Manual 2

Participant Follow-Up
Manual of Operations

Version 10.0
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ARIC Coordinating Center
Department of Biostatistics (CSCC) CB# 8030
University of North Carolina
Bank of America Building, Suite 400
137 East Franklin Street
Chapel Hill, NC 27514

National Heart, Lung, and Blood Institute
of the National Institutes of Health
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1 INTRODUCTION

The Atherosclerosis Risk in Communities (ARIC) Study is a prospective investigation of the etiology and natural history of subclinical and clinically manifest atherosclerosis, including community surveillance of all-cause mortality, and cardiovascular disease hospital admissions, and a cohort of 15,792 middle-aged (45 to 64 years of age at baseline) randomly selected men and women. ARIC also measures variation in cardiovascular disease risk factors, medical care, and disease by ethnicity, gender, place, and time.

In the cohort component, recruitment occurred between 1987 and 1989 in four U.S. communities: Forsyth County, North Carolina; Jackson, Mississippi; seven northwestern suburbs of Minneapolis, Minnesota; and Washington County, Maryland. For the cohort component of ARIC, approximately 4,000 participants were recruited from each study community. The ethnic composition of the cohort reflected the local populations in Minneapolis and Washington County. African-Americans were over-sampled in Forsyth County, and African-Americans were exclusively sampled in Jackson.

After a home interview that established a baseline socio-demographic and cardiovascular disease profile of all enumerated residents in each study community who were willing to have an interview, age eligible residents were invited to participate in a baseline, and in three subsequent clinical examinations, scheduled at three year intervals. Approximately one third of the cohort was examined each year. The baseline examinations were conducted between 1987 and 1989; Visit 2 was held between 1990 and 1992; Visit 3 between 1993 and 1995; and the last clinical examination (Visit 4) was conducted between 1996 and 1998. After the baseline exam, ARIC cohort members were contacted annually by telephone (even during the years in which they also had a clinical exam) to establish vital status and assess incidences of cardiovascular disease, including hospitalizations.

2 OVERVIEW OF PROCEDURES

2.A Summary of Changes across Annual Follow-up Interview Forms

Since the inception of the cohort component, the ARIC study has elected to collect a core set of information on its participants, both at its clinical exams and during its annual telephone interviews. For reasons of cost efficiency, it has also been study policy to add or remove items which reflect expanding areas of research interest or information that does not require annual data collection. With the completion of the fourth round of clinical exams, several of the core data collection elements from the clinical exam have been transferred to the annual telephone interviews. These are summarized in Table 1 below.

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 characterization 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 ARIVC 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 Table 4).

Table 1. Summary of Data Collected During Annual Follow-Up Interview From ARIC Cohort Members

<table>
<thead>
<tr>
<th>Data Item</th>
<th>Version of Annual Follow-up Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>DATE OF STATUS DETERMINATION</td>
<td>A B C D E F G H I J K L M</td>
</tr>
<tr>
<td>VITAL STATUS</td>
<td>X X X X X X X X X X X X X</td>
</tr>
<tr>
<td>DATE OF DEATH</td>
<td>X X X X X X X X X X X X X X</td>
</tr>
<tr>
<td>LOCATION OF DEATH</td>
<td>X X X X X X X X X X X X X X</td>
</tr>
<tr>
<td>COMPARISON OF HEALTH TO OTHERS ONE’S OWN AGE</td>
<td>X X X X X X X X X X X X X X</td>
</tr>
<tr>
<td>CHEST PAIN ON EFFORT (Rose questionnaire)</td>
<td>X X X X X X X X X X X X X X</td>
</tr>
<tr>
<td>POSSIBLE INFARCTION</td>
<td>X X X X X X X X X X X X X X</td>
</tr>
<tr>
<td>INTERMITTENT CLAUDICATION (Rose questionnaire)</td>
<td>X X X X X X X X X X X X X X</td>
</tr>
<tr>
<td>STROKE/TIA</td>
<td>X X X X X X X X X X X X X X</td>
</tr>
<tr>
<td>HOSPITALIZATIONS</td>
<td>X X X X X X X X X X X X X X</td>
</tr>
<tr>
<td>FUNCTIONAL STATUS</td>
<td>X X X X X X X X X X X X X</td>
</tr>
<tr>
<td>WEIGHT LOSS &gt; 10 POUNDS IN PAST YEAR</td>
<td>X X X X X X X X X X X X X X</td>
</tr>
<tr>
<td>MARITAL STATUS</td>
<td>X X X X X X X X X X X X X X</td>
</tr>
<tr>
<td>DEATH OF SOMEONE CLOSE</td>
<td>X X X X X X X X X X X X X X</td>
</tr>
<tr>
<td>RESIDENCE WITHIN ARIC STUDY BOUNDARIES</td>
<td>X X X X X X X X X X X X X X</td>
</tr>
<tr>
<td>NURSING HOME ADMISSIONS</td>
<td>X X X X X X X X X X X X X X</td>
</tr>
</tbody>
</table>
### 2.B Summary of Layout of Manual of Operations

This document serves as the Manual of Operations for ARIC staff who administer the components of the AFU interview, and as a reference manual for ARIC staff who perform community surveillance activities. Cohort follow-up and community surveillance are closely linked within the ARIC study. All cohort members who have CHD or heart failure (HF) related hospitalizations and all cohort deaths are investigated by surveillance. HF outpatient diagnoses occurring within 3 years of the AFU beginning in the fall of 2006 are investigated by contacting the physician for information to confirm the diagnosis (Physician Heart Failure Questionnaire (PHF)). In addition, identification and validation of events in cohort members takes place as part of the community surveillance procedures, although data collection for hospitalizations or deaths on cohort members are more exhaustive than for community residents who are not part of the ARIC cohort. Consequently, close coordination between AFU and community surveillance activities is required, as is the sharing of information on vital status and contact persons.

The Manual of Operations contains procedural information for conducting AFU interviews. The appendices provide paper version of the data collection forms, and the question by question
instructions for administering each of the forms, a prototype letter which can be sent to cohort participants explaining the rationale and scheduling of the next AFU interview, a summary on how to conduct a standardized interview, and general instructions for recording data on paper forms.

Chapter 3 of the narrative portion of this manual provides operational information on identifying which and when cohort participants are to be contacted, a review of the general interviewing techniques that were used by ARIC interviewers at the clinical examinations, procedures for initiating and administering the data collection forms in the AFU interview, linkage procedures between the cohort AFU and community surveillance staff, and a description of the data management system which supports both the AFU and the surveillance activities.

3 ANNUAL FOLLOW-UP OF COHORT MEMBERS

3.A Introduction

AFU of cohort members is used to: (1) maintain contact and correct address information on ARIC cohort participants; (2) update tracing information on two contact persons; (3) ascertain the participant's vital status; and (4) document general health, medical events, hospitalizations, life events, and functional, socio-economic, and smoking status since the last contact with ARIC staff.

There are five primary components in this process: (1) the generation of scheduling material by the ARIC field centers; (2) the scheduling of the AFU interview by field center staff and the administration of the AFU interview which includes the ascertainment of medical information relating to hospitalizations for cardiovascular disease and documentation of fatal events; (3) the review of hospitalization information collected during the AFU interview to determine whether additional diagnostic or abstracting procedures are required in hospital medical records; (4) the transfer of information obtained during the AFU interview to the surveillance staff; and (5) contact physicians for information on outpatient HF diagnosis (began in fall, 2006 for diagnosis of past 3 years from AFU date). These steps are summarized in Table 2 and described in the following sections.

Table 2. Components of Annual Follow-up

<table>
<thead>
<tr>
<th>Generation of Scheduling Materials</th>
<th>Participant Contact</th>
<th>Forward Information to Surveillance Staff</th>
<th>Act on Information Provided by Cohort Staff</th>
<th>Contact Physician for information on HF diagnosis if less than 3 years from AFU date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Generate participant contact lists; send pre-AFU interview letters.</td>
<td>Contact participant or informant by phone; document participant’s vital status; administer AFU interview; update tracking information; update informed consent if requested by participants.</td>
<td>Transfer vital status and hospital discharge information to Surveillance database.</td>
<td>Review hospitalizations from interview; perform additional diagnostic procedures; abstract discharge summaries and medical records when indicated.</td>
<td>Obtain permission from the participant to send the physician the PHF Questionnaire to give the information regarding the HF diagnosis. Enter the PHF form in DES once received. This begins in the fall of 2006 with AFU.</td>
</tr>
</tbody>
</table>
3.B Eligibility Requirements for Annual Follow-up Interviews

Participants who completed at least part of the baseline examination (Visit 1) have been contacted annually since Visit 1. Individuals excluded from AFU were only those enumerated residents who completed the home interview, but did not sign the informed consent form at the first field center examination (Visit 1).

Unless deceased, requested otherwise by the participant, or a participant is lost-to-follow-up, an attempt is made annually to contact all ARIC cohort members regardless of whether they had continued after Visit 1 to participate in field center examinations, or missed a given contact year’s (CY) AFU interview. This includes participants who have a designated proxy and those who have moved away from the community in which they were recruited. Telephone AFU interviews can be conducted anywhere in the continental U.S. and other countries. Addresses and telephone numbers of cohort members with multiple residences are kept on file to contact participants on their target anniversary date.

3. B. 1. Proxy Respondents for ARIC Cohort Members

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

a. Role of a Proxy

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

b. Conducting an Interview with a Proxy

When an interview is completed by a proxy, the proxy is asked to answer for the participant (to the best of his/her knowledge) instead of the participant responding him/herself with the help of the “proxy.” If the proxy does not know the answer, "Unknown" is recorded rather than a guess. During the interview the participant's name or "him/her" should replace "you" in the specific questions, where appropriate. When an interview is completed by a proxy this is recorded on the AFU for as Result Code 3B - Contacted, Interview Complete (by) Proxy/Informant.

c. When is a Proxy Needed?

If the interviewer has indications that the participant may have cognitive problems the interviewer uses his/her judgment to determine if the participant is cognitively impaired and unable to answer questions reliably. If the interviewer is unsure or unable to make this determination, the supervisor should be contacted before proceeding with the interview.
The ARIC study does not track mental status in its cohort participants with a screener because, among other reasons, brief screening questionnaires are not always accurate (in either direction). Moreover, since a screening questionnaire does not substitute for an interviewer’s educated judgment the ARIC study does not rely on a screening tool as the criterion for activation of a proxy. Instead, through their interaction with the participants (or based on the use of a proxy in a previous AFU interview) the ARIC interviewer determines whether the participant has the ability to respond. Because the criteria that trigger the use of a proxy are subjective the AFU interviewers are offered additional training to assist in making this decision.

Before scheduling an AFU interview ARIC personnel determines whether the previous AFU interview was conducted with a proxy, in order to contact him/her to schedule the call. Other criteria available to the AFU interviewer to determine whether a proxy is needed are a history of clinical stroke or a diagnosis of dementia or cognitive impairment noted on hospital records. If either of these conditions is noted on the report retrieved from the DES, the AFU interviewer performs a screening interview as part of the AFU interview or proceeds directly to proxy activation if it is apparent that the study participant has difficulty answering health related questions.

d. Identification and Tracking of the Proxy

The proxy may be one of the persons initially named by the study participant as a contact. It may also be the case that ARIC field center staff has already recorded a proxy and his/her contact information for a cohort participant. At this point a more formal process is introduced to help ARIC cohort members to identify a proxy (see below). This information is recorded and updated as needed on the Proxy Tracking Form which is completed at the time of a proxy designation, and updated at subsequent contacts as needed. If at any time the proxy has changed, the Proxy Tracking Form is updated with the correct name and contact information for the new proxy.

e. Designating a Proxy

Prior to the AFU anniversary date participants are sent a letter entitled “Follow-up by Proxy” and they are asked to complete the designation form and return it to the ARIC field center. Participants who are unwilling to designate a proxy are asked to return a portion of the letter that identifies their wish not to designate a proxy. Two copies of the proxy packet are sent to the participant, one for them to keep, the other for the participant to give to the “proxy”. Prototypes of these materials are found in Appendix G. If these materials are not returned, during the annual follow-up call participants will be asked to designate a proxy for the ARIC Study.

