study: III. Eight-year incidence of coronary heart disease. American Journal of Epidemiology, 111, 37-58.
- Miller, T.Q., Smith, T.W., Turner, C.W., Guijarro, M.L., & Hallet, A.J. (1996). A meta-analytic review of research on hostility and physical health. Psychological Bulletin 119(2) 322-48.

#### 4.4.3.3 Administration

The CHO will be administered to all participants, as a paper-and-pencil questionnaire, as one of the four measures making up the Hassles and Mood Inventory. Following the JHS baseline exam, participants will be provided with the Hassles and Mood Inventory. Participants will be asked to complete the packet of questionnaires at home. Participants will be read a general statement explaining the instructions for completing the packet of questionnaires and briefly explaining the rationale (see Appendix). The completed questionnaire will be picked up from the participant's home by the Sample Coordinator. When picking up the Hassles and Mood Inventory, the Sample Coordinator will check the questionnaires for completeness and will offer assistance to those who may have had difficulty completing the questionnaires (e.g., due to illiteracy, visual deficit, etc.). Detailed instructions for the CHO are provided in the QXQ instructions (see Forms Appendix).

#### 4.4.3.4 Data Collection

The CHO will be completed on paper, self-administered in the participant's home. When necessary interviewer assistance will be available. Subsequently, the CHO data will be entered into the data entry system by clinic staff.

#### 4.4.3.5 Scoring/Coding

Three subscale scores are derived from this instrument: Cynicism (13 items), Hostile Affect (5 items), and Aggressive Responding (9 items). One point is assigned for each true response, except for items 18 and 21, which are reverse-scored, i.e., 1 point each for a false response. The specific subscale-item assignments follow below ("R" indicates reverse scoring):

<u>Dimension</u>	<u>Items</u>
Cynicism	1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13
Hostile Affect	14, 16, 17, 21R, 24
Aggressive Responding	15, 18R, 19, 20, 22, 23, 25, 26, 27

#### 4.4.4 Hassles and Moods D: Anger (STX)

The Hassles and Moods D: Spielberger Anger Expression Inventory (STX) (see Form Appendix) will assess anger expression using the 16-item anger-in and anger-out subscales of the standardized STX (Spielberger, et al., 1988). Participants are asked to describe her/his reactions when feeling angry, by rating how often they react in the manner described by each item. Each item is rated on a 5-point, Likert-type scale from never (1) to almost always (4). The STX will be administered to all participants in the Take Home Questionnaires following the baseline exam, as one of the measures making up the Hassles and Mood Inventory.

##### 4.4.4.1 Background, Rationale and Hypotheses

Several negative emotions have been identified as possible risk factors for coronary heart disease (CHD) (Booth-Kewley, et al., 1987). These negative or "coronary-prone" emotions have been found to influence the incidence, symptom expression, morbidity, and mortality associated with CHD.

Chronic anger and hostility have emerged as the primary (toxic) components thought to underlie associations between Type A and CHD. Several epidemiologic studies have found that chronic anger and/or maladaptive anger coping styles are associated with an increased risk of CHD-related morbidity and mortality (Barefoot, et al., 1989; Barefoot, et al., 1983; Barefoot, et al., 1995; Dembroski, et al., 1989; Everson, et al., 1997; Kawachi, et al., 1996; Haynes, et al., 1980). Anger has also been associated with all-cause mortality in a number of studies (Miller, et al., 1996). Anger is not a unitary construct. The measures of anger selected for use in the study assess key components of this multidimensional construct, i.e., cynicism and anger expression.

Hypotheses include:

1. Anger will be associated with an increased risk of hypertension, CHD events, and mortality independent of the contribution of traditional CHD risk factors.
2. The relationship observed between anger, hypertension, and CHD events will be moderated by social support, coping style, SES, and education.

#### 4.4.4.2 References

Spielberger, C. D., Krasner, S., & Solomon, E. (1988). The experience, expression, and control of anger. In M. P. Janisse (Ed.), Health psychology: Individual differences and stress (pp. 89-108). New York: Springer Verlag.

Booth-Kewley, S., & Friedman, H.S. (1987). Psychological predictors of heart disease: A quantitative review. Psychological Bulletin, 101, 343-362.

Barefoot, J.C., Dodge, K.A., Peterson, B.L., Dahlstrom, W.G., & Williams, R.B. (1989). The Cook-Medley Hostility Scale: Item content and ability to predict survival. Psychosomatic Medicine, 51, 46-57.

Barefoot, J.C., Dahlstrom, W.G., & Williams, R.B. Jr. (1983). Hostility, CHD incidence and total mortality: A 25-year follow-up study of 255 physicians. Psychosomatic Medicine, 45, 59-63.

Barefoot, J.C., Larsen, S., von der Lieth, L., et al., (1995). Hostility, incidence of acute myocardial infarction, and mortality in a sample of older Danish men and women. Am J Epidemiol, 142, 477-84.

Dembroski, T.M., MacDougall, J.M., Costa, P.T. Jr., & Grandits, G.A. (1989). Components of hostility as predictors of sudden death and myocardial infarction in the Multiple Risk Factor Intervention Trial. Psychosomatic Medicine, 51, 514-522.

Everson, S.A., Kauhanen, J., Kaplan, G.A., Goldberg, D.E., Julkunen, J., Tuomilehto, J., & Salonen, J.T. (1997). Hostility and increased risk of mortality and acute myocardial infarction: The mediating role of behavioral risk factors. American Journal of Epidemiology, 146, 142-152.

Kawachi, I., Sparrow, D., Spirro, A. III, Vokonas, P., Weiss, S.T. (1996). A prospective study of anger and coronary heart disease: The Normative Aging Study. Circulation, 94, 2090-2095.

Haynes SG, Feinleib M, Kannel WB. (1980). The relationship of psychological factors to coronary heart disease in the Framingham study: III. Eight-year incidence of coronary heart disease. American Journal of Epidemiology, 111, 37-58.

Miller, T.Q., Smith, T.W., Turner, C.W., Guijarro, M.L., & Hallet, A.J. (1996). A meta-analytic review of research on hostility and physical health. Psychological Bulletin 119(:2) 322-48.

#### 4.4.4.3 Administration

The STX will be administered to all participants, as a paper-and-pencil questionnaire, as one of the four measures making up the Hassles and Mood Inventory. Following the JHS baseline exam, participants will be provided with the Hassles and Mood Inventory. Participants will be asked to complete the packet of questionnaires at home. Participants will be read a general statement explaining the instructions for completing the packet of questionnaires and briefly explaining the rationale (see Appendix). The completed questionnaire will be picked up from the participant's home by the Sample Coordinator. When picking up the Hassles and Mood Inventory, the Sample Coordinator will check the questionnaires for completeness and will offer assistance to those who may have had difficulty completing the questionnaires. Detailed instructions for the STX are provided in the QXQ instructions (see Forms Appendix).

#### 4.4.4.4 Data Collection

The STX will be completed on paper, self-administered in the participants home. When needed, interviewer assistance will be available. Subsequently, the STX data will be entered into the data entry system by clinic staff.



#### 4.4.4.5 Scoring/Coding

Two scores are calculated from the STX, anger-in and anger-out. Each item is rated on a 5-point, Likert-type scale from never (assigned 1 point) to almost always (assigned 4 points). The instrument is scored by summing the responses to items for each of the two subscales. Thus the minimum score for a subscale is 8 and the maximum is 32. The specific subscale-item assignments are follows:

<u>Dimension</u>	<u>Items</u>
Anger-In	2, 3, 4, 7, 9, 11, 12, 14
Anger-Out	1, 5, 6, 8, 10, 13, 15, 16



## 5.0 MEDICAL DATA REVIEW

Through the participants' informed consent and the cover letters for the final results reports sent to the cohort and their health care providers it is made clear that the interviews and exam components are not a substitute for regular medical care. One of the benefits to participants, however, is the summary of clinically relevant results distributed by the Exam Center at the conclusion of, and several weeks following the baseline clinical exam. At the end of the Exam Center visit, participant interview and examination data are reviewed by the trained staff to provide the participant with a summary of study results for height, weight, sitting blood pressure and a preliminary report of the ECG and PFTs (see Appendix). Participants are reminded that additional clinically relevant data will be processed at the Central Lab and Reading Centers and will not be available for several weeks.

### 5.1 Rationale

The primary objectives of the Medical Data Review are to safeguard participant safety and to inform the participant of findings detected during the clinical components and through responses to the interview/questionnaires. Clinical and interview data are reviewed with participants to confirm selected positive symptoms reported during the interviews/exams and to determine if these appear to warrant immediate (same day), urgent (same week) or routine medical follow-up. Conditions requiring emergency referral are dealt with as soon as observed and, in general, have been dealt with before the Medical Data Review takes place. For example, cardiac events, blood pressure readings  $\geq 210/120$  mm Hg and acute pattern abnormalities detected on the ECG are attended to as soon as observed. Table 19 indicates the classification of blood pressure for adults. The JHS physician is consulted, the clinic visit terminated, the person referred for immediate medical care, and a return visit to complete missed procedures and interviews is scheduled as appropriate. Persons with elevated blood pressures less than 210/120 mm Hg are referred to her/his source of medical care at the Medical Data Review following the guidelines shown in Table 20. Likewise, observations of an ECG abnormality identified as major in Table 21 are reviewed by a JHS physician on call before the participant leaves the Exam Center.

When clinically relevant laboratory data processed at the study's central agencies (laboratories and reading centers) have been received at the Exam Center, the data are again reviewed prior to producing summary reports for participants and her/his physicians. As part of this review, JHS clinical personnel again may recommend follow-up if symptoms/conditions appear to warrant further medical attention.

At the Exam Center, participants' clinically relevant data are reviewed at three levels. The first review takes place during the Medical Data Review (see below, section 5.3), which is conducted after all interviews and physical exams have been completed and data have been assembled as part of the data inventory step (section 5.2). The second and third levels of medical data review take place after data processed at the study's central agencies are returned to the Exam Centers and are reviewed by study clinicians and summarized for inclusion in the final results reports that are mailed to participants and her/his providers of medical care.

### 5.2 Data Inventory

The data inventory step initiates the last fixed component of the Exam Center examination sequence and is done after all interviews and examination procedures have been completed in preparation for the Medical Data Review. Participant data are collected by various means during the course of the baseline exam and require summarization and placement in the participant's folder for nurse/clinician review.

### **5.2.1 Rationale**

Although the JHS study does not diagnose or treat any medical condition, the participant's health and safety is of paramount concern. Therefore, data collected during the examination that could indicate the need for immediate (same day), urgent (within one week) or routine (within one to two months or first convenient appointment) referral for medical care (Table 21) are put together into one document, the Medical Data Review Printout (see Appendix), and reviewed with the participant prior to the completion of the examination.

### **5.2.2 Procedures**

A staff person reviews the participant itinerary to determine that all interviews and procedures have been completed, checks participants' folders to verify that they contain the paper versions of the forms to be completed by JHS staff, and reviews participants' self-administered forms to determine completeness of the forms and to determine the necessity of assistance in completing the forms. After completion of the baseline exam and confirmation of quality control procedures, participants are invited to change back into street clothes while the data are being prepared for the medical data review.

### **5.2.3 Training**

The Clinic Manager is responsible for training the personnel charged with data inventory, and the assembly of study materials for the Medical Data Review.

### **5.2.4 Certification**

Certification for data inventory is the responsibility of the Clinic Manager. No recertification is required, but staff performance is monitored by the Clinic Manager.

### **5.2.5 Quality Assurance**

Quality assurance consists of observation by the supervisor and retraining or corrective action, as required.

## **5.3 Procedures**

Trained staff conduct the medical data review to

1. summarize the results of selected measurements obtained during the baseline exams/interviews
2. determine whether a reported stroke/TIA symptom(s) constitute a possible CVA
3. identify potential medical problems
4. answer participant questions

**Table 19. Classification of Blood Pressure for Adults, Based on Joint National Committee on Detection, Evaluation and Treatment of High Blood Pressure (JNC-VI, 1997) Guidelines**

<b>Category</b>	<b>SBP (mm Hg)</b>		<b>DBP (mm Hg)</b>
<b>Optimal</b>	<120	and	<80
<b>Normal</b>	< 130	and	< 85
<b>High normal</b>	130-139		85-89
<b>Hypertension</b>			
Stage 1	140-159	or	90-99
Stage 2	160-179	or	100-109
Stage 3	≥ 180	or	≥ 110

When SBP and DBP fall into different categories, use the higher category.

**Table 20. Medical Care Referral Guidelines for Blood Pressure, Based on Joint National Committee on Detection, Evaluation and Treatment of High Blood Pressure (JNC-VI, 1997) Guidelines**

<b>Referral Classification</b>	<b>Examination Findings</b>	<b>Recommendation to Participant<sup>1</sup></b>	<b>Explanation to Participant</b>
Emergency Referral	SBP $\geq$ 260 or DBP $\geq$ 130	Transportation to emergency care facility. Stop exam and reschedule clinic visit.	Your BP is very high.
Immediate Referral	SBP 210-259 or DBP 120-129	Consult with JHS MD. Refer to source of care immediately (today). Stop exam and reschedule clinic visit.	Your BP is very high.
Urgent Referral	SBP 180-209 or DBP 110-119	Consult with JHS MD and proceed unless otherwise indicated. Refer to source of care within 1 week.	Your BP is high.
Routine Referral	SBP 160-179 or DBP 100-109	Refer to source of care within 1 month.	Your BP is elevated.
	SBP 140-159 or DBP 90-99	Refer to source of care within 2 month.	Your BP is elevated.
No Referral	SBP 130-139 or DBP 85-89	Recheck in 1 year (no JHS referral)	Your BP is high normal.
	SBP $<$ 130 <sup>2</sup> or DBP $<$ 85 <sup>2</sup>	Recheck in 2 years (no JHS referral)	Your BP is normal.

