INSTRUCTIONS FOR THE ANNUAL FOLLOW-UP INTERVIEW (AFU, VERSION 1, 04/20/2011) AND PARTICIPANT TRACING REPORTS QxQ 12/19/2012

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. Each routine follow-up is completed by telephone.

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

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

If the participant is contacted and agrees to be interviewed, two forms are routinely completed during the annual follow-up (AFU) interview: the AFU Questionnaire (Version 1), the Contact Information Update Form (CIU, formerly the UPD - Update Form). An important new element of the AFU interview includes asking participants to identify a follow-up proxy to answer questions about the participant's health if he/she is unable to provide that information themselves. This information is collected on the Contact Information Update CIU form.

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

Interviewers may also need to request authorization to contact the participant's physician for information on selected health problems, additional to that reported by the participant during the AFU interview. When the participant reports that he/she has been diagnosed as having heart failure (HF) by a physician 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 Survey Form (PHF).

Consent to Release Protected Health Information

The PHF form is sent to each physician the participant provides consent to release medical information to ARIC. An example of the Consent to Release Protected Health Information is provided at the end of these QxQ instructions (Appendix 1). In addition, consent for access to the participant's medical records is also needed to investigate admissions to emergency rooms or admissions to hospitals that are located outside of the ARIC Study Areas. ARIC Exam 5 staff requests permission to access medical records (from the participant or their proxy) at the time of consent for Exam 5, a signed medical release will also be required for cohort participants who do not participate in Exam 5 if their response to the AFU determines the need to contact their care provider.

Reports available through the Data Management System

Two reports are available to assist field centers in scheduling AFU interviews: the Participant Tracing Report lists all participant IDs that are to be contacted for AFU during a given interval and contact year; the Participant Tracing Information Sheet provides the most recent consent status and other pertinent information for a given cohort participant.

Changes with AFU Version 1

AFU Version 1 replaces AFU Version M. The major changes in AFU Version 1 are:

1. Result Codes and Final Codes have been combined to streamline responses.
2. Questions that pertain to deceased participants have been grouped together.
3. Questions related to chronic diseases (i.e., conditions that are not cured or are managed under these same diagnosis over time) are not asked again if a 'yes' response has been recorded in an earlier AFU (see items 18 – 28).

Data entry screens for the AFU interview:

1. Annual Follow-Up Questionnaire (AFU)
2. Contact Information Update (CIU)
3. Physician Heart Failure Survey (PHF)
4. Informed Consent Tracking (ICT)
5. Telephone Interview for Cognitive Status (one-time administration)

II. Annual Follow-up Procedures

Preparation for AFU Interviews

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

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

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

2. The Participant Tracing Information Sheet provides detailed, confidential information for individual participants including address, date of birth, , Social Security Number (optional), driver's license number, contact persons, Visit 1 date, contact status at the most recent AFU (or SAF) interview and information about whether participant previously reported that physician said he/she had heart failure or weak heart. Data security procedures that apply to confidential information must be in place to access, store, transport and dispose of these reports. It is each field center's responsibility to comply with the HIPAA regulations and its Institution's data security policy in processing data with personal identifiers and PHI.

3. In preparing for the annual ARIC call the interviewer reviews the information presented on the tracing sheets to determine the date of last contact, and whether this date corresponds to an interview with the participant, a contact or a proxy, or whether the participant could not be reached during the previous contact window. The SAF and also the AFU tracing sheets include information additional to the contact year number to indicate whether last contact was part on an

AFU, as SAF, or historical information retrieved from an earlier version. On the SAF tracing sheet, this information is presented in a field named 'Last Contact Type.'

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

Contacting Procedures and Rules

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

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

During the call, the Contact Information Update (CIU) is reviewed with the participant for accuracy, and updated, if necessary. An important new element that is tracked on the CIU is the participant's follow-up proxy who can answer questions about the participant's health if he/she is unable to provide that information themselves.

