



INSTRUCTIONS FOR THE ANNUAL FOLLOW-UP INTERVIEW (AFU, VERSION 2, 01/22/2014) AND PARTICIPANT TRACING REPORTS QxQ

01/22/2014

updated

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I. General Instructions

Annual follow-up of the JHS Study 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. Each routine follow-up is completed by telephone.

The interview target date for the annual follow-up call is the participant's Visit 1 anniversary date. Semi-annual follow-up contacts are scheduled to take place between the annual follow-up interviews.

The annual as well as the semi-annual interview target dates each have a 3-month scheduling window before and after the target date. These scheduling windows allow for flexibility to accommodate the study participant's preferences, unanticipated absences or illness. JHS protocol requires study personnel to adhere to the target dates in scheduling the follow-up interviews, to the degree possible. Scheduling the annual calls earlier than the target date or later can only be done to accommodate study participant needs.

If the participant is contacted and agrees to be interviewed, three forms are routinely completed during the annual follow-up (AFU) interview: the AFU Questionnaire (Version 2), the Medical Conditions Update Form (MCU), the Contact Information Update Form (CIU, formerly the UPD - Update Form). An important element of the AFU 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.

Two other forms may be completed during the AFU interview. If during the course of the AFU interview a participant requests a change in his or her consent level, i.e., use/storage of DNA, use of other study data, access to medical records, or withdrawal from the study, the Informed Consent Tracking (ICT) form is also completed. Note that the ICT form can be completed any time a participant requests a change in consent even if this does not occur during the AFU phone call (see instructions for ICT form).

Reports available through the Data Management System

Two reports are available to assist field centers in scheduling AFU interviews: the Participant Tracing Report lists IDs for all participants to be contacted for AFU during a given interval and contact year; the Participant Tracing Information Sheet provides the most recent consent status and other pertinent information for a given cohort participant. When needed to determine the last time actual contact was made with the participant, a third report, the Contact History report, is available to display all prior cyclic contacts with the participant or participant's representative.

Data entry screens for the AFU interview:

1. Annual Follow-Up Questionnaire (AFU)
2. Medical Conditions Update Form (MCU)
3. Contact Information Update (CIU)
4. Physician Heart Failure Survey (PHF)
5. Informed Consent Tracking (ICT)

II. Annual Follow-up Procedures

Preparation for AFU Interviews

Two reports are provided to assist field centers in scheduling AFU interviews:

1. The Participant Tracing Report lists IDs for all participants to be contacted for AFU for a given contact year and time frame. It lists all participants who are to be contacted because their Visit 1 anniversary date falls within the date range selected for the report, and who have not yet completed this contact.

The Participant Tracing Report has an option to allow printing of a "Record of Calls" to track attempts to contact the participant (select "Show Call Record" option). If this option is chosen, there is a one-page-per-participant listing for recording contact attempts and status codes.

2. The Participant Tracing Information Sheet provides detailed, confidential information for individual participants including address, date of birth, , Social Security Number (optional), driver's license number, contact persons, Visit 1 date, contact status at the most recent AFU (or SAF) interview. Data security procedures that apply to confidential information must be in place to access, store, transport and dispose of these reports. It is each field center's responsibility to comply with the HIPAA regulations and its Institution's data security policy in processing data with personal identifiers and PHI.
3. In preparing for the annual JHS call the interviewer reviews the information presented on the tracing sheets to determine the date of last contact, and whether this date corresponds to an interview with the participant, a contact or a proxy, or whether the participant could not be reached during the previous contact window. The SAF and also the AFU tracing sheets include information additional to the contact year number to indicate whether last contact was part on an AFU, as SAF, or historical information retrieved from an earlier version. On the SAF tracing sheet, this information is presented in a field named 'Last Contact Type.'

If the information on date of last contact presented on the tracing sheets indicates that neither the participant nor a proxy could be reached during the previous contact window, the actual date of last contact is used during the current interview to identify the occurrence of JHS study outcomes (health events, hospitalizations, revascularizations, etc.). This date can be sought by using the Contact History Report, which lists the final status of all cyclical contacts with the participant or participant's representative. Use this date with items that ask the participant (or the proxy) "Since we last contacted you [name] on [mm/dd/yy] has a doctor said that ..." and it also applies to deceased cohort members (e.g. "Was [name] hospitalized for a heart attack, or heart condition, or stroke since our last contact on [mm/dd/yy]?"). Thus, health outcomes in the AFU (and also the SAF) form are ascertained with reference to the last actual contact, even if it occurred before the previous contact window.

