

**INSTRUCTIONS FOR THE ANNUAL FOLLOW-UP TRACING FORM AND
QUESTIONNAIRE, AFU, VERSION C.
8/23/2006**

I. GENERAL INSTRUCTIONS

Annual follow-up of the Jackson Heart Study (JHS) cohort is used to maintain contact and correct address information of cohort participants, ascertain vital status, and document interim medical and life course events, which have occurred since the last contact. Annual follow-up contacts are scheduled approximately every 12 months. Each routine follow-up is completed by telephone.

Four data collection forms are routinely completed in the annual follow-up (AFU) interview: the AFU Record of Calls, the AFU Questionnaire Form, and the Contact Form. If during the course of the AFU interview a participant requests a change in his or her consent level for the use/storage of DNA, the use of other study data, or the study's access to medical records, a fourth form, the Informed Consent Tracking (ICT) Form, is also filled in after the telephone call has been completed. The participant's most recent consent status is listed on the Participant Tracing Information Sheet (see below). If a participant calls in to change the consent after the AFU has been completed, another ICT form needs to be completed, using the contact year (CY) following the AFU contact year time window.

Beginning with the AFU Version C, interviewers will occasionally ask a participant for authorization to contact their physician for information on selected health problems, additional to that reported by the participant during the AFU interview. When the participant reports that a physician has diagnosed heart failure (HF) during an outpatient visit, and during the time frame specified in the AFU, the interviewer initiates the process that enables JHS to send that physician a request to complete the Physician Heart Failure Form (PHF). The PHF form is sent to each physician for whom the participant submits an authorization for access to information from the physician's records.

Also beginning with Version C of the AFU, JHS is expanding its ascertainment of possible events to record admissions to an emergency room or a medical facility for outpatient treatment. The procedures to ascertain overnight hospitalizations remain unchanged, per extant JHS protocol.

To assist field centers in scheduling AFU interviews, coordinating center personnel generates the Participant Tracing Information Sheet, an information sheet retrieved from the JHS Data Entry System (DES), i.e., not a data collection form. It lists the most current information on participant's address, date of birth, state of birth, contact persons, physician, employer, dates of the previous JHS visits, and the final contact status at the most recent AFU interview.

The cover page of the JHS Annual Follow-Up Questionnaire Form is a "Record of Calls" for use in contacting a participant. The Annual Follow-up Questionnaire includes sections to record vital status information and to gather information on participants' cardiovascular health, functional status and major life events, and a "Hospitalizations" section to record information on any hospitalizations reported by the cohort participant. Direct data entry of this information is preferred, but collection of the AFU information on paper is acceptable. In case of computer malfunction paper forms must be used for delayed data entry, and thus must be available.

The Contact Form is a DES-generated form containing the participant's most recent address and telephone number, and the names, addresses and telephone numbers of two contact persons. It is reviewed with the participant for accuracy, and updated, if necessary.

When contact is made with the participant or an informant, the interviewer attempts to determine the participant's present address (or residence immediately prior to death) to assist in JHS surveillance tasks. At the completion of the AFU interview, the location of the participant's residence is recorded as within the ARIC surveillance boundaries (YES), outside of the surveillance area (NO), or UNKNOWN in Item 53 of the AFU form. The JHS Coordinating Center obtains the surveillance boundary information from the surveillance staff. For participants who have expired, the place of residence refers to the person's address immediately prior to death. The interviewer also documents whether the respective JHS Coordinating center will continue to be able to get the participant's medical or vital statistics records from community surveillance.

II. ANNUAL FOLLOW-UP PROCEDURES

A. Contacting Procedures and Rules

The Coordinating Center – periodically generates the JHS Annual Follow-Up Tracing Forms for a group of participants. This form contains the tracing information needed to contact the participant.

The "Contact Year Date Range" appearing on the "Record of Calls" is determined as follows:

- The target date is the one-year anniversary of the participant's first clinic visit.
- The earliest date falls six months prior to the target date.
- The latest date falls six months after the target date.

For example, if a participant's clinic visit occurred on 11/14/86, then the target date for contact year 2 is 11/14/87. The earliest date of contact is 5/14/87, and the latest date is 5/13/88. In future years, these dates include the same month and day:

<u>Contact Year</u>	<u>Earliest</u>	<u>Target</u>	<u>Latest</u>
02	5/14/87	11/14/87	5/13/88
03	5/14/88	11/14/88	5/13/89
04	5/14/89	11/14/89	5/13/90
05	5/14/90	11/14/90	5/13/91
06	5/14/91	11/14/91	5/13/92
07	5/14/92	11/14/92	5/13/93
08	5/14/93	11/14/93	5/13/94
09	5/14/94	11/14/94	5/13/95
10	5/14/95	11/14/95	5/13/96
11	5/14/96	11/14/96	5/13/97
12	5/14/97	11/14/97	5/13/98
13	5/14/98	11/14/98	5/13/99
14	5/14/99	11/14/99	5/13/00
15	5/14/00	11/14/00	5/13/01
16	5/14/01	11/14/01	5/13/02
17	5/14/02	11/14/02	5/13/03
18	5/14/03	11/14/03	5/13/04
19	5/14/04	11/14/04	5/13/05
20	5/14/05	11/14/05	5/13/06

The initial call for annual contact is made no more than three weeks or so before the target date. Ideally, the contact takes place as closely as possible to the "target" date. If for some reason contact is not made until after the "Latest" date, this contact is assigned to the following Contact

Year. This procedure is described in more detail in the section on vital status below.

The "Participant Tracing Information Sheet" contains detailed information to be used in contacting the participant and/or changing the participant's categories of informed consent. It is generated as part of the tracing form. Refer to the separate protocol section on tracing for special procedures to use in difficult cases.

NOTE: Cohort participants who have moved outside of the study area continue to be traced, contacted and interviewed, and hospitalization or death information is obtained as applicable.

B. Performing the Interview

Form sections are typically completed in the following order:

- 1) Record of Calls
- 2) Questionnaire
- 3) Hospitalizations
- 4) Tracing information on the Update Form
- 5) Consent to access information in a physician's medical records

1. Record of Calls

The Record of Calls (ARC) is used to keep track of attempts to contact a participant. One line is used for each attempted contact, and a result code is assigned. Assigning the RESULT CODE at each contact is very important, as the code may be necessary for determining the final vital status in the event that the participant is not successfully contacted. Result codes for contacts (with possible final codes indicated by*) are shown in the following table.

