

**INSTRUCTIONS FOR THE ANNUAL FOLLOW-UP TRACING FORM AND  
QUESTIONNAIRE, AFU, VERSION K, 010/18/2004  
PREPARED 11/23/04**

**I. GENERAL INSTRUCTIONS**

Annual follow-up of the ARIC 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. Annual follow-up contacts are scheduled approximately every 12 months. Each routine follow-up is completed by telephone.

Three data collection forms are routinely completed in the annual follow-up (AFU) interview: the AFU Record of Calls, the AFU Questionnaire Form, and the Update 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.

To assist the field centers in scheduling AFU interviews, the individual field centers generate the Participant Tracing Information Sheet. This is an ARIC Data Entry System (DES)-generated information sheet, i.e., not a data collection form, which lists the most current information on every participant's address, date of birth, state of birth, social security number, drivers license number, contact persons, physician, employer at Visit 3, dates of the previous ARIC visits, and the final contact status at the most recent AFU interview.

The ARIC Annual Follow-Up Questionnaire Form contains a "Record of Calls" cover page for use in contacting a participant, and the Annual Follow-up Questionnaire, which is used 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. It is the field center choice to either do direct data entry or paper collection. In cases of computer malfunction, paper forms must be used for delayed data entry.

The Update 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 ARIC surveillance activities. 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 34 of the AFU form. Each field 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 field 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

Either the Coordinating Center or the field center staff periodically generates the ARIC 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	5/14/1998	11/14/1998	5/13/1999
14	5/14/1999	11/14/1999	5/13/2000

The initial call for annual contact is made no more than three weeks or so before the target date except in contact years 4, 7 and 10, in which the contact can be made up to 4 months earlier to aid clinic scheduling. 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 are still traced and interviewed, and hospitalization or death information is obtained if necessary.

## 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

### 1. Record of Calls

The Record of Calls (TRC) 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:

#### RECORD OF CALLS RESULTS CODES

<u>RESULT CODE</u>	<u>RESPONSE CATEGORY</u>	<u>EXPLANATION</u>
01	<b>No Action Taken</b>	No attempt has yet been made to contact the participant.
02	<b>Tracing; Not yet contacted any source</b>	Attempts are being made to locate the participant, but so far neither the participant nor another reliable source have been contacted.
*03	<b>Contacted, Interview Complete</b>	The participant was successfully contacted by phone or in person, and the entire interview, including the questionnaire and hospitalization information was completed.
*04	<b>Contacted, Interview Partially Complete or Rescheduled</b>	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.
*05	<b>Contacted, Interview Refused</b>	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.
06	<b>Reported Alive, Will Continue to Attempt Contact This Year</b>	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.

*07	<b>Reported Alive, Contact Not Possible This Year</b>	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.
*08	<b>Reported Deceased</b>	Reliable information indicates that the participant has died.
*09	<b>Unknown</b>	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.
*98	<b>Does Not Want Any Further Contact</b>	The participant has requested 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 recruitment 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 by the study.

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 TRC form. This result code is subsequently entered as Item 36 in the data entry system of the Annual Follow-up form (AFUH).

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 looks to the participant for an answer. What appears to be dead time to the interviewer may represent the participant's review of a lifetime of events. Other types of probing include repetition of the original question, channeling ("tell me more about..."), clarification ("when did your doctor tell you that?"), elaboration/continuation ("what happened next?"), encouragement ("I see, um, huh, 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 ARIC Study.  
May I please speak with (NAME OF PARTICIPANT)?"**

Determine the participant's availability and vital status. The interviewer introduces her(him)self at the beginning of the interview with each participant in the household.

If DECEASED, offer condolences, and then determine the date (Item 4) and location of death (Item 5), and continue with the section on HOSPITALIZATIONS (Section F). At the end of the interview, inform the respondent of the possible need for someone from the ARIC staff to contact a family member later on, and ask when would be the best time to call. Record this information in the NOTES of the RECORD OF CALLS.

