INSTRUCTIONS FOR THE SEMI-ANNUAL FOLLOW-UP CORE QUESTIONS (10/22/2020) (SAF, VERSION 3, 01/11/2023)

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, four forms are routinely completed during the semi-annual follow-up interview: the semi-annual follow-up Core Questions (SAF), the General Interview, the Medical Conditions Update Form (MCU) and the Contact Information Update Form (CIU) 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, the Medical Conditions Update form (MCU) and the Contact Information Update Form (CIU) are completed during the interview. The MCU is not completed for deceased participants. The Death Information (DEC) and the AD8 Dementia Screening Interview (ADS) are 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).

Reports available through the Data Management System

Two reports are available to assist field centers in scheduling sAFU interviews: the Semi-Annual Tracing Report lists IDs for all participants to be contacted for sAFU during a given interval and contact year; the Semi-Annual Tracing Sheet provides the most recent consent status and other pertinent information for a given cohort participant. When needed to determine the last time actual contact was made with the participant, a third report, the Contact History report, is available to display all prior cyclic contacts with the participant or participant's representative.

Data entry screens accessed for the sAFU interview include:

1. Semi-Annual Follow-Up Core Questions (SAF)
2. Medical Conditions Update Form (MCU)
3. Semi-Annual Follow-Up General Interview

4. Death Information (DEC)
5. AD8 Dementia Screening Interview (ADS)
6. Contact Information Update (CIU)
7. Physician Heart Failure Survey (PHF)
8. 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 IDs for all participants to be contacted for SAF for a given contact year and 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 who 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.

2. 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. 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 date can be sought by using the Contact History Report, which lists the final status of all cyclical contacts with the participant or participant’s representative. Use this date with 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 next annual call. ARIC is asking all study participants if it would be okay to make contact 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 and/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 Scenarios

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

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

3. At AFU, **participant** completes interview; a while later, participant's obituary is published
   - Complete **DEC** Section A. DEATH INFORMATION Q1-3 & Section F. ADMINISTRATIVE INFORMATION Q13 (select "b").
   - When the proxy is interviewed about the death, complete **SAF** Section A. STATUS, Section F. 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. Complete the ADS.

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. Complete the ADS.

The protocol with regards to discontinuation of dementia surveillance stated in ARIC Dementia Surveillance Manual 20 applies to the above Participant Death Scenarios. The administration of the ADS is discontinued if 1) an Impaired score is recorded on the ADS prior to the deceased interview, or 2) two SIS interviews are scored as Impaired prior to the deceased interview, or 3) an ADS has been administered within 1 year of the participant's death, and this ADS was scored as not Impaired.

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 <u>ever</u>") 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.

<u>Script</u>: "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 recent health"?

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.

If exceptional circumstances require that the follow-up interview be collected by email or mail instead of by phone, record "Data were collected by email" or "Data were collected by mail." in the note log field for Q0a, to document this.

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. If the interview is done with the participant and the responses are confirmed or updated per a proxy/informant, record item 1 as 'A. Participant contacted, agreed to be interviewed' and add 'Confirmed with proxy/informant' in the notelog for item 1.

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 2a. If the interview is interrupted or the participant requests the interview be done at another time during a given time frame, complete F. 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 F. ADMINISTRATIVE INFORMATION item 33 and enter A. Complete, and then add a note in the administrative information field (Question 0g) on the CIU to indicate when you may contact the participant again.

2. If this interview was refused for this year **and for future years**, go to Section F. 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.
Action: Begin interview at Item 2. If the respondent is unable to provide reliable information about the participant go to Section F. 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 F. 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)	F. 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 F. ADMINISTRATIVE INFORMATION item 33 and enter A. Complete. Then complete the DEC form. If no, continue with Q2a.

B. CANCER INFORMATION

2a. This question asks the participant/proxy/informant to recall a diagnosis of cancer since the last contact. If the participant/proxy/informant does recall a diagnosis of cancer, record 'Yes' for this item. If the participant/proxy/informant responds that they do not know if there was a diagnosis of cancer, record 'No' and go to item 10.

