INSTRUCTIONS FOR THE SEMI-ANNUAL FOLLOW-UP CORE QUESTIONS (11/06/2012) (SAF, VERSION 1, 12/15/2011)

I. General Instructions

Semi-annual follow-up of the ARIC Study cohort is used to maintain contact and update address information of cohort participants, ascertain vital status, document interim medical and life course events that occurred since the last contact, and obtain information about medical care. The semi-annual follow up is completed by telephone.

Semi-annual follow-up contacts should be scheduled once a year, to take place between annual follow-up interviews. The interview target date for the annual follow-up call is the participant's Visit 1 anniversary date; *the target date for the semi-annual interview is 6 months following the annual contact target date*.

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, availability and/or illness. ARIC protocol requires study personnel to adhere to the target dates in scheduling follow-up interviews, to the degree possible. Scheduling the annual or semi-annual calls earlier than the target period 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 semi-annual follow-up interview: the semi-annual follow-up Core Questions (SAF) and the General Interview. If the participant is unable to answer questions about his/her health and a proxy/informant or other person is contacted, only the semi-annual follow-up Core Questions are completed during the interview. The Death Information (DEC) is completed in addition to the semi-annual follow-up core questions in the event that the proxy/informant reports that the participant is deceased.

If during the course of the SAF interview, a participant requests a change in his or her consent level, such as access to medical records, use, storage or sharing of genetic material, 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 an annual or semi-annual phone call (see instructions for the ICT form).

As part of the SAF interview, it may also be necessary to request authorization to contact the participant's physician for information on selected health problems, additional to those reported by the participant. 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 SAF, the interviewer initiates the process (see below) that enables ARIC to send the physician a request to complete the Physician Heart Failure Form (PHF).

Consent to Release Protected Health Information

The PHF form is sent to a physician only after 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 needed to investigate admissions to emergency rooms or admissions to hospitals. While ARIC Exam 5 staff request permission to access medical records (from the participant or their proxy) at the time of consent for Exam 5, a signed medical release is also required for cohort participants who do not participate in Exam 5 if their response to the SAF determines the need to contact their provider of care.

Data entry screens accessed for the sAFU interview include:

1. Semi-Annual Follow-Up Core Questions (SAF)
2. Semi-Annual Follow-Up General Interview
3. Death Information (DEC)
4. Contact Information Update (CIU)
5. Physician Heart Failure Survey (PHF)
6. Informed Consent Tracking (ICT)

II. Semi-annual Follow-up Procedures

Preparation for SAF Interviews

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

1. The Semi-Annual Participant Tracing Report lists all IDs that are to be contacted for SAF a given time frame. It lists all participants who are to be contacted because their Visit 1 date anniversary + 6 months falls within the date range selected for the report, and how have not yet completed this contact.

   The Semi-Annual 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.

   The Semi-Annual Participant Tracing 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.

   In preparing for the semi-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 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 SAF (and also the AFU) 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 sAFU interview is the date 6 months following 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.

There are three likely situations when calling a participant for a follow-up interview:

1. They participated in Visit 5 and have been asked about consent to be contacted twice per year. Item 1 on the ICT indicates the current consent status for AFU and SAF for these participants.
2. They were called for annual follow-up and have been asked about consent to be contacted twice per year.
3. They have not yet been called since an AFU of version M or earlier and thus have not been asked about being contacted twice per year.

If the participant has a **blank value** for informed consent, we must obtain it:

"You may be wondering why ARIC is calling you earlier than the normal once per year. ARIC is asking all study participants if it would be okay to make contacts twice per year instead of once per year. This will make it easier for ARIC participants to remember the health information ARIC has been collecting by phone.. Do you give consent for ARIC to contact you twice per year?"

If the participant gave consent to be contacted only **once** per year:

Do NOT contact them for the semi-annual interview. Contact only during annual follow-ups.

If the participant **refused** contact (withdrew consent):

Do NOT contact them either for the semi-annual or the annual follow-up.

