Atherosclerosis Risk in Communities Study Protocol

Manual 2

Cohort Component Procedures

Visit 4

Version 6.0

July 1997

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FOREWORD

This manual, entitled Cohort Component Procedures is one of a series of protocols and manuals of operation for the Atherosclerosis Risk in Communities (ARIC) Study. The complexity of the ARIC Study requires that a sizeable number of procedures be described, thus this rather extensive list of materials has been organized into the set of manuals listed below. Manual 1 provides the background, organization, and general objectives of the ARIC Study. Manuals 2 and 3 describe the operation of the Cohort and Surveillance Components of the study. Detailed Manuals of Operation for specific procedures, including those of reading centers and central laboratories, make up Manuals 4 through 11 and 13 through 18. Manual 12 on Quality Assurance contains a general description of the study's approach to quality assurance as well as the details for quality control for the different study procedures.

ARIC Study Protocols and Manuals of Operation

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3	Cohort and Community Surveillance
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5	Electrocardiography
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INTRODUCTION

The ARIC cohort consists of 15,792 men and women who were between the ages of 45-64 when they were selected at random and recruited from four U.S. study communities between 1986 and 1989. To date, these cohort members have participated in three sets of clinical examinations and interviews related to their cardiovascular health every three years, and have agreed to short annual telephone interviews. The baseline examination (Visit 1) occurred between 1987 and 1989; Visit 2 from 1990 to 1992; Visit 3 from 1993 to 1995; and Visit 4 (the subject of the manual) from 1996 to 1998. The routine annual contact, which began in the study's second year, consists of a telephone interview to maintain correct contact information on study participants and to ascertain their vital status and interim medical events associated with coronary heart (CHD) and cerebrovascular (CVD) diseases. Every three years, i.e., in Contact Years 4, 7, and 10, participants are also scheduled for a field center visit at the conclusion of their annual follow-up (AFU) interview to coincide with the date of their first field center examination (their anniversary date).

Chapter 1 of this manual describes the procedures for scheduling and conducting the AFU interview (Sections 1.2 - 1.3) and for scheduling the participant's fourth field center examination (Sections 1.4 - 1.6). The first portion of Chapter 2 provides an overview of the design, objectives and content of the fourth clinical examination (Visit 4), and describes the logistics for setting up the clinical examination. It then provides the rationale and description of each interview, the training and certification required to administer the form, the quality assurance activities, and the data collection instruments and procedures. Chapter 3 provides similar information for the procedure performed during Visit 4. Chapter 4 describes the rationale and procedures of the medical data review performed before the participant leaves the field center. Chapter 5 covers the study's referral and review guidelines. Chapter 6 describes the procedures associated with the review of the clinically relevant study results by the ARIC physician prior to release to ARIC participants. Chapter 7 describes the activities associated with reporting results to participants and their physicians. Chapter 8 outlines the procedures at the field center to ensure participant safety.

1.0 RECRUITMENT AND FOLLOW-UP OF THE ARIC COHORT AT VISIT 4

1.1 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, an attempt is made annually to contact all surviving ARIC cohort members, 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 1.5.5 for procedures for the scheduling of Visit 4 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.

1.2 Annual Follow-Up

1.2.1 Time Window for Annual Contacts Between Field Center Examinations

Study participants are recontacted annually on their initial (anniversary) examination 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 (Table 1).

Table 1. Contact Years by Visit Dates

ALL VISIT YEARS	Clinic Exam (86) 1987	YEAR OF 1st ARIC VISIT 1988	1989
		VISIT 1	
(86) 1987	CY01		
1988	CY02	CY01	
1989	CY03	CY02	CY01
		VISIT 2	
1990	CY04	CY03	CY02
1991	CY05	CY04	CY03
1992	CY06	CY05	CY04
		VISIT 3	
1993	CY07	CY06	CY05
1994	CY08	CY07	CY06
1995	CY09	CY08	CY07
		VISIT 4	
1996	CY10	CY09	CY08
1997	CY11	CY10	CY09
1998	CY12	CY11	CY10

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 contacted 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.

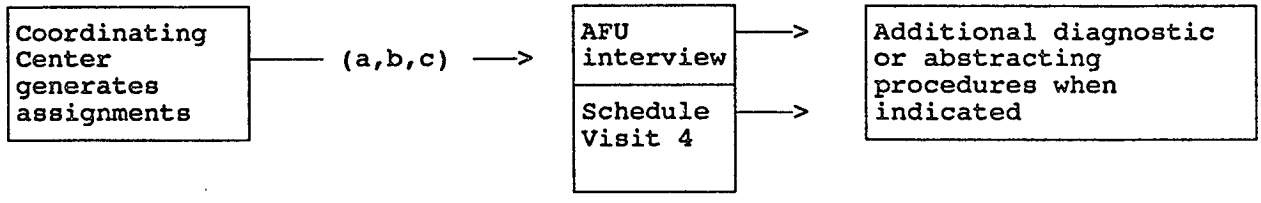
The contact year to which a participant death is assigned is determined by two factors: the date of death and whether or not the participant had already been interviewed during the contact year in which the death occurred. For example,

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.

1.2.2 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 and documentation of fatal events. These steps are summarized in Figure 1 and described in the following sections.



(a) Send Pre-AFU Interview (Visit 4) reminder letter (Optional).
(b) Conduct Annual Follow-up telephone interview.
(c) Send Annual Contact Letter/Pre-Visit 4 Letter for cohort members who cannot be contacted by telephone.

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

Field centers initiate the AFU procedures by generating several times a year AFU materials for use in scheduling and conducting the AFU interview. These materials include the participant tracing information sheet (Appendix 1.1) and 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; 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 4 scheduling interview) and lists the current data on file for the names and addresses of the participant and his/her two contact persons.

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 4 scheduling), establishing contact, administering the AFU form, scheduling Visit 4, and recording

participant-reported medical events to ARIC surveillance staff. The procedures for scheduling Visit 4 and event classification are described in sections 1.5 and Manual 3, respectively.

Using the list of participant anniversary dates, field centers identify participants for annual contact. The 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. 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.

However, all participants 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. 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 the scheduling of Visit 4 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 or 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 family members, friends, employers, or physicians the participants identified as contact persons 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 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 10, or subsequently if necessary, to schedule the fourth 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 10) 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.

1.2.3 Annual Cohort Interview

In Contact Year 10, version "F" of the AFU form is administered, unless the one-time only version "E" with its companion AFU Medical History Form (AMHA) have not yet been administered. Question by question (QxQ) instructions for

the Record of Calls and version "F" of the AFU form and prototype scripts for their administration have been prepared for the AFU interview (See Appendix 1.7). The interview includes the use of three forms (UPD, TRC and AFU) which update address and tracing information of cohort participants (See Appendix 1.2 or 1.3, UPDATE form); and ascertain 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, weight loss, and life events (AFU, section I) (See Appendix 1.6, Annual Follow-up form). The Record of Calls is used throughout the contacting process to log each participant's interim and final contact and appointment status (when applicable). 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. Detailed information on diagnostic criteria and event determination of the cardiovascular events is provided in Chapters 4 and 5, respectively, of Manual 3, Surveillance Component Procedures.

The components of the AFU interview are usually done in the following order: (1) completion of the Record of Calls; (2) administration of the AFU questionnaire; (3) documentation of the participant's hospitalizations during the past year - section K of the AFU form; (4) scheduling of the appointment for Visit 4 (Contact Year 10); and (5) updating of the contact information (UPD form).

The Record of Calls (TRC form) is used to keep track of attempts to contact a participant and to schedule Visit 4 (Contact Year 10). The participant's name, ID, contact year, and contact year date ranges are pre-printed 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 ten contact RESULT CODES. The final result code is circled and entered into the data entry system. The paper copy of the form is kept in the participant's folder to assist in future contacts.

*RESULT CODES (CIRCLE THE FINAL SCREENING RESULT CODE (AFUF Item 46)

01 No Action Taken
02 Tracing (Not yet contacted any source)
03 Contacted, Interview Complete
04 Contacted, Interview Partially Complete or Rescheduled
05 Contacted, interview refused
06 Reported Alive, Will Continue to Attempt Contact this Year
07 Reported Alive, Contact Not Possible this Year
08 Reported Deceased
09 Unknown
98 Does Not Want Any Future AFU Contact.

Codes 01, 02, 04, and 06 are interim codes. Codes 03, 05, 07-09, 98 are final codes. See Appendix 1.7 for detailed instructions for completing the form, and a description of the Results Codes for contacts. It should be noted that these codes are required for all AFU contacts, in contrast to the APPOINTMENT CODES which are only used in the Contact Years in which the participant is scheduled for a clinic visit.

Once contact has been made, the entire AFU interview is administered to surviving participants. When a 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 records 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 claudication. Guidelines for administering this section are provided below, in Section 1.2.3.1. Sections H and K on the AFU form are administered to all respondents (participants and proxies) to document overnight hospitalizations in acute or chronic medical care facilities. The surveillance staff is notified of every cohort hospitalization and an event investigation is initiated. Section I is administered only to surviving participants.

Tracing information listed on the pre-printed 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.

1.2.3.1 Administration of London School of Hygiene Questionnaire

The questions in Sections D-F (CHEST PAIN ON EFFORT, POSSIBLE INFARCTION, and INTERMITTENT CLAUDICATION) of the AFU form are based on the London School of Hygiene Questionnaire. The purpose of the London School of Hygiene Questionnaire (generally referred to as the 'Rose Questionnaire') is to standardize the identification of 'angina on effort' as defined by Dr. Geoffrey Rose. It is <u>not</u> 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 <u>exactly</u> 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. <u>Supplementary questions (probing) should rarely be used</u>. 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."

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.

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

The folders of ARIC participants to be scheduled for Visit 4 who report 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 4 by a trained interviewer administering the Health History Form and the Medical Data Review.

1.4 Window for Visit 4

The scheduling of Visit 4 is made in conjunction with the annual contact in Contact Year 10. The optimal time frame for scheduling Visit 4 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 4 within this time frame, it is still possible for Visit 4 to be completed at any time during Contact Years 10 through 12. For example, if the participant refuses or does not show for a visit in Contact Year 10, scheduling is attempted in Contact Years 11 and 12. The Visit 4 data are entered into the database as Contact Year 10 data, even if the field center exam occurs during Contact Years 11 and 12. This is in contrast to the recording of the actual contact year number (e.g., 11 or 12) of the AFU interview in which Visit 4 is successfully scheduled. For example, if a participant has an AFU interview and is scheduled for Visit 4 in Contact Year 10, does not come to the field center within the remaining time during Contact Year 10, is recontacted in Contact Year 11, and agrees to rescheduling and completes Visit 4 during Contact Year 11, the AFU contacts are listed as Contact Year 10 and Contact Year 11, but the Visit 4 contact year is listed as Contact Year 10.

There are 11 APPOINTMENT CODES which are completed on the Record of Calls (TRC), Version F in Contact Year 10. 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. Like contact status (result) codes, final codes indicating permanent disenfranchisement from the study must be approved by the supervisor. The final appointment code is circled and entered into the data entry system.

** APPOINTMENT CODES (AFUF Item 47)

00 Appointment scheduled (record date, time and special needs)
01 Clinic examination completed
02a Appointment deferred (by clinic staff)
02b Appointment pending due to sickness or other concerns/ condition of the participant
03 Moved outside of the study area, will be contacted annually for follow-up
04 Rescheduled many times, unlikely to complete appointment
05a Appointment refused, permanently incapacitated
05b Appointment refused, other reason
06 Refused clinic visit and does not want any further contact
07 Unable to locate
08 Deceased

1.5 Scheduling of Visit 4 Field Center Examination

1.5.1 Outline of Scheduling Procedures for Visit 4

The steps in the scheduling procedures for Visit 4 are similar to those for scheduling and conducting the AFU interview, but also includes recruitment for the Oral Glucose Tolerance Test (OGTT) and screening and recruitment for the dental examination.

1. The Participant Tracing Information Sheet is a list of participants to be contacted, their tracing information, the target contact date, and the six month time window around the target date which 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 4 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 North Carolina and Mississippi 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 4 will be set (Appendix 1.8). A brief description of Visit 4 is provided in the letter, as well as a request to have a calendar available to facilitate scheduling Visit 4.

3. The participant is telephoned, the Annual Follow-up Form is completed in the usual manner. Participants are reminded that it is time for their next clinical examination (Visit 4). The new procedures (oral glucose tolerance test, heart rate variability test, and the dental examination) which have been included in Visit 4 are reviewed, the dental screening form is administered to all cohort members and all eligible participants are recruited for the dental examination. A prototype script for introducing the dental exam is provided in Appendix 2.6.c. An appointment for Visit 4 is scheduled. Some home interviews may be necessary for individuals unreachable by telephone or for special circumstances. After the appointment is set, basic instructions for Visit 4 are provided. The need for adequate hydration while maintaining fasting is stressed to facilitate venipuncture and the collection of a urine sample at the beginning of the examination.

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 4 appointment, additional efforts to schedule Visit 4 at a later date are made. If a participant refuses to return to the field center for the fourth examination, continued annual contact in subsequent years is attempted, as well as the scheduling of Visit 4, 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 4 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 fourth field center examination (Visit 4) 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 4 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 and (5) the DENTAL SCREENING form. Using the prototype scripts provided in the question by question instructions (Appendix 1.7, the AFU form; and Appendix 2.6.a, the Dental Screening Form), 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.

1.5.3 Making the Clinic Appointment

After completing the annual follow-up interview for all participants in a household, the interviewer describes the clinic visit, including the new components, and schedules the participant's Visit 4 appointment following the prototype script provided in the question by question instructions for the Annual Follow-Up form. A separate one page prototype Visit 4 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.

1.5.4 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 on proper hydration while maintaining the fast;
   c) Instructions concerning restrictions on the use of tobacco and vigorous physical activity the morning prior to the visit;
   d) 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 and address of dentist if participating in dental exam;
   d) Name, address, and phone number of contact persons;
   e) Medication Instruction Sheet:
      Instructions for bringing prescription and over-the-counter medications, including 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 4 (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 (e.g., 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 their field center. Sufficient appointments are scheduled each day for Monday through Friday to meet the requirement of approximately 25 appointments per week.

Ultrasound B-mode examinations of the carotid arteries are scheduled for all Minneapolis and Washington County participants who did not have an ultrasound exam in Visit 3, and for approximately 50% of the participants from the Forsyth County and Jackson field centers. The collection of a urine sample is attempted from all participants and was implemented at the start-up of Visit 4. Eligibility to participate in the oral glucose tolerance test (OGTT) is determined during reception and all cohort members who are not diabetic on hypoglycemic medication are encouraged to participate. OGTT was implemented at start-up. The measurement of heart rate variability is performed on all participants and was implemented several months after start-up, beginning in May, 1996. The dental exam was implemented after start-up, and is performed on all eligible participants. Cohort members who completed their Visit 4 exam prior to implementation of the heart rate variability study and dental examination are invited to return for these procedures.

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 4 field center appointment (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.

1.5.5.1 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 fourth exam 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. 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 <u>on paper</u>, assigning the <u>original study ID</u>. These forms are photo-copied; 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.

1.6 Retention of ARIC Participants

1.6.1 Introduction

Projected Visit 4 clinic re-examination rates (ranging from 80 to 90 percent) are dependent upon each field center's ability to contact eligible participants and schedule return appointments.

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) pre-appointment contacts, (3) no show procedures, (4) reimbursement of transportation costs, and (5) publicity.

1.6.2 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 centrally 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.

1.6.3 Pre-appointment Contacts

To increase respondent participation following the Annual Follow-up/Visit 4 Scheduling telephone call by an ARIC interviewer, a pre-Visit 4 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 and requesting time-off during work hours (see Appendix 1.11).