2a1. This question asks about the location of the reported cancer. Record the part of the body in which the cancer was diagnosed.

The participant/proxy/informant may be non-specific about the type of cancer. For example, they may report a "female cancer", "cancer of the womb", or "blood cancer". If the participant is non-specific about the type of cancer, you may use the probe "Could you be more specific?" Record the response in 28a.

2b. Enter the approximate date of the cancer diagnosis in month/year format (specific day is not needed).

2c1-2d. Questions regarding 'doctor information for cancer' and 'permission to send the release form to the participant' have been disabled in CDART.

C. <u>CARDIOVASCULAR EVENTS</u>

3. Indicate whether the respondent is able to answer some more questions about the participant's health. If yes, go to item 10.

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

4-9b. Questions were moved to MCU form and no longer accessible in the SAF.

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

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).

14a. 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.

14b. Indicate whether the participant was hospitalized for a blood clot in the leg or deep vein thrombosis (DVT). This includes observation stays in a hospital for a blood clot in the leg or deep vein thrombosis.

14c-14d. 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).

15. This question was moved to MCU form and no longer accessible in the SAF.

15a. This question specifically asks about physician-diagnosed blood clot in the lungs or pulmonary embolus. If no, go to item 16.

15b. Indicate whether the participant was hospitalized for a blood clot in your lungs or a pulmonary embolus. If no, go to item 16.

15c-15d.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).

16. This question specifically asks about physician-diagnosed stroke, slight stroke, transient ischemic attack, or TIA. A “stroke in the eye” or blockage of a blood vessel in the retina qualifies as a stroke and is recorded as Yes to this question. If the participant responds that s/he had an episode of Transient Global Amnesia (TGA) but was unsure whether that was a TIA, the question should be recorded as No. 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).

D. OTHER ADMISSIONS

19. This question asks the participant/informant to recall whether they had any **overnight** hospitalizations or overnight observation stays in a hospital since their last contact that they have not yet mentioned. This includes observation stays in a hospital, but interviewers should not probe whether these were inpatient or outpatient admissions.

If there was a positive response to overnight hospitalizations or observation for any 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, and does NOT include being seen in an emergency room or urgent care facility for outpatient treatment and sent home. Use neutral probes to elicit <u>all</u> hospitalizations. For the (first) overnight stay, record the reason for the hospitalization, the hospital name, city, and state, and the discharge date (month and year) of the hospitalization. Probe for additional hospitalizations

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).

Starting in Nov 2020, priority is given for reporting COVID-19 hospitalization to the surveillance/abstractor staff at your field center. If the reason for hospitalization is COVID-19 related, please relay this information on to abstractor staff, using existing field center procedures, but in an expedited fashion. At a minimum, the CEL (including ICD-10 codes) should be entered in CDART as soon as possible.

25-26. The intent of these two questions, in sequence, is to capture visits to an emergency room or medical facility for outpatient treatment related to difficulty breathing or a heart problem. This could include outpatient treatment of angina, blood clots, heart failure, or angioplasty.

These two questions are specifically trying to identify any OTHER cardiovascular events or procedures that may have occurred in the outpatient setting (the participants have already been asked explicitly about being 'hospitalized' [but not necessarily clarifying overnight or not] for heart attack, blood clot in leg, blood clot in lungs and stroke/TIA [refer to item 11 on the SAF form, item 14 on the MCU form, and items 15b and 17 on the SAF form], and have further been asked about OTHER OVERNIGHT hospitalizations. If the participant answers 'yes' to both #25 and #26, then answer items 27a, 27a1 and 27b. Otherwise, the form skips to item 28.

27a-b These questions ask the participant/informant to recall emergency room visits or other medical facility visits for outpatient treatments related to difficulty breathing or heart problems. 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 visit date in month/year format (specific day is not needed). Although the name of the facility and the date of visit are recorded, a release of protected health information is not requested.