When PARTICIPANT IS ON THE LINE, begin the interview with Item 6 by reading:

**"Hello (NAME OF PARTICIPANT). [My name is (YOUR NAME) and I am from the ARIC Study]. Even though we do not plan to have any more clinic visits, we are able to continue our yearly follow-up calls. I would like a few minutes of your time to find out about your health in the past year".**

Use the sentence in [ ] each time you begin a new interview.



When an ARIC 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, 9, 10, 37-39 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 and intermediary to relay and/or interpret the participant's answers.

When an ARIC 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 ARIC interviewer attempts to interview the informant on the questions on VITAL STATUS (Questions 2 and 3) and HOSPITALIZATIONS (Questions 9, 10, 37-39). Do NOT administer the questions on FUNCTIONAL STATUS. 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 ARIC Field Center 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 ARIC Field Center 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 33, 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 9 and 10).

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 ARIC Field Center, 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>
3	6/28/88	U

3. It is Contact Year 2. The participant's baseline visit was on 2/24/87. His "Latest" date is 8/23/88. Neither the participant nor a reliable source can be located. Finally, on 8/24/88 (one day after the "Latest" date), the participant is located and interviewed. The interview must be recorded under Contact Year 3, and the status for CY 2 is "Unknown." Record as:

<u>Contact Year</u>	<u>Date of Status Determination</u>	<u>Status</u>
2	8/23/88	U
3	8/25/88	C

4. It is Contact Year 2. The participant's "Earliest" date is 2/12/87 and his "Latest" date is 2/11/88. The participant was contacted on his "Target" date, 8/12/87, and the questionnaire was administered routinely. One month later, his obituary is seen in the newspaper. The death may not be reported until the next Contact Year. Record as:

<u>Contact Year</u>	<u>Date of Status Determination</u>	<u>Status</u>
2	8/12/87	C
3	2/12/88	D

A death investigation may, however, be started at any time.

## B. DEATH INFORMATION

4. **Date of death.**
5. **Location of Death: (a) City/County); (b) State.**

If the participant has died, attempt to secure the date and location (city/county, state) of death from the source of information, whether it is a relative or an obituary. Take steps to begin a death investigation by initiating a Cohort Event Eligibility Form. Obtain as much information as possible from the informant on items 4 and 5. For example, if only the year and month of death are known, record them, (and not the



day). Similarly, if the state is known, but not the city/county, record as much information as is available. Continue with Item 9, Section E (OVERNIGHT ADMISSIONS).

### C. GENERAL HEALTH

The time frame for most of the questions in Sections C - I is "since the last contact", which is usually, but not necessarily, the last Annual Follow-up (AFU) call. Generally this is about 12 months. Exceptions to this could result from one or more missed AFU contacts, or the last contact having been Visit 4. Note, the major exceptions to this one year time frame are for Item 7, in which the time frame is a "life time history" (i.e., "Have you ever had ..."), and Item 16, in which the time frame is "the past two weeks", and Section I (FUNCTIONAL STATUS), where "now" refers to the past 4 weeks. It is important that the participant understand the time frame, and care must be taken to clearly introduce the shifts in time frame from one section to the next.

**6. Now I will ask you some questions about your health. Over the past year, compared to other people your age, would you say that your health has been excellent, good, fair or poor?**

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.

- 7. Has a doctor ever said you had any of the following?**
- a. Heart attack
  - b. Heart failure or congestive heart failure
  - c. High blood pressure
  - d. Diabetes or sugar in the blood
  - e. Blood clot in a leg or deep vein thrombosis
  - f. Blood clot in your lungs or pulmonary embolus
  - g. Chronic lung disease, such as bronchitis, or emphysema
  - h. Asthma
  - i. Cancer

Read the questions/statements as written. Do not otherwise define the condition for the respondent. Do not define the condition yourself, based on the respondent's answer. Record ambiguous responses as UNKNOWN and enter the text response in a note log.