3.C Time Window for Annual Contacts

Study participants are contacted annually on their initial (anniversary) examination date at approximately the same time each year. The target date for the AFU interview is the date of the baseline visit. Contact years are numbered sequentially, starting with the year of the baseline examination, i.e., CY 01 was assigned to all participants at Visit 1, regardless of the year in which they completed their baseline exam (Table 3).

Because recruitment was done over a three-year period, participants could be in any one of three ARIC CYs during the calendar year in which annual contact interviews are conducted. For example, in 1993, interviewers contacted participants in CYs 05, 06, and 07. Regardless of the CY, the optimal time for placing the initial call each year for annual contact is generally not more than three weeks before the target (anniversary) date. A one year window, up to 6 months before and 6 months after the target date, is the maximum allowed for each annual contact.
When the contact window expires and no contact is made, a final result code for that window is entered in two places, on the Record of Calls (Appendix D.1) and in Item 36 of the AFU form (Appendix D.2), and a new window begins.

The CY to which a participant death is assigned is determined by two factors: (1) the date of death, and (2) whether or not the participant had already been interviewed during the CY in which the death occurred. For example, if the death is determined during or prior to the regularly scheduled AFU interview, the death is assigned to the CY in which the AFU form was administered. If, however, a participant is interviewed during CY 07, dies a short time thereafter, and the family notifies the field center of the death, the death is assigned to the next CY, i.e., on the date CY 08 first opens (not before).
Table 3. ARIC Contact Years by Calendar Year

<table>
<thead>
<tr>
<th>Calendar Year</th>
<th>Baseline year</th>
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</tr>
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<tbody>
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<td></td>
<td>1987</td>
<td>1988</td>
<td>1989</td>
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<tr>
<td></td>
<td>Visit 1</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>1987</td>
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<td>--</td>
<td></td>
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<td>1988</td>
<td>CY02</td>
<td>CY01</td>
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<td>CY03</td>
<td>CY02</td>
<td>CY01</td>
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<td>Visit 2</td>
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<td>1990</td>
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<td>CY06</td>
<td>CY05</td>
<td>CY04</td>
<td></td>
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<td></td>
<td>Visit 3</td>
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<td>CY07</td>
<td>CY06</td>
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<td>Post Visit 4</td>
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</tr>
<tr>
<td>2012</td>
<td>CY26</td>
<td>CY25</td>
<td>CY24</td>
<td></td>
</tr>
</tbody>
</table>

Underlined and bold CY indicate years in which a clinic exam was administered or terminated.
3.D Contacting the Participant

Field centers initiate the AFU procedures by generating the contact and verification report from the local cohort database, which includes the Participant Tracing Information Sheet, the Verification of Tracing Information, the Record of Calls, a listing of ARIC "IDs" which are missing prior AFU forms, a listing of IDs which are missing UPD forms, and a HF history report (specifically called, ARIC AFU participant HF history as known to ARIC study). (The contents and use of each of these is described below.) The contact and verification report can be programmed to identify participants with Visit 1 anniversary dates which correspond to manageable time periods, such as 3 to 4 months. For example, if a field center chose to begin scheduling AFU interviews for participants who were originally seen between January 1 and March 30, 1987 for CY 13 at the beginning of their 6 month contact window, the contact and verification reports for these participants could be printed in July 1999 to initiate scheduling for their AFU interview for CY 13 in January 2000. "Recruitment" logs at each field center have also been used to track and update the contact status of each ARIC participant from the inception of the study, and can be used as a local management tool to document who should be contacted and when, and whether the contact has been completed within the contact window, prior to receiving a missing form request from the Coordinating Center.

3.D.1 Participant Contact Lists

The scheduling of AFU interviews at the field centers is done year round. At specified times throughout the year, generally quarterly, (the schedule is determined by local option) field centers generate lists of ARIC participants, sorted by CY and anniversary date, which includes the participant's ID number, full name, address and telephone number.

Using the contact and verification reports, field centers identify participants for annual contact. The use of letters prior to the AFU interview reminding participants that they will be contacted by telephone by a staff member from the ARIC field center for their annual interview is optional. This letter needs to contain the following information. (A prototype letter is provided in Appendix C.)

(1) A reminder that the addressee is in the study and the annual contact interview will continue for several more years, even though there are no current plans to schedule another clinic visit.

(2) A description of the purpose of the contact.

(3) Information that the participant should obtain to assist with the interview (e.g., hospitalizations and physicians visits).

(4) A request to call the ARIC study office to set up a time to complete the AFU Interview.

However, all participants who cannot be contacted by phone are sent this letter on ARIC study stationery as a reminder and “forwarding and address correction requested” is stamped on the envelope. Participants who do not have phones, have trouble communicating by telephone, or have special needs are not contacted by telephone but are visited in person. If these participants can be identified in advance, the letter indicates that an interviewer will call and schedule a visit to the home, extended care facility, etc., and the AFU interview takes place there.

Participants found to have moved or who are otherwise lost to follow-up are traced using the tracing information obtained at Visit 1 and during subsequent AFU contacts or from other local sources of
information, such as the telephone directory, city directory, etc. By using the Participant Tracing Information Sheet (Appendix A), field center staff can call or write to the family members, friends, employers, or physicians the participants identified as contact persons during previous interviews. By using social security numbers, periodic searches of the National Death Index are done. Every attempt is made to schedule and complete an AFU interview for each participant.

AFU interviewers telephone study participants at their homes at optimal times (i.e., late afternoons, evenings, or weekends) to conduct the AFU interview. When the timing of the initial contact is inconvenient for the participant, the interviewer reschedules the AFU interview. When a cohort member cannot be reached on the first call, the interviewer documents the contact status for each call on the Record of Calls (TRC), the AFU form cover sheet, and makes return calls as necessary, at varying times of the day and week until either the participant is contacted or a decision is made to initiate tracing procedures. On the AFU TRC (Appendix D.1 for Version L) and in Item 36 (Result Code) in the AFU forms, a final contact status (result) code indicating the participant cannot be located (i.e., is lost to follow-up) is only assigned after all tracing avenues have been exhausted and supervisor approval has been obtained. Experience has shown that participants who are lost to follow-up in one year may be located in subsequent years of follow-up and only participants who die or insist on no further contact with the ARIC study should be considered irreparably lost to the study.

3.D.2 Participant Tracing Information Sheet

The Participant Tracing Information Sheet (Appendix A) is generated from the central ARIC cohort study database at the field centers for each participant prior to scheduling the AFU interview. This information sheet is the primary source of information on contacts and level of informed consent on record. It contains the participant's name, ID, the CY in which the information was collected, the participant's mailing address, home phone, other phone, nick name, maiden name (women only), sex, race, birth date, state of birth, social security number, driver's license, dates of clinic visits, contact status and the date and CY at which the most recent contact was made, indication of whether the participant lives in an ARIC study community, employment status, the employer's name and address (Jackson and Washington County, only), the name, address and telephone numbers of two contact persons, the name and address of the participant’s physician (Jackson and Washington County, only); restrictions on DNA use, procedures and/or study data, and permission status to access medical records; and miscellaneous, narrative information on how/when/if to contact participant.

The Participant Tracing Information Sheet is reviewed by the interviewer prior to initiating the AFU call to verify that the contact window is correct. Addresses and phone numbers of the participant and his or her two contact persons are compared with those on the Update (UPD) form (Appendix B.1), and inconsistencies are reconciled. Information from the Participant Tracing Information Sheet is also used as the basis for selecting questions and/or responses in the AFU form. For example, the gender of the participant is completed by the interviewer in Item 18 [Is the participant male or female?]. As gender is not always apparent from a person's name or voice, the Participant Tracing Information Sheet can be consulted as the basis for the selection of the response category: Male or Female. Knowledge of whether the participant has completed a previous version of the AFU form is required for Items 12, 14 and 19 [Has the participant completed a previous version of AFU?], and is listed on the Participant Tracing Information Sheet under Final Status/Date Determined.

The Participant Tracing Information Sheet is also a reference for the interviewer to establish the type/level of informed consent on record in the study's central database when/if the participant
requests a change in his or her level of restrictions on the use of DNA, study data, or access to medical records, and this information is updated on the Informed Consent Tracking form (Appendix E.1).

3.D.3 Scheduling the Annual Follow-up Interview

At field center option, a reminder letter (Appendix C) can be mailed to participants prior to making the first AFU telephone call, or participants can be contacted directly by telephone. As indicated in section C. above, a one year window, up to 6 months before and 6 months after the target (anniversary) date, is the maximum allowed for each annual contact. Calls can be scheduled on any day of the week, and at different times during the day, first at the convenience of the staff member, and then at the convenience of the ARIC participant if the first contact is unsuccessful. Information on each contact attempt is recorded on the TRC, the cover sheet of the AFU Form. This includes the CY and the date ranges during which contacts can be made, the day of the week and time of the day on which each call is placed, handwritten notes about the call which will facilitate further contact and interim and final results codes which numerically track the contact process. Instructions for using the codes below are provided in part (B) of the question by question (QxQ) instructions for the AFU Interview form (Appendix D.3 for version M). Codes with an asterisk (*) can only be used to identify final contacting status (Table 4). When the AFU form has been successfully administered, or the interviewer supervisor determines that all contact efforts have been exhausted, the final screening code is circled on the TRC, and entered in Item 36 of the AFU Form.

Table 4. RECORD OF CALLS - RESULTS CODES

<table>
<thead>
<tr>
<th>RESULT CODE</th>
<th>RESPONSE CATEGORY</th>
<th>EXPLANATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>01</td>
<td>No Action Taken</td>
<td>No attempt has yet been made to contact the participant.</td>
</tr>
<tr>
<td>02</td>
<td>Tracing; Not yet contacted any source</td>
<td>Attempts are being made to locate the participant, but so far neither the participant nor another reliable source has been contacted.</td>
</tr>
<tr>
<td>*03A</td>
<td>Contacted, Interview Complete-Cohort Member</td>
<td>The participant was successfully contacted by phone or in person, and the entire interview, including the questionnaire and hospitalization information was completed.</td>
</tr>
<tr>
<td>*03B</td>
<td>Contacted, Interview Complete-Proxy/Informant</td>
<td>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.</td>
</tr>
<tr>
<td>*04</td>
<td>Contacted, Interview Partially Complete or Rescheduled</td>
<td>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.</td>
</tr>
<tr>
<td>*05</td>
<td>Contacted, Interview Refused</td>
<td>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.</td>
</tr>
</tbody>
</table>
| 06          | Reported Alive, Will Continue to Attempt               | Reliable information (e.g. from a relative, employer, etc.) indicates that the participant is living, but direct contact has
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>Contact This Year</strong></td>
<td>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.</td>
</tr>
<tr>
<td>*07</td>
<td><strong>Reported Alive, Contact Not Possible This Year</strong></td>
<td>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.</td>
</tr>
<tr>
<td>*08</td>
<td><strong>Reported Deceased</strong></td>
<td>Reliable information indicates that the participant has died.</td>
</tr>
<tr>
<td>*09</td>
<td><strong>Unknown</strong></td>
<td>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.</td>
</tr>
<tr>
<td>*98</td>
<td><strong>Does Not Want Any Further Contact</strong></td>
<td>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.</td>
</tr>
</tbody>
</table>
3.D.3.a Contact with the Participant

Prototype scripts for contacting ARIC participants are provided in the AFU QxQs (Appendix D.3 for Version M). The ARIC interviewer always identifies her (him) self and the study by name in the first or second sentence. Beyond that point, the script has been revised from previous years to briefly explain that even though no more clinic visits are currently planned, yearly interviews will continue for the foreseeable future. When contact is made, and the participant agrees to begin the interview, the date of the call and the person's vital status are recorded in section A. (Vital Status) of the AFU (Version M) form.

