INSTRUCTIONS FOR THE ANNUAL FOLLOW-UP TRACING FORM AND QUESTIONNAIRE
AFU, VERSION M, 02/07/2008
QxQ 06/16/09

(Note : Questions were re-numbered in version M)

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.

Beginning with the AFU version L, interviewers occasionally ask a participant for authorization to contact their physician for information on selected health problems, additional to that reported by the participant during the AFU interview. When the participant reports that a physician has diagnosed heart failure (HF) during an outpatient visit, and during the time frame specified in the AFU, the interviewer initiates the process that enables ARIC to send that physician a request to complete the Physician Heart Failure Form (PHF). The PHF form is sent to each physician for whom the participant submits an authorization for access to information from the physician's records. An example of the Consent to Release Protected Health Information is provided at the end of these QxQ instructions.

Also beginning with version L of the AFU, ARIC expanded its ascertainment of possible events to record admissions to an emergency room or a medical facility for outpatient treatment. The procedures to ascertain overnight hospitalizations remained unchanged, per extant ARIC protocol.

Beginning with AFU version M the time frame for the questions introduced in version L and those related to the ascertainment of heart failure are changed to the last AFU contact with the participant. Specifically, many questions previously asked in the format "has a doctor ever said…" are framed in AFU version M as "since we last contacted you …" Also beginning with version L of the AFU the ARIC interviewers more formally and systematically identify proxies for ARIC cohort members who are unable to provide the information ascertained during the AFU interview. As in the past, if the ARIC interviewer determines that the cohort member is not fully oriented or provides information that is contradictory or seems questionable, the interviewer asks for the participant's input and authorization to contact a proxy informant.

Consistent with the modifications introduced in version M of the AFU the result codes for the record of calls were expanded. Result code 3A refers to an interview complete with the cohort

member and code 3B applies to an interview successfully complete with a participant's proxy (see Section B.1, below).

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

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

The 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 who do not live with the participant. 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 tasks. At the completion of the AFU interview, the location of the participant's residence is recorded as within the ARIC surveillance boundaries (YES), outside of the surveillance area (NO), or UNKNOWN in Item 53 of the AFU form. 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

Field center staff – or if necessary the Coordinating Center – 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 (minus one day).

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:

Contact Year	Earliest	Target	Latest
02	5/14/87	11/14/87	5/13/88
03	5/14/88	11/14/88	5/13/89
04	5/14/89	11/14/89	5/13/90
05	5/14/90	11/14/90	5/13/91
06	5/14/91	11/14/91	5/13/92
07	5/14/92	11/14/92	5/13/93
08	5/14/93	11/14/93	5/13/94
09	5/14/94	11/14/94	5/13/95
10	5/14/95	11/14/95	5/13/96
11	5/14/96	11/14/96	5/13/97
12	5/14/97	11/14/97	5/13/98
13	5/14/98	11/14/98	5/13/99
14	5/14/99	11/14/99	5/13/00
15	514/00	11/14/00	5/13/01
16	5/14/01	11/14/01	5/13/02
17	5/14/02	11/14/02	5/13/03
18	5/14/03	11/14/03	5/13/04
19	5/14/04	11/14/04	5/13/05
20	5/14/05	11/14/05	5/13/06

The initial call for annual contact is made no more than three weeks or so before the target date. Ideally, the contact takes place as closely as possible to the "target" date. If for some reason contact is not made until after the "Latest" date, this contact is assigned to the following Contact Year. This procedure is described in more detail in the section on vital status below.

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

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

B. Performing the Interview

Form sections are typically completed in the following order:

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

1. **Record of Calls**

The Record of Calls (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 shown in the following table.