RECORD OF CALLS - RESULTS CODES

RESULT CODE	RESPONSE CATEGORY	EXPLANATION
B	No Action Taken	No attempt has yet been made to contact the participant.
K	Tracing	Attempts are being made to locate the participant, but so far neither the participant nor another reliable source has been contacted.
N	Contacted, Interview Complete	The participant was successfully contacted by phone or in person, and the entire interview, including the questionnaire and hospitalization information was completed.
O	Contacted, Interview Partially Complete or Rescheduled	The participant was successfully contacted by phone, letter, or in person, but the interview is incomplete or was not done at all. This may be a temporary code if it is possible that the interview may be completed at a later date within the same contact year.
P	Contacted, Interview Refused	The participant was successfully contacted by phone, letter, or in person, but the interview was not done and will not be completed at a later date within the same contact year.
Q	Reported Alive, Will Continue to Attempt Contact This Year	Reliable information (e.g. from a relative employer, etc.) indicates that the participant is living, but direct contact has not yet been made. It is possible that contact will be made during this same contact year through further efforts. For example, "temporarily away" would fit in this category.
R	Reported Alive, Contact Not Possible This Year	Reliable information indicates that the participant is living, but direct contact has not yet been made. This code should be used only if repeated contact attempts have been made, or when it has been determined that it is not possible that contact will be made during this same contact year.
S	Reported Deceased	Reliable information indicates that the participant has died.
T	Unknown	Neither the participant nor another source of information has been contacted in a manner sufficient to provide reliable vital status data during the specified date range.
U	Does Not Want Any Further Contact	The participant has indicated that s/he does not wish to be contacted any more by the ARIC study. This code alerts staff that no additional contacts should be attempted during the same contact year. Notes should be kept on the record of call to describe the nature of the refusal. The supervisor at each field center determines the type of action to be taken at the following contact anniversary date, e.g., a polite letter, post card, or an alternative which is sensitive to any known reasons for this participant's desire not to be contacted again.
AA*	Interview completed by proxy/informant	The interview is completed by a reliable source or someone other than the participant (e. g. spouse or caregiver).

When the AFU has been successfully administered, or the supervisor determines that all contact efforts have been exhausted (see below), the final screening result code is circled in the RESULTS CODE BOX on the ARC form. This result code is subsequently entered as Item 54 in the data entry system of the Annual Follow-up form (AFUL).

Supervisor Review: The follow-up supervisor is responsible for reviewing cases of ambiguity or difficulty. Among these are:

- a. Refusals (attempt conversion).
- b. Difficult contacts or other non-completes. In particular, the supervisor decides when it is no longer practical to continue to investigate a person. All possible alternatives must be exhausted for this decision to be made.
- c. Undocumented deaths. If a death is reported for which no death certificate can be located, the surveillance staff reviews the case and attempts to resolve it. If no death certificate is ultimately located, including an NDI search, the vital status may be changed to "Unknown".

2. Questionnaire

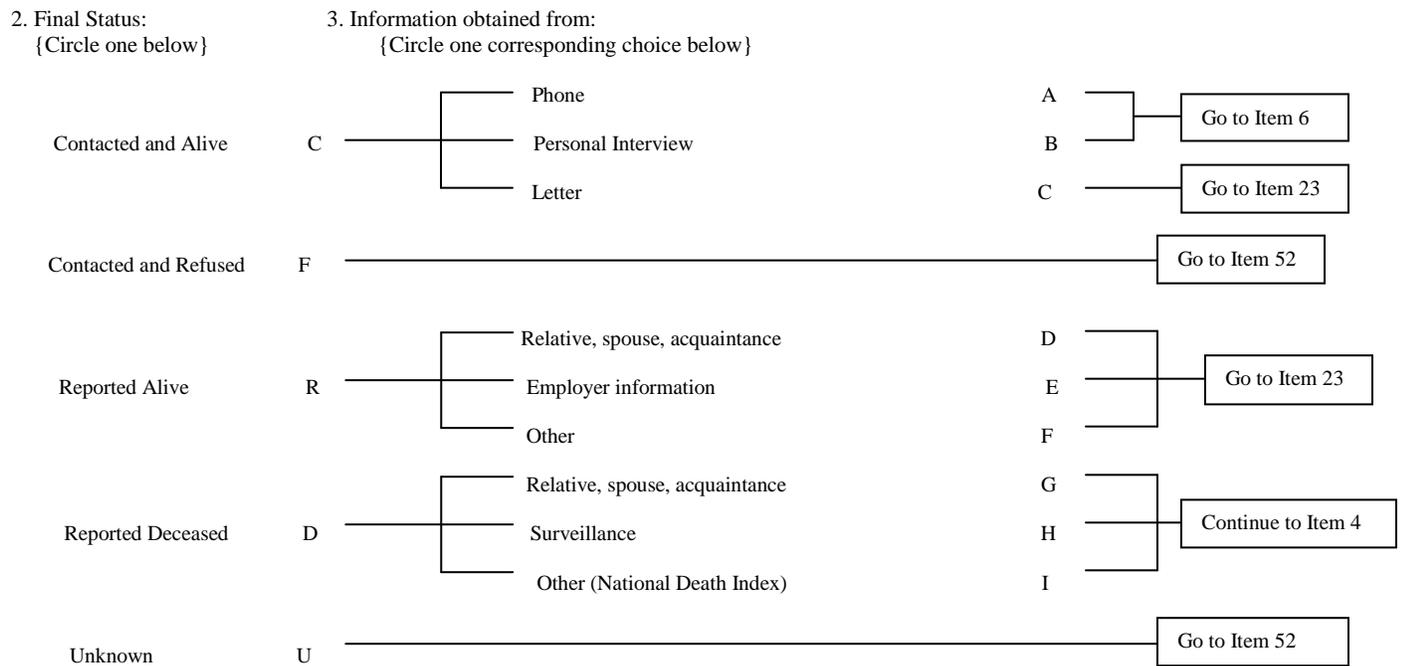
Interviews are the structured, one-sided passing of information, not a conversation. The pacing of questions is based on the comfort and comprehension of the participant with each interview; it may vary as the content, complexity or period of recall of the person or subject matter changes. During an 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.