Enter YES, NO or UNKNOWN for each item that identifies a specific condition (7a-i). A response is positive only if the condition was diagnosed by a physician. NO is coded if (1) the respondent was told by a doctor that he/she did not have the condition specified, (2) was never told by a doctor that he/she had the condition, or (3) was never tested for the condition. UNKNOWN is recorded if the respondent is not sure that the doctor said he/she had this condition. The code of UNKNOWN is most frequently used when the respondent cannot remember accurately what the doctor said. Follow the skip patterns closely for responses of NO or UNKNOWN.

For Item 7.i (cancer), go to Item 8 if the response is NO or UNKNOWN. If the response is YES, ask

**"Can you tell me in what part of the body the most recently diagnosed cancer was located?" (Item 7.j) and date of diagnosis (Item 7.k).**

Ask if the participant has **had another cancer (Item 7.l)**. If NO or UNSURE, go to Item 8. If YES, record **the site (Item 7.m)** and **date of diagnosis (Item 7.n)**. NOTE: Space is provided for recording

information on only two cancers. Do not probe to determine whether these diagnoses represent two separate malignancies or a malignancy and its recurrence.

#### **D. STROKE/TIA**

**8a. 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 by a physician. If the participant is unsure, record as "No."

**8b. 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. OVERNIGHT ADMISSIONS**

The purpose of questions 9 and 10 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 9 and 10 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 9) or other condition (Item 10), select the response category UNKNOWN.

**9. 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. The term 'heart attack' refers to the person's admitting diagnosis or discharge diagnosis. For example, the response to Item 9 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.

**10. 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 other (than heart attack) condition. If the participant answered yes to item 8 (stroke, slight stroke, transient ischemic attack or TIA?) and it was a hospitalization, be sure that the hospitalization is recorded here.

If the response to Item 9 or 10 is positive, complete Section F:Q37 – 39 (HOSPITALIZATIONS) at this time. When the participant is deceased, and this question is answered by an informant, complete Section F on hospitalizations, if appropriate, then go to Section K (ADMINISTRATIVE INFORMATION).

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 Q9 or Q10. The AFU interviewer should not probe at the time of the AFU to find out the length of the hospital stay.

(Section E Overnight Admissions continued after Section F)

## F. HOSPITALIZATIONS

### A. Collection of data

If there was a positive response to Items 9 and/or 10, 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 40.a-f), H indicates that the hospitalization was reported; N indicates that the hospitalization was fully sought by Surveillance and not found.

**37-40.** Following the questionnaire, 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.) Use the Hospitalizations section of the Annual Follow-Up Form. This is a long question that will have to be obtained in parts. Use neutral probes to elicit all hospitalizations. For the (first) overnight stay, record the reason for the hospitalization (Item 37.a-f), the hospital name, city, and state (Item 38.a-f), and the discharge date (month and year) of the hospitalization (Item 39.a-f). Probe for additional hospitalizations and follow the directions for the first hospitalization. There is space to complete six hospitalizations. If there are more than six, record and enter the six 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 six times, select those with heart disease or stroke as reasons for hospitalization.

40.a-f. 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 any deaths or hospitalizations that are encountered during AFU contact attempts are brought to the attention of the Surveillance Event Investigation staff, and vice-versa.

The surveillance staff is to be notified of every cohort hospitalization and an investigation should be initiated. The hospitalizations sheet provides a check box to indicate that the information has been transmitted to the surveillance staff.

## E. OVERNIGHT ADMISSIONS, CONT.

### 11.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 12.

### 11.b Are you currently staying in a nursing home?

“Currently” refers to the day on which the interview is conducted.

## G. INVASIVE PROCEDURES

Read the transition statement.