RECORD OF CALLS - RESULTS CODES

RESULT CODE	RESPONSE CATEGORY	EXPLANATION
01	**No Action Taken**	No attempt has yet been made to contact the participant.
02	**Tracing; Not yet contacted any source**	Attempts are being made to locate the participant, but so far neither the participant nor another reliable source has been contacted.
*03A	**Contacted, Interview Complete-Cohort Member**	The participant was successfully contacted by phone or in person, and the entire interview, including the questionnaire and hospitalization information was completed.
*03B	**Contacted, Interview Complete-Proxy/Informant**	The participant's proxy or informant was successfully contacted by phone or in person, and the entire interview, including the questionnaire and hospitalization information was completed.
*04	**Contacted, Interview Partially Complete or Rescheduled**	The participant was successfully contacted by phone, letter, or in person, but the interview is incomplete or was not done at all. This may be a temporary code if it is possible that the interview may be completed at a later date within the same contact year.
*05	**Contacted, Interview Refused**	The participant was successfully contacted by phone, letter, or in person, but the interview was not done and will not be completed at a later date within the same contact year.
06	**Reported Alive, Will Continue to Attempt Contact This Year**	Reliable information (e.g. from a relative, employer, etc.) indicates that the participant is living, but direct contact has not yet been made. It is possible that contact will be made during this same contact year through further efforts. For example, "temporarily away" would fit in this category.
*07	**Reported Alive, Contact Not Possible This Year**	Reliable information indicates that the participant is living, but direct contact has not yet been made. This code should be used only if repeated contact attempts have been made, or when it has been determined that it is not possible that contact will be made during this same contact year.
*08	**Reported Deceased**	Reliable information indicates that the participant has died.
*09	**Unknown**	Neither the participant nor another source of information has been contacted in a manner sufficient to provide reliable vital status data during the specified date range.
*98	**Does Not Want Any Further Contact**	The participant has indicated that s/he does not wish to be contacted any more by the ARIC study. This code alerts staff that no additional contacts should be attempted during the same contact year. Notes should be kept on the record of call to describe the nature of the refusal. The supervisor at each field center determines the type of action to be taken at the following contact anniversary date, e.g., a polite letter, post card, or an alternative which is sensitive to any known reasons for this participant's desire not to be contacted again.

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 54 in the data entry system of the Annual Follow-up form (AFUL).

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

a. Refusals (attempt conversion).

b. Difficult contacts or other non-completes. In particular, the supervisor decides when it is no longer practical to continue to investigate a person. All possible alternatives must be exhausted for this decision to be made.

c. Undocumented deaths. If a death is reported for which no death certificate can be located, the surveillance staff reviews the case and attempts to resolve it. If no death certificate is ultimately located, including an NDI search, the vital status may be changed to "Unknown".

2. Questionnaire

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

Probing is appropriate to seek further information, provoke further discussion along a certain line of thought or explanation, or to question the respondent. In general, and unless specifically countermanded in the QxQ instructions of the interview, probing is appropriate when an answer is unclear, incomplete, inconsistent or no response is given. The best and most frequently employed probe is silence. In a silent probe, the interviewer pauses or hesitates and waits for the participant to answer. What appears to be dead time to the interviewer may represent the participant’s review of a lifetime of events. Other types of probing include repetition of the original question, channeling (“tell me more about...”), clarification (“when did your doctor tell you that?”), elaboration/continuation (“what happened next?”), encouragement (“I see, um, huh, hmmm”) and completion (“anything else?”; “can you tell me anything more about that?”).

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

INTRODUCTION:

"Hello, this is (YOUR NAME) from the 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.