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 waits for the participant to 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, hmmm") and completion ("anything else?"; "can you tell me anything more about that?").

Once the participant is called, the interviewer begins by reading the following script:

INTRODUCTION:

**"Hello, this is (YOUR NAME) from the Jackson Heart Study.
May I please speak with (NAME OF PARTICIPANT)?"**



When a JHS participant is incapable of speaking on the telephone with an AFU interviewer, but is capable of responding to the questions if an informant acts as an intermediary, all (or as many as possible) of the questions on the AFU form are administered. If it is not possible to conduct the full interview, questions 1-3, 8-10, 22-24, 28-35 are the most important. Record the FINAL STATUS in question 2 as 'C' and the INFORMATION OBTAINED FROM as A or B. No provision is made to record that the interview was done using an intermediary to relay and/or interpret the participant's answers.

When an JHS participant is incapable of speaking on the telephone with an AFU interviewer, AND is NOT capable of responding to the questions even if an informant acts as an intermediary, the JHS interviewer completes the questions on VITAL STATUS (Questions 2 and 3) and attempts to interview the informant on HOSPITALIZATIONS (Questions 22-24, 28-35). Record the FINAL STATUS in question 2 as 'R' and code the INFORMATION OBTAINED FROM as D or E or F in question 3.

If direct contact is not made, but a reliable source of information has provided a status of "Reported alive" or "Reported deceased" in item 2, then hospitalization information may be obtained from this source. It is important that the source's identity be recorded in the call record.

The following are the criteria for each final status:

Contacted and alive (C): The participant has been directly contacted in some way by the JHS Annual Follow-Up staff during the present contact year. This contact preferably takes the form of a phone call or personal interview (so that the entire questionnaire can be administered), but a letter written by the participant is also acceptable for assigning this status. In this last case, it is

obviously not possible to ask the remaining questions on the form. Note that this status corresponds to a final result code of 03, 04, or 05 on the "Record of Calls."

Contacted and refused (F): The participant has been directly contacted in some way by the JHS Annual Follow-Up staff during the present contact year, but he/she refused to answer the annual follow-up questions. This status corresponds to a final result code of 05 or 98 on the "Record of Calls". Go to Item 52, and complete the administrative section of the form.

Reported alive (R): Reliable information indicates that the participant is living, but direct contact has not yet been made. If this is the final status, it is therefore implied that it is not possible that contact will be made during this same contact year. Since one would generally continue to make attempts at a direct contact up until the "Latest" date, it is reasonable that the "date of status determination" would fall on or just before that "Latest" date, when this is the final status. Note that this status corresponds to a final result code of 07 on the "Record of Calls." Reliability of the information is evaluated by supervisor review. It is therefore important to document the source in as much detail as possible on the Record of Calls. When contact with the participant is not possible, but contact has been made with an informant who reports that the participant is living, attempt to collect information on the participant's overnight admissions to hospitals (Items 23 and 24).

Reported Deceased (D): Reliable information indicates that the participant has died. In this case, the "date of status determination" is the date on which the death became known to the JHS Annual Follow-Up staff NOT the date of death. Note that this status corresponds to a final result code of 08 on the "Record of Calls." Reliability of the information is evaluated by supervisor review. It is therefore important to document the source in as much detail as possible.

Unknown (U): Neither the participant nor another source of information has been contacted in a manner sufficient to provide reliable vital status data. In this case, the "date of status determination" is either the date on which the unknown status is being assigned, or the participant's "Latest" contact date for the specified contact year, whichever is earlier. Note that this status corresponds to a final result code of 09 on the "Record of Calls."

NOTE: A FINAL STATUS CODE SHOULD NOT BE ASSIGNED UNTIL THE END OF THE CONTACT YEAR OR UNTIL IT BECOMES OBVIOUS THAT THE STATUS CANNOT CHANGE. AS DESCRIBED ELSEWHERE, A DEATH OCCURRING AFTER A CONTACT, BUT BEFORE THE END OF THE CONTACT YEAR, IS ASSIGNED TO THE NEXT CONTACT YEAR.

Examples:

1. It is Contact Year 2. The participant cannot be contacted, nor can any reliable information be found regarding his vital status. His baseline visit was on 3/5/87, and his "Latest" CY 02 date is 9/4/88. Record as:

<u>Contact Year</u>	<u>Date of Status Determination</u>	<u>Status</u>
2	9/4/88	U

2. It is Contact Year 3. The participant cannot be contacted, nor can any reliable information be found regarding his vital status. His status in CY 02 was "Unknown," as determined on 6/28/88. His baseline visit was on 1/23/87. Record as:

<u>Contact Year</u>	<u>Date of Status Determination</u>	<u>Status</u>

Read the question, gently stressing the time frame, and pausing slightly between each of the response categories. Read all four categories, and record the participant's selection. When necessary, reread the second sentence.

The next series of questions are being implemented for the first time with the L version of the AFU form. These questions probe for information about history of heart failure or a history of heart failure signs or symptoms.

7.a **[DO NOT ASK] Has the participant previously completed Version C of the AFU form?**

Persons who have completed Version C of the AFU are skipped to Item 9; persons who have not yet completed Version C are read Item 7b. During the first year of administering the AFU-L persons who have not previously completed the AFU-L will possibly be asked about a previous report of heart failure. After having completed the AFU-L once, the participant will be asked if they have been diagnosed with heart failure since the last contact.

7b. **[DO NOT ASK] Has participant ever reported a heart failure diagnosis in AFU without a documented HF hospitalization in the JHS database?**

This question refers to a self report of heart failure on a previous AFU interview. A list will be provided to the interviewer of participants to which this question applies. This will only be completed in the first year of administering the AFU-L. If the answer is NO, skip to question 9.

8. **In a previous JHS phone call in [< year >], you indicated that you had been diagnosed with heart failure or congestive heart failure. Do you recall that you had such a diagnosis of heart failure?**

Read the question, again emphasizing the year to help participants remember the self-report. If the answer is NO or UNKNOWN, skip to question 9.

8.a-b. **What is the name and address of the doctor you last saw for heart failure?**

Collect the name and address of the doctor last seen for heart failure.