Update information

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

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

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

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

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

1. Refusals (attempt conversion).
2. Difficult contacts or other non-completes. In particular, the supervisor decides when it is no longer practical to continue to investigate a person. All possible alternatives must be exhausted for this decision to be made.
3. Undocumented deaths. If a death is reported for which no death certificate can be located, the surveillance staff reviews the case and attempts to resolve it. If no death certificate is ultimately

located, including an NDI search, the vital status can be assigned the special missing value of "Unknown".

Linkage between Annual Follow-up and Event Investigation

The Surveillance staff is to be notified of every cohort hospitalization (and death), and an investigation is initiated by ARIC Surveillance. No information pertaining to these events needs to be returned by Surveillance staff to cohort follow-up personnel.

Participant Death Outside a Scheduled Interview

When the death of a participant is identified outside of a scheduled interview (e.g., through an obituary or if the death is reported to ARIC by a next of kin), the research staff opens a DEC form under this participant's ID and enters as much information as is available from the obituary or other source about the date and place of death. At least three months are then allowed to elapse, to give next of kin time to grieve before scheduling an interview with the proxy respondent. At that time, administer the remainder of the DEC. This action applies to all deaths identified outside of an interview, regardless of the scheduling window during which the death occurred, was identified, or the follow-up interview is made. A DEC form pending resolution may trigger automatic queries from the ARIC CC; these should be considered reminders to assist in managing such pending interviews.

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

Participant Death Mortality Scenarios

1. At AFU, **Proxy** reports participant death
   - Complete AFU Section A. STATUS, Section B. DEATH INFORMATION [CLOSURE SCRIPT] & Section H. ADMINISTRATIVE INFORMATION.

2. At semi-AFU, **Proxy** reports participant death
   - Complete **SAF** Section A. STATUS, Section E. ADMINISTRATIVE INFORMATION & **DEC**

3. At AFU, **participant** completes interview; a while later, participant's obituary is published
   - Complete **DEC** Section A. DEATH INFORMATION Q1-3 & Section E. ADMINISTRATIVE INFORMATION Q13 (select "b").
   - When the proxy is interviewed about the death, complete **SAF** Section A. STATUS, Section E. ADMINISTRATIVE INFORMATION & remainder of **DEC**. Change DEC Q13 to "a". Make the date of **DEC** Q0a. Completion Date the same as the **SAF** Q0a. Completion Date.

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

Performing the Interview

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

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

III. Detailed Instructions for Each Item

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

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

Determine the participant's availability and vital status.

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

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

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

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

0a. Enter the date of contact or the date the status determination was made. THIS DATE MUST FALL DURING THE TIME FRAME SPECIFIED IN THE ANNUAL FOLLOW-UP, i.e., no earlier than the EARLIEST date and no later than the LATEST date on the Participant Tracing Report.

0b. Enter the staff ID for the telephone follow-up interviewer ID or the staff ID that made last contact attempt.

0c. Contact Year. If the participant has dies, and the death occurred after a contact, but before the end of the contact year, the death information is assigned to the next contact year. For example, if participant's EARLIEST and LATEST dates span 2/12/11 through 2/11/12 and the AFU interview is completed on the TARGET date, 8/12/11, but the participant dies one month later (e.g., his obituary is seen in the newspaper), the death is reported for the next Contact Year. A death investigation may, however, be started at any time.

A. STATUS

1. Result of contact for the interview. Enter the contact status code that describes whether or not the AFU interview was completed and the person interviewed.

A. Participant contacted, agreed to be interviewed

B. Contact refused to be interviewed

C. Proxy/Informant contacted

D. Other person contacted

E. Contact pending; continue to attempt to contact

F. Window closed; unable to contact

A. Participant contacted, agreed to be interviewed:
Action: Begin interview at item 17. If the interview is interrupted or the participant requests the interview be done at another time during the present contact year, complete H. ADMINISTRATIVE INFORMATION item 71. The interviewer will continue to attempt to contact during the current contact window.