Note: the "final status" codes on the TRC are different from those in section A of the AFU form. The AFU contact status and source of information codes are summarized below in Table 5. This may be an interactive process, and the date of status determination (Item 1) on AFU form (Version M) and the final status (Item 2) and information obtained from (Item 3) are not entered into the data entry system until it becomes obvious that the status cannot change (e.g., when an interview is completed), or until the end of the CY. The final status of "unknown" is only recorded when the interviewer supervisor determines that all contacting options have been exhausted. Once a "final status" has been assigned and entered into the database, it cannot be changed during the same CY without written authorization from the Coordinating Center.
Table 5. Summary of Vital Status and Source of Information

<table>
<thead>
<tr>
<th>Participant Status and Source of Information</th>
<th>Operational Steps for Completing AFU Version M</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Contacted and interviewed</strong></td>
<td>Administer AFU by phone; begin with Item 1, skip to Item 6. Administer AFU in person interview, begin with Item 1, skip to Item 6. Administer AFU by phone; begin with Item 1, skip to Item 6.</td>
</tr>
<tr>
<td>Phone</td>
<td></td>
</tr>
<tr>
<td>Personal Interview</td>
<td></td>
</tr>
<tr>
<td>Proxy</td>
<td></td>
</tr>
<tr>
<td><strong>Contacted and refused</strong></td>
<td>Complete Items 1-2, 52-55.</td>
</tr>
<tr>
<td>Acquaintance (not a proxy)</td>
<td>Administer AFU by phone; begin with Item 1, skip to Item 23. Administer AFU by phone; begin with Item 1, skip to Item 23. If the participant contacts the field center attempt to complete the full interview (see above: Contacted and interviewed); otherwise, skip to Item 23. Administer AFU by phone; begin with Item 1, skip to Item 23.</td>
</tr>
<tr>
<td>Employer information</td>
<td></td>
</tr>
<tr>
<td>Correspondence by email or letter</td>
<td></td>
</tr>
<tr>
<td><strong>Reported deceased</strong></td>
<td>administer AFU by phone; complete Item 1-5; skip to Item 23. Complete Items 1-5 and 52-55; complete Item 23 and section on hospitalizations when informant can be contacted. Complete Items 1-5 and 52-55; complete Item 23 and section on hospitalizations when informant can be contacted.</td>
</tr>
<tr>
<td>Relative, spouse, acquaintance</td>
<td></td>
</tr>
<tr>
<td>ARIC Surveillance</td>
<td></td>
</tr>
<tr>
<td>Other (National Death Index)</td>
<td></td>
</tr>
<tr>
<td><strong>Unknown</strong></td>
<td>Complete Items 1-2, 52-55.</td>
</tr>
</tbody>
</table>

When the participant does not have time to complete the interview, interviews can be rescheduled until all the questions on the form have been answered. The TRC and Vital Status section of the AFU are updated, accordingly.

3.D.3.b Contact with Informant

When the participant cannot be contacted, either by telephone or correspondence, contact is attempted through (1) the contact persons identified by the participant, (2) the participant’s employer if the participant was still working at last contact, or (3) the participant’s physician at Visit 4. This information is printed on the Participant Tracing Information Sheet. The interviewer introduces her/himself as a staff member of the ARIC study, and if necessary, a brief description of the ARIC study is offered: “ARIC is a study on hardening of the arteries (atherosclerosis), heart attacks and strokes which is funded by the National Institutes of Health and has been conducted by scientists from [name of local university] since 1986.” The informant is told that the person we are looking for has been a participant in the ARIC study for over 10 years, and has provided us with his/her name [name of informant] as a contact person should we not be able to locate him/her [name of participant]. When the informant can provide a current telephone number or address for the study participant, the informant is thanked, told h/she may have to be called again if contact with the participant is not successful, and contact with the participant is attempted. It is always preferable to conduct the AFU interview with the
participant, rather than obtain second hand information through a proxy. However, information from an informant is better than no information, and the contact person is recalled, and the AFU form administered, when contact with the participant is not possible.

3.D.3.b.i Participant Deceased

When the contact person indicates that the study participant has died, offer condolences, and then determine the date and location of the participant's death. Record this information in Section A (Vital Status) of the AFU form. If possible, also administer the section of the AFU form on hospitalizations. If the date/location of death or information on hospitalizations prior to the demise is unknown, ascertain who else might be called to obtain that information. Even when the information is known, indicate that someone from the ARIC staff may also wish to contact the informant or a family member later on, [and ask who should be contacted], and when would be the best time to call. This information is recorded on the TRC. ARIC surveillance staff is notified every time a cohort member is reported as being deceased, and provided with data from the AFU form and the TRC.

3.D.3.b.ii Participant Lost to Follow-up

When contact with a participant is unsuccessful but an informant provides reliable information that the participant is living but is unwilling or unable to provide other information on the participant during the contact window, the participant can be classified as "reported alive." This code should only be used if repeated contact attempts have been made, or when it has been determined that it will not be possible to make contact in the time period of six months before or after the participant's ARIC anniversary date.

A separate "final status" option is used to denote participants who indicate they do not want any further contact with the study. This code indicates that the participant has requested that h/she does not wish to be contacted any more by the ARIC study, and alerts staff that no additional contacts should be attempted during the same CY. Notes should be kept on the TRC 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.

3.D.3.c No Contact

When neither the participant nor any of the contact persons have been contacted, and there is no reliable source of information to determine the participant's vital status, the final contact status on the AFU form can be set to "unknown" after the contact window has expired.

3.E General Interviewing Techniques

The goal of data collection by interviewing is the collaborative acquisition of epidemiologic data, using standardized techniques at each examination site for the duration of the study.
3.E.1 Interviewer Bias

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

3.E.2 Characteristics of a Good Interview

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

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

3.E.3 Characteristics of a Good Interviewer

Interviewers are responsible for being familiar with the questions, response categories and skip patterns of each interview. In the role of a telephone interviewer, the field center staff member thinks as an interviewer, an impartial collector of data, and not, for example, as a clinician, investigator, friend or neighbor. Interviewers use a conversational tone and establish a pace consistent with the interest and ability of the participant. A good interviewer projects the importance of the interview to the participant and attempts to gain his/her confidence, while remaining impartial and nonjudgmental. For example, a verbal response (or body language when the interview is being conducted in person) which indicates positive feedback is always inappropriate, even in the light of participant reports of behavioral modifications which in a clinical setting would result in praise and encouragement. Participant confidence in the confidentiality of each response/measurement is established.

3.E.4 Communication Traps

Communication traps include: (1) anticipating or answering questions directed to the participant with the interviewer's own thoughts; (2) hearing what one expects to hear; or (3) being drawn into a conversation. The putative sensitivity of a question is often as much a perceptual problem of the interviewer as it is the participant. Questions thought to be "sensitive" should be asked in a neutral manner which does not differ from the normal professional flow of the interview.
3.E.5 Conducting the Interview

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

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

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

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

Appropriate styles of interviewing include providing supportive noises to reassure, pacify or reduce the intensity of the respondent's feelings. These include general clucking or an understanding murmur. Nondirective or understanding statements, such as a repetition of what the respondent has just said (in contrast to paraphrasing), reassure or show interest without intruding on the flow of the response.

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

"How do you mean that?", instead of "Why?"
"I would like your opinion."

"Can you tell me more about this?"

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

"How are you using that term?"

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

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

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

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

3.E.6   Quality Assurance of Interviews

The quality of data collected during interviews is maintained through a series of standardized quality assurance procedures. All interviewer-administered interviews are based on the reading of written questionnaires, supported by a Manual of Operations and question by question (QxQ) instructions. Interviewers are trained and certified in interviewing techniques (Appendix F), the subject matter, terminology, and flow of each data collection form. Certification requires attendance at the central training workshop at the beginning of the study (or local training provided by the interviewer supervisor), local practice, and the successful completion of three taped interviews on surrogate, age and sex appropriate participants. Successful completion consists of demonstrated ability in the following five areas:

(1) Knowledge of the substantive matter in the interview;

(2) Use of an even pace and conversational tone;

(3) Demonstration of a professional and nonjudgmental demeanor;

(4) Use of appropriate probing techniques;

(5) Ability to accurately record the participant's response.

Interviewers are re-certified at least once a year by the AFU interviewer supervisor listening to
interviews the staff member conducts with actual participants, and reviewing the contents of the AFU and Informed Consent Tracking form. Field centers report to the CC local certification activities.

In addition, a round robin review of taped interviews is organized by the CC on a yearly schedule. For each locally certified interviewer, one tape with three interviews and their corresponding paper forms are prepared. The tape specifies the interviewer code and field center name. One field center's AFU supervisor reviews another center's taped AFU interviews. Before listening to AFU tapes, the reviewer reads the certification check list (see Table 6).

According to round robin comments, field center AFU supervisors (supervisors / trainers must be certified and also conduct a sufficient number of calls to retain their skills and certification) determine whether interviewers require additional training. If the retraining is extensive, a new tape with three interviews is prepared and submitted for review by the original round robin partner.

At the conclusion of the round robin, each field center's AFU supervisor sends the following materials to the CC:

1. one check list for each interviewer; and
2. three interviews recorded on tape(s) and three AFU paper forms per interviewer.

Monitoring of the interviewing skills of each interviewer is recommended every 3 to 4 months. Interviewers who experience difficulty in maintaining their skills are retrained. Recertification is documented at least every 12 months. The Coordinating Center serves as the central repository of certification status and informs study coordinators when the interviewer certification status is about to lapse. Continuous certification is considered a critical component of the study's quality assurance program to the extent that study data obtained from non-certified interviewers are excluded from analysis. The accuracy of data entry from the paper form into the data entry system (DES) is monitored by the ARIC Coordinating Center.

Table 6
AFU Certification Check List
For AFUL: Fall, 2006

Note for Certifier: Before you listen to the AFU interview tapes for certification, please read the following check list and note these items specifically. Any comments on other issues are welcomed.

<table>
<thead>
<tr>
<th>AFU Certifier Code</th>
<th>at</th>
<th>Field Center</th>
<th>AFU Interviewer Code</th>
<th>at</th>
<th>Field Center</th>
<th>ID #</th>
</tr>
</thead>
<tbody>
<tr>
<td>Items to Note</td>
<td></td>
<td>Comments</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does interviewer note and research previous HF reports prior to the call?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the interviewer read each question in the exact words and in the exact sequence as in the questionnaire?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is the pronunciation correct (especially note words such as asthma, angioplasty, etc)?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### 3.F Administering the Annual Follow-up Interview

The contents of the AFU Interview for the first post-visit 4 contact have been revised to exclude the sections on chest pain on effort, possible infarction, intermittent claudication, and deaths of persons close to the participant. The interview has been expanded to include questions updating health-related and socio-demographic data which were routinely ascertained at clinic visits, and new questions about overnight admission to nursing homes. Questions on out-patient HF were added in the fall, 2006. The Informed Consent form, documenting any changes requested by participants on the use of their study data and/or the study's access to their medical records, is updated by the interviewer when necessary. The Update Form is administered as has been done previously to update and verify contact information.

