



The Jackson Heart Study

Manual 16

Participant Retention and Follow-Up Manual of Operations

Version 1.0

May 2017

JHS Coordinating Center
350 West Woodrow Wilson Drive
Suite 701
Jackson, MS 39213

Table of Contents

I. Introduction.....	1
A. Background.....	1
B. Objectives of the Study.....	1
C. Rationale.....	2
D. Eligibility requirements for follow-up interviews.....	2
II. Retention and Follow-up of JHS Participants.....	3
A. Annual follow-up of participants.....	3
III. Maintaining contact and correct address information on participants.....	3
A. Updating contact information.....	3
B. Tracing participants unable to contact.....	4
C. Following-up on participants returned mail.....	4
D. Following-up on disconnected and wrong numbers.....	4
E. Follow-up on participants who are reported “deceased”.....	5
IV. Proxy role for JHS Cohort Members.....	5
A. Role of a Proxy.....	5
B. Conducting an interview with a Proxy.....	5
C. When is a proxy needed.....	6
D. Identification and tracking of the Proxy.....	6
V. Time window for follow-up contacts.....	6
A. General instructions for conducting follow-up interviews.....	6
B. Scheduling annual follow-up interview.....	7
C. Interim contact procedures	9
D. Annual follow-up Other (AFO).....	9
1. Congestive Heart Failure Questions	9
a. Background, Rationale, and Hypotheses.....	9
b. References.....	10
2. Diagnostics Tests/Invasive Procedures Questions.....	11
a. Background, Rationale, and Hypotheses.....	11
b. References.....	11
3. Update Family History Questions.....	11
a. Background, Rationale, and Hypotheses.....	11
4. Update Global Psychosocial Questions.....	11
a. Background, Rationale, and Hypotheses.....	12
b. Scoring	12
5. Access to care questions	12
a. Background, Rationale, and Hypotheses	12
b. References	13
VI. Interviewing Techniques.....	14
1. Interview Bias.....	14
2. Characteristics of a good interview	14
3. Characteristics of a good interviewer.....	14
4. Communication traps.....	14
5. Conducting the interview.....	15
6. Participant death and interview schedule.....	16
7. Linkage of follow-up and surveillance activities.....	17
VII. Quality Assurance.....	17
1. Data completeness and data consistency.....	18
2. Training and certification.....	18
a. Suggestions for interview training.....	18
3. Data security and confidentiality.....	19
VIII. The JHS Data Management System (DMS).....	19

a. Description.....	19
b. Overview of data collection using the DMS.....	20

I. INTRODUCTION

A. Background

The Jackson Heart Study (JHS), sponsored by the National Heart, Lung, and Blood Institute (NHLBI) is a large community-based, observational study whose 5306 participants were non-institutionalized African American adults from urban and rural areas in three counties (Hinds, Madison, and Rankin) that make up the Jackson, MS metropolitan statistical area (MSA). Jackson is the capital of Mississippi, the state with the largest percentage of (36.3%) of African Americans in the United States. The Cohort Component of the JHS study began in 1999, participants received an extensive examination, including medical, social, and demographic data. These participants were re-examined regularly with the first screen (baseline) occurring in 2000-04, the second in 2005-08, and the third in 2009-12. To date, the JHS project has published over 400 articles in peer-reviewed journals.

In addition, there are two sub cohorts of the JHS participants; JHS only and JHS-ARIC (Atherosclerosis Risk in Communities). The JHS only sub-cohort includes only participants in JHS, not ARIC. The JHS performs all surveillance and annual follow-up procedures for these participants. The other sub-cohort, JHS-ARIC includes participants who are participating in both the JHS and ARIC studies. ARIC conducts all surveillance and some of the annual follow up activities for participants. JHS collaborates with ARIC to ensure that these procedures remain consistent across the two studies. The JHS-ARIC participants receive an annual follow-up call from the JHS to gather information that is specific to JHS.

B. Objectives of the Study:

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

1. Identification of factors, which influence the development, and worsening of CVD in African Americans, with an emphasis on manifestations related to high blood pressure (such as remodeling of the left ventricle of the heart, coronary artery disease, heart failure, and stroke and disorders affecting the blood vessels of the kidney).
2. Building research capabilities of minority institutions at the undergraduate and graduate level by developing partnerships between minority and majority institutions and enhancing participation of minority investigators in large-scale epidemiologic studies.
3. Attracting minority students to and preparing for careers in health sciences.

C. Using the Manual

This document serves as the Manual of Operations for JHS staff who administer the components of the Cohort follow-up interview, and as a reference manual for JHS staff who perform surveillance activities. Cohort follow-up and surveillance are closely linked within the JHS study. High quality of data and a strict standardization of interviews throughout the duration of the study are essential for the success of the JHS study. This makes it important for the JHS Field Center personnel to be familiar with this manual of procedures. To meet our scientific goals, JHS Field Center staff must be fully trained and certified in the

procedures described in this manual, and must remain standardized throughout the data collection phase. A complete knowledge of the procedures described in this manual is required so that patterns in the JHS data can reflect differences between study participants and their characteristics, as opposed to differences between interviewers or deviations from study protocol.

The narrative portion of this manual provides operational information on scheduling contacts with participants, procedures for initiating and administering the data collection forms in the follow-up interview, linkage procedures between the annual follow-up and surveillance staff, and a description of the data management system.

D. Rationale

Annual Follow-up (AFU) interviews are conducted for the purpose of reviewing the health-related developments occurring since the last contact with the JHS. Each follow-up is completed by telephone (preferred) or in-person (if necessary). Each JHS participant is re-contacted approximately every 12 months on a time schedule based on the date of the baseline clinic examination.

Annual follow-up Other (AFO) form-The JHS has elected to collect a core set of information on participants, both at its clinical exams and during the annual telephone interviews. For reasons of cost efficiency, it has been study policy to add or remove items which reflect expanding areas of research interest or information that does not require annual data collection. Over the history of the study, several of the core data collection elements from the clinical exams were transferred to the annual telephone interviews. These questions are included in the Annual Follow-up Other form. The AFO is administered annual to all JHS participants (JHS-only and JHS-ARI sub cohorts) by the JHS AFU interviewers.

Follow-up and surveillance are closely linked within the JHS study. JHS-only sub cohort participants who have CHD or heart failure (HF) related hospitalizations and all deaths are investigated by the JHS surveillance personnel. Heart failure outpatient diagnoses occurring within 3 years of follow-up are investigated by the contacting physician for information to confirm diagnosis.

ARIC administers the annual follow-up interviews and conducts surveillance activities for the JHS ARIC sub cohort participants. These participants will therefore receive calls from the ARIC and JHS Interviewers. To maintain consistency with ARIC, the JHS administers the same interview forms to the JHS-only participants. JHS surveillance personnel receive the same training and perform the same procedures that are performed by ARIC.

E. Eligibility Requirements for follow-up interviews

Participants who completed an informed consent document and at least part of the baseline examination (Visit 1) have been contacted annually since Visit 1. Individuals who completed the home interview during the initial enrollment period but did not sign the informed consent form at the first Field Center examination (Visit 1) were not enrolled in JHS. These individuals are not eligible for annual follow-up or any other study procedures.

An attempt is made to contact all JHS cohort members regardless of whether they continued after Visit 1 to participate in the Field Center examinations or missed a given contact year's (CY) interview. This includes participants who have a designated proxy and those who have moved away from the community in which they were recruited. Telephone follow-up interviews can be conducted anywhere in the continental U.S. and other countries. Addresses and telephone numbers of cohort members with multiple residences are kept on file to contact participants on their target date. AFU Interviewers do not call participants who have been reported as deceased or who have withdrawn consent for follow-up calls.