B. Contact refused to be interviewed: Contact was made with the participant, follow-up proxy, or other informant, but he/she refused to be interviewed.
Action: There are two levels of refusal - 1) refused the interview for this year, or 2) refused the interview for this year and for future years (no more contact). After review by the Supervisor (the follow-up Supervisor is responsible for reviewing cases of ambiguity or difficulty), complete the interview as follows:

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

2. If the interview was refused for this year **and for future years**, go to Section H. ADMINISTRATIVE INFORMATION item 71, enter A. Complete and code the ICT form item 1 as 'do NOT agree to AFU contact-withdraw AFU consent'. Once this is done, no further AFU will be required.

C. Proxy/Informant contacted: Contact was made with follow-up proxy or other informant who is knowledgeable and able to answer the interview questions on behalf of the participant (e.g., relative, spouse).
Action: Begin interview at Item 2. If the respondent is unable to provide reliable information about the participant go to Section H. ADMINISTRATIVE INFORMATION item 71. Reliability of the information provided by "other person" is evaluated by supervisor review and documented in the notelog.

D. Other person contacted: Contact was made with a person who has not been explicitly identified as a follow-up proxy who may not be familiar with detailed health of the participant (e.g., acquaintance).
Action: Begin interview at Item 2. If the respondent is unable to provide reliable information about the participant go to Section H. ADMINISTRATIVE INFORMATION item 71. Reliability of the information provided by "other person" is evaluated by supervisor review and documented in the notelog.

E. Contact pending; continue to attempt to contact: Contact pending.
Action: No action necessary; save and close form. This AFU completion status is not final, as further attempts will be made to complete the interview.

F. Window closed; unable to contact: Neither the participant nor another source of information was able to be contacted within the contact year.

Action: No action necessary; save and close form

A. STATUS (ITEM 1)	H. ADMINISTRATIVE INFORMATION (ITEM 71)	EXPLANATION
E	**--**	Attempts are being made to locate the participant, but so far neither the participant nor another reliable source has been contacted.
A	**A**	The participant was successfully contacted and the entire interview, including the questionnaire and hospitalization information was completed.
C	**A**	The participant's proxy or informant was successfully contacted and the entire interview, including the questionnaire and hospitalization information was completed.
D	**A**	Other person was successfully contacted by phone or in person, and the entire interview, including the questionnaire and hospitalization information was completed.
E	**--**	The participant was successfully contacted but the interview is incomplete or was not done at all. This may be a temporary status if it is possible that the interview may be completed at a later date within the same contact year.
B	**C**	The participant was successfully contacted and vital status obtained, but the interview was not done and is not completed within the contact year.
E	**--**	Reliable information (e.g. from a relative, employer, etc.) indicates that the participant is living, but direct contact has not yet been made. It is possible that contact will be made during this same contact year through further efforts. For example, "temporarily away" would fit in this category.
E	**--**	Reliable information indicates that the participant is living, but direct contact has not yet been made. This status should be used only if repeated contact attempts have been made, or when it has been determined that it is not possible that contact will be made during this same contact year.
F	**--**	Neither the participant nor another source of information was contacted that could provide reliable vital status data during the specified date range.
B	**A**	The participant has indicated that s/he does not wish to be contacted any more by the 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.

2. Indicate whether the participant deceased.

B. DEATH INFORMATION

3. Indicate the person who reported the death
   a. Relative/Spouse/Acquaintance
   b. Surveillance
   c. Other (e.g., Obituary, Social Security Administration)
4. If the participant has died, provide the exact date of death, or the month and year if exact date is unknown, or the date on which the death became known to the ARIC Field Center if even partial date is not known.

5. Location of death: If the participant has died, attempt to secure the date and location (city/county, state) of death. Note, this information may be provided in the obituary. Take steps to begin a death investigation by initiating a Cohort Event Eligibility Form. Obtain as much information as possible from the informant. If the state is known, but not the city/county, record as much information as is available.

6. Determine whether the respondent is able to answer questions about hospitalizations prior to the participant's death. If the respondent is unable to answer these questions, try to identify another contact person who might be able to provide this information. Go to Section H. ADMINISTRATIVE INFORMATION item 71 and code as 'Partially complete - interruptions' and get contact information for the person. Ensure the information is in the CIU.

