

INSTRUCTIONS FOR THE ANNUAL FOLLOW-UP TRACING FORM AND QUESTIONNAIRE
AFU, VERSION C, 05/08/90
PREPARED 07/06/90

I. GENERAL INSTRUCTIONS

Annual follow-up of the ARIC Study cohort is used to (1) maintain contact and correct address information of cohort participants and (2) ascertain interim medical events between the three-year comprehensive examinations. Annual follow-up contacts are scheduled approximately every 12 months after the participant's clinic examination. Each follow-up is completed by telephone (preferred) or in person (if necessary). The follow-up call in CY02 and CY04 is preceded by a letter sent by mail about two weeks in advance of the call.

Two data collection forms are used in completing the annual follow-up. The ARIC Annual Follow-Up Tracing Form is a computer-generated paper form which contains a "Participant Tracing Information Sheet" to use to update selected tracing information. The ARIC Annual Follow-Up Form contains a "Record of Calls" cover page for use in contacting a participant, the Annual Follow-up Questionnaire used to record vital status information and to gather information on the participant's cardiovascular health since their clinic visit, and a "Hospitalizations" section to record information on any hospitalizations. The questionnaire should always be completed on paper and then batch-entered into the local database. AFU Contact Years 02 and 03 should be entered into the Visit 1 ARDES, and contact years 04, 05, and 06 should be entered in the Visit 2 system.

Contact Year 04 AFU will also include the scheduling of the second clinic visit. If the participant refuses or does not show for a visit in Contact Year 04, scheduling should also be attempted in Contact Years 05 or 06.

II. ANNUAL FOLLOW-UP PROCEDURES

A. Contacting Procedures and Rules

The Coordinating Center periodically generates the ARIC Annual Follow-Up Tracing Forms for a group of participants. This form contains the tracing information needed to contact the participant.

The "Contact Year Date Range" appearing on the "Record of Calls" is determined as follows:

The Target date is the one-year anniversary of the participant's first clinic visit.

The Earliest date falls six months prior to the Target date.

The Latest date falls six months after the Target date.

For example, if a participant's clinic visit occurred on 11/14/86, then the target date for contact year 2 is 11/14/87. The earliest date of contact is 5/14/87, and the latest date is 5/13/88. In future years, these dates include the same month and day:

<u>Contact Year</u>	<u>Earliest</u>	<u>Target</u>	<u>Latest</u>
02	5/14/87	11/14/87	5/13/88
03	5/14/88	11/14/88	5/13/89
04	5/14/89	11/14/89	5/13/90
05	5/14/90	11/14/90	5/13/91

The initial call for annual contact should be no more than three weeks or so before the target date except in CY04, in which the contact can be made up to 4 months earlier to aid clinic scheduling. Ideally, the contact should take place as closely as possible to the "Target" date. If for some reason contact is not made until after the "Latest" date, this contact must be assigned to the following Contact Year. This is described in more detail in the section on vital status below.

The "Participant Tracing Information Sheet" contains detailed information to be used in contacting the participant. It is generated as part of the tracing form. Refer to the separate protocol section on tracing for special procedures to use in difficult cases.

As mentioned previously, the first step in the contacting procedures in CY02 and CY04 is a letter sent to the participant about two weeks prior to the first attempted phone call. Before placing the phone call, the interviewer assembles the participant's computer-generated tracing form (provided by the Coordinating Center), the Annual Follow-up (AFU) form, the accompanying QXQ instructions, and an appointment calendar for scheduling Visit 2.

NOTE: Cohort participants who have moved outside of the study area are still traced and interviewed, and hospitalization or death information is obtained if necessary.

B. Performing the Interview

Form sections are completed in the following order:

- 1) Record of Calls
- 2) Questionnaire
- 3) Hospitalizations
- 4) Appointment scheduling (if due)
- 5) Tracing Form: Verification of Tracing Information

If an appointment is to be scheduled with more than one respondent, it may be easier to conduct all interviews first and then schedule appointments together.