<sup>1</sup> If the systolic and diastolic categories are different, follow recommendations for the shorter time follow-up (e.g., 160/85 mm Hg should be evaluated or referred to source of care within 1 month).

<sup>2</sup> Unusually low readings should be evaluated for clinical significance.

In summary, factual information is given to participants about her/his results during the Medical Data Review, identifying abnormalities and recommending referral as needed, but avoiding medical advice about prognosis, prevention or therapy. Physician back-up is available at all times.

#### **5.4 Training**

Staff are trained for the Medical Data Review tasks by the Exam Center Clinic Manager.

#### **5.5 Certification**

The Exam Center Clinic Manager is responsible for certification of the clinicians responsible for medical data review.

## **5.6 Quality Assurance**

The Exam Center PI is responsible for ensuring that the medical data review, referrals and reporting of results are done according to procedures in the JHS protocol.





## 6.0 REFERRALS AND REVIEW GUIDELINES

### 6.1 Rationale

Participants are referred based on the guidelines for referral listed below (Table 21). Prior to the Medical Data Review (described in section 5), a data entry utility system retrieves affirmative responses (from the questionnaires) to key items indicative of hypertension, diabetes, ischemic heart disease, hypercholesterolemia, cancer, uterine bleeding, chest pain on effort, congestive heart failure, TIA/stroke, and intermittent claudication. Guidelines for conducting the Medical Data Review are provided in the Medical Data Review instructions.

Referrals for follow-up care can be made at the Medical Data Review or in subsequent communications. Uniform criteria for emergency, immediate, urgent and routine referrals have been established, (section 5.1.2), and are summarized in Table 20 and 21. Sources of medical care for participants who do not have a health care provider will be identified in consultation with the representatives of the local medical community. All referrals are documented on a separate Report/Referral Form (REF) and the JHS Alert/Referral log (ALT) (see Forms Appendix). Detailed QxQ instructions are specified in the Forms Appendix.

### 6.2 Procedures

Referrals are made during the Medical Data Review or upon receipt of the study's clinically relevant data, which follow the criteria listed below.

1. Emergency Referral. Transportation to the nearest emergency care facility is provided or an emergency squad is called.
2. Immediate Referral. The participant is urged to see her/his health care provider within one day.

The nurse/clinician consults with the JHS physician, and the participant's health care provider is called. The participant's health care provider is also sent a letter of explanation (see Appendix).

Participants who have no health care provider are referred based on consultation with a provider in the community.

3. Urgent Referral. The participant is asked to see her/his health care provider in one week.

The nurse/clinician confirms the decision with the JHS physician, and explains the reason(s) for an urgent referral to the participant. This usually occurs during the Medical Data Review, but can occur when alert values are returned to the exam center from a central agency. The JHS physician calls the participant's health care provider and sends a referral letter (see Appendix). Follow-up letters are also sent to the participant (see Appendix).

Participants who have no health care provider are referred based on consultation with a provider in the community.

4. Routine Referral. The participant is asked to see her/his health care provider at the first convenient appointment.

The nurse/clinician advises a visit to the participant's health care provider. A referral letter is sent to the participant (see Appendix) and her/his health care provider (see Appendix) as a cover letter for the final results report.

5. No Referral. The study results are summarized for the participant and her/his health care provider and sent along with cover letters (see Appendix).

Procedures/symptom-specific guidelines are summarized in Table 21. Certain interview items or measurements (identified with an asterisk) require confirmation from additional questions during the Medical Data Review. The reviewer determines the acuteness of the findings, and determines whether or not a health care provider is monitoring the condition. If the participant is aware of and being followed medically for a condition, judgment is exercised about whether to refer, and the degree of urgency. The types of participant and health care provider referral and results letters used for each of the five referral categories are summarized in Table 23; examples of the texts of these letters are provided in the Appendix.

**Table 21. Medical Care Referral Guidelines**

<b>Referral Classification</b>	<b>Examination Findings</b>	<b>Recommendation to Participant</b>	<b>Explanation to Participant</b>
IMMEDIATE Referral	*SBP $\geq$ 210 mm Hg or DBP $\geq$ 120 mm Hg	See health care provider Today	BP very high
	*Unstable angina	"	Your chest pains may be important.
	*Neurologic symptoms in past week.	"	Your symptoms may be important.
	*Other severe symptoms or findings.	"	Your symptoms may be important.
URGENT Referral	*Angina, stable but untreated/ not being followed	See health care provider within a week	Your chest pains may be important.
	* Neurologic symptoms, untreated, one week to six months ago.	"	Your symptoms may be important.
	*Acute congestive heart failure	"	Your symptoms may be important.
	*Other acute, but less severe symptoms	"	Your symptoms may be important.
	*SBP $\geq$ 180-209mm Hg or *DBP $\geq$ 110-119mm Hg	"	Your BP high.
ROUTINE Referral	*Old MI (Rose questionnaire), previously unrecognized	See health care provider within month or at first earliest convenient appointment.	Your chest pains may be important.
	*Neurologic problem (stroke, TIA exam, findings) >6 months unrecognized	"	Your symptoms may be important.
	*Claudication, previously unrecognized	"	Your symptoms may be important.
	*Other symptoms or findings needing evaluation/ not being followed	"	Your symptoms may be important.
	*Uterine bleeding; response I,O,D on Reproductive Hx form	"	Your symptoms may be important.

\*Interview items/measurements require confirmation during Medical Data Review

**(con't) Table 20. Medical Care Referral Guidelines**

<b>Referral Classifications</b>	<b>Examination Findings</b>	<b>Recommendation To Participant</b>	<b>Explanation To Participant</b>
ROUTINE Referral	*SBP 160-179 mm Hg or DBP 100-109 mm Hg	See health care provider within one month	Your BP is high
	*SBP 140-159 mm Hg or DBP 90-99 mm Hg	See health care provider within two months	Your BP is high
NO Referral	*Angina, stable on treatment/being followed	None	Confirm only
	*MI, previously documented	None	Confirm only
	* SBP 130-139mm Hg or DBP 85-89mm Hg	Recheck in one year	Your reading is high normal
	*SBP $\leq$ 140mm Hg and DBP $\leq$ 90mm Hg	Recheck in two years	Your reading was normal
	Height, weight	None	Report only
ECG findings requiring review by M.D. before participant leaves Exam Center	Acute Pattern abnormalities (MI, ischemia)*	Per review by health care provider	Would like to review with health care provider
Other ECG findings or Normal ECG	Any other ECG finding, alone or in conjunction with symptoms, causing concern. <sup>1</sup>		A copy of the ECG will be sent to your health care provider with the other results

\* Interview items/measurements require confirmation during Medical Data Review.

1. Acute pattern abnormalities, 2<sup>nd</sup> or 3<sup>rd</sup> degree block, ventricular tachycardia, R on T, atrial fib/flutter with ventricular rate <60 or >110, sinus bradycardia <50, sinus tachycardia >110, PR interval >0.26 sec.

## **7.0 CLINICIAN REVIEWS**

### **7.1 General Policies**

The second level of medical data review is a review of the participant's data by the Clinic Manager within one week of the visit. This procedure includes the information initially reviewed during the Medical Data Review; labs received from the local lab; clinical chemistries, hemostasis or lipid alert values reported by telephone or e-mail from the Central Lab; and Reading Center alert values.

This general medical review provides a clinical staff's interpretation of the study results and an overview of referrals and reports from the Exam Center.

### **7.2 Procedures**

The Clinic Manager review is an ongoing activity at the Exam Center. Once a week the Clinic Manager reviews the data of participants seen in the preceding week. After the examination of the participant's Medical Data Review printout and ECG, the Clinic Manager records the interpretation of the Medical Data Review printout and reviews the preliminary interpretation. The Clinic Manager also confirms the local laboratory results for alert values. Any referrals made during Medical Data Review are reviewed at this time, and sent to a JHS physician for review.



## 8.0 RESULTS REPORTING

This activity concludes a process that extends over 4 to 8 weeks after the participant completes the JHS baseline exam. When all study results are received from the Central Laboratory and Reading Centers by the Coordinating Center, they are summarized for final disposition by Exam Center medical staff. Final summaries of the study results are compiled, according to the criteria in section 5.1.2, and mailed to participants and health care providers.

As urgent and immediate alert values are returned from the Central Laboratory and Reading Centers, the medical staff reviews them and assumes responsibility for referrals (see Table 21). Routine results may bypass physician review until the final report is generated. The JHS physician or Clinic Manager reviews all letters and reports sent to the participants and her/his health care provider.

With participant approval, normal and abnormal results of the clinically relevant medical tests are reported to the participant's health care provider. Whenever the therapeutic implications of results are not known, a statement to that effect is included in the report to the health care provider. Clinically relevant medical tests are differentiated from those with strictly research value based on their empirical value for diagnosis and/or treatment. Medical tests with strictly research value are not reported. Some results with equivocal clinical utility for cardiovascular outcomes may be reported as they have potential implication for therapy in certain subsets of the population, for example, folate levels for women of child-bearing age. Copies of all reports and letters concerning examination results sent to participants and health care providers are kept on file at the Exam Center.

Reporting of baseline exam values is made in the context of medical history where relevant. The alert values listed in Table 22 are reported with recommendations for medical follow-up. The Clinic Manager may initiate a telephone follow-up with the participant to clarify prior history. A copy of the abnormal study result, however, is included in the summary of results sent to the participants and her/his health care provider.

If verification or follow-up is needed, the participant is advised to discuss the results with the health care provider. JHS personnel provide no specific medical advice or interpretation of results. This is felt to be the responsibility of the participant's regular health care provider. Consistent with this policy, clear instructions are given to all JHS staff to avoid interpreting study results. If the participant has no health care provider, referral is available.

Even though the JHS is an observational study, the recommendation that the participant's health care provider performs any additional tests or procedures to confirm or evaluate JHS findings is considered an acceptable and necessary consequence of study participation.

**Table 22. Laboratory Alert, and Normal Reference Values**

<b>Chemistries</b>	<b>Normal Range for JHS Labs**</b>	<b>Alert Values*</b>
Total Cholesterol	<200 desirable 200-239 mildly elevated ≥240 markedly elevated	N/A
LDL	<130	N/A
HDL	>35	N/A
Triglycerides	<220	>1000
Creatinine (males) Creatinine (females)	=< 1.4 =< 1.2	>2.5 >2.5
Fasting glucose	74 – 106	<60; >200
Sodium	136 – 146	<125; >155
Chloride	98 – 108	<80; >115
Potassium	3.5 – 5.1	<3.2; >5.5
Uric Acid (males) Uric Acid (females)	=< 8.5 =< 7.5	>12 >12
Hemoglobin (males) Hemoglobin (females)	14.0 – 18.0 12.5 – 15.5	<12; >20 <10; >17
Hematocrit (males) Hematocrit (females)	42.0 – 49 39.0 – 45	<35; >53 <30; >50
Platelets	130 – 400 x 10 <sup>3</sup>	<50 x 10 <sup>3</sup> ; >500 x 10 <sup>3</sup>
Vitamin B <sub>12</sub>	=>223	<150
Folic Acid	=>2.7	N/A
Hgb A,C	=<6.1	>7
<b>URINE 24-hr.</b>		
Microalbumin	=<25	>25
<b>EXAM COMPONENTS</b>		
EKG	Reading Center Reading Discretion	Acute pattern abnormalities, 2 <sup>nd</sup> or 3 <sup>rd</sup> degree block, VT, R on T, atrial fib/flutter with ventricular rate <60 or >110, sinus bradycardia, <50, sinus tachycardia >110, PR interval >0.26 sec.
Echocardiogram	Reading Center Reading Discretion	Emergent: aortic dissection, vegetations, tumors, flial leaflet, thrombus, cardiac tamponade urgent: LVEF <30%; aortic aneurysm, LVH, AS
Carotid Ultrasound		≤ 2mm residual lumen
Pulmonary Function Test		FEV1 is <50% predicted

\*Laboratory notifies exam enter; Exam Center MD takes referral/notification action.

\*\*Reference ranges are provided on JHS Results Reports.