In general, the annual AFU contact is a 5 to 15 minute interview that is administered over the telephone. The participants' responses are entered onto the DES directly, or recorded on the paper versions of the forms for delayed data entry into a data management system housed and maintained by each ARIC study center. The paper version of the AFU form, and the QxQ instructions for administering the form are provided in Appendix D.3. The TRC exists only as a paper form, however, the participant's final contact status is recorded in the administrative section of the AFU form.

Beginning in the fall of 2006, the AFU interviewers will need to track questions 8e, 9f, and 10f from AFUL form and follow up with release forms to the participant. Once release forms are received, the Physician Heart Failure (PHF) Questionnaire will need to be sent to between 1-3 physicians for completion and the data will need to be entered on the DES (see PHF form) once

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does interviewer give ample time for participant to recall previous HF diagnosis?</td>
<td></td>
</tr>
<tr>
<td>Does the interviewer probe for hospitalizations?</td>
<td></td>
</tr>
<tr>
<td>Was the interviewer familiar with the questions, response categories and skip patterns?</td>
<td></td>
</tr>
<tr>
<td>Was medication data collected smoothly with minimal interruption?</td>
<td></td>
</tr>
<tr>
<td>Was interview friendly, but businesslike?</td>
<td></td>
</tr>
<tr>
<td>Were questions asked at an even pace and in conversational tones?</td>
<td></td>
</tr>
<tr>
<td>Were sensitive questions asked in a neutral manner?</td>
<td></td>
</tr>
<tr>
<td>Were response styles of interviewer appropriate?</td>
<td></td>
</tr>
<tr>
<td>Did the interviewer stay focused on the interview?</td>
<td></td>
</tr>
<tr>
<td>Was the participant thanked at the end?</td>
<td></td>
</tr>
<tr>
<td>Other comments?</td>
<td></td>
</tr>
</tbody>
</table>

Certify__________ Date____________________        Revised 8/2006
it is returned from the physician. No physician should be sent more than one form for a given participant. If PHF questionnaires are not returned within one month, please do a follow up questionnaire to that physician. Once the PHF is returned to the field center, the interviewer enters the data on the AFU DES and transports that data to the CC with other data.

3.F.1 Record of Calls

The TRC Form is the cover sheet (Appendix A) to the AFU interview form, and its contents and administration are unchanged from the previous version. Its purpose is to keep track of attempts to contact a participant. QxQ instructions are provided in the first section of the AFU form QxQs (Appendix D.3).

The participant's name, ID, CY, and CY date ranges are pre-printed at the top of the form. Space is provided to document contact attempts, pertinent information for future contacts, and the outcome of the contact. One line is used for each attempted contact. The interviewer's ID who attempts each contact, and the contact result code are entered on the paper form for each contact initiative. Information that is or will be relevant to assist in future contacts with a participant can be entered in the administrative field (Item 6) of the UPD form (Appendix B.1). This information will be printed in the administrative section of the Participant Tracing Information Sheet the next time it is generated.

Forsyth County and Minneapolis have elected to have additional contact information stored in Item 6 notelogs printed on the Participant Tracing Information sheet.) Assigning the result code (see Table 4) at each contact is very important, as the code may be necessary for determining the participant's final vital status in the event that the person is not successfully contacted. When the AFU form 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, and entered in Item 55 on the AFU form.

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

1. Refusals. The supervisor determines how and when conversion attempts should be initiated.

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

3. Undocumented deaths. When a death is reported for which no death certificate can be located, information on the putative event is transferred to the surveillance staff, which reviews the case and attempts to resolve it. If no death certificate is ultimately located, including a National Death Index search, the participant's final results code is listed as “unknown”.

The paper copy of the form is kept in the participant's folder to assist in future contacts.
3.F.2 Annual Follow-up Interview Forms

The post-visit 4 AFU (version L) which began use in fall, 2006, has significant changes from other post-visit 4 AFU forms (versions G-K). Specifically, the version L AFU form has added questions on previous diagnosis of HF and current prescribed medication use. In addition, this version removed the gynecologic surgery and hormone replacement therapy information, the employment status and life style questions.

If field centers choose to send a pre-contact letter to participants which notifies them that the AFU interview has been expanded to contain new questions (Appendix C), participants may be more receptive to the new interview format. In contrast to the usual time frame for answering questions in previous AFU interviews which was generally "since our last contact", the inclusion of questions from the Visit 4 clinic visit results in frequent shifts in the time frame to which the questions in any section may refer. Therefore, interviewers must be conscious of stressing the appropriate reference period to the participant. These are contained in the transition statement at the beginning of each section. Interviewers may need to consciously "train" respondents to listen more carefully in order to frame their responses in terms of the new and inconsistent time frame.

Once contact has been made, the entire AFU interview is administered to surviving participants. When a participant has expired prior to the annual contact, the relevant portions of the AFU form (sections A, B, E and J) are administered to a member of the participant's household (or a contact person) in order to officially record the death and to obtain the date and location of death and other relevant medical information.

Section A of the AFU form is unchanged from previous versions, and documents the participant's vital status and the date on which the status determination was made. The criteria for establishing participant vital status are defined in the form's instructions (Appendix D.3). Section B (also unchanged) is completed on individuals who have died and records demographic information necessary for obtaining a copy of a death certificate. Sections C-D, and F-I are administered to all surviving participants. These sections document general health (section C), including questions from the Visit 4 exam on life-time history of cardiovascular disease, lung disease and cancer, recent history of stroke and/or transient ischemic attack (section D), recent history of hospitalizations (section F), invasive and/or diagnostic procedures for cardiovascular disease (section G), interview that includes recent history (last 2 weeks) of prescribed medications plus aspirin use (section H).

The questions 23-24 in section E (Overnight Admissions) are administered to all respondents (participants and proxies) to document overnight hospitalizations in acute or chronic medical care facilities. For participants who are deceased, reported alive, or who are contacted only by letter, the interviewer completes the administrative section (Section J), the hospitalization section when the participant was hospitalized for any reason, and ends the interview. The surveillance staff is notified of every cohort hospitalization and an event investigation is initiated. For surviving participants with whom the interviewer has direct contact, the interview continues with the remaining questions (25-27) in section E on nursing home admissions.

Miscellaneous questions on current smoking and marital status (section I) are identical to those which were administered in section J in the previous AFU interview (AFU J).
Questions in the Administrative Information (section J) are not administered to participants, but are completed on all forms by the interviewer. These include the interviewer’s staff ID number, information on whether the participant currently lives in the boundaries of the ARIC study community from which the interview is initiated (information which may not be available until verifying and/or updating the participant’s current address on the UPD form), and whether the study has access to the participant’s medical records (information which may not be available until revising the Informed Consent Tracking form).

3.G Update/Verification of Contact Information

Tracing information listed on the pre-printed UPD form (Appendix B.1) is verified at the conclusion of the AFU form. Updated information for either the ARIC participant and/or the contact persons can be written on the Verification of Tracing Information Sheet for later data entry, or incorrect information on the preprinted UPD form can be marked out, and updated information written in (again for delayed data entry), at the discretion of the field centers. Instructions for administering the form and a prototype script are provided at the end of the AFU instructions. Any changes to tracing information recorded on the Verification of Tracing Information Sheet or the paper version of the UPD form during the telephone interview are entered into the computerized version of the UPD form by staff certified in the use of the ARIC DES.

3.H Update/Verification of Participant's Informed Consent

The Informed Consent Tracking form (Appendix E.1) is an internal form, and is NOT administered to participants. The purpose of the form is to document and track in the ARIC central database any changes (revisions) following Visit 4 to a participant’s consent on the use of DNA, the use of other study data, or access to medical records by the ARIC staff. Changes are not actively solicited. However, a change in consent status or access to medical records is documented as soon as a participant requests a change to be made to his or her consent status that is on file at the ARIC Coordinating Center. The current consent status for each of the three categories (use/storage of DNA, use of other study data, access to medical records) is documented on the participant’s Participant Tracing Information Sheet. Interviewers need to be familiar with the field center specific ARIC informed consent document that is read and signed by all study participants. Interviewers are required to seek the advice of/or refer the participant to their interviewer supervisor for questions which require an interpretation, and cannot be answered by a direct quotation from the informed consent document. The definitions of the terms in the Informed Consent Tracking form are provided in the QxQ instructions (Appendix F.2).

The Informed Consent Tracking form can be filled out on the paper (Appendix E.1) for delayed data entry, or completed directly on to the DES, following the QxQ instructions in Appendix E.2.

3.I Linkage of Annual Follow-up and Community Surveillance Activities

The health and illness of members of the ARIC cohort are monitored continuously, both through annual telephone contact, and through community surveillance which tracks hospitalizations for cardiovascular and related diseases and all-cause mortality. Two-way communication between
the staffs of these two activities must also be continuous. Staff involved in annual contact activities inform the surveillance staff about hospitalizations and deaths documented of ARIC cohort members when the AFU form is administered each year, and information on how to contact to contact the person or the contact persons which are on file in the ARIC cohort data base in the UPD form. Table 6 summarizes the minimum data from the AFU and UPD forms that must be given to the surveillance staff, regardless of whether data are transmitted electronically or on paper forms.

Table 7. Shared Information between Annual Follow-Up and Surveillance Staff

<table>
<thead>
<tr>
<th>Form</th>
<th>Item Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Annual Follow-Up (AFU-G)</td>
<td>2</td>
<td>Final Status - Reported deceased</td>
</tr>
<tr>
<td></td>
<td>4 &amp; 5</td>
<td>Date of death, location of death</td>
</tr>
<tr>
<td></td>
<td>9</td>
<td>Hospital admission for heart attack</td>
</tr>
<tr>
<td></td>
<td>10</td>
<td>Hospital admission for other reason</td>
</tr>
<tr>
<td></td>
<td>34</td>
<td>Participant lives in ARIC study boundaries</td>
</tr>
<tr>
<td></td>
<td>35</td>
<td>Medical records available through community surveillance</td>
</tr>
<tr>
<td></td>
<td>36</td>
<td>Result code of contact = 08 (reported deceased)</td>
</tr>
<tr>
<td></td>
<td>37a-39f</td>
<td>Hospitalization reason/name/date</td>
</tr>
<tr>
<td></td>
<td>40a-40f</td>
<td>linkage status (hospital record found, or not found)</td>
</tr>
<tr>
<td>Verification of Tracing Information (UPD-B)</td>
<td>1</td>
<td>Participant's Name</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>Address</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>Phone number</td>
</tr>
<tr>
<td></td>
<td>7-9</td>
<td>1st Contact Person's name, address, phone</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2nd Contact Person's name, address, phone</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Employer's name, address, phone (Jackson/Washington Co., only)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Physician's name, address, phone (Jackson/Washington Co., only)</td>
</tr>
<tr>
<td>Cohort Eligibility Form (CEL-C)</td>
<td>1</td>
<td>Participant's name and social security number</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>Participant's ARIC ID number</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>Visit 1 date</td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>Date of hospital discharge or death/ date of birth</td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>Source used to identify death</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>Death</td>
</tr>
<tr>
<td></td>
<td>7</td>
<td>out-of-hospital death</td>
</tr>
<tr>
<td></td>
<td>8a</td>
<td>hospital name</td>
</tr>
<tr>
<td></td>
<td>8b</td>
<td>can hospital information be found</td>
</tr>
</tbody>
</table>
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## Appendix A
### FIELD CENTERS’ PARTICIPANT TRACING INFORMATION SHEET - Sample