Each of these sections is described below.

1. Record of Calls

The Record of Calls is used to keep track of attempts to contact a participant and appointment scheduling. One line should be used for each attempted contact. For each attempted contact, a result code is assigned. This is very important, as it may be necessary for determining the final vital status in the event that the participant is not successfully contacted. Result codes for contacts (with possible final codes indicated by *) are:

- 1: "No Action Taken" - No attempt has yet been made to contact the participant.

- 2: "Tracing" - Attempts are being made to locate the participant, but so far neither the participant nor another reliable source have been contacted.
- * 3: "Contacted, Interview Complete" - The participant was successfully contacted by phone or in person, and the entire interview, including the questionnaire and hospitalization information was completed.
- * 4: "Contacted, Interview Partially Complete or Rescheduled" - The participant was successfully contacted by phone, letter, or in person, but the interview is incomplete or was not done at all. This may be a temporary code if it is possible that the interview may be completed at a later date within the same contact year.
- * 5: "Contacted, Interview Refused" - The participant was successfully contacted by phone, letter, or in person, but the interview was not done and will not be completed at a later date within the same contact year.
- 6: "Reported Alive, Will Continue to Attempt Contact This Year" - 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.
- * 7: "Reported Alive, Contact Not Possible This Year" - Reliable information indicates that the participant is living, but direct contact has not yet been made. This code should be used only if repeated contact attempts have been made, or when it has been determined that it is not possible that contact will be made during this same contact year.
- * 8: "Reported Deceased" - Reliable information indicates that the participant has died.
- * 9: "Unknown" - Neither the participant nor another source of information has been contacted in a manner sufficient to provide reliable vital status data during the specified date range.

Appointment codes (with possible final codes indicated by *) are:

- * 00: "Appointment Made"
- * 01: "Has Moved and Cannot Return for Exam"
- * 02: "Physically Unable to Attend Clinic:"
- * 05: "Refusal"
- 06: "Other"-- Includes appointment not yet set.

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

- a. Refusals (attempt conversion).
- b. Difficult contacts or other non-completes. In particular, the supervisor decides when it is no longer practical to continue to investigate a person. All possible alternatives must be exhausted for this decision to be made.
- c. Undocumented deaths. If a death is reported for which no death certificate can be located, the supervisor reviews the case and attempts to resolve it. If no death certificate is ultimately located, including an NDI search, the vital status may be changed to "Unknown."

2. Questionnaire

Once direct contact has been made with the participant, the interviewer should begin by reading the following script:

INTRODUCTION: Hello, this is (YOUR NAME) from (NAME OF INSTITUTION) and I'm calling for the National Institutes of Health ARIC study. (NAMES(S) OF PARTICIPANT(S)) has/have been taking part in the study since (DATE OF FIRST VISIT). May I please talk with (NAME(s) OF PARTICIPANT(s))?

DETERMINE PARTICIPANT'S AVAILABILITY AND VITAL STATUS.

IF DECEASED, OFFER CONDOLENCES, THEN GET DATE AND LOCATION OF DEATH (STARTING WITH ITEM 4). AT END OF INTERVIEW, INFORM RESPONDENT OF POSSIBLE NEED TO CONTACT A FAMILY MEMBER LATER, AND ASK BEST TIME TO CALL IN THAT CASE.

WHEN PARTICIPANT IS ON THE LINE (CY02, CY03, CY05, CY06), READ: Hello, this is (YOUR NAME) from (NAME OF INSTITUTION) and I'm making an annual contact call for the National Institutes of Health ARIC study. I would like a few minutes of your time to find out about your health in the past year (lead in to item 6.)

WHEN PARTICIPANT IS ON THE LINE (CY04), READ: Hello, this is (YOUR NAME) from (NAME OF INSTITUTION) and I'm making an annual contact call for the National Institutes of Health ARIC study. I would like a few minutes of your time to find out about your health in the past year and, as explained in our letter, to schedule your next visit for an examination at the ARIC Field Center (lead in to item 6.)