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. 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 non-response, and examine performance trends by interviewer and by area. When deemed appropriate, supervisors initiate re-contact with refusing participants to attempt their conversion. Detailed records of all contacts are maintained.

2.0 INTERVIEWS IN THE VISIT 4 CLINICAL EXAM

2.1 Introduction

During the annual follow-up interview, cohort members in the Contact Year 10 are invited to return for a fourth field center exam (Visit 4). As envisaged during the initial design of the ARIC study, a core component of the cohort examination has remained constant in Visit 4 to provide comparability. From the outset, each examination has included measurements of blood chemistries (glucose, lipids, hemostatic factors); blood pressure (sitting and supine blood pressure); body/frame size (anthropometry); resting electrocardiogram (ECG); and carotid artery B-mode ultrasound imaging. Core interviews have documented prevalent/incident cardiovascular disease, symptoms and medical care; fasting status prior to venipuncture; use of medications (prescription, over-the-counter, vitamins and mineral supplements and gonadal hormones in women); menstrual status in women (natural, pharmacological and surgical); and prevalent/incident cerebrovascular disease (stroke and TIA). In addition to the core elements, some ARIC procedures and interviews have been included with the intention of collecting data on a one-time-basis, and some at six year intervals. A test of cognitive function, originally administered to all participants in Visit 2 and to participants in Forsyth County, NC and Jackson, MS in Visit 3 who had cerebral MRI scans, is re-administered to all participants in Visit 4. The Spielberger Trait Anger interview, which was originally administered to all participants in Visit 2, is re-administered in Visit 4 as a measure of psychosocial status. New procedures in Visit 4 include the documentation of male pattern baldness; the collection of a urine sample for the assessment of microalbuminuria; and the administration of an oral glucose tolerance test. New interviews include medical histories of chronic inflammatory diseases, physical ability and socioeconomic status at birth and middle age (see Table 2.1.a). A repeatability study of the Visit 3 retinal exam is scheduled for the first few months of Visit 4 and its procedures and data collection forms are provided in Appendix 3.10, because it is only conducted on approximately 800 participants (200 per field center) and is not considered a primary component of Visit 4. Two ancillary studies, an oral examination to assess putative association(s) of chronic inflammation and the measurement of heart rate variability, have been integrated into Visit 4 and are conducted on all eligible participants (see Table 2.1.b).

Table 2.1.a Core Components of the Visit 4 ARIC Cohort examination, listed in alphabetical order, and location of the procedures in the Manuals of Operation

Work station	Description	Manual
Anthropometry	Measure weight, height, waist and hips. In men, assess male pattern baldness.	2.3
ECG	Obtain resting 12 lead ECG	2.3, 5
Informed Consents	Obtain informed consent for core Visit 4 exam including authorization for collection of DNA and other study data, access to medical records, release of study data and separate consents for ancillary studies	2.2
Interviews	Collect sociodemographic data; health care, and medical, personal and reproductive (women only) history; medication/vitamin use; physical ability; dental screening and history; history of chronic inflammation (two forms); OGTT screening; SES data; cognitive function	2.2
Medical Data Review	Ascertain the completeness of exam; verify abnormal results. Review results of medical history with participant, and provide a written clinic summary report. Refer participant for diagnosis or treatment elsewhere if needed. Return medication; answer questions; thank participants. Reschedule for missed procedures.	2.4
Microalbuminuria	Collect urine sample at beginning of exam or any time prior to exit.	2.3
Oral Glucose Tolerance Test	Collect fasting and 2 hour post glucose load blood specimens	2.3
Reception	Greet the participant; obtain informed consents; determine fasting status; verify eligibility for OGTT: verify identifying information; obtain tracing data; collect medications.	2.2
Sitting Blood Pressure	Assess sitting blood pressure using random zero sphygmomanometer; average of 2 measurements	11
Snack	Provide snack with no stimulants to persons not doing the oral glucose tolerance test	2.3
Ultrasound	Obtain B-mode scan of extracranial carotid arteries. Record heart rate and blood pressure changes as participant arises from supine position.	6,11
Venipuncture	Obtain blood samples for laboratory tests and storage of specimens.	7

Table 2.1.b Components of the Repeatability and Ancillary Studies in the Visit 4 examination, and the location of the procedures in the Manuals of Operation

Work station	Description	Manual
REPEATABILITY STUDIES AT VISIT 4		
Retinal	Repeatability study of procedures done in Visit 3 to photograph ocular fundus on 200-250 participants at each field center at the beginning of Visit 4.	App.3.10
ANCILLARY STUDIES INTERFACING WITH VISIT 4		
Dental Study	Collect history of periodontal disease on all ppts;Screen all for eligibility in dental exam; Perform screening exam of oral hygiene; level of caries, missing teeth, plaque; collect gingival crevicular fluid; collect plaque; assess gingival inflammation; determine probing depth, cemento-enamel junction and bleeding on probing; provide summary of results of dental exam.	Manual 2-Chap. 3.6 DENTAL STUDY MOP
Heart Rate Variability	Assess cardiac autonomic activity by obtaining 6 min R-R interval data after 12 lead ECG on all participants prior to OGTT; performed after a 10 minute rest in the supine position when done on make-up participants	Manual 2-Chap 2.3 HRV MOP

Chapters 2-6 of this manual provide an overview of the fourth cohort examination, procedures for administering participant interviews and conducting exams, references to the pertinent manuals of the protocol for those examination procedures not covered in detail in Manual 2, and appendices of forms and question by question instructions for their administration. Chapter 2 provides an overview of the design, objectives and content of the fourth clinical examination (Visit 4), and describes the logistics for setting up the clinical examination. Chapter 3 provides the rationale and describes the procedures, the training and certification required to perform the procedure, the quality assurance activities, and the data collection instruments and procedures. Chapter 4 provides similar information for the interviews administered during Visit 4. Chapter 5 describes the activities associated with reporting results. Chapter 6 outlines the procedures at the field center to ensure participant safety.

Table 2.1.a lists the main components of Visit 4, identifying the activities at each work station and cross-referencing each procedure with its respective manual of operation. Table 2.1.b lists components from Visit 3 which are being repeated for quality control purposes and ancillary studies which have either been integrated into the clinical exam or for which additional blood samples are being drawn.

In general, the numbering of sections within chapters 2 - 6 follows a standard format: a description of and the rationale for the interview, procedure, or activity (.1), operational procedures (.2), training requirements (.3), the certification criteria (.4), routine quality assurance activities (.5), and

data collection procedures (.6).

The rationale (.1) for core interviews, measurements and procedures briefly summarizes the major premise(s) for its inclusion in the ARIC study and its continued use in Visit 4. A more detailed rationale is provided for the new components in Visit 4.

The section on operational procedures (.2) describes in detail the procedures for administering the interviews, conducting examinations or taking measurements, or gives a reference to the appropriate manual of operations for the procedures with their own separate protocols. Standardized definitions of terms for use by the interviewer or respondent in an interview or instructions for administering or filling in individual questions on the data collection forms for each interview, measurement or procedure are provided in the question by question (QxQ) instructions which are located in the Appendix, immediately following the individual data collection form.

Training requirements (.3) and certification criteria (.4) are listed separately from their traditional rubric of quality assurance to provide easier reference for study personnel. Training materials additional to those in this manual of operations on data management, general interviewing techniques, the administration of all interviews, the measurement techniques for procedures, informed consent, results reporting and referral guidelines were compiled for the Visit 4 central training workshop and are available in a separate notebook at each field center.

To reduce the use of repetitive statements for each procedure in the sections on training and certification for interviews and procedures, it is understood that the minimum training and certification requirements/criteria for all Visit 4 interviewers, technicians and clinicians are a command of the pertinent protocol sections and forms, and demonstrated proficiency on the ARIC direct Data Entry System or back-up procedures for data collection on paper forms. Detailed instructions for completing paper forms and for standardized interviewer techniques are found in appendices 2.1 and 2.2, respectively.

Table 2.2 lists the personnel responsible for the central and local training of each interview/procedure at the outset of Visit 4. The Quality Assurance section (.5) briefly summarizes and/or references the additional quality control activities that are carried out locally by field center personnel and globally by the Coordinating Center and other Central Agencies, see Manual 12, Quality Assurance and Quality Control.

The final section in each section is on Data Collection (.6) which briefly summarizes the standard and backup operating procedures for data collection using both the direct and delayed entry systems. A separate manual, The Data Management Manual, serves as the official reference document for all data collection and systems management procedures.

The appendices for this manual provide support material for Chapters 1-8, and include interviewing scripts, the data entry screen and paper versions of all forms, the detailed question by question instructions for administering each form, prototypes of all participant results reports and quality control checklists.

Table 2.2 Certification Criteria: Visit 4 Cohort Exam Procedures and Interviews

PROCEDURE OR INTERVIEW	CERTIFICATION REQUIREMENT	CERTIFIER OR REVIEWER	RECERTIFICATION REQUIREMENTS	RECERTIFIER OR REVIEWER
AFU (CY10-12) Annual Follow-up - typically done by telephone	Local review of AFU procedures	Supervisor or Lead Interviewer	Annual Rose Questionnaire Exercises Annually Annual local review	G. Heiss-UNC Supervisor or Lead Interviewer
ANTHROPOMETRY height weight waist hip baldness	Lead Technician certified at central training; all others @ central training or by lead tech. @ field centers. 1 cm of trainer 1 cm of trainer 1 cm of trainer 1 cm of trainer agreement w/trainer	Central trainer or Lead Technician	Biannually (Jan/Jul) @ field centers; results sent to CC for documentation once a year. Annual recertification for Lead Technician during monitoring visit	Lead technician @ field centers Monitor
BLOOD PRESSURE, SITTING 2-replicate measures digit preference mean values	Lead Technician certified at central training; all others @ central training or by lead tech. @ field centers. < 4 mmHg/reading < 3 mmHg/average none	Central trainer or Lead Technician Coordinating Center Coordinating Center Coordinating Center	Biannually (Jan/Jul) @ field centers; results sent to CC for documentation once a year. Annual recertification for Lead Technician during monitoring visit Continuous Continuous Continuous Continuous	Lead technician @ field centers Monitor Coordinating Center Coordinating Center Coordinating Center Coordinating Center
COGNITIVE FUNCTION	Adequate technique on 5 taped interviews	Supervisor or Lead interviewer	Annually, 1 taped interview (non-interviewer staff) included in round robin	4 field center interview supervisors monitoring round robin tapes
DENTAL HISTORY interview	Adequate technique on 5 taped interviews	Supervisor or Lead interviewer	Annually, 1 taped participant interview included in round robin	4 field center interview supervisors monitoring round robin tapes
DENTAL SCREENING interview (phone or in-person)	Local review of interviews	Supervisor or Lead interviewer	none	none
12 LEAD ECG	Adequate technique on 5 ECG tracings	Epicare reviews ECG quality Review of procedures by Lead Technician	Monitored continuously @ Epicare with quarterly reports to field centers Biannual review of technique @ field center (Jan/July);results sent to CC once a year.	Epicare Lead Technician
HEALTH HISTORY interview	Adequate technique on 5 taped interviews	Supervisor or Lead interviewer	Annually, 1 taped participant interview included in round robin	4 field center interviewer supervisors monitoring round robin tapes

PROCEDURE OR INTERVIEW	CERTIFICATION REQUIREMENT	CERTIFIER OR REVIEWER	RECERTIFICATION REQUIREMENTS	RECERTIFIER OR REVIEWER
HEALTH/LIFE PROFILE self-administered form	Adequate explanation on 5 taped introductions to participants	Supervisor or Lead interviewer	none	none
HEART RATE VARIABILITY	Adequate technique on 1 week of tracings, or 5 procedures	Ultrasound Reading Center	Monitored continuously @ URC with quarterly reports to field centers. Annual retraining and biannual review of technique w/ECG @ field center (Jan/July); results sent to CC once a year.	Ultrasound Reading Center Ultrasound Reading Center
INFLAMMATION interview	Adequate technique on 5 taped interviews	Supervisor or Lead Interviewer	Annually, 1 taped participant interview included in round robin	4 field center interviewer supervisors monitoring round robin tapes
LETTERS/REPORTS Participant results reports	Local approval	Supervisor or PI	Methods reviewed annually during CC monitoring visit	Supervisor and Monitor
MEDICAL DATA REVIEW	Local approval	Supervisor or PI	Methods reviewed annually during CC monitoring visit	Supervisor and Monitor
MEDICAL HISTORY self-administered form	Adequate explanation on 5 taped introductions to participants	Supervisor or Lead interviewer	none	none
MEDICATION SURVEY Interview Transcription/coding	Adequate technique on 5 taped interviews 80% correct on coding exercise	Supervisor or Lead Interviewer Supervisor or Lead Interviewer	Annually, 1 taped participant interview included in round robin Methods reviewed annually during CC monitoring visit	4 field center interviewer supervisors monitoring round robin tapes Monitor
MICROALBUMINURIA Urine collection and processing	Lead technician certified at central training; all others @ central training or by lead tech @ field centers	Central trainer or lead technician	Biannual (Jan/July) review of techniques Annual CC or central lab monitoring visit	Lead Technician Monitor
ORAL GLUCOSE TOLERANCE TEST	Lead technician certified at central training; all others @ central training or by lead tech @ field centers	Central trainer or lead technician	Biannual (Jan/July) review of techniques Annual CC or central lab monitoring visit	Lead Technician Monitor
PERIODONTAL EXAM Examiner Recorder	Examiners certified at central training and satisfactory performance of 5 exams Certified at central training or by examiner at field centers	Dental Study PI Central trainer or hygienist	Annual central refresher training Annual CC monitoring visit	Dental Study PI Monitors

PROCEDURE OR INTERVIEW	CERTIFICATION REQUIREMENT	CERTIFIER OR REVIEWER	RECERTIFICATION REQUIREMENTS	RECERTIFIER OR REVIEWER
PERSONAL HISTORY interview	Adequate technique on 5 taped interviews	Supervisor or Lead interviewer	Annually, 1 taped participant interview included in round robin	4 field center interviewer supervisors monitoring round robin tapes
PHYSICAL ABILITY self-administered form	Adequate explanation on 5 taped introductions to participants	Supervisor or lead interviewer	none	none
RECEPTION Informed consent Fasting/tracking form OGTT Screening	Adequate methods on 5 taped receptions	Supervisor or lead interviewer	Annual review Annual CC monitoring visit	Supervisor or Lead Interviewer Monitor
UPDATE form	none	none	none	none
REPRODUCTIVE HISTORY interview Transcription/coding	Adequate technique on 5 taped interviews 80% correct on coding exercises	Supervisor or Lead interviewer Supervisor or Lead interviewer	Annually, 1 taped participant interview included in round robin Annual CC monitoring visit	4 field center interviewer supervisors monitoring round robin tapes Monitor
SES interview	Adequate technique on 5 taped interviews	Supervisor or Lead Interviewer	Annually, 1 taped participant interview included in round robin	4 field center interviewer supervisors monitoring round robin tapes
TIA/STROKE interview Med review abn. symptoms	Adequate technique on 5 taped interviews Local approval	Supervisor or Lead Interviewer Supervisor or PI	Annually, 1 taped participant interview included in round robin	4 field center interviewer supervisors monitoring round robin tapes
ULTRASOUND Scan and postural change	Attend central training @ URC Submit 10 acceptable B-mode scans	URC /Chief sonographer	Monitored continuously at URC Biannual QC review	URC URC and QC Committee
VENIPUNCTURE	Lead technician certified at central training; all others @ central training or by lead tech at field centers	Central trainer or Lead Technician	Biannual (Jan/July) Annual CC or central lab monitoring visit	Lead Technician Monitor

2.2 Participant Flow

The participant flow is based on a paradigm used successfully since Visit 1, and modified to reflect study requirements in subsequent visits and the operational needs of the individual field centers. The schedule is divided into fixed and non-fixed sequences to accommodate legal requirements, scientific constraints of which measurements cannot precede another, the daily fluctuations in field center staffing patterns and unforeseen number of participants who keep scheduled appointments, the configuration of each field center's physical layout, equipment availability and function; the integration of ancillary studies, and so forth. Participant flow and the approximate time associated with each workstation are outlined in Table 2.3.