II. RETENTION AND FOLLOW-UP OF JHS Participants

A. Annual follow-up of participants is used to:

- Maintain contact and correct address information on JHS participants
- Update tracing information on up to three contact persons
- Ascertain the participant's vital status
- Update information regarding hospitalizations, medical events, general health, life events, and functional, socio-economic, and smoking status since the last contact with JHS
- Update information regarding health care access, functional status, and discrimination (Note Table 1 provides a summary of the follow-up data collected).

The primary components of the annual follow-up process:

- Maintaining contact information
- Conducting annual follow-up interviews
 - a. Generation of scheduling materials by JHS Field Center
 - b. Scheduling the follow-up interview by the Field Center staff
 - c. Administration of the follow-up interview by the AFU interviewers
 - i. Collection of information relating to hospitalizations for cardiovascular disease.
 - ii. Documentation of vital status
- Support for surveillance activities
 - a. Review of hospitalization and vital status to determine the need for surveillance of death or CVD events
 - b. If necessary, transfer of the hospital and mortality information to the surveillance staff.

III. Maintaining Contact and Correct Address Information on Participants

A. Updating Contact Information

Every attempt is made to schedule and complete an AFU interview for each participant. Tracing information listed on the computer-generated Participant Contact Information Sheet is verified at the conclusion of the AFU form using the CON form (Appendix C: CON 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 DMS, a hard copy of the current version is printed, dated, and placed in the participant file for future reference.

B. Tracing Participants Unable to Contact

Participants found to have moved or who are otherwise lost to follow-up are traced using the tracing Information obtained at baseline exam, Exam 3, 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, Data Acquisitions Unit 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.

C. Following up on Participants' Returned Mail

(1.) All returned mail should be given to the sender.

(2.) After the sender documents what specific mailing did not reach the intended participant, the returned mail should be sorted as follows:

- a. If there is a forwarding address, the mail should be given to the designated staff for entry into the DMS, and, if appropriate, to re-address and re-send the mail to the participant at the new address.
- b. If there is no forwarding address, it should be given to the designated staff for tracing. The designated tracing staff will enter information from the returned mail into a spread sheet in the following order: Last name; first name; JID#. The spread sheet should be e-mailed to the designated staff who will obtain the participant's "Contact Sheet"
- c. The tracing staff will attempt to reach the participant by calling the contact persons listed on the "Contact Sheet" in the order listed and when new participant contact information is obtained, he/she will enter it on the spread sheet, document how the new information was obtained, and e-mail the spread sheet to the designated staff for entry into the DMS, and to the sender, along with the piece of mail that was traced.
- d. The sender will make the decision to resend the same piece of mail to the new address or, if it is outdated or obsolete, to send any other appropriate mail.
- e. When a new phone number is obtained, the tracing staff will call the phone number to verify both the phone number and the address. He/She will enter the new phone number on the spread sheet, verify that the address is correct, or enter a new address if appropriate, document how the information was obtained and e-mail the spread sheet to the designated staff for entry into the DMS and to the sender along with the piece of mail that was traced.
- f. When attempts to locate the participant via contacts have been exhausted, internet search sites such as zabasearch.com anywho.com and msn.intellius.com and others may be used. The online Social Security Death Index may be used to identify lost participants who are deceased.

B. Follow-up on Disconnected and Wrong Phone Numbers

- a. JHS staff who attempt to reach participants via telephone and receive a message of a disconnected or wrong telephone number should follow the appropriate steps to contact the participant.
- b. AFU Staff will follow the "AFU Participant Tracing Instructions"
- c. Non-AFU staff members should submit the contact information to the Manager of Retention and Surveillance for follow-up by AFU staff members. Other staff sends to the Manager

Surveillance/Retention the participant's information such as (Last Name, First Name and JID) for her referral to the appropriate staff.

- d. When AFU staff has exhausted all of the attempts to reach a participant via the listed contact persons, they should refer this record to the Manager Surveillance/Retention for his/her referral to the appropriate staff
- e. When the participant is reached, the tracing staff will update the participants' address, phone number and contacts and refer the participant to the appropriate Research Interviewer or to the Manager Surveillance/Retention for the next appropriate steps such as conducting the AFU interview, scheduling a call-back time.

f. Follow-up on Participants Who are Reported "Deceased"

- a. Participants may be reported deceased from a variety of resources such as obituaries in newspapers, announcement in church, word of mouth etc.
- b. Reports of deceased participants should be referred directly to the Manager of Retention and Surveillance who will request that the appropriate AFU staff call to confirm the death and express condolences.

IV. Proxy Role for JHS Cohort Members

For purposes of the JHS follow-up call, a proxy is defined as a well-informed individual who can answer health related questions on behalf of a JHS cohort member and authorize the release of medical records should the participant be unable to do either. Examples of a proxy are: legal next-of-kin (spouse, son or daughter, brother or sister, or their doctor), power of attorney, or a Legal Health Care Proxy. If a Power of Attorney (POA) has been designated, photocopy of the documentation is necessary for a medical records department to release records in the event the participant becomes cognitively impaired and the proxy signs a release form. Other options for a well-informed proxy include partners and close friends.

A. Role of a Proxy

It is important not to confuse the role of a proxy with that of a contact person. Study participants at times request the help of a family member or friend to answer some of the questions. A contact person might be a spouse or relative living in the house that keeps track of the participant's activities. The contact person's role is different than that of the proxy identified by the participant in that the contact merely helps the participant locate or remember needed information. The contact does not respond to opinion questions for the participant. Instead, a proxy responds to both the factual and assessment questions on behalf of the study participant.

B. Conducting an Interview with a Proxy

When an interview is completed by a proxy, the proxy is asked to answer for the participant (to the best of his/her knowledge) instead of the participant responding him/herself with the help of the "proxy." If the proxy does not know the answer, "Unknown" is recorded rather than a guess. During the interview the participant's name or

"him/her" should replace "you" in the specific questions, where appropriate. An interview completed by a proxy is recorded as directed in the follow-up form QxQ.

C. When is a Proxy Needed?

If the interviewer has indications that the participant may have cognitive problems the interviewer uses his/her judgment to determine if the participant is cognitively impaired and unable to answer questions reliably. If the interviewer is unsure or unable to make this determination, the Field Center Supervisor should be contacted before proceeding with the interview.

Through interaction with the participant (or based on the use of a proxy in a previous follow-up interview) the JHS interviewer determines whether the participant has the ability to respond.

Because the criteria that trigger the use of a proxy are subjective, the follow-up interviewers are offered additional training to assist in making this decision.

Before scheduling a follow-up interview, JHS personnel determines whether the previous follow-up interview was conducted with a proxy, in order to contact him/her to schedule the call. Other criteria available to the follow-up interviewer to determine whether a proxy is needed are a self-report of hearing problems or cognitive impairment.

D. Identification and Tracking of the Proxy

The proxy may be one of the persons initially named by the study participant as a contact. It may also be the case that JHS Field Center staff has already recorded a proxy and his/her contact information for a cohort participant. An important element of the follow-up interview includes asking participants to identify a follow-up proxy to answer questions about the participant's health if he/she is unable to provide that information themselves. This information is collected on the Contact Information Update (CIU) form.

V. Time window for follow-up contacts

The **TARGET** date for the Annual Follow-Up interview is the Visit 1 anniversary date for the given contact year. The **EARLIEST** date is 6 months before the **TARGET** date and the **LATEST** date is 6 months after the **TARGET** date. Phone interviews can take place no sooner than the earliest date and no later than the latest date. Three key dates defining when the participant is to be contacted are provided on the Participant Tracing Report. Example: Participant X had a visit 1 date of July 1, 2001. The window for his annual follow-up interview is January 1 through January 30, with a target date of July 1.