A. VITAL STATUS

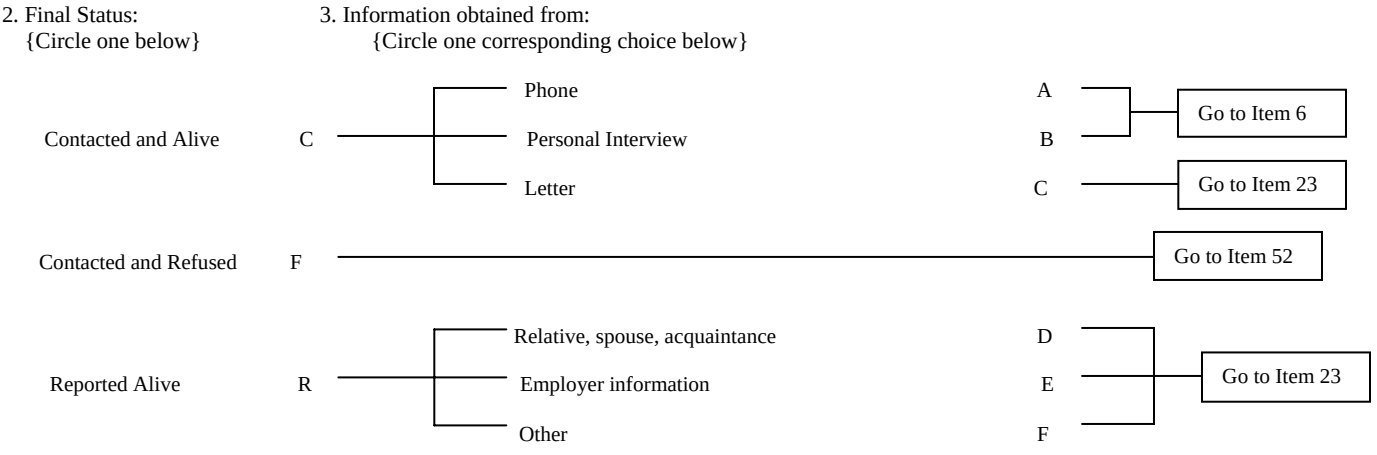
1. **Date of status determination**: ___ ___ / ___ ___ / ___ ___ ___ ___
   Month Day Year

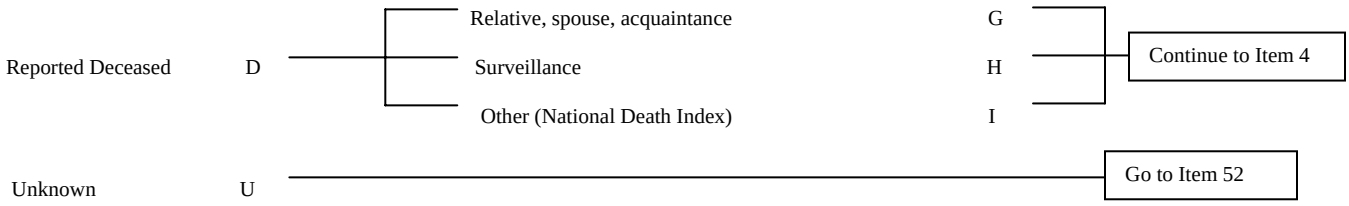
The date of status determination is the date on which the participant's final vital status becomes known to the interviewer (see item 2 below). THIS DATE MUST FALL DURING THE PARTICIPANT'S CONTACT YEAR, i.e., no earlier than the "Earliest" date given on the Tracing Form and no later than the Latest Date on that form. It is generally the last date on the "Record of Calls."

2. **Final Status** and
3. **Information obtained from:**

Record the participant's final vital status for the present contact year, and indicate the source of that information. THE RESPONSE TO ITEM 3 MUST CORRESPOND TO ITEM 2 AS SHOWN ON THE FORM. Thus, if item 2 is "C" then item 3 must be "A," "B," or "C". Similarly, if item 2 is "R", then item 3 must be "D," "E," or "F." If item 2 is "D," then item 3 must be "G," "H," or "I." After completing item 3, follow the corresponding skip rule indicated for that response.

Example: If participant was contacted over the phone, record, Q2 as 'C' and Q3 as 'A'.





When an ARIC participant is incapable of speaking on the telephone with an AFU interviewer, but is capable of responding to the questions through an intermediary or has a proxy, all (or as many as possible) of the questions on the AFU form are administered. If it is not possible to conduct the full interview, questions 1-3, 8-10, 23-24, 28-35 are the most important. Record the FINAL STATUS in question 2 as 'C' and the INFORMATION OBTAINED FROM as A or B. No provision is made to record that the interview was done using 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, is NOT capable of responding to the questions even through an intermediary, the ARIC interviewer completes the questions on VITAL STATUS (Questions 2 and 3) and attempts to obtain the information on HOSPITALIZATIONS (Questions 23-24, 28-35) from a proxy or informant. 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 or a person who is knowledgeable in the opinion of the interviewer and able to answer the interview questions on behalf of the cohort member 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). At times it may not be possible to ask all the questions on the form. Note that this status corresponds to a final result code of 03A, 03B, or 04 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 52, and complete the administrative section of the form.