2.2.1 Rationale

The fixed components of scheduling participant flow are identical at all four field centers reflecting the requirement to initiate the examination with the administration of informed consent, the scientific constraints which establish the grouping of procedures which require fasting, and the logistical necessity of conducting medical data reviews after all other procedures have been completed. The flexible components reflect the advantages of having the separate field centers conduct the majority of the interviews and examinations in accordance with the physical layout and the scheduling patterns of the individual field centers. This approach is intended to minimize participant burden to approximately 4 hours and reduce variability in study measurements.

2.2.2 Fixed Sequences

The introduction of the oral glucose tolerance test (OGTT) and measurements of heart rate variability (HRT) in Visit 4 has substantially increased the number of components that must be conducted while the participant is fasting. An outline of the components, and the order in which they must be scheduled, is provided in Table 2.3. As has been done in Visits 1-3, Visit 4 always begins with the administration of the informed consent at the reception workstation and always ends with the reporting of preliminary study results to participants at the medical data review workstation. The collection of a urine sample from the participant is simplified when done in conjunction with the change from street clothes to a scrub suit and is therefore scheduled at the conclusion of the reception workstation and prior to the anthropometry/blood pressure workstation. (Note: a urine specimen can be collected at any time during the exam if the participant cannot void immediately after reception.) Because the measurement of sitting blood pressure requires knowledge of the circumference of the right arm in order to select the appropriate blood pressure cuff, anthropometry is

Table 2.3 Participant Flow in Visit 4

PROCEDURES/WORKSTATIONS	Approximate Time
FIXED SEQUENCING	
RECEPTION	15 min
Informed consent	
Informed consent tracking	
Update of contact information	
Fasting status	
OGTT Screening	
CHANGE CLOTHES/ COLLECTION OF URINE SAMPLE	6 min
ANTHROPOMETRY	6 min
SITTING BLOOD PRESSURE	10 min
12 LEAD ECG	15 min
HEART RATE VARIABILITY	15 min
VENIPUNCTURE	6 min
GLUCOSE TOLERANCE TEST	5 min
FLEXIBLE SEQUENCING	
DENTAL EXAM	35 min
STAFF ADMINISTERED INTERVIEWS	30 min
Cognitive Function; Dental History; Health History; Inflammation; Medication Survey; Personal History; Reproductive History; Socioeconomic Status; TIA/Stroke	
SELF-ADMINISTERED INTERVIEWS	10 min
Health and Life Profile (Self-Admin)	
Medical History Questionnaire (Self-Admin)	
Physical Ability Questionnaire (Self-Admin)	
ULTRASOUND	40 min
Carotid arteries/Postural change in blood pressure	
2ND VENIPUNCTURE	2 min
SNACK (After 2nd blood draw)	8 min
FIXED SEQUENCING	
DATA INVENTORY	6 min
CHANGE CLOTHES	5 min
MEDICAL DATA REVIEW	10 min
Medical Data Review	
TIA/Stroke Summary (not study data)	
LAG TIME BETWEEN WORKSTATIONS	12 min
TOTAL FOR ULTRASOUND PROTOCOL	4 hours
TOTAL FOR OTHER 50 PERCENT	3 hrs 20 min

generally performed prior to sitting blood pressure, and is generally performed at the same workstation. Venipuncture must be done while the participant is in the fasting state, therefore venipuncture is always scheduled prior to the administration of the glucose load. The administration of the glucose load is known to affect heart rate variability. Therefore, the ECG/HRT sequence is always scheduled prior to venipuncture. A minimum of 5 minutes needs to elapse between a procedure in the supine position (such as the ECG and the measurement of heart rate variability) and the blood draw. The order in which anthropometry/sitting blood pressure and ECG/HRV, however, is a local option. The 2nd venipuncture of cohort members participating in the OGTT must be scheduled 2 hours after the ingestion of the glucose load. Interviews or the dental exam may be interrupted by the laboratory technician to perform the 2nd venipuncture if waiting would result in the post-glucose sample being drawn more than 10 minutes before or after than the target collection time.

2.2.3 Flexible Sequences

The staff- and self-administered interviews, oral exam, ultrasound scan of the carotid arteries, and 2nd venipuncture are scheduled in the non-fixed portion of the exam.

The Participant Information (PIN) Sheet (Appendix 2.16) is prepared by the Coordinating Center and serves as a summary of clinically relevant data from previous ARIC exams for use during reception, interviews and medical data review. The participant's record of data acquisition is documented on the ARIC Cohort Inventory (CXI, Appendix 2.3.a) form within the Data Entry System, and manually on the Sample Inventory Record (SMP, Appendix 2.3.b) in the DES. The CXI is completed as a function of the DES software as each interview or procedure is completed and monitors the completion of data collection forms. The SMP serves as the summary of procedures performed during the clinic visit is entered into the DES following the participant's visit. The Participant Itinerary Sheet (Appendix 2.17) is prepared by the individual field center and is attached to a participant's folder. It has several purposes: to monitor the amount of time it takes to complete each component of the examination; to provide staff with information about where the participant is in the process, or to establish the participant's sequence of procedures and interviews based on daily staffing patterns.

2.3 Reception

The reception workstation initiates the Visit 4 interviews and clinical measurements at the field center. Prior to the participant's arrival, a Visit-4 folder is assembled which contains labelled data collection forms: the most recent Annual Follow-up (AFUF) and Record of Calls and Scheduling (TRCF) forms (these may also be filed in a separate, recruitment folder at the discretion of the field center, but are available for use during the ARIC exam), the Update (UPDB) form, the Participant Itinerary Sheet (PIN), the Dental Screening (DSRA) Form, and blank copies of the ARIC Visit 4 and Dental Study Informed Consent forms, the Fasting/Tracking (FTRD) form, the Oral Glucose Tolerance Test screening (GTSB) form, the Venipuncture (LABB) and Oral Glucose Tolerance Administration (GTAA) forms (data are collected on paper for delayed data entry), the Cognitive Function Test (CNFC) form (data are collected on paper for delayed data entry), and the Health and Life Profile (HPCB), Medical History (MHQA), and Physical Ability (PAQA) forms (self-administered forms completed by participants between work stations). Folders also contains previously completed Report and Referral forms and ALERT/REFERRAL logs and blank copies for use in Visit 4. The Itinerary Sheet is attached to the outside of the clinic visit folder.

On arriving at the field center, the participant is greeted and welcomed. Informed consent for the full ARIC exam (Appendix 2.11.a) is obtained before administering any other ARIC interviews. The ARIC Dental Study informed

consent (Appendix 2.11.b) is administered in conjunction with or after the ARIC study informed consent, at local discretion. Participant questions are answered. Demographic and tracking information (Update Form, Appendix 2.22) are updated. Fasting status (Fasting/Tracking form, Appendix 2.7) is determined. The person's eligibility (OGTT Screening Form, Appendix 2.15 and previous status of treated diabetes on the PIN sheet) and consent to participate in the oral glucose tolerance test are ascertained. Consent to tape interviews for quality assurance assessment is requested and documented on the Itinerary sheet (Appendix 2.17). The Informed Consent Tracking form (Appendix 2.12) is completed either during or after the participant has left the reception work station. Medication bags are logged and labelled.

General instructions on how to administer each interview are given in the text of Chapter 2 under the name of the data collection form. Specific instructions for completing each item on the data collection form are given in the question by question (QxQ) instructions which follow the form in the Appendix.

When screening for the Dental Study has not been done prior to the Visit 4 exam, the Dental Screening form (Appendix 2.6) is administered at the reception work station, and eligible cohort members are recruited to have a dental exam, the same day if possible, and the Dental Study informed consent is administered.

The schedule for reporting the participant's study results can be reviewed with the participant at the reception work station as a local option. The interviewer explains that some of the study results are reported at the conclusion of the exam before the participant leaves the field center. All study results done during the visit are reviewed with the ARIC clinician after the participant has left the field center (Appendix 5). A final summary report is mailed to the participant and his/her physician (with his/her permission) 6 - 8 weeks after the clinic visit date, as described in Chapter 7 (RESULTS REPORTING). Referral letters are mailed to participants and their physicians in conjunction with their final summary report when study results are out-side of the study's reference ranges, or prior to that when study results are found to be an alert value (Chapter 7, Appendix 6 and 7).

When informed consent and the Update, Fasting and OGTT Screening forms have been administered, and eligibility to do the glucose tolerance test confirmed, the participant is shown where to change into an examination gown/robe, asked to remove all jewelry, and to place clothing and valuables in a secured locker. The participant is requested to provide a urine sample, if possible, and then empty the bladder prior to beginning the examination. Specific instructions on how to collect the urine sample are given in Chapter 3.5.

Staff are trained for the reception work station at central training and locally by the Study Coordinator at each field center. Certification requirements include the successful completion of training on general interviewing techniques, Informed Consent, the Fasting/Tracking form, Direct Data Entry System, and OGTT Screening. Although no formal certification schedule has been established, interviewers working at the reception work station are observed by the local study coordinator for quality assurance and standardization.

2.4 Cognitive Function

In Visit 4, a standardized test of Cognitive Function (CNFC) is administered to all participants (Appendix 2.4). The blank data collection form (Appendix 2.4.a) is filed in the participant's folder. The three components (Delayed Word Recall, Digit Symbol Substitution Task, and the Word Fluency Task) are those administered to all participants in Visit 2, and the participants in Forsyth County, NC and Jackson, MS who had cerebral MRI scans. The administration and scoring instructions, and the data entry system (DES)

screen are unchanged from previous visits. This includes a prohibition of the taping of the procedure.

2.4.1 Rationale

The main objective of cognitive function testing in Visit 2 was to establish a baseline for future comparison. Although the ARIC study population continues to be too young in Visit 4 to focus on frank dementia, the repeated measurement of cognitive function provides the opportunity to investigate changes in cognitive function over time. This in turn can be correlated with specific risk factors.

The three measures used in Visit 2 are repeated: the Delayed Word Recall, Digit-Symbol Substitution and Word Fluency tests. None of these tests have an upper limitation on performance, and can be expected to allow small changes in mental performance to be detected longitudinally.

The Delayed Word Recall is a test of short term memory. This test has the added feature of allowing participants to encode the words to be recalled (use each word in a sentence) to enhance retrieval. Ten words are given which in effect removes the ceiling or upper limit of performance.

The Digit Symbol Substitution Test requires response speed, sustained attention, and visual-spatial skills. It is part of the Wechsler Adult Intelligence Scale. This test requires that the participant fill in a series of symbols within 90 seconds.

The Word Fluency Test measures verbal function. This too requires speed and sustained attention, but measures mental agility in retrieving words.

2.4.2 Administration

A trained ARIC interviewer administers the cognitive function tests, one right after the other, in a quiet room which is sheltered from distracting noises and has sufficient work space for the participant to place the Digit Symbol Substitution form on a table and fill in the blanks on the form. The purpose of the tests is briefly explained to each participant. The tests are administered following the instructions printed on the Cognitive Function paper forms (Appendix 2.4.a) and QxQ instructions (Appendix 2.4.c). Responses to Parts A and C are recorded on a paper form by the interviewer. Part B is completed by the participant. Test results are tabulated by the interviewer after the participant has completed the tests and left the room. Test results are entered on the Cognitive Function DES screen (Appendix 2.4.b) by the interviewer.

2.4.3 Training

Interviewers are trained centrally prior to Visit 4. The field center interviewer supervisor is responsible for the training and certification of new field center interviewers.

2.4.4 Certification

Certification for administering the Cognitive Function form is achieved by the demonstration of adequate technique on interviews on non-ARIC participants, and approved by the supervisor or lead interviewer. Recertification is done annually, and requires the successful completion of one interview reviewed by the local interviewer supervisor.

2.4.5 Quality Assurance

Technique and adherence to protocol are monitored by Coordinating Center Monitors; data quality is monitored by the Quality Control Committee semi-annually.

2.4.6 Data Collection

Results of the Delayed Word Recall and the Word Fluency Task are recorded by the interviewer on the Cognitive Function form. Symbols for digits are recorded on the form by the participant. Test scores are calculated and entered by the interviewer on the last page of the form for delayed data entry (Appendix 2.4.b), after the participant has left the work station.

2.5 Dental History

The Dental History (DHSA) form is included in Visit 4 as part of the initiative to study the association of chronic inflammation, as measured in individuals with periodontal disease, with atherosclerosis and its sequelae (Appendix 2.5.a). The Dental History form is administered to all ARIC participants, regardless of whether they are scheduled for the dental examination. The questions are designed to document aspects of the participant's dental status, which may be related to a history of chronic inflammation. The form includes questions on the cause(s) of tooth loss, loose teeth, false teeth, root canal(s), dental implant(s), frequency of brushing and flossing, and the use of dental care.

2.5.1 Rationale

During Visit 4, data on chronic inflammation are being collected to explore its association with atherosclerosis and thrombo-embolytic events. During the interviews at the field center, self-reported medical histories of chronic infections are recorded on the Inflammation Form and the Medical History Questionnaire. Periodontal disease also represents a form of chronic inflammation which can be assessed both by recording a person's history of periodontal disease, as is done in the Dental History form (see below), and by performing a non-invasive clinical examination of the mouth, which is done in the dental exam (see the ARIC Dental Procedures Manual of Operations). By administering the Dental History form to all study participants, it is possible to collect a history of conditions which may reflect or result in periodontal disease as a surrogate measure of chronic inflammation.

2.5.2 Administration

The Dental History form is designed to be administered to all ARIC participants by trained and certified ARIC interviewers as part of the standard battery of interviewer-administered interviews. Like other ARIC forms, the questions on dental history are written using lay terminology, and are supported by QxQ instructions (Appendix 2.5.c) for the interviewer. Participant responses are either entered on a paper form for delayed data entry or entered directly into the DES (Appendix 2.5.b).

2.5.3 Training

The field center interviewer supervisor is responsible for the training and certification of new field center interviewers.

2.5.4 Certification

Certification for administering the Dental History form is identical to that required for the administration of the other ARIC interviewer-administered forms, and is achieved by the demonstration of adequate technique on 5 taped

interviews on non-ARIC participants, reviewed and approved by the supervisor or lead interviewer. The dental examiner or hygienist performing the dental examination may administer the Dental History and record participant responses on a paper form for delayed data entry only when certified to administer the form. Recertification is done annually, and requires the successful completion of one taped interview of an actual ARIC participant. With participant approval, all interviews are taped for quality control. This tape is included in the round robin which is reviewed by the four interviewer supervisors selected to monitor each year's round robin tapes.

2.5.5 Quality Assurance

With participant approval, most staff-administered interviews are taped for quality control. A non-systematic sample of the taped Dental History interviews are reviewed by the supervisor. Technique and adherence to protocol are also monitored by Coordinating Center Monitors; data quality is monitored by the Quality Control Committee semi-annually.

2.5.6 Data Collection

The Dental History form data are collected by direct data entry on a data entry screen (Appendix 2.5.b) unless the computer is not operational.