A. General Instructions for Conducting Follow-up Interviews

The participants' responses are entered onto the DMS directly, or recorded on the paper versions of the forms for delayed dataentry into a data management system housed and maintained at the JHS study center. The follow-up forms, and the QxQ instructions for administering the follow-up forms are provided on the JHS website.

B. Scheduling Annual Follow-Up Interview

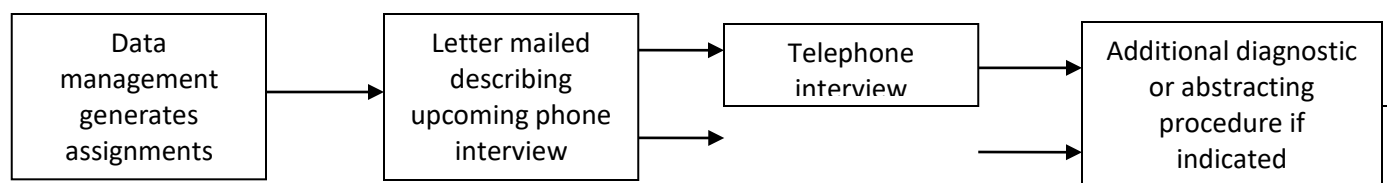
The Coordinating Center initiates the AFU procedures by generating several times a year AFU materials for use in scheduling and conducting the AFU interview. The list of participants includes the participant name, participant ID, date of baseline exam, and date of Visit, sorted in the order requested by the Manager Research Retention. The Participant Tracing Information Sheet includes the participant's name, address, telephone number(s); gender, date of birth, state of birth, date of baseline exam; and the names, addresses, and telephone numbers of two contact persons, and the primary 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.

Table 1. Summary of Data Collected During Cohort Follow-up Interview from JHS Participants

DATE OF STATUS DETERMINATION						
VITAL STATUS						
D						
A						
COMPARISON OF HEALTH TO OTHERS ONE'S OWN AGE						
CHEST PAIN ON EFFORT (Rose questionnaire)						
POSSIBLE INFARCTION						
INTERMITTENT CLAUDICATION (Rose questionnaire)						
STROKE/TIA						
HOSPITALIZATIONS						
FUNCTIONAL STATUS						
WEIGHT LOSS > 10 POUNDS IN PAST						
MARITAL STATUS						
DEATH OF SOMEONE CLOSE						

IDENTITY WITHIN JHS STUDY BOUNDARIES						
RESIDING HOME ADMISSIONS						
HISTORY OF CARDIOVASCULAR AND RELATED DISEASES						
DIAGNOSTIC PROCEDURES FOR CVD						
INVASIVE PROCEDURES/ TREATMENT FOR CVD						
CURRENT MEDICATIONS FOR HYPERTENSION, HIGH						
REGULAR OR CURRENT USE OF ASPIRIN						
HISTORY OF HRT USE OR GYNECOLOGIC SURGERY						
CURRENT CIGARETTE SMOKING						
CURRENT EMPLOYMENT STATUS						
INVESTIGATE HISTORY OF OUTPATIENT HF/CHF						
HISTORY OF ATRIAL FIBRILLATION,						
SWELLING FEET OR ANKLES						
LEG DISEASE						
BATHING PROBLEMS						
HISTORY OF ASTHMA						
HISTORY OF PAD OR INTERMITTENT CLAUDICATION						
PRESCRIBED MEDICATIONS						
ULCER						

C. Interim Contact Procedures between Clinical Examinations in the JHS Cohort Study



The components of the AFU interviews are usually done in the following order:

- 1) Completion of the Record of Calls
- 2) Administration of the appropriate AFU questionnaires
 - Annual Follow-up Form (JHS-only sub cohort, this form is done by ARIC for the JHS-ARIC participants)
 - Completion of the Annual Follow-up Other (AFO) form
 - Updating of the Contact Information (CON) and Proxy Designation forms
 - Updating the General Interview(GNE) and Medical Condition Update (MCU) forms

D. Annual Follow-Up Other (AFO)

The AFO form is administered to determine recent medication use related to chest pain or some other heart condition, whether the participant has experienced any of the signs or symptoms of congestive heart failure, had any invasive procedures or diagnostic tests with their associated indication (reasons), update family history, assess the degree of global psychosocial experiences over the previous year, and health care access.

a. Congestive Heart Failure Questions

Detailed information on congestive heart failure (CHF) symptoms that may have been experienced in the past year, since the last JHS contact, is assessed as part of the AFO form. Participants are asked about possible symptoms of CHF as detailed in the table below. Difficulty breathing or swelling of the feet or ankles are common symptoms that are assessed by a series of questions that request information about shortness of breath when at rest or that awakens the participant at night, needing extra pillows to improve his/her breathing, night time cough, or lower extremity swelling. The items included in this battery were derived from several standardized sources used by Multiethnic Study of Atherosclerosis (MESA), Framingham and Cardiovascular Health Study (CHS) (1-4).

Table 2. Congestive Heart Failure Criteria Symptoms List

- | | |
|----|---|
| a. | Paroxysmal nocturnal dyspnea Orthopnea |
| b. | Dyspnea on exertion |
| c. | Shortness of breath (dyspnea at rest) Night Cough |
| d. | Bilateral lower extremity edema |

b. Background, Rationale, and Hypotheses

Congestive heart failure (CHF) is a syndrome that disproportionately affects African Americans (5- 6). National Health Surveys were unable to document differences in self-reported heart failure between blacks and whites (7), but there is evidence that African American ancestry is a major risk factor for hypertension and hence congestive heart failure (6). CHF is lethal in African Americans, and contributes significantly to high prevalence of cardiovascular disease morbidity and mortality in African Americans nationally (7-8). African Americans appear to develop asymptomatic left ventricular dysfunction (ALVD) which is a precursor for the development of symptomatic congestive heart failure (9). It also appears that African American males are at a greater risk of developing ALVD (10). Risk factors for the development of CHF are numerous, but two major ones are hypertension and coronary heart disease (9). Congestive heart failure mortality rate increases with age in African Americans and at every age mortality rates for African Americans exceed rates for the white population (11). CHF may occur earlier in life in African Americans because of the high prevalence of hypertension in this group (12). National surveys reported that African Americans have higher prevalence and incidence of hypertension and heart failure across every age group when compared to whites (13). Most of these studies also reported that CHF is at least 50% higher in African Americans than in whites. Overall, the heart failure rates are 3 to 7 times higher in African Americans when compared to other ethnic groups nationally.

The management of heart failure is characterized by high rates of hospital admissions and readmissions. For African Americans, the most practiced self-care behavior for heart failure is the use of prescribed medications, with the least practiced behavior of symptom monitoring and management (14) of the contributable risk factors such as coronary heart disease and hypertension. This suggests that African Americans respond more to intervention than prevention and this may account for high re-admission rates into hospitals (5). Clinical studies reported higher rate of readmission in elderly African American patients with CHF when compared with whites, but case fatality CHF mortality rates are similar (8).