12. [DO NOT ASK]. Has participant completed a previous version “G”, “H”, “I” or “J” of Annual Follow-up? Check the Participant Information Sheet to determine whether the participant has previously completed version “G”, “H”, “I” or “J” of the AFU form. Select the appropriate response category (YES or NO), and follow the skip patterns. Persons who have completed Version G or H of the AFU are read Item 12.a; persons who have not yet completed version G or H are read Item 12.b. The difference between the two versions of Item 12 part (a) and part (b) is the setting in which the questions were asked: item 12.a is for participants who were last contacted during an AFU interview; item 12.b is for persons whose last contact was at a clinic visit at a field center.

12.a Since we last contact you on (mm/dd/yyyy), ....

12.b Since your last ARIC 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 14, selecting the part (a or b) which corresponds to the part you are completing here. When YES, continue with next questions.

**13.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 13.b or 13.e are YES.

## DEFINITIONS AND SYNONYMS FOR THERAPEUTIC AND DIAGNOSTIC PROCEDURES

<u>DIAGNOSTIC PROCEDURES</u>		<u>SYNONYMS</u>
<b>ECHOCARDIOGRAM</b>	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
<b>ELECTROCARDIOGRAM</b>	A graphic record of the electrical impulses produced by the heart.	ECG EKG
<b>TREADMILL CARDIAC STRESS TEST</b>	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.	
<b>THALLIUM SCAN OF THE HEART SPECT</b>	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
<b>HOLTER MONITOR</b>	A small, portable ECG machine worn by patients.	
<b>HEART RHYTHM or CONDUCTION STUDIES</b>	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.	

<b>CAROTID ULTRASOUND STUDIES</b>	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
<b>MRI of BRAIN</b>	A diagnostic procedure using powerful magnets to look inside the skull. Computer-generated pictures image the brain and can identify abnormalities such as damage from a stroke or a head injury.	Cerebral MRI
<b>CAT SCAN of BRAIN</b>	A non-invasive diagnostic technique, which produces an image of the brain and can identify abnormalities.	
<b>CORONARY BYPASS or BYPASS SURGERY</b>	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
<b>OTHER HEART PROCEDURES</b>	Examples include valve replacement, ventricular aneurysm resection, Aortic Stenosis, Ventricular Stenosis. Defect repair, Patent ductus closure, Pacemaker, Implantation of automatic defibrillator, Coronary atherectomy.	
<b>ENDARTERECTOMY</b>	Surgery to take out plaque from an artery, to restore blood flow in one or both of the arteries in the neck.	
<b>OTHER ARTERIAL REVASCULARIZATION</b>	Any procedure where additional blood flow is brought to an artery via a bypass from a location elsewhere in the body.	
<b>BALLOON ANGIOPLASTY</b>	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)
<b>CATHETERIZATION</b>	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

14. [DO NOT ASK]. Has participant completed a previous version “G”, “H”, “I” or “J” of Annual Follow-up? This question is comparable to Item 12. Check the response to Item 12, or check the Participant Information Sheet to determine whether Version G, H, I or J has been administered. If YES, read Item 14.a to the participant. If NO, read Item 14.b. Carefully follow the skip patterns.
- 14.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?**
- 14.b **Since your last visit to the ARIC 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 Q15 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:

15. **Did you have:**
- Angioplasty or stent of coronary arteries?**
  - Angioplasty or stent in the arteries of your neck?**
  - 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.”**

16. **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

It is not necessary for these medications to have been prescribed by a physician. Unlike the procedures for the medication survey in the clinical exams for the ARIC cohort, the names of these medications are not transcribed. For each of the three 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.

Introduce Item 17 with a new transition statement which defines the new terms in the next question.

**“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.”**

17. **Are you NOW taking aspirin, or a medicine containing aspirin, on a regular basis? This does not include Tylenol, nor Advil.**

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 List. 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 not an aspirin containing drug, code the answer as ‘no’.