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 Semi-Annual 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 SAF Section, Item 1 for status codes). Assigning a status code at each contact is very important, as it is helpful in assigning the final SAF contact status (SAF Section A) if the participant is not successfully contacted.

When the SAF 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 SAF form.

Supervisor Review: The follow-up supervisor is responsible for reviewing instances when a participant is difficult to contact or the outcome is ambiguous. Among these are:

1. Refusals (attempt conversion).
2. Difficult contacts or other reasons for non-completion. The supervisor decides when it is no longer practical to continue attempts to contact a participant. All possible alternatives must be exhausted for this decision to be made.

Linkage between Semi-Annual Follow-up and Event Investigation

The procedures in place for the semi-annual follow-up call to insure that deaths and hospitalizations identified during semi-annual follow-up interviews are brought to the attention of the Surveillance staff for investigation remain in place for the semi-annual call. The Surveillance staff is notified of every cohort hospitalization, and an investigation is initiated by ARIC Surveillance. The hospitalizations sheet provides a check box to indicate that the information has been transmitted to the surveillance staff. No information pertaining to these hospital admissions 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 found 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 sAFU window, complete the SAF 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, the interviewer answers questions from the participant with neutral, nonjudgmental responses: questions other than those on the form 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 OR participant's) health in the last six months"?

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 SEMI-ANNUAL FOLLOW-UP, i.e., no earlier than the EARLIEST date and no later than the LATEST date on the Semi-Annual Participant Tracing Report.

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

A. STATUS

1. Result of contact for the interview. Enter the contact status code that describes whether or not the SAF 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: Contact was made with the participant and he/she agreed to be interviewed. The interview was done with the participant or someone who assisted the participant in answering the questions, i.e., not a proxy.

Action: Begin interview at item 4. If the interview is interrupted or the participant requests the interview be done at another time during a given time frame, complete E. ADMINISTRATIVE INFORMATION item 33. The interviewer will continue to attempt to contact during the given time frame.

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 this interview, or 2) refused this interview and future interviews (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 this interview was refused, go to Section E. ADMINISTRATIVE INFORMATION item 33 and enter A. Complete.

2. If this interview was refused for this year **and for future years**, go to Section E. ADMINISTRATIVE INFORMATION item 33, enter A. Complete and code the ICT form item 1 as 'Agree to once per year' OR ''do NOT agree to AFU contact-withdraw AFU consent' to reflect the consent status provided by the participant. Once this is done, no further sAFU 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 E. ADMINISTRATIVE INFORMATION item 33. 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 E. ADMINISTRATIVE INFORMATION item 33. 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 SAF completion status is not final, as further attempts will be made to complete the interview.

F. Window closed; unable to contact: Neither the participant, the proxy, nor another person was able to be contacted within the 3-month scheduling window.
Action: No action necessary; save and close form.

A. STATUS (ITEM 1)	E. ADMINISTRATIVE INFORMATION (ITEM 33)	EXPLANATION
A	**A**	The participant was successfully contacted and the entire interview, including the questionnaire and hospitalization information was completed.
A	**B**	The participant was successfully contacted and agreed to be interviewed but the interview is incomplete or was not done at all due to interruptions. This may be a temporary status if it is possible that the interview may be completed at a later date within the given time frame.
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 given time frame. 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.
B	**C**	The participant was successfully contacted and vital status obtained, but the interview was not done and is not completed within the given time frame.
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	**--**	1. Attempts are being made to locate the participant, but so far neither the participant nor another reliable source has been contacted. 2. 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 the given time frame through further efforts. For example, "temporarily away" would fit in this category.
F	**--**	Neither the participant nor another source of information was contacted that could provide reliable vital status data during the specified date range.

2. Indicate whether the participant deceased. If yes, go to Section E. ADMINISTRATIVE INFORMATION item 33 and enter A. Complete. Then complete the DEC form.

B. CARDIOVASCULAR EVENTS

3. Indicate whether the respondent is able to answer questions about the participant's health. If yes, go to item 4.

3a. 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 E. ADMINISTRATIVE INFORMATION item 33 and code as 'Partially complete - interruptions' and get contact information for the person. Ensure the information is in the CIU.