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

attempt to collect information on the participant's overnight admissions to hospitals (Items 23 and 24).

Reported Deceased (D): Reliable information indicates that the participant has died. In this case, the "date of status determination" is the date on which the death became known to the 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:

Contact Year	Date of Status Determination	Status
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:

Contact Year	Date of Status Determination	Status
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:

Contact Year	Date of Status Determination	Status
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:

Contact Year	Date of Status Determination	Status
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 23, Section E (ADMISSIONS).

C. GENERAL HEALTH

In version M of the AFU the questions in Section C were reformulated from a "life time history" (e.g., "Has a doctor ever said you have...") to our last contact with the participant. Questions now read "Since we last contacted you on mm/dd/yyyy,…" or "Since we last contacted you has a doctor said…" An exception is question 8 if the participant has not previously completed version L of the AFU. The interviewers are aware of that for many years these questions were asked as "Has a doctor ever said you have...", which at this point may surprise or confuse study participants. Another possible source of confusion is that several of the conditions we ask about are chronic conditions that once diagnosed will persist, even if treated and controlled. By asking "Since we last contacted you has a doctor said…" we are interested in identifying newly occurring, or newly diagnosed conditions. If a participant responds by saying "Yes, my doctor told me that I have diabetes and I have had this for several years" the response to this question (question 15) is No. If the answer provided by the participant to questions in Section C suggests to the interviewer that this may not be a condition that has newly occurred since the last AFU interview, the participant is asked to clarify whether this is the first time a physician has said that she/he has this condition. Only new diagnoses of a condition since the last contact with the participant are recorded as Yes.

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.

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

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

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

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

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

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

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

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

Collect the name and address of the doctor last seen for heart failure. The address field is there not as data but as a convenience for the field center staff in determining where to send PHF Questionnaire if permission is obtained from the participant.

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

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

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

8.e. **"The ARIC study would like to ask your physician to tell us more about your health. If you agree to do this I will send you a form that tells your physician that you authorize the ARIC study to get this information from your doctor. Once you sign that form and mail it back to me I will contact your physician's office."**
May I send you this release form and an addressed envelope for you to mail it back?

This question requests permission for the participant's doctor to release medical information to ARIC. Note that ARIC is not requesting the release of medical records, but rather an authorization from the participant for ARIC to ask the physician additional questions about a possible diagnosis of heart failure, such as may be contained in the participant's medical records.

Since this is the first time ARIC requests information from the participant's physician (in addition to our routine questions about hospitalizations) participants may have questions about this new procedure. In response, indicate that heart failure is a condition known by different names and can occur in different forms. Thus, we request the participant's authorization to send a letter to their physician to get more detail about the type of heart failure identified by their medical practitioner. If the participant has any doubts about this, mention that the information requested of their physician is a one-page questionnaire about tests for heart conditions, diagnosis and treatments, and offer to send the questionnaire to the participant along with the authorization form.
Lastly, note that this authorization for release of medical information is not a consent form (it should not be identified as such), and that its purpose is to help the providers of medical care be compliant with HIPAA. The terms specified on the release form can be reworded to suit the medical practitioner / the establishment that provides the protected health information (PHI). The IRB that oversees the work of the ARIC field center may or not wish to see (and approve) changes in wording in this release form if requested by a local provider of care. Thus, the authorization form attached to these QxQ instructions is a prototype and not an ARIC form, and that the use of this release form is a prerogative of the provider of medical care. The ARIC study understands the responsibility the provider of medical care has to protect the information of their patients and our study procedures support it.

Please note that if the participant agrees to sign the release form on the call, however later refuses to sign the mailed form, the interviewer needs to change the answer for Q8e from earlier-entered "Y" into "N".

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

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

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

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

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

Read the question, emphasizing the year of the most recent phone call to help participants remember the self-report. If the answer is NO or UNKNOWN, skip to question 10.