Instructions for the Annual Follow-up questionnaire are given below:

A. VITAL STATUS

1. Date of status determination:

		/			/		
Month			Day			Year	

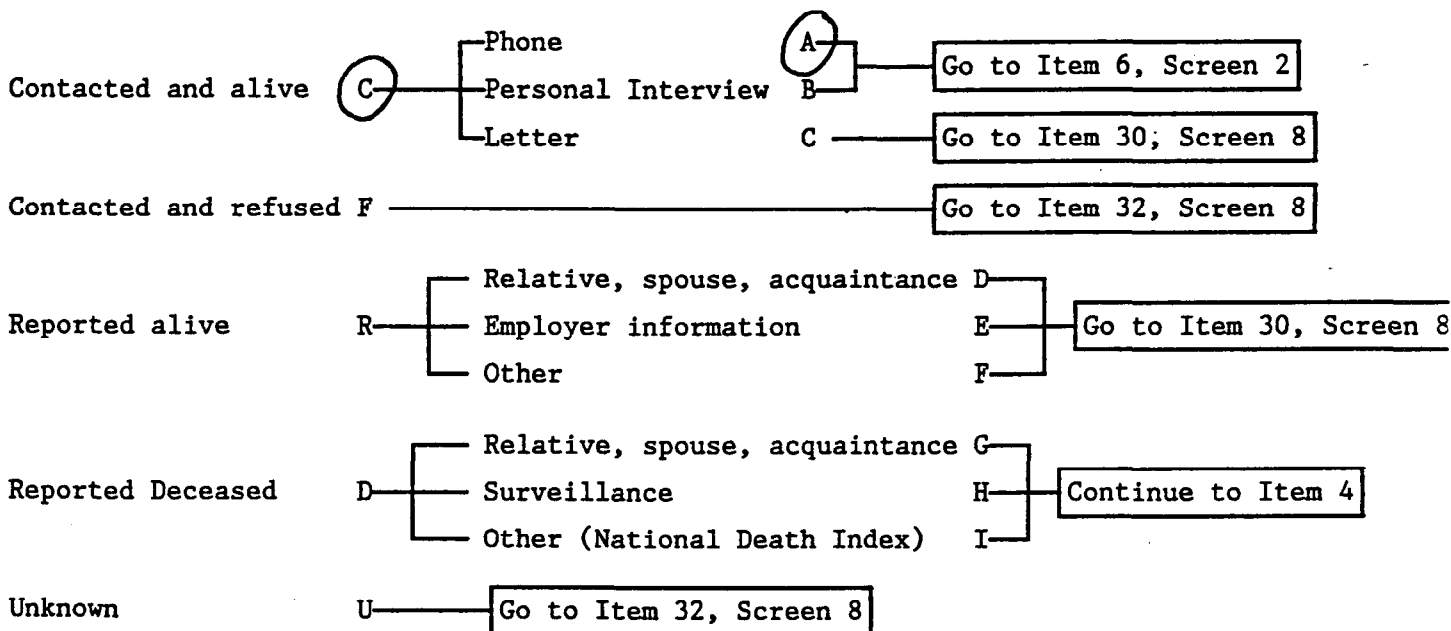
The date of status determination is the date on which the participant's final vital status became known to the interviewer (see item 2 below). THIS DATE MUST FALL WITHIN THE PARTICIPANT'S CONTACT YEAR UNLESS THE STATUS IS "UNKNOWN," i.e. no earlier than the "Earliest" date given on the Tracing Form and no later than the Latest Date on that form. It is generally the last date on the "Record of Calls."

2 & 3. Final Status / Information obtained from:

Record the final vital status of the participant for the present contact year, and indicate the source of that information. THE RESPONSE TO ITEM 3 MUST CORRESPOND TO ITEM 2 AS SHOWN ON THE FORM. Thus, if item 2 is "C" then item 3 must be "A," "B," or "C". Similarly, if item 2 is "R", then item 3 must be "D," "E," or "F." If item 2 is "D," then item 3 must be "G," "H," or "I." After completing item 3, follow the corresponding skip rule indicated for that response.