7-13. These items pertain to hospitalizations since the previous contact AFU interview for participants who have died. Up to five hospitalizations can be entered. In the rare case that a participant reports more than space allows, interviewers should record those most relevant to ARIC, specifically cardiovascular disease, pulmonary disease, and cancer in that order. Other hospitalization need not be recorded in the data entry system. Staff may write any additional hospitalization on paper and communicate this to surveillance staff. Enter the date of hospitalization in month/year format (specific day is not needed). Select the hospital name/city/state from drop down list, or specify if the hospital if not on the list.

14-16. These items pertain to admission to an emergency room or other medical facility since the previous contact AFU interview for participants who have died. Enter the date of admission in month/year format (specific day is not needed). Select the facility name/city/state from drop down list, or specify if the facility name if not on the list.

C. GENERAL HEALTH

17. Indicate the participant's health making sure you gently stress the time frame (over the past year) and pausing slightly between each of the response categories. Read all four categories, and record the participant's selection.

18-28. These items ask about chronic health conditions (i.e., conditions that are not cured or do not go away once you have them). Therefore, some of these items are not asked if a 'yes' response has been recorded in an earlier AFU.

Question 20 (Since we last contacted you, has a doctor told you that you had chronic lung disease, such as bronchitis, or emphysema?) is a special case. If the answer to question 20 is Yes (i.e., a first report from the participant of a physician diagnosis of chronic bronchitis or emphysema), a skip is activated that that takes the interviewer to question 24 (Since we last contacted you on [mm/dd/yyyy], has a doctor said had asthma?). Questions 21-23 are skipped because the participant's diagnosis seems to be new/recent, the condition may still be decompensated, or treatment not yet optimized.

If Question 20 was answered in the affirmative in a previous AFU it will be greyed out in the DMS, but questions 21 through 23 are still asked because the respiratory signs and symptoms they refer to may be indications of heart failure (or a combination of heart failure and chronic respiratory disease).

Item 26 (Do you have pain in your legs caused by a blockage of the arteries?) 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.

Item 27 (Do you often have swelling in your feet or ankles at the end of the day?) 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.

Item 28 (Has a doctor said you have cancer). Enter the date it was diagnosed in month/year format (specific day is not needed).

D. CARDIOVASCULAR EVENTS

29. Determine whether the respondent is able to answer questions about the participant’s health. If the respondent is unable to answer these questions, try to identify another contact person who might be able to provide this information. Go to Section H. ADMINISTRATIVE INFORMATION item 71 and code as ‘Partially complete - interruptions’ and get contact information for the person. Ensure the information is in the CIU.

30. This item is skipped if a ‘yes’ response to heart failure diagnosis has been recorded in an earlier AFU.

31. This item is skipped if a ‘Yes’ response to having a weak heart or having a heart that does not pump as strongly as it should has been recorded in an earlier AFU.

    Relation of the answers to items 30-31 to question 33 in AFU version 1. In the previous version of the AFU (AFU version M) a participant’s report that she/had been told of heart failure or a weak heart by a physician was followed up with a PHF form only if the participant was not hospitalized for heart failure. This was done to reduce burden on the study participants and the ARIC staff. Because the number of newly reported heart failure events each year is small, ARIC now requests a PHF form of all newly reported diagnoses of heart failure/weak heart, whether or not the participant reports being hospitalized at that time. Thus, if the physician’s name and location information are known, a release of medical information and a PHF are requested even if the participant responds “yes” to question 33 (“Were you hospitalized at that time?”)

32-32e. These items are only completed for participants who have never reported heart failure or a weak heart. The name of the physician who indicated that the cohort member has heart failure or has a weak heart is recorded on line 32.a. If the physician’s name is unknown or the information is unavailable, enter the name of the clinic, emergency service or hospital service where the encounter took place. In addition to the name of the establishment, indicate whether this is an emergency service, an outpatient clinic, or other facility. A release of medical records is not requested if the physician’s name is unknown, nor for encounters that occurred in an emergency service, an outpatient clinic or a hospital, nor is a PHF form sent.