1 Reference values obtained from University of Mississippi Medical Center Clinical Lab.



## 8.1 Overview of Results Reporting

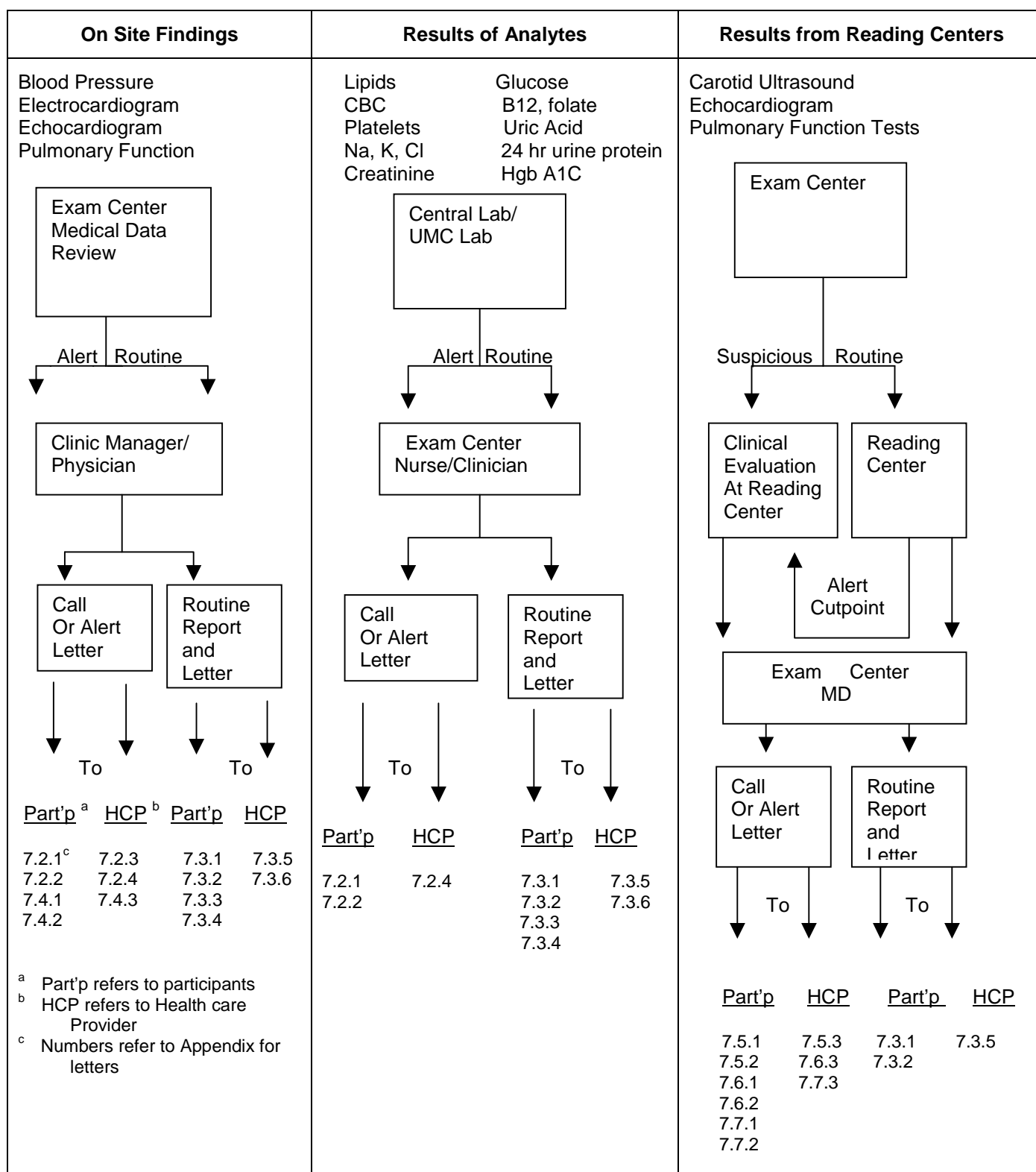
Figure 3 provides an overview of the process of results reporting and illustrates the interface between the review of medical data, the referral process, and the notification of study results. The figure also illustrates that certain results are reported on a routine basis, whereas potentially abnormal study results are reported to participants and her/his health care providers on an expedited basis.

The reports to the participant and/or the health care provider provide a minimum, standard set of study results. Reports to participants include a statement indicating either that all study results are within ranges considered normal, or that a study result requires confirmation or further evaluation. Normal ranges and brief explanatory statements are provided. Health care providers receive a letter of explanation (see Appendix) and a copy of the participant's result report, and are thus aware of any results flagged as being outside the JHS reference range, and the wording and explanations provided to her/his patients.

The following is a review of results reporting procedures.

1. At reception, the Schedule of JHS Results Reporting (see Appendix) is reviewed with the participant to describe the tests to be reported to the participant. The participant is also given a time range for return of results.
2. At Medical Data Review, a Participant Medical Data Review Printout (see Appendix) is generated summarizing findings for the Medical Data Review. Items flagged for review are automatically retrieved from the data base and printed on this form. The nurse/clinician conducts the Medical Data Review with the participant as described in section 5.1. A pre-printed summary of the exam results that do not require processing by the Central Lab or a Reading Center is completed during the Medical Data Review and given to the participant (see Appendix).
3. At the Medical Data Review, a referral may be necessary. Three levels of referral are designated: Immediate (same day), Urgent (within one week), Routine (within one or two months, depending on study guidelines), and the corresponding referral letters are sent to the participant's health care provider (see Appendix). (Emergent referrals are made as soon as condition is observed and are generally not held for the Medical Data Review). For immediate or urgent referrals, a phone call to the participant's health care provider may be made to facilitate the referral recommendation given to the participant.
4. Once a week, a clinician's review occurs during which the Clinic Manager reviews participant data and interprets ECG tracings. If an abnormality is detected at this time, a report and referral letter is sent to the participant and her/his health care provider (see Appendix).
5. The Central Lab and Reading Centers send the Exam Center the clinically relevant study results 4-6 weeks after the participant's exam. If there are "alert values," the participant is notified using the Alert Value Referral Letters (see Appendix) and the health care provider is notified (see Appendix). If there are no "alert values," normal results reports and cover letters indicating no abnormal findings are sent to the participants and her/his health care providers if designated.
6. When all results are available, the Results Report to the participant and health care provider and accompanying cover letters are generated. The types of cover letters are summarized in Table 23 and prototype letters are found in the Appendix.
7. The Exam Center Clinic Manager or physician reviews all results and letters before they are mailed.

8. A record is kept of all alert values and referrals on the Report and Referral (REF) form (see Forms Appendix) and on the Alert/Referral Log (ALT) (see Forms Appendix). Copies of all referral letters and results reports are filed in participant folders.

**Figure 3. JHS Referral/Notification Procedures**

**Table 23. Cover Letters for the Reports to Participants and Health Care Providers**

Recipient	Type Of Cover Letter For Results Reports
Health care provider  Participant	REFERRAL LETTERS FOR ALERT VALUES  a) Referral post clinic visit  b) Referral post clinic visit (N / A) c) Referral post clinic visit (w / MD) d) Referral post clinic visit (no / MD)
Health care provider  Participant	COVER LETTERS FOR SUMMARY VISIT RESULTS REPORT  a) Normal results b) Abnormal results, no previous referral made c) Abnormal results, previous referral made  a) Normal results b) Abnormal results c) Normal results, no MD designated d) Abnormal results, no MD designated
Insurance	Study results sent to third party

## 8.2 Report of Ultrasound B-Mode Scan Measurements

The ultrasound study of the carotid arteries will evaluate intimal medial thickness at specified sites in three distinct segments of the extra cranial carotid system – common carotid, carotid bifurcation, and internal carotid. The JHS ultrasound examination is oriented toward the detection of early atherosclerotic changes in the arterial wall and does not provide clinical documentation of the extent of lesions that might be of medical importance. Portions of the internal carotid artery, which may have disease, are not visualized at all. There are some specific early arterial changes and non-lumen encroaching wall thickness measurements that will be documented on JHS participants, but are presently of research interest only and of no known medical value. Such results are not routinely reported to the participant and her/his health care provider, and the participant is made aware of this during the process of consenting.

Procedures for reporting possible alert values are initiated when the minimum residual lumen in the evaluated artery is less than or equal to 2mm. Identification of these possible alert values is made by either the sonographers performing the scans at the JHS Exam Center or by the readers at the Ultrasound Reading Center (URC). The Clinic Manager is notified if in the course of the ultrasound scanning the sonographer discovers a minimum residual lumen of 2mm or less. In addition, if during the reading process at the URC, readers confirm measurements revealing a minimum residual lumen of 2mm or less, the Clinic Manager is informed of this alert. The participant and her/his health care provider are notified of the findings through letters (see Appendix). Because the JHS carotid ultrasound examination is a limited study and measurements obtained are of research value only, obtaining a more complete, clinically-focused carotid ultrasound is recommended in the letter.

## 8.3 Report of Echo Measurements and Findings

The echocardiogram study will evaluate a variety of structural and functional parameters in the JHS participant. Structural parameters to be studied include LV wall and chamber dimensions, and LV mass (calculated from dimensions). Cardiac functional data will be derived from measurements of systolic performance and from Doppler data describing left ventricular diastolic filling.

Each echo will be interpreted clinically by one of the Echocardiogram Reading Center (ERC) cardiologists within a few days of the exam. If there is any question raised by the echo technician regarding clinically important abnormalities, the echo study is read immediately following the completion of the study. The established echo “alert” (emergent) parameters include aortic dissection, vegetations, tumor, flial leaflet, thrombus, or cardiac tamponade. These will trigger an urgent phone call by the Reading Center cardiologist to the Exam Center co-investigator with oversight of the JHS participants’ clinical issues. The ERC cardiologist will contact the participant’s health care provider of record, if so directed by the Exam Center physician.

Urgent, not emergent, parameters will be reported promptly, but not emergently to the Exam Center PI. These parameters include: LVEF less than 30%; aortic aneurysm; LV enlargement (LV end-diastolic dimensions greater than 6.5 cm); aortic stenosis (aortic valve area less than 1 cm squared or peak velocity > 4m/sec.). A cover letter (see Appendix) is sent to the participant and her/his health care provider along with the notification of the abnormality.

#### **8.4 Report of Spirometry Testing**

The pulmonary function parameters to be assessed include the FEV1, FVC, and maximal inspiratory pressures. Each participant completing a test of acceptable quality will be provided a preliminary report of her/his lung function prior to leaving the clinic.

The participant is informed of the usual normal ranges: FEV1 greater than 80% predicted; FVC greater than 80% predicted; FEV1/FVC greater than 65% predicted.

The alert value for FEV1 is <1.0 liter and <40% predicted value. If either the FEV1 or FVC is less than 50% predicted normal value the health care provider is notified through an alert letter (see Appendix). A copy of the preliminary report is included with the letter. A subsequent final report is also sent to the health care provider from the PFT Reading Center.

#### **8.5 Routine Notification of Study Results**

Results of routine medical examinations, normal or abnormal, are reported to the participant and her/his health care provider, unless the participant has not designated a health care provider (refer to Appendix for prototype letters). This is explained to the participant during the baseline clinic visit, and the participant is provided a schedule for results reporting.

##### **8.5.1 Results Routinely Reported to the Participant**

Results reported to the participant during the clinic visit include current weight and height, current blood pressure, preliminary spirometry results, a statement that the ECG tracing will be read for inclusion in the summary report, and a statement that only abnormalities of the carotid artery scan will be reported.

Within three months after baseline exam, the Summary of the JHS Baseline Exam Results for participants and her/his health care providers (see Appendix) is mailed to the participant. This report includes the following confirmed study results from baseline exam: weight and height, blood pressure, summary reports of ECG, echocardiogram, PFT’s, B-scan ultrasound exam of the carotid arteries (lumen diameter), and blood and urine analytes (total cholesterol, LDL and HDL-cholesterol, triglycerides, serum creatinine, fasting glucose, serum electrolytes, B12, folate, hemoglobin A1C, CBC results, platelets, and 24-hr urine).

### **8.5.2 Results Routinely Reported to the Health Care Provider**

Participants' health care providers receive a copy of the reports sent to her/his patients. In addition, health care providers are notified of any important symptoms reported by the participant and they are provided with a copy of the participant's electrocardiogram.

### **8.5.3 Results Reported Only by Request**

All other study measurements, i.e. those not routinely reported to participants and/or her/his health care provider, are considered to be of research value only. If a participant requests them in writing, these values are provided on an ad hoc basis.

On the rare occasion that the Exam Center receives a request for a participant's study results from a third party medical care payor, a results report can be released according to the following steps.

1. A signed statement from the participant authorizing the release of JHS data to anyone other than the participant or her/his identified health care provider is required prior to the release of the study data by the JHS. A copy of the request and the authorization for release of study data is kept in the participant's folder.
2. The report contains only the information that was released to the participant's health care provider (or the participant), i.e., and exact copy of the cover letter, the results report and the ECG tracing.
3. This information is sent with a cover letter (see Appendix) from the Exam Center stating that the JHS does not provide diagnostic services or treatment.
4. The information is sent directly to the third party with an exact copy to the study participant, indicating the date on which the information was sent.

### **8.5.4 Reporting of Genetic Data**

The results of any genetic study will be handled as any other results not routinely reported as they are of research value only (See section 8.5.3).

If, during the course of the JHS, a genetic polymorphism is discovered which has clear clinical relevance and is treatable, information will be released study wide to participants regarding these polymorphisms. A description of the polymorphism, its health risk and treatment will appear in the JHS participant newsletter along with a mechanism to receive more information and a referral for gene testing. The cost of any such referral is the responsibility of the participant.

### **8.5.5 Study Results Requiring Special Notification**

The JHS protocol identifies certain potentially abnormal findings that require expedited notification to the participant or her/his health care provider. These include flagged responses to the medical history questionnaire. These items, and the corresponding referral and notification criteria, are described in section 7.1. Similarly, "alert value" levels have been defined for the functional tests and laboratory measurements.