Contacting Procedures and Rules

Three key dates defining when the participant is to be contacted are provided on the Participant Tracing Report. The TARGET date for the AFU interview is the Visit 1 anniversary date for the given contact year. The EARLIEST date is 3 months before the TARGET date. The LATEST date is 3 months after the TARGET date. Phone interviews can take place no sooner than the earliest date and no later than the latest date.

Phone calls should be initiated no more than 3 months before the TARGET date shown on the Participant Tracing Report. Ideally, contact takes place as close as possible to the TARGET date. If contact is not made until after the LATEST date, the contact is assigned to the following Contact Year.

During the call, the Contact Information Update (CIU) is reviewed with the participant for accuracy, and updated, if necessary. An important element that is tracked on the CIU is the participant's follow-up

proxy who can answer questions about the participant's health if he/she is unable to provide that information themselves.

Update information

During the call, the Contact Information Update (CIU) is reviewed with the participant for accuracy, and updated, if necessary.

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

The Participant Tracing Report has an option to allow printing of a "Record of Calls" to track attempts to contact the participant (select "Show Call Record" option). One row is used for each contact attempt, and a status code is assigned (see AFU Section A, Item 1 for status codes). Assigning a status code at each contact is very important, as it is helpful in assigning the final AFU contact status (AFU Section H) if the participant is not successfully contacted.

When the AFU is successfully administered, or the supervisor determines that all contact efforts have been exhausted (see below), the final status code is recorded in the STATUS CODE box on the "Record of Calls" and subsequently entered in Section A, Item 1 of the AFU form.

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

1. Refusals (attempt conversion).
2. 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.
3. 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 can be assigned the special missing value of "Unknown".

Linkage between Annual Follow-up and Event Investigation

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.

Participant Death Outside a Scheduled Interview

When the death of a participant is identified outside of a scheduled interview (e.g., through an obituary or if the death is reported to JHS by a next of kin), the research staff 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 remainder of the DEC. 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 DEC form pending resolution may trigger automatic queries from the JHS CC; these should be considered reminders to assist in managing such pending interviews.

When the follow-up call is made to the proxy respondent, determine the type of scheduling window (AFU or sAFU) during which the interview occurs because the death needs to be documented with either the AFU or SAF form. If this interview falls during the AFU window, complete the AFU form.

Participant Death Mortality Scenarios

1. At AFU, **Proxy** reports participant death
 - Complete AFU Section A. STATUS, Section B. DEATH INFORMATION [CLOSURE SCRIPT] & Section H. ADMINISTRATIVE INFORMATION.
2. At semi-AFU, **Proxy** reports participant death
 - Complete **SAF** Section A. STATUS, Section E. ADMINISTRATIVE INFORMATION & **DEC**
3. At AFU, **participant** completes interview; a while later, participant's obituary is published
 - Complete **DEC** Section A. DEATH INFORMATION Q1-3 & Section E. ADMINISTRATIVE INFORMATION Q13 (select "b").
 - When the proxy is interviewed about the death, complete **SAF** Section A. STATUS, Section E. ADMINISTRATIVE INFORMATION & remainder of **DEC**. Change DEC Q13 to "a". Make the date of **DEC** Q0a. Completion Date the same as the **SAF** Q0a. Completion Date.
4. At semi-AFU, **participant** completes interview; a while later, participant's obituary is published
 - Complete **DEC** Section A. DEATH INFORMATION Q1-3 & Section E. ADMINISTRATIVE INFORMATION Q13 (select "b").
 - When proxy is interviewed about the death, complete **AFU** Section A. STATUS Q1-2 & Section H. ADMINISTRATIVE INFORMATION. Continue with DEC Q4-12 and change DEC Q13 to "a". Make the date of **DEC** Q0a. Completion Date the same as the **AFU** Q0a. Completion Date.

Performing the Interview

Interviews are a structured, one-sided passing of information, not a conversation. The pacing of questions is directed by the comfort and comprehension of the participant; it may vary as the content, complexity or period of recall 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?").

III. Detailed Instructions for Each Item

When the interviewer makes contact with someone on the telephone (may or may not be the participant), read the following script.

Script: "Hello, this is (YOUR NAME) from the JHS Study. May I please speak with (NAME OF CONTACT)?"

Determine the participant's availability and vital status.