2.6 Dental Screening

The Dental Screening (DSRA) form is usually administered during the recruitment/scheduling call (Appendix 2.6.a). It can also be administered at the reception work station if eligibility to participate in the dental exam has not been established prior to the clinic visit. However, delayed determination of eligibility compromises the efficient scheduling of dental exams of eligible participants. Screening determines whether the participant has any teeth or whether the person would be placed at risk if a dental examination were performed without coverage by an antibiotic. See Section 3.2 for a description of the procedures in the Dental Study.

2.6.1 Rationale

Screening of ARIC participants prior to their clinic visit is done to identify persons in whom an oral examination is not informative, and as a safety precaution, following American Heart Association guidelines.

2.6.2 Administration

The Dental Screening form is a new form in Visit 4, and is designed to be administered as part of the Annual Follow-Up interview and Visit 4 scheduling call. An introductory script is provided in the QxQ instructions (Appendix 2.6.c) to aid the interviewer in providing a standardized explanation that a dental exam has been added to the procedures in Visit 4. The script is read to participant prior to administering the form. A table of definitions and synonyms of the medical terms used in the questions is also included in the QxQ instructions to assist interviewers in interpreting participant responses or defining terms to participants who are unsure as to whether or not they have had one or more of the medical conditions which would result in exclusion from the dental exam. As soon as an exclusion criterion is identified, the interviewer skips to the end of the form and informs the participant that he/she is not eligible to participate, either because (1) the person does not have any of his/her natural teeth; (2) the person has been told by a dentist that he/she needs to take antibiotics before every dental exam; or (3) the person reports having had a medical condition which requires the person to have antibiotics before a dental exam or procedure, according to American Heart Association guidelines. When no exclusion criteria are identified, the interviewer, using the script printed on the form, explains what takes place during the dental exam and attempts to recruit the participant.

When a participant is uncertain about the need to have an antibiotic prescribed for all dental exams or procedures, or is uncertain whether he/she has one of the medical conditions on the form, the interviewer selects the response category of UNKNOWN, does not exclude the person, and encourages the person to contact his/her doctor or dentist and resolve the uncertainty prior to coming to the ARIC exam. In situations where the participant indicates that he or she does not have a doctor/dentist with whom to consult, the interviewer can volunteer to discuss the situation with the local ARIC physician. When the person comes to the field center and the uncertain status of an exclusion criterion has not been resolved, the UNKNOWN status is changed to YES, and the person is excluded from the dental examination, unless the ARIC physician has indicated otherwise.

When a participant meets an American Heart Association exclusion criterion, AND REQUESTS the dental examination, the person can be recruited into the study if he/she agrees to take the antibiotics required for a dental examination. These antibiotics have to be prescribed by a dentist or physician, with the knowledge of the date of the ARIC exam. A special note is made and initialed on the Dental Exam Informed Consent that the participant has an exclusion criterion and is taking the required antibiotics.

2.6.3 Training

The field center recruitment interviewer supervisor is responsible for the training and certification of new field center interviewers.

2.6.4 Certification

Certification for administering the Dental Screening form is identical to that required for the administration of the other ARIC interviewer-administered forms, and is achieved by the demonstration of adequate technique and adherence to protocol, reviewed and approved by the supervisor or lead interviewer.

2.6.5 Quality Assurance

Routine quality assurance is provided at each field center by means of observation by the local study coordinator and recruitment supervisor. Administrative techniques and adherence to protocol are also monitored by Coordinating Center and Dental Study Monitors; frequency distributions of consent preferences recorded on the Dental Screening Form are routinely monitored by the Dental Study investigators and by the ARIC Quality Control Committee semi-annually.

2.6.6 Data Collection

In general, data are recorded on the paper version of the form during the AFU/Visit 4 Scheduling interview for delayed data entry into the ARIC DES. When necessary, the form can be administered (1) during an extra telephone when it is necessary to call back a participant who has already attended his/her Visit 4 exam, or (2) it can be administered to the participant at the reception work station when the person arrives at the field center without having had his/her eligibility ascertained. In all cases, the paper version of the form is completed for delayed data entry into the ARIC DES (Appendix 2.6.b).

2.7 Fasting/Tracking

The Fasting/Tracking (FTRD) form (Appendix 2.7.a) is a core data collection form which is unchanged since Visit 2. The form is administered at reception and documents the participant's fasting status, confirms one of the criteria for participation in the OGTT (minimum fasting for 10 hours), and establishes the participant's official visit date for Visit 4.

2.7.1 Rationale

The participant's fasting status affects the measurement of glucose, and the lipid and hemostatic profiles. To standardize measurements, participants are requested to take nothing by mouth except water for 12 hours prior to arriving at the field center.

2.7.2 Administration

QxQ instructions for administering the Fasting/Tracking form are provided in Appendix 2.7.c. The participant's fasting status is verified. Strict fasting is defined as nothing taken by mouth, except water, for the preceding 12 hours. However, for purposes of results reporting of the clinical chemistries, participants can be considered fasting if they have fasted for at least 10 hours or if they have ingested no more than one cup of black, unsweetened coffee/tea within the past 10 hours. Ingestion of more substantive liquids or solids constitutes breaking the fast. The participant's fasting status is recorded in number of hours on the Fasting/Tracking form, but the consumption of coffee/tea is recorded in a note log. Likewise for determining eligibility for the OGTT, participants who have fasted for at least 10 hours are considered fasting (see Section 2.15 for further instructions on determining OGTT eligibility).

Blood samples are drawn on all participants, <u>regardless of fasting status</u>. If the participant has not fasted for 10 hours, the participant is also offered the opportunity to repeat blood drawing in the fasting state at a later date. The Fasting/Tracking Form is completed; the non-fasting state and rescheduled date of venipuncture are noted on the Participant Inventory Form. When the participant returns in the fasting state for venipuncture, the questions concerning fasting status and recent blood donation on the Fasting/Tracking form are updated, and the Lipid and Hemostasis laboratories are notified that replacement samples are being shipped (See Section 3.9).

The Fasting/Tracking Form also documents whether the participant has given blood within the last 7 days. It is assumed that very few cohort members will have donated blood within the last week as they are reminded during both the scheduling calls not to do so, or to reschedule their clinic visit if they have had to give blood. Recent donors are not rescheduled once they come for Visit 4; the response to question 5 on the Fasting/Tracking form is recorded to reflect the recent blood donation and the individual is sent to the venipuncture workstation.

2.7.3 Training

Staff are centrally trained before Visit 4 and the study coordinator is responsible for providing training for new staff.

2.7.4 Certification

Certification for administering the Fasting/Tracking form is achieved by the observation of reception procedures by the Study Coordinator or interviewer supervisor. Recertification is done annually, and requires the successful completion of one taped interview. With participant approval, all interviews are taped for quality control. This reception tape is included in the round robin which is reviewed by the four interviewer supervisors selected to monitor each year's round robin tapes.

2.7.5 Quality Assurance

Routine quality assurance is locally provided by observation of the study coordinator. Protocol adherence and interviewing techniques are reviewed at least biannually by Coordinating Center field center monitors. Deviations from protocols and possible remedial actions are discussed with study

coordinators and staff at that time. Major deviations are brought to the attention of the ARIC Cohort Operations Committee.

2.7.6 Data Collection

The Fasting/Tracking form is collected by direct data entry on a data entry screen unless the computer is not operational. Computed fasting time is calculated by the Data Entry System (DES). A paper version of the form is available for back-up and subsequent data entry. Computed fasting time may be hand calculated, or obtained from a precalculated chart in the Fasting/Tracking form question by question instructions, and written in the margin to assist in determining the need to reschedule the participant for venipuncture. The computed fasting time is calculated by the data entry system when the data are batch entered into the data entry system (Appendix 2.7.b).

2.8 Health History

The Health History (HHXD) form (Appendix 2.8.a) is a core data collection form which is administered during the flexible component of the exam. In Visit 4, it serves as a follow-up to participant-reported chest pain on effort reported by the participant during the previous year (i.e., ascertained during the most recent AFU interview). The occurrence of the participant-reported chest pain is confirmed as positive angina and/or myocardial infarction by London School of Hygiene criteria. The questionnaire also documents the occurrence of procedures to diagnose or treat cardiovascular disease since the last ARIC exam, records information on the life time occurrence of head injuries which either resulted in loss of consciousness or required medical care and the age of the first blood transfusions and the source(s) of the first and any subsequent transfusions any time prior to the interview, and whether the participant requires aid in walking or standing.

2.8.1 Rationale

A major objective of the ARIC Study is the assessment of coronary heart disease (CHD) in the study population at each clinical examination and across time since the baseline examination. This is done, in part, by the documentation of the symptoms of heart disease and exposure to diagnostic and therapeutic procedures of each participant at each Visit. Another objective is a similar assessment of cerebrovascular disease (stroke). Questions on the life-time history of serious head injuries, defined as those which resulted in a loss of consciousness or required medical care, help evaluate other information collected symptoms of TIA or stroke. Information on the receipt of blood transfusions may help in the assessment of the associations of infections with atherosclerosis.

2.8.2 Administration

The Health History form is administered by trained and certified interviewers with an understanding of the medical terms and diagnostic procedures referred to in this instrument. The frame of reference for questions in Section A (chest pain on effort) and Sections B and C (invasive/non-invasive diagnostic and therapeutic cardiovascular procedures) is the time period between the 3rd and 4th ARIC examinations. Detailed procedures for administering the form are provided in the question by question instructions immediately following the form in Appendix 2.8.c and in the central training manual. Interviewers refer to the PIN sheet in the participant's folder to determine whether chest pain reported during the most recent AFU interview meet diagnostic criteria for Rose positive angina.

2.8.3 Training

Field center staff are centrally trained before Visit 4; they are responsible for providing training to new staff in interviewing techniques, technical terminology, and the question by question instructions for the Health History form.

2.8.4 Certification

Certification for administering the Health History form is achieved by the demonstration of adequate technique on 5 taped interviews, reviewed and approved by the supervisor or lead interviewer. Recertification is required annually, and requires the successful completion of one taped interview. With participant approval, all interviews are taped for quality control. This tape is included in the round robin which is reviewed by the four interviewer supervisors selected to monitor each year's round robin tapes.

2.8.5 Quality Assurance

With participant approval, most staff-administered interviews are taped for quality control. A non-systematic sample of taped Health History interviews are reviewed once a month by the supervisor. Technique and adherence to protocol are also monitored at least semi-annually by Coordinating Center Monitors; data quality is monitored by the Quality Control Committee on a semi-annual basis.

2.8.6 Data Collection

Data from the Health History form are collected by direct data entry unless the work station computer is inoperable. A paper version of the form is available for back-up and delayed data entry (Appendix 2.8.b).

2.9 Health and Life Profile

The Health and Life Profile (HPCB) form in Visit 4 (Appendix 2.9.a) repeats one portion of the form (Part C) which was originally administered during Visit 2. Part C is the Spielberger Trait Anger form and was designed to measure personality traits. The form is self administered. Although a brief explanation of the hypotheses to be tested is given below, no explanations, other than those provided on the form, are given to participants if they inquire as to why they need to respond to the statements on the form.

2.9.1 Rationale

Several components of Type A behavior, such as anger and hostility, have been shown in some studies to be associated with the risk factors and the expression of heart disease and stroke. This portion of the Health and Life Profile is administered to test many of the current hypotheses, and is being re-administered to assess consistency or changes over time in this putative measure of anger as a personality trait at the population level.

2.9.2 Administration

The Health and Life Profile form is designed to be self-administered, but can be interviewer administered if necessary. QxQ instructions are in Appendix 2.9.c. The form begins with printed instructions, is followed by ten statements (Items 1-10) to which the participant selects a response of ALMOST NEVER, SOMETIMES, OFTEN, ALMOST ALWAYS, and ends with an administrative section (Items 11-13) which is completed by the interviewer. The interviewer records in Item 12 of the Administrative Section whether the form was self-administered (A), interviewer-administered (B), both (C), or not done (D). Because the majority of participants will use this as a self-administered form, the option for no response and the definitions of type of administration

are not printed on the form. Detailed instructions for self- or interviewer-administration are provided in the QxQ instructions in Appendix 2.9.c. Prototype scripts which can be read to introduce and explain how to complete the self- or interviewer-administered versions of the form and are also included at the end of the QxQ instructions (2.9.d).

2.9.3 Training

Staff are centrally trained and the study coordinator is responsible for providing training for new staff.

2.9.4 Certification

Certification for administering the Health and Life Profile form is achieved by the demonstration of adequate technique in administering the instructions on how to complete the form and approved by the supervisor or lead interviewer. Recertification is required annually, and requires the successful completion of an explanation, observed by the interviewer supervisor.

2.9.5 Quality Assurance

Routine quality assurance is locally provided by observation of the study coordinator. Protocol adherence and interviewing techniques are reviewed by Coordinating Center field center monitors. Deviations from protocols and possible remedial actions are discussed with study coordinators and staff at that time. Major deviations are brought to the attention of the ARIC Cohort Operations Committee.

2.9.6 Data Collection

The Health and Life Profile form is designed to be self-administered, and even though it can be interviewer administered, it is always completed on paper. Data are subsequently keyed by the interviewer into the DES (Appendix 2.9.b). The HPCB data entry screen is one of the few DES screens that is different from the paper version of the form in that an additional response category, "E" for "no response" is available in Items 1-10 for the interviewer to document the participant did not respond to the statement.

2.10 Inflammation

The Inflammation (INFA) form is a new interview in Visit 4 to collect information on the participant's prior history of a series of chronic infectious diseases, treatment with antibiotics, and a history of periodontal disease (Appendix 2.10.a). The introductory script of the interview serves as a brief explanation to the participant as to why questions on a history of chronic infectious diseases and periodontal disease is being collected, and tangentially, why the periodontal exam is also being performed.

2.10.1 Rationale

A growing body of literature recognizes infection and/or inflammation as a risk factor for atherogenesis and thromboembolitic events (Thom DH et al. Association of prior infection with Chlamydia pneumoniae and angiographically demonstrated coronary artery disease. JAMA 1992;268:68-72; Lopes-Virella MF et al. Immunological and microbiological factors in the pathogenesis of atherosclerosis. Clin Immunol Immunopathol 1985;37:377-386) and documents an association between periodontal disease and acute myocardial infarction (Mattila K et al. Association between dental health and acute myocardial infarction. Mr Med J. 1989;298: 779-782). The ARIC study administers this questionnaire on a history of chronic and/or repeated infection.

2.10.2 Administration

The Inflammation Form is administered by a study-certified nurse/nurse practitioner, licensed practical nurse or an equivalently trained field center staff member with a general understanding of the medical terminology referred to in this interview. The time frame during which these conditions were diagnosed varies, requiring careful administration of each question. The exact wording and order of the questions are followed to ensure standardization. QxQ instructions and a table of standardized definitions and synonyms for the use of the interviewer are provided in Appendix 2.10.c. As a positive response to most (note, not all) of the lead-in questions of the diseases and conditions covered in the interview requires the diagnosis by a physician, the name of the disease/condition should be familiar to the participant. As with the administration of all other interviews, the definition of a term is only provided if the participant requests clarification.

2.10.3 Training

Interviewers are trained centrally prior to Visit 4. The field center interviewer supervisor is responsible for the training and certification of new field center interviewers.

2.10.4 Certification

Certification is achieved by the demonstration of adequate technique on 5 taped interviews, reviewed and approved by the supervisor or lead interviewer. Recertification is required annually, and requires the successful completion of one taped interview of an actual participant. With participant approval, all interviews are taped for quality control. This tape is included in the round robin which is reviewed by the four interviewer supervisors selected to monitor each year's round robin tapes.