Laboratory and ultrasound results are not available at the time of the clinic visit. Local laboratory results performed at UMC's lab are reviewed at the Exam Center for alert values within several days of the clinic examination. Notification in response to an alert value in laboratory results occurs after review of the participant's record. The Central Laboratory, the Ultrasound Reading Center, the Pulmonary Function Reading Center and the Echo Reading Center notify the Exam Center directly of "alert values." Notification of alert values to the Exam Center is by telephone, electronic mail or FAX

abiding by all confidentiality requirements and using only JHS ID numbers as identifiers; confirmation and acknowledgement is required. The laboratory alert values are in Table 22.

## 9.0 PARTICIPANT SAFETY

The safety and welfare of the JHS participants is protected by:

1. specific measurements taken in the design or conduct of the examination for her/his safety;
2. the mechanisms established for handling potential emergencies;
3. routine notification of participants and her/his health care providers regarding the results of the examination, and
4. the procedures JHS staff use to review all potentially medically important results and make the appropriate referrals.

An important factor in participants' welfare involves her/his expectations regarding the examination. If they believe the JHS examination is a substitute for a clinical examination, delay in seeking needed medical care could occur. Therefore, the provision of adequate information is a requisite to the JHS informed consent procedures (described in section 2.11).

### 9.1 Measures to Protect the Participant

Examination procedures which convey potential risk to participants include the fasting requirement and venipuncture. Methods by which participant risk is minimized (more fully described elsewhere in JHS Manuals) include the following:

- The possibility of hypoglycemia with a 12-hour fast is diminished by routine inquiry about reasons that should exempt the participant from fasting during the scheduling of baseline exam. Other medical conditions or dietary restrictions, which may be incompatible with the snack provided in the clinic, are also ascertained.
- Hematomas or prolonged bleeding may result from venipuncture. These are usually avoided if well-trained technicians follow the procedures for blood drawing and take the precautions described in JHS Manual 9: Specimen Collection and Processing. Prior to venipuncture, the participant is asked: "Do you have any bleeding disorders?" If the participant answers affirmatively or is uncertain, s/he is asked about whether s/he has had blood drawn previously and if so, whether there were any problems such as swelling or continuing to bleed at the venipuncture site. If the answer to this question is "yes," the Clinic Manager is summoned to approve the venipuncture. Occasionally, with any participant, bleeding persists after the venipuncture. Procedures described in Manual 9: Specimen Collection and Processing are followed. If the measurements taken have not stopped all bleeding within 30 minutes, and there is no obvious explanation for the prolonged bleeding, a medical referral is made. Also, the participant is instructed to seek medical care promptly if bleeding recurs after leaving the JHS clinic.
- Participants may experience syncope during the venipuncture. Methods for handling major and minor emergencies are described in sections 9.3.1 and 9.3.2, respectively.
- The JHS ultrasound exam involves no more ultrasound exposure that is usually the case when examining superficial arteries clinically. See JHS Manual 7: Ultrasound for details. The American Institute for Ultrasound in Medicine has issued the following statement concerning the safety of ultrasound:

#### Safety for Training and Research

Diagnostic ultrasound has been in use for over 25 years. No confirmed adverse



biological effects on patients resulting from this usage have ever been reported. Although no hazard has been identified that would preclude the prudent and conservative use of diagnostic ultrasound in education and research, experience from normal diagnostic practice may or may not be relevant to extended exposure time and altered exposure conditions. It is therefore considered appropriate to make the following recommendations: In those special situations in which examinations are to be carried out for the purposes other than direct medical benefit to the anticipated exposure conditions, and of how these compare with conditions for normal diagnostic practice.

Following the 45-minute ultrasound examination, the participant is asked to rise slowly, sit and then stand so that postural changes in blood pressure and pulse rate can be monitored. These procedures are described in JHS Manual 7: Ultrasound. The precautions against adverse effects of orthostasis are summarized here.

Before beginning, the procedures for monitoring postural changes are explained to the participant. The participant is asked whether or not s/he ever feels faint on standing. If the question is answered in the affirmative, permission to make the measurement (postural change) is still sought. Should the person decline, the procedure is not performed. In the absence of a reason not to continue, however, the participant is asked if s/he is taking medications that produce light-headedness when standing (postural effects). When the postural changes are measured, the sonographer is positioned closely behind the person as a protective measure should s/he become faint. A sturdy chair is positioned close at hand so that the participant may sit down promptly should s/he feel the need. Furthermore, examinees are advised to notify staff immediately if not feeling well and to ask for the chair. Clinic staff are instructed to watch the participant for signs of distress. In the event that the participant faints, the procedures described below in Section 8.3.2 and in Manual 9: Ultrasound, are followed.

## **9.2 Stopping Rules for Interviews and Procedures**

Participant safety and comfort during the clinical examination are monitored throughout the clinic visit. Interviewers and technicians observe participants for signs of fatigue or physical and/or emotional discomfort. When any one of these conditions are observed, participants are offered the opportunity to discontinue the interview or procedure, and are given an opportunity to rest before the next procedure. Persons incapable of completing all of the clinical exam are invited to change back into her/his street clothes and participate in the medical data review and reschedule the clinic exam on another day.

For persons with conditions which require emergency and immediate referrals, such as cardiac events, unstable angina, ECGs with acute pattern abnormalities, or blood pressure  $\geq 210/120$  mm Hg (see Tables 16 and 17), the JHS physician is consulted immediately, the clinic exam is terminated as soon as the condition is observed, and another appointment for baseline exam rescheduled as appropriate. For blood pressures requiring referral within one week (SBP 180-209 mm Hg or DBP 110-119 mm Hg; the urgent referral category in Table 20), the JHS physician is also consulted, and the clinic exam is either continued and the participant advised to seek medical care within one week or the clinic exam is terminated and rescheduled, based on the JHS physician's recommendation. The termination of any interview or procedure is documented on the Participant Itinerary Sheet (PIN).

## **9.3 Methods for Handling Emergencies**

While all life-threatening emergencies (e.g., acute MI) require immediate evaluation of the participant at an acute care facility, some emergency measures may be required in the clinic before departure (e.g., cardiac arrest). In addition, there are minor emergencies (hypotension, fainting, etc.) which may require treatment in the clinic only. Although most emergencies are of the less severe nature, the JHS Exam Center is prepared for both types.

### 9.3.1 Major Emergencies

In a serious event the primary concern of the Exam Center staff is to implement pre-established procedures to get the participant to the nearest medical facility. The JHS clinic is located within a few city blocks of a large, general, acute-care hospital. A staff person with certification in basic life support is on duty and physically present at every clinic session. Needed life support procedures are continued until emergency care arrives or the participant is transported to a hospital. The JHS Exam Center, has specific emergency procedures, which define:

1. Who is in charge during the emergency
2. Who is to administer treatment
3. Who is to be notified
4. What action clinic staff is to take
5. Which reports are to be filed

In addition to trained personnel and emergency equipment, the Exam Center has posted in a conspicuous place (e.g., the reception area): phone number of police and fire stations, ambulance services, and specific phone numbers or codes to alert medical teams, if applicable.

In each participant's folder, the name and phone number of her/his health care provider or usual source of medical care and the home and work telephone numbers of one or more contact person are available on the CON form. The Exam Center is required to have either a physician or a registered nurse on site at all times when participants are interviewed and examined.

All emergency situations are coordinated by the staff person designated, a priori, or by a physician if present. The Exam Center has a designated physician on duty for each clinic session. If not physically present in clinic, s/he is within immediate reach by phone or paging system and within a short distance to the clinic. The physician duty roster is posted with the clinic secretaries and in the office of the nurse/clinician so that the name of the responsible physician is readily accessible. However, in no case is emergency referral and/or care deferred while staff is attempting to locate a clinic doctor.

JHS staff are trained to carry out her/his specific responsibility during an emergency. Retraining is the responsibility of the Exam Center, following institutional guidelines.

All emergencies, whether serious or minor, are documented. This requires filling out an institutionally-approved form identifying the type of emergency. This is done by the person in charge at the time, and all reports are co-signed by a clinic physician and are filed at the Exam Center.

### 9.3.2 Minor emergencies

The most common minor emergency is simple syncope (fainting) and near syncope. These events may occur during the postural blood pressure measurements or venipuncture. Management of simple syncope or near syncope is the same whether associated with measuring postural blood pressure changes or drawing blood. Many syncopal episodes can be prevented if clinic staff are alert to early signs. In any situation in which syncope is likely, e.g., after the venipuncture, staff verify that the participant does not look or feel faint. If the participant looks faint or feels faint in the venipuncture area:

1. Have the person remain in the reclining position or in the chair, sitting with head between the knees
2. Crush an ampule of smelling salts and wave it under the participant's nose for a few seconds
3. Provide the participant with a basin and a towel if s/he feels nauseous
4. Have the participant stay in the reclining position or chair until s/he feels better and her/his color returns

If the participant continues to feel sick, recline the chair, place a cold wet towel on the back of the person's neck, and notify the supervisor. If a participant feels faint, s/he is cautiously lowered to the supine position on the floor and one attendant immediately calls for an in-house nurse/clinician to assist the patient. The remaining attendant raises the participant's legs above the plane of the body to increase venous return. Prior to this, the staff member momentarily palpates for a carotid pulse and checks to be sure the subject is breathing. If life support measures are needed, the procedures outlined in section 8.2.1 are followed.

#### **9.4 Emergency equipment**

A basic first aid kit is maintained at the Exam Center. The kit contains a reference guide of its contents, and is checked every year and immediately after each use. The Clinic Manager identifies a person responsible for this task.

## 10.0 FOLLOW-UP OF THE JHS COHORT

### 10.1 Eligibility Requirements for Annual Follow-up Interviews

Participants who completed at least part of the baseline clinic examination are contacted annually. Individuals excluded from annual follow-up (AFU) and subsequent examinations at the beginning of the study are only those enumerated residents who completed the home interview, but did not sign the informed consent form at the Exam Center examination (baseline exam).

Unless requested otherwise by the participant, or a participant is lost to follow-up, an attempt is made annually to contact all surviving JHS cohort members. This includes participants who have moved away from the community in which they were recruited. Telephone AFU interviews can be conducted anywhere in the continental U.S. Addresses and telephone numbers of cohort members with multiple residences are kept on file to contact participants on her/his target anniversary date.

### 10.2 Annual Follow-Up

#### 10.2.1 Annual Contacts between Exams

Each study participant is re-contacted approximately 12 months after her or his initial examination and then approximately every 12 months after that for the next two years. These three follow-up contacts review the health-related developments occurring since the last contact. Each follow-up is completed by telephone (preferred) or in person (if necessary). The follow-up call is preceded by a letter sent by mail about two weeks in advance of the call (see Appendix). Information for this mailout is taken from the study data base.

#### 10.2.2 Time Window for Annual Contacts between Exam Center Examinations

Study participants are re-contacted annually on her/his initial (anniversary) examination date at approximately the same time each year. The target date for the AFU interview is the date of the baseline visit. Contact years are to be numbered sequentially, starting with the year of the baseline examination, i.e., Contact Year 01 is assigned to all participants at baseline exam, regardless of the year in which they completed her/his baseline exam (Table 24).

**Table 24. Contact Years by Visit Dates**

<b>Contact Year 01 Baseline Exam</b>	<b>Contact Year 02 AFU 1</b>	<b>Contact Year 03 AFU2</b>	<b>Contact Year 04 AFU 3</b>
9/26/2000-9/25/2001	9/26/2001-9/25/2002	9/26/2002-9/25/2003	9/26/2003-9/25/2004
9/26/2001-9/25/2002	9/26/2002-9/25/2003	9/26/2003-9/26/2004	9/26/2004-9/25/2005
9/26/2002-9/25/2003	9/26/2003-9/25/2004	9/26/2004-9/25/2005	9/26/2005-9/25/2006

Because recruitment is done over a three-year period, all participants will be in any one of three JHS baseline examination contact years during the calendar year in which annual contact interviews are conducted. Regardless of the contact year, the optimal time for placing the initial call each year for annual contact is generally not more than three weeks before the target (anniversary) date. A one year window, up to 6 months before and 6 months after the target date, is the maximum allowed for each annual contact. This window will allow accommodation of ARIC with JHS AFU.

When the contact window expires and no contact is made, a final result code for that window is entered on the Annual Follow-Up Record of Calls (see Appendix), and a new window begins.

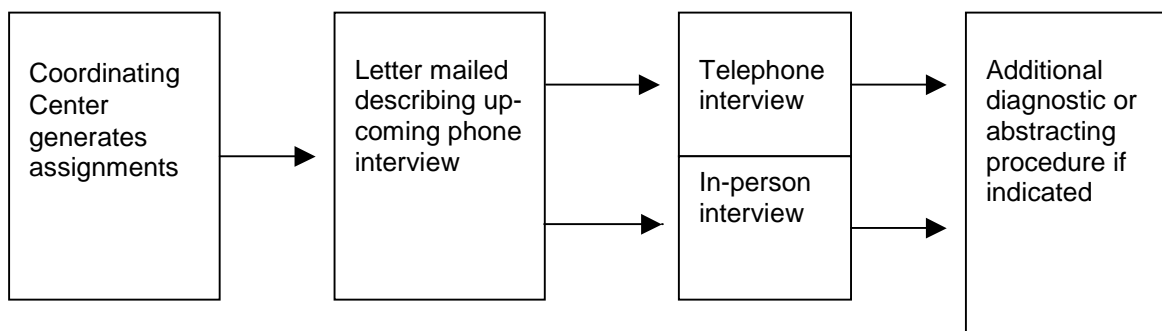
The contact year to which a participant death is assigned is determined by two factors: the date of death and whether or not the participant had already been interviewed during the contact year in which the death occurred. For example, if the death is determined during or prior to the regularly scheduled AFU interview, the death is assigned to the contact year in which the AFU form was administered. If however, a participant is interviewed in Contact Year 02, dies a short time afterwards, and the family notifies the Exam Center of the death, the death is assigned to the next contact year, i.e. Contact Year 03.