    Record the name and address of the hospital in items 32b-32c. Then enter the date heart failure or weak heart was diagnosed in month/year format (specific day is not needed) and proceed to item 33. If in the sequence of items 30-32d the participant reports being told by a physician of a weak heart or heart failure while in a hospital service, the name of the hospital is recorded prior to asking item 33 (Were you (Was [name]) hospitalized at that time?). If the answer to item 33 is Yes, the hospital or medical facility is recorded in items 34a or 34a1, even if it corresponds to the same facility recorded in items 32-32d.

33. Indicate whether the participant was hospitalized for heart failure or a weak heart. Admissions to "rule out", as well as discharge diagnoses of heart failure/weak heart, are both coded YES.

34a-34b. The term "hospitalized" includes staying overnight in any acute or chronic care facility which excludes nursing homes. Only inpatient care should be included, e.g., ER or outpatient visits not involving an overnight stay are coded as NO. If the participant or informant is unsure,

doesn't know or can't provide information about the overnight hospitalization(s) for heart attack or other condition, enter NO. Select hospital from drop down list. If the hospital is not on the drop down list, enter the hospital name. Enter the admission date in month/year format (specific day is not needed).

35. If yes, remember to update the PHF (Physician Heart Failure Survey Form) item 0c once the release form is sent to the participant. When the release form is returned, the second box in PHF item 0c should be checked. This will help reconcile the requested and returned releases from the AFU participants. A PHF form is not sent if the physician's name is unknown, nor for encounters that occurred in an emergency service, an outpatient clinic or a hospital (thus, a release of medical information is not requested). In such a case, a special missing value for Item 35 is set to 'Not applicable.'

36. Indicate whether the participant has had a heart attack making sure you gently stress the time frame (since the last contact).

37. Indicate whether the participant was hospitalized for a heart attack. Frequently, a patient is admitted for heart attack but discharged with a diagnosis other than a heart attack, such as tachycardia (uneven heart rate) or esophageal reflux (indigestion).

38a-39b. Select hospital from drop down list. If the hospital is not on the drop down list, enter the hospital name. Enter the admission date in month/year format (specific day is not needed). Complete items 39a-39b for a second hospitalization.

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

41. This question specifically asks about a physician-diagnosed atrial fibrillation.

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

43. Indicate whether the participant was hospitalized for a blood clot in the leg or deep vein thrombosis.

44a-44b. Select hospital from drop down list. If the hospital is not on the drop down list, enter the hospital name. Enter the admission date in month/year format (specific day is not needed).

45. This question specifically asks about physician-diagnosed blood clot in the lungs or pulmonary embolus.

46. Indicate whether the participant was hospitalized for a blood clot in your lungs or a pulmonary embolus.

47a-47b. Select hospital from drop down list. If the hospital is not on the drop down list, enter the hospital name. Enter the admission date in month/year format (specific day is not needed).

48. This question specifically asks about physician-diagnosed stroke, slight stroke, transient ischemic attack, or TIA.

49. Indicate whether the participant was hospitalized for stroke or TIA.

50a-50b. Select hospital from drop down list. If the hospital is not on the drop down list, enter the hospital name. Enter the admission date in month/year format (specific day is not needed).

E. ADMISSIONS

51. This question asks the participant/informant to recall 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 there was a positive response to hospitalizations for any other reason, read the following script:

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

    This does NOT include overnight admissions to nursing facilities and/or rehabilitation centers. Use neutral probes to elicit all hospitalizations. For the (first) overnight stay, record the reason for the hospitalization, the hospital name, city, and state, and the discharge date (month and year) of the hospitalization. Probe for additional hospitalizations

52a-58. Record information on all hospitalizations reported since the time of last contact. There is space to complete 5 hospitalizations. If there are more than 5, enter the 5 most relevant to ARIC (e.g., those related to cardiovascular disease). Select hospital from drop down list. If the hospital is not on the drop down list, enter the hospital name. Enter the admission date in month/year format (specific day is not needed).

59a-59b. This question asks the participant/informant to recall admissions to an emergency room or a medical facility for outpatient treatment for any condition other than heart attack, heart failure, stroke, or TIA. The other conditions would include blood clots, angina, heart failure, or angioplasty. Collect and record the date of this visit. Remind the participant that this is the most recent visit to an emergency room or outpatient medical facility for the heart problem or difficulty breathing. Select the ER or medical facility name from drop down list. If the facility is not on the drop down list, enter the name. Enter the admission date in month/year format (specific day is not needed). Although the name of the facility and the date of admission 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.