CHF mortality rates in Mississippi are about 4 to 6 times higher than US National rates for ages 20- 64 (15). Finally, the CHF mortality rates in African Americans in Mississippi are increasing, according to the most recent available data (11). Data on incidence and prevalence of CHF in African Americans is limited or unavailable. JHS is an African American study and will be an excellent resource for studying CHF in African Americans. The CHF questions will collect incident data on CHF in cohort participants during the annual follow-up interview. The next phases (II and III) of the JHS will include CHF event ascertainment. This will parallel the current system that is utilized by JHS to identify, classify, review and adjudicate both coronary heart disease (CHD) and stroke.

c. References

1. Bild DE, Detrano R, Peterson D, Guerci A, Liu K, Shahar E, Ouyang P, Jackson S, Saad MF. Ethnic differences in coronary calcification: the Multi-Ethnic Study of Atherosclerosis (MESA). *Circulation*. 2005 Mar 15;111(10):1313-20.
2. Vasan RS, Sullivan LM, Roubenoff R, Dinarello CA, Harris T, Benjamin EJ, Sawyer DB, Levy D, Wilson PW, D'Agostino RB; Framingham Heart Study. Inflammatory markers and risk of heart failure in elderly subjects without prior myocardial infarction: the Framingham Heart Study. *Circulation*. 2003;107(11):1486-91.
3. Lloyd-Jones DM. The risk of congestive heart failure: sobering lessons from the Framingham Heart Study. *Curr Cardiol Rep*. 2001;3:184-90.
4. Schellenbaum GD, Heckbert SR, Smith NL, Rea TD, Lumley T, Kitzman DW, Roger VL, Taylor HA, Psaty BM. Congestive heart failure incidence and prognosis: case identification using central adjudication versus hospital discharge diagnoses. *Ann Epidemiol*. 2005; Jun 15.
5. Alexander M, Grumbach K, Remy L, Rowell R, Massie BM. Congestive heart failure hospitalizations and survival in California: patterns according to race/ethnicity. *American Heart Journal*. 1999; 137(5): 919-27.
6. He J, Whelton PK Epidemiology and prevention of hypertension. *Medical Clinics of North America*. 1997; 81(5): 1077-97. -
7. Ni H. Prevalence of self-reported heart failure among U.S. adults from the 1999 National Health Interview Survey. *American Heart Journal*. 2003;146(1): 121-8
8. Vaccarino V, Gahbauer E, Kasl SV, Charpentier PA, Acampora D, Krumholz HM. Differences between African Americans and whites in the outcome of heart failure: Evidence for a greater functional decline in African Americans. *American Heart Journal*. 2002;143(6):1058-67.

Philbin EF, DiSalvo TG. Influence of race and gender on care process, resource use, and hospital-based outcomes in congestive heart failure. *American Journal of Cardiology*. 1998; 82(1): 76-81.

9. Malki, Q et al. Clinical presentation, hospital length of stay, and readmission rate in patients with heart failure with preserved and decreased left ventricular systolic dysfunction. *Clinical Cardiology*. 2002; (4):149-152.

10. Wolinsky FD, Overhage JM, Stump TE, Lubitz RM, Smith DM. The risk of hospitalization for congestive heart failure among older adults. *Medical Care*. 1997; 10:1031-43.

11. Bosworth HB, Oddone EZ. A model of psychosocial and cultural antecedents of blood pressure control, *Journal of National Medical Association*. 2002;94(4):236-48.

12. McCullough, PA et al. Confirmation of a heart failure epidemics: findings from the Resource Utilization Among Congestive Heart Failure (REACH) Study. *Journal of the American College of Cardiology*. 2002; 39:1.

13. Artinian NT, Magnan M, Sloan M, Lange MP. Self-care behaviors among patients with heart failure. *Heart and Lung*. 2002;31(3):161-72.

14. Yancy, Clyde W. Treatment of heart failure in African Americans: clinical update. *Ethnicity and Disease*. 2002 Winter;12(1):S1-19-26

2. Diagnostic Tests / Invasive Procedures Questions

These items are included to assess the type and reasons for any cardiovascular diagnostic tests or procedures the participant may have had in the previous year. They are intended to update and supplement information previously gathered. A series of likely clinical indicators are included for each relevant test procedure. Items are based upon standard clinical care practices for cardiovascular disease diagnosis / intervention.

a. Background, Rationale, and Hypotheses

Capturing these data may be very important. Cardiac catheterizations are done very frequently, and coronary disease is clearly the leading killer of the JHS cohort. But, paradoxically, there are unresolved questions about the high rate of negative catheterizations (i.e., catheterizations that don't lead to definitive interventions like PTCA or surgery) in African American patients (vs the rates of procedures in whites). The whole notion that African Americans were somehow "immune" to coronary disease found support in the high frequency of negative catheterizations seen in studies like the National Heart Lung and Blood Institute's CASS Study (which set the standards for bypass surgery that are followed by most surgeons today). An increasing number of cardiac catheterizations are done outside the hospital. Our data may shed some light on this as we collect these data points longitudinally.

b. References

1. Taylor HA.; Chaitman BR.; Rogers, William J.; Kern MJ.; Terrin ML Aguirre FV.; Sopko G; McMahon Ross RN.; Bovill, EC.; TIMI Investigators Myocardial Infarction: Race and Prognosis After Myocardial Infarction: Results of the Thrombolysis in Myocardial Infarction (TIMI) Phase II Trial. *Circulation*. 88(4):1484-1494, October 1993.
2. Cooper R, Ford E. Coronary heart disease among blacks and whites in the NHANES-I Epidemiologic Follow-up Study: incidence of new events and risk factor prediction. *Ann Epidemiol*. 1992;2:637- 645.
3. Strogatz DS. Use of medical care for chest pain:- differences between blacks and whites. *AM J PublHealth*. 1990;80:290-294.
4. Sempos C, Cooper R, Kovar MH, McMillen M. Divergence of the recent US trends in coronary mortality for the four major sex-race groups. *Am J Publ Health*. 1988;78:1422-1427.

3. Update Family History Questions

The intent is to determine if there have been any deaths or new diagnoses among natural parents, full siblings, or natural children of participants since the last JHS contact. The items were modified from those asked in the Personal and Family History (PFH) form, Exam 1. Original items were modified from those used in ARIC. Additional questions were added in the JHS on the health history of full siblings and natural children to assure that a wide range of essential family health data can be captured.

A. Background, Rationale and Hypotheses

An extensive, well-accepted body of data supports the relationship between health history and risk for development of CVD. We hypothesize that 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 etc.

4. Update Global Psychosocial 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.

A. 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 are assessed at baseline. An annual global assessment will provide valuable information on change over the years' 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.

B. Scoring/Coding

Each item is read to the participant and requires a rating on a 6-point Likert-type scale. One score is derived for each of the Psychosocial Annual Follow-up Questions. Each rating scale ranges from 0 (assigned 0 points) to 5 (assigned 5 points).

5. Access to Care Questions

Items 11 through 29 were included to supplement the information collected at the baseline and subsequent visits regarding participant access to health care resources. These questions will provide ongoing information regarding the status of JHS participants in terms of type and stability of health insurance coverage, prevalence of prescription medication insurance coverage, out of pocket expenditures for medications, prevalence of health care access barriers, interactions with health care providers, and satisfaction with health care. These items were derived from items frequently used in population-based surveys such as the Medical Expenditure Panel Survey [1], National Health Interview Survey, Community Tracking Survey [2], which are frequently used to inform policy makers, legislators, and the public regarding health care access and utilization issues in the United States.

A. Background, Rationale, and Hypotheses

Health insurance status is an important determinant of health care access and satisfaction with health care. Numerous researchers have determined that regardless of race, the lack of health insurance status is associated with poor health outcomes, decreased use and expenditures for a variety of health services, increased prevalence of experiencing health care access barriers, decreased satisfaction with care, decreased quality of health care, and increased financial burden [3-5].

Simply asking questions regarding current health insurance coverage with each round of data collection does not address the considerable changes in health insurance status that can occur between data collection periods. Health insurance coverage instability can occur when a person gains or loses coverage as well as when the person experiences changes in coverage such as reduced benefits or increased co-payments. Instability in coverage has been associated with the same health care access barriers experienced by persons who are uninsured. Furthermore, asking uninsured persons about the length of time uninsured is important since longer time uninsured is associated with increased financial burden and access barriers [6].

A means of measuring health insurance instability is needed to accurately determine the impact of health insurance status on health care access, utilization, and the health of JHS participants. The prevalence of health insurance instability among JHS participants is unknown. Annually asking about current health insurance coverage, the type of coverage, and gaps in coverage, will provide information about the current health insurance status as well as stability of coverage over time.