8.c. **What was the approximate date?**

Collect and record the approximate date of the visit. Stress to the participant that this should be the most recent time they have been seen by a doctor for heart failure.

8.d. Record whether the approximate date provided is within 3 years of the day you are completing the interview ("today's date"). Do not ask the participant if the date was within the last three years. If the answer to question 8.d is "NO" or "UNKNOWN," then do not collect the Consent to Release Medical Record Information (8e).

This question requests permission for the participant's doctor to release of medical information to JHS. Note that JHS is not requesting the release of medical records, but rather an authorization from the participant for JHS to ask the physician additional questions about a possible diagnosis of heart failure, such as may be contained in the participant's medical records. If the participant has any doubts about this process mention that the information requested of their physician is a one-page questionnaire about tests for heart conditions, diagnosis and treatments, and offer to send the questionnaire to the participant along with the authorization form.

Lastly, note that this authorization for release of medical information is not a consent form (and should not be identified as such), that its purpose is to help the providers of medical care be compliant with HIPAA, and that the terms specified on the release form can be reworded to suit the medical practitioner / the establishment that provides the protected health information. The IRB that oversees the work of the Jackson Heart Study may or may not wish to see (and approve) changes in wording in this release form if requested by a local provider of care. Thus, note that the authorization form attached to these QxQ instructions is a prototype and not a JHS form, and that the use of this release form is a prerogative of the provider of medical care that JHS supports and facilitates.

8.f. Were you hospitalized for heart failure at that time?

If YES, go to “obtain hospital information and date” Section F Q 28a and then return to Q 8g. Stress that this hospitalization is associated with the reported diagnosis of heart failure in question 8.

8.g. Were you hospitalized for heart failure or congestive heart failure at another time?

If YES, go to “obtain hospital information and date” Section F Q 28a and return to Q 10.

9. Since we last contacted you on mm/dd/yyyy, has a doctor said that you had heart failure or congestive heart failure?

This question is similar to questions 7-8 above, but instead places the time frame as “since the last contact.” If no or unknown skip to Q 10. Emphasize that this question relates to a diagnosis of heart failure since the last contact, whereas question 8 refers to diagnoses made up until the last contact.

9.a-b What is the name and address of the doctor you last saw for heart failure?

Collect the name and address of the doctor last seen for heart failure. If name and address of the doctor is the same as the last physician’s name and address, the dup key feature in the data entry system can be used.

9.c. What was the approximate date?

Collect and record the approximate date of the visit. Stress to the participant that this should be the most recent time they have been seen by a doctor for heart failure.

9.d. Record whether the approximate date provided is within 3 years of the day you are completing the interview (“today’s date”). Do not ask the participant if the date was within the last three years. If the answer to question 9.d is “NO” or “UNKNOWN,” then do not collect the Consent to Release Protected Health Information (9f).

9.e. Were you hospitalized for heart failure at that time ?

If Yes obtain hospital information and date and record in Section F and return to Q.10. If no or unknown and the participant was seen as outpatient within 3 yrs (i.e., question 9.d is YES), go to Q 9f “obtain release of medical records from MD.” If Question 9.d. is NO or UNKNOWN, skip to question 10.

This question requests permission to send a release form to the participant's doctor. If this is the same provider of care as listed in Q.8.e. there is no need to re-read the script, but offer to answer questions.

10. Has a doctor ever said that your heart is weak, or does not pump as strongly as it should, or that you had fluid on the lungs?

If the answer is NO or UNKNOWN, skip to question 11.a.

10a-b. What is the name and address of the doctor you saw?

Collect the name and address of the doctor last seen for heart failure. If name and address of the doctor is the same as the last physician's name and address, the dup key feature in the data entry system can be used.

10.c. What was the approximate date ?

Collect and record the approximate date of the visit. Stress to the participant that this should be the most recent time they have been seen by a doctor for heart failure.

10.d. Record whether the approximate date provided is within 3 years of the day you are completing the interview ("today's date"). Do not ask the participant if the date was within the last three years. If the answer to question 10.d. is "NO" or "UNKNOWN," then do not collect the Consent to Release Protected Health Information.

10.e. Were you hospitalized for the weak heart muscle?

If Yes obtain hospital information and date and record in Section F and return to question 11a. If NO or UNKNOWN and the participant was seen as outpatient within 3 yrs (i.e., question 10d is YES) complete Q 10.f. "obtain release of medical records from MD." If Question 10.d. is NO or UNKNOWN, skip to question 11.a.

This question requests permission to send a release form to the participant's doctor. If this is the same doctor as listed in Q.8.e. or Q.9.f. you do not need to re-read the script

11.a Has a doctor ever said that you had a heart attack?

11.b. Has a doctor ever said that you have angina, angina pectoris, or chest pain due to heart disease?

If the answer is no or unknown go to question 12.

11.c. Were you first told that you had angina since we last contacted you on mm/dd/yyyy?

12. Has a doctor ever said that you had an irregular heart beat called atrial fibrillation, or atrial fibrillation on a heart scan or electrocardiogram tracing?

13.a. Do you often have swelling in your feet or ankles at the end of the day?

If the answer is no or unknown go to question 14.

13.b. Is the swelling in your feet or ankles gone in the morning?

It is left to the respondent to define whether the swelling is “gone” in the morning. Somewhat, or less than complete resolution of the swelling is recorded as N

14. Has a doctor ever said you had high blood pressure?

15. Has a doctor ever said you have diabetes or sugar in the blood?

16. Has a doctor ever said that you had a blood clot in a leg or deep vein thrombosis?

Deep vein thrombosis refers to clots in the veins that run inside (deep) in a thigh or leg as opposed to superficial veins, whether or not varicose, that may be visibly associated with inflammation (phlebitis) and pain. This question specifically asks about a physician-diagnosed deep vein thrombosis.

16.a-b. What is the name and address of the doctor you saw?

Collect the name and address of the doctor who last said that the participant had a blood clot in a leg, or deep vein thrombosis. If name and address of doctor is the same as the last physician’s name and address, the dup key feature in the data entry system may be used.

16.c. What is the approximate date?

Collect and record the approximate the date.

16.d. Were you hospitalized for a blood clot in a leg or deep vein thrombosis at that time?