60. A nursing home refers to a skilled nursing facility or an extended care facility; it does not include assisted living facilities.

61. "Currently" refers to the day on which the interview is conducted.

F. INVASIVE PROCEDURES

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

62. This question refers to "major" therapeutic surgery on the heart or arteries of the neck or legs. "Legs" refers to the entire lower extremity (not "just below the knee", which is the restricted anatomical definition). "Surgery" does not include lower extremity arteriography, even though it is an "invasive" procedure, nor surgery for varicose veins. Note also that "abdominal aortic aneurysm repair" is not included here.

63a. Definition of coronary artery bypass is provided in the table of Definitions and Synonyms of Diagnostic and Therapeutic Procedures.

63b. Examples of other heart procedures are provided in the table of Definitions and Synonyms of Diagnostic and Therapeutic Procedures.

63c-d. Definition of carotid endarterectory is provided in the table of Definitions and Synonyms of Diagnostic and Therapeutic Procedures. Indicated the side(s) of the neck intervened upon.

63e. Examples of other arterial revascularizations are provided in the table of Definitions and Synonyms of Diagnostic and Therapeutic Procedures.

63f. Indicate any other surgery on the heart or arteries of the neck or legs.

64a-c. When the response is positive (the definition of angioplasty can be read to the participant if he or she asks for clarification), continue with parts a, b, and c.

DEFINITIONS AND SYNONYMS FOR THERAPEUTIC AND DIAGNOSTIC PROCEDURES

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

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

G. INTERVIEW

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

65a-d. It is not necessary for these medications to have been prescribed by a physician. Select unknown as special missing value if the respondent is unclear as to whether he or she has the medical condition, or whether any of the medication(s) being taken are specifically used to treat that condition.

66. This question documents the current use of aspirin or aspirin containing medications on a regular basis, regardless of the amount, or the reason for its use. These medications do not include Tylenol (acetaminophen), Advil (ibuprofen), etc. If the participant specifies a brand or type of medication, verify that the medicine actually contains aspirin by locating the product on the Aspirin Look-up table (List #1 below). If the product does not contain aspirin, code the participant's response as 'no'. If it is unclear whether the product contains aspirin, consult with your supervisor.

67-68. **[*These questions are not asked in the first year of recruitment for Exam 5, since this information will be collected during the exam for a large proportion of the cohort. The following instructions are subject to change once they are activated in the Data Management System.*]**
If the participant is taking NO medications or the answer is otherwise unknown, skip question 68. If a participant supplies only part of their medications and will not provide the remaining medications taken, indicate this in the notelog to question 67. 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.

Once participant has all medications or prescriptions, read the following script.
"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.

As you type the medication name, the displayed list will change to provide possible medications with the same starting letters as you have typed in. 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.

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

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

H. ADMINISTRATIVE INFORMATION

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

A. Complete

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

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

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

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

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

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

VERIFICATION OF CONTACT INFORMATION UPDATE (CIU) FORM

Verify the items on the CIU 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 information on the contact people and the name of a follow-up proxy. The current data on file appear on the left hand side of the page, with blank spaces for corrections or changes provided on the right side. Information only needs to be entered in these blanks in the case of changes to the data. For example, a change of mailing address would be recorded as:

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

Any changes to the information in the CIU must be recorded in the database. The interviewer who updated the computer file enters his/her ARIC Staff Code Number.

CLOSING SCRIPT

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."

If participant deceased: "We may call back if we need more information. When would be a good time to call in that case?" The proxy informant can verify the Contact Information Update form.

Otherwise: "Thank you very much for answering these questions. We will call _____ in about a year." DO NOT verify the Contact Information Update form.

List #1: Commonly Used Aspirin-Containing Medications

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

List #1: Commonly Used Aspirin-Containing Medications

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

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

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

Appendix 1

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 (2011-2016). 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_____