Question 9 is similar to questions 7-8 above (for participants who have not completed an AFU version L), but instead places the time frame as "since the last contact." If the participant has just been asked questions 7-8, emphasize that this question relates to a diagnosis of heart failure since the last contact (whereas question 8 refers to diagnoses made up until the last contact).

Participants who previously reported heart failure may respond to question 9 stating that since the last contact by ARIC a doctor has said that they have failure. Although this is not a new heart failure event for this participant and probably not a new heart failure diagnosis, it is a plausible answer to this question and is recorded as Yes. Similarly, since it is not unusual for individuals diagnosed with heart failure to have periodic controls or medical check-ups, participants who in answer to this question report seeing a physician for heart failure since the last ARIC contact also are recorded as Yes to question 9.

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

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

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

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

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

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

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

9.f. **"The ARIC study would like to ask your physician to tell us more about your health. If you agree to do this I will send you a form that tells your physician that you authorize the ARIC study to get this information from your doctor. Once you sign that form and mail it back to me I will contact your physician's office."**

May I send you this release form and an addressed envelope for you to mail it back?

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

Please note that if the participant agrees to sign the release form on the call, however later refuses to sign the mailed form, the interviewer needs to change the answer for Q9f from earlier-entered "Y" into "N".

10. **Since we last contacted you has a doctor said that your heart is weak, or does not pump as strongly as it should, or that you had fluid on the lungs?**

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

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

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

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

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

10.d. Deleted

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

If Yes, obtain hospital information and date and record in Section F and return to question 11a.

10.f. **"The ARIC study would like to ask your physician to tell us more about your health. If you agree to do this I will send you a form that tells your physician that you authorize the ARIC study to get this information from your doctor. Once you sign that form and mail it back to me I will contact your physician's office."**

May I send you this release form and an addressed envelope for you to mail it back?

This question requests permission to send a release form to the participant's doctor. If this is the same doctor as listed in Q.8. or Q.9. you do not need to re-read the script.
Please note that if the participant agrees to sign the release form on the call, however later refuses to sign the mailed form, the interviewer needs to change the answer for Q10f from earlier-entered "Y" into "N".

11.a **Since we last contacted you on mm/dd/yyyy, has a doctor said that you had a heart attack?**

11. b. Deleted

11.c. **Since we last contacted you has a doctor said that you had angina, angina pectoris or chest pain due to heart disease?**

A positive answer to either of the conditions mentioned is recorded as Y. If a participate indicates that h/she never had angina but had chest pain due to heart disease, the answer is Y (as is the case if the participant never had chest pain due to heart disease but had angina).

12. **Since we last contacted you, has a doctor said that you had an irregular heart beat called atrial fibrillation, or atrial fibrillation on a heart scan or electrocardiogram tracing?**

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

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

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

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

14. **Since we last contacted you has a doctor said you had high blood pressure?**

15. **Since we last contacted you has a doctor said you have diabetes or sugar in the blood?**

16. **Since we last contacted you has a doctor said that you had a blood clot in a leg or deep vein thrombosis?**
Deep vein thrombosis refers to clots in the veins that run inside (deep) in a thigh or leg as opposed to superficial veins, whether or not varicose, that may be visibly associated with inflammation (phlebitis) and pain. This question specifically asks about a physician-diagnosed deep vein thrombosis.

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

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

16.c. **What is the approximate date?**

Collect and record the approximate date. If more than one blood clot in the leg is reported, only the most recent event is recorded on the form.

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

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

16. e. Deleted

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

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

17.b. **Since we last contacted you were you hospitalized for a blood clot in your lungs or a pulmonary embolus at that time?**

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

18.a. Deleted

18.b. **Since we last contacted you has a doctor told you that you had chronic lung disease, such as bronchitis, or emphysema?**

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

19.b. **Do you have trouble breathing or shortness of breath when hurrying on the level?**

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

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

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

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

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

19.e. **Do you stop for breath after walking 100 yards on the level?**

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

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

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

20. Deleted

20.a. **Since we last contacted you on mm/dd/yyyy has a doctor said that you had asthma?**

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

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

20.c. **Since we last contacted you has a doctor said that you that peripheral vascular disease or intermittent claudication?**