<table>
<thead>
<tr>
<th>Field</th>
<th>Information</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>NAME:</strong></td>
<td><strong>BUMBLEBEE, MR. RODNEY SIDNEY</strong></td>
</tr>
<tr>
<td><strong>ID:</strong></td>
<td><strong>T162032</strong></td>
</tr>
<tr>
<td><strong>SEX:</strong></td>
<td><strong>M</strong></td>
</tr>
<tr>
<td><strong>RACE:</strong></td>
<td><strong>B</strong></td>
</tr>
<tr>
<td><strong>Address:</strong></td>
<td><strong>121 MAIN ST</strong></td>
</tr>
<tr>
<td><strong>birth date:</strong></td>
<td><strong>04/24/32</strong></td>
</tr>
<tr>
<td><strong>State:</strong></td>
<td><strong>HIGH POINT NC 27383</strong></td>
</tr>
<tr>
<td><strong>Social Security No:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Home Phone:</strong></td>
<td><strong>336-333-3456</strong></td>
</tr>
<tr>
<td><strong>Other Phone:</strong></td>
<td><strong>336-321-3421</strong></td>
</tr>
<tr>
<td><strong>Nickname:</strong></td>
<td><strong>PENNY</strong></td>
</tr>
<tr>
<td><strong>Maiden Name:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Date of Baseline Visit:</strong></td>
<td><strong>01/05/88</strong></td>
</tr>
<tr>
<td><strong>Final Status:</strong></td>
<td><strong>CY12 Contacted, Alive</strong></td>
</tr>
<tr>
<td><strong>Date Determined:</strong></td>
<td><strong>02/08/98</strong></td>
</tr>
<tr>
<td><strong>Live in Study area?</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Contact Person 1:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>contact name:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>contact address1:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>contact address2:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>contact address3:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>contact city st zip:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>phone number:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>relationship:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Physician:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Employer:</strong></td>
<td></td>
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<tr>
<td><strong>Restrictions and Permissions:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>DNA Restrictions?</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Procedures/Study Data Restrictions?</strong></td>
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</tr>
<tr>
<td><strong>Permission to Access Med Records?</strong></td>
<td></td>
</tr>
<tr>
<td>CURRENT DATA ON FILE</td>
<td>CORRECTIONS/CHANGES TO DATA</td>
</tr>
<tr>
<td>----------------------</td>
<td>----------------------------</td>
</tr>
<tr>
<td>Name:</td>
<td>Name:</td>
</tr>
<tr>
<td>Mailing Address:</td>
<td>Mailing Address:</td>
</tr>
<tr>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Home Phone:</td>
<td>Home Phone: (___) <em><strong>-</strong></em></td>
</tr>
<tr>
<td>Other Phone:</td>
<td>Other Phone: (___) <em><strong>-</strong></em></td>
</tr>
<tr>
<td>Two people who are likely to know your address at all times:</td>
<td>Two people who are likely to know your address at all times:</td>
</tr>
<tr>
<td>(1)</td>
<td>(1)</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>FRIEND</td>
<td>(___) <em><strong>-</strong></em></td>
</tr>
<tr>
<td>(2)</td>
<td>__________________________</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>FRIEND</td>
<td>(___) <em><strong>-</strong></em></td>
</tr>
<tr>
<td>(rpt_trc2 - Use with AFUK)</td>
<td>__________________________</td>
</tr>
</tbody>
</table>
Appendix B.1
(UPDB screen 1 of 5)

A. VERIFICATION OF IDENTIFYING INFORMATION

1. a. Title:__________________  b. First Name:__________________  
   c. Middle Name:__________________  d. Last Name:__________________

2. Mailing Address: 
   a ______________________  
   b ______________________  
   c ______________________
   d. City:_______________  e. State:_____  f. Zip Code:_______________

3. Home Phone Number: _____________  

4. Other Phone Number: _________
   area-###-####

5. if missing, request Social Security Number: ______________________
   (Show disclosure statement) ### - ## - ####

6. Administrative use:_______________________________

(UPDB screen 2 of 5)

B. CONTACT PERSON 1

(Call Help to produce explanatory statement before proceeding.)

7. a. Title:_______  b. First Name:_________________________  
    c. Last Name: _________________________________

8. Mailing Address: 
   a. ______________________  
   b. ______________________  
   c. ______________________
   d. City:_______________  e. State: _____  f. Zip Code:_______________

C. CONTACT PERSON 2

11. a. Title: _____  b. First Name: _______________________
   c. Last Name:______________________________________

12. Mailing Address:
   a. ______________________
   b. ______________________
   c. ______________________
   d. City:___________________ e. State:______ f. Zip Code:____________

13. Telephone: _______________
   area-###-####

14. Relationship: __________________________
   I

D. PHYSICIAN-INFORMATION

15. a. First Name: ____________________
   b. Last Name:  ____________________

16. a. Clinic/Building: _________________________________
    Mailing Address:
    b. ______________________
    c. ______________________
    I
E. ADMINISTRATIVE INFORMATION {Show and explain Results Reporting Sheet.}

17. Our usual procedure is to send results to you and your physician as shown on this sheet. _

(Enter "U" unless participant has no personal physician or volunteers that this procedure is not satisfactory. If no physician, enter "T". If participant requests another procedure, offer those given below.)

U - Usual procedure (detailed results to physician, summary to participant)

T - Detailed results to participant, but not to physician

B - Detailed results to both participant and physician

18. Date of data collection/update: ______________

mm/dd/yyyy

19. Code number of person completing/updating this form: ______
At Post-Visit 4 contacts, all participants should have a UPDB in the central data base at the field centers. The UPDATE form is therefore updated in the "change" mode, based on information in the Verification Tracing Sheet which is obtained during Annual Follow-up contacts. The UPD form confirms the participant’s demographic data and updates the tracking data. Unlike the AFUG and Informed Consent forms, this form already contains data retrieved from the study’s central data base. An UPDATE form must be present in the local database in order for other Post-Visit 4 forms to be added for this participant. If one is not already present in the local database, it must be added prior to adding other forms. When the form is administered using the computerized version of the UPDATE form, it is entered in the CHANGE mode of the data entry system.

If a paper form should be needed, print the UPDATE form from the local database.

INTRODUCTION OF THE FORM

"I would like to verify some of the information we have collected from you over the telephone."

A. VERIFICATION OF IDENTIFYING INFORMATION

1. (a-d) Read the participant’s title, first, middle and last name. If there is a question as to spelling of any of the names, verify the spelling.

2. (a-f) Read the mailing address to the participant, indicating that you need the mailing address and not the participant’s residence, and verify its accuracy.

3. Confirm the home telephone number.

4. Confirm the "other" telephone number. If none is (has been) given, ask if there is another telephone number where the participant could be reached.

Prior to Post Visit 4 contacts, the participant was asked to fill out an information sheet with the names and addresses of two contact persons, the primary care physician, and their social security number. As if he/she has the information sheet, and offer to review it together while updating the next few questions.

5. The social security number is requested only if is missing. Read the participant the SOCIAL SECURITY DISCLOSURE STATEMENT and ask if he/she is willing to provide the number.

6. This item is for field center administrative use. Information, such as winter residences or patient numbers, can be entered here.

B. CONTACT PERSON 1

7-10 Read the name, address, telephone number and relationship of the first contact person on the form to the participant. Ask if it needs to be updated.

C. CONTACT PERSON 2

11-14 Read the name, address, telephone number and relationship of the second contact person on the form to the participant. Ask if it needs to be updated.
D. PHYSICIAN INFORMATION

15.(a-b) Read the first and last names of the participant’s physician. If there is a question as to spelling of any of the names, verify the spelling. Ask if it needs to be updated, and enter the new name, if appropriate.

16.(a) Read the Clinic/Building name to the participant and verify its accuracy, or ask if there is one, if the field is empty.

16.(b-f) Read the mailing address to the participant, and verify its accuracy if the physician’s name has not been updated. If the participant has changed physicians, record the new address.

E. ADMINISTRATIVE INFORMATION

17. Usual procedures for results reporting. No longer applicable. SKIP THIS QUESTION.

18. Date on which UPD is changed. Enter the date on which the UPD is updated, entering the month, day and year (all four fields).

19. ARIC staff ID. Enter the ID number.
Dear <__________>  

I write to remind you that the anniversary date of your first ARIC examination visit is approaching, which is when we have our brief telephone interview each year. I will call you next week to update our information about you, as we do every year. If you prefer to schedule a time at your convenience, please call me at (___) xxx-xxxx during office hours or send me an email at <__________>.  

This year we have added a few additional questions about your health, similar to the ones we asked you before but have not updated for several years. As a result, the interview may last an additional 10 minutes. Also different this year, we would like to learn what medications prescribed for you by a doctor you are taking at this time. To make this easier and to save you time, as part of our telephone interview we will ask you to read the names of the medications you are taking. I want to share this with you prior to the call so that you can make any preparations needed to have your medications on hand.  

As always, thank you for being part of the ARIC study. I look forward to talking to you.

(ARIC Interviewer / AFU Supervisor)  
Telephone  
USPS address  
email address
# Appendix D.1

## RECORD OF CALLS – ARIC COHORT ANNUAL FOLLOW-UP

**CONTACT YEAR 13 NAME:**

**DATE RANGE**

<table>
<thead>
<tr>
<th>Earliest:</th>
<th>Target:</th>
<th>Latest:</th>
</tr>
</thead>
<tbody>
<tr>
<td>07/26/1998</td>
<td>01/26/1999</td>
<td>07/25/1999</td>
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### RECORD OF CALLS

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<thead>
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<th>Time</th>
<th>Notes</th>
<th>Result Code*</th>
<th>Int ID</th>
</tr>
</thead>
<tbody>
<tr>
<td>S M T W T F S</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>/ /</td>
<td>A</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>S M T W T F S</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>/ /</td>
<td>A</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>S M T W T F S</td>
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<td>A</td>
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</tr>
<tr>
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<tr>
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<td>A</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>S M T W T F S</td>
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<td>S M T W T F S</td>
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<td>A</td>
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<td>/ /</td>
<td>A</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Result Codes

- 01 No Action Taken
- 02 Tracing (Not yet contacted)
- 03A Contacted, interview complete by Cohort Member
- 03B Contacted, Interview complete, Proxy/Informant
- 04 Contacted, Interview Partially Complete or Rescheduled
- 05 Contacted, Interview Refused
- 06 Reported Alive, Will continue to Attempt Contact This Year
- 07 Reported Alive, Contact Not Possible This Year
- 08 Reported Deceased.
- 09 Unknown
- 98 Does Not Want Any Further Contact.
### ANNUAL FOLLOW-UP QUESTIONNAIRE (AFUM)

#### A. VITAL STATUS

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

2. Final Status:

   {Circle one below}

   - Contacted and Alive
   - Contacted and Refused
   - Reported Alive
   - Reported Deceased
   - Unknown

3. Information obtained from:

   {Circle one corresponding choice below}

   - Phone
   - Personal Interview
   - Letter
   - Relative, spouse, acquaintance
   - Employer information
   - Other
   - Surveillance
   - Other (National Death Index)

   - A  Go to Item 6
   - B  Go to Item 23
   - C  Go to Item 52
   - D  Go to Item 23
   - E  Go to Item 23
   - F  Go to Item 52
   - G  Continue to Item 4

INSTRUCTIONS: This form should be completed during the interview portion of the participant's annual follow-up. ID Number, Contact Year, and Name must be entered above. Whenever numerical responses are required, enter the number so that the last digit appears in the rightmost box. Enter leading zeros where necessary to fill all boxes. If a number is entered incorrectly, mark through the incorrect entry with an "X". Code the correct entry clearly above the incorrect entry. For "multiple choice" and "yes/no" type questions, circle the letter corresponding to the most appropriate response. If a letter is circled incorrectly, mark through it with an "X" and circle the correct response.
B. DEATH INFORMATION

4. Date of death:

   Month / Day / Year

5. Location of death:
   a. City/County

   b. State:

   After Item 5, skip to Item 23, Screen

C. GENERAL HEALTH

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?"