Example: If the participant was contacted over the phone, record as:

2. Final Status: 3. Information obtained from:
 {Circle one below} {Circle one corresponding choice below}



In this situation, continue the interview by going to item 6 on screen 2.

The following are the criteria for each final status:

Contacted and alive (C): The participant has been directly contacted in some way by the ARIC Field Center during the present contact year. This contact preferably takes the form of a phone call or personal interview (so that the entire questionnaire can be administered), but a letter written by the participant is also acceptable for assigning this status. In this last case, it is obviously not possible to ask the remaining questions on the form. Note that this status corresponds to a final result code of 3, 4, or 5 on the "Record of Calls."

Contacted and refused (F): The participant has been directly contacted in some way by the ARIC Field Center during the present contact year, but he/she refused to answer the annual follow up questions.

Note: In Year 04, do not confuse this AFU status with refusing an appointment (code 05 of appointment codes). "Contacted and refused" as a final status refers to the AFU questionnaire only.

Reported alive (R): Reliable information indicates that the participant is living, but direct contact has not yet been made. If this is the final status, it is therefore implied that it is not possible that contact will be made during this same contact year. Since one would generally continue to make attempts at a direct contact up until the "Latest" date, it is reasonable that the "date of status determination" would fall on or just before that "Latest" date, when this is the final status. Note that this status corresponds to a final result code of 7 on the "Record of Calls." Reliability of the information is evaluated by supervisor review. It is therefore important to document the source in as much detail as possible.

Reported Deceased (D): Reliable information indicates that the participant has died. In this case, the "date of status determination" is the date on which the death became known to the ARIC Field Center, NOT the date of death. Note that this status corresponds to a final result code of 8 on the "Record of Calls." Reliability of the information is evaluated by supervisor review. It is therefore important to document the source in as much detail as possible.

Unknown (U): Neither the participant nor another source of information has been contacted in a manner sufficient to provide reliable vital status data. In this case, the "date of status determination" is the date on which the unknown status is being assigned or the participant's "Latest" contact date for the specified Contact Year, whichever is earlier. Note that this status corresponds to a final result code of 9 on the "Record of Calls."

NOTE: ONCE A FINAL STATUS HAS BEEN ASSIGNED AND ENTERED INTO THE DATABASE, IT CANNOT BE CHANGED AT THE FIELD CENTER DURING THE SAME CONTACT YEAR WITHOUT WRITTEN AUTHORIZATION FROM THE COORDINATING CENTER. THEREFORE, A FINAL STATUS CODE SHOULD NOT BE ASSIGNED TO A PARTICIPANT UNTIL THE END OF THE CONTACT YEAR OR UNTIL IT BECOMES OBVIOUS THAT THE STATUS CANNOT CHANGE. AS DESCRIBED ELSEWHERE, A DEATH OCCURRING AFTER A CONTACT, BUT BEFORE THE END OF THE CONTACT YEAR, IS ASSIGNED TO THE NEXT CONTACT YEAR.

Examples:

1. It is Contact Year 2. The participant cannot be contacted, nor can any reliable information be found regarding his vital status. His baseline visit was on 03/05/87 and his "Latest" CY02 date is 09/04/88. Record as:

<u>Contact Year</u>	<u>Date of Status Determination</u>	<u>Status</u>
2	09/04/88	U

2. It is Contact Year 3. The participant cannot be contacted, nor can any reliable information be found regarding his vital status. His status in CY 2 was "Unknown" as determined on 06/28/88. His baseline visit was on 1/23/87. Record as:

<u>Contact Year</u>	<u>Date of Status Determination</u>	<u>Status</u>
3	06/28/88	U

3. It is Contact Year 2. The participant's baseline visit was on 02/24/87. His "Latest" date is 08/23/88. Neither the participant nor a reliable source can be located. Finally, on 08/25/88 (one day after the "Latest" date), the participant is located and interviewed. The interview must be recorded under Contact Year 3, and the status for CY 2 is "Unknown." Record as:

<u>Contact Year</u>	<u>Date of Status Determination</u>	<u>Status</u>
2	08/23/88	U
3	08/25/88	C

4. It is Contact Year 2. The participant's "Earliest" date is 2/12/87 and his "Latest" date is 2/11/88. The participant was contacted on his "Target" date, 8/12/87, and the questionnaire was administered routinely. One month later, his obituary is seen in the newspaper. The death may not be reported until the next Contact Year. Record as:

<u>Contact Year</u>	<u>Date of Status Determination</u>	<u>Status</u>
2	8/12/87	C
3	2/12/88	D

A death investigation may, however, be started at any time.

B. Death Information

- 4-5. If the participant has died, attempt to secure the date and location (city/county, state) of death from the source of information, whether it be a relative or an obituary. Take steps to begin a death investigation by initiating a Cohort Event Eligibility Form.

C. General Health

6. Read the question verbatim, substituting the date on which the participant was most recently contacted (directly) where indicated. The time frame for the next set of questions is since the last call or visit, generally about one year. It is important that the participant understand the time frame.

D. Chest Pain on Effort

7. If the participant previously had chest pain, but none since last contact, mark item 7 "No." The remaining questions 8-16 refer to pain in this time interval. Confirm that the pain was during the correct time interval. Note all skip patterns.

8-13. These questions refer to the usual characteristics of the pain or discomfort. Unequivocal answers need not be probed; but answers such as "occasionally" or "sometimes" should be probed by a question of the type: "Does this happen on most occasions?" Skip rules must be adhered to.

8. The answer must be interpreted strictly. If pain is experienced only during some other form of exertion (e.g., cycling, stairclimbing, lawn mowing), it must be recorded "No."

13. Sternum: the breast bone. To locate upper, middle and lower, divide the breast bone into thirds, starting at the neck and working down.

Left anterior chest: the front rib cage to the left of the sternum (breast bone) and below the clavicle (collar bone).

Left arm: includes the area below the clavicle (collar bone) and above the left hand.

Other: include here all other locations, such as the left shoulder (clavicle and above), neck and jaw, or other locations beyond the above defined regions.

14. Record any additional areas in item 13.

E. Possible Infarction

17-19. Refer to pain since the last contact only. Ask questions exactly as printed. Skip rules must be observed for the questions to make sense.

F. Intermittent Claudication

20-28. Refer to leg pain since last contact only. Ask questions exactly as they are printed; interpret answers strictly.

- 22-24, 26-28. These questions refer to the usual characteristics of the pain or discomfort. Unequivocal answers need not be probed; but answers such as "occasionally" or "sometimes" should be probed by question of the type: "Does this happen on most occasions?" Skip rules must be adhered to.

G. Stroke/TIA

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

H. Hospitalizations

30. The purpose of the question is to determine whether it is necessary to complete the "Hospitalizations" section after the questionnaire has been completed. Generally, this question is asked directly of the participant. However, if direct contact is not made, but a reliable source of information has provided a status of "Reported alive" or "Reported deceased" in item 2, then question 30 may be asked of this source. In this case, replace the words "Were you" with "Was ___(participant)". "Hospitalized" includes staying in any acute or chronic facility and would include a nursing home. This question is intended to specifically enhance the participant's or other source's recall about cardiovascular-related hospitalizations. Only inpatient care should be included, e.g., ER or outpatient visits not involving overnight stay are excluded.
31. This question asks for recall of any other hospitals. It should be asked prior to completing the Hospitalizations section.

I. Interviewer Code Number

32. The person at the clinic who has performed the interview and completed the form must enter his/her code number in the boxes provided.

3. Hospitalizations

A. Collection of data

Following the questionnaire, record information on all hospitalizations reported since the time of last contact. Use the Hospitalizations section of the Annual Follow-Up Form. This is a long question that will have to be obtained in parts. Use neutral probes to elicit all hospitalizations. For each overnight stay, record the reason for the hospitalization, the hospital name, city, and state, and the date (month and year) of the hospitalization. After completing this, if there were any hospitalizations, read the statement about obtaining records, which is

found at the end of the Hospitalizations list. If the participant objects to ARIC obtaining records, gently remind the participant that he/she signed a consent to do this and that medical information will be treated confidentially. If he/she still objects, state that we will not access records without his/her permission and that you'd like to have your supervisor call to discuss it. Take steps to begin investigating each reported hospitalization by initiating a Cohort Event Eligibility Form.

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

B. Linkage between Annual Follow-up and Event Investigation

Certain procedures are necessary to ensure that any deaths or hospitalizations that are encountered during AFU contact attempts are brought to the attention of the Surveillance Event Investigation staff, and vice-versa.

The surveillance staff is to be notified of every cohort hospitalization and an investigation undertaken. The hospitalizations sheet provides a check box to indicate that the information has been transmitted to the surveillance staff.

4. Appointment Scheduling

A. Clinic visit not being scheduled

Choose the appropriate ending:

END (talking to participant): "Thank you very much for answering these questions. We will (call you/see you at the clinic) in about a year." Proceed to Verification of Tracing Information.

END (if participant deceased): "We may need to contact a family member later. When would be a good time to call in that case?" DO NOT proceed to the Verification of Tracing Information.

END (otherwise): "Thank you very much for answering these questions. We will call _____ in about a year." DO NOT proceed to the Verification of Tracing Information.

B. Scheduling Visit 2 Appointment

You may want to schedule all appointments in a household together. Prototype script: "Now let's decide on your clinic appointment date(s). This ARIC clinic visit will be much like the one you had three years ago. You may remember that it takes 3 to 4 hours, and you will be asked to fast for 12 hours before you come in unless you have a medical reason not to. We also can provide a taxi, if you need transportation. We have some openings in (MONTH).

Our appointment times are at (TIMES). Is there a day or time that would be best for you?"

1. IF RESPONDENT(S) IS UNABLE TO SCHEDULE APPOINTMENT AT THIS TIME, INDICATE ON RECORD OF CALLS, SPECIFY REASON AND PROSPECTS FOR RECONTACTING, AND GO TO CLOSING (TOP OF PAGE 13).
2. IF RESPONDENT IS UNWILLING TO SCHEDULE A CLINIC VISIT, INDICATE ON RECORD OF CALLS, VERIFY TRACING INFORMATION.

I'm sorry you are unwilling to come back for a second exam. We would, however, like to continue calling you once a year. As we've done in the past, we would like to verify the information we have on how to contact you. Let me make sure that I have your full name. (ADMINISTER PART A OF THE VERIFICATION OF TRACING FORM. THEN GO TO CLOSING, TOP OF PAGE 13.)

3. IF APPOINTMENT IS MADE, RECORD DATE AND TIME ON RECORD OF CALLS. CIRCLE THE APPROPRIATE APPOINTMENT CODE ON THE RECORD OF CALLS. THIS CODE WILL BE ENTERED AS ITEM 34 OF THE ANNUAL FOLLOW-UP FORM ON THE DES.

Appointment Codes for Final Status of "Deceased" or "Unknown" should be "=".

The "Other" appointment code should be used primarily as a temporary code by interviewers waiting for the participant to set an appointment. It should be used as a final code only if the AFU window has expired and no other AFU Appointment Code (e.g., refusal) can be rightly assigned. Examples might be when a) the participant is temporarily away, b) the participant had surgery but wishes to participate in another year, c) etc.

Appointment Codes should be updated on the DES as appropriate given changes in the participant's status.

- a. CONTINUE WITH FASTING INSTRUCTIONS.

We ask that you fast for the visit unless you have a medical reason not to. Do you take insulin for sugar diabetes or have any other reason that you cannot fast for 12 hours?

IF NO

Since your appointment is at _____, you should begin fasting at _____ the night before. This means nothing by mouth but water and essential medications. We do encourage you to drink plenty of water. As with your previous exam, you will be given a snack at the clinic.

IF YES

There is no need for you to fast.

- b. ASK ABOUT SPECIAL NEEDS.

Will you need any assistance getting around the clinic or do you have other special needs we should know about?

IF YES, INDICATE ON RECORD OF CALLS AND INFORM CLINIC.

c. REVIEW MEDICATION SURVEY PREPARATIONS.

We will want you to bring the bottles of any medications, vitamins, or supplements you have taken in the TWO WEEKS before your appointment. This includes ALL medicines including prescription drugs from your physician or dentist; prescription drugs you may have received from other people, such as friends or relatives; and over the counter medicines bought at a drug store or supermarket, such as medicines for colds, vitamins, minerals, and the like. We ask that you bring the containers so that we can copy information from the labels. If you don't have the container, please bring the prescription or the loose pills or capsules. A bag to carry them will be in the packet mailed to you.

d. GIVE RESTRICTIONS ON DONATING BLOOD PRIOR TO THE CLINIC VISIT.

Please do not donate blood during the week before your clinic appointment. If it becomes necessary to give a pint of blood or plasma within 7 days of your appointment, please call the field center and reschedule your appointment.

e. RESOLVE ANY QUESTIONS OR CONCERNS.

Do you have any questions?

f. UPDATE MAILING ADDRESS (VERIFY TRACING INFORMATION.)

Finally, this is a good time to verify your mailing address to make sure that all the material you need for the clinic appointment reaches you. This will take only a few more minutes. Let me make sure that I have your full name (Mr. ___'s full name). (ADMINISTER THE VERIFICATION OF TRACING INFORMATION FORM.)

You should receive your packet in a few days and we will see you on _____. If it is necessary to change your appointment or you think of any (other) questions, please call the clinic.

CLOSING

NO ADDITIONAL INTERVIEWS

Thank you for your time. Good bye.

ADDITIONAL INTERVIEWS

Now I would like to interview (NAME). Thank you for your time.

IF THE PARTICIPANT IS AVAILABLE,
RETURN TO THE BEGINNING OF THE
ANNUAL FOLLOW-UP INTERVIEW.

IF THE NEXT PARTICIPANT IS
UNAVAILABLE, DETERMINE WHEN
HE/SHE MIGHT BE CONTACTED.

Is there a date and a time that
would be best for me to speak
with (NAME)?

RECORD DATE AND TIME ON RECORD OF CALLS

. Tracing Form: Verification of Tracing Information

Verify the items on the Verification of Tracing Information sheet for contact next year by saying: "You have previously provided us with information on how to contact you. To help us contact you next year, please tell me if the information I have is still correct." These include the participant's name, address, phone number(s), and driver's license number and state(if moved out-of-state), as well as (except in Y04) the information on the two contact people provided during the clinic visit. The current data on file appear on the left hand side of the page, with blank spaces for corrections or changes provided on the right side. Information only needs to be entered in these blanks in the case of changes to the data. For example, a change of mailing address could be recorded as:

MAILING ADDRESS:

Highland View Apts.

Apt. 73A

3465 Highland Lane

Chapel Hill, NC 27514

MAILING ADDRESS:

ANY CHANGES TO TRACING INFORMATION RESULTING FROM CY02 OR CY03 AFU MUST BE RECORDED BY CHANGING THE IDENTIFICATION AND/OR FASTING/TRACKING FORMS FROM THE PARTICIPANT'S BASELINE VISIT USING THE ARIC DATA ENTRY SYSTEM. CHANGES RESULTING FROM CY04-CY06 AFU MUST BE MADE ON THE UPD FORM IN THE VISIT 2 SYSTEM.

Data should be updated as necessary immediately after the follow-up contact only by someone certified in use of the ARIC Data Entry System. The interviewer who updated the computer file enters his/her ARIC Staff Code Number on the Verification of Tracing Information Sheet provided by the Coordinating Center.