### 10.2.3 Follow-up Procedures

Annual follow-up of cohort members is used to (1) maintain contact and correct address information on cohort participants, (2) update tracing information on three contact persons, (3) ascertain the participant's vital status, and (4) document interim medical events/hospitalizations, life events and functional status between the three-year comprehensive examinations.

There are four primary components to annual follow-up: (1) the generation of scheduling material by the JHS Coordinating Center; (2) the scheduling of the AFU interview by Exam Center staff; (3) the administration of the AFU interview; (4) the ascertainment of medical information relating to hospitalizations for cardiovascular disease and documentation of fatal events. It is anticipated that the scheduling of a Exam Center examination every third contact year will occur during the annual follow up call in AFU Year 03. These steps are summarized in Figure 4 and described in the following sections.

**Figure 4. Interim Contact Procedures between Clinical Examinations in the JHS Cohort Study**



The Coordinating Center initiates the AFU procedures by generating several times a year AFU materials for use in scheduling and conducting the AFU interview. These materials include the Participant Tracing Information Sheet (see Forms Appendix). The list of participants includes the participant name, participant ID, date of baseline exam, and date of Visit 2 (optional), sorted in the order requested by the Exam Center. The Participant Tracing Information Sheet includes the participant's name, address, telephone number(s); sex, race, date of birth, state of birth, social security number, driver's license state and number; employer's name and address; date of baseline exam; and the names, addresses and telephone numbers of two contact persons and the personal health care provider. The Contact (CON) form lists the current data on file for the names and addresses of the participant and her/his three contact persons.

The scheduling of AFU interviews at the Exam Center is done year round and involves identifying the participants who require scheduling, establishing contact, administering the AFU form, and recording participant-reported medical events to JHS surveillance staff. The procedures for scheduling baseline exam and event classification are described in sections 1.6.5 and Manual 10: Cohort Surveillance,

respectively.

Using the list of participant anniversary dates, the Exam Center identifies participants for annual contact. All participants will be sent a letter (see Appendix) prior to the AFU interview reminding them that they will be contacted by telephone by a staff member from the JHS Exam Center for her/his annual interview. This letter is sent on JHS stationery and "forwarding and address correction requested" is stamped on the envelope. This letter contains:

1. A reminder that the addressee is in the study and that annual contact is involved.
2. A description of the purpose of the contact.
3. Information that the participant should obtain to assist with the interview (e.g., hospitalizations, physicians visits).
4. A request to call the JHS office to set up a time to complete the Annual Follow-up Interview.

Participants who do not have phones, have trouble communicating by telephone, or have special needs are not contacted by telephone but are visited in-person. If these participants can be identified in advance, the letter indicates that an interviewer will visit the home, and annual follow-up takes place there.

Participants found to have moved or who are otherwise lost to follow-up are traced using the tracing information obtained at baseline exam and during subsequent annual follow-up contacts or other local sources of information, such as the telephone directory, city directory, etc. By using the Contact Form, Exam Center staff can call or write to the family members, friends, employers, or physicians the participants identified as contact persons during previous interviews. By using Social Security numbers, periodic searches of the National Death Index are done. Every attempt is made to schedule and complete an AFU interview for each participant.

AFU interviewers telephone study participants at her/his contact numbers (home or work) at optimal times (i.e., late afternoons, evenings, or weekends) to conduct the annual follow-up interview. When the timing of the initial contact is inconvenient for the participant, the interviewer reschedules the AFU interview. When a cohort member can not be reached on the first call, the interviewer makes return calls as necessary, at varying times of the day and week until either the participant is contacted or a decision is made to initiate tracing procedures. On the Annual Follow-up Record of Calls (see Forms Appendix), a final contact status (result) code indicating the participant cannot be located (i.e., is lost to follow-up) is only assigned after all tracing avenues have been exhausted and supervisor approval has been obtained. Experience has shown that participants who are lost to follow-up in one year may be located in subsequent years of follow-up and only participants who die or insist on no further contact with the JHS should be considered irreparably lost to the study.

#### **10.2.4 Annual Cohort Interview**

In Contact Year 01, version "A" the AFU form is administered with AFU Year 1 supplementary questions. In each subsequent Contact Year 02 and Year 03, the baseline "A" version is used with the appropriate annual follow-up year supplementary questions. QxQ instructions for the Record of Calls and version "A" of the AFU form and prototype scripts for their administration have been prepared for the AFU interview (See Forms Appendix). The interview includes the use of three forms (CON, ARC and AFU) which update address and tracing information of cohort participants (See Forms Appendix); and ascertain her/his vital status (AFU, section A), death information (AFU, section B); perceptions of general health (AFU, section C); chest pain on effort (AFU, section D); possible infarction (AFU, section E); intermittent claudication (AFU, section F); TIA/stroke (AFU, section D); hospitalizations (AFU, sections H and K); and functional status, weight loss, and life events (AFU, section I) (See Forms Appendix, Annual Follow-up form). The Record of Calls (ARC) is used throughout the contacting process to log each participant's interim and final contact and appointment

status (when applicable). At some point after the AFU interview, every participant-reported hospitalization is verified and the discharge diagnoses recorded. Potential cardiovascular events are reviewed further by the abstraction of participants' hospital records to document the presence/absence of JHS Study endpoint criteria. Detailed information on diagnostic criteria and event determination of the cardiovascular events is provided in Chapters 4 and 5, respectively, of Manual 10, Surveillance Component Procedures.

The components of the AFU interview are usually done in the following order: (1) completion of the Record of Calls; (2) administration of the AFU questionnaire; (3) documentation of the participant's hospitalizations during the past year - section K of the AFU form; (4) scheduling of the appointment for Visit 2 exam (Contact Year 4, if funding has been continued); and (5) updating of the contact information (CON form).

The Record of Calls (ARC form) is used to keep track of attempts to contact a participant. The participant's name, ID, contact year, and contact year date ranges are pre-printed at the top of the form. Space is provided to document contact attempts, pertinent information for future contacts, and the outcome of the contact. There are ten contact RESULTS CODES. The final result code is circled and entered into the data entry system. The paper copy of the form is kept in the participant's folder to assist in future contacts. The results codes are as follows:

- 01** No Action Taken
- 02** Tracing (Not yet contacted any source)
- 03** Contacted, Interview Complete
- 04** Contacted, Interview Partially Complete or Rescheduled
- 05** Contacted, interview refused
- 06** Reported Alive, Will Continue to Attempt Contact this Year
- 07** Reported Alive, Contact Not Possible this Year
- 08** Reported Deceased
- 09** Unknown
- 98** Does Not Want Any Future AFU Contact

Codes 01, 02, 04, and 06 are interim codes. Codes 03, 05, 07-09, 98 are final codes. See Forms Appendix for detailed instructions for completing the form, and a description of the Results Codes for contacts. It should be noted that these codes are required for all AFU contacts, in contrast to the APPOINTMENT CODES which are only used in the Contact Years in which the participant is scheduled for a clinic visit.

Once contact has been made, the entire AFU interview is administered to surviving participants. When a participant has expired prior to the annual contact, the relevant portions of the AFU form (Sections A, B, H and K) are administered to a member of the participant's household (or a contact person) in order to officially record the death and to obtain the date and location of death and other relevant medical information.

Section A of the AFU form documents the participant's vital status and the date on which the status determination was made. The criteria for establishing participant vital status are defined in the form's instructions. Section B is completed on individuals who have died and records demographic information necessary for obtaining a copy of a death certificate. Sections C-G are administered to all surviving participants and document perceptions of health and interim (since the previous AFU interview) medical events; the majority of the questions were taken from the London School of Hygiene Questionnaire for chest pain on effort, possible infarction, and intermittent claudication. Guidelines for administering this section are provided below, in Section 10.2.4.1. Sections H and O

on the AFU form are administered to all respondents (participants and proxies) to document overnight hospitalizations in acute or chronic medical care facilities. The surveillance staff is notified of every cohort hospitalization and an event investigation is initiated. Section I is administered only to surviving participants. Section J is administered to all respondents to ascertain any changes in stress, coping and social support and negative emotions of anxiety or depression. Additional year questions for Contact year 02, 03, and 04 are administered in the corresponding annual follow-up year 1,2, or 3.

Tracing information listed on the pre-printed CON form (see Forms Appendix) is verified at the conclusion of the AFU form. Instructions for administering the form and a prototype script are provided at the end of the annual follow-up instructions. Any changes to tracing information recorded on the paper form during the telephone interview are recorded on the computerized version of the CON form by staff certified in the use of the JHS Data Entry System. Prior to making any changes in the DES, a hard copy of the current version is printed, dated, and placed in the participant file for future reference.

#### **10.2.4.1 Administration of London School of Hygiene Questionnaire**

The questions in Sections D-F (CHEST PAIN ON EFFORT, POSSIBLE INFARCTION, and INTERMITTENT CLAUDICATION) of the AFU form are based on the London School of Hygiene Questionnaire. The purpose of the London School of Hygiene Questionnaire (generally referred to as the 'Rose Questionnaire') is to standardize the identification of 'angina on effort' as defined by Dr. Geoffrey Rose. It is not the purpose of the questionnaire to arrive at a medical diagnosis. The questionnaire will fail to identify angina pectoris in some participants whose pains are regarded by the physician as genuinely ischemic. It may categorize other cases as pain due to a quite different cause. Any special effort, however, to alter the conduct of the interview in such instances would destroy the basic purpose of the questionnaire technique, which is to insure uniformity in the eliciting of defined symptoms.

Questions must be put to the participant exactly as they are printed: small changes can make unexpectedly large differences in responses. Unequivocal answers must be recorded as such, whether they seem reasonable or not. Supplementary questions (probing) should rarely be used. When they have to be asked, they should depart as little as possible from the wording of the initial question, and must not be such as to suggest any one particular answer to the participant.

If serious doubt arises about the correct interpretation of a particular answer, it is recorded in such a way as to exclude the suspected condition. An example of this type of situation is demonstrated in the following question and hypothetical response.

{Question} "Do you get it when you walk uphill or hurry?"  
{Response} "Well, I think I might, but I really can't remember."

This answer is recorded as NO and no probes are employed.

An exception is made to this rule only if a negative response to the lead-in question is an interpretation or denial of a positive response.

{Question} "Have you ever had any pain or discomfort in your chest?"  
{Response} "No. Only indigestion."

The answer is recorded as YES, because the participant's interpretation of the symptom is disregarded.



A frequently made error in the administration of the Rose Questionnaire is to extrapolate the participant's response to similar, but not defined, situations in the question.

{Question} "Do you get it when you walk uphill or hurry?"  
{Response} "Yes, the chest pain occurs when I cut the grass."

The answer to this question is recorded as NO, i.e., a strict interpretation is required. If pain is experienced only during some other form of exertion (e.g., cycling, stair climbing, lawn mowing, etc.), it must always be recorded NO. The response 'NEVER HURRIES OR WALKS UPHILL' can only be coded if the participant specifically denies walking uphill or hurrying.

For the remaining questions, unequivocal answers need not be probed. However, responses qualified by terms describing frequency of events, such as 'occasionally' or 'sometimes' should be probed by a question such as 'Does it happen on most occasions?' Individual QxQ instructions are provided in the Forms Appendix.

#### **10.2.4.2 Psychosocial Annual Follow-up Questions**

Five questions will be used to assess global psychological functioning each year at annual follow-up. Participants will be asked to rate her/his response to each question on a 6-point Likert-type scale. The specific psychological domains assessed include: major stressors, depressed mood, anxiety, coping, and social support.

##### **10.2.4.2.1 Background, Rationale and Hypotheses**

Epidemiologic and clinical studies have identified a number of psychosocial risk factors that appear to influence the incidence, morbidity, and mortality associated with cardiovascular disorders. Measures of each of these psychosocial domains is assessed at baseline. An annual global assessment will provide valuable information on change over the year's time.

Hypotheses include:

1. Greater global distress will be associated with an increased risk of hypertension and CHD events independent of the contribution of traditional CHD risk factors.
2. The relationship observed between global psychological distress, hypertension, and CHD events will be moderated by global social support, global coping, SES, and education.

##### **10.2.4.2.2 Administration**

The Psychosocial Annual Follow-up Questions will be administered to all participants during each year of Annual Follow-up. Each item is read to the participant and requires a rating on a 6-point Likert-type scale. Detailed instructions for the Psychosocial Annual Follow-up Questions are provided in the QxQ instructions (see Forms Appendix).

##### **10.2.4.2.3 Scoring/Coding**

One score is derived for each of the Psychosocial Annual Follow-up Questions. Each rating scale ranges from A (assigned 0 points) to F (assigned 5 points).

#### **10.2.4.3 Annual Follow-up Year 01 Questions**

##### **10.2.4.3.1 Life Events Scale**

Major life events will be assessed using an 11-item life events inventory. This measure was developed for use in the Eastside Village Survey. Items were derived from existing major life event

scales and community focus groups.