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

21.a. **Since we last contacted you has a doctor said that you had cancer?**

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

21.b. **"Can you tell me in what part of the body <u>the most recently diagnosed</u> cancer was located?"**

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

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

D. STROKE/TIA

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

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

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

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

E. ADMISSIONS

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

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

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

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

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

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

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

Admissions to an emergency room or a medical facility for outpatient treatment since the last contact are recorded (item 25.a), as well as the participant's response to whether the visit was related to a heart problem or difficulty breathing (25.b). Although the name of the facility and the date of the encounter are recorded, this does not lead to a request for a release of protected health information. At this time ARIC does not request records from emergency rooms or outpatient medical facilities.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

F. HOSPITALIZATIONS

A. Collection of data

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

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

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

For linkage (Items 28.d.-39.d.), H indicates that the hospitalization was reported; N indicates that the hospitalization was fully sought by Surveillance and not found.
28-39. Record information on all hospitalizations reported since the time of last contact. NOTE: this does NOT include overnight admissions to nursing facilities and/or rehabilitation centers. (The information needed for diagnosis of a cardiovascular disease event will be obtained from the primary hospital admission.) The Hospitalizations section of the Annual Follow-Up Form is a long question that has to be obtained in parts. Use neutral probes to elicit <u>all</u> hospitalizations. For the (first) overnight stay, record the reason for the hospitalization, the hospital name, city, and state, and the discharge date (month and year) of the hospitalization. Probe for additional hospitalizations and follow the directions for the first hospitalization. There is space to complete 12 hospitalizations. If there are more than 12, record and enter the 12 most relevant to ARIC. List the others on a separate sheet, so all can be transmitted to surveillance. If the person was hospitalized overnight more than 12x times, select those with heart disease, stroke, or heart failure as reasons for hospitalization.
28d-39d. (letter "d" only). If any hospitalizations are reported, enter H beside the appropriate letter corresponding to each hospitalization. That is, if 3 hospitalizations are reported, enter H for items a, b, and c. Send a copy of the Hospitalizations page(s) or screen printouts to the surveillance supervisor and check the appropriate boxes for "Transmit to Surveillance." The surveillance staff will investigate each hospitalization. If a reported hospitalization cannot be found, the surveillance supervisor will notify the staff person responsible for annual follow-up, who then changes the "H" to "N". Be certain that the "H" changed corresponds exactly to the hospitalization in question (for example, if the second hospitalization is actually an outpatient visit, item b. <u>H</u> should become b. <u>N</u>).

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

B. Linkage between Annual Follow-up and Event Investigation

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

G. INVASIVE PROCEDURES

Read the transition statement.

40. **[DO NOT ASK]. Has participant completed a previous version "G" or later of Annual Follow-up?**

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

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

41.b. **Since your last 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 44.a, selecting the part (a or b) which corresponds to the part you are completing here. When YES, continue with next questions.

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

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

DEFINITIONS AND SYNONYMS FOR THERAPEUTIC AND DIAGNOSTIC PROCEDURES

DIAGNOSTIC 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 from collapsing, stents (stainless steel supports) can be inserted into the artery during angioplasty.	Percutaneous angioplasty Balloon dilation Balloon test / procedure PTCA Stent(s)
CATHETERIZATION	A procedure used to examine the heart or an artery by introducing a thin tube (catheter) into a vein or artery (e.g., carotid artery).	Angiography

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43. **[DO NOT ASK]. Has participant completed a previous version "G" or later of Annual Follow-up?** This question is comparable to Item 40. Check the response to Item 40, or check the Participant Information Sheet to determine whether Version G or later has been administered. If YES, read Item 44.a to the participant. If NO, read Item 44.b. Carefully follow the skip patterns.