   Excellent ... E
   Good ....... G
   Fair ....... F
   Poor ...... P

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

7b. [DO NOT ASK] Has participant ever reported a heart failure diagnosis in AFU without a documented HF hospitalization in the ARIC database? (to be done for 1 year only). Y N

   If YES, go to Q9
   If NO, skip to Q9

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?

   Y N U

   No or Unknown, skip to Q9

What is the name and address of the doctor you last saw for heart failure?

8.a. Name: __________________________________________

8.b. Address: __________________________________________

8.c. What was the approximate date M M / MM / YYY Y YY

8.d [DO NOT ASK] Was this within 3 yrs. of today’s date? Y N U

If you answered NO or UNKNOWN in 8.d, skip 8.e.

[Request for authorization to release medical records for selected self-reported diagnoses / physician visits]
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?  Y  N

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

<table>
<thead>
<tr>
<th>Y</th>
<th>N</th>
<th>U</th>
</tr>
</thead>
</table>
If Yes, go to “obtain hospital information and date” Section F Q 28a and then return to Q 8g

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

<table>
<thead>
<tr>
<th>Y</th>
<th>N</th>
<th>U</th>
</tr>
</thead>
</table>
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?  

<table>
<thead>
<tr>
<th>Y</th>
<th>N</th>
<th>U</th>
</tr>
</thead>
</table>
No or Unknown skip to Q 10.

What is the name and address of the doctor who said you had heart failure?

9.a. Name: _______________________________________

9.b Address: _______________________________________________________

9.c. What was the approximate date:  

<table>
<thead>
<tr>
<th>M</th>
<th>M</th>
<th>/</th>
<th>Y</th>
<th>Y</th>
<th>Y</th>
<th>Y</th>
</tr>
</thead>
</table>

9.d. [DO NOT ASK] Was this within 3 yrs. of today’s date?  

<table>
<thead>
<tr>
<th>Y</th>
<th>N</th>
<th>U</th>
</tr>
</thead>
</table>

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

<table>
<thead>
<tr>
<th>Y</th>
<th>N</th>
<th>U</th>
</tr>
</thead>
</table>
If Yes, go to “obtain hospital information and date” Section F Q 28a and return to Q 10.

If you answered NO or UNKNOWN in 9d, skip 9f.

[Request for authorization to release medical records for selected self-reported diagnoses / physician visits. If this is the same doctor as listed in Q.8. you do not need to re-read the script.]

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?  Y  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?  

<table>
<thead>
<tr>
<th>Y</th>
<th>N</th>
<th>U</th>
</tr>
</thead>
</table>
No or Unknown skip to Q 11a.
What is the name and address of the doctor you saw?

10.a. Name: _______________________________________

10.b. Address: _______________________________________________________

10.c. What was the approximate date? M M Y Y Y Y

Question 10d deleted

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

Y N U

If Yes: go to obtain hospital information and date Section F Q 28a and return to question 11a

[Request for authorization to release medical records for selected self-reported diagnoses / physician visits. If this is the same doctor as listed in Q.8. or Q.9. you do not need to re-read the script.]

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? Y N

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

Y N U

Question 11b 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?

Y N U

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?

Y N U

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

Y N U

No or Unknown skip to Q 14.

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

Y N U

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

Y N U

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

Y N U

16. Since we last contacted you has a doctor said that you had a blood clot in a leg or deep vein thrombosis?

Y N U

No or Unknown skip to Q 17a.
What is the name and address of the doctor you saw? (If same physician as above, no need to record address)

16.a. Name: ________________________________

16.b. Address: ______________________________

16.c. What was the approximate date?      

               M M    Y Y Y Y

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

       Y      N      U  

If Yes: go to obtain hospital information and date Section F Q 28a and return to Q.17a, below.

Question 16e deleted

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

       Y      N      U  

       No or Unknown skip to Q 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?

       Y      N      U  

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

Question 18a deleted

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

       Y      N      U  

If Yes skip to Q 20a.

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

       Y      N      U  

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

       Y      N      U       Unable to walk  Go to Q 19 f

If No or U: Go to Q 19 f

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

       Y      N      U  

If No or U: Go to Q 19 g

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

       Y      N      U  

If No or U: Go to Q 19 g

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

       Y      N      U  

If No or U: Go to Q 19 g
19.f. Do you have difficulty breathing when you are not walking or active?
   Y N U

19.g. Do you usually have some cough or wheezing?
   Y N U

Question 20 deleted

20.a. Since we last contacted you on mm/dd/yy has a doctor said you had asthma?
   Y N U

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

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

21.a. Since we last contacted you has a doctor said that you had cancer?
   Y N U

   Go to Item 22a

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

21.c. And the date it was diagnosed?

   Month / Year

D. STROKE/TIA

22.a. 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? ............ Yes Y

   No N

   If “No”, go to question 23

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

   Yes Y

   No N

   If "Yes", ensure that this event is included in the "HOSPITALIZATIONS" section, Section F Q 28a, if appropriate.
E. ADMISSIONS

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

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

   If "Yes" to either 23 or 24, add to "HOSPITALIZATIONS" section F Q28a and return to Q. 25a.

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)?
   Y N U

   If No or Unknown: Go to Q 27a

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

   If No or Unknown: Go to Q27a

   What is the name and address of this medical facility?

   26.a. Name: _______________________________________

   26.b. Address: _______________________________________________________

   26.c. What was the approximate date?

   M M / Y Y Y Y

27.a. Since our last contact, (Did [name] stay) have you stayed overnight as a patient in a nursing home? .................

   Yes Y

   Go to Item 40.

   No N

   For DECEASED, REPORTED ALIVE, or CONTACTED BY LETTER statuses, go to Q.52

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

   Yes Y

   No N

   On the paper form skip Section F and continue to Item 40. To skip in the DMS Page down to, or jump-to (CTRL-J), to Item 40.

F. HOSPITALIZATIONS

For each time you were (he/she was) a patient in a hospital, I would like to obtain the reason you were (he/she was) admitted, the name 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/dd/yyyy of last contact)? [Fill in, probing as necessary. Press F3 for a list of hospitals and press <ENTER> on the correct one if found. Otherwise press <ESC> and type in the appropriate information. Probe for additional hospitalizations. For linkage, H indicates that the hospitalization was reported; N indicates that the hospitalization was fully sought by Surveillance, and not found.]
28.a. Hospitalization Reason:

_______________________________________________________________________________________

28.b. Hospital Name, City, and State:

_______________________________________________________________________________________

28.c. Month and Year: 28.d. Linkage Status:  
M M Y Y Y Y

28.a. Hospitalization Reason:

_______________________________________________________________________________________

29.b. Hospital Name, City, and State:

_______________________________________________________________________________________

29.c. Month and Year: 29.d. Linkage Status:  
M M Y Y Y Y

29.a. Hospitalization Reason:

_______________________________________________________________________________________

30.b. Hospital Name, City, and State:

_______________________________________________________________________________________

30.c. Month and Year: 30.d. Linkage Status:  
M M Y Y Y Y

30.a. Hospitalization Reason:

_______________________________________________________________________________________

31.b. Hospital Name, City, and State:

_______________________________________________________________________________________

31.c. Month and Year: 31.d. Linkage Status:  
M M Y Y Y Y

31.a. Hospitalization Reason:

_______________________________________________________________________________________

32.b. Hospital Name, City, and State:

_______________________________________________________________________________________

32.a. Hospitalization Reason:

_______________________________________________________________________________________
<table>
<thead>
<tr>
<th></th>
<th>Month and Year:</th>
<th></th>
<th>Linkage Status:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>32.c.</td>
<td>M M Y Y Y Y</td>
<td></td>
<td>(H) or (N)</td>
<td></td>
</tr>
<tr>
<td>32.a.</td>
<td>Hospitalization Reason:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>32.b.</td>
<td>Hospital Name, City, and State:</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>33.c.</td>
<td>M M Y Y Y Y</td>
<td></td>
<td>(H) or (N)</td>
<td></td>
</tr>
<tr>
<td>33.a.</td>
<td>Hospitalization Reason:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>33.b.</td>
<td>Hospital Name, City, and State:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>34.c.</td>
<td>M M Y Y Y Y</td>
<td></td>
<td>(H) or (N)</td>
<td></td>
</tr>
<tr>
<td>34.a.</td>
<td>Hospitalization Reason:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>34.b.</td>
<td>Hospital Name, City, and State:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>35.c.</td>
<td>M M Y Y Y Y</td>
<td></td>
<td>(H) or (N)</td>
<td></td>
</tr>
<tr>
<td>35.a.</td>
<td>Hospitalization Reason:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>35.b.</td>
<td>Hospital Name, City, and State:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>36.c.</td>
<td>M M Y Y Y Y</td>
<td></td>
<td>(H) or (N)</td>
<td></td>
</tr>
<tr>
<td>36.a.</td>
<td>Hospitalization Reason:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>36.b.</td>
<td>Hospital Name, City, and State:</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
37.a. Hospitalization Reason: ____________________________

37.b. Hospital Name, City, and State: ____________________________

37.c. Month and Year: _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _
(M M Y Y Y Y)
37.d. Linkage Status: _ (H) or (N)

38.a. Hospitalization Reason: ____________________________

38.b. Hospital Name, City, and State: ____________________________

38.c. Month and Year: _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _
(M M Y Y Y Y)
38.d. Linkage Status: _ (H) or (N)

39.a. Hospitalization Reason: ____________________________

39.b. Hospital Name, City, and State: ____________________________

39.c. Month and Year: _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _
(M M Y Y Y Y)
39.d. Linkage Status: _ (H) or (N)

G. INVASIVE PROCEDURES

"The following questions ask about various types of surgery and procedures. We are interested in both those that occurred in the hospital or as an outpatient."

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

Yes    Y

Go to Item 41b.

No     N

41.a. Since we last contacted you on (mm/dd/yyyy) have you had surgery on your heart, or the arteries of your neck or legs, excluding surgery for varicose veins?

Go to Item 42a. Yes    Y

Go to Item 44a. No     N
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?

<table>
<thead>
<tr>
<th>Yes</th>
<th>Y</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>N</td>
</tr>
</tbody>
</table>

Go to Item 44b.

42. Did you have:

a. Coronary bypass? ............ Yes Y
   No N

b. Other heart procedure? ....... Yes Y
   No N

Specify: _____________________________________________________________________

c. Carotid endarterectomy? ...... Yes Y
   No N

Go to Item 42e.

d. Site: .................... Right R
   Left  L
   Both  B

e. Other arterial revascularization? ...... Yes Y
   No N

Specify: _____________________________________________________________________

f. Any other type of surgery on your heart or the arteries of your neck or legs? .................. Yes Y
   No N

43. [DO NOT ASK]

Has participant completed a previous version 'G' or later of Annual Follow-up?

<table>
<thead>
<tr>
<th>Yes</th>
<th>Y</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>N</td>
</tr>
</tbody>
</table>

Go to Item 44b.

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?

<table>
<thead>
<tr>
<th>Yes</th>
<th>Y</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>N</td>
</tr>
</tbody>
</table>

Go to Item 45a.

Go to Item 46a.
49

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?

Yes Y
No N

Go to Item 46a.

45. Did you have:

a. Angioplasty or stent of the coronary arteries:

Yes Y
No N

b. Angioplasty or stent in the arteries of your neck:

Yes Y
No N

c. Angioplasty or stent of the lower extremity arteries:

Yes Y
No N

H. INTERVIEW

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

46. Did you take any medications during the past two weeks for:

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
<th>Unknown</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. High blood pressure?</td>
<td>Y</td>
<td>N</td>
<td>U</td>
</tr>
<tr>
<td>b. High blood cholesterol?</td>
<td>Y</td>
<td>N</td>
<td>U</td>
</tr>
<tr>
<td>c. Diabetes or high blood sugar?</td>
<td>Y</td>
<td>N</td>
<td>U</td>
</tr>
<tr>
<td>d. Heart failure?</td>
<td>Y</td>
<td>N</td>
<td>U</td>
</tr>
</tbody>
</table>

"Now I would like to ask about the prescription medications you currently use [optional: as mentioned in the scheduling reminder we sent recently]. 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?

