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

1.1 Introduction

The ARIC cohort consists of approximately 4,000 men and women ages 45-64 at Visit 1, from each community. Annually, participants are recontacted by telephone in order to maintain correct addresses and to ascertain interim medical events. Every third year, participants are contacted for reexamination at the field centers.

1.2 Annual Follow-Up

1.2.1 Annual Contacts Between Exams

Each study participant is recontacted annually after his or her initial examination at approximately the same time each year. The target date for the annual follow-up interview is the date of the baseline visit. However, a 1 year window, up to 6 months before and 6 months after the target date, is allowed for each annual contact. The initial call for annual contact generally should be no more than three weeks before the target date, except in contact year 4 (CY04) when initial calls can occur up to 4 months in advance of the target date. These follow-up contacts review the health-related developments which have occurred since the last contact. Follow-up interviews are preferably conducted by telephone, but can be done in person if necessary. Beginning February 1990, letters (Appendix 1.1) will not be sent to participants prior to the telephone interview for Contact Years 03, 05 and 06 unless the person cannot be reached by phone.

1.2.2 Follow-up Procedures

Annual follow-up of the ARIC Study cohort is used to (1) maintain contact and correct address information on cohort participants and (2) ascertain vital status and interim medical events between the three-year comprehensive examinations.

The basic procedure for interim contacts is described below and summarized in Figure 1.1.

```
Coordinating Center generates assignments → (a,b,c) → Telephone interview → Additional diagnostic or abstracting procedure if indicated
                           ↓                       ↓
                           in-Person interview
```

(a) Send Annual Contact Letter at Contact Year 2.
(b) Send Pre-Visit 2 Contact Letter at Contact Year 4.
(c) Send Annual Contact Letter/Pre-Visit 2 Letter for cohort members who cannot be contacted by telephone.

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

ARIC PROTOCOL 2. Cohort Component Procedures - Visit 2. VERSION 3.0 8/90
At the baseline examination the following information was collected and stored in the data base to facilitate future contacts:

1. I.D. Number
2. Name, address, telephone number
3. Age
4. Physician/hospital name, address, telephone number
5. All tracing information, such as the names of close friends, social security number, employer, etc.

This file is used for preparing results letters, annual contact letters, and rescheduling follow-up exams.

The preferred time-window for making interim contacts is within a month of the anniversary date of the original examination. The telephone interviews are generally scheduled no more than three weeks before to three weeks after the target date.

For persons being contacted for their first annual follow-up (Contact Year 2) or those in subsequent years (Contact Years 03, 05, 06) not reached by phone after three attempts at ideal times, letters on ARIC Study stationery and "forwarding and address correction requested" on the envelope are mailed and further attempts are made (Appendix 1.1). These letters contain:

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.

Extensive efforts are made to maintain contact with every cohort participant.

1.2.3 Annual Cohort Interview

The annual follow-up interview of the ARIC Study cohort updates address and tracing information of cohort participants, ascertains vital status, interim hospitalizations, and new cardiovascular symptoms. (See Appendix 2.2.a.) Its main purpose is to identify possible cardiovascular events or treatment requiring hospitalization. Every hospitalization is verified and the discharge diagnoses recorded. Potential cardiovascular events are reviewed further for ARIC Study endpoint criteria by abstraction of hospital records.

Every attempt is made to identify cohort deaths before the annual contact, through regular review of death certificates. When deaths are ascertained, a mortality interview is conducted at an appropriate time.

1.3 Eligibility Requirements for Post-Baseline Examinations

Participants who completed at least part of the baseline examination are followed and, if alive, invited to subsequent ARIC examinations. This excludes enumerated residents who completed the home interview, but did not sign the informed consent form at the field center.
Participants do not have to still live in the community to participate in subsequent annual follow-up interviews or examinations. Those who have moved are invited to return for examinations, but study reimbursement for long distance travel is unavailable.

1.4 Window for Visit 2

The scheduling of Visit 2 is made in conjunction with the annual contact in the fourth contact year. The optimal timeframe for scheduling Visit 2 is within 30 days of the participant's annual contact target date. It is anticipated that most of the field center visits will be completed within at least 90 days. However, if the participant cannot complete Visit 2 within this window, it is still possible for Visit 2 to be completed at any time during Contact Years 4 through 6. The Visit 2 data is entered into the database as Contact Year 4 data, regardless when Visit 2 occurs.