If the interviewer is notified that the participant is DECEASED, offer condolences and ask permission to continue the interview. The contact may a) agree to schedule another call during the given time frame, b) agree to complete the interview, or c) refuse the interview.

Action: At the end of the interview, inform the respondent of the possible need to contact a family member later on, and ask when would be the best time to call.

If the participant or follow-up proxy ("respondent") is available, greet them with the following script.

Script: "Hello (NAME OF RESPONDENT). My name is (YOUR NAME) and I am from the JHS Study. May I have a few minutes of your time to ask about your recent health?"

- 0a. Enter the date of contact or the date the status determination was made. THIS DATE MUST FALL DURING THE TIME FRAME SPECIFIED IN THE ANNUAL FOLLOW-UP, i.e., no earlier than the EARLIEST date and no later than the LATEST date on the Participant Tracing Report.
- 0b. Enter the staff ID for the telephone follow-up interviewer ID or the staff ID that made last contact attempt.

A. **STATUS**

- 1. Result of contact for the interview. Enter the contact status code that describes whether or not the AFU interview was completed and the person interviewed.
 - A. **Participant contacted, agreed to be interviewed**
 - B. **Contact refused to be interviewed**
 - C. **Proxy/Informant contacted**
 - D. **Other person contacted**
 - E. **Contact pending; continue to attempt to contact**
 - F. **Window closed; unable to contact**
- A. Participant contacted, agreed to be interviewed:

Action: Begin interview at item 17. If the interview is interrupted or the participant requests the interview be done at another time during the present contact year, complete H. ADMINISTRATIVE INFORMATION item 71. The interviewer will continue to attempt to contact during the current contact window.
- B. Contact refused to be interviewed: Contact was made with the participant, follow-up proxy, or other informant, but he/she refused to be interviewed.

Action: There are two levels of refusal - 1) refused the interview for this year, or 2) refused the interview for this year and for future years (no more contact). After review by the Supervisor (the follow-up Supervisor is responsible for reviewing cases of ambiguity or difficulty), complete the interview as follows:

 - 1. If the interview was refused for this year, go to Section H. ADMINISTRATIVE INFORMATION item 71 and enter A. Complete.

2. If the interview was refused for this year **and for future years**, go to Section H. ADMINISTRATIVE INFORMATION item 71, enter A. Complete and code the ICT form item 1 as 'do NOT agree to AFU contact-withdraw AFU consent'. Once this is done, no further AFU will be required.
- C. Proxy/Informant contacted: Contact was made with follow-up proxy or other informant who is knowledgeable and able to answer the interview questions on behalf of the participant (e.g., relative, spouse).
Action: Begin interview at Item 2. If the respondent is unable to provide reliable information about the participant go to Section H. ADMINISTRATIVE INFORMATION item 71. Reliability of the information provided by "other person" is evaluated by supervisor review and documented in the notelog.
- D. Other person contacted: Contact was made with a person who has not been explicitly identified as a follow-up proxy who may not be familiar with detailed health of the participant (e.g., acquaintance).
Action: Begin interview at Item 2. If the respondent is unable to provide reliable information about the participant go to Section H. ADMINISTRATIVE INFORMATION item 71. Reliability of the information provided by "other person" is evaluated by supervisor review and documented in the notelog.
- E. Contact pending; continue to attempt to contact: Contact pending.
Action: No action necessary; save and close form. This AFU completion status is not final, as further attempts will be made to complete the interview.
- F. Window closed; unable to contact: Neither the participant nor another source of information was able to be contacted within the contact year.
Action: No action necessary; save and close form

A. STATUS (ITEM 1)	H. ADMINISTRATIVE INFORMATION (ITEM 71)	EXPLANATION
E	--	Attempts are being made to locate the participant, but so far neither the participant nor another reliable source has been contacted.
A	A	The participant was successfully contacted and the entire interview, including the questionnaire and hospitalization information was completed.
C	A	The participant's proxy or informant was successfully contacted and the entire interview, including the questionnaire and hospitalization information was completed.
D	A	Other person was successfully contacted by phone or in person, and the entire interview, including the questionnaire and hospitalization information was completed.
E	--	The participant was successfully contacted but the interview is incomplete or was not done at all. This may be a temporary status if it is possible that the interview may be completed at a later date within the same contact year.
B	C	The participant was successfully contacted and vital status obtained, but the interview was not done and is not completed within the contact year.
E	--	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.

E	--	Reliable information indicates that the participant is living, but direct contact has not yet been made. This status 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.
F	--	Neither the participant nor another source of information was contacted that could provide reliable vital status data during the specified date range.
B	A	The participant has indicated that s/he does not wish to be contacted any more by the JHS 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.