If Yes obtain hospital information and date and record in Section F and return to Q.17a, below.

17.a. Has a doctor ever said that you had a blood clot in your lungs or a pulmonary embolus?

If the answer is no or unknown skip to question 18.

17.b. Were you hospitalized for a blood clot in your lungs or a pulmonary embolus at that time?

If Yes go to the “obtain hospital information and date” Section F Q 28a and return to Q.18.a, below.

18.a. Has a doctor ever told you that you had chronic lung disease, such as bronchitis, or emphysema?

If the answer is no or unknown, skip to question 19a.

18.b. Were you told by the physician that you had chronic lung disease since we last contacted you on mm/dd/yyyy?

If the answer is YES to either 18.a or 18b, go to question 20.

19.a. Are there times when you wake up at night because of difficulty breathing?

19.b. **Do you have trouble breathing or shortness of breath when hurrying on a flat surface?**

If no or unknown, go to question 19f. If the participant is unable to walk indicate this on the form and go to question 19f.

19.c. **Do you have trouble breathing or shortness of breath when walking at ordinary pace on a flat surface?**

If the answer is NO or UNKNOWN to question 19g.

19.d. **Do you stop for breath when walking at your own pace?**

If the answer is NO or UNKNOWN to question 19g.

19.e. **Do you stop for breath after walking 100 yards on a flat surface?**

If the answer is NO or UNKNOWN to question 19g.

19.f. **Do you have difficulty breathing when you are not walking or active?**

19.g. **Do you usually have some cough or wheezing?**

20. **Has a doctor ever said you had asthma?**

If the answer is NO, go to question 20b.

20.a. **Did the doctor say that you have asthma since we last contacted you on mm/dd/yyyy?**

20.b. **Do you have pain in your legs caused by a blockage of the arteries?**

If asked, this question refers to sharp, stabbing pain in a leg (or intense burning sensation) that comes on when climbing or walking. It is typically caused by blockage of an artery in the lower extremity. The pain typically subsides on stopping.

20.c. **Has a doctor ever said that peripheral vascular disease or intermittent claudication?**

Peripheral vascular disease is the blockage of an artery in a lower extremity. Intermittent claudication is the pain of sudden onset that comes on during climbing or walking and disappears when the person stops.

21.a. **Has a doctor ever said that you had cancer?**

For Item 21a (cancer), go to Item 22a if the response is NO or UNKNOWN.

21.b. **“Can you tell me in what part of the body the most recently diagnosed cancer was located?”**

21.c. **And the date it was diagnosed?**

Collected the date it was diagnosed in month/year format (specific day is not needed).

D. STROKE/TIA

22a. Since our last contact on (mm/dd/yyyy), have you been told by a physician that you had a stroke, slight stroke, transient ischemic attack, or TIA?

Here we are specifically looking for a physician diagnosis of stroke or TIA. Light stroke, minor stroke or small stroke would all be considered appropriate synonyms resulting in a "Yes" response if participant was told this by a physician. If the participant is unsure, record as "No." If answer is 'No', skip to Q23.

22b. Were you hospitalized for this stroke, slight stroke, transient ischemic attack or TIA?

Here we want to know if the participant was hospitalized for this stroke. If YES, complete the HOSPITALIZATIONS section of the form.

E. ADMISSIONS

The purpose of questions 23 and 24 is to determine whether it is necessary to complete the "Hospitalizations" section (SECTION F). Substitute the date on which the participant was most recently contacted (directly) where indicated after the questionnaire has been completed. Generally, these questions are asked directly of the participant, but the participant or the interviewer can ask to have a spouse or more knowledgeable person in the household to provide information on the individual hospitalizations in Section F. When direct contact is not made with the participant, but a reliable source of information has provided a status of "Reported alive" or "Reported deceased" in item 2, questions 23-27a may be asked of this source. If speaking with an informant, replace the words "Were you" with "Was ____ (participant)". The term "hospitalized" includes staying overnight in any acute or chronic care facility which excludes nursing homes. Only inpatient care should be included, e.g., ER or outpatient visits not involving an overnight stay are coded as NO. If the participant or informant is unsure, doesn't know or can't provide information about the overnight hospitalization(s) for heart attack (Item 23) or other condition (Item 24), select the response category UNKNOWN.

23. Were you (Was [name]) hospitalized for a heart attack since our last contact on (mm/d/yyyy)?

The question is intended to specifically enhance the participant's or informant's recall about cardiovascular-related hospitalizations since the last contact. This is different from Question 11.a., which asks about life-time history of a heart attack. The term 'heart attack' refers to the person's admitting diagnosis or discharge diagnosis. For example, the response to Item 23 would be YES for a person admitted to a hospital overnight to rule out a suspected heart attack. Frequently, such a patient is discharged with a diagnosis of something other than a heart attack, for example, tachycardia (uneven heart rate) and esophageal reflux (indigestion). In other words, admissions to "rule out", as well as discharge diagnoses of a heart attack, are both coded YES. If YES, complete the HOSPITALIZATION section.

24. Have you stayed (Did [name] stay) overnight as a patient in a hospital for any other reason since our last contact?

This question asks the participant/informant to recall overnight hospitalizations in acute or chronic care facilities, such as hospitals, for any condition other than heart attack, heart failure, stroke, or TIA.

If the response to Item 23 or 24 is positive, complete Section F:Q28 – 39 (HOSPITALIZATIONS) at this time. When the participant is deceased, and this question is answered by an informant, complete Section F on hospitalizations.

If a participant reports to the AFU interviewer that they were hospitalized and the surveillance abstractors finds the hospitalization does not exist (perhaps participant was an outpatient), then the surveillance abstractor can ask the AFU staff to change the answer to Q23 or Q24. The AFU interviewer should not probe at the time of the AFU to find out the length of the hospital stay.

25.a. Were you (Was [name]) admitted to an emergency room or a medical facility for outpatient treatment since our last contact on(mm/dd/yyyy)?

This question applies an admission to a medical facility for observation and/or treatment that did not require an overnight stay. This could apply to episodes of decompensation of a health problem that were treated at a medical facility on an ambulatory basis, or medical procedures that were conducted as an outpatient.

If the answer is NO or UNKNOWN, then go to question 27.a.

25.b. Was this related to a heart problem or difficulty breathing ?