2.10.5 Quality Assurance

With participant approval, most staff-administered interviews are taped for quality control. A non-systematic sample of Inflammation forms are reviewed by the supervisor. Technique and adherence to protocol are also monitored by Coordinating Center Monitors; data quality is monitored by the Quality Control Committee semi-annually.

2.10.6 Data Collection

The Inflammation form is designed to be interviewer-administered and collected by direct data entry (Appendix 2.10.b) unless the work station system is inoperable. A paper version of the form is available for back-up and delayed data entry. The format for most of the conditions is a lead-in question in which the time frame is a life time history and the disease must have been diagnosed by a doctor, followed by a question on the frequency of episodes within the past 10 years and concluding with a question as to whether the person has had at least one episode in the 12 month's prior to the interview. Negative or equivocal responses to lead-in questions trigger a skip to the next disease/condition.

2.11 Informed Consent

Administration of informed consent precedes all other activities at the field center. The core content and consent options of the Visit 4 (Appendix 2.11.a) and the Dental Study (Appendix 2.11.b) informed consent documents comply with the National Institutes of Health and the National Heart, Lung, and Blood Institute guidelines on the protection of human subjects, the American Society of Human Genetics' statement on informed consent for genetic research and the approval of the ARIC Steering Committee. The wording of the consent forms

administered at the individual field centers, however, has been tailored to meet the specific requirements of their local Institutional Review Board, which reviews and approves all human research sponsored by their university.

2.11.1 Rationale

The primary objective of re-administering the Visit 4 informed consent is to reaffirm that the participant understands (1) the purpose of the research; (2) what data collection procedures are used; (3) the risks and benefits of participation; (4) what procedures are in place to protect confidentiality; (5) he/she is free to participate, refuse any procedure or answer any question, and to withdraw at any time; (6) and that withdrawing carries no penalties. The updated informed consent has a record of the project director and a contact person. Signing permits the participant to indicate his/her current preference for the use and disposition of study data, including genetic materials, and to change his/her preference at a future date; reaffirms permission to release clinically relevant study data to the physician of his/her choice, and updates the participant's permission to abstract his/her medical records in the event of hospitalization or death. Because the dental study is funded as an ancillary study in ARIC, separate informed consent is obtained to have the dental examination. This second informed consent document more clearly identifies for each participant the exclusion criteria specific to the dental examination, which do not apply to the regular ARIC exam.

2.11.2 Administration

The goals of the ARIC study at the fourth exam and the dental study are reviewed with the participant prior to the administration of any other data collection instrument. Consent to participate in the regular ARIC examination (Visit 4) and the periodontal examination (ARIC Dental Study) is documented on two separate informed consent forms. (In general, eligibility and willingness to participate in the dental study will have been determined prior to the participant's arrival at the field center. Refer to Section 2.6, Dental Screening.) Time is allowed for the person to read and ask questions about the informed consent documents in a confidential setting. If the participant is visually handicapped or otherwise incapable of reading the study description and informed consent page, the narrative portion is read to him/her and then the person is asked to sign the document. The original Informed Consent documents are filed in the participant's ARIC study folder. At local option, a copy of each informed consent can be given to the participant.

2.11.3 Training

Interviewers are centrally trained in general interviewing techniques and the goals and objectives of informed consent. Study coordinators or interviewer supervisors are responsible for providing local staff training for new staff.

2.11.4 Certification

Although there is no formal certification schedule, interviewers who administer informed consent are observed by the local study coordinator or interviewer supervisor.

2.11.5 Quality Assurance

Routine quality assurance is provided at each field center by means of observation by the local study coordinator. Administrative techniques and adherence to protocol are also monitored at least semi-annually by Coordinating Center Monitors; frequency distributions of consent preferences recorded on the Informed Consent Tracking form (ICTA) are monitored by the Quality Control Committee on a semi-annual basis.

2.11.6 Data Collection

Descriptions of the study and the signature pages acknowledging informed consent for Visit 4 and the Dental Study are paper forms. The participant has the option of receiving a copy of the full informed consent document or the signed consent statement. In all cases, the original signature page must be kept at the field center and stored in the participant's ARIC study folder.

2.12 Informed Consent Tracking

The Informed Consent Tracking (ICTA) form is an internal form that applies to the consent given by cohort members to participate in the regular ARIC study (Appendix 2.12.a). It tracks each participant's type of consent (full or partial), restrictions on use or storage of DNA (yes or no), type of restrictions on DNA use or storage (CVD research, ARIC only, no use/storage of DNA, other), other restrictions on procedures or use of study data (yes or no), type of restrictions on procedures or use of study data (CVD research, ARIC only, other), restrictions on release of results to participant's physician and permission to access medical records. The form is completed by ARIC staff, and NOT administered to participants.

2.12.1 Rationale

The purpose of the form is to document and track in the ARIC central database the initial level of, and subsequent (if any) changes to, participants' restrictions on the use of their DNA or other study data by ARIC investigators.

2.12.2 Administration

Items 1-8 on the Informed Consent Tracking form are completed by an interviewer at the reception workstation, and participants have read and signed the Visit 4 Informed Consent form. Items 9 through 14 are completed when a participant notifies the study of a desire to either change his/her type of consent or access to medical records, or to withdraw from the study. QxQ instructions are provided in Appendix 2.12.c.

2.12.3 Training

Staff are trained locally by the study coordinator or interviewer supervisor.

2.12.4 Certification

No certification is required.

2.12.5 Quality Assurance

Frequency distributions of consent preferences recorded on the Informed Consent Tracking form (ICTA) are monitored by the Quality Control Committee on a semi-annual basis.

2.12.6 Data Collection

Data for the Informed Consent Tracking form can be directly entered into the DES (Appendix 2.12.b) or collected on the paper version of the form for delayed data entry.

2.13 Medical History Questionnaire

The Medical History Questionnaire (MHQA, Appendix 2.13.a) is a new self-administered form in Visit 4 to document a life-time medical history of clinically diagnosed or symptoms of arthritis, hay fever, cataracts, thyroid diseases, systemic lupus, gout, stomach or duodenal ulcers, adenoma or polyp

of the colon, deep vein thrombosis, pulmonary embolus, Parkinson's disease, gallbladder diseases, fractured hip/wrist/spine, urinary frequency, or for males, prostate surgery for reasons other than cancer.

2.13.1 Rationale

The collection of a medical history on each participant permits the assessment of overall health, and various non-cardiovascular morbid conditions.

2.13.2 Administration

The Medical History Questionnaire is a self-administered questionnaire given to each participant to complete between work stations or during snack. Usually, the form is attached to a clip board with a cover sheet for confidentiality to allow participants to carry it with them. The type of presentation, however, is left to local option. Each participant is instructed on how to complete the Medical History Questionnaire using a demonstration form (Appendix 2.13.c). Interviewers explain and administer the demonstration form, watch the participant complete the demonstration form, answer questions and determine whether assistance in completing the Medical History Questionnaire is requested or required. If assistance is needed, the Itinerary sheet is annotated, and the three self-administered forms (Medical History, Physical Ability and Health/Life Profile) are added to the interviews for staff-administration. If no assistance is requested, the participant is invited to work on the forms between work stations and return the clip board (or other carrying mechanism) to any ARIC staff upon completion. The forms are reviewed for completeness prior to the medical data review, and if incomplete, the participant is asked if assistance to complete the forms is needed. The administration date, type of administration (self (A), staff (B), both (C), not done (D)) and staff ID code are entered in Items 27-29 on the form.

One of the objectives of this form is to determine in a standardized fashion whether a doctor ever diagnosed the participant as having any of the medical conditions mentioned. Because the questions in the Medical History Questionnaire are phrased as "has a doctor ever told you that you had (name of condition)", the response requires the participant to have heard the name of the condition from the doctor. Therefore, a table of definitions has not been provided for this form. For persons who request a definition of a medical term, respond by saying

> "If you don't recognize (or understand the meaning of) a medical term, mark NO or DON'T KNOW on the form and go on to the next question".

Note, lack of familiarity with a medical term is different from not being able to read the name of the disease or condition on the form. For persons who cannot read the form, offer to do the form with them at some point during the visit.

2.13.3 Training

ARIC staff are locally trained by study coordinators or interviewer supervisors in the explanation and monitoring of self-administered forms.

2.13.4 Certification

No certification is required.

2.13.5 Quality Assurance

Routine quality assurance is locally provided by observation of the study coordinator or interviewer supervisor. Protocol adherence and interviewing

techniques are reviewed by Coordinating Center field center monitors. Deviations from protocols and possible remedial actions are discussed with study coordinators and staff at that time. Major deviations are brought to the attention of the ARIC Cohort Operations Committee. Frequency distributions of the medical conditions recorded on the Medical Health Questionnaire by field center and interviewers are monitored by the Quality Control Committee on a semi-annual basis.

2.13.6 Data Collection

The Medical History Questionnaire is designed to be self-administered, and even though it can be interviewer administered, it is always completed on paper. Data are subsequently keyed by the interviewer into the DES (Appendix 2.13.b).

2.14 Medication Survey

The Medication Survey (MSRD, Appendix 2.14.a) is part of the core data collection instruments which was introduced during the first examination and continues to be administered to all participants during Visit 4. The survey covers the use of any prescribed or over-the-counter medications, including vitamins or mineral supplements, used within the two weeks prior to the participant's interview, and has been updated to ascertain the epidemiology of the current and regular use of aspirin and non-steroidal anti-inflammatory drugs in the ARIC population.

2.14.1 Rationale

As in previous examinations, the goal of the Medication Survey is to ascertain medication usage by coding both prescription and nonprescription drugs used by the respondent within the two weeks preceding the interview. This information assists in measuring patterns of medication use in the study communities, temporal changes in medical care practice, diagnostic classification of cardiovascular diseases, interpretation of laboratory results, and predictors of study end points.

2.14.2 Administration

The Medication Survey questionnaire is divided into three major sections. Question by question instructions are located in Appendix 2.14.c. During reception, the interviewer determines and records in Part A of the form whether the participant has brought in all medications taken within the last two weeks. Identification labels are placed on the participant's medication bag and Medication Survey form. If the participant has not brought in any (all) medications, inquiries are made to differentiate between non-compliance with pre-visit instructions or non-use of medications in the prior two weeks. In case of inadvertent omissions, arrangements are made for obtaining the information, usually by telephone interview. The deliberate omission to bring medications to the Field Center is recorded on the Medication Survey and on the Participant Itinerary Sheet (Appendix 2.17) and conversion is attempted later with the participant during the review of medical data. Subsequent parts of the Medication Survey can be administered during reception (if the area affords the opportunity for maintaining confidentiality) or later, by trained interviewers or the ARIC nurse/clinician in areas in the field center usually designated for conducting interviews.

Before starting Part B of the Medication Survey, the name on the medication bag is checked against the name on the Medication Survey form. Medication containers are removed from the participant's medication bag and the medication name and concentration are transcribed into column (a) of Section B on the form. Medications that are not in a container are examined only in front of the participant, with his/her permission. When there are more than 17 medications, recording the name and concentration is continued on the back

of the page if a paper form is used. If the Medication Survey DES (Appendix 2.17.b) is used and more than 17 medications need to be entered, the name and concentration of the additional medications are written on a piece of paper labelled with the participant's ID, and filed in the participant's folder for future coding. See below for coding instructions. If the name of the medication exceeds the number of fields in the DES, the name is abbreviated on the screen.

When more than 17 medications have been recorded, the priority algorithm for data entry and coding of the medications is as follows: prescription medications first; aspirin and aspirin containing medications (aspirin, Alka Seltzer, headache powders, cold medications, medication for arthritis, etc.); anti-inflammatory drugs (ibuprofen, motrin, nuprin, etc.); then over-the-counter-medications, followed by vitamins and food supplements.

To administer Parts B and C, a trained interviewer or the ARIC nurse/clinician shows each container of medication to the participant, transcribes its name in column (a) of Section B (MEDICATION RECORDS), records medication's concentration in column (b), and asks and records in column (d) whether the medication was used within the last 24 hours.

When preparing to ask the participant about each medication, the interviewer removes all containers from the bag and sets them in front of the participant. As each medication is reviewed, it is shown to the participant while keeping the other medications in view. After the participant answers the questions for each medication, its container is placed back in the carrying bag to minimize confusion and to assure that all medications are returned.

The interviewer verifies the transcription of medication names and makes corrections on the paper (or DES) form as required. Use the American Drug Index and Physician's Desk Reference for unknown and incomplete names.

Part C of the Medication Survey ascertains (1) whether any of the participant-reported medications were used to treat cardiovascular diseases or symptoms (high blood pressure; high blood cholesterol; angina; arrhythmia; heart failure; blood thinning; diabetes; stroke; intermittent claudication) or (2) whether aspirin or aspirin containing medications were used in the last two weeks and the reason for their use; current, regular use (at least once per week for several months) of aspirin or other non-steroidal anti-inflammatory drugs.

2.14.3 Training

Interviewers and medication coding specialists are centrally trained and are responsible for providing local staff training in the transcription and coding of medications.

2.14.4 Certification

Certification to administer the Medication Survey is achieved by the demonstration of adequate technique on 5 taped interviews, reviewed and approved by the supervisor or lead interviewer. Recertification is required annually, and requires the successful completion of one taped interview of an actual participant. This tape is included in the round robin which is reviewed by the four interviewer supervisors selected to monitor each year's round robin tapes.

Separate certification is required for medication coding, based on a minimum of 80% correct responses on the certification test provided by the Coordinating Center and administered at central training or by the local medication coding specialist. Recertification for medication coding is also required annually. For the medication coding specialist, this includes coding a set of selected medication names circulated for this purpose and

adequate performance on blinded re-coding of medications recorded during the previous year. Recertification criteria for field center medication coders require meeting minimum standards of coding repeatability (by interviewer/transcriptionist) and a review at the Coordinating Center of the accumulated performance on quality control repeat medication coding.

2.14.5 Quality Assurance

With participant approval, most staff-administered interviews are taped for quality control. A non-systematic sample of Medication Survey forms are reviewed by the supervisor. Technique and adherence to protocol are also monitored by Coordinating Center Monitors; data quality is monitored by the Quality Control Committee semi-annually.

For each person certified to code medications a ten percent sample of medication coding records is identified by the Coordinating Center for blinded repeat coding at the field center.

2.14.6 Data Collection

The Medication Survey is designed to be interviewer-administered and collected by direct data entry (Appendix 2.14.b) unless the work station system is inoperable. A paper version of the form is available for back-up and delayed data entry. The six digit medication code numbers are listed in a hard copy or DES version of the Medication Coding Dictionary. The Medispan code in part (c) can be matched to the drug name while transcribing the name of the drug in part (a) into the DES screens, or can be ascertained later. Drug names are listed alphabetically. The medication code of a drug not listed in the dictionary is left blank, and its status code is always set to "Q" (questionable) so that the pharmacist at the Coordinating Center can develop a code number and update the dictionary. Detailed instructions for coding medications are provided in the QxQ instructions for the Medication Survey (Appendix 2.14.c).

2.15 Oral Glucose Tolerance Screening

The Oral Glucose Tolerance Screening (GTSB) is a new interview in Visit 4, administered at the reception work station, to document cohort members' eligibility and willingness to participate in a test of their ability to process glucose during the fourth clinical exam (Visit 4). See Chapter 3.6 for a discussion of the rationale and procedures for administering the oral glucose tolerance test.

2.15.1 Rationale

Although the OGTT could be performed safely on all ARIC participants, data obtained from **diabetics taking insulin or oral hypoglycemic medication** would be difficult to interpret, and thus these diabetics are **excluded** from the OGTT. Persons treating their diabetes by diet alone are encouraged to participate. Persons who have not fasted for at least 10 hours or who have a history of diabetes treated by oral or injectable hypoglycemic medication are ineligible to participate in the OGTT.