Health insurance coverage does not always include coverage for prescription medications. Recent changes in Medicare prescription coverage have sparked interest in examining how elderly Americans cope with prescription medication expenditures. Co-payments and restrictions in coverage influence participants' ability to purchase medications and other health services. Out of pocket (OOP) expenses for prescription medication affect use of medications and ultimately health. However, not much has been written regarding factors that influence prescription medication use and expenditures for African Americans or non-elderly Americans. Asking questions about the status of insurance coverage for prescription medication and the OOP associated with prescription medication use will allow investigation of factors influencing prescription medication expenses and the effect of these expenses on the lives of JHS participants [7,8].

Few questions were asked at the baseline visit regarding health care access barriers and the use of health services. The AFO delves more deeply into use of primary care services and the existence and nature of health care access barriers experienced by JHS participants. Self-report of the number of primary care visits has been shown to be a fairly reliable measure of the level of utilization. In addition to asking about problems getting care the participant is asked about whether he or she/ has gone without care, the type of care foregone, and confidence with getting high quality care. The inclusion of these measures of realized health care access will allow analyses of the relationship between primary care use, health insurance status, and health status [8,9].

The relationship of the JHS participant and health care providers is an important aspect of health care access. Being listened to and respected, having things explained, and having the provider spend enough time with a person are important aspects of these relationships which can have an impact on a person's perception of how they are treated by health care professionals as well as trust and satisfaction with health care. These attitudes can also influence JHS participants' willingness to access the health care system [10].

Hypotheses that can be examined with these health care access measures include:

- a. Health insurance status (including instability in coverage) will be associated with the use of primary care services, prevalence of having unmet healthcare needs, satisfaction with care, confidence with getting care, prevalence of symptoms indicating angina or heart failure exacerbation, and level of stress anxiety.
- b. Prescription medication coverage status will be associated with the use of medications to treat chest pain and heart failure and out of pocket (OOP) expenditures for prescription medications, OOP expenditures for prescription medications will be associated with the use of medications to treat chest pain and heart failure
- c. Interactions with health care providers will be associated with use of and satisfaction with health care

B. References

1. Monheit, A.C., R. Wilson, and R.H. Arnett, *Informing American Health Care Policy: The Dynamics of Medical Expenditure and Insurance Surveys, 1977-1996*. 1999, San Francisco: Jossey-Bass Publishers.
2. Center for Studying Health System Change, *Design and methods for the Community Tracking Study*. 2002, Robert Wood Johnson Foundation.
3. Committee on the Consequences of Uninsurance, *Coverage matters: Insurance and health care*. 2001, Washington, DC: Institute of Medicine. 169.

4. Hadley, J., *Sicker and poorer--the consequences of being uninsured: a review of the research on the relationship between health insurance, medical care use, health, work, and income*. Medical Care Research and Review, 2003. 60(2 Suppl): p. 3S-75S; discussion 76S-112S.
5. Smedley, B.D., A.Y. Stith, and A.R. Nelson, *Unequal treatment: Confronting racial and ethnic disparities in health care*. 2002, Washington, DC: National Academy Press.
6. Short, P.F., D.R. Graefe, and C. Schoen, *Churn, churn, churn: how instability of health insurance shapes America's uninsured problem*. 2003, The Common Wealth Fund: Washington, DC. p. 1-15.
7. Cunningham, P.J., *Affording prescription drugs: Not just a problem for the elderly*. 2002, Center for Studying Health System Change: Washington, DC. p. 1-26.
8. Henry J. Kaiser Family Foundation, *How do patterns of prescription drug coverage and use differ for white, African American, and Latino Medicare beneficiaries under 65 and 65+?* 2003, Henry J. Kaiser Family Foundation: Washington, DC. p. 1-20.
9. Kasper, J.D., *Asking about access: Challenges for surveys in a changing healthcare environment*. Health Services Research, 1998. 33(3 Pt 2): p. 715-740; discussion 761-766.
10. Collins, K.S., et al., *Diverse communities, common concerns: Assessing health care quality for minority Americans*. 2002, Commonwealth Fund: New York, NY.

VI. Interviewing Techniques

The goal of data collection by interviewing is the collaborative acquisition of epidemiologic data, using standardized techniques at each examination site for the duration of the study.

1. Interviewer Bias

The use of rigidly, standardized interviewing techniques is employed to reduce one of the many potential sources of misclassification; i.e., interviewer bias, a *systematic* difference between responses obtained by different interviewers. Although introductory scripts may be modified to respond to different situations an interviewer may encounter scheduling the follow-up interview, administration of each question exactly as worded and use of standardized definitions or explanations are critical.

2. Characteristics of a Good Interview

Interviews are friendly but businesslike. At the beginning of each encounter the interviewer makes introductions and verifies the participant's name. Participants are always thanked at the conclusion of interview sessions. Interview areas should be as quiet and private as possible. Although this is often out of the control of the interviewer, participants should be encouraged to reschedule their interviews at a time when these conditions are possible.

Interviews are the structured, one-sided passing of information, not a conversation. The pacing of questions is based on the comfort and comprehension of the participant with each interview; it may vary as the content, complexity or period of recall of the person or subject matter changes. During an interview, questions from the participant are answered with neutral, nonjudgmental responses: questions to the participant are limited to probes to clarify or resolve incomplete, ambiguous or inconsistent responses; repeating a question is most appropriate when the participant does not appear to understand the intent or meaning of the question. Gently stressing the portion of the question which was not understood when the question is repeated (e.g., "has a doctor ever") is often more efficacious than rereading it in exactly the same manner.

3. Characteristics of a Good Interviewer

Interviewers are responsible for being familiar with the questions, response categories and skip patterns of each interview. In the role of a telephone interviewer, the Field Center staff member acts as an interviewer, an impartial collector of data, and not, for example, as a clinician, investigator, friend or neighbor. Interviewers use a conversational tone and establish a pace consistent with the interest and ability of the participant. A good interviewer projects the importance of the interview to the participant and attempts to gain his/her confidence,

while remaining impartial and nonjudgmental. For example, a verbal response (or body language when the interview is being conducted in person) which indicates positive feedback is always inappropriate, even in the light of participant reports of behavioral modifications which in a clinical setting would result in praise and encouragement. Participant confidence in the confidentiality of each response/measurement is established.

4. **Communication Traps**

Communication traps include: (1) anticipating or answering questions directed to the participant with the interviewer's own thoughts; (2) hearing what one expects to hear; or (3) being drawn into a conversation. The putative sensitivity of a question is often as much a perceptual problem of the interviewer as it is the participant. Questions thought to be "sensitive" should be asked in a neutral manner which does not differ from the normal professional flow of the interview.

5. **Conducting the Interview**

Many interviews require the interviewer to train the respondent. During a telephone interview this has to be done by verbal instructions. For example, responses may follow a series of patterned questions, e.g., a doctor diagnosed condition, age at onset, and age at treatment during the participant's lifetime or may require the selection of the most appropriate category from a series of descriptors, e.g., almost never, sometimes, often and almost always. These instructions should be repeated until it is clear that the respondent understands them, and then subsequently offered only as needed.

The most important technique for conducting a rigorously standardized interview is to read the question in the exact words and in the exact sequence as printed in the questionnaire. When questions are to be asked out of the printed sequence, a skip instruction is printed on the form. Every question must be asked, even if the participant appears to have provided the information in the answer to another question.

Reading the transition statements exactly as they are worded is equally important in maintaining standardization.. The transition statements are designed to inform the participant about the nature of a question or a series of questions, to define a term, establish a time frame or describe what is being asked in the question. This is particularly important in this version of the AFU form. Most of the questions are familiar to the JHS participant, either from previous AFU interviews, or from participation in the clinic visits. However, the time frames for these questions are frequently different from those that were in a previous section of the AFU, or different from those that were administered during a previous interview.