If the answer is NO or UNKNOWN, go to question 27.a.

26.a-b. What is the name and address of this medical facility and date of visit to facility ?

Collect the name and address of the emergency room or outpatient medical facility visited for the heart problem or difficulty breathing.

26.c. What was the approximate date ?

Collect and record the date of this visit. Remind the participant that this is the most recent visit to an emergency room or outpatient medical facility for the heart problem or difficulty breathing.

27.a. Since our last contact, have you stayed overnight as a patient in a nursing home?

If asked, a nursing home refers to a skilled nursing facility or an extended care facility; it does not include assisted living facilities. If NO, go to Item 40.

If the participant is REPORTED DECEASED or REPORTED ALIVE in question 1, then skip to question 52.

27.b. Are you currently staying in a nursing home?

“Currently” refers to the day on which the interview is conducted. On the paper form skip over Section F and continue to Item 40.

F. HOSPITALIZATIONS

A. Collection of data

If there was a positive response to Items 23 and/or 24, read the following script to the respondent/informant:

For each time you were (he/she was) a patient over night in a hospital, I would like to obtain the reason you were (he/she was) admitted, the name and location (city, state) of the hospital, and the date.' When was the first time you were (he/she was) hospitalized since our last contact with you (him/her) on (mm/yyyy) (date of last contact)?

Fill in, probing as necessary. Abbreviations can be used for local hospitals. Probe for additional hospitalizations.

For linkage (Items 28.d.-39.d.), H indicates that the hospitalization was reported; N indicates that the hospitalization was fully sought by Surveillance and not found.

28-39. Record information on all hospitalizations reported since the time of last contact. NOTE: this does NOT include overnight admissions to nursing facilities and/or rehabilitation centers. (The information needed for diagnosis of a cardiovascular disease event will be obtained from the primary hospital admission.) The Hospitalizations section of the Annual Follow-Up Form is a long question that has to be obtained in parts. Use neutral probes to elicit all hospitalizations. For the (first) overnight stay, record the reason for the hospitalization, the hospital name, city, and state, and the discharge date (month and year) of the hospitalization. Probe for additional hospitalizations and follow the directions for the first hospitalization. There is space to complete 12 hospitalizations. If there are more than 12, record and enter the 12 most relevant to ARIC. List the others on a separate sheet, so all can be transmitted to surveillance. If the person was hospitalized overnight more than 12x times, select those with heart disease, stroke, or heart failure as reasons for hospitalization.

28d-39d. (letter "d" only). If any hospitalizations are reported, enter H beside the appropriate letter corresponding to each hospitalization. That is, if 3 hospitalizations are reported, enter H for items a, b, and c. Send a copy of the Hospitalizations page(s) or screen printouts to the surveillance supervisor and check the appropriate boxes for "Transmit to Surveillance." The surveillance staff will investigate each hospitalization. If a reported hospitalization cannot be found, the surveillance supervisor will notify the staff person responsible for annual follow-up, who then changes the "H" to "N". Be certain that the "H" changed corresponds exactly to the hospitalization in question (for example, if the second hospitalization is actually an outpatient visit, item b. H should become b. N).

If direct contact is not made, but a reliable source of information has provided a status of "Reported alive" or "Reported deceased" in item 2, then hospitalization information may be obtained from this source. It is important that the source's identity be recorded in the call record.

B. Linkage between Annual Follow-up and Event Investigation

Certain procedures are necessary to insure that deaths and hospitalizations identified during AFU contact attempts are brought to the attention of the Surveillance staff for investigation, and vice-versa. The Surveillance staff is to be notified of every cohort hospitalization and an investigation is initiated. The hospitalizations sheet provides a check box to indicate that the information has been transmitted to the surveillance staff.

G. INVASIVE PROCEDURES

Read the transition statement.

40. **[DO NOT ASK]. Has participant completed a previous version “A or B” or later of Annual Follow-up?**

Check the Participant Information Sheet to determine whether the participant has previously completed version “G” or later of the AFU form. Select the appropriate response category (YES or NO), and follow the skip patterns. Persons who have completed Version G or later of the AFU are read Item 41a; persons who have not yet completed version G or later are read Item 41.b. The difference between the two versions of Item 41 part (a) and part (b) is the setting in which the questions were asked: item 41.a is for participants who were last contacted during an AFU interview; item 41.b is for persons whose last contact was at a clinic visit at a field center.

41.a. **Since we last contacted you on (mm/dd/yyyy),**

41.b. **Since your last JHS visit on (mm/dd/yyyy),
Have you had surgery on your heart, or the arteries of your neck or legs, excluding surgery for varicose veins?**

This question refers to “major” therapeutic surgery on the heart or arteries of the neck or legs. “Legs” refers to the entire lower extremity (not “just below the knee”, which is the restricted anatomical definition). “Surgery” does not include lower extremity arteriography, even though it is an “invasive” procedure, nor surgery for varicose veins. Note also that “abdominal aortic aneurysm repair” is not included here. When NO, go to Item 44.a, selecting the part (a or b) which corresponds to the part you are completing here. When YES, continue with next questions.

42.a-f. **Did you have: coronary bypass; other heart procedure; carotid endarterectomy; site; other arterial revascularization; any other type of surgery on your heart or the arteries of your neck or legs?**

Standardized definitions and synonyms of invasive cardiac procedures are listed below in the table of Definitions and Synonyms of Diagnostic and Therapeutic Procedures. The definitions can be read to participants who are unclear as to the meaning(s) of a term, and the synonyms can be used by the interviewer to help determine whether or not the participant has had the procedure in question. Specify the type of procedure in the spaces provided when responses to Items 42.b or 42.e are YES.