2.15.2 Administration

The OGTT Screening form (GTSB, Appendix 2.15.a) is administered during reception, after the fasting form. (QxQ instructions and prototype scripts for the OGTT Screening form are provided in Appendix 2.15.c. Eligibility criteria are discussed below in Section 2.15.2.1.) The PIN sheet is reviewed to select the response to Item 1 on the OGTT Screening form to determine whether the person was being treated for diabetes in Visit 3. In Item 2, participants are asked about **current** regular treatment of diabetes with medication. The interviewer verifies a participant's denial of the current treatment of

diabetes by reviewing the medications brought in to the field center to determine whether insulin or oral hypoglycemic medication have been used within the past two weeks. This can be done with the participant or while the participant is changing clothes. The Fasting/Tracking form is reviewed to select the response to Item 3 to determine whether the person has fasted for a minimum of 10 hours. Items 4 and 5 cover medical conditions that could subject the participant to undue risk and positive responses result in ineligibility. When a participant is ineligible, the interviewer reads the appropriate exclusion statement using a standard introduction and conclusion and selecting one of the statement's four exclusion options. Eligible participants are then asked if they are willing to participate. Eligibility status is also documented on the Itinerary Sheet.

2.15.2.1 Eligibility

Scheduling information during the Annual Follow-up interview and the appointment material mailed prior to the date of the ARIC exam need to remind all participants to come to the field center in the morning after a 12-hour fast on the date of their appointment. The inclusion of the OGTT as one of the new procedures for Visit 4 is mentioned during the telephone interview and participants are asked if they have diabetes which is being treated by oral or injectable medications. Although the OGTT could be performed safely on all ARIC participants, data obtained from **diabetics taking insulin or oral hypoglycemic medication** would be difficult to interpret, and thus these **diabetics are excluded** from the OGTT. Persons treating their diabetes by diet alone are encouraged to participate.

During reception, participant eligibility (the absence of diabetes treated by oral or injectable hypoglycemics and fasting for at least 10 hours) and willingness to participate are determined and documented on the OGTT Screening Form. Responses are keyed into the DES and eligibility for the OGTT is determined by means of a pre-established algorithm. At the Jackson center, individuals whose PIN sheet indicates a fasting blood glucose value of $\geq$ 300 mg/dL at Visit 3 and who are not on hypoglycemic treatment at the time of their Visit 4 examination are asked an additional set of questions on polydypsia and polyuria.

Fasting in ARIC is defined as the abstinence from all food and drink (except water or one cup of black, unsweetened, decaffeinated coffee or tea) for a minimum of 10 hours prior to the clinic visit. Note: as has been done in Visits 1-3, participants are told to fast for 12 hours prior to their clinic visit when Visit 4 is scheduled. When a participant comes to the field center having fasted for less than 10 hours, the initial blood samples are drawn with the caveat to the participant that his/her non-fasting state may affect the values of some of the studies. **The minimum fasting requirement for participation in the OGTT is 10 hours. Participants who have not fasted for a minimum of 10 hours are not offered the OGTT.** A return appointment for the OGTT in the fasting state, however, should be scheduled if the participant agrees. The participant's fasting status is recorded on the Fasting/Tracking form.

Hypoglycemic medications are one of two classes of medications that lower blood sugar: **insulin**, which is administered by injection, and **oral hypoglycemics**. Participants taking these medications are automatically excluded from the OGTT and the OGTT Screening form coded accordingly.

Fasting and Use of Medications. During the Annual Follow-up and Visit 4 scheduling call (and in the mailed appointment material) participants are told they cannot drink nor eat anything during the period between the administration of the glucola and the 2-hour blood drawn, nor take any medications that can be postponed for two hours. If in doubt, participants are encouraged to verify with their physician how best to rearrange their a.m. medication schedule.

Because there are many misconceptions regarding the OGTT, ARIC staff should reassure participants that the OGTT is safe and has few, if any, side effects. This is particularly relevant prior to documenting a person's willingness to participate. Participants who are unwilling to participate are excluded from the OGTT and the OGTT Screening Form is marked accordingly.

2.15.3 Training

Interviewers are trained centrally prior to Visit 4. The field center interviewer supervisor is responsible for the training and certification of new field center interviewers.

2.15.4 Certification

Certification is achieved by the demonstration of adequate technique on 5 taped interviews, reviewed and approved by the supervisor or lead interviewer. Recertification is done annually, and requires the successful completion of one taped interview. With participant approval, all interviews are taped for quality control. This tape is included in the round robin which is reviewed by the four interviewer supervisors selected to monitor each year's round robin tapes.

2.15.5 Quality Assurance

A non-systematic sample of OGTT Screening forms is reviewed by the supervisor. Technique and adherence to protocol are also monitored by Coordinating Center Monitors; data quality is monitored by the Quality Control Committee semi-annually.

2.15.6 Data Collection

The OGTT Screening form is designed to be interviewer-administered. It can be collected by direct data entry (Appendix 2.15.b) or by hand using the paper version of the form for delayed data entry. It is imperative that the participant's OGTT eligibility status is documented on the Itinerary Sheet, particularly if the data are collected by direct data entry and the paper form is not available in the participant's folder.

2.16 Personal History

The Personal History (PHXB, Appendix 2.16.a) form collects current information on the participant's access to and use of medical care for general medical complaints and conditions related to cardiovascular disease, and updates information on smoking, passive smoking, and alcohol consumption.

2.16.1 Rationale

The re-administration of questions on access to/payment for medical care, occurrence of medical conditions related to cardiovascular disease, exposure to active and passive tobacco smoke, and use of alcoholic beverages is to document current practices within the cohort and changes since the baseline exam which may in part explain differences in cardiovascular diseases and their treatment by such factors as age, ethnicity, gender and socioeconomic factors.

2.16.2 Administration

The Personal History form is administered by certified interviewers within the flexible sequence of the participant examination. Detailed instructions for administering each question are provided in the QxQ instructions (Appendix 2.16.c). Questions on smoking and alcohol consumption may be considered sensitive by participants and care must be exercised to administer each section in a non-judgmental format.

2.16.3 Training

Interviewers are centrally trained before Visit 4. Study coordinators and interviewer supervisors are responsible for providing training to new staff in interviewing techniques and the question by question instructions.

2.16.4 Certification

Certification to administer the Personal History form is achieved by the demonstration of adequate technique on 5 taped interview and approved by the supervisor or lead interviewer. Recerti-fication is done annually, and requires the successful completion of one taped interview of a participant. This tape is included in the round robin which is reviewed by the four interviewer supervisors selected to monitor each year's round robin tapes.

2.16.5 Quality Assurance

With participant approval, the majority of the staff-administered interviews are taped for quality control. A non-systematic sample of interviews is reviewed by the study coordinator or interviewer supervisor. Technique and adherence to protocol are monitored by the Coordinating Center monitors; data quality is monitored by the Quality Control Committee.

2.16.6 Data Collection

Data from the Personal History form are collected by direct data entry (Appendix 2.16.b) unless the work station computer is inoperable. A paper version of the form is available for backup and delayed data entry.

2.17 Physical Ability

The Physical Ability (PAQA) Questionnaire is a new self-administered form in Visit 4 to document current physical ability to stand, walk, sit down, bend, lift, and perform activities of daily living (e.g., cook, clean house, eat, dress, manage personal finances, etc.).

2.17.1 Rationale

The collection of a measure of physical ability and activities of daily living on each participant permits the assessment of pre-symptomatic (e.g., atherosclerosis) and symptomatic cardiovascular disease (e.g., clinically diagnosed heart attacks and stroke) within the context of the cohort's overall health.

2.17.2 Administration

The Physical Ability Questionnaire is a self-administered questionnaire and is given to each participant along with the Health and Life Profile and the Medical History Questionnaire to complete between work stations or during snack. Usually, the form is attached to a clip board with a cover sheet for confidentiality to allow participants to carry it with them. The type of presentation, however, is left to local option.

The interviewer instructs each participant in how to complete the Physical Ability Questionnaire by reading the text in the instruction box at the top of the form (Appendix 2.17.a). Because this is a self-administered form, there are no additional QxQ instructions. Interviewers explain that the selection of the response category (no difficulty, some difficulty, much difficulty, unable to do, don't know or do not do) should be based on the level of difficulty that best describes the person's ability to do the activity by him(her)self and without the use of aids. Participants' questions are answered and the interviewer determines whether assistance in completing the Physical Ability Questionnaire is requested or required. If assistance is

needed, the Itinerary sheet is annotated, and the three self-administered forms (Medical History, Physical Ability and Health/Life Profile) are added to the interviews for staff-administration. If no assistance is requested, the participant is invited to work on the forms between work stations and return the clip board (or other carrying mechanism) to any ARIC staff upon completion. The forms are reviewed for completeness prior to the medical data review, and if incomplete, the participant is asked if assistance to complete the forms is needed. The administration date, type of administration (self (A), staff (B), both (C), not done (D)) and staff ID code are entered in Items 18-20 on the form. Note, the type of administration is not annotated on the form and must be memorized by the interviewer prior to administration.

2.17.3 Training

ARIC staff are locally trained by study coordinators or interviewer supervisors in the explanation and monitoring of self-administered forms.

2.17.4 Certification

No certification is required.

2.17.5 Quality Assurance

Routine quality assurance is locally provided by observation of the study coordinator or interviewer supervisor. Protocol adherence and interviewing techniques are reviewed by Coordinating Center field center monitors. Deviations from protocols and possible remedial actions are discussed with study coordinators and staff at that time. Major deviations are brought to the attention of the ARIC Cohort Operations Committee. Frequency distributions of the medical conditions recorded on the Medical Health Questionnaire by field center and interviewers are monitored by the Quality Control Committee.

2.17.6 Data Collection

The Physical Ability Questionnaire is designed to be self-administered, and even though it can be interviewer administered, it is always completed on paper. Data are subsequently keyed by the interviewer into the DES (Appendix 2.17.b).

2.18 Reproductive History

The Reproductive History form (RHXC) is unchanged since Visit 3 and is administered to female cohort members during the flexible component of the exam. The objective of this questionnaire is to update the menopausal status, the use of exogenous gonadal hormones since the last field center examination, and to update her history of gynecological surgery since Visit 3.

2.18.1 Rationale

The questions on menstrual patterns and hormone use have been expanded slightly to help establish with more certainty whether menopause has taken place. Questions addressing exogenous gonadal hormone exposure are used because of the belief that they may play a role in the development of atherosclerosis.

2.18.2 Administration

The Reproductive History form (Appendix 2.18.a) is administered by certified interviewers within the flexible sequence of the participant examination. Detailed instructions for administering each question are provided in the question by question instructions (Appendix 2.18.c). Questions on menstrual history and the use of female hormones may be considered sensitive by

participants and care must be exercised to administer each section in a non-judgmental format.

The questionnaire is divided into 3 sections: (1) recent menstrual history and onset of menopause; (2) the use of exogenous hormones since Visit 3; and (3) a history of gynecological surgery since Visit 3.

Item 1 is not read aloud. The response category is based on information printed on menopausal status on the PIN sheet. The majority of the questions on the form are closed-ended or pre-coded questions designed for direct entry into the computer by the interviewer. Open-ended questions are to obtain names of female hormones being used, age, or some other concept of time.

The exact wording and order of the questions is followed to ensure standardization. Questions are not skipped unless indicated by the skip pattern.

2.18.3 Training

Interviewers are trained centrally prior to Visit 4. The field center interviewer supervisor is responsible for the training and certification of new field center interviewers.

2.18.4 Certification

Certification is achieved by the demonstration of adequate technique on 5 taped interviews, reviewed and approved by the study coordinator or interviewer supervisor. Recertification is done annually, and requires the successful completion of one taped interview of an actual participant. With participant approval, all interviews are taped for quality control. This tape is included in the round robin which is reviewed by the four interviewer supervisors selected to monitor each year's round robin tapes.

2.18.5 Quality Assurance

A non-systematic sample of Reproductive History forms is reviewed by the supervisor. Technique and adherence to protocol are also monitored by Coordinating Center Monitors; data quality is monitored by the Quality Control Committee.

2.18.6 Data Collection

Data from the Reproductive History form are collected by direct data entry (Appendix 2.18.b) unless the work station computer is inoperable. A paper version of the form is available for backup and delayed data entry.

2.19 Socioeconomic Status

The Socioeconomic Status (SESA) form is a new data collection instrument in Visit 4 to track participant's socioeconomic status (SES) at different stages of development, using birth weight, education, income and occupation as measures of SES. The administration of this form in Visit 4 increases the information on SES during each participant's infancy and early adulthood, and updates information on marital status, employment or retirement status, occupation, and annual household income.

2.19.1 Rationale

SES is a known predictor of coronary heart disease worldwide. Several studies have suggested that a person's SES at birth may be equally or more important in predicting morbidity and mortality. These data permit a longitudinal assessment of SES at birth, youth, young and middle adulthood.

2.19.2 Administration

The Socioeconomic Status form (Appendix 2.19.a) is administered by certified interviewers within the flexible sequence of the participant examination. Detailed instructions for administering each question are provided in the QxQ instructions (Appendix 2.19.b). Questions on marital status, income, parents' SES status may be considered sensitive by participants and care must be exercised to administer each section in a non-judgmental format. The first portion of the form updates each participant's current marital status, employment/retirement status, occupation if it has changed since Visit 3, and annual household income for the 12 months prior to Visit 4. These questions are repeated from previous interviews. Subsequent sections collect information which may help classify each participant's socioeconomic status at birth and between ages 25 to 45.

2.19.3 Training

Interviewers are trained centrally prior to Visit 4. The field center interviewer supervisor is responsible for the training and certification of new field center interviewers.

2.19.4 Certification

Certification is achieved by the demonstration of adequate technique on 5 taped interviews, reviewed and approved by the supervisor or lead interviewer. Recertification is done annually, and requires the successful completion of one taped interview of an actual participant. With participant approval, all interviews are taped for quality control. This tape is included in the round robin which is reviewed by the four interviewer supervisors selected to monitor each year's round robin tapes.

2.19.5 Quality Assurance

A non-systematic sample of the SES form is reviewed by the supervisor. Technique and adherence to protocol are also monitored by Coordinating Center Monitors; data quality is monitored by the Quality Control Committee.

2.19.6 Data Collection

Data from the Socioeconomic Status form are collected by direct data entry (Appendix 2.19.b) unless the work station computer is inoperable. A paper version of the form is available for backup and delayed data entry.

2.20 TIA/Stroke

The TIA/Stroke (TIAE/TIBE) form is one of the core data collection instruments which was introduced during the first examination and continues to be administered to all participants during Visit 4 to assess the prevalence and incidence of stroke and transient ischemic attack. The interview is administered during the flexible component of the ARIC exam.

2.20.1 Rationale

Stroke and transient ischemic attack (TIA) are identified as end points in the ARIC study. A baseline history of TIA/stroke was collected during Visit 1. New occurrence(s) of cerebrovascular disease is updated by repeating all questions in the TIA/Stroke form, but restricting the response period to the interim between Visit 3 and Visit 4.

2.20.2 Administration

The TIA/Stroke Form (Appendix 2.20.a) is administered by certified interviewers. Positive symptoms are recorded during the standardized

interview along with their speed of onset, duration, and co-morbid manifestations. QxQ instructions are in Appendix 2.20.c). Section A of the form documents the participant's medical history of a TIA or stroke since the last ARIC exam. The subsequent sections cover six neurologic symptoms which are associated with strokes and TIAs and are administered in a standardized format. Descriptors of the neurologic symptoms (earliest, longest and worst) often require probing, but the definitions are left to the respondent.