Response styles of an interviewer influence the willingness of the participant to respond to questions and the quality of the response. Inappropriate styles include those that are evaluative or judgmental, interpretive or pedantic. Interrupting responses for reasons other than to focus or channel the participant's answer is counterproductive.

Appropriate styles of interviewing include providing supportive noises to reassure, pacify or reduce the intensity of the respondent's feelings. These include general clucking or an understanding murmur. Nondirective or understanding statements, such as a repetition of what the respondent has just said (in contrast to paraphrasing), reassure or show interest without intruding on the flow of the response. Probing is appropriate to seek further information, provoke further discussion along a certain line of thought or explanation, or to question the respondent. In general, and unless specifically countermanded in the QxQ instructions of the interview, probing is appropriate when an answer is unclear, incomplete, inconsistent or no response is given. The best and most frequently employed probe is silence. In a silent probe, the interviewer pauses or hesitates and looks to the participant for an answer. What appears to be dead time to the interviewer may represent the participant's review of a lifetime of events. Other types of probing include repetition of the original question, channeling ("tell me more about ..."), clarification ("when did your doctor tell you that?"), elaboration/continuation ("what happened next?"), encouragement ("I see, um, huh, hmm") and completion ("anything else?"; "can you tell me anything more about that?").

The most effective, spoken probes are neutral, such as:

"How do you mean that?", instead of "Why?"

"I would like your opinion."

"Can you tell me more about this?"

"Can you give me an example?" or "Can you explain that in a little more detail?"

"How are you using that term?"

"If you had to choose, which would you say?"

"What else can you tell me about that?" instead of "Anything else?"

The cautions in using probes are similar to those for the other interviewing techniques: do not interrupt; do not give the impression you are not listening; do not paraphrase the respondent's words and do not suggest an answer.

The most frequent obstacles to the administration of a standardized interview are: (1) a perceived conflict by the interviewer between the need to standardize the question or probing approach with the desire to obtain the truth; (2) the interviewer's goals of rapport with the participant being in conflict with standardization; (3) inadequate training of the interviewer; and (4) inadequate training of the participant.

6. Participant Death and Interview Schedule

When the death of a participant is found identified outside of a scheduled interview (e.g., through an obituary or if the death is reported to JHS by a next of kin), a staff member at the site opens a DEC form under this participant's ID and enters as much information as is available from the obituary or other source about the date and place of death. At least three months are then allowed to elapse, to give next of kin time to grieve, before scheduling an interview with the proxy respondent. At that time, administer the TERA and AFU. This action applies to all deaths identified outside of an interview, regardless of the scheduling window during which the death occurred, was identified, or the follow-up interview is made. A TERA form pending resolution may trigger automatic queries from the JHS CC; these should be considered reminders to assist in managing such pending interviews.

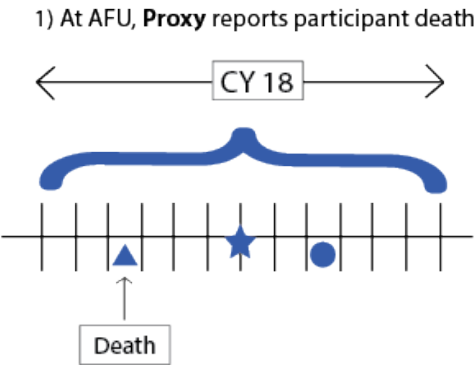
Conducting interviews at scheduled intervals is critical to ensure that reported data is sufficient and accurate. Additionally, following the guidelines for the timing of interviews can reduce nonresponse and improve retention of participants.

Early contact as soon as the contact window opens will increase the likelihood of achieving a successful contact. Information provided by the DMS collected during previous calls can optimize the timing and length of subsequent calls.

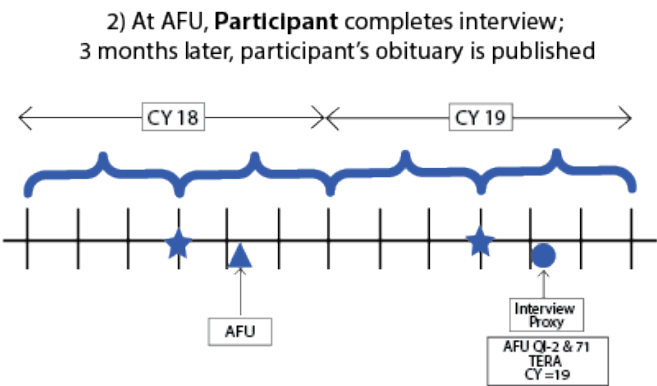
See Figure 1 for potential mortality scenarios for what forms to complete.

Figure 1. Mortality Scenarios

Mortality Scenarios



Mortality Scenarios



7. **Linkage of Follow-Up and Surveillance Activities**

The Surveillance staff is to be notified of every cohort hospitalization (and death), and an investigation is initiated by JHS Surveillance. No information pertaining to these events needs to be returned by Surveillance staff to cohort follow-up personnel.

8. **Quality Assurance**

Quality assurance is defined as any method or procedure for collecting, processing or analyzing data that is aimed at maintaining or enhancing their reliability or validity.

The purpose of quality assurance is to assure that data is collected in accordance with approved procedures, to maintain high-quality data collection. The JHS data collection procedures are clearly defined and described in detail in the follow-up documentation. The quality of data collected during interviews is maintained through a series of standardized quality assurance procedures. All interviewer-administered interviews are based on the reading of questionnaires, supported by a Manual of Operations and question by question (QxQ) instructions.

Quality Control Committee (QCC) is designated by the JHS Steering Committee to coordinate and direct the quality control activities. The QCC prepares recommendations to the Steering Committee in matters of quality assurance.

The JHS Coordinating Center (CC) monitors the study to ensure that the research staff performs those functions to standard. Certification of study personnel is an essential aspect of effective quality assurance as well as quality control in clinical research. In order to maintain proper collection of data despite potential for personnel changes over the study period, the JHS CC is responsible for establishing and providing the requisite minimum criteria and training and ensuring continued adherence to standards.

Training and certification of interviewers is required to insure proper interviewing technique and data entry accuracy. All interviewers are required to complete structured training sessions provided by the JHS CC and Field Center Supervisors. Training involves theory and practice in standardized survey interviewing techniques, covering the full range of critical interviewing skills and knowledge, including general interviewing techniques, probing, refusal conversions, and quality issues in scientific research, ethics and confidentiality issues. Certification indicates that an acceptable performance standard has been mastered or an adequate knowledge of material has been achieved.

Interviewers are trained and certified in interviewing techniques, the subject matter, terminology, and flow of each data collection form.

Training of interviewers is key to data quality. The purpose of ongoing training is to:

- ensure a uniform application of the study instruments (forms)
- explain the rationale of the study and study protocol
- provide an understanding of the intent of each question/question set
- motivate interviewers
- provide practical suggestions on how to deal with respondents

- improve the overall quality of the data

A. Data Completeness and Data Consistency

Data completeness means that all information provided by the informant was captured during the interview. Data consistency is achieved when interviewers collect data in the same way, as defined in the Manual of Procedures. Data completeness and data consistency are critical steps in assuring the data quality of the JHS study's complex instruments. Site supervision and the recertification process help identify and minimize data collection deficiencies to ensure that data collection is of good quality. Training provides information to data collectors in a structured manner. Interviewer supervisors provide immediate feedback on errors. Recertification is the means by which interviewer knowledge about the protocol and competence in data collection can be assessed on a continuing basis, particularly when changes in procedures or definitions are implemented.

To insure that data collection is complete and consistent, it is important to provide regular training with clear instructions on how to use data collection instruments, and how to conduct interviews.