18. [DO NOT ASK] Is the participant male or female? When male, select M, and go to Section I (FUNCTIONAL STATUS). When female, select F, and continue with Item 19 to determine whether the most recent contact was the Visit 4 exam, or whether it was an Annual Follow-Up call (Version G or H of the AFU). As was done for Item 12, the last contact venue determines the introduction to the next question.
19. [DO NOT ASK]. Has participant completed a previous version “G” or “H” of Annual Follow-up? Check the Participant Information Sheet to determine whether the participant has previously completed version “G” or “H” of the AFU form. Select the appropriate response category (YES or NO), and follow the skip patterns. Persons who have completed Version G or H of the AFU are read Item 19.a; persons who have not yet completed version G or H are read Item 19.b. The difference between the two versions of Item 19 part (a) and part (b) is the setting in which the questions were asked: item 19.a is for women who were last contacted during an AFU interview; item 19.b is for women whose last contact was at a clinic visit at a field center.
- 19.a Since we last contact you on (mm/dd/yyyy),**  
**19.b Since your last ARIC visit on (mm/dd/yyyy),**  
**.... have you taken or used any female hormone pills, skin patches, shots or implants?**
- 19.c Please give me the names of the female hormones you have used**  
**(Part .a) since our last contact**  
**(Part .b) since that exam**  
**starting with any you may be taking currently or with the most recent one. Please exclude hormone creams: \_\_\_\_\_**

Items 19-22 record information on a maximum of two different hormone preparations, starting with the most recent one. “Current” means either in a cycle at the time of the interview or between cycles, or currently in a program of female hormone shots or implants. Information on the first hormone is recorded in Items 19 and 20; information on the second hormone is recorded in Items 21 and 22. If more than two hormones were used in the contact interim, only record the two which were most recent. However, this may require the use of a generic name (estrogen/progesterone) and GPI code that has been added to the medication dictionary to identify estrogen/progesterone compounds. For example, if a woman is currently taking “Prempro” (a recently released compound estrogen-progesterone drug which comes as one pill) but was also taking opposed estrogens for hormone replacement therapy (which was prescribed as two pills, i.e., one estrogen and one progesterone) within the time frame since the last contact, Item 19.c (Name 1) would be completed as “Prempro”, and Item 21.a (Name 2) would be completed as “estrogen/progesterone”. If, however, the participant is currently taking two separate estrogen and progesterone drugs for hormone replacement therapy (i.e., not Prempro or another combination estrogen/progesterone pill), then the name of the estrogen drug is recorded in Item 19.c and the name of the progesterone drug is entered in Item 21.a.

If NO, go to Section I (FUNCTIONAL STATUS).



If YES, transcribe the name of the hormone. It is not necessary to record the concentration as was done at the field centers. If the participant does not know the name of the medication, but knows she is taking hormone replacement therapy, draw two horizontal lines here and through the boxes for medication code (Item 20: Code 1).

20. Code 1: After the AFU interview has been completed, look up the medication code of the hormone in either the paper or data entry system versions of the Hormone Replacement Therapy Dictionary, and record the six digit code in the fields provided on the paper form. In selecting the code for a preparation with multiple hormones, identify the code based on the full name of the product, not just the first hormone. When the participant does not know the name of the hormone, on the paper form draw two horizontal lines through (in the Data Entry System, enter “==” in) the medication code boxes.
21. **Have you also used a second female hormone since we last contacted you?** If NO, go to Section I (FUNCTIONAL STATUS). If YES, follow QxQs for Items 19.
22. Code 2: follow the instructions for Item 20.

## I. FUNCTIONAL STATUS

Begin this section with the transition statement:

**"Now I would like to find out whether you can do some physical activities without help. By 'without help,' I mean without the assistance of another person. These questions refer to the last 4 weeks."**

This time frame is different from the previous section on medications. In general, you are trying to assess the participant's current functional status. This time period (i.e., the last 4 weeks rather than the day of the interview) has been chosen because we do not want to document decreases in functional ability that might be due to temporary conditions such as a headache, a cold or the flu, or a sprained ankle, etc. The intent of these questions is to record the individual's overall ability to perform the various activities (i.e., heavy work around the house, walk upstairs without assistance, walk half a mile, or work outside the home).