2.20.3 Training

Interviewers are centrally trained before Visit 4 and study coordinators and chief interviewers are responsible for training new staff, based on a standardized interview techniques (Appendix 2.1), question by question instructions for the TIA/Stroke Form, practice scripts, and role playing.

2.20.4 Certification

Certification is achieved by the demonstration of adequate technique on 5 taped interviews, reviewed and approved by the supervisor or lead interviewer. Recertification is done annually, and requires the successful completion of one taped interview of an actual participant. With participant approval, all interviews are taped for quality control. This tape is included in the round robin which is reviewed by the four interviewer supervisors selected to monitor each year's round robin tapes.

2.20.5 Quality Assurance

With participant approval, most staff-administered interviews are taped for quality control. A non-systematic sample of the taped TIA/Stroke interviews is reviewed by the supervisor. Technique and adherence to protocol are also monitored by Coordinating Center Monitors; data quality is monitored by the Quality Control Committee.

2.20.6 Data Collection

Data from the TIA/Stroke form are collected by direct data entry (Appendix 2.20.b) on two data collection forms (TIAE and TIBE) unless the work station computer is inoperable. A paper version of the form is available for backup and delayed data entry.

2.21 Update

The Update (UPDB) form is the primary source of tracking information for each participant and is administered yearly to all cohort members. During Visit 4, it is administered at the Reception Workstation.

2.21.1 Rationale

The previously collected name, address and telephone number of the participant and two contact persons, permission to send study results to the participant's physician updated and the physician's mailing address are verified on the Update form. This form is generated by the Coordinating Center from information stored in the study's central database, and sent to the field centers.

2.21.2 Administration

After greeting the participant and obtaining his/her informed consent, the information on the Update (UPD) Form screen (Appendix 2.21.a) is verified by reviewing with the participant the information which was filled out on the form sent to his/her home in the Visit 4 information packet (see Appendix 1.10) or is listed on the UPD data entry screen. For example, names or addresses which could have multiple/unusual spellings are verified and missing

information is completed. If the social security number has not been collected previously, the social security disclosure statement (Appendix 2.21.b) is given to or read to the participant prior to requesting the number. This form also includes mailing information for the health care provider designated to receive the participant's study results. Question by question instructions are located in Appendix 2.21.b.

In recognition of the confidential nature of the information collected on the Update form, the information sheet that was brought in is either returned to the participant or torn up and disposed of in front of the participant.

2.21.3 Training

Staff are centrally trained before Visit 4 and study coordinators are responsible for providing local training for new staff.

2.21.4 Certification

Certification is required, provided by the study coordinator.

2.21.5 Quality Assurance

Routine quality assurance is provided locally by the study coordinator, by observing staff performance. Protocol adherence and interviewing technique are reviewed by Coordinating Center monitors. Deviations from protocols and possible remedial actions are discussed with study coordinators and staff. Major deviations are brought to the attention of the ARIC Cohort Operations Committee.

2.21.6 Data Collection

The Coordinating Center provides an Update Form for each participant with demographic and tracking information from the most current information on the consolidated database. During reception, data in this form are modified using Change Mode of the DES (Appendix 2.21.a).

3.0 PROCEDURES IN THE VISIT 4 CLINICAL EXAM

3.1 Anthropometry

Height, weight and body size are measured during Visit 4 following the same procedures used during Visit 3. Male pattern baldness in male participants is assessed for the first time in Visit 4. All measurements are recorded on the Anthropometry form (Appendix 3.1.a). Procedures for measuring the height, weight, waist and hip girths, and hair patterns are provided below. Separate instructions for completing the data collection form are provided in the Anthropometry form QxQ instructions (Appendix 3.1.c). At the option of the field center, the circumference of the right upper arm (to determine blood pressure cuff size) can also be measured at this work station and recorded on the sitting blood pressure form.

3.1.1 Rationale

The same anthropometric measurements as measured during Visit 3 are obtained in Visit 4 to assess height, weight and body fat distribution cross-sectionally and prospectively. In addition, a new set of procedures to classify male pattern baldness in male participants has been added to assess the recently reported, putative association(s) between certain patterns of male pattern baldness and coronary heart disease.

3.1.2 Procedures

Anthropometry is performed before the clinic snack and after the participant has changed into a scrub suit or examination gown and been given the opportunity to empty his/her bladder. All measurements are made with the participant wearing light-weight, non-constricting underwear. Participants wearing nylon hose or other forms of constricting undergarments are instructed to remove them. Each field center determined at the beginning of the study whether hip measurements were to be taken over or under the scrub suit and has followed that procedure consistently for the duration of the study. Weight and height are measured without shoes. Technicians complete the procedures on every participant by following the general checklist for performing anthropometric measurements (Appendix 3.1.d).

All anthropometric measurements are taken by either a team of two persons (one serving as observer; the other as recorder) or by one technician using a full length mirror to aid in the appropriate placement of the tape measure to record the girths. Using the team approach, the observer calls out the name of the next measurement, takes the measurement, and keeps the measuring instrument in place until the recorder repeats the number. The recorder checks the position of the examinee and verifies the horizontal placement of the measuring instrument during each procedure, and records the result. When a single technician performs the measurements, she verifies the horizontal placement of the measuring instrument (using the mirror when appropriate) for each measurement and records each measurement immediately after it is taken. Values are rounded down to the unit indicated for each measurement.

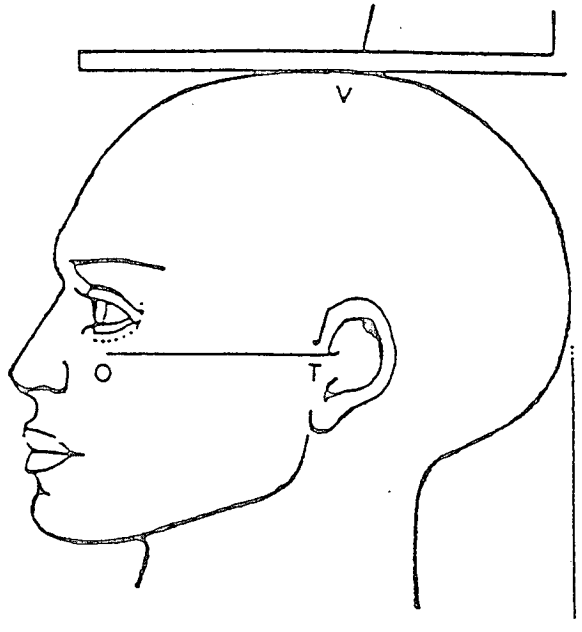
3.1.2.1 Standing height

The participant stands erect on the floor or the horizontal platform with his/her back against the vertical metal centimeter ruler mounted on the wall. The heels are placed together and positioned against the vertical ruler. The participant is instructed to stand as straight as possible, but with feet flat on the floor. The participant looks straight ahead with his/her head in the Frankfort horizontal plane (i.e., the horizontal plane which includes the lower margin of the bony orbit -- the bony socket containing the eye -- and the most forward point in the supratragal notch -- the notch just above the anterior cartilaginous projection of the external ear) (Figure 3.1). The

right angle is brought down snugly, but not tightly, on the top of the head. A foot stool is used if the examiner is shorter than the participant, such that the examiner's view is level with the point of measurement on the head of the participant. The certified technician follows a checklist for height measurement (Appendix 3.1.f) which outlines the procedures for checking the equipment and measuring the participant's height and enters study data on the Anthropometry form. The participant's height is recorded to the centimeter, rounding down. A chart converting centimeters to inches is available for use in informing the participant of his/her height in inches (Appendix 3.1.k).

The height rule is observed weekly to see that it (a) touches the hard-surfaced floor or platform on which measurements are done, and (b) is perpendicular to the floor. This weekly check is recorded on the Anthropometry Equipment Calibration Log (Appendix 3.1.e).

Figure 3.1 Frankfort Plane for Measuring Body Height



ORBITALE: Lower margin of eye socket
TRAGION: Notch above tragus of ear or at upper margin of zygomatic bone at that point
FRANKFORT PLANE: Orbitale-tragion line horizontal

3.1.2.2 Body weight

Before a participant is weighed, the scale is balanced so that the indicator is at zero when no weight is on the scale. The scale must be level and on a firm surface (not a carpet). The participant is instructed to stand in the middle of the platform of the balance scale (Detector, model #437) with head erect and eyes looking straight ahead. Weight is adjusted on the indicator until it is balanced. Results are recorded to the pound, rounding down.

To maintain accuracy, the scale is zero balanced daily and calibrated with a known weight (50 lbs) every week or whenever the scale is moved. The daily zero balance and the weekly scale calibration are documented on the Anthropometry Equipment Calibration Log (Appendix 3.1.e). The scale is professionally calibrated and serviced annually. The certified technician follows a checklist for weight measurement (Appendix 3.1.g) which outlines the procedures for checking the equipment and measuring the participant's weight and enters study data on the Anthropometry form.

3.1.2.3 Abdominal girth

The participant is instructed to stand erect and relaxed with the feet approximately 6 inches apart and the weight equally distributed on both feet. The participant is asked to lift the scrub suit top just high enough to make the area visible (hands must not go above waist level). An anthropometric tape is applied at the level of the umbilicus (navel) and the participant is instructed to breathe quietly. The tape should be snug, but not so tight as to compress tissue. (Figure 3.2). The full length mirror or recorder verify that the participant is standing erect and that the tape is horizontal. The measurement is recorded to the nearest centimeter, rounding down at the point of relaxed end exhalation. The technician follows a checklist for the measurement of the maximal abdominal girth (Appendix 3.1.h).

3.1.2.4 Hip girth

The participant stands erect, yet relaxed, with weight distributed equally over both feet and with the feet together. The hip girth is measured at the level of the maximal protrusion of the gluteal muscles (hips). (Figure 3.2). The tape is placed horizontally level around the participant's gluteal muscles (hips) at the level of maximal protrusion. The position is verified by passing the tape measure above and below the observed maximum. The tape is kept horizontal at this level and the measurement is recorded to the centimeter, rounding down.

A checklist for maximal hip circumference measurement (Appendix 3.1.i) is used for measuring each participant. The most common source of error for this measurement is due to not having the
tape horizontal and not verifying that the maximum width is being measured. The position of the tape is checked from both the front and the back.

The tapes used for measuring girth are calibrated monthly against the metal height rule, as indicated on the Anthropometry Equipment Calibration Log. Tapes that show damage or wear or that do not measure within the required range are replaced.

Figure 3.2.a Location of Waist Girth Measurement

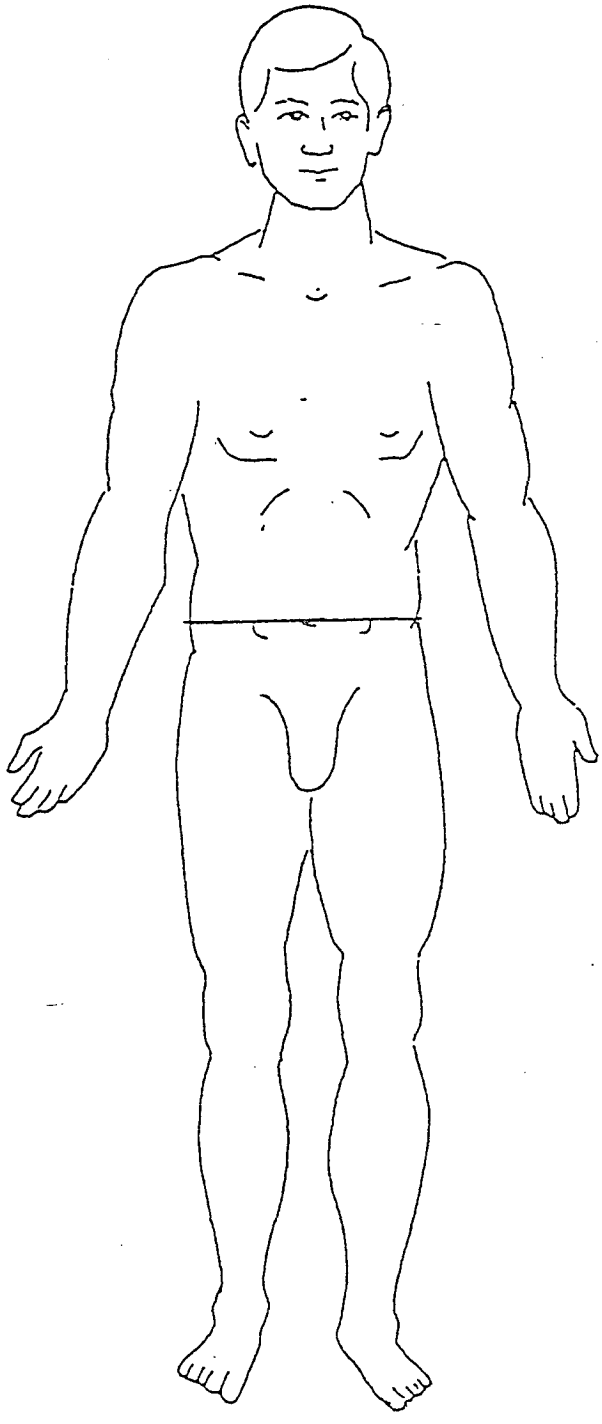


Figure 3.2.b Location of Hip and Upper Arm Girth Measurements and the Subscapular Skinfold

