INSTRUCTIONS FOR THE ANNUAL FOLLOW-UP INTERVIEW (AFU, VERSION 4, 06/01/2023) AND PARTICIPANT TRACING REPORTS QxQ 06/01/2023

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, four forms are routinely completed during the annual follow-up (AFU) interview: the AFU Questionnaire, the Six Item Screener (SIS) or the AD8 Dementia Screening Interview (ADS), the Medical Conditions Update Form (MCU), the Contact Information Update Form (CIU, formerly the UPD - Update Form). An important 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).

Reports available through the Data Management System

Two reports are available to assist field centers in scheduling AFU interviews: the Participant Tracing Report lists IDs for all participants 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. 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 for the AFU interview:

1. Annual Follow-Up Questionnaire (AFU)
2. Six Item Screener (SIS)/AD8 Dementia Screening Interview (ADS)
3. Medical Conditions Update Form (MCU)
4. Contact Information Update (CIU)
5. Physician Heart Failure Survey (PHF)
6. Informed Consent Tracking (ICT)

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 IDs for all participants 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. 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 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 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 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 and/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 G) 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 Scenarios

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

2. At semi-AFU, **Proxy** reports participant death
   - Complete **SAF** Section A. STATUS, Section E. 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 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. 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 G. 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, 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 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 ANNUAL FOLLOW-UP, i.e., no earlier than the EARLIEST date and no later than the LATEST date on the 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 AFU 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:
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 G. 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 G. ADMINISTRATIVE INFORMATION item 71 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 the interview was refused for this year **and for future years**, go to Section G. 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.
Action: Begin interview at Item 2. If the respondent is unable to provide reliable information about the participant go to Section G. 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 G. 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)	G. 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 G.

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. Indicate whether the participant was hospitalized for a heart attack, or heart condition, or stroke since the previous contact AFU interview. 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).

8a-9b. 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 9a-9b for a second hospitalization.

10. This question asks the proxy/informant to recall whether the participant had any **overnight** hospitalizations or overnight observation stays in a hospital for any other reason since his/her last contact. 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 he/she was admitted overnight as a patient in a hospital, I would like to obtain the reason he/she was admitted, the name and location (city, state) of the hospital, and the date.' When was the first time he/she was hospitalized since our last contact with 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. These types of visits are recorded in items 14-16b.

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.

11a-13c. Record information on all hospitalizations reported since the time of last contact. There is space to complete 3 hospitalizations. If there are more than 3, enter the 3 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.

14-15. The intent of these two questions, in sequence, is to capture visits of the deceased participants 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. If the informant answers 'yes' to both #14 and #15, then answer items 16a, 16a1 and 16b. Otherwise, the form skips to item 71.

16a-16b. These questions ask the proxy/informant to recall emergency room visits or other medical facility visits of the deceased participants for outpatient treatments related to difficulty breathing or heart problems. Collect and record the date of this visit. Remind the informant that this is the participant's 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.

C. GENERAL HEALTH

Script: "Now I will ask you some questions about your 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.

18-20. Questions were moved to MCU form and no longer accessible in the AFU.

21a, 21d, 21e, 21f and 23. Questions were discontinued in AFU Version 4.0 and no longer accessible in the AFU.

22, 21b and 21c.These items ask about respiratory signs and symptoms that may be indications of heart failure (or a combination of heart failure and chronic respiratory disease).

24-25. Questions were moved to MCU form and no longer accessible in the AFU.

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

27. This question does not specify a frequency of the reported swelling, for comparability with other surveys and because we are recording a subjective assessment by the participant. If the participant requests guidance in defining "often" the interviewer provides a non-directive synonym, such as "frequently" or "on most days." If based on this the participant still is unable to answer, the definition of often given to the participant is "on most days of the week, for at least one month." If the swelling is unilateral (affects only one foot or ankle) record No. If a participant has one leg, record Yes if the participant reports swelling in the foot or ankle at the end of the day.

27a. Indicate whether the swelling in the feet or ankles is gone in the morning.

28. 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'.

28a. 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/proxy/informant is non-specific about the type of cancer, you may use the probe "Could you be more specific?" Record the response in 28a.

28b. Enter the approximate date of the cancer diagnosis in month/year format (specific day is not needed).

28c1-28d. Questions regarding 'doctor information for cancer' and 'permission to send the release form to the participant' were discontinued on April 30, 2018 and no longer accessible in the AFU.

29-29a. Determine whether the respondent is able to answer some more 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 G. ADMINISTRATIVE INFORMATION item 71 and code as 'Partially complete - interruptions' and get contact information for the person. Ensure the information is in the CIU.

30-35 and 41. Questions were moved to MCU form and no longer accessible in the AFU.