44.a. **Since we last contacted you on (mm/dd/yyyy) have you had a balloon angioplasty or stent on the arteries of your heart, neck or legs?**

44.b. **Since your last visit to the 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 Q45 parts a, b, and c. When the response is negative (unknown is also coded as NO), go to Section H (INTERVIEW), otherwise, ask the following:

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

H. INTERVIEW

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

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

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

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

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

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

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

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

If the participant is taking NO medications, REFUSES to provide medication information to the interviewer or the answer is otherwise UNKNOWN, skip to question 49. If a participant supplies only part of their medications and will not provide the remaining medications taken, code as

REFUSES. Some field centers have had good success in asking a time to call back when an adult child or caregiver is available to read the medication names over the phone; this strategy should be attempted to avoid a refusal.

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

The use of many medications is fairly common, and tends to increase with age. However, even if a participant reports using more than 20 medications, only 20 can be transcribed (items 48.a – 48.t), which makes it necessary to prioritize the medications recorded on the AFUM form. When a study participant reports more than 20 medications the following algorithm guides prioritization:
[1] all medications prescribed for the participant by a physician. If more than 20, enter the additional medications in a note log attached to item 48.t. Then (if fewer than 20 medications in this category),
[2] aspirin, aspirin-containing medications and anti-inflammatory drugs (lists 1 and 2, below). Then,
[3] over-the-counter medications that may not have been prescribed. Finally,
[4] vitamins, herbals, and supplements.

Medication names can be 60 characters long. Begin typing the medication name into the look-up table (F3 brings up the look-up table). The table will pull up possible answers as you fill in the name. Select (by highlighting and pressing <enter>) the correct name from the list provided. The "Code" field will be filled once the medication name is selected with a medication code number up to 10 characters long. You will not be able to edit this field. If your medication is not in the look-up table, press <ESC> and you will return to the empty field where you may type the medication name in the name field, but no code will be allowed. Ignore any dosage or frequency information listed in the medication lookup table. If you enter a medication and/or code incorrectly, you may delete the medication name and then record a 'blank' entry from the look up table. If there is no code corresponding to a medication, use the 'blank' entry to leave the code field empty.

> **"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."**

List #1: Commonly Used Aspirin-Containing Medications (page 1)

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

List #1: Commonly Used Aspirin-Containing Medications (page 2)

CHOLINE SALICYLATE
CMT
COPE
CVS BACKACHE RELIEF
CVS EFFERVESCENT ANTACID
CVS HEADACHE RELIEF
CVS MIGRAINE RELIEF
DEWITT'S PILLS
DIFLUNISAL
DISALCID
DOAN'S
DOLOBID
DOLOREX
DURABAC
DURAXIN
EASPRIN
ECASA
ECK MIGRAINE RELIEF
ECOTRIN
ECPIRIN
ED-FLEX
EFFERVESCENT ANTACID / PAIN
EFFERVESCENT PAIN RELIEF
EFFERVESCENT PAIN RELIEVE
EQUAGESIC
EXCEDRIN
EX-PAIN
EXTRA STRENGTH BAYER
EXTRAPRIN
FARBITAL
FIORINAL
FORTABS
FRENADOL
GENACED
GENACOTE
GOODY'S
HALFPRIN
HCA PAIN RELIEVER
HEADACHE FORMULA ADDED ST
HEADACHE RELIEF
HEADRIN EX STRENGTH PAIN
HM ADULT ANALGESIC
LEVACET
LOBAC
MAGAN
MAGNAPRIN
MAGNESIUM SALICYLATE
ACETAMINOPHEN
MAGNESIUM SALICYLATE / DIPHENHYDRAMINE
MAG-PHEN
MAGSAL
MEDI-SELTZER
MEPROBAMATE / ASPIRIN
MIDOL MAXIMUM STRENGTH
MIGRAINE FORMULA
MIGRAINE RELIEF
MINITABS
MOBIDIN
MOBIGESIC
MOMENTUM MUSCULAR BACKACH
MONO-GESIC
MP ENCOPRIN
MP REGRIPRIN
MST 600
MYOGESIC
NEUTRALIN
NINOPRIN
NOVASAL
OSCO ADDED STRENGTH PAIN
OSCO ANALGESIC ADULT STRE
OSCO EFFERVESCENT ANTACID
OSCO LOW STRENGTH ENTERIC
P-A-C
PAIN RELIEF
PAIN RELIEF EXTRA STRENGT
PAIN RELIEF EXTRA STRENGT
PAIN RELIEVER ADDED STREN
PAIN RELIEVER PLUS
PAINAID
PAIN-OFF
PANRITIS FORTE
PHENYLTOLOXAMINE / MAGNESIUM SALICYLATE
PIROSAL
QC PAIN RELIEVER PLUS
RA ANTACID PAIN RELIEF
RA MIGRAINE RELIEF
RID-A-PAIN COMPOUND
SALETO
SALICYLAMIDE / CAFFEINE
SALFLEX
SALSALATE
SAV-ON ADDED STRENGTH PAI
SAV-ON ANALGESIC ADULT ST
SAV-ON BACKACHE RELIEF EX
SAV-ON EFFERVESCENT ANTAC
SB BACKACHE EXTRA STRENGT
SB EFFRSCENT ANTACID/PAIN
SB LOW DOSE ASA EC
SB MENSTRUAL
SB PAIN RELIEF F/ACT
SB PAIN RELIEF X-STR
SG EFFERVESCENT ANTACID/P