B. Training and Certification

Interviewers are trained and certified in general interviewing techniques and the administration of the follow-up interview forms. Current knowledge of procedures and competence in data collection is essential, since follow-up instruments are complex and changing. Supervisors regularly monitor staff interviewing skills. Interviewers who experience difficulty in maintaining their skills are retrained.

a. Suggestions for interviewer training:

1. Review all materials (study instruments, QxQs, Manual) to check understanding of specific question/question sets.
2. Review various aspects of data collection, focusing on those aspects that are proving complex and difficult or those that are not being adhered to sufficiently by interviewers.
3. Conduct mock interviews, using role playing and practice interviews with feedback discussion.

Initial interviewer certification is provided by the JHS CC. Certification materials are made accessible for review to the Field Centers through the secure website or sent directly to the AFU supervisor. Certification training will also be provided by the JHS CC when significant modifications of follow-up questionnaires occur.

Annual recertification of the Field Center is required, with the recommendation of periodic refresher courses and retraining if quality assurance analyses indicate poor performance or inconsistent results.

The JHS CC has oversight organizing the annual recertification. This is done once a year by review of interviews with actual participants.

Each locally certified interviewer completes three audio-recorded interviews. The reviewing Field Center Supervisor reviews audio recordings. Supervisors must be certified and also conduct a sufficient number of calls to retain their skills and certification. Reviewers evaluate and rate each interview by completing the Follow-up Interviewer Recertification form.

b. Successful completion of the recertification consists of demonstrated ability in the following five areas:

1. Knowledge of the substantive matter in the interview
2. Use of an even pace and conversational tone
3. Demonstration of a professional and nonjudgmental demeanor
4. Ability to accurately record the participant's response

After all reviews have been completed, the JHS CC prepares a final report of the Field Center with scores and recommendations for each interviewer for discussion with the respective Field Center Supervisor, the PI, and the JHS QC Committee.

The Field Center Supervisor determine whether interviewers require additional training. Interviewer retraining is initiated when recertification results show a lack of knowledge of the protocol, lack of adherence to the QxQ specifications, poor interviewing technique, or shortcomings identified in the review process, regardless of the interviewer's overall score. If the retraining is extensive, a new audio recording with three interviews is prepared and submitted for review by the JHS FC director or a designee.

VII. Data Security and Confidentiality

Federal, State and Institutional information security regulations apply to JHS personnel and to the work done by JHS. All JHS personnel are required to be current in their training in ethical conduct of research and in information security training. Information security provisions apply to all data collected in JHS.

Access to systems and data should be based on the principles of least privilege and separation of duties. No individual should be assigned access privileges that exceed job requirements, and no individual should be in a role that includes access rights that would allow circumvention of controls or the repudiation of actions within the system. In all cases, access should be limited to authorized individuals.

VIII. THE JHS Data Management System (DMS)

a. Description

The JHS Data Management System [DMS], also known as Clintrial is a set of programs provided for collecting data for annually.

The DMS provides the following major functions:

- **Data Entry:** Allows data to be keyed, edited, and updated. All data entry is done directly into forms in the Clintrial DMS.
- **Reports:** Several reports are provided to identifying information about participants to help staff make contact with participants.

b. Overview of the Data Collection Using the DMS

In the course of performing a study, data for a number of participants must be collected at various times for later analysis. These data items are organized into groups of logically related information called forms or form types. Each form is then assigned a brief mnemonic code for easy reference, i.e. "AFU" for Annual Follow-up Form, etc.

It is sometimes necessary to change the content of a form during the course of a study. To allow for such changes, a version number is assigned to each form. However, for the General Interview Form, the form code is changed for every new version.

Since follow-up interview forms are collected repeatedly, extra information is included to uniquely identify each recorded instance or record of a form. For AFU, AFO, MCU, and the General Interview form, this is contact year.

We refer to all data items on a form as questions and assign a question number to each item. Typical question numbers may include both letters and numbers, e.g. 1, 2, 3a, 3b, etc.

Data items are usually entered directly into the JHS DMS, as this practice results in better data quality than transcribing data from paper forms.



Annual Follow-up Record of Calls

FORM CODE: ARC
VERSION A
03/30/2016

PARTICIPANT ID NUMBER:

CONTACT YEAR:

LAST NAME:

INITIALS:

DATE OF BASELINE VISIT:

EARLIEST DATE OF CONTACT:

m m d d y y y y

TARGET CONTACT DATE:

m m d d y y y y

LATEST CONTACT DATE:

m m d d y y y y

INSTRUCTIONS: Use this form to record every call to the participant. Complete as indicated, including appropriate Result Codes.

A. RECORD OF CALLS

	A. Day of Week	B. Date mm/dd/yyyy	D. Time	E.	F. Result Code *	G. Notes
	1 T W H F A	/ /	A P			
	1 T W H F A	/ /	A P			
	1 T W H F A	/ /	A P			
	1 T W H F A	/ /	A P			
	1 T W H F A	/ /	A P			
	1 T W H F A	/ /	A P			

* RESULT CODES [ENTER AND CIRCLE THE FINAL SCREENING RESULT CODE IN ITEM 15.f] (Continue on next page)

letter sent
action taken
answer
no signal
working machine
busy block
connected/non-working
number
ording/# Change

J participant lived here, but moved
permanently
missing
L socially/mentally incompetent
language barrier
contacted, interview complete
contacted, interview partially completed or
scheduled
P contacted, interview refused

S participant died, contact not possible this year
participant deceased
known/lost to AFU
participant does not want further contact
or
in AFU
X not scheduled
Y clinic exam not scheduled, pending
clinic exam not scheduled, refused
participant is deceased

B. THE SOURCE OF INFORMATION FOR ARC RESULT CODES L, Q, R and S

--	--	--	--	--	--	--	--	--	--	--	--

Source's Name

--	--	--	--	--	--	--	--	--	--	--	--

Number/Street/RFD

--	--	--	--	--	--	--	--	--	--	--	--

n n n n n n n n n n

City Telephone Number

--	--	--	--	--	--	--	--	--	--	--	--

--	--

State

--	--	--	--	--

Zip Code

RECORD OF CALLS (cont'd)

	A. Day of Week	B. Date mm/dd/yyyy	D. Time	E. I	F. Result Code *	G. Notes
	1 T W H F A	/ /	A P			
	1 T W H F A	/ /	A P			
	1 T W H F A	/ /	A P			
	1 T W H F A	/ /	A P			
	1 T W H F A	/ /	A P			
	1 T W H F A	/ /	A P			
	1 T W H F A	/ /	A P			
	1 T W H F A	/ /	A P			
	1 T W H F A	/ /	A P			
	AL CODE OFFICE USE ONLY					

* RESULT CODES [ENTER AND CIRCLE THE FINAL SCREENING RESULT CODE IN ITEM 15.f]

letter sent	J	participant lived here, but moved	R	ported alive, contact not possible this year
action taken		manently	S	orted deceased
answer	<	cing	T	nown/lost to AFU
r signal	L	sically/mentally incompetent		s not want further contact
working machine		guage barrier	V	er
city block		tacted, interview complete		AFU
connected/non-working		tacted, interview partially completed or	X	n scheduled
iber		cheduled	Y	ic exam not scheduled, pending
ording/# Change	P	tacted, interview refused	Z	ic exam not scheduled, refused
participant does not live		orted alive, will continue to attempt to		tacted, interview complete by proxy/
:/unknown		tact this year		rmant

Does participant live within official JHS boundaries?..... Yes

No 2

Unknown 0

tact not possible/exhausted all options



CONTACT INFORMATION UPDATE FORM

FORM CODE: CON VERSION: B

4/26/2016

ID NUMBER:

CONTACT YEAR:

LAST NAME:

INITIALS:

ADMINISTRATIVE INFORMATION

0a. Completion Date:

 / /

Month Day Year

0b. Staff ID:

0c. Does participant have hearing problem/loss? Yes ☐

No ☐

0d. Does participant have cognitive impairment? Yes ☐

No ☐

0e. Participant has a spouse in the JHS study.

s

ID number of spouse:

Go to item 0g

☐

0g. Administrative information:

Instructions: This form is updated any time a participant's information changes.