4. If the Participant Tracing Sheet indicates that a doctor previously said that the participant had heart failure or congestive heart failure, enter yes and go to item 10.

4a. If yes, go to item 6a.

5. If the Participant Tracing Sheet indicates that a doctor previously said that the participant's heart was weak, or did not pump as strongly as it should, or that the participant had fluid on the lungs, enter yes and go to item 10.

5a. If yes, enter the doctor information for weak heart. If no, go to item 10.

Relation of the answers to items 4a and 5a to item 8 in SAF version 1. In the previous version of the AFU (AFU v. 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 8 ("Were you hospitalized at that time?").

6-6e. These items are only completed for participants who have never reported heart failure or a weak heart. The name of the physician or practice who indicated that the cohort member has heart failure or has a weak heart is recorded on line 6a. 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 facility, 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 6b-6c. Then enter the date heart failure or weak heart was diagnosed in month/year format (specific day is not needed) and proceed to item 7. If in the sequence of items 4-6e 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 8 (Were you (Was [name]) hospitalized at that time?). If the answer to item 8 is Yes, the hospital or medical facility is recorded in items 9a or 9a1, even if it corresponds to the same facility recorded in items 6a-6d.

7. 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 SAF 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 7 is set to 'Not applicable.'

8. 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.

9a-9b. 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).

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

11. Indicate whether the participant was hospitalized for a heart attack, as conformed at discharge from the hospital. It is not unusual for a patient to be admitted for a heart attack but discharged with a diagnosis other than a heart attack, such as an arrhythmia (uneven heart rate), typical or atypical chest pain that does not progress to a heart attack, or even esophageal reflux (indigestion). Such situations are recorded a No.

12a-12b. 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 13a-13b for a second hospitalization.

14. A positive response to any 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).

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

16. This question specifically asks about physician-diagnosed stroke, slight stroke, transient ischemic attack, or TIA. If no, go to item 19.

17. Indicate whether the participant was hospitalized for stroke or TIA. If not, go to item 19.

18a-18b. 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).

C. OTHER ADMISSIONS

19. 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

20a-24c. 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).

25. These questions ask 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.

26. These 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.

27a-b 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.

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

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

D. 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.

30. 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.

31a. Definition of coronary artery bypass is provided in the table of Definitions and Synonyms of Diagnostic and Therapeutic Procedures.

31b. Examples of other heart procedures are provided in the table of Definitions and Synonyms of Diagnostic and Therapeutic Procedures.

31c-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.

31e. Examples of other arterial revascularizations are provided in the table of Definitions and Synonyms of Diagnostic and Therapeutic Procedures.

31f. Indicate any other surgery on the heart or arteries of the neck or legs.

32 and 32c. 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.

If the response for item 32 is NO, and **you interviewed the participant directly** (i.e.,item 1 is entered as 'a. Participant contacted, agreed to be interviewed'), go to Section E. ADMINISTRATIVE INFORMATION item 33, and **then complete the GENERAL INTERVIEW form**.

If the response for item 32 is NO, and you interviewed someone other than the participant (i.e.,item 1 is entered as 'c. Proxy/Informant contacted' or 'd. Other person contacted',) go to Section E. ADMINISTRATIVE INFORMATION item 33.

DEFINITIONS AND SYNONYMS FOR THERAPEUTIC AND DIAGNOSTIC PROCEDURES

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

	bypass (from leg veins) 3, (4-5, etc.). Vessel bypass.	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

CLOSURE SCRIPT:

If Proxy/Informant/Other person contacted: "Thank you very much for answering these questions. We will call you in about six months."

E. ADMINISTRATIVE INFORMATION

33. SAF core questions completion status. Enter the code that describes whether or not the SAF core questions were 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 given time frame. 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 SAF Core Questions Completion Status for the given time frame 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 given time frame.

When the SAF core questions have 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.

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_____