#### **10.2.4.3.1.1. Background, Rationale, and Hypotheses**

Exposure to stress, both acute events and chronic burden, has been related to CHD risk. The frequency and types of stressors experienced by an individual may be influenced by broad societal factors operating on a given segment of the population. Stress exposure has been related to social class and, to a lesser extent, ethnicity and thus may contribute to SES or ethnic differences in CHD risk. In the JHS, we will assess 3 types of stress exposure: major life events (at annual follow-up), minor life events, and chronic stress.

Hypotheses include:

1. High stress will be associated with an increased risk of hypertension and CHD events independent of the contribution of traditional CHD risk factors.
2. The relationship observed between stress, hypertension, and CHD events will be moderated by social support, coping style, SES, and education.

#### **10.2.4.3.1.2 Administration**

The Life Events Scale will be administered to all participants in the First Year Annual Follow-up call. Each item is read to the participant and requires a “Yes” or “No” response. Detailed instructions for the Life Events Scale are provided in the QxQ instructions (see Forms Appendix).

#### **10.2.4.3.1.3 Scoring/Coding**

The Life Events Scale yields a total score. Each “Yes” response is assigned 1 point. The total score is calculated by summing the “Yes” responses.

#### **10.2.4.3.2 Parental SES**

Parental Socioeconomic Status (PSE) (see Forms Appendix) questions incorporated in the Year 1 Annual Follow-up questionnaire provides information on early life social circumstances (home ownership, household amenities and conveniences) and parental education and occupation as a supplement to individual level information collected during the HII.

#### **10.2.4.3.2.1 Background, Rationale, and Hypotheses**

See section 1.6.4.13 for additional discussion of SES. Preliminary findings from ARIC suggest there is a role of childhood SES in the development of subclinical atherosclerosis. Variations across the life course and association with multiple psychosocial and behavioral intervening variables call for additional data, especially in African-Americans.

#### **10.2.4.3.2.2 Administration**

The Parental SES questions will be administered to all participants in the First Year Annual Follow-up call. Detailed instructions are provided by QxQ instructions.

### **10.2.4.4 Annual Follow - up Year 02 Questions**

#### **10.2.4.4.1 Life Orientation Test (LOT)**

The Life Orientation Test (LOT) (see Forms Appendix) is designed to assess an optimistic approach to life. It complements other measures included in the JHS psychosocial assessment that emphasize the evaluation of negative perspectives and emotions. This has been shown to be valuable in the

prediction of cardiovascular outcomes.

#### **10.2.4.4.1.1 Background, Rationale and Hypotheses**

Optimism has been shown to be a predictor of CVD morbidity and mortality. Recent evidence has further demonstrated a decrease in re-hospitalizations (various reasons) for patients with post coronary artery bypass surgery who rated high in optimism (Carver & Scheirer, 1999; Scheirer & Bridges, 1995). The effects associated with optimism are independent of the variance subsumed by traditional risk factors, and some research exists demonstrating this relationship is independent of depression as well. However, little research exists examining the relationship between optimism and CV outcomes once various other psychosocial risk factors are controlled for (e.g., coping, social support, hostility, etc.). Further, there is a need to examine interactions between optimism and these psychosocial variables as a means to improving outcome predictions.

Consistent with previous research, a primary hypothesis is that optimism will be negatively associated with the incidence of CVD. High-optimism individuals with subclinical or clinical CVD will demonstrate lower levels of clinical symptom expression, as well as CV-related morbidity and mortality, relative to disease-level matched low-optimism individuals. Finally, optimism is expected to interact with other psychosocial variables in determining outcomes. For example, optimism should have a greater impact on disease parameters for those individuals endorsing higher levels of environmental stressors (daily or chronic), and is expected to decrease the impact of stable, personal characteristics that previous work has established as predictors of disease development and progression (e.g., hostility).

#### **10.2.4.4.1.2 References**

Carver, C.S. & Scheier, M.F. (1999). Stress, coping, and self-regulatory processes. In L.A. Pervin and O.P. John (Eds), Handbook of personality: Theory and research, 2nd ed. (pp. 553-575). New York, NY, US: The Guilford Press.

Scheirer, M.F. & Bridges, M.W. (1995). Person variables and health: Personality dispositions and acute psychological states as shared determinants of disease. Psychosomatic Medicine, 57, 255-268.

#### **10.2.4.4.1.3 Administration**

The LOT will be administered during the Second Year Annual Follow-Up, to be administered by a trained interviewer. Responses are made based on a global frequency-based Likert-type scale ranging from Not At All Like Me (1) to A Lot Like Me (3). The interviewer will instruct the participant to listen to each item, and then choose the response that indicates how well that statement describes them in general. Detailed instructions are provided in the QxQ instructions.

#### **10.2.4.4.1.4. Scoring and Coding**

Each of the 6 items is rated on a 4-point Likert-type scale with the following descriptors:

<u>Descriptor</u>	<u>Point Value</u>
A Lot Like Me	3
Somewhat Like Me	2
A Little Like Me	1
Not At All Like Me	0

The instrument is scored by summing all responses to produce a total score. The minimum score is 0, and the maximum is 18.

#### 10.2.4.4.2 Job Strain

An adaptation of the Karasek job strain measures will be used to assess job satisfaction, job control and job strain. Supervisory or managerial responsibility and ethnic/racial work comparison are also assessed.

##### 10.2.4.4.2.1 Background, Rationale, and Hypothesis

Issues of job control including factors such as job satisfaction, security, decision latitude and complexity, as well as organization of work have been implicated in the development of CVD. Evidence from both laboratory and observational studies indicates that control over the planning and execution of work influences blood pressure, smoking and eating habits Schnall, 1994; Schnall, et al., 1990; Marmot, 1991; Johnson, et al., 1996; Schnall et al., 1992; Alterman, 1994; Fine, 1996). Recent longitudinal studies (Bosmal, et al., 1997) have shown increased risk of CHD with low job control. Investigating the relationship of both imputed observer's rating and worker's self reports of occupational stressors to asymptomatic atherosclerosis, findings from ARIC (Muntaner, et al., 1998) provide further support for the notion of a protective effect of job control over work on the etiology of CVD. Substantive complexity, skill discretion and decisional authority were all negatively associated with intima-medial thickness of the carotid artery wall, an indicator of atherosclerosis. Even with adjustment for various risk factors, including income, this potential risk factor deserves closer scrutiny. The need for prospective study of the etiologic role of work organization in atherosclerosis is further supported by evidence from a recent Finnish study (Lynch, et al., 1997) showing a significant association between work demands and progression of atherosclerosis. As no psychosocial work environment scales were directly administered to ARIC participants, the JHS plans to fill this void by including a subset of the measures developed and validated by Karasek (1981, 1982).

##### 10.2.4.4.2.2 References

Alterman, T, Shekelle, RB, Vernon, SW, Burau, KD. (1994). Decision latitude, psychological demand, job strain, and coronary heart disease in the Western Electric study. American Journal of Epidemiology, 139: 620-7.

Bosma, H, Marmot, MG, Hemingway, H, Nicholson, AC, Brunner, E, Stansfeld, SA. (1997). Low job control and risk of coronary heart disease in Whitehall II (prospective cohort) study. BMJ, 314: 558-65

Fine, LJ. The psychosocial work environment and heart disease. (1996). American Journal of Public Health, 86: 301-33.

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Karasek, R, Baker, D, Marxer, F, Ahlbom, A, Theorell, T. (1981). Job decision latitude, job demands, and cardiovascular disease: A prospective study of Swedish men. American Journal of Public Health, 71(7): 694-705.

Karasek, RA, Schwartz, JE, Pieper, C (1982). A job characteristics scoring system for occupational analysis: Part I. New York: Center for the Social Sciences, Columbia University.

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Marmot, MG, Smith, GD, Stansfeld, S., et al. (1991). Health inequalities among British civil servants: The Whitehall II study. Lancet, 337: 1387-93.

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#### **10.2.4.4.2.3 Administration**

The job strain measures will be administered during the Second Year Annual Follow-up call. A series of 10 items related to job satisfaction and other work-related factors are asked by trained interviewers. The last three questions relate to ethnicity in the work environment and may be sensitive for the respondent. A non judgmental attitude is essential in asking these questions. Specific directions included in the QxQ instructions.

#### **10.2.4.5 Annual Follow-up Year 03 Questions**

##### **10.2.4.5.1 John Henryism**

The John Henryism scale is administered as part of the Year 3 Annual Follow-up Interview. It was designed to assess the degree to which an individual believes s/he can overcome environmental demands through hard work. The relevance to the JHS is that when this orientation occurs in the context of an environment in which the necessary resources are lacking, the risk of poor health outcome increases.

##### **10.2.4.5.1.1 Background, Rationale, and Hypotheses**

John Henryism is defined as an individual's self-perception that s/he can meet the demands of the environment through hard work and determination. It epitomizes the value of hard work and determination even in the face of overwhelming odds. James and colleagues have argued that individuals high in John Henryism but with few resources, such as a low level of education, are at greater risk for hypertension than those in other John Henryism by education groups (James, Harnett, & Kalsbeek, 1983).

Support for the John Henryism hypothesis has been mixed. James, et al. (1983) found support for the hypothesis in a study of blood pressure among black men and in a study of hypertension among samples of black men and women in the southern United States (James, et al. 1987). Duijkers, et al. (1988) also found that the combination of John Henryism and low education was associated with elevated blood pressure in a study of white men and women in the Netherlands. However, three subsequent studies of John Henryism among blacks in the United States have failed to find support for the hypothesis (James, et al., 1992; Wiist & Flack, 1992), including a large prospective study including over 5,000 blacks and whites (i.e., CARDIA; McKetney & Ragland, 1996). However, given the young age of this latter sample, it seems unlikely that an adequate test of John Henryism by socioeconomic status has been conducted. The JHS should provide a better opportunity to address this question adequately.

##### **10.2.4.5.1.2 References**

Duijkers, T.J., Drigver, M., Kromhout, D., et al. (1988). "John Henryism" and blood pressure in a Dutch population. Psychosomatic Medicine, 50, 353-359.

James, S.A., Harnett, S.A., & Kalsbeek, W.D. (1983). John Henryism and blood pressure differences among black men. Journal of Behavioral Medicine, 6, 259-278.

James, S.A., Keenan, N.L., Strogatz, D.S., et al. (1992). Socioeconomic status, John Henryism, and blood pressure in black adults: The Pitt County study. American Journal Epidemiology, 135, 59-67.

James, S.A., Strogatz, D.S., Wing, S.B., et al., (1987). Socioeconomic status, John Henryism, and hypertension in blacks and whites. American Journal of Epidemiology, 126, 664-673.

McKetney, E.C. & Ragland, D.R. (1996). John Henryism, education, and blood pressure in young adults. American Journal of Epidemiology, 143, 787-791.

Wiist, W.H. & Flack, J.M.(1992). A test of the John Henryism hypothesis: Cholesterol and blood pressure. Journal of Behavioral Medicine, 15, 15-29.

#### **10.2.4.5.1.3 Administration**

The John Henryism Scale will be administered by a trained interviewer in the Third Year of Annual Follow-Up call. Each item is read to the participant and requires a graded response based on how closely each item reflects the participant. Specific directions are included in the QxQ instructions.

#### **10.2.4.5.2 Neighborhood SES**

The Neighborhood SES questions (see Forms Appendix) incorporated in the Year 2 Annual Follow-Up interview are designed to provide an assessment of neighborhood characteristics including cohesion, violence and resources. Questions are adapted from Sampson, et al. (1997).

##### **10.2.4.5.2.1 Background, Rationale, and Hypotheses**

Sampson, et al. (1997), among others, note that neighborhood context may serve as both a stressor (neighborhood violence and disorder) or a buffer ( social cohesion and resources) for the development of CVD. Further, social class of a neighborhood may have a direct or indirect effect on subclinical or clinical disease. Geo-coded census block information will be attached to each participant record for later determination of neighborhood/community measures of social class according to techniques described by Krieger (1992) and Diez-Roux (1997, 1999).

Hypotheses include:

1. Neighborhood environment will be related to risk factors, hypertension, subclinical disease and CVD independent of individual level SES.

##### **10.2.4.5.2.2 References**

Diez-Roux, A.V., Nieto, F.J., Muntaner, C., Tyroler, H.A., Comstock, G.W., Shahar, E, Cooper, L.S., Watson, R.L., Szklo, M. (1997). "Neighborhood environments and coronary heart disease: A multilevel analysis American Journal of Epidemiology. 146(1):48-63.

Diez-Roux AV, Nieto FJ, Caulfield L, Tyroler HA, Watson RL, Szklo M. (1999). Neighbourhood differences in diet: The Atherosclerosis Risk in Communities (ARIC) Study. J Epidemiol Comm Health 53:55-63.

Krieger N. (1992). Overcoming the absence of socioeconomic data in medical records: Validation and application of a census-based methodology. American Journal of Public Health. 82:703-710.

Sampson, R, Raudenbush, S, Earls F. (1997). Neighborhoods and violent crime: A multilevel study of collective efficacy. Science. 227:918-924.

#### **10.2.4.5.2.3 Administration**

The Neighborhood SES questions are administered by trained interviewers to all participants as part of the Year 3 Annual Follow-Up. A series of questions in each of the three domains of social cohesion, neighborhood violence and disorder, and resources are asked. Respondents reply using a Likert-like scale to rate her/his own experience. A nonjudgmental attitude is essential as the interviewer asks these sensitive questions. Specific instructions are included in the QxQ instructions.