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.

E. <u>INVASIVE PROCEDURES</u>

In reading this script, emphasize that "we are interested in procedures that occurred in the hospital, or as an outpatient." 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.

Script: " Next I am going to ask about various types of surgery and medical procedures. We are interested in those that occurred in the hospital, or as an outpatient."

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. If the participant seems unclear about reporting a procedure that was not conducted in a hospital, mention again that "we are interested in procedures that occurred in the hospital, or as an outpatient."

32a- 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. If the participant has had a revascularization procedure for more than one of these arteries, record this information for the last/latest revascularization.

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 F. ADMINISTRATIVE INFORMATION item 33, and **then complete the GENERAL INTERVIEW form and MCU**.

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 F. ADMINISTRATIVE INFORMATION item 33 and complete the MCU.

32d-f. Enter the date the invasive procedure was performed, or the admission if applicable, 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. If the facility reported is a hospital, do not update any previous entries on hospital admissions on this form.

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	ECG

	produced by the heart.	EKG
TREADMILL CARDIAC STRESS TEST	An exercise test on a treadmill, bicycle, or similar device in which people increase their heart rate in order to have the function of the heart measured, usually by ECG.	
THALLIUM SCAN OF THE HEART SPECT	A computer image of the heart done by injecting in a dye into the bloodstream. Computer-generated pictures then find them in the heart. These tests show how well the heart muscle is supplied with blood, how well the heart is functioning, or identify a part of the heart damaged by a heart attack.	Heart Scan
HOLTER MONITOR	A small, portable ECG machine worn by patients.	
HEART RHYTHM or CONDUCTION STUDIES	Invasive procedures, usually performed under anesthesia, to assess cardiac arrhythmias. Catheters are placed in the heart to map the spread of electrical impulses during each heartbeat.	
CAROTID ULTRASOUND STUDIES	A diagnostic method in which pulses of sound are transmitted into the neck arteries and the echoes returning from the surfaces of the artery walls are electronically plotted to produce a picture of a small portion of the carotid artery showing the amount of atherosclerosis (hardening of the arteries) that can be seen in the arterial wall.	Echo
CAT SCAN of BRAIN	A non-invasive diagnostic technique, which produces an image of the brain and can identify abnormalities.	Cerebral CAT scan
CORONARY BYPASS or BYPASS SURGERY	Surgery to improve blood supply to the heart muscle. This surgery is performed when narrow coronary arteries reduce the flow of oxygen-containing blood to the heart. Vein bypass (from leg veins) 3, (4-5, etc.). Vessel bypass.	CABG “cabbage operation” Bypass graft or operation
OTHER HEART PROCEDURES	Examples include valve replacement, ventricular aneurysm resection, Aortic Stenosis, Ventricular Stenosis. Defect repair, Patent ductus closure, Pacemaker, Implantation of automatic defibrillator, Coronary atherectomy.	
ENDARTERECTOMY	Surgery to take out plaque from an artery, to	

	restore blood flow in one or both of the arteries in the neck.	
OTHER ARTERIAL REVASCULARIZATION	Any procedure where additional blood flow is brought to an artery via a bypass from a location elsewhere in the body.	
BALLOON ANGIOPLASTY	A procedure used to dilate (widen) narrowed arteries. A catheter with a deflated balloon angioplasty on its tip is passed into the narrow artery segment, the balloon inflated, and the narrow segment widened. Angioplasties can now also be done by laser. To keep arteries from collapsing, stents (stainless steel supports) can be inserted into the artery during angioplasty.	Percutaneous angioplasty Balloon dilation Balloon test / procedure PTCA Stent(s)
CATHETERIZATION	A procedure used to examine the heart or an artery by introducing a thin tube (catheter) into a vein or artery (e.g., carotid artery).	Angiography

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.

CLOSURE SCRIPT:

If participant deceased: "We may need to contact a family member later. When would be a good time to call in that case?"