Yes........................................................................... Y
No........................................................................... N

Participant refused to provide medication information........... R
Unknown ................................................................. U

If the answer is NO, REFUSED, or UNKNOWN, skip to question 49
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]

<table>
<thead>
<tr>
<th>Medication Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>48.a. ________________________________</td>
</tr>
<tr>
<td>48.b. ________________________________</td>
</tr>
<tr>
<td>48.c. ________________________________</td>
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<tr>
<td>48.d. ________________________________</td>
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<td>48.e. ________________________________</td>
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<td>48.f. ________________________________</td>
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<td>48.g. ________________________________</td>
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<td>48.h. ________________________________</td>
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<td>48.i. ________________________________</td>
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<td>48.l. ________________________________</td>
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<td>48.m. ________________________________</td>
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<td>48.o. ________________________________</td>
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<tr>
<td>48.p. ________________________________</td>
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<tr>
<td>48.q. ________________________________</td>
</tr>
<tr>
<td>48.r. ________________________________</td>
</tr>
<tr>
<td>48.s. ________________________________</td>
</tr>
<tr>
<td>48.t. ________________________________</td>
</tr>
</tbody>
</table>

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

49. Are you NOW taking aspirin, or a medicine containing aspirin, on a regular basis? This does not include Tylenol or Advil. [Use look-up table]

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>Y</td>
</tr>
<tr>
<td>No</td>
<td>N</td>
</tr>
<tr>
<td>Unknown</td>
<td>U</td>
</tr>
</tbody>
</table>
I. OTHER ITEMS
"Next, I have a few miscellaneous questions."

50. Do you now smoke cigarettes? .. Yes Y
    No N

51. Please tell me which of the following describes your current marital status:

    [READ EACH CATEGORY]
    
    Married .......... M
    Widowed .......... W
    Divorced .......... D
    Separated ....... S
    Never Married ... N

J. ADMINISTRATIVE INFORMATION

52. Code number of person completing this form:

53. Does participant (still) live within official
    ARIC study boundaries? ..... Yes Y
    No N
    Unknown U

54. Will your center (still) be able to get his/her records
    via community surveillance? ..... Yes Y
    No N

55. Result code:

Result Codes

01 – No Action Taken
02 – Tracing (Not yet contacted any source)
3A – Contacted, Interview Complete by Cohort Member
3B - Contacted, Interview Complete, Proxy/Informant
04 – Contacted, Interview Partially Complete or Rescheduled
05 – Contacted, Interview Refused
06 – Reported Alive, Will Continue to Attempt Contact This Year
07 – Reported Alive, Contact Not Possible This Year
08 – Reported Deceased
09 – Unknown
98 – Does Not Want Any Further AFU Contact
Appendix D.3
INSTRUCTIONS FOR THE ANNUAL FOLLOW-UP TRACING FORM AND QUESTIONNAIRE
AFU, VERSION M, 02/07/2008
QxQ 04/09/08

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

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.

<table>
<thead>
<tr>
<th>RESULT CODE</th>
<th>RESPONSE CATEGORY</th>
<th>EXPLANATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>01</td>
<td>No Action Taken</td>
<td>No attempt has yet been made to contact the participant.</td>
</tr>
<tr>
<td>02</td>
<td>Tracing; Not yet contacted any source</td>
<td>Attempts are being made to locate the participant, but so far neither the participant nor another reliable source has been contacted.</td>
</tr>
<tr>
<td>*03A</td>
<td>Contacted, Interview Complete-Cohort Member</td>
<td>The participant was successfully contacted by phone or in person, and the entire interview, including the questionnaire and hospitalization information was completed.</td>
</tr>
<tr>
<td>*03B</td>
<td>Contacted, Interview Complete-Proxy/Informant</td>
<td>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.</td>
</tr>
<tr>
<td>*04</td>
<td>Contacted, Interview Partially Complete or Rescheduled</td>
<td>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.</td>
</tr>
<tr>
<td>*05</td>
<td>Contacted, Interview Refused</td>
<td>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.</td>
</tr>
<tr>
<td>06</td>
<td>Reported Alive, Will Continue to Attempt Contact This Year</td>
<td>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.</td>
</tr>
<tr>
<td>*07</td>
<td>Reported Alive, Contact Not Possible This Year</td>
<td>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.</td>
</tr>
<tr>
<td>*08</td>
<td>Reported Deceased</td>
<td>Reliable information indicates that the participant has died.</td>
</tr>
<tr>
<td>*09</td>
<td>Unknown</td>
<td>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.</td>
</tr>
</tbody>
</table>
RECORD OF CALLS - RESULTS CODES

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’.

<table>
<thead>
<tr>
<th>2. Final Status:</th>
<th>3. Information obtained from:</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Circle one below)</td>
<td>(Circle one corresponding choice below)</td>
</tr>
<tr>
<td>Contacted and Alive</td>
<td>C</td>
</tr>
<tr>
<td></td>
<td>Phone</td>
</tr>
<tr>
<td></td>
<td>Personal Interview</td>
</tr>
<tr>
<td></td>
<td>Letter</td>
</tr>
<tr>
<td>Contacted and Refused</td>
<td>F</td>
</tr>
<tr>
<td>Reported Alive</td>
<td>R</td>
</tr>
<tr>
<td></td>
<td>Reported Alive</td>
</tr>
<tr>
<td></td>
<td>Reported Deceased</td>
</tr>
<tr>
<td></td>
<td>Other</td>
</tr>
<tr>
<td></td>
<td>unknow</td>
</tr>
</tbody>
</table>

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:

<table>
<thead>
<tr>
<th>Contact Year</th>
<th>Date of Status Determination</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>9/4/88</td>
<td>U</td>
</tr>
</tbody>
</table>

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:

<table>
<thead>
<tr>
<th>Contact Year</th>
<th>Date of Status Determination</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>6/28/88</td>
<td>U</td>
</tr>
</tbody>
</table>

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:

<table>
<thead>
<tr>
<th>Contact Year</th>
<th>Date of Status Determination</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>8/23/88</td>
<td>U</td>
</tr>
<tr>
<td>3</td>
<td>8/25/88</td>
<td>C</td>
</tr>
</tbody>
</table>

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:

<table>
<thead>
<tr>
<th>Contact Year</th>
<th>Date of Status Determination</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>8/12/87</td>
<td>C</td>
</tr>
<tr>
<td>3</td>
<td>2/12/88</td>
<td>D</td>
</tr>
</tbody>
</table>

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?**

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

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

Collect the name and address of the doctor last seen for heart failure 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 the most recently diagnosed cancer was located?”
21.c. And the date it was diagnosed?

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

D. STROKE/TIA

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

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

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

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

E. ADMISSIONS

The purpose of questions 23 and 24 is to determine whether it is necessary to complete the "Hospitalizations" section (SECTION F). Substitute the date on which the participant was most recently contacted (directly) where indicated after the questionnaire has been completed. Generally, these questions are asked directly of the participant, but the participant or the interviewer can ask to have a spouse or more knowledgeable person in the household to provide information on the individual hospitalizations in Section F. When direct contact is not made with the participant, but a reliable source of information has provided a status of "Reported alive" or "Reported deceased" in item 2, questions 23-27a may be asked of this source. If speaking with an informant, replace the words "Were you" with "Was [participant]"

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
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 all hospitalizations. For the (first) overnight stay, record the reason for the hospitalization, the hospital name, city, and state, and the discharge date (month and year) of the hospitalization. Probe for additional hospitalizations and follow the directions for the first hospitalization. There is space to complete 12 hospitalizations. If there are more than 12, record and enter the 12 most relevant to ARIC. List the others on a separate sheet, so all can be transmitted to surveillance. If the person was hospitalized overnight more than 12x times, select those with heart disease, stroke, or heart failure as reasons for hospitalization.
28d-39d. (letter “d” only). If any hospitalizations are reported, enter H beside the appropriate letter corresponding to each hospitalization. That is, if 3 hospitalizations are reported, enter H for items a, b, and c. Send a copy of the Hospitalizations page(s) or screen printouts to the surveillance supervisor and check the appropriate boxes for "Transmit to Surveillance." The surveillance staff will investigate each hospitalization. If a reported hospitalization cannot be found, the surveillance supervisor will notify the staff person responsible for annual follow-up, who then changes the "H" to "N". Be certain that the "H" changed corresponds exactly to the hospitalization in question (for example, if the second hospitalization is actually an outpatient visit, item b. H should become b. N).

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

B. Linkage between Annual Follow-up and Event Investigation

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

G. INVASIVE PROCEDURES

Read the transition statement.

40. [DO NOT ASK]. Has participant completed a previous version “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.

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DEFINITIONS AND SYNONYMS FOR THERAPEUTIC AND DIAGNOSTIC PROCEDURES

<table>
<thead>
<tr>
<th>DIAGNOSTIC PROCEDURES</th>
<th>SYNONYMS</th>
</tr>
</thead>
<tbody>
<tr>
<td>ECHOCARDIOGRAM</td>
<td>Echo</td>
</tr>
<tr>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>ELECTROCARDIOGRAM</td>
<td>ECG</td>
</tr>
<tr>
<td>A graphic record of the electrical impulses produced by the heart.</td>
<td>EKG</td>
</tr>
<tr>
<td>TREADMILL CARDIAC STRESS TEST</td>
<td></td>
</tr>
<tr>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>THALLIUM SCAN OF THE HEART SPECT</td>
<td>Heart Scan</td>
</tr>
<tr>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>HOLTER MONITOR</td>
<td></td>
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<tr>
<td>A small, portable ECG machine worn by patients.</td>
<td></td>
</tr>
<tr>
<td>HEART RHYTHM or CONDUCTION STUDIES</td>
<td></td>
</tr>
<tr>
<td>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.</td>
<td></td>
</tr>
<tr>
<td><strong>CAROTID ULTRASOUND STUDIES</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>CAT SCAN of BRAIN</strong></td>
<td>A non-invasive diagnostic technique, which produces an image of the brain and can identify abnormalities.</td>
</tr>
<tr>
<td><strong>CORONARY BYPASS or BYPASS SURGERY</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>OTHER HEART PROCEDURES</strong></td>
<td>Examples include valve replacement, ventricular aneurysm resection, Aortic Stenosis, Ventricular Stenosis. Defect repair, Patent ductus closure, Pacemaker, Implantation of automatic defibrillator, Coronary atherectomy.</td>
</tr>
<tr>
<td><strong>ENDARTERECTOMY</strong></td>
<td>Surgery to take out plaque from an artery, to restore blood flow in one or both of the arteries in the neck.</td>
</tr>
<tr>
<td><strong>OTHER ARTERIAL REVASCULARIZATION</strong></td>
<td>Any procedure where additional blood flow is brought to an artery via a bypass from a location elsewhere in the body.</td>
</tr>
<tr>
<td><strong>BALLOON ANGIOPLASTY</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>CATHETERIZATION</strong></td>
<td>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).</td>
</tr>
</tbody>
</table>
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 currently use [optional: as mentioned in the scheduling reminder we sent recently]. To make it easier to get the names of the medications you currently use, can I ask you to bring all the prescription
medications you are taking to the telephone?

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

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

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 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.”