1.5 Recruitment

1.5.1 Outline of Recruitment for Visit 2

The steps in the recruitment process for Visit 2 are as follows:

1. A list of participants to be contacted, their tracing information, and the target contact date is provided to field centers by the Coordinating Center at least 3 months in advance of the contact date.

2. Field Centers mail a letter to the participant indicating that the usual Annual Follow-up telephone call will be coming, and at that time an appointment for Visit 2 will be set. A brief description of Visit 2 is provided in the letter.

3. The participant is telephoned, the Annual Follow-up Form is completed in the usual manner, and the participant is recruited for Visit 2. Some home interviews may be necessary for individuals unreachable by telephone or for special circumstances. After the appointment is set, basic instructions for Visit 2 are provided.

4. Soon afterwards, field centers send a reminder letter indicating the appointment time and providing full instructions for the visit.

5. A reminder telephone call precedes the visit.

6. If the participant is not available during the usual time window for his/her Visit 2 appointment, centers keep trying to recruit for Visit 2 at a later date. Even if a participant refuses Visit 2 during contact year 4, he/she is to be invited in future contact years unless the supervisor considers it inappropriate.

1.5.2 Contacting Participants

The Coordinating Center generates from the ARIC database a list of participants to be contacted for Visit 2 and the target contact date. The list is similar to the lists 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.

Participant information sheets are generated that contain pertinent information from Visit 1 to be used in the Visit 2 (e.g., baseline vital status of parents, baseline menopausal status, etc.) clinic examination.

Field centers mail a letter to each participant indicating that the usual Annual Follow-up call is due and that Visit 2 will be scheduled. A prototype letter is provided in Appendix 1.4. The Coordinating Center generates data files from which the field centers produce address labels for the mailing. Letters are sent "forwarding and address correction requested", so that participants who have moved can be identified. Approximately one week after the letter is mailed, a telephone call is placed to the home. All Annual Follow-up interviews are completed, and tracing information is updated. The interviewer then asks to schedule a clinic appointment as described in Section 1.5.3. The interviewer must be aware of available appointment times and be able to convey basic clinic instructions. 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 subsequent annual follow-up contacts. Periodic searches of the National Death Index are made. Every attempt is made to schedule and complete a visit for each cohort participant.

1.5.3 Making the Clinic Appointment

At the end of the annual follow-up for all participants in a household, the clinic visit is described and a request made for an appointment. 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 for) the participant. Participants are scheduled for appointments at their convenience, dependent upon clinic schedule. For convenience of the study participants, eligible members of a single household are scheduled for examination on the same day whenever possible.

1.5.4 Instructions for the Follow-up Clinic Examinations

The instructions for clinic visits are specified on an information sheet (Appendix 1.5) 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 the tobacco and vigorous activity restrictions the morning prior to the visit;
   c) Appropriate clothing to wear for the visit.

3. Things to bring:
   a) Eyeglasses for reading;
   b) Name of primary care physician and/or clinic;
   c) Name, address, and phone number of contact persons;
   d) Driver’s license;
   e) Social Security Card (or number);
   f) Medication Instruction Sheet: Instructions for bringing medications taken within the last two weeks and a bag for bringing the medications to the field center.

4. Overview of Clinic Operations:
   a) A snack is provided after the initial part of the exam.
   b) 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 for reimbursement.

1.5.5 Scheduling Appointments

Interviewers scheduling examinations report appointment information to the field center. Sufficient appointments are scheduled each day for Monday through Friday to meet the requirement of approximately 30 appointments per week. Each clinic maintains:

1. Assignment record of ID labels for the clinics.

2. A listing of telephone numbers and dates and times to conduct the telephone reminder calls.

3. Daily appointment schedule 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 for their examination.

4. Clinic schedules are maintained.
1.6 Completeness of Re-Examination

1.6.1 Introduction

The projected clinic re-examination rates (ranging from 80 to 90 percent) are dependent upon each clinic's ability to recruit eligible participants and to maintain their clinic attendance. Every effort is made to make the clinic 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, and (5) publicity.

1.6.2 Qualified Interviewers

Interviewers make initial contact with households at optimal times (i.e., late afternoons, evenings, or weekends), and schedule appointments for interviews as needed. Additionally, interviewers make return calls as necessary, at varying times of the day and week. No unlocatable code may be entered without supervisor approval.

1.6.3 Pre-appointment Contacts

To increase respondent participation following the Annual Follow-up/Visit 2 Scheduling telephone call by an ARIC interviewer, a pre-Visit 2 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 1.5.4.

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 (see Appendix 1.6).

1.6.4 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.

1.6.5 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.

1.6.6 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.

1.6.7 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.