2. Indicate whether the participant deceased.

B. DEATH INFORMATION

3. Indicate the person who reported the death
 - a. Relative/Spouse/Acquaintance
 - b. Surveillance
 - c. Other (e.g., Obituary, Social Security Administration)
4. If the participant has died, provide the exact date of death, or the month and year if exact date is unknown, or the date on which the death became known to the JHS Field Center if even partial date is not known.
5. Location of death: If the participant has died, attempt to secure the date and location (city/county, state) of death. Note, this information may be provided in the obituary. Take steps to begin a death investigation by initiating a Cohort Event Eligibility Form. Obtain as much information as possible from the informant. If the state is known, but not the city/county, record as much information as is available.
6. Determine whether the respondent is able to answer questions about hospitalizations prior to the participant's death. If the respondent is unable to answer these questions, try to identify another contact person who might be able to provide this information. Go to Section H. ADMINISTRATIVE INFORMATION item 71 and code as 'Partially complete - interruptions' and get contact information for the person. Ensure the information is in the CIU.
- 7-13. These items pertain to hospitalizations since the previous contact AFU interview for participants who have died. Up to five hospitalizations can be entered. In the rare case that a participant reports more than space allows, interviewers should record those most relevant to JHS, specifically cardiovascular disease, pulmonary disease, and cancer in that order. Other hospitalization need not be recorded in the data entry system. Staff may write any additional hospitalization on paper and communicate this to surveillance staff. Enter the date of hospitalization in month/year format (specific day is not needed). Select the hospital name/city/state from drop down list, or specify if the hospital if not on the list.
- 14-16. These items pertain to admission to an emergency room or other medical facility since the previous contact AFU interview for participants who have died. Enter the date of admission in month/year format (specific day is not needed). Select the facility name/city/state from drop down list, or specify if the facility name if not on the list.

C. GENERAL HEALTH

Script: "Now I will ask you some questions about your health."

17. Indicate the participant's health making sure you gently stress the time frame (over the past year) and pausing slightly between each of the response categories. Read all four categories, and record the participant's selection.
- 18-20. Questions were moved to MCU form and no longer accessible in the AFU.
- 21a-23. These items ask about chronic health conditions (i.e., conditions that are not cured or do not go away once you have them). The respiratory signs and symptoms they refer to may be indications of heart failure (or a combination of heart failure and chronic respiratory disease).
- 24-25. Questions were moved to MCU form and no longer accessible in the AFU.
26. 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.
27. This question does not specify a frequency of the reported swelling, for comparability with other surveys and because we are recording a subjective assessment by the participant. If the participant requests guidance in defining "often" the interviewer provides a non-directive synonym, such as "frequently" or "on most days." If based on this the participant still is unable to answer, the definition of often given to the participant is "on most days of the week, for at least one month." If the swelling is unilateral (affects only one foot or ankle) record No.
- 27a. Indicate whether the swelling in the feet or ankles is gone in the morning.
28. This question asks the participant to recall a diagnosis of cancer since the last contact. If the participant does recall a diagnosis of cancer, record 'Yes' for this item. If the participant responds that they do not know if there was a diagnosis of cancer, record 'No'.
- 28a. This question asks about the location of the reported cancer. Record the part of the body in which the cancer was diagnosed.
- The participant may be non-specific about the type of cancer. For example, they may report a "female cancer", "cancer of the womb", or "blood cancer". If the participant is non-specific about the type of cancer, you may use the probe "Could you be more specific?" Record the response in 28a.
- 28b. Enter the approximate date of the cancer diagnosis in month/year format (specific day is not needed).
- Script:** "Please provide the contact information of the doctor you most recently visited for your cancer."
- 28c. This question asks the participant to report the doctor that they have most recently visited for their cancer treatment or diagnosis. Here are a few examples of types of doctors that are often involved in cancer treatment: a medical oncologist who is treating their cancer with chemotherapy, a radiation oncologist who is treating their cancer with radiation, or a surgeon who surgically treated their cancer.
- 28c1-28c5. Record the name and address of the doctor who performed the surgery in these items.

28c6. Enter the approximate date the participant most recently visited the reported doctor in month/year format.

Script: “The JHS study would like to ask your health care providers to tell us more about your cancer diagnosis and treatment. If you agree to do this, I will send you a form that tells your providers that you authorize the JHS study to get this information from them. Once you sign that form and mail it back to me, I will contact your health care providers.”