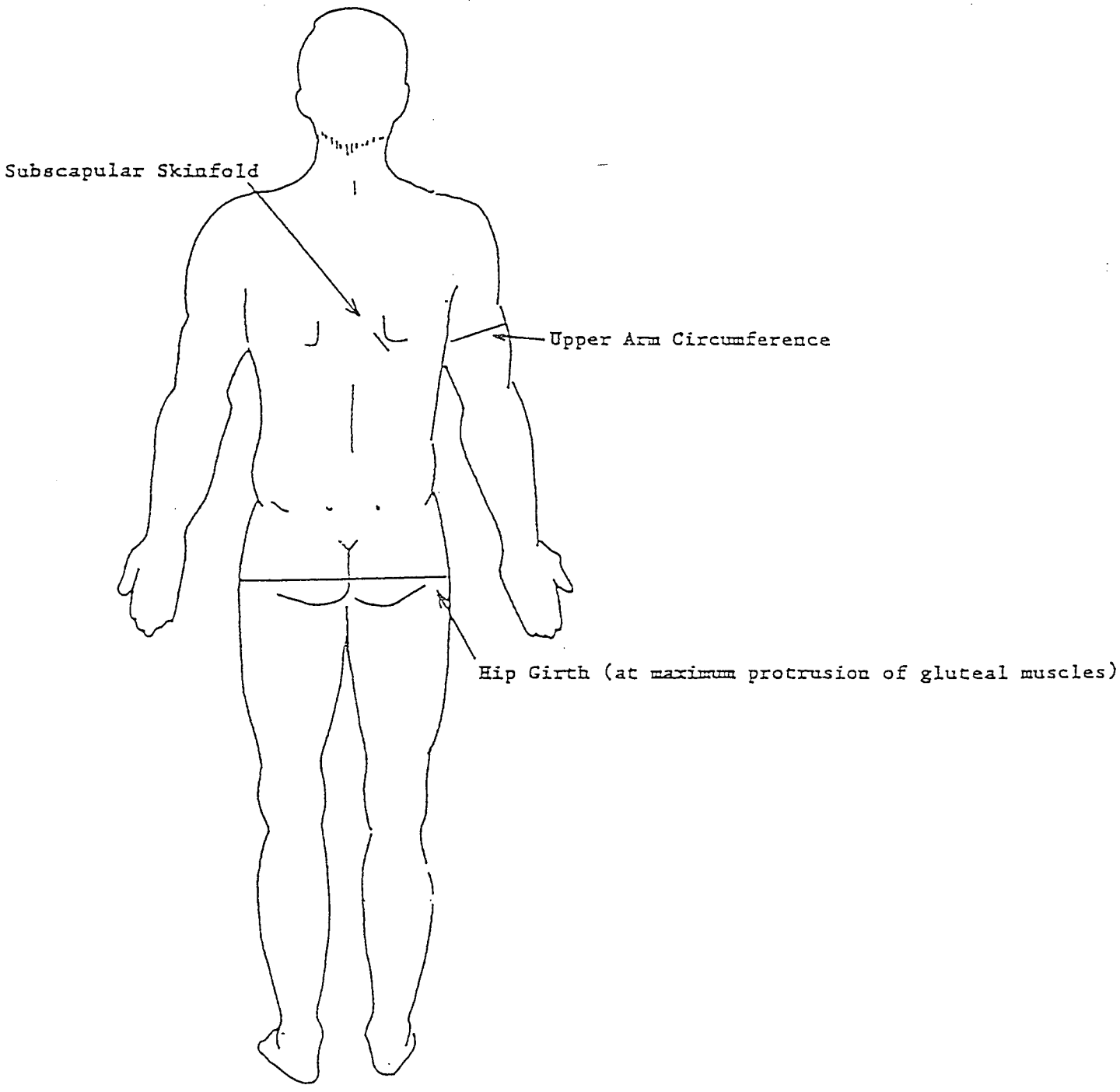
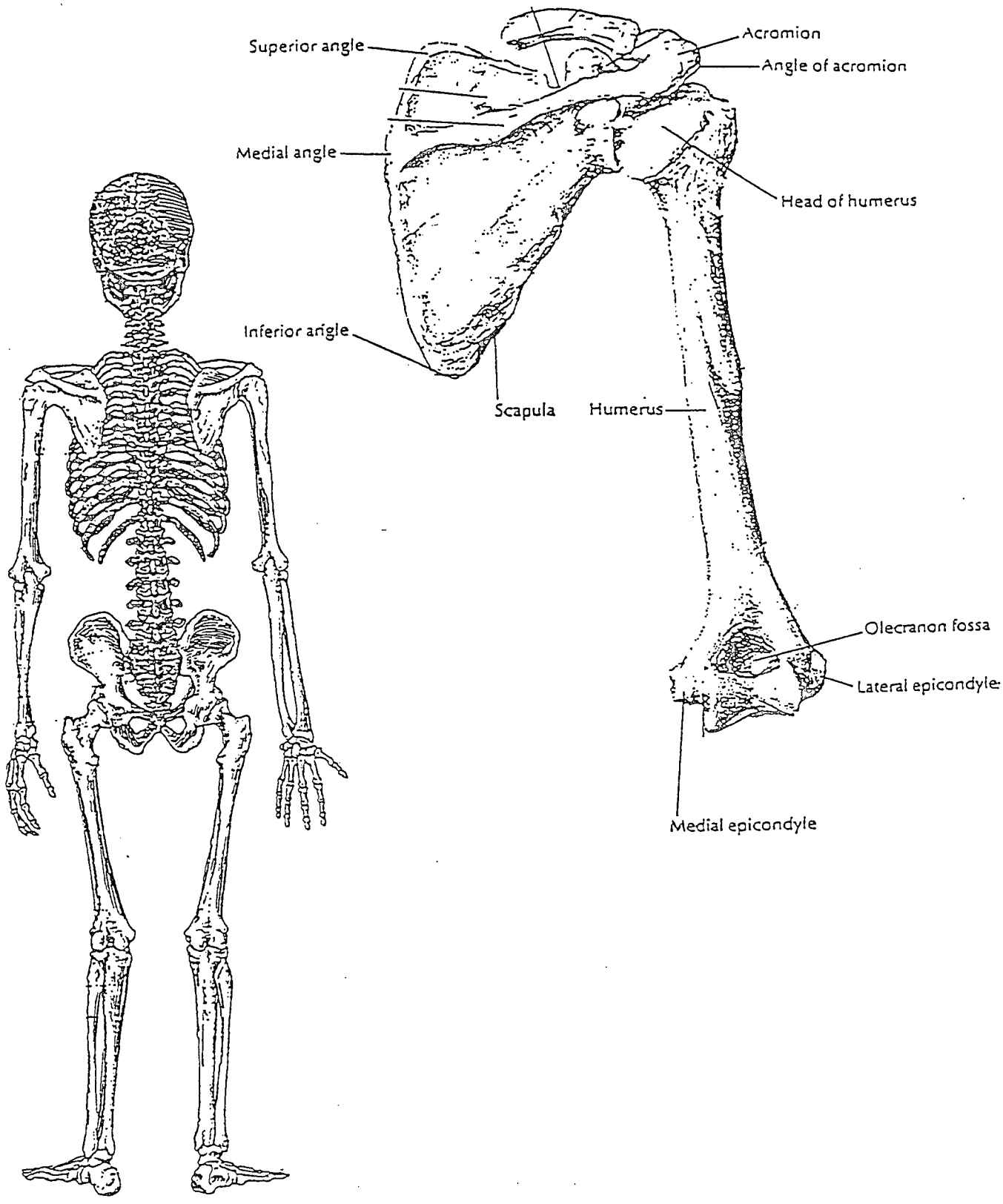


Figure 3.3 Bony Landmarks for Anthropometric Measurements



3.1.2.5 Arm Circumference

The participant stands facing away from the technician with the right arm flexed at 90 degrees at the elbow, hand across midsection. The observer determines and marks the tip of the olecranon (elbow). Bony landmarks for measuring the circumference of the right arm are depicted in Figure 3.3. The participant straightens the arm, allowing it to hang loosely at the side. The technician then determines and marks the posterior tip of the acromion process (shoulder bone). Using a centimeter tape, the technician measures the length of the upper arm between the two marks and marks the midpoint (+).

The technician wraps the tape around the arm at the midpoint mark, making sure that the tape is level. The arm circumference is measured to the nearest centimeter, rounding down, and is recorded in Item 6 (SBPD) or on the participant's itinerary sheet as a reference for the subsequent completion of the sitting blood pressure form.

3.1.2.6 Male Pattern Baldness

After the anthropometric measurements have been taken, the technician briefly explains to the male participants why male pattern baldness is being assessed at Visit 4 and requests their permission to observe their natural hair pattern. A standardized explanation is included in the introductory script which is printed on the data collection form (Appendix 3.1.a). This is read to each male participant and his willingness to participate is recorded in Item 5.a (ANTD). If the participant agrees, the technician first observes the person's natural hair patterns from the right and left sides and from above, and selects the diagrams on the modified Hamilton Baldness Scale (Figure 3.4, and Appendix 3.1.1) which most closely resemble the person's hair patterns as observed from the three angles. The technician then inquires about the age of onset of hair loss (if any) and a history of treatment for hair loss. The instructions for completing the data collection form are provided in Appendix 3.1.c.

Typically male pattern baldness affects two parts of the head: the forehead (frontal baldness) and the vertex (top of the head). Using the Hamilton Baldness Scale (Figure 3.4), technicians assess the person's natural hair pattern. There are 12 baldness patterns, each shown from 2 views. In general, the extent of baldness increases from Figure 1 to Figure 12, but there are more subtle differences between categories. When the vertex is not involved (e.g., when there is no hair loss from the vertex), the technician chooses from among Figures 1-5 or Figure 8. When the vertex is involved, the choice among Figures 6, 7 and 9-12 depends upon the extent of vertex baldness and the extent and type of frontal baldness. Complete baldness (not shown in the diagram) is coded as "13" in Item 5.b (ANTD).

FIGURE 1 on the scale shows little or no hair loss in the frontal area and no vertex baldness.

FIGURE 2 shows some (or a little) hair loss in the frontotemporal areas. Areas tend to be triangular and symmetrical and the hair loss stops well before the ear. There is no vertex baldness.

FIGURE 3 shows midfrontal hair loss; the hairline lies high on the forehead; there is no vertex baldness.

FIGURE 4 shows somewhat the same hair loss pattern as Figure 2, but is more severe. There are deep frontotemporal recessions; there is no vertex baldness and the midfrontal area is relatively spared.

FIGURE 5 shows midfrontal hair loss that has progressed further back than in Figure 3; there is no vertex baldness.

FIGURE 6 shows some vertex baldness. There may also be some frontal recession.

FIGURE 7 shows vertex baldness that is more severe than in Figure 6. Frontal baldness is also more severe. The two areas are separated by a band of moderately dense hair.

FIGURE 8 shows recession from the front has progressed beyond that in Figure 5. There is no vertex baldness.

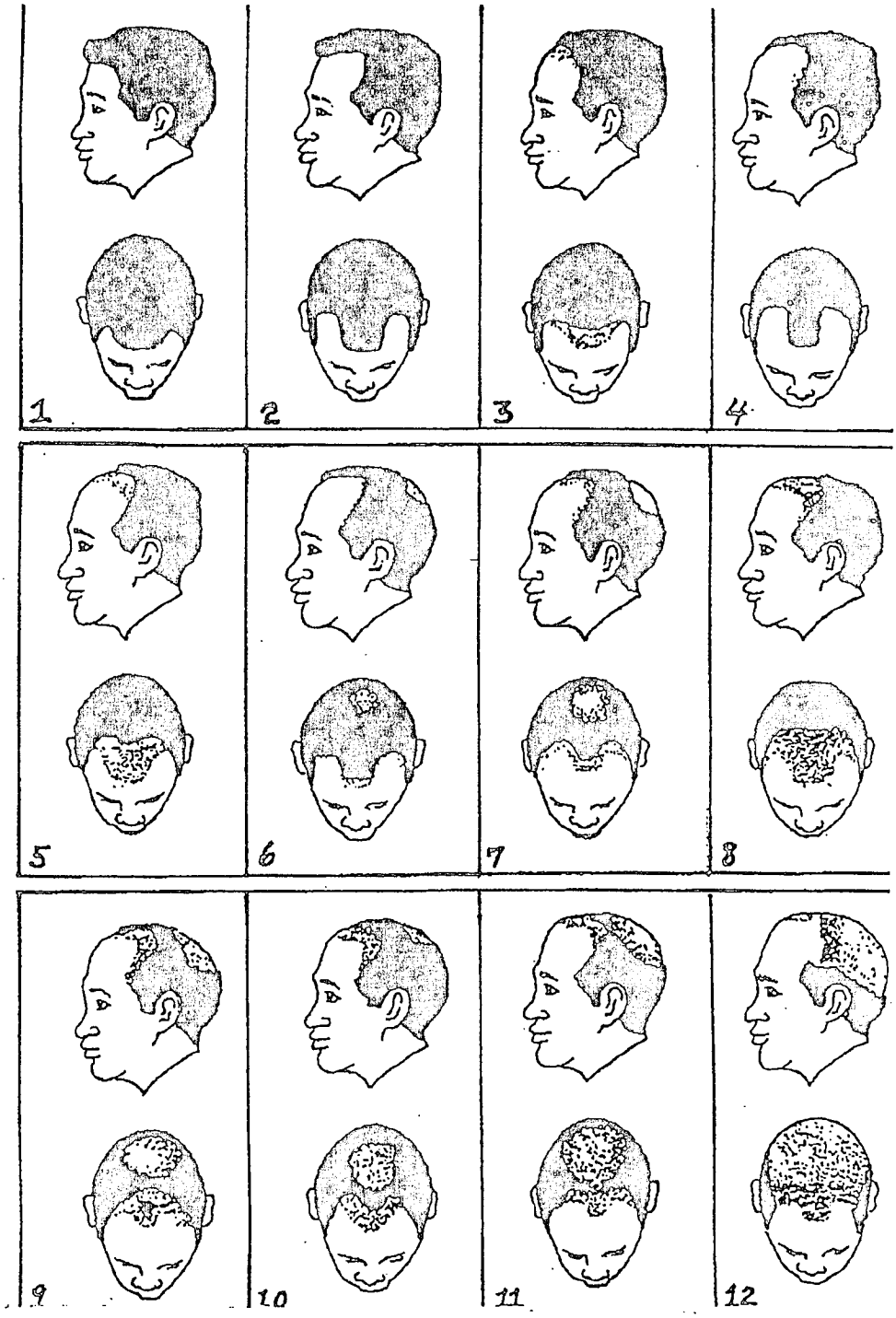
FIGURE 9 shows both vertex and frontotemporal baldness and hair loss is more severe than in Figure 7. The areas of loss are now larger but still separated by a narrower, sparser band of hair, so separation is not as distinct.

FIGURE 10 appears to have less vertex baldness than Figures 9 and 11.

FIGURE 11 shows a large area of baldness, but not as extensive as Figure 12.

FIGURE 12 shows all that remains is a narrow, horseshoe-shaped band of hair.

Figure 3.4 The Hamilton Scale (modified by Norton) of Male Pattern Baldness



The goal is to identify the "natural" pattern and not the cosmetic appearance. For example, vertex baldness may sometimes be "disguised" by cosmetic combing. The natural pattern is observed to the best of the technician's ability without asking the person to recomb his hair. Unless the participant volunteers that he has a toupee, he is not asked. The following guidelines are followed when selecting the diagram which best depicts the hair pattern.

1. Always classify each participant according to the best matching figure, even if none matches exactly.

2. Ask the participant to turn his head to the right and to the left. If one side shows more baldness than the other, classify according to the side that has the more severe baldness.

3. If there is difficulty deciding between two classifications, choose the one with the LESSER baldness.

4. Vertex baldness is thought to be more significant than frontal baldness. If there is difficulty selecting a figure that resembles both the vertex and frontal baldness, classify the participant according to the vertex baldness.

3.1.3 Training

Technicians are trained centrally and are responsible for the local training of newly hired technicians (observers) and recorders. Training includes an (1) introduction to the rationale for body size measurements and male pattern baldness, the expected limits of reproducibility, and usual errors; (2) a demonstration of proper and improper procedures; (3) practice on volunteers and (4) testing on volunteers with four different body types - lean, obese, athletic and aged - and on men with as many different types of patterns of baldness as is practical.

3.1.4 Certification

Common criteria are used for initial certification and recertification for anthropometry. Field center anthropometry supervisors and technicians are certified after participating in central training or locally by the chief technician, and all observers are recertified bi-annually (January and July) by the local expert. Each technician practices on volunteers with a variety of body shapes and male pattern baldness, and for the assessment of certification and re-certification, measures one volunteer, meeting the following criteria:

1. The standing height measurement must agree within 1.0 cm of the trainer/certifier.

2. The waist and hip circumference measurements must agree within 1.0 cm of the trainer/certifier.

3. Weight must agree within 1 lb of the trainer/certifier.

4. Selection of hair pattern must agree with trainer.

Recertification is performed locally every 6 months at the field centers. The following additional certification criteria for each type of measurement need to be met:

1. Absence of end digit preference for more than 6 months during one year;

2. Absence of systematic differences in mean values;

3. Adequate performance on replicate measurements.

3.1.5 Quality Assurance

In addition to annual recertification, protocol adherence in the performance of each procedure is reviewed at least annually by the by Coordinating Center field center monitors. Deviations from protocol and possible remedial actions are discussed with study coordinators and staff at that time. Quality control observations of technicians by an observer are also performed biannually by field center staff in January and July of each year and documented on the Report on Use of Observation and Equipment Checklist (Appendix 3.1.j). These are sent to the ARIC Coordinating Center for review. