1.0 RECRUITMENT AND FOLLOW-UP OF THE ARIC COHORT AFTER VISIT 1

1.1 Introduction

The ARIC cohort consists of 15,800 men and women ages 45-64 who were selected at random and recruited from four U.S. study communities between 1986 and 1990, the period referred to as Visit 1. The cohort members participated in an extensive set of examinations and interviews related to their cardiovascular health, and agreed to short annual telephone interviews and repeat examinations every three years for the duration of the study. The routine annual contact consists of a telephone interview to maintain correct addresses and to ascertain vital status and interim medical events; every three years on the date of the first field center examination (their anniversary date) the participant is also scheduled for a field center visit at the conclusion of the annual follow-up (AFU) interview.

Chapter one of this manual describes the procedures for scheduling and conducting the AFU interview (Sections 1.2 - 1.3) and for scheduling the participants third field center examination (Sections 1.4 - 1.6). Chapter two provides the rationale and description of the procedures or the interviews, the training and certification required to perform/administer the item, the quality assurance procedures, and the data collection mechanisms associated with each procedure or interview conducted during the third field center examination (Visit 3). Chapter 3 (procedures for event classification) outlines the procedures and criteria for ascertaining whether participant reported medical events are related to their cardiovascular health.

1.2 Eligibility Requirements for Annual Follow-up Interviews

Participants who completed at least part of the baseline examination (Visit 1) are contacted annually and, if capable, are invited to subsequent ARIC examinations. Individuals excluded from annual follow-up and subsequent examinations at the beginning of the study are only those enumerated residents who completed the home interview, but did not sign the informed consent form at the first field center examination (Visit 1).

Unless requested otherwise by the participant, or a participant is lost-to-follow-up, all surviving ARIC cohort members are contacted annually, regardless of whether they continue to participate in field center examinations. This includes participants who have moved away from the community in which they were recruited. Telephone AFU interviews can be conducted anywhere in the continental U.S. Addresses and telephone numbers of cohort members with multiple residences are kept on file to contact participants on their target anniversary date. Those who have moved are also invited to return for examinations, either at their recruitment or a sister field center. Reimbursement for long distance travel, however, is unavailable. See Section 1.6.5 for procedures for the scheduling of Visit 3 examinations of ARIC participants who have moved away from the community in which they were recruited and are willing to be examined in one of the other field centers.

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1.3 Annual Follow-Up

1.3.1 Time Window for Annual Contacts Between Field Center Examinations

Study participants are recontacted annually on their initial examination date (the anniversary date) at approximately the same time each year. The target date for the AFU interview is the date of the baseline visit. Contact years are numbered sequentially, starting with the year of the baseline examination, i.e., Contact Year 01 was assigned to all participants at Visit 1, regardless of the year in which they completed their baseline exam. Because recruitment was done over a three year period, participants could be in any one of three ARIC contact years during the calendar year in which annual contact interviews are conducted. For example, in 1993, interviewers contact participants in Contact Years 05, 06, and 07. Regardless of the contact year, the optimal time for placing the initial call each year for annual contact is generally not more than three weeks before the target (anniversary) date. A one year window, up to 6 months before and 6 months after the target date, is the maximum allowed for each annual contact.

When the contact window expires and no contact is made, a final result code for that window is entered on the Record of Calls (Appendix 1.5), and a new window begins.

The contact year to which a participant death is assigned is determined by two factors: the date of death and whether or not the participant had already been interviewed during the contact year in which the death occurred. For example, if the death is determined during or prior to the regularly scheduled AFU interview, the death is assigned to the contact year in which the AFU form was administered. If, however, a participant is interviewed during Contact Year 07, dies a short time thereafter, and the family notifies the field center of the death, the death is assigned to the next contact year, i.e., Contact Year 08.

1.3.2 Follow-up Procedures

Annual follow-up of cohort members is used to (1) maintain contact and correct address information on cohort participants (2) update tracing information on two contact persons, (3) ascertain the participant's vital status, and (4) document interim medical events/hospitalizations, life events and functional status between the three-year comprehensive examinations.

There are five primary components to annual follow-up: (1) the generation of scheduling material by the ARIC Coordinating Center; (2) the scheduling of the AFU interview by field center staff; (3) the administration of the AFU interview; (4) the scheduling of a field center examination every third contact year; and (5) the ascertainment of medical information relating to hospitalizations for cardiovascular disease. These steps are summarized in Figure 1 and described in the following sections.

The ARIC Coordinating Center begins the AFU procedures by generating and distributing to field centers several times a year AFU materials for use in scheduling and conducting the AFU interview. These materials include a (1) list of participants with anniversary dates for a minimum of three months; (2)
The participant tracing information sheet (Appendix 1.1); and (3) the verification of tracing information (UPD) form (Appendices 1.2 and 1.3). The list of participants includes the participant name, participant ID, date of Visit 1, and date of Visit 2 (optional), sorted in the order requested by the field center. The Participant Tracing Information Sheet includes the participant's name, address, telephone number(s); sex, race, date of birth, state of birth, social security number, driver's license state and number; employer's name and address; date of Visit 1, date of Visit 2; and the names, addresses and telephone numbers of two contact persons and the personal physician. The Verification of Tracing Information (UPD) form is available in long and abbreviated versions (depending on whether it is administered with the routine AFU interview or the AFU/Visit 3 scheduling interview) and lists the current data on file for the names and addresses of the participant and his/her two contact persons.

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The scheduling of AFU interviews at the field centers is done year round and involves identifying the participants who require scheduling, determining the type of contact needed (routine AFU or AFU/Visit 3 scheduling), establishing contact, administrating the AFU form, scheduling Visit 3, and ascertaining the relevance of participant-reported medical events to ARIC data needs. The procedures for scheduling Visit 3 and event classification are described in sections 1.6 and Chapter 3, respectively.

Using the list of participant anniversary dates, field centers identify participants for annual contact. The routine use of letters (Appendix 1.4) prior to the AFU interview reminding participants that they will be contacted by telephone by a staff member from the ARIC field center for their annual interview is optional. All participants, however, who cannot be contacted by phone are sent this letter on ARIC Study stationery as a reminder and "forwarding and address correction requested" is stamped on the envelope.

Figure 1.1 Interim Contact Procedures Between Clinical Examinations in the ARIC Cohort Study

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This letter contains:

1. A reminder that the addressee is in the study and that annual contact is involved.

2. A description of the purpose of the contact.

3. Information that the participant should obtain to assist with the interview (e.g., hospitalizations, physicians visits).

4. A request to call the ARIC Study office to set up a time to complete the Annual Follow-up Interview.

Participants who do not have phones, have trouble communicating by telephone, or have special needs are not contacted by telephone but are visited in-person. If these participants can be identified in advance, the letter indicates that an interviewer will visit the home, and annual follow-up and recruitment takes place there.

Participants found to have moved or who are otherwise lost to follow-up are traced using the tracing information obtained at Visit 1 and during subsequent annual follow-up contacts and other local sources of information, such as the telephone directory, city directory, etc. By using the Participant Tracing Information Sheet, field center staff can call or write to the individuals, employers, or physicians the participants identified during previous interviews. By using social security numbers, periodic searches of the National Death Index are done. Every attempt is made to schedule and complete an AFU interview for each cohort participant.

AFU interviewers telephone study participants at their homes at optimal times (i.e., late afternoons, evenings, or weekends) to conduct the annual follow-up interview (and during Contact Year 07, or subsequently if necessary, to schedule the third field center exam). When the timing of the initial contact is inconvenient for the participant, the interviewer reschedules the AFU interview. When a cohort member cannot be reached on the first call, the interviewer makes return calls as necessary, at varying times of the day and week until either the participant is contacted or a decision is made to initiate tracing procedures. On the Annual Follow-up Record of Calls (Appendix 1.5), a final contact status (result) code (and appointment status code in Contact Year 07) indicating the participant cannot be located (i.e., is lost to follow-up) is only assigned after all tracing avenues have been exhausted and supervisor approval has been obtained. Experience has shown that participants who are lost to follow-up in one year may be located in subsequent years of follow-up and only participants who die or insist on no further contact with the ARIC study should be considered irreparably lost to the study.

1.3.3 Annual Cohort Interview

Question by question (QxQ) instructions and prototype scripts have been prepared for administering the AFU interview (See Appendix 1.7). It can usually be administered by telephone in less than 10 minutes. The interview updates address and tracing information of cohort participants (See Appendix
1.2 or 1.3, UPDATE form); ascertains their vital status (AFU, section A),
death information (AFU, section B); perceptions of general health (AFU,
section C); chest pain on effort (AFU, section D); possible infarction (AFU,
section E); intermittent claudication (AFU, section F); TIA/stroke (AFU,
section G); hospitalizations (AFU, sections H and K); and functional status
(AFU, section I) (See Appendix 1.6, Annual Follow-up form). At some point
after the AFU interview, every participant-reported hospitalization is
verified and the discharge diagnoses recorded. Potential cardiovascular
events are reviewed further by the abstraction of participants’ hospital
records to document the presence/absence of ARIC Study endpoint criteria.
Refer to Chapter 3.

Since Visit 2, a new section on functional status and ‘life events’ has been
added to the AFU interview. The questions on functional status assess the
participant’s current functional status and whether or not a perceived
diminution in activity levels were due to cardiovascular disease. Life events
questions document current marital status and the demise in the previous year
of one or more individuals close to the participant. Additionally, the
section documenting overnight hospitalizations in acute care facilities has
been reformatted to facilitate computerized data collection.

Form sections are typically completed in the following order: (1) Record of
Calls; (2) questionnaire; (3) hospitalizations; (4) appointment scheduling (if
applicable); and (5) tracing form. The Record of Calls (TRC form) is used to
keep track of attempts to contact a participant. The participant’s name, ID,
contact year, and contact year date ranges are preprinted at the top of the
form. Space is provided to document contact attempts, pertinent information
for future contacts, and the outcome of the contact. There are nine contact
result codes: (1) no action taken; (2) tracing (tracing unsuccessful but still
being attempted); (3) contacted, interview complete; (4) contacted, interview
partially complete or rescheduled; (5) contacted, interview refused; (6)
reported alive, will continue to attempt contact this year; (7) reported
alive, contact not possible this year; (8) reported deceased; (9) unknown;
(98) does not want any future contact. Code types 3, 5, 7-9, 98 are final
codes. See Appendix 1.7 for detailed instructions for completing the form,
and a description of the Results Codes for contacts.

Once contact has been made, the entire AFU interview is administered to
surviving participants. When the participant has expired prior to the annual
contact, the relevant portions of the AFU form (Sections A, B, H and K) are
administered to a member of the participant’s household (or a contact person)
in order to officially record the death and to obtain the date and location Of
death and other relevant medical information.

Section A of the AFU form documents the participant’s vital status and the
date on which the status determination was made. The criteria for
establishing participant vital status are defined in the form’s instructions.
Section B is completed on individuals who have died and obtains demographic
information necessary for obtaining a copy of a death certificate. Sections
C-G are administered to all surviving participants and document perceptions
of health and interim (since the previous AFU interview) medical events; the
majority of the questions were taken from the London School of Hygiene
Questionnaire for chest pain on effort, possible infarction, and intermittent

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Claudication. Guidelines for administering this section are provided below, in Section 1.3.3.1. Sections H and K on the AFU form are administered to all respondents (participants and proxies) to document overnight hospitalizations in acute or chronic care facilities. The surveillance staff is notified of every cohort hospitalization and an event investigation is initiated. As indicated above, Section I (functional status) is a new to the AFU interview and is administered only to surviving participants.

Tracing information listed on the preprinted UPD form (Appendix 1.3) is verified at the conclusion of the AFU form. Instructions for administering the form and a prototype script are provided at the end of the annual follow-up instructions. Any changes to tracing information recorded on the paper form during the telephone interview are recorded on the computerized version of the UPD form by staff certified in the use of the ARIC Data Entry System.

1.3.3.1 Administration of London School of Hygiene Questionnaire

The purpose of the London School of Hygiene Questionnaire (the 'Rose Questionnaire') is to standardize the identification of 'angina on effort' as defined by Dr. Geoffrey Rose. It is not the purpose of the questionnaire to arrive at a medical diagnosis. The questionnaire will fail to identify angina pectoris in some participants whose pains are regarded by the physician as genuinely ischemic. It may categorize other cases as pain due to a quite different cause. Any special effort, however, to alter the conduct of the interview in such instances would destroy the basic purpose of the questionnaire technique, which is to insure uniformity in the eliciting of defined symptoms.

Questions must be put to the participant exactly as they are printed: small changes can make unexpectedly large differences in responses. Unequivocal answers must be recorded as such, whether they seem reasonable or not. Supplementary questions (probing) should rarely be used. When they have to be asked, they should depart as little as possible from the wording of the initial question, and must not be such as to suggest any one particular answer to the participant.

If serious doubt arises about the correct interpretation of a particular answer, it is recorded in such a way as to exclude the suspected condition. An example of this type of situation is demonstrated in the following question and hypothetical response.

{Question} "Do you get it when you walk uphill or hurry?"
{Response} "Well, I think I might, but I really can't remember."

This answer is recorded as NO and no probes are employed.

An exception is made to this rule only if a negative response to the lead-in question is an interpretation or denial of a positive response.

{Question} "Have you ever had any pain or discomfort in your chest?"
{Response} "No. Only indigestion."

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The answer is recorded as YES, because the participant's interpretation of the symptom is disregarded.

A frequently made error in the administration of the Rose Questionnaire is to extrapolate the participant's response to similar, but not defined, situations in the question.

{Question} "Do you get it when you walk uphill or hurry?"

{Response} "Yes, the chest pain occurs when I cut the grass."

The answer to this question is recorded as NO, i.e., a strict interpretation is required. If pain is experienced only during some other form of exertion (e.g., cycling, stair climbing, lawn mowing, etc.), it must always be recorded NO. The response 'NEVER HURRIES OR WALKS UPHILL' can only be coded if the participant specifically denies walking uphill or hurrying.

For the remaining questions, unequivocal answers need not be probed. However, responses qualified by terms describing frequency of events, such as 'occasionally' or 'sometimes' should be probed by a question such as 'Does it happen on most occasions?'. Individual question by question instructions are provided in Appendix 1.7.

1.4 Linkage of AFU Ascertained Reports of Positive Cardiovascular Events and the Field Center Examination

The folders of ARIC participants to be scheduled for Visit 3 who reported during their AFU interview symptoms of chest pain on effort or intermittent claudication, physician diagnosis of myocardial infarction or TIA/stroke, or hospitalization(s) for cardiovascular disease are flagged. These responses are subsequently confirmed during Visit 3 by a trained interviewer administering the Health History Form and the Medical Data Review.

1.5 Window for Visit 3

The scheduling of Visit 3 is made in conjunction with the annual contact in Contact Year 07. The optimal timeframe for scheduling Visit 3 is within 30 days of the participant's annual contact target date, but can be made up to 4 months earlier to aid clinic scheduling. It is anticipated that most field center visits will be completed within 90 days of the target annual follow-up contact date. If the participant cannot complete Visit 3 within this timeframe, it is still possible for Visit 3 to be completed at any time during Contact Years 07 through 09. For example, if the participant refuses or does not show for a visit in Contact Year 07, scheduling is attempted in Contact Years 08 and 09. The Visit 3 data are entered into the database as Contact Year 07 data, even if the field center exam occurs during Contact Years 08 and 09. This is in contrast to the recording of the actual contact year number (e.g., 08 or 09) of the AFU interview in which Visit 3 is successfully scheduled. For example, if a participant has an AFU interview and is scheduled for Visit 3 in Contact Year 07, does not come to the field center within the remaining time during Contact Year 07, is recontacted in Contact Year 08, and agrees to rescheduling and completes Visit 3 during Contact Year 08, the AFU
contacts are listed as Contact Year 07 and Contact Year 08, but the Visit 3 contact year is listed as Contact Year 07.

The appointment code is entered into the appropriate column on the Record of Calls form to describe the participant’s (interim and) final appointment status. Appointment codes have been revised since Visit 2 and are fully described in the AFU instructions (Appendix 1.7). Like contact status (result) codes, final codes indicating permanent disenfranchisement from the study must be approved by the supervisor.

1.6 Scheduling of Visit 3 Field Center Examination

1.6.1 Outline of Scheduling Procedures for Visit 3

The steps in the scheduling procedures for Visit 3 are similar to those for scheduling and conducting the AFU interview.

1. The Participant Tracing Information Sheet, i.e., a list of participants to be contacted, their tracing information, the target contact date, and the six month time window around the target date is provided to field centers by the Coordinating Center at least 4 months in advance of the contact date. The materials for identifying and scheduling participants for Visit 3 differ from the regular lists of annual follow-up, (the list of participants with anniversary dates for a minimum of three months, the participant tracing in formation sheet) only in that those printed for field centers in Minneapolis and Washington County identify which participants have been randomly selected for an ultrasound examination.

2. At the discretion of each field center, a letter is mailed to the participant indicating that the usual Annual Follow-up telephone call will take place, and at that time an appointment for Visit 3 will be set (Appendix 1.8). A brief description of Visit 3 is provided in the letter, as well as a request to have a calendar available to facilitate scheduling Visit 3.

3. The participant is telephoned, the Annual Follow-up Form is completed in the usual manner, and the participant is scheduled for Visit 3. Some home interviews may be necessary for individuals unreachable by telephone or for special circumstances. After the appointment is set, basic instructions for Visit 3 are provided.

4. Shortly before the appointment, field centers send a reminder letter indicating the appointment time.

5. A reminder telephone call also precedes the visit.

6. If a participant is unavailable during the usual time window for the Visit 3 appointment, additional efforts to schedule Visit 3 at a later date are made. If a participant refuses to return to the field center for the third examination, continued annual contact in subsequent years is attempted, as well as the scheduling of Visit 4, unless the supervisor considers it inappropriate.
1.6.2 Contacting Participants

The Coordinating Center generates from the ARIC database a list of participants to be contacted for Visit 3 and their target contact date. The list is similar to that provided for Annual Follow-up, and is generated well in advance of the contact window to allow field centers to schedule the lengthier interviews, and if necessary, to trace hard to find participants.

Field centers have the option of mailing a letter to all participants (or just those who cannot be contacted by telephone) indicating that the routine Annual Follow-up call is due and that the third field center examination (Visit 3) will be scheduled at that time. A prototype letter is provided in Appendix 1.8. Participant address files for producing mailing labels are routinely updated and distributed to the field centers by the Coordinating Center. These letters in envelopes stamped "forwarding and address correction requested" are sent, to assist in tracing participants who have moved.

Approximately one week after the letter is mailed, a telephone call is placed to the participant's home. Prior to initiating the joint AFU interview - Visit 3 scheduling telephone call, the interviewer has assembled (1) the AFU Record of Calls, (2) the AFU questionnaire, (3) calendar for scheduling the field center appointment and (4) the UPDATE form. Using the prototype scripts provided in the question by question instructions (Appendix 1.7), the interview is typically conducted in the order in which the forms are listed above. If a field center appointment is to be scheduled with more than one cohort member during a single call, it is often more expedient to conduct all AFU interviews first and then schedule appointments together. The short tracking information sheet (Appendix 1.2) is updated. More detailed information on contacts and primary medical care provider is updated during the clinic exam.

1.6.3 Making the Clinic Appointment

After completing the annual follow-up interview for all participants in a household, the interviewer describes the clinic visit and schedules the participant's Visit 3 appointment following the prototype script provided in the question by question instructions for the Annual Follow-Up form. A separate one page prototype Visit 3 Scheduling Script to standardize the scheduling of participant appointments is provided in Appendix 1.9. If there is more than one ARIC cohort member in a household, the interviewer has the option of completing the AFU and clinic scheduling portions of the interview with each cohort member, or completing the AFU portion with each individual before jointly scheduling their field center appointments. The interviewer inquires about several items to assist in scheduling the appointment:

1. Preferred time and date of examination;
2. Any medical conditions (e.g., diabetes, dietary restrictions) which might affect the physical examination and/or type of snack provided;
3. Need for assistance getting to or moving about the clinic.
If possible, the interviewer schedules appointments for the examination during the 30 days following the telephone call. The interviewer notifies the clinic scheduler to set an appointment day and time. The appointment is recorded on a reminder sheet which is mailed to (or left with) the participant. When possible, cohort members are scheduled for appointments at their convenience, this includes scheduling all eligible members of a single household for examinations on the same day whenever possible.

1.6.4 Instructions for the Clinic Examinations

The instructions for clinic visits are specified on an information sheet (Appendix 1.10) prepared by each Field Center, and mailed (or delivered) to the participant soon after the appointment is made. The instructions include:

1. Appointment date and time.

2. Preparations:
   a) Instructions how to complete the 12-hour fast;
   b) Instructions concerning restrictions on the use of tobacco and vigorous physical activity the morning prior to the visit;
   c) Appropriate clothing to wear for the examinations.

3. Things to bring:
   a) Eyeglasses for reading;
   b) Name and address of primary care physician and/or clinic;
   c) Name, address, and phone number of contact persons;
   d) Medication Instruction Sheet:
      Instructions for bringing medications, vitamins and mineral supplements taken within the two weeks prior to the examination and a bag for bringing the medications to the field center.

4. Overview of Clinic Operations:
   a) A listing of the interviews and procedures for Visit 3 (optional);
   b) A reminder that a snack is provided during the exam;
   c) Clinic hours and phone number for questions or rescheduling appointment.

5. Directions to the clinic (a map) and to parking facilities,
   a) All Field Centers provide free parking or reimbursements.

6. Transportation:
   a) Some centers provide transportation and arrange for participant pick-up.
   b) In Jackson, those who drive are asked to record mileage reimbursement.

1.6.5 Scheduling Appointments

Interviewers scheduling examinations report appointment information to their field center. Sufficient appointments are scheduled each day for Monday through Friday to meet the requirement of approximately 25 appointments per week.
In contrast to the first two examinations, only 50 percent of participants from the Minneapolis and Washington County field centers receive ultrasound B-mode examinations of their carotid arteries during Visit 3. These individuals are randomly selected by algorithms applied at the Coordinating Center. Their names are flagged on the list of participants sent to the field centers, as are their individual Participant Tracing Form. The predetermined quotas of the number of ultrasound examinations which can be performed in a week influence the scheduling of participants. Therefore, ARIC staff administering the AFU interviews and scheduling the Visit 3 appointments must adjust appointments to accommodate the reduced ultrasound examination resources in these two field centers.

At a minimum, each field center maintains the following scheduling documentation:

1. Assignment record of ID labels for the clinics, generated and distributed by the ARIC Coordinating Center.

2. A listing of participants by ID, name, telephone number, anniversary date and earliest and latest dates during which to conduct the AFU interview and schedule the Visit 3 field center appointment (the Participant Tracing Information Sheet).

3. Daily appointment log with participant name, ID number, appointment time, and special considerations such as health restrictions or child care requests. This schedule is used to structure that day's appointments and to check in participants as they arrive.

1.6.5.1 Guidelines for ARIC participants who relocate near another center

It is anticipated that over time, some members of the ARIC cohort will move far enough away from the community in which they were recruited to make the return for clinical follow-up impractical. Such individuals continue to be contacted annually. They are also offered the opportunity to have their third (and subsequent) exams at a sister field center. In essence, however, they remain members of the original field center cohort. In spite of the fact that study data are collected 'off-site' (i.e., the alternate center), these data are entered and monitored at the original field center, and the original field center is responsible for preparing results reports and letters. The guidelines for implementing these procedures are as follows:

1. The original field center continues to perform all Annual Follow-up calls and the scheduling of field center examinations.

2. When participants are interested in completing their next clinic visit at another field center, the original field center contacts the closest ARIC field center (i.e., the alternate field center) and arranges for scheduling the appointment.

3. The original center sends the ARIC Coordinating Center and the alternate center written notification of the participant ID, as soon as the participant agrees to complete the exam at the new field center.
4. The original field center sends labels and a copy of the Participant Information Sheet (PIN), current Annual Follow-up form, and any other pertinent information to the alternate center. Other pertinent information includes mention of any 'special needs', and copies of prior study results reports and letters to participants and physicians. All of this is treated as confidential information. Although the alternate centers does not prepare the equivalent materials for the current cohort visit, the person in charge of Medical Data Review needs to know about these items.

5. The Medical Data Review which occurs at the end of the clinic visit is performed by the alternate center. This includes any immediate follow-up to findings during the clinic visit. The subsequent notification of any alert values and the preparation of the report of study results and the accompanying letter(s) to the participant's provider of medical care are the responsibility of the original center.

6. The alternate center collects the study data on paper, assigning the original study ID. These forms are photocopied; the originals sent to the original field center for data entry and a copy kept on file at the alternate center.

7. The original centers send the ARIC Coordinating Center and the alternate center a copy of the CXI once data entry of the forms collected at the alternate center are keyed. The alternate center verifies that all forms collected on paper were entered and then the photocopied forms can be discarded.

8. The alternate field center annotates all central agency sample inventory sheets, indicating the special situation. The central agencies (laboratories and reading centers) correspond with the original field center in the event of alert values or other special issues related to relocated participant data. The original center then sends a copy of the alert to the nurse/clinician at the alternate center for their information, since the participant may call either center with a question.

1.7 Retention of ARIC Participants

1.7.1 Introduction

The projected Visit 3 clinic re-examination rates (ranging from 80 to 90 percent) are dependent upon each field center's ability to recruit eligible participants and to maintain their clinic attendance.

Every effort is made to make the field center visit as pleasant and burden free as possible. Additionally, the following features are part of the effort to maximize participation: (1) qualified interviewers, (2) preappointment contacts, (3) no show procedures, (4) reimbursement of transportation costs, and (5) publicity.
1.7.2 Certification of Annual Follow-up Interview Staff

Interviewers are trained and certified in general interviewing techniques and the administration of the Annual Follow-up form. This requires familiarity with the contents and procedures for administering the AFU form, assigning contact and appointment status codes on the AFU Record of Calls, scheduling a field center appointment, and verifying contact information on the UPDATE form. Staff are certified by the field center supervisor in administering the Rose Questionnaire after review of a standardized protocol. Recertification is required annually with the recommendation of periodic refresher courses and retraining if quality assurance analyses indicate poor performance or inconsistent results.

1.7.3 Pre-appointment Contacts

To increase respondent participation following the Annual Follow-up/Visit 3 Scheduling telephone call by an ARIC interviewer, a pre-Visit 3 appointment packet is mailed at some centers prior to the scheduled appointment. This packet confirms the examination date and time and reviews the preparation procedures as listed in section 1.6.4.

Reminder calls are made to each participant one or two days prior to the examination. At this time, the information concerning the fasting requirements, medications bags, and other details is reviewed with the participant. Participants are asked if they have any special needs and every effort is made to answer participant’s questions.

When appropriate, a letter is sent to the participant’s employer explaining the ARIC Study and requesting time-off during work hours (see Appendix 1.11).

1.7.4 Contacts for No Shows

Eligible participants who fail to arrive for a scheduled appointment or who cancel their appointments are contacted by telephone to reschedule the appointment. At that time, the scheduler attempts to address any concerns or fears that the participant may still have.

Each no-show case is individually reviewed by the interviewer and when necessary by the supervisory staff. Conversion efforts include a combination of telephone contacts, in-person visits, and/or conversion letters. A participant is considered a refusal following three conversion contacts or three broken appointments.

1.7.5 Reimbursement

Each center provides for, or reimburses, local transportation and/or parking. Long distance transportation for participants who have moved is not provided. For those who are reimbursed, records are maintained for accounting purposes according to Office of Management and Budget (OMB) regulations and each university’s guidelines.
1.7.6 Publicity

To enhance participation, the Field Centers maintain active contact with the media in their communities. Periodic attempts are made to provide them with updates of the study and to enhance community support.

1.7.7 Supervision

Throughout the entire process from initial interview to final examination or refusal, close supervision helps maximize the rate of response. Supervisors record reasons for nonresponse, and examine performance trends by interviewer and by area. When deemed appropriate, supervisors initiate recontact with refusing participants to attempt their conversion. Detailed records of all contacts are maintained.