### **10.3 Retention of JHS Participants**

Continuation of JHS participants from completion of the HII through completion of the baseline exam and 24-hour measures and beyond is dependent on a variety of participant, organizational, protocol and community involvement (POPCI) factors (Wyatt, et al., 1999). A Participant Recruitment Study (PRS) for the JHS was conducted in 1999 to ascertain from the study community the issues and concerns about study participation over time. Not unexpectedly, one of the major concerns a series of issues related to safeguarding political and moral concerns: trust, truth, and honesty; understandable consent and protocol; and community co-involvement in all aspects of the study. Further, ways of recruiting and retaining as "gathering the JHS family" were uncovered as well as ways of building community partnerships as "friends of the JHS family." JHS investigators have seriously heeded each of these lessons in planning and developing the full study and strategies for maintaining participation. For a full report of the recommendations emanating from the PRS, the reader is referred to the Final Report of that study. A summary table of recommendations is included in the Appendix.

Projected recruitment (60-80%) and completed clinic examination (80-90%) rates rely on careful attention to the complex interplay among all aspects of the study design and community co-involvement in decision-making. Building and sustaining community and participant trust is an ongoing, iterative process requiring interpersonal effort coupled with an organizational infrastructure to assure success. Study investigators and staff makes every effort to maximize each interaction with the study community and the participants. An office of Community Partnership for Awareness and Health Education (CPAHE) provides ongoing information and education to the community, building partnerships with all elements of the community. A plan for engaging the community as beneficiaries and supporters of the JHS is enacted through the involvement of the CPAHE (see Community Partnership and Health Education Plan).

Every effort is made to make the HII and Exam Center visit as pleasant and burden-free as possible. The following selected features are part of the effort to maximize participation across the study: (1) qualified interviewers, (2) pre-appointment contacts, (3) clinic greeting/welcoming procedures, (4) no show procedures, (5) reimbursement of transportation costs and child/adult care, (6) recognition of participant and personal contact, (7) supervision, (8) participant follow-up, and (9) community awareness.

#### **10.3.1 Certification of Interviewers**

Interviewers are trained and certified in general interviewing techniques and the administration of all relevant HII, clinic, or AFU interviews. This requires familiarity with the contents and procedures for administering the forms, assigning contact and appointment status codes on the appropriate Record of Calls form, schedule an Exam Center appointment, and verifying contact information on the CON form. Staff are certified in administering all forms and questionnaires after review of a standardized protocol. Re-certification is required annually with the recommendation of periodic refresher courses and retraining if quality assurance analysis indicate poor performance or inconsistent results.

#### **10.3.2 Pre-appointment Contacts**

To increase respondent participation in the baseline exam, a pre-appointment reminder packet is mailed following the HII regarding the scheduled baseline examination appointment. The packet

thanks the participant for taking part in the HII, confirms the examination date and time, and reviews the preparation procedures as listed in section 1.7.3.

Reminder calls are made to each participant one or two days prior to the examination. At this time, the information concerning the fasting requirements, medication bags, and other details is reviewed with the participant. Participants are asked if they have any special needs and every effort is made to answer participant's questions. Participants are specifically reminded to take all medications that can be taken without food prior to coming to the clinic appointment.

When appropriate, a letter is sent to the participant's employer explaining the JHS and requesting time off during working hours (see Appendix).

### **10.3.3 Clinic Greeting / Welcoming Procedures**

Upon arrival at the Exam Center clinic, the clinic receptionist welcomes each participant. When possible, an interviewer/recruiter is assigned to the clinic each week to greet participants and assure that there is a smooth transition from the initial contact in the HII and the subsequent clinic exam visit. Volunteers will also serve as clinic hostess/hosts to assure that any participant needs are met during the clinic visit. These volunteers may assist with reading forms, providing snacks, talking with participants between procedures, and so forth.

### **10.3.4 Contact for No Shows**

Eligible participants who fail to arrive for a scheduled appointment or who cancel her/his appointments are contacted by telephone to reschedule the appointment. At that time, the scheduler attempts to address any concerns or fears that the participant may still have. A volunteer Council of Elders contact may also be initiated. (When necessary, the interviewer/recruiter who completed the HII may re-visit the home to ascertain any difficulties or answer any questions.) Recruiter/interviewers will monitor the show rate of their participant appointments making additional contact as needed to encourage rescheduling and completion of the baseline exam.

### **10.3.5 Reimbursement and Child/Adult Care**

The Exam Center provides for, or reimburses, local transportation from the participant's home to the JHS clinic. For those who are reimbursed, records are maintained for accounting purposes according to the Office of Management and Budget regulations and the University of Mississippi Medical Center guidelines.

Additionally, child or adult care will be provided in the JHS clinic for participants who need such assistance to enable them to attend the baseline examination. Space for such care is designated within the JHS clinic and volunteer staff is scheduled to provide oversight of children or adults when requested in advance by the participant.

### **10.3.6 Recognition of Participant and Personal Contact**

A personal thank you is sent to each participant immediately following the HII and each AFU interview (see Appendix). At the time of the clinic visit, each participant receives a small gift of appreciation for taking part in the exam as well as a more substantial gift or \$25 as selected by the participant. Another thank you and formal recognition as a participant in the JHS is mailed immediately after completion of the baseline exam and 24-hour measures. This recognition is a certificate of membership in the JHS cohort that is suitable for framing (see Appendix).

The Exam Center maintains personal contact with each participant throughout the year on special occasions such as birthday, holidays and special cultural events significant to the African-American community. The Office of Community Partnership issues a quarterly JHS Participant Newsletter



mailed to all cohort participants updating them on study progress including new and emerging findings.

#### **10.3.7 Supervision**

Throughout the entire process, from HII to baseline examination, annual follow-up, or refusal, close supervision helps maximize the rate of response. Supervisors record reasons for non-response and examine performance trends by interviewer and by area. When deemed appropriate, supervisors initiate re-contact with refusing participants to attempt her/his conversion. Detailed records of all contacts are maintained.

#### **10.3.8 Participant Follow-up and Satisfaction**

A "Comments and Suggestions" box is prominently located in the reception area of the Exam Center clinic. Forms and pencils are provided for participants to comment on their clinic visit. An Evaluation of Clinic Visit (see Appendix) is conducted at the conclusion of the clinic visit to obtain a global rating of the visit and suggestions for improvement. (A Participant Satisfaction Survey (see Appendix) is conducted by telephone on a 5-10% random sample of the cohort. This satisfaction instrument is designed to gather information about all components of the HII, clinic and 24-hour examination. Additionally, in-depth interviews regarding the experience of participating in the JHS will be conducted with a designated percentage of the cohort. Interviewer/recruiters and clinic staff will notify the Exam Center co-PI of any participants who have had particularly notable experiences for follow-up interviews. These interviews will provide ongoing information for quality improvement and retention of the JHS cohort. Findings from the satisfaction surveys and in-depth interviews will be reviewed regularly by the Council of Elders, Participant Recruitment, and Cohort Operations Committees who will advise on strategies to improve study performance.

#### **10.3.9 Community Awareness, Resources and Education**

To enhance continuous participation, the Coordinating Center Office of Community Partnership maintains active contact with the media and key community organizations and resources. Updates about the study are provided regularly to provide information and enhance community support. Community events and educational offerings are sponsored by the JHS to provide benefit from the study beyond direct participation in examinations. A regular JHS newsletter is distributed to key community sites to ensure regular communication about the JHS and provide heart health education.



## **11.0 DIET AND PHYSICAL ACTIVITY SUB-STUDY**

### **11.1 Introduction**

The JHS has unique potential for investigating diet and physical activity associations with coronary heart disease (CHD) in African-Americans. Most studies have not included adequate samples of African-Americans and instruments used to assess these health factors in other studies, including the ARIC, have typically not been validated in African-Americans. Therefore, a primary purpose of the Diet and Physical Activity Sub-Study is to provide data for the validation of the diet and physical activity instruments used in the entire cohort of the JHS. The sub-study data, which is collected in association with ambulatory blood pressure monitoring (ABPM), 24-hour urine, 24-hour physical activity monitoring (PAM), and other data from the home induction interview and clinic exam will enhance interpretation of these other measures as well as their interrelationships. A sample including 500 male and female JHS participants, with representation from varying socioeconomic levels, ages, and physical activity levels, will be selected to participate.

### **11.2 Background, Rationale, and Hypotheses**

#### **11.2.1 Diet**

The Willett Food Frequency Questionnaire (FFQ) was used in the ARIC study to assess usual diet intake patterns. The Willett FFQ (62 items) was validated against four 1-week dietary records among 173 women in the Boston area. It is critical to note that only a small percentage of this sample was African-American. Investigators have raised significant concerns regarding whether another instrument would be more appropriate in assessing diet within African-American populations, specifically the cohort in Jackson, MS. The Delta Nutrition Intervention Research Initiative (NIRI) Food Frequency Questionnaire (FFQ), developed exclusively with African-Americans in the Southeast, was selected as the most robust FFQ for the JHS.

A shortened version of this FFQ will be used to assess the entire JHS cohort. In addition to providing more detailed diet information on a subset of the cohort, the diet sub-study will assess the validity of the new short form. The integrity of significant items on the modified Delta NIRI FFQ will be maintained to allow the short FFQ to be analyzed as a subset of the longer Delta NIRI FFQ. By combining the initial short FFQ with the sub-study data, both the original and shortened versions of the Delta NIRI FFQ can be analyzed and validated, expanding nutrient-based research capabilities for both studies.

The sub-study is designed to calibrate as well as validate the Delta NIRI FFQ by comparing the calculated nutrient intakes from two Delta NIRI FFQs with the average intakes of four 24-hour diet recalls per participant. This will provide data on the validity of the FFQ and detailed information, which may be useful to improve the recipes, serving sizes, and other assumptions behind the development of the FFQ. We expect to document the validity of the Delta NIRI FFQ in assessing usual dietary intake patterns of African-Americans within the JHS cohort.

#### **11.2.2 Physical Activity**

Participants will wear a step counter during the week prior to some of the diet recall return clinic visits. The step counter data will provide a measure of average daily physical activity over several days across several occasions. The monitoring, coupled with the concurrent ABPM and PAM obtained on the full JHS cohort (see section 4.3, Manual 2: Cohort Procedures), will provide objective data for validation of the JHS physical activity survey instrument.

The JHS Physical Activity form (PAC) assesses self-reported habitual leisure, home, occupational and sport physical activity. It is administered during the interview at the home induction visit. A validation study for the parent instrument for the JHS survey included representative samples of

ethnic minorities, but that study was conducted only with women. In most population groups, men are more active than women and are involved in different types of activities than women; thus this sub-study validation process is important to the interpretation of the JHS physical activity survey data. In addition, some survey items were changed for the JHS to reduce the time required to administer the instrument and to include activities that may be more prevalent in men. We expect that physical activity reported on the JHS survey instrument will be significantly correlated with activity monitoring data, step counts, and physical activity reported at the sub-study interview visits.

The physical activity data from the sub-study will also be evaluated in relationship to established and potential cardiovascular disease risk factors such as obesity and body composition; diet composition and energy intake from the diet instruments; urine components associated with exertion; and psychosocial and neighborhood environment characteristics. We expect that physical activity level will be correlated with energy intake, body composition, blood pressure, resting heart rate, and cardiovascular disease risk factors and endpoints. The concurrent 24-hour diet assessments and multiple day physical activity data collection in this sub-study will provide unique data for improving understanding of the correlation of energy intake and expenditure in community samples and specifically in the understudied African-American population.

### **11.3 Sampling Design and Recruitment**

#### **11.3.1 Sample Inclusion and Exclusion Criteria**

Inclusion criteria are: 1) attendance at JHS clinical examination visit; 2) willing and able to wear the step counter and CSA® accelerometer for 24-hour study; 3) willing to volunteer for sub-study and 4) completion of informed consent. Exclusion criteria are: 1) unable to walk (may use aid such as cane); 2) lack of interest in participating; 3) interviewer or JHS investigator determination that participation is not in best interest of participant.

#### **11.3.2 Sampling Procedures for Sub-study Cohort Selection**

The JHS sampling design is described in section 1.3, Manual 2: Cohort Procedures. The cohort is comprised of remaining ARIC participants, a community random sample, and a family sample. All JHS participants will be asked to wear the activity monitor and step counter during the 24-hour monitoring following the clinic exam. Exceptions will occur when equipment is not available, participants request to not wear this additional equipment, and when study staff or investigators believe it is not in the best interest of the participant. Thus, the 24-hour activity monitoring will be a collected on a large sample approximating the sampling distribution of the JHS entire cohort.

All JHS participants having completed PAM are eligible for inclusion in the Diet/Physical Activity Sub-Study. A total of 500 participants will be recruited to complete the follow-up diet and physical activity interviews for the sub-study. Initially every second participant with usable data retrieved from the 24-hour PAM will be invited to participate in the sub-study. Eligibility will be established using the Diet and Physical Activity Sub-study Eligibility Screening (SEL) form (see Forms Appendix). A Recruiting Roster will be maintained to document those eligible (see Appendix). After the first 100 participants have been entered, the investigators will examine their characteristics in terms of gender, SES, age, and activity to make a determination of the need for inclusive over-sampling to adequately sample the different levels of these characteristics.