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                  ---------------------------
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 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.
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** ____________
## INFORMED CONSENT TRACKING FORM

### ID NUMBER: [ ] [ ] [ ] [ ]
### CONTACT YEAR: [ ]
### FORM CODE: [ ] [ ]
### VERSION: B 09/30/98
### LAST NAME: [ ] [ ] [ ] [ ] [ ] [ ]
### INITIALS: [ ] [ ]

Public reporting burden for this collection of information is estimated to average 9 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: Paper Reports Clearance Officer, No. 257-P, Humphrey Building, 200 Independence Ave., SW, Washington, D.C. 20201, ATT: PRA (0925-0281). Do not return the completed form to this address.

**INSTRUCTIONS:** ID Number, Contact Year and Name must be entered above. Wherever numerical responses are required, enter the number so that the last digit appears in the rightmost box. Enter leading zeroes where necessary to fill all boxes. On the paper form, if a number is entered incorrectly, mark through the incorrect entry with an "X" and circle the correct response. For "multiple choice" questions, circle the letter corresponding to the most appropriate response. If a letter is circled incorrectly, mark through it with an "X" and circle the correct response.

### A. POST-VISIT CONSENT MODIFICATION

1. Change in restrictions on use/storage of DNA?
   - Yes
   - No

2. Type of restriction on use/storage of DNA:
   - Full use
   - CVD research
   - ARIC only
   - No use/storage of DNA
   - Other

Specify details of DNA restrictions:

### B. Type of restriction on use of study data:

- Full use
- CVD research
- ARIC only
- Other

Specify details of restrictions on use of study data:

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<table>
<thead>
<tr>
<th>3.a. Change in permission to access medical records?</th>
<th>...</th>
<th>Yes</th>
<th>Y</th>
</tr>
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<tbody>
<tr>
<td>[Go to Item 4.]</td>
<td>No</td>
<td>N</td>
<td></td>
</tr>
<tr>
<td>b. Type of restriction on access to medical records:</td>
<td>Full access</td>
<td>F</td>
<td></td>
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<tr>
<td>No access</td>
<td>N</td>
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<tr>
<td>Partial access</td>
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<td>If partial, specify:</td>
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<tr>
<td>B. ADMINISTRATIVE INFORMATION</td>
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<tr>
<td>4. Date of data collection:</td>
<td>m</td>
<td>d</td>
<td>y</td>
</tr>
<tr>
<td>5. Code number of person completing post-visit consent:</td>
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Appendix E.2

INSTRUCTIONS FOR THE ARIC INFORMED CONSENT TRACKING FORM
ICT, VERSION B, 09/30/08
PREPARED 1/01/99

I. GENERAL INSTRUCTIONS

This form is an internal form and is NOT administered to participants. The purpose of the form is to document and track in the ARIC central database any changes (revisions) following Visit 4 to a participant’s consent on (a) the use of DNA, (b) the use of other study data, or (c) access to medical records by the ARIC staff. Changes are not actively solicited. However, a change in consent status or access to medical records is documented as soon as a participant requests a change be made to his or her consent status which is on file at the Coordinating Center. Use the contact year from the AFU time window whenever an update of the informed consent is needed.

II. DETAILED INSTRUCTIONS FOR EACH ITEM

1.a Change in restrictions on use/storage of DNA? Refer to the Participant Tracing Information Sheet for the participant’s currently documented consent level on the use/storage of DNA. Record YES to Item 1.a only when the participant has specifically requested some type of change be made to the use or storage of his/her DNA which is different from what is indicated on the Participant Tracing Information Sheet, and continue with Item 1.b; otherwise, record NO, and skip to Item 2.a.

One of the two following statements in the informed consent at Visit 4 was signed by every ARIC participant. The first statement places no restrictions on the type of medical research; the second statement limits the use of study data for future studies of cardiovascular disease and other medical conditions related to them. One or both of these statements can be read to those participants who ask about the ARIC study policy on the use/storage of DNA.

(1) By signing this consent form, I am granting permission for the ARIC Study investigators and the scientists with whom they are collaborating to use the information and samples collected on me (including results of questionnaires, clinic examination, blood tests, DNA). Blood samples and DNA will be stored by the ARIC Study for future studies. These will include medical research projects on such conditions as heart disease, stroke, hypertension, obesity, diabetes and cancer. My name or other information that could identify me will not be released.

(2) By signing this consent form, I am granting permission for the ARIC study investigators and the scientists with whom they are collaborating to use the information and samples collected on me (including results of questionnaires, clinic examination, blood tests, DNA). Blood samples and DNA will be stored by the ARIC study for future studies of cardiovascular diseases and other medical conditions related to them, such as diabetes and obesity. I understand that my name or other information that could identify me or my family will not be released.

1.b Type of restriction on use/storage of DNA: There are five consent categories on the use/storage of DNA, one which places no restrictions on the use/storage of DNA, and four which place increasing restrictions on its use or storage: FULL Use; CVD research; ARIC only; No use/storage of DNA; other.

FULL USE means the participant has placed no restrictions on storage or use of their DNA, and their DNA samples can be used in any type of medical research.

CVD RESEARCH means participants have agreed to the storage and use of their DNA only in studies on cardiovascular diseases.
ARIC ONLY is more limited, and means participants restrict the storage and use of their DNA to the ARIC Study.

NO USE/STORAGE OF DNA is used to indicate absolute refusal of any DNA storage or DNA use.

OTHER means that one of the above limitations on the use of DNA may have been requested and/or participants have indicated ADDITIONAL/OTHER restrictions on the use of their DNA. List all of these restrictions under "specify", even if they include "CVD research" or "ARIC only".

2.a Change in restrictions on use of study data? Refer to the Participant Tracing Information Sheet for the current consent level on the use of study data. Record YES to Item 2.a only when the participant has specifically requested some type of change be made to the use of his or her study data which is different from what is indicated on the Participant Tracing Information Sheet, and continue with Item 2.b; otherwise, record NO, and skip to Item 3.a.

2.b Type of restriction on use of study data: There are four consent categories on the use of study data; one which places no restrictions on its use, and three which place increasing restrictions on the use of study data: FULL Use, CVD research; ARIC only; other. Record the category requested by the participant.

FULL USE means participants have agreed to the use of their study data in any type of medical research.

CVD RESEARCH means participants have agreed to the use of their study data only in studies on cardiovascular diseases.

ARIC ONLY is more limited, and means participants restrict the use of their study data to the ARIC Study.

OTHER means that one of the above limitations on the use of their study data may have been requested and/or participants have indicated ADDITIONAL/OTHER restrictions in the use of their study data. List all of these restrictions under "specify", even if they include "CVD research" or "ARIC only".

3.a Change in Permission to access medical records? Refer to the Participant Tracing Information Sheet for current consent level on permission to access medical records. Record YES to Item 3.a only when the participant has specifically requested some type of change be made on the type of access by ARIC staff has had to his or her medical data which is different from what is indicated on the Participant Tracing Information Sheet, and continue with Item 3.b; otherwise, record NO, and skip to Item 4.
3.b **Type of restriction on access to medical records:** there are three consent categories for permission to access medical records: one which places no restrictions on access, and two which place increasing restrictions on the study's access to medical records: FULL ACCESS, NO ACCESS, and PARTIAL ACCESS.

**FULL ACCESS**  
F   Participants have agreed that the ARIC study has unrestricted access to their medical records.

**NO ACCESS**  
N   Complete refusal to have ARIC staff access their medical records.

**PARTIAL**  
P   Some restrictions, less than full, have been placed on ARIC staff accessing the participant's medical records. Details of the type of PARTIAL restriction are listed under "specify".

If PARTIAL, Specify: ____________________________

4. **Date of completion:** Record the date on which the form is completed, entering all four digits of the year.

5. **Code number of person completing post-visit consent:** Enter the staff identification code of the person completing this form.
OVERVIEW OF INTERVIEW SKILLS AND TECHNIQUES

I. Interview bias -- includes anything that creates a systematic difference between responses obtained by different interviewers.

   A. Respondent’s perception of the interviewer and his/her reaction to that perception.

   B. Interviewer’s perception of the respondent and his/her reaction to that perception.

II. Characteristics of a good interview:

   A. There is an appropriate atmosphere; friendly but business-like.

   B. The respondent is at ease. Interviewer should be able to put respondent at ease and ensure their confidentiality.

   C. Interviewer obtains the answer to the question asked through proper use of probes and does not interpret questions or try to argue.

   D. Interviewer gives only neutral responses to the respondent’s answers and clarifies confusing responses but does not challenge an answer.

III. Specific skills required for interviewers include the following:

   A. Be able to ask questions at an even pace and in conversational tones.

   B. Know the question and response categories well enough to keep the interview flowing smoothly.

   C. Know when there are probes that can be used, and know how to use them. Understand when it is inappropriate to probe.

   D. Be able to think as an interviewer, putting aside other roles (ECG tech, mother, father, etc.) for the period of the interview. FOCUS on the interview.

   E. Be able to maintain a positive attitude about the interview so that the respondent feels that the interview is important.

   F. Be able to keep some level of control over the interview process, i.e., by keeping the interview focused on the specific question and not arguing with the respondent.

   G. Ensure that data is coming from the respondent. Listen carefully and avoid being engaged in the answer. Often respondents will use a tack such as, "What do you think?" or "Let me tell you about that so that you can help me with the answer." These attempts encourage the interviewer to be "helpful" and can result in bias by leading the respondent to an answer. Remember that you are the interviewer administering the interview, not the respondent being interviewed. We need the information on the respondent, not on you.

   H. Interviewers should dress professionally, be neat, pleasant looking. Additionally, they should be not too timid, but not too aggressive.

   I. Eye contact with interviewers is very important but by the same token, it is not a good idea "to stare them down" or to act as though you do not believe their answers.
A very important goal of the Atherosclerosis Risk in Communities (ARIC) Study is to keep track of any major changes in your health. This information is important for answering scientific questions about heart disease and other health conditions. You are the best source of information regarding your health, but there may be times when you are not able to provide these details yourself. We are asking you to provide us with the name of a person that can answer questions about your health if you cannot. This person will be considered your “proxy” for the ARIC Study. The person you designate would only be contacted once per year, should you be unable to respond. Only your ARIC center can contact your proxy.

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

**Why is a proxy needed?**
For almost 20 years you have been providing information about your health to ARIC. This important information should not be lost, even when you are unable to provide it yourself.

**What does a proxy do?**
Should it be necessary we would ask your proxy to answer questions about your health, just like the questions you have been asked each year by the ARIC staff.

**Whom should I name as my proxy?**
You should select someone who knows you well enough to provide health information about you. For example, your proxy can be your power of attorney, your legal health care proxy, or your legal next-of-kin (including your spouse, son, daughter, brother, sister, etc).

**Am I allowed to change my proxy?**
Yes, you may change your proxy at any time by either calling ARIC or by indicating your wishes at your annual ARIC phone call.

**Will you give my earlier information to my proxy?**
No, all of your information is strictly confidential and will not be provided to your proxy.

**What would you like me to do now?**
Using the attached form please indicate whom you have chosen to be your proxy.
indicate his/her name, contact information, relationship to you, sign the form and mail it to the ARIC field center in the enclosed envelope.

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

If you have any questions call Mr/Ms. ........ ARIC Study Manager at (xxx) xxx-xxxx

Thank you for your continued dedication to ARIC Study!
The ARIC Study

Participant Name: ________________________________ ARIC ID: __________

First                Last                   MI

I have named as my proxy: _______________________________________
(Name of person you choose as ARIC Proxy)

Relationship:________________________________________

Proxy Address:______________________________________

______________________________________

______________________________________

Proxy Phone Number:________________________________

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

___________________________________ _____________
Participant’s Signature  Date

___________________________________ _____________
Witness  Date

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

___________________________________ ________________________________
(Name)        (Street)

________________________________
(City/Town)         (State)

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

_______________________________________________________________
(name of person you choose as your alternate proxy)

of______________________________________________________________

(street)                             (city/town)                  (state)         (phone)