List #1: Commonly Used Aspirin-Containing Medications (page 3)

SG PAIN RELIEVER ADDED ST	SUPAC	UNI-TREN
SM HEADACHE ADDED STRENGT	SUPER STRENGTH PAIN RELIE	VANQUISH
SM HEADACHE PAIN RELIEVER	SUREPRIN	V-R EFFERVESCENT PAIN REL
SOBA ANALGESIC	TETRA-MAG	ZEE-ZELTZER
SOBA PAIN RELIEVER HEADAC	THERAPY BAYER	ZORPRIN
SODIUM SALICYLATE	THIOCYL	
ST JOSEPH ADULT	TRICOSAL	
STANBACK	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	

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

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

I. OTHER ITEMS

Begin this section with another transition statement.

"Next I have a few miscellaneous questions."

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

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

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

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

J. ADMINISTRATIVE INFORMATION

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

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

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

53. **Does participant (still) live within official 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.

54. **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.

55. **Result code. (Left justify)**

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. 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.

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

Specification of time period covered by the Consent to Release PHI. The AFUL asks ARIC personnel whether the reported episode / medical encounter occurred within 3 years of the time of the interview, in which case the participant is asked to provide an authorization to release information contained in the medical records. The authorization then specifies a time period to be filled in by ARIC staff, i.e., “provide information from my medical records, including treatments and/or hospitalization between _____ and _____ “

Unless the participant specifies differently it is recommended that a three year time period be specified on this form, based on the date of the interview. Note, however, that some medical establishments do not allow such a wide time period. Since in this case the study participant provides this authorization to his/her provider of care or personal physician a three-year time frame on this authorization may not be challenged. Field center personnel needs to be prepared to adjust the authorization to a time frame specified by provider of medical care.

Attachment

Consent to Release Protected Health Information

I hereby give my consent for:

_____
doctor(s) and/or health care provider(s)

to provide information from my medical records, including treatments and/or hospitalization between:
_____ and _____

to the *Atherosclerosis Risk in Communities (ARIC) Study* at the University of _____

Purpose, Restrictions, and Re-disclosure:
The health information that is released will be used only for research purposes by the ARIC study at its Field Center at the University of _____ and the ARIC Coordinating Center at the University of North Carolina at Chapel Hill, and will be held in strict confidence. **All information released WILL NOT be re-disclosed.** I place no limitations on information pertaining to diagnosis and history of illness to be used for research by ARIC.

Revocation Statement and Expiration:
I understand that my participation in ARIC is not conditioned upon signing this authorization and that I may revoke the authorization at any time by requesting such in writing to the ARIC Study Field Center at ___ < **address, phone number** > ____, except to the extent that action has already been taken in accord with this consent. This consent is effective upon signing and shall remain valid for the duration of the ARIC study (2006-2010). A photocopy of this document is as valid as the original.

Name:_____**Date:_____**
(PLEASE PRINT)
Signature_____

If legal representative or proxy, sign below and state relationship and authority to do so:

Signature of legal representative/proxy:_____

Relationship/Authority_____ Date_____