DEFINITIONS AND SYNONYMS FOR THERAPEUTIC AND DIAGNOSTIC PROCEDURES

<u>DIAGNOSTIC PROCEDURES</u>		<u>SYNONYMS</u>
ECHOCARDIOGRAM	A test in which sound is transmitted into the body is electronically plotted to produce a picture of the heart's size, shape, and movements.	Echo
ELECTROCARDIOGRAM	A graphic record of the electrical impulses produced by the heart.	ECG EKG
TREADMILL CARDIAC STRESS TEST	An exercise test on a treadmill, bicycle, or similar device in which people increase their heart rate in order to have the function of the heart measured, usually by ECG.	
THALLIUM SCAN OF THE HEART SPECT	A computer image of the heart done by injecting in a dye into the bloodstream. Computer-generated pictures then find them in the heart. These tests show how well the heart muscle is supplied with blood, how well the heart is functioning, or identify a part of the heart damaged by a heart attack.	Heart Scan
HOLTER MONITOR	A small, portable ECG machine worn by patients.	
HEART RHYTHM or CONDUCTION STUDIES	Invasive procedures, usually performed under anesthesia, to assess cardiac arrhythmias. Catheters are placed in the heart to map the spread of electrical impulses during each heartbeat.	
CAROTID ULTRASOUND STUDIES	A diagnostic method in which pulses of sound are transmitted into the neck arteries and the echoes returning from the surfaces of the artery walls are electronically plotted to produce a picture of a small portion of the carotid artery showing the amount of atherosclerosis (hardening of the arteries) that can be seen in the arterial wall.	Echo
CAT SCAN of BRAIN	A non-invasive diagnostic technique, which produces an image of the brain and can identify abnormalities.	Cerebral CAT scan
CORONARY BYPASS or BYPASS SURGERY	Surgery to improve blood supply to the heart muscle. This surgery is performed when	CABG "cabbage"

	narrow coronary arteries reduce the flow of oxygen-containing blood to the heart. Vein bypass (from leg veins) 3, (4-5, etc.). Vessel bypass.	operation” Bypass graft or operation
OTHER HEART PROCEDURES	Examples include valve replacement, ventricular aneurysm resection, Aortic Stenosis, Ventricular Stenosis. Defect repair, Patent ductus closure, Pacemaker, Implantation of automatic defibrillator, Coronary atherectomy.	
ENDARTERECTOMY	Surgery to take out plaque from an artery, to restore blood flow in one or both of the arteries in the neck.	
OTHER ARTERIAL REVASCULARIZATION	Any procedure where additional blood flow is brought to an artery via a bypass from a location elsewhere in the body.	
BALLOON ANGIOPLASTY	A procedure used to dilate (widen) narrowed arteries. A catheter with a deflated balloon angioplasty on its tip is passed into the narrow artery segment, the balloon inflated, and the narrow segment widened. Angioplasties can now also be done by laser. To keep arteries from collapsing, stents (stainless steel supports) can be inserted into the artery during angioplasty.	Percutaneous angioplasty Balloon dilation Balloon test / procedure PTCA Stent(s)
CATHETERIZATION	A procedure used to examine the heart or an artery by introducing a thin tube (catheter) into a vein or artery (e.g., carotid artery).	Angiography

43. **[DO NOT ASK]. Has participant completed a previous version “A or B” or later of Annual Follow-up?** This question is comparable to Item 40. Check the response to Item 40, or check the Participant Information Sheet to determine whether Version G or later has been administered. If YES, read Item 44.a to the participant. If NO, read Item 44.b. Carefully follow the skip patterns.
- 44.a. **Since we last contacted you on (mm/dd/yyyy) have you had a balloon angioplasty or stent on the arteries of your heart, neck or legs?**
- 44.b. **Since your last visit to the JHS clinic on (mm/dd/yyyy) have you had a balloon angioplasty or stent on the arteries of your heart, neck, or legs?**

When the response is positive (the definition of angioplasty can be read to the participant if he or she asks for clarification), continue with Q45 parts a, b, and c. When the response is negative (unknown is also coded as NO), go to Section H (INTERVIEW), otherwise, ask the following:

45. **Did you have:**
- a. **Angioplasty or stent of coronary arteries?**
 - b. **Angioplasty or stent in the arteries of your neck?**
 - c. **Angioplasty or stent of the lower extremity arteries?**

H. INTERVIEW

This section contains questions about the use of medications used for the treatment of, or are related to, one or more cardiovascular conditions. These are questions which were routinely asked during the clinic visits, but have not routinely been asked during the Annual Follow-up interviews. It is important to note that the time frames change for each set of questions. Begin this section with the following transition statement, gently stressing the time frame, as “the past two weeks”.

“Now I would like to ask about medication use during the past two weeks.”

- 46a-d. **Did you take any medications during the past two weeks for (a) high blood pressure, (b) high blood cholesterol, (c) diabetes or high blood sugar?**

The following synonyms may be given in response to participant questions:

For High Blood Pressure,	Hypertension
For High Blood Cholesterol	Hypercholesterolemia
For High Blood Sugar	Diabetes
For Heart Failure	

It is not necessary for these medications to have been prescribed by a physician. Unlike the procedures for the next question, the names of these medications are not transcribed. For each of these conditions, select a response of YES, NO, or UNKNOWN, based on the participant’s knowledge. UNKNOWN could indicate that the respondent is unclear as to whether he or she has the medical condition, or whether any of the medication(s) being taken are specifically used to treat that condition.

Now I would like to ask about the prescription medications you currently use [optional: as mentioned in the scheduling reminder we sent recently]. To make it easier to get the names of the medications you currently use, can I ask you to bring all the prescription medications you are taking to the telephone ?

47. **[DO NOT ASK} Does the participant have medications to report?**

If the participant is taking NO medications, REFUSES to provide medication information to the interviewer or the answer is otherwise UNKNOWN, skip to question 49.

48a-t. **[Once participant has all medications or prescriptions] Please read the names of all the medications prescribed by a doctor. This includes pills, liquid medications, skin patches, inhalers, and injections. Please do not include over the counter medications, unless prescribed by a doctor. [If asked: currently taking applies to medications taken in the past two weeks. Use the look-up table to enter, if medication is available in table]**

Medication names can be 60 characters long. Begin typing the medication name into the look-up table (F3 brings up the look-up table). The table will pull up possible answers a you fill in the name. Select (by highlighting and pressing <enter>) the correct name from the list provided. The “Code” field will be filled once the medication name is selected with a medication code number up

to 10 characters long. You will not be able to edit this field. If your medication is not in the look-up table, press <ESC> and you will return to the empty field where you may type the medication name in the name field, but no code will be allowed. Ignore any dosage or frequency information listed in the medication lookup table.

“Next I would like to ask you about your regular use of aspirin. This includes aspirin alone or in a combination with another drug, such as aspirin in a cold medicine. By regular use, I mean taking aspirin at least once a week for several months.”

49. **Are you NOW taking aspirin, or a medicine containing aspirin, on a regular basis? This does not include Tylenol, nor Advil. [Use look up table]**

This question documents the current use of aspirin or aspirin containing medications on a regular basis, regardless of the amount, or the reason for its use. These medications do not include Tylenol (acetaminophen), Advil (ibuprofen), etc. Select a response of “yes”, “no”, or “unknown”, based on the participant’s answer to the question as stated on the form. If the participant specifies a brand or type of medication, verify that the medicine actually contains aspirin by locating the product on the Aspirin Look-up table (press F3 to bring up the table). When the look-up table appears, type the first few letters of what you want to check, or scroll down to what you want. If you find the drug, highlight it, and press <enter> and the answer will be recorded as ‘Y’ for yes. If the product does not contain aspirin, code the participant’s response as ‘no’. If it is unclear whether the product contains aspirin, consult with your supervisor. If the participant says ‘yes, I’m taking medication X’ and medication X is does not contain aspirin, code the answer as ‘no’.

I. OTHER ITEMS

Begin this section with another transition statement.

“Next I have a few miscellaneous questions.”

50. **Do you now smoke cigarettes?**

If asked, “now” refers to the last 4 weeks. Current smokers are coded as YES; former smokers and non-smokers are coded as NO.

51. **Please tell me which of the following describes your current marital status: married, widowed, divorced, separated, never married.**

Read the statement, gently stressing the time frame, and pausing between each response category. Read all five categories, even if the person selects a category before you finish reading. If asked, instruct the participant to select the term which best describes his/her living situation, regardless of legal status.

J. ADMINISTRATIVE INFORMATION

Questions in the administrative section are NOT read to the participant.

52. **Code number of person completing this form.**

The person at the clinic who has completed this form enters his/her code number in the boxes provided.

53. Does participant (still) live within official Jackson Heart Study boundaries?

This information is needed to know whether the participant's hospital records would be routinely found through community surveillance. Complete this item after the current address is verified and discussing questionable addresses with the surveillance staff. The location of the participant's residence is recorded as within the JHS surveillance boundaries (YES), outside of the surveillance area (NO), or UNKNOWN, based on your center's definition of community boundaries. For participants who have expired, the place of residence refers to the person's address immediately prior to death. A response of UNKNOWN is used only as a last resort; interviewers who are unsure as to whether or not an address is within the study boundary should work with the AFU supervisor.

54. Will your center (still) be able to get his/her records via community surveillance?

In some centers, if the participant has requested that JHS not access medical records, the surveillance staff does not access them, even if found by routine community surveillance. In other centers, these records are assumed to be accessible through hospital permission to access through community surveillance. If this person has requested that his/her records not be accessed for cohort follow-up (see Participant Information Sheet), and the surveillance staff indicates that the study will not be able to get them through community surveillance, answer NO. Otherwise, select YES.

55. Result code.

When the AFU has been successfully administered, or the supervisor determines that all contact efforts have been exhausted, the final screening result code is circled in the RESULTS CODE BOX on the TRC form, and entered in this field.

NOTE: ONCE A FINAL STATUS HAS BEEN ASSIGNED AND ENTERED INTO THE DATABASE, IT CANNOT BE CHANGED DURING THE SAME CONTACT YEAR WITHOUT WRITTEN AUTHORIZATION FROM THE COORDINATING CENTER. THEREFORE, A FINAL STATUS CODE SHOULD NOT BE ASSIGNED UNTIL THE END OF THE CONTACT YEAR OR UNTIL IT BECOMES OBVIOUS THAT THE STATUS CANNOT CHANGE. AS DESCRIBED ELSEWHERE, A DEATH OCCURRING AFTER A CONTACT, BUT BEFORE THE END OF THE CONTACT YEAR, IS ASSIGNED TO THE NEXT CONTACT YEAR.

L. Verification of Tracing Information, the Update (UPD) form:

Contact information is verified with participants who complete part or all of the AFU interview. The Update Form is not reviewed with an informant of a deceased participant.

END (talking to participant): "Thank you very much for answering these questions. You have previously provided us with information on how to contact you. To help us contact you next year, please tell me if the information I have is still correct."

END (if participant deceased): "We may need to contact a family member later. When would be a good time to call in that case?" DO NOT proceed to the Verification of Tracing Information.

END (otherwise): "Thank you very much for answering these questions. We will call _____ in about a year." DO NOT proceed to the Verification of Tracing Information.

Verify the items on the Verification of Tracing Information sheet for contact next year by saying: "You have previously provided us with information on how to contact you. To help us contact you next year, please tell me if the information I have is still correct." These include the participant's name, address, and phone number(s), as well as (except in CY10) the information on the two contact people provided during the clinic visit. The current data on file appear on the left hand side of the page, with blank spaces for corrections or changes provided on the right side. Information only needs to be entered in these blanks in the case of changes to the data. For example, a change of mailing address would be recorded as:

OLD MAILING ADDRESS:	NEW MAILING ADDRESS:
Highland View Apts.	-----
Apt. 73A	-----
3465 Highland Lane	-----
Chapel Hill, NC 27514	-----

ANY CHANGES TO TRACING INFORMATION MUST BE RECORDED ON THE UPD FORM IN THE DATA ENTRY SYSTEM .

Data should be updated on the UPD form as necessary immediately after the follow-up contact, but only by someone certified in use of the ARIC Data Entry System. The interviewer who updated the computer file enters his/her ARIC Staff Code Number on the Verification of Tracing Information Sheet.

M. Closing

NO ADDITIONAL INTERVIEWS

"Thank you for your time. We will call you in about a year. Goodbye."

ADDITIONAL INTERVIEWS

"Now I would like to interview _____ (NAME). We will call you in about a year. Thank you for your time."

IF THE PARTICIPANT IS AVAILABLE, RETURN TO THE BEGINNING OF THE ANNUAL FOLLOW-UP INTERVIEW. IF THE NEXT PARTICIPANT IS UNAVAILABLE, DETERMINE WHEN HE/SHE MIGHT BE CONTACTED.

"Is there a date and a time that would be best for me to speak with (NAME)?"

RECORD DATE AND TIME ON RECORD OF CALLS