36-50b. Questions were discontinued in AFU Version 4.0 and no longer accessible in the AFU.

D. ADMISSIONS

51. 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. 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. These types of visits are recorded in items 57 – 59.

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.

52a-56c. 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.

57-58. 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 37 on the AFU form, item 14 on the MCU form, and items 46 and 49 on the AFU form], and have further been asked about OTHER OVERNIGHT hospitalizations. If the participant answers 'yes' to both #57 and #58, then answer items 59a, 59a1 and 59b. Otherwise, the form skips to item 60.

59a-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.

60. This question asks whether a participant has stayed overnight as a patient in a care facility. A care facility can include an assisted living facility or a nursing home. A nursing home refers to a skilled nursing facility or an extended care facility.

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

E. INVASIVE PROCEDURES

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 in an emergency department, or as an outpatient."

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-f: Question were discontinued in AFU Version 4.0 and no longer accessible in the AFU.

64 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."

64a-c. Questions were discontinued in AFU Version 4.0 and no longer accessible in the AFU.

64d-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 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 produced by the heart.	ECG EKG
TREADMILL CARDIAC STRESS TEST	An exercise test on a treadmill, bicycle, or similar device in which people increase their heart rate in order to have the function of the heart measured, usually by ECG.	
THALLIUM SCAN OF THE HEART SPECT	A computer image of the heart done by injecting in a dye into the bloodstream. Computer-generated pictures then find them in the heart. These tests show how well the heart muscle is supplied with blood, how well the heart is functioning, or identify a part of the heart damaged by a heart attack.	Heart Scan
HOLTER MONITOR	A small, portable ECG machine worn by patients.	
HEART RHYTHM or CONDUCTION STUDIES	Invasive procedures, usually performed under anesthesia, to assess cardiac arrhythmias. Catheters are placed in the heart to map the spread of electrical impulses during each heartbeat.	
CAROTID ULTRASOUND STUDIES	A diagnostic method in which pulses of sound are transmitted into the neck arteries and the echoes returning from the surfaces of the artery walls are electronically plotted to produce a picture of a small portion of the carotid artery showing the amount of atherosclerosis (hardening of the arteries) that can be seen in the arterial wall.	Echo
CAT SCAN of BRAIN	A non-invasive diagnostic technique, which produces an image of the brain and can identify abnormalities.	Cerebral CAT scan
CORONARY BYPASS or BYPASS SURGERY	Surgery to improve blood supply to the heart muscle. This surgery is performed when narrow coronary arteries reduce the flow of oxygen-containing blood to the heart. Vein bypass (from leg veins) 3, (4-5, etc.). Vessel bypass.	CABG "cabbage operation" Bypass graft or operation
OTHER HEART PROCEDURES	Examples include valve replacement, ventricular aneurysm resection, Aortic Stenosis, Ventricular Stenosis. Defect repair, Patent ductus closure, Pacemaker, Implantation of automatic defibrillator, Coronary atherectomy.	
ENDARTERECTOMY	Surgery to take out plaque from an artery, to restore blood flow in one or both of the arteries	

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

F. 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 four weeks".

Script: "Now I would like to ask about medication use during the past four weeks."

65. Indicate whether the participant took any medications prescribed by a health professional during the past four weeks.

65a-m. These questions ask about medications prescribed for specific conditions. 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. Participants can be told that we are not collecting medication names but whether they are taking a medication prescribed by a health professional for one of the conditions we are asking about. It is acceptable for participants to report taking a medication for more than one condition.

65i. Aspirin prescribed by a health professional qualifies as Yes for item 65i (blood thinning).

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

66. This question documents the regular use of aspirin or aspirin containing medications (i.e. Alka-Seltzer, cold and allergy medication or headache powder) on a regular basis, regardless of the amount, or the reason for its use. If asked by the participant, "regular" is defined as at least once a week for several months. These medications do not include acetaminophen (for example, Tylenol), ibuprofen (for example, Advil, Motrin or Nuprin), and naproxen (for example, Aleve). 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.

66a. This question documents the current use of medications on a regular basis for pain or inflammation that do not contain aspirin, regardless of the amount. These medications include Tylenol, Advil, Motrin, Nuprin, Midol, or Ibuprofen among others. If taken for pain or inflammation, the use of cannabidiol (CBD), one of the chemical compounds found in marijuana and hemp, is recorded as Yes for item 66a.

67-68. These questions were removed from version 2.0 and 3.0 of the AFU form and deactivated in the Data Management System.

Script: "Next, I have a few miscellaneous questions."

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. E-cigarettes are considered a tobacco product and therefore would be coded as "Yes".

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.

G. 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.

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?"

List #1: Commonly Used Aspirin-Containing Medications

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

List #1: Commonly Used Aspirin-Containing Medications

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