23. **Are you able to do heavy work around the house, like shoveling snow or washing windows, walls or floors, without help?**

For this question, the examples are just guidelines. If a person can do any heavy work (not necessarily all of the things specified in the question), then record YES. Other examples of heavy work around the house could be "cutting the grass with a hand or power mower" (but not a riding lawn mower), or "painting walls or wallpapering."

24. **Are you able to walk up and down stairs without help?**

The focus of the question is on the participant's ability to walk up and down stairs without the assistance of another person. If the participant says something like, "We have a ranch house, so I don't have to go up stairs," say that you want to know if he/she is able to walk up and down stairs. If the respondent is uncertain, code as NO.

25. **Are you able to walk half a mile without help? That's about 8 ordinary blocks.**

Again, the emphasis is on the ability to do the activity, in this case, to walk half a mile. The concept of help in this item refers to persons helping. Therefore, the use of

equipment would not be considered assistance and you would code YES for a participant who reported walking half a mile with the use of a cane. One, it keeps the definition consistent with those in Items 23 and 24. Two, it is assumed (and was the experience in Framingham) that anyone requiring either a second individual to assist ambulating or the use of a rehabilitative device (such as a three-pronged cane or walker) is not able to walk half a mile.

### **26.a Are you ABLE to go to work?**

The focus of this question is whether the ability to work outside the home has been primarily compromised due to poor health (i.e., the participant is completely unable to engage in his or her occupation).

If YES, go to Item 27.a.

If the participant (1) does not work outside the home or (2) is not capable of working but would normally not be working outside the home (e.g., a homemaker, retired, or unemployed and not looking for work), code as NOT APPLICABLE, skip Item 26.b, and go to Item 28.a.

If NO, select the appropriate code, and determine in the next question (Item 26.b) if the poor health and the resultant disability were due to heart disease.

### **26.b Is a heart problem the main cause of your not being able to work?**

If asked about the meaning of "a heart problem," do not interpret nor offer a medical explanation, but rather let the participant decide whether s/he is "unable to work because of a heart condition or heart disease." Regardless of the response, continue with Item 28.a.

### **27.a During the past 4 weeks, have you missed work for at least half a day because of your health?**

The focus of question is absence from work anytime within the four weeks prior to the interview for at least half a day (4 hours or more) because of personal illness. If this occurred (YES for Item 27.a), **determine how many days the participant was absent from work (Item 27.b)**. The maximum number of days not worked is 28. The minimum is 1 because less than 4 hours of missed work would have been coded as NO in Item 27.a and Item 27.b would not have been asked. Therefore, 4 hours or more of missed work during a day is counted as 1; less than 4 hours is rounded down. For example, 3 days and 3 hours is entered as "03", whereas 3 days and 6 hours is entered as "04".

### **28.a Are you able to do your usual activities, such as work around the house or recreation?**

The focus of this question is to determine whether the ability to pursue one's normal activities around the house has been compromised by poor health.

For example, you would code as NO a homemaker who is no longer able to clean house or perform the usual daily activities. **If NO, determine if this is due to a heart problem (Item 28.b)**, and go to Item 30, skipping Item 29. If asked about the meaning of "a heart problem," do not interpret nor offer a medical explanation, but rather let the participant decide whether s/he is "unable to work because of a heart condition or heart disease." If a participant indicates that s/he is able to carry on with the usual activities around the house, but is not able to do his/her usual recreational activities -- such as bowling, walking, any form of recreational exercise -- code NO, determine in item 28.b if this is due to a heart problem, and go to item 30, skipping item 29.

However, you would code as YES a retired brick layer (who is physically incapable of laying bricks) but who is able *to do his usual retirement activities* such as gardening or housework. Continue with Item 29.a.