INTRODUCTION SCRIPT: "Hello Mr/Mrs [name of participant or proxy]. My name is _____. I would like to verify some of the information we have collected from you [name] in the past. First, your [name's] personal information; I'll read the information we have and you can let me know if anything needs to be changed."

A. VERIFICATION OF IDENTIFYING INFORMATION

1. a. Title: _____

b. First Name: _____

c. Middle Name: _____

d. Last Name: _____

2. Mailing Address:

a. _____

b. _____

c. City: _____

d. County: _____

e. State:

f. Zip Code: -

g. Is this mailing address your [name's] physical address? (i.e. where you [name] live[s])

Yes **Go to item 3**
No ☐

Physical Address:

h. _____

i. _____

j. City: _____

k. County: _____

l. State:

m. Zip Code: -

3. Home Phone Number: () - (land line)

3a. Work Phone Number: () -

4. Cell Phone Number: () - Does not use cell phone ☐

5. Email Address: _____ Does not use email ☐

6. Is there another place where you [name] live[s]? Yes ☐

No ☐ **to item 9**

Mailing Address:

a. _____

b. _____

c. City: _____

d. County: _____

e. State:

f. Zip Code: -

7. Phone Number at this second residence: () -

8. What time of year do you (does [name]) live at this second residence? from

month to month

9. Are you a veteran? Yes ☐

No ☐

B. CONTACT PERSON 1

"Now I would like to verify the information we have for your [name's] contacts. These are the people we can contact if we are unable to reach you [name] I'll read the information we have and you can let me know if anything needs to be changed."

10. a. Title: _____

b. First Name: _____

c. Middle Name: _____

d. Last Name: _____

11. Mailing Address:

a. _____

b. _____

c. City: _____

d. County: _____

e. State: f. Zip Code: -

12a. Telephone #1: () -

b. Telephone #2: () -

c. Telephone #3: () -

13. Relationship:

13a. Is this person either the primary or secondary contact? (check only one)

Primary ☐

Secondary ☐

Neither primary nor secondary ☐

C. CONTACT PERSON 2

14. a. Title: _____

b. First Name: _____

c. Middle Name: _____

d. Last Name: _____

15. Mailing Address:

a. _____

b. _____

c. City: _____

d. County: _____

e. State:

f. Zip Code: -

16a. Telephone #1: () -

b. Telephone #2: () -

c. Telephone #3: () -

17. Relationship:

17a. Is this person either the primary or secondary contact? (*check only one*)

Primary ☐ Secondary ☐

Neither primary nor secondary ☐

☐
☐
☐

D. CONTACT PERSON 3

18. a. Title: _____

b. First Name: _____

c. Middle Name: _____

d. Last Name: _____

19. Mailing Address:

a. _____

b. _____

c. City _____

d. County: _____

e. State:

f. Zip Code: -

20a. Telephone #1: () -

b. Telephone #2: () -

c. Telephone #3: () -

21. Relationship:

21a. Is this person either the primary or secondary contact? (*check only one*)

☐ Primary

☐ Second

☐ ary

Neither primary nor secondary

E. FOLLOW-UP PROXY INFORMATION

“We are asking all our JHS participants to give us the name of a person that can answer questions about your [name’s] health if you [name] cannot. This person will be considered your [name’s] follow-up proxy for the JHS Study. Only your JHS center can contact your [name’s] follow-up proxy.”

22. Is one of the contact people you have already identified going to be this person for you

☐ [name]?” Yes

No ☐ **Go to item 23**

22a. Which contact person is your [name’s] follow-up proxy?

Go to

item 27

1 = Contact #1

2 = Contact #2

3 = Contact #3

Please identify your [name's] follow-up proxy.

23. a. Title: _____

b. First Name: _____

c. Middle Name: _____

d. Last Name: _____

24. Mailing Address:

a. _____

b. _____

c. City _____

d. County: _____

e. State:

f. Zip Code: -

25a. Telephone #1: () -

b. Telephone #2: () -

c. Telephone #3: () -

26. Relationship:

Instructions: If updating for Follow-up, this form is complete.
Questions 27 – 29f are asked during the recruitment phone call in preparation for the clinic visit.

F. PHYSICIAN INFORMATION

“We would also like the name, address, and telephone number of your primary health care provide. Can you give me this information now?”

27. [DO NOT ASK: RECORD APPROPRIATE RESPONSE.]

Complete physician contact information obtained
Refusal or no health care provider

O Participant will call back with the information C
R

28. Is your primary health care provider a physician,
nurse practitioner, or some other provider?

Physician

P Nurse Practitioner N Other

a. If other specify: _____

29. a. First Name: _____

b. Last Name: _____

30. Mailing Address:

a. Clinic/Building: _____

b. _____

c. _____

d. City: _____

e. State:

f. Zip Code: -



Appendix 2

Follow-Up by Proxy

A very important goal of the Atherosclerosis Risk in Communities (JHS) Study is to keep track of any major changes in your health. This information is important for answering scientific questions about heart disease and other health conditions. You are the best source of information regarding your health, but there may be times when you are not able to provide these details yourself. We are asking you to provide us with the name of a person that can answer questions about your health if you cannot. This person will be considered your “proxy” for the JHS Study. The person you designate would only be contacted once per year, should you be unable to respond. Only your JHS center can contact your proxy.

What is a proxy?

A proxy is someone who can “stand in” for you and tell us about your health when you cannot because of illness.

Why is a proxy needed?

For almost 20 years you have been providing information about your health to JHS. This important information should not be lost, even when you are unable to provide it yourself.

What does a proxy do?

Should it be necessary we would ask your proxy to answer questions about your health, just like the questions you have been asked each year by the JHS staff.

Whom should I name as my proxy?

You should select someone who knows you well enough to provide health information about you. For example, your proxy can be the person who has your power of attorney, your legal healthcare proxy, or your legal next-of-kin (including your spouse, son, daughter, brother, sister, etc).

Am I allowed to change my proxy?

Yes, you may change your proxy at any time by either calling JHS or by indicating your wishes at your annual JHS phone call.

Will you give my earlier information to my proxy?

No, all of your information is strictly confidential and will not be provided to your proxy.

What would you like me to do now?

Using the attached form please indicate whom you have chosen to be your proxy. Please indicate his/her name, contact information, relationship to you, sign the form and mail it to the JHS field center in the enclosed envelope.

We have sent a copy of this form for your own records and one to give to your proxy. This material should be kept by him/her so he/she understands your wishes as a participant in the JHSStudy.

If you have any questions call Ms. Debra Wilson, JHS Surveillance Manager at (601) 815-5065



Thank you for your continued dedication to the JHS Study!

JHS Proxy Designation Form

Participant Name: _____
First Last MI

JHS ID: _____

I have named as my proxy: _____
(Name of person you choose as JHSProxy)

Relationship: _____

Proxy Address: _____

Proxy Phone Number: _____

He/she has the authority to provide medical information, and/or to sign a Medical Release Form to obtain hospital records or physician records for the JHS Study.

Participant's Signature

Date

Witness

Date

Complete only if participant is physically unable to sign: I have signed the Participant's name above at his/her direction in the presence of the Participant and witness.

(Name)

(Street)

(City/Town) (State)

Optional: If my JHS Proxy is unwilling or unable to serve, then I appoint as my Alternate JHS Proxy:

(name of person you choose as your alternate proxy)

of _____ (street)(city/town