28d. The medical release form is sent to a physician only after the participant provides consent to release medical information to JHS.

This question requests permission to send the release form to the participant. If the participant's response is “No”, do not send the release form.

D. CARDIOVASCULAR EVENTS

- 29-29a. Determine whether the respondent is able to answer questions about the participant's health. If the respondent is unable to answer these questions, try to identify another contact person who might be able to provide this information. Go to Section H. ADMINISTRATIVE INFORMATION item 71 and code as ‘Partially complete - interruptions’ and get contact information for the person. Ensure the information is in the CIU.
- 30-35. Questions were moved to MCU form and no longer accessible in the AFU.
36. Indicate whether the participant has had a heart attack making sure you gently stress the time frame (since the last contact).
37. Indicate whether the participant was hospitalized for a heart attack. Frequently, a patient is admitted for heart attack but discharged with a diagnosis other than a heart attack, such as tachycardia (uneven heart rate) or esophageal reflux (indigestion).
- 38a-39b. Select hospital from drop down list. If the hospital is not on the drop down list, enter the hospital name. Enter the admission date in month/year format (specific day is not needed). Complete items 39a-39b for a second hospitalization.
40. A positive answer to either of the conditions mentioned is entered as Yes. If a participant indicates that he/she never had angina but had chest pain due to heart disease, the answer is Yes (as is the case if the participant never had chest pain due to heart disease but had angina).
41. This question was moved to MCU form and no longer accessible in the AFU.
42. 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 vJHSoose, that may be visibly associated with inflammation (phlebitis) and pain. This question specifically asks about a physician-diagnosed deep vein thrombosis.
43. Indicate whether the participant was hospitalized for a blood clot in the leg or deep vein thrombosis (DVT). This includes observation stays in a hospital for a blood clot in the leg or deep vein thrombosis.
- 44a-44b. Select hospital from drop down list. If the hospital is not on the drop down list, enter the hospital name. Enter the admission date in month/year format (specific day is not needed).
45. This question specifically asks about physician-diagnosed blood clot in the lungs or pulmonary embolus.
46. Indicate whether the participant was hospitalized for a blood clot in your lungs or a pulmonary embolus.

- 47a-47b. Select hospital from drop down list. If the hospital is not on the drop down list, enter the hospital name. Enter the admission date in month/year format (specific day is not needed).
48. This question specifically asks about physician-diagnosed stroke, slight stroke, transient ischemic attack, or TIA.
49. Indicate whether the participant was hospitalized for stroke or TIA.
- 50a-50b. Select hospital from drop down list. If the hospital is not on the drop down list, enter the hospital name. Enter the admission date in month/year format (specific day is not needed).

E. ADMISSIONS

51. This question asks the participant/informant to recall whether they had any **overnight** hospitalizations or overnight observation stays in a hospital since their last contact, that they have not yet mentioned. This includes observation stays in a hospital.

If there was a positive response to overnight hospitalizations or observation for any reason, read the following script:

“For each time you were (he/she was) admitted overnight as a patient 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)??”

This does NOT include overnight admissions to nursing facilities and/or rehabilitation centers, and does NOT include being seen in an emergency room or urgent care facility for outpatient treatment and sent home. These types of visits are recorded in items 57 – 59.

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.

- 52a-56c. Record information on all hospitalizations reported since the time of last contact. There is space to complete 5 hospitalizations. If there are more than 5, enter the 5 most relevant to JHS (e.g., those related to cardiovascular disease). Select hospital from drop down list. If the hospital is not on the drop down list, enter the hospital name. Enter the admission date in month/year format (specific day is not needed).
- 57-58. The intent of these two questions, in sequence, is to capture visits to an emergency room or medical facility for outpatient treatment related to difficulty breathing or a heart problem. This could include outpatient treatment of angina, blood clots, heart failure, or angioplasty.
- These two questions are specifically trying to identify any OTHER cardiovascular events or procedures that may have occurred in the outpatient setting (the participants have already been asked explicitly about being ‘hospitalized’ [but not necessarily clarifying overnight or not] for heart attack, blood clot in leg, blood clot in lungs and stroke/TIA [refer to item 37 on the AFU form, item 14 on the MCU form, and items 46 and 49 on the AFU form], and have further been asked about OTHER OVERNIGHT hospitalizations. If the participant answers ‘yes’ to both #57 and #58, then answer items 59a, 59a1 and 59b. Otherwise, the form skips to item 60.
- 59a-b. These questions ask the participant/informant to recall emergency room visits or other medical facility visits for outpatient treatments related to difficulty breathing or heart problems. 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. Select the ER or medical facility name from drop down list. If the facility is not on the drop down

list, enter the name. Enter the visit date in month/year format (specific day is not needed). Although the name of the facility and the date of visit are recorded, a release of protected health information is not requested.

- 60. A nursing home refers to a skilled nursing facility or an extended care facility; it does not include assisted living facilities.
- 61. "Currently" refers to the day on which the interview is conducted.

F. INVASIVE PROCEDURES

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.

Script: "Next I am going to ask about various types of surgery and medical procedures. We are interested in those that occurred in the hospital, or in an emergency department, or as an outpatient."

- 62. 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 vJHSose veins. Note also that "abdominal aortic aneurysm repair" is not included here.
- 63a. Definition of coronary artery bypass is provided in the table of Definitions and Synonyms of Diagnostic and Therapeutic Procedures.
- 63b. Examples of other heart procedures are provided in the table of Definitions and Synonyms of Diagnostic and Therapeutic Procedures.
- 63c-d. Definition of carotid endarterectomy is provided in the table of Definitions and Synonyms of Diagnostic and Therapeutic Procedures. Indicated the side(s) of the neck intervened upon.
- 63e. Examples of other arterial revascularizations are provided in the table of Definitions and Synonyms of Diagnostic and Therapeutic Procedures.
- 63f. Indicate any other surgery on the heart or arteries of the neck or legs.
- 64a-c. The definition of angioplasty can be read to the participant if he or she asks for clarification. When the response is positive, continue with parts a, b, and c. If the participant has had a revascularization procedure for more than one of these arteries, record this information for the last/latest revascularization.
- 64d-f. These items pertain to admissions to a medical facility since the previous contact. Enter the date of admission in month/year format (specific day is not needed). Select the facility name/city/state from drop down list, or specify if the facility name if not on the list.

DEFINITIONS AND SYNONYMS FOR THERAPEUTIC AND DIAGNOSTIC PROCEDURES

PROCEDURES		SYNONYMS
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 narrow coronary arteries reduce the flow of oxygen-containing blood to the heart. Vein bypass (from leg veins) 3, (4-5, etc.). Vessel bypass.	CABG "cabbage 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	Percutaneous angioplasty Balloon dilation Balloon test / procedure PTCA

	from collapsing, stents (stainless steel supports) can be inserted into the artery during angioplasty.	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

G. 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 four weeks”.

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

65. Indicate whether the participant took any medications prescribed by a health professional during the past four weeks.

65a-m. These questions ask about medications prescribed for specific conditions. Select unknown as special missing value if 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. Participants can be told that we are not collecting medication names but whether they are taking a medication prescribed by a health professional for one of the conditions we are asking about. It is acceptable for participants to report taking a medication for more than one condition.

Script: “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.”

66. 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 acetaminophen (for example, Tylenol), ibuprofen (for example, Advil, Motrin or Nuprin), and naproxen (for example, Aleve). 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 (List #1 below). 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.

66a. This question documents the current use of medications on a regular basis for pain or inflammation that do not contain aspirin, regardless of the amount. These medications include Tylenol, Advil, Motrin, Nuprin, Midol, or Ibuprofen among others.

67-68. These questions were removed from version 2.0 of the AFU form and deactivated in the Data Management System.

Script: “Next, I have a few miscellaneous questions.”

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

70. 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.

H. ADMINISTRATIVE INFORMATION

71. AFU completion status. Enter the code that describes whether or not the AFU interview was completed.

A. Complete

B. Partially complete, contact again within window (interruptions)

C. Partially complete, unable to complete within window (done)

A. Complete: Direct contact was made within the present contact year. The contact either refused the interview, or the contact provided all the questionnaire information they could offer. The contact is not required to answer every questionnaire item to have completed the interview.

B. Partially complete, contact again within window (interruptions): Direct contact was made, but the questionnaire could not be fully administered due to an interruption – not because of a refusal. This status is not a final status, as the interviewer will be attempting another contact to continue the interview. The final AFU Completion Status for the current contact year must be a. Complete, or c. Partially complete; unable to complete within window (done).

C. Partially complete, unable to complete within window (done): Direct contact was made, but the questionnaire could not be fully administered in the current contact year.

When the AFU has been successfully administered, or the supervisor determines that all contact efforts have been exhausted, the final status code is circled in the STATUS CODE box on the Participant Tracing Information – Record of calls. If information is provided by a proxy or informant, verify that the proxy/informant who provided the information is identified as an informant, with current contact information. If not listed as an informant, ask the proxy whether she/he can serve as our contact and update contact information.

CLOSURE SCRIPT:

If participant deceased: “We may need to contact a family member later. When would be a good time to call in that case?”

List #1: Commonly Used Aspirin-Containing Medications

1/2HALFPRIN	ASPIRIN / ANTACID
ACETAMINOPHEN / MAGNESIUM SALICYLATE / CAFFEINE	ASPIRIN / CAFFEINE
ACETAMINOPHEN / SALICYLAMIDE	ASPIRIN / ACETAMINOPHEN / CAFFEINE
ACETAMINOPHEN / SALICYLAMIDE / CAFFEINE	ASPIRIN / ALUMINUM HYDROXIDE / MAGNESIUM HYDROXIDE / CALCIUM CARBONATE
ACETAMINOPHEN / SALICYLAMIDE / PHENYLTOLOXAMINE	ASPIRIN / ALUMINUM HYDROXIDE / MAGNESIUM HYDROXIDE
ACETYL SALICYLIC ACID	ASPIRIN / ACETAMINOPHEN / CAFFEINE / CALCIUM GLUCONATE
ADDED STRENGTH HEADACHE R	ASPIRIN / ACETAMINOPHEN / SALICYLAMIDE / CAFFEINE
ADDED STRENGTH PAIN RELIE	ASPIRIN / CAFFEINE
ADPRIN B	ASPIRIN / CAFFEINE / BUTALBITAL
ADULT STRENGTH ANALGESIC	ASPIRIN / CA CARBONATE
ADULT STRENGTH PAIN RELIE	ASPIRIN / CINNAMEDRINE / CAFFEINE
AF-MIGRAINE	ASPIRIN / SALICYLAMIDE / CAFFEINE
ALBERTSON'S EFFERVESCENT	ASPIR-LOW
ALBERTSON'S ENTERIC COATE	ASPIR-MOX
ALBERTSON'S HEADACHE FORM	ASPIRTAB
ALKA-SELTZER	ASPIR-TRIN
AMIGESIC	ASPRIDROX
ANABAR	BACK PAIN-OFF
ANACIN	BACKACHE MAXIMUM STRENGTH
ANALGESIC	BACKACHE RELIEF EXTRA STR
ACETAMINOPHEN / SALICYLAMIDE / PHENYLTOLOXAMINE / CAFFEINE	BAYER LOW STRENGTH
ARTHRITIS PAIN FORMULA	BAYER PLUS EXTRA STRENGTH
ARTHRITIS STRENGTH BC	BC
ARTHROPAN	BL MIGRAINE FORMULA
ASA	BUFFASAL
ASCRIPITIN	BUFFERIN
ASP	BUFPIRIN
ASPERGUM	BUTALBITAL / ASA / CAFFEINE
ASPIR-81	BUTALBITAL / ASPIRIN / CAFFEINE
ASPIRCAF	BUTALBITAL COMPOUND
ASPIRIN	CETAZONE-T
ASPIRIN GUM	CHOLINE / MAGNESIUM SALICYLATES
ASPIRIN / DIPHENHYDRAMINE EFFERVESCENT	CHOLINE MAGNESIUM TRISALICYLATE

List #1: Commonly Used Aspirin-Containing Medications

CHOLINE SALICYLATE	GENACOTE	OSCO ADDED STRENGTH PAIN
CMT	GOODY'S	OSCO ANALGESIC ADULT STRE
COPE	HALFPRIN	OSCO EFFERVESCENT ANTACID
CVS BACKACHE RELIEF	HCA PAIN RELIEVER	OSCO LOW STRENGTH ENTERIC
CVS EFFERVESCENT ANTACID	HEADACHE FORMULA ADDED	
CVS HEADACHE RELIEF	ST	P-A-C
CVS MIGRAINE RELIEF	HEADACHE RELIEF	PAIN RELIEF
	HEADRIN EX STRENGTH PAIN	PAIN RELIEF EXTRA STRENGT

DEWITT'S PILLS	HM ADULT ANALGESIC	PAIN RELIEF EXTRA STRENGT
DIFLUNISAL	LEVACET	PAIN RELIEVER ADDED STREN
DISALCID	LOBAC	PAIN RELIEVER PLUS
DOAN'S	MAGAN	PAINAID
DOLOBID	MAGNAPRIN	PAIN-OFF
DOLOREX	MAGNESIUM SALICYLATE	PANRITIS FORTE
DURABAC	ACETAMINOPHEN	PHENYLTOLOXAMINE / MAGNESIUM SALICYLATE
DURAXIN	MAGNESIUM SALICYLATE /	PIROSAL
EASPRIN	DIPHENHYDRAMINE	QC PAIN RELIEVER PLUS
ECASA	MAG-PHEN	RA ANTACID PAIN RELIEF
ECK MIGRAINE RELIEF	MAGSAL	RA MIGRAINE RELIEF
ECOTRIN	MEDI-SELTZER	RID-A-PAIN COMPOUND
ECPIRIN	MEPROBAMATE / ASPIRIN	SALETO
ED-FLEX	MIDOL MAXIMUM STRENGTH	SALICYLAMIDE / CAFFEINE
EFFERVESCENT ANTACID / PAIN	MIGRAINE FORMULA	SALFLEX
EFFERVESCENT PAIN RELIEF	MIGRAINE RELIEF	SALSALATE
EFFERVESCENT PAIN RELIEVE	MINITABS	SAV-ON ADDED STRENGTH PAI
EQUAGESIC	MOBIDIN	SAV-ON ANALGESIC ADULT ST
EXCEDRIN	MOBIGESIC	
EX-PAIN	MOMENTUM MUSCULAR	SAV-ON BACKACHE RELIEF EX
EXTRA STRENGTH BAYER	BACKACH	SAV-ON EFFERVESCENT ANTAC
EXTRAPRIN	MONO-GESIC	SB BACKACHE EXTRA STRENGT
FARBITAL	MP ENCOPRIN	SB EFFRSCENT ANTACID/PAIN
FIORINAL	MP REGRIPRIN	SB LOW DOSE ASA EC
FORTABS	MST 600	SB MENSTRUAL
FRENADOL	MYOGESIC	SB PAIN RELIEF F/ACT
GENACED	NEUTRALIN	SB PAIN RELIEF X-STR
SG PAIN RELIEVER ADDED ST	NINOPRIN	SG EFFERVESCENT ANTACID/P
SM HEADACHE ADDED	NOVASAL	UNI-TREN
STRENGT	SUPAC	
SM HEADACHE PAIN	SUPER STRENGTH PAIN	VANQUISH
RELIEVER	RELIE	
SOBA ANALGESIC	SUREPRIN	V-R EFFERVESCENT PAIN REL
SOBA PAIN RELIEVER	TETRA-MAG	ZEE-ZELTZER
HEADAC		
SODIUM SALICYLATE	THERAPY BAYER	ZORPRIN
ST JOSEPH ADULT	THIOCYL	
STANBACK	TRICOSAL	
	TRILISATE	

List #2: Commonly Used Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)

ACTRON	KETOPROFEN
ADDAPRIN	KETOROLAC
ADVANCED PAIN RELIEF	LANSOPRAZOLE / NAPROXEN
ADVIL	LODINE
ALEVE	MECLOFENAMATE
ALL DAY RELIEF	MEDI-PROFEN
ANAPROX	MEDIPROXEN
ANSAID	MEFENAMIC ACID
ARTHROTEC	MELOXICAM
BEXTRA	MENADOL
CATAFLAM	MIDOL
CELEBREX	MOBIC
CELECOXIB	MOTRIN
CLINORIL	NABUMETONE
CVS INFANTS' CONCENTRATED	NALFON
DAYPRO	NAPRELAN
DICLOFENAC	NAPROSYN
DICLOFENAC / MISOPROSTOL	NAPROXEN
DYSPEL	NUPRIN
ELIXSURE	ORUDIS
ETODOLAC	ORUVAIL
FELDENE	OXAPROZIN
FENOPROFEN	PHENYLBUTAZONE
FLURBIPROFEN	PIROXICAM
GENPRIL	PONSTEL
HALTRAN	PREVACID / NAPRAPAC
IBU	PROFEN
IBU-DROPS	PROVIL
IBUPROFEN	Q-PROFEN
IBUTAB	RELAFEN
INDOCIN	ROFECOXIB
INDOMETHACIN	RUFEN
I-PRIN	SULINDAC
TAB-PROFEN	VALDECOXIB
TOLECTIN	VIOXX
TOLMETIN	VOLTAREN
TORADOL	