**29.a During the past 4 weeks, have you had to cut down on your usual activities, (such as work around the house or recreation), for half a day or more because of your health?**

The focus of this question is a reduction in the participant's usual activities (in contrast to a cessation of these activities in Item 28) during the four weeks prior to the interview because of poor health. The reduction in activities had to occur for at least half a day, i.e., 4 hours or more. **If this occurred (YES for Item 29.a), determine on how many days the participant had to reduce his or her activity level (Item 29.b).** The maximum number of days of reduced activity is 28. The minimum is 1 because less than 4 hours of reduced activity would have been coded as NO in Item 29.a and Item 29.b would not have been asked. Therefore, four hours or more of reduced activity during a day is counted as 1; less than 4 hours is rounded down. For example, 3 days and 3 hours is entered as "03", whereas 3 days and 6 hours is entered as "04".

**J. OTHER ITEMS**

Begin this section with another transition statement.

**“Next I have a few miscellaneous questions.”**

**30. 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.

**31. 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.

**32.a Please tell me which of the following best describes your employment status:**

Homemaking.....A \_\_\_\_\_ Go to Item 33, Screen 16

Employed.....B

Unemployed.....C \_\_\_\_\_ Go to Item 32.c.

Retired.....D \_\_\_\_\_ Go to Item 32.d.

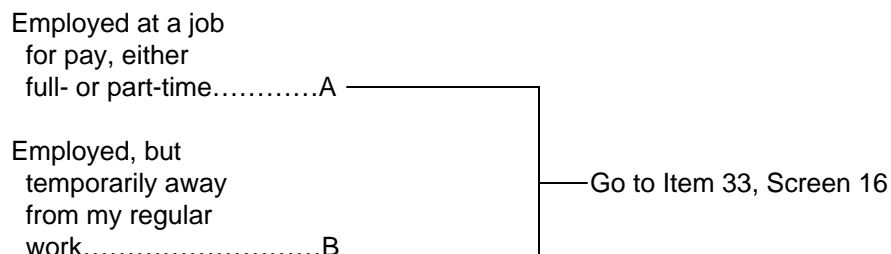
Read the four categories to the participant. Select the letter which most closely corresponds to the participant's choice, and follow the skip patterns for each responses category.

If the participant is on medical or workers compensation disability (neither working nor retired), the person is coded as 'C'.

If the participant selects “employed”, continue with Item 32.b

**If a participant answers Q32a inconsistently with the answer to a previous question (such as Q26a Are you ABLE to go to work?), the interviewer may go back and probe for the inconsistency. The interviewer may not, however, change the answer without asking for clarification from the participant. The answers in Q32a are not mutually exclusive, so a participant may answer this question in more than one way correctly.**

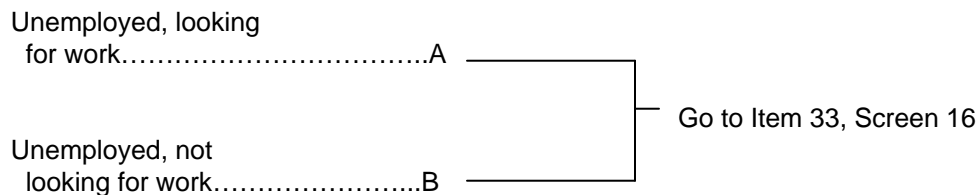
**32.b Which of these two categories best describes your “employed” status:**



Category B, “employed, but temporarily away from my regular work” most often refers to school teachers who work 9 or 10 months out of the year, have the summers off, and return to their regular job at the end of the school vacation.

If the participant selects “unemployed”, go to Item 32.c.

**32.c Which of these two categories best describes your “unemployed” status:**



**32.d Which of these two categories best describes your “retired” status.**

Retired from my  
usual occupation  
and not working.....A

Retired from my  
usual occupation,  
but working for pay.....B

**K. ADMINISTRATIVE INFORMATION**

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

33. 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.

34. Does participant (still) live within official ARIC 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 ARIC 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.

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

In some centers, if the participant has requested that ARIC 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.

36. 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