Investigators will pre-screen participants to determine sub-study eligibility using data from the Home Induction Interview, if this becomes necessary to optimize sub-study recruiting. Using the appropriate items on the SEL, they will extract Home Induction Interview data to classify potential participants. Gender and age will be obtained from the ELG form completed at the Home Induction Interview. The recruiting goal is for one-half the sub-study participants to be women. The sub-study sampling goal also includes approximately equal numbers of participants in younger (34-64) and older (65 and older) age groups, from lower and higher socioeconomic status groups, and from lower and higher

physical activity groups. Socioeconomic Status (SES) groups will be classified as poverty or non-poverty level participants. Classification will be based on the participants' responses of the Personal Data-Socioeconomic Status form. A poverty classification requires a response of "yes" to items 27e, f, g, or h or if the family income reported for item 28a falls on or below income level 3. Participants will be classified in the lower physical activity group if: the response is "0" on Item 7 (indicating no leisure time vigorous activity) *and* the response is A, B, or C on item 9 (indicating work activity is the same as or lighter than others of their age) *and* the response is N on Item 19 (indicating no exercise and sports participation) on the Physical Activity form (PAC).

### 11.3.3 Informed Consent

Participants from the JHS who may be eligible for the sub-study will be given a brochure (see Appendix) as they complete their clinic visit. They will be contacted by telephone and invited to volunteer for the sub-study. Those who agree will be given a clinic appointment. Written consent will be obtained when the sub-study participant reports to the clinic for the first follow-up visit. At that time, the participant will be asked to sign the IRB-approved Diet and Physical Activity Informed Consent Form (see Forms Appendix) documenting their willingness to participate.

## 11.4 Scheduling and Mail Out Procedures

### 11.4.1 Scheduling

Within about two weeks following the clinic exam, eligible JHS participants will be contacted by telephone using a standard script to invite participation in the sub-study. All contact attempts for recruitment and scheduling are documented on the Diet and Physical Activity Sub-study Record of Calls (SRC) (see Forms Appendix). Those who agree will be scheduled for a return visit for their first follow-up diet interview at the JHS clinic at a time that is convenient for them and about four weeks following the baseline clinic exam. The sub-study staff member will record appointments scheduled using the sub-study Appointment (SAP) form (see Forms Appendix).

There will be six data collection occasions for the sub-study participants. Scheduling criteria to assure data will include differing days of the week and seasonal variation will include:

FFQ encounter # 1 (short version) followed by 24-hour activity and step counter monitoring: Initial JHS exam visit, (any day of the week except Sunday)

24-hour recall #1 with step counter data collection and past week physical activity: about one month after initial exam

24-hour recall # 2 with step counter data collection and past week physical activity: about 2 months after initial exam

24-hour recall # 3 with step counter data collection and past week physical activity: three months after initial exam

24-hour recall # 4 with past week physical activity: at least five months after initial exam

FFQ encounter #2 (long version): within one week of last 24-hour recall (any day of the week)

Data collection encounters for each sub-study participant will be scheduled as follows:

Two 24-hour diet recalls and physical activity measures should be scheduled for any of the following:

Monday's intake:	Assessed on Tuesday
Tuesday's intake:	Assessed on Wednesday
Wednesday's intake:	Assessed on Thursday

Thursday's intake                      Assessed on Friday

One 24-hour diet recall and physical activity measure should be scheduled for:

Friday's intake:                      Assessed on Saturday

One 24-hour diet recall and physical activity measure should be scheduled for:

Sunday's intake:                      Assessed on Monday

It is estimated that the time between the initial short version FFQ and final long version FFQ will be approximately 6 months, which should allow for variation in seasonal intake and activity.

#### 11.4.2 Mail Out Procedures

After confirming the sub-study participant's willingness to return for a diet and physical activity interview, a Sub-study Appointment Reminder (see Appendix) letter will be mailed. The caller will also offer to mail a second copy of the sub-study brochure. Prior to the second, third, and fourth return visits, the mail out will include the step counter in a padded envelope, and the Step Counter Log (SCL) Form (see Forms Appendix), which includes instructions on the reverse side for wearing the step counter and recording the step count daily. The step counter and form will be mailed about a week prior to the scheduled follow-up visit so the participant can collect data for three days prior to the visit.

#### 11.5 Data Collection Procedures and Equipment

Participants will return to the clinic for five follow-up visits over a six-month period of time. All interviews will be administered face-to-face at the JHS Exam Center. Figure 1 contains a schedule of data collection measures for the sub-study.

**Figure 5. Schedule of Measures**

	Visit 1 (Clinic Exam)	Follow-Up Visit 2	Follow-Up Visit 3	Follow-Up Visit 4	Follow-Up Visit 5	Follow-Up Visit 6
Informed Consent for sub-study		X				
24 hr ABPM	X					
24 hr urine	X					
Anthropometric Measures	X					Weight
Clinical examination and sociocultural measures	X					
24 hr CSA Monitoring	X					
Diet FFQ	X Short					X Long
Diet 24-hour Recall		X	X	X	X	
3 day step count			X	X	X	
Past Week PA recall		X	X	X	X	X

### **11.5.1 Diet**

The 24-hour diet recalls will be administered using the Minnesota Nutrition Data System (NDS). During the final follow-up visit, the long form of the Delta NIRI FFQ is administered (see Forms Appendix). Interview tracking, whether it is 24-hour diet recall or FFQ, will be recorded on the Diet Interview Tracking (DIT) (see Forms Appendix).

#### **11.5.1.1 Administration of 24-hour diet recall and FFQ**

This design will include 2000 24-hour dietary recalls (4/participant) using the MN-NDS using a multiple-pass approach and 1000 FFQ (2/participant). Several food models, beverage containers and three-dimensional portion size estimation tools will be used to aid participants in estimation of portions. A US Supplement Ingredient Form (see Forms Appendix) will be administered to record the participant's supplement usage. For administering 24-hour diet recalls, the NDS Training Manual should be referenced. Refer to the Interviewer's Training Manual (see Appendix) and the Interviewer's Reference Guide for guidelines on administering the Delta NIRI FFQ.

### **11.5.2 Physical Activity**

Digiwalker step counters will be used to assess physical activity involving walking during the week prior to three of the return visits. Step counts are recorded by the participant on the SCL form (see Forms Appendix). The study staff member will use the Post Step Counter (PSC) form (see Forms Appendix) to record whether the step counter was returned and the log completed according to instructions. The previous weeks' physical activity will also be assessed at the follow-up visit by interview using the 12-item Past Week Activity (PWA) form (see Forms Appendix). The questions ask about activity at work, frequency and duration of moderate level activities, frequency and duration of vigorous activities, walking frequency and duration, and muscle strength and toning exercise during the past week. Items on this form have been validated in previous studies (Ainsworth, et al., 2000).

#### **11.5.2.1 Administration of Past-Week Physical Activity Recall Form**

The interviewer reads each question and records the response on the PWA. See the QXQ (Forms Appendix) for detailed instructions.

#### **11.5.2.2 Use of Step Count Form**

Special instructions for each physical activity form are contained in the QXQ's (Forms Appendix). Participants will be asked to wear the step counter for three days during the week prior to three of the visits and to record the step count each evening on a log that they return to the study staff.

The step counter instructions ask participants to wear the step counter at their waist, above the hip, for 3 days. To get daily step counts as a marker for level of physical activity, participants will be asked to record the total number displayed on their Digiwalker each evening on the SCL form and then reset the instrument to "0" to begin a new count for the next day. If they do not wear the step counter for part of a day, they do not record the total for that day. They reset the counter to "0" and wait until the next morning to wear the counter. If they forget to reset the counter in the evening, they let it count until the end of the next day and make a note on the form that the count is for two days.

Participants will not be given information that would help them interpret whether the number of steps recorded is "high" or "low," or "good" or "poor." If they ask, they will be told that this is what the investigators are trying to learn. Steps per day are different depending on the amount of walking involved in each person's physical activity (Welk, et al., 2000).

If feasible, a study staff member may phone the participants to remind them to record step counts and return the step counter at the visit. The interviewer retrieves the step counter from the participant at the beginning of the sub study clinic follow-up visit, examines the information recorded on the SCL form by the participant, and completes the sub-study PSC. If participants forget to bring the step counter and form to the clinic with them, they are given a padded, addressed, postage-paid envelope and asked to mail these back as soon as possible.

## **11.6 Data Management**

### **11.6.1 Diet Data**

Dietary data will be grouped into batches. Batches will be in SAS format. Each batch should include 50 participants and contain a complete set of dietary data. A complete set includes four 24-hour diet recalls and two FFQ's. Each batch is named in numerical order beginning with "Batch 01." An Access® data management roster will be maintained by DPASS personnel to keep track of the batch names and the individual participants ID numbers included in each batch. No data will be sent to Tufts until a complete set for 50 participants has been obtained. Identifiers will be recorded on 24-hour recall records or FFQ's, that will be sent to Tufts.

#### **11.6.1.1 Checking Data (before sending to Tufts)**

24-hour diet recalls and NDS require identification of a unique project name for entering data. Each project name will be named corresponding to its batch number. Diet data for the first 50 participants' dietary data sets are identified as "Batch 01." The NDS project name for each will be named corresponding to the Batch number (e.g. "Batch 01," "Batch 02," etc). Although personal identifying data will be omitted on all diet records, the JHS identification number will allow linkages of diet data to other data variables. Identical to the dietary shipments to Tufts described above, each project name will have 50 participants with their four 24-hour recalls. The 24-hour diet recalls will be entered and reviewed for final edits before sending to Tufts by DPASS personnel.

Food Frequency Questionnaires. All FFQs should be assigned the same batch name as the 24-hour diet recalls. All FFQ's will be reviewed for missing data, bends, rips, folds, stray marks, or incomplete erasures before sending to Tufts. If there are missing data in the FFQ, diet sub-study staff should contact the participant for complete data. If the participant is unable to answer or can not be contacted, then the missing data should be recorded as "never eaten" and specific notes to this effect kept for future reference. Please note: all data empty spaces must be completed to get a final FFQ analysis.

A Diet Shipping form (see Forms Appendix) will be used to accurately keep track of the data transfer. See QXQ (see Forms Appendix) for detailed instruction for completion of the form.

#### **11.6.1.2 Data Transfer procedures (JHS CC/Tufts)**

Upon completion of a 50 participant batch file, DPASS personnel will transfer diet data to Tufts using a File Transfer Protocol (FTP).

To ensure data accuracy, for the first 50 participants, data from only the first and second 24-hour diet recall and first FFQ will be sent to Tufts for review. The 24-hour diet recall data should include the NDS project file and food file and can be sent electronically. The original FFQ form must be sent by mail.

Once these initial 50 participants have completed their third and fourth 24-hour diet recall and last FFQ, these completed data sets should be sent to Tufts in the same format described as above.

Thereafter, data batches will be transferred to Tufts as complete sets of 50 participants (two FFQs and four 24-hour diet recalls per participant X 50 participants.)



Every six months a SAS® transport file will be generated by Tufts and shipped electronically to JHS. This data file will include daily totals of the 24-hour diet recalls and FFQs.

### **11.6.2 Physical Activity**

The physical activity sub-study data will be managed in Jackson by the JHS study staff and the sub-study principal investigator. All physical activity sub-study data will be maintained internally by sub-study staff and exported to the JHS CC on a regular schedule.

#### **11.6.2.1 Step Counter Data**

To minimize or explain missing data, study staff will review the portion of the Step Counter Log (SCL) form completed by participants with them during the visit. See QXQ (see Forms Appendix) for detailed instructions.

## **11.7 Training, Certification, and Quality Assurance**

### **11.7.1 Diet**

Diet sub-study staff will be required to complete an extensive training and certification protocol conducted by the JHS diet principal investigators and Tufts. Certification will be completed upon satisfactory completion of:

Completion of the Tufts training course and seven accurate Delta NIRS FFQ administrations is required prior to administering JHS interviews. The final two FFQ's are audio taped and must have <3% error rate upon review. A 5-10% random check of the original FFQ's will be conducted by Tufts to check for missing data or unused portion sizes.

Completion of a two-day NDS training program and accurate completion of seven NDS 24-hour diet recalls must be attained to administering JHS interviews. The final two are audio taped and must have a <6% error rate upon review.

All 24-hour diet recalls will be tape recorded to aid in reviewing and editing for accuracy.

Five percent of FFQ administrations will be audio taped. A second interviewer will recheck these FFQ tapes and 5% of 24-hour diet recalls for quality control. These reviews will be conducted randomly and completed prior to data transfer to Tufts.

Tufts will check the data set by batch for outliers, with nutrient totals, gram weights, frequency and serving sizes for both the 24-hour diet recalls and FFQ. Comparison of mean intakes from the 24-hour recall and the FFQ will be done every six months.

Problematic administration techniques or data entry errors will be discussed during scheduled diet study staff meetings. Specific interviewer deficits will be documented and reviewed with the interviewer in private. A Quality Assurance Tape Review form (see Appendix) will be used to identify problems and provide solutions.

Maintaining certification will be achieved by ongoing review of data collection. If any interviewer falls below acceptable accuracy ranges, they will be required to be complete several recertification exercises under the direction of the diet study investigator to bring this accuracy level within the desired range. This review is conducted monthly as an ongoing quality assurance activity.

### **11.7.2 Physical Activity**

All sub-study staff are required to complete physical activity training conducted by the physical activity

sub-study principal investigator and consultants. Certification of competency for all forms will follow the same procedures as the diet instruments. Administration of the items on the form will be audio taped along with samples of the 24-hour diet recall data. This will allow verification of accurate recording of the responses for a 3% sample by a second interviewer and spot-checking by the Physical Activity sub-study principal investigator.

**12.0 SURVEILLANCE**

"TO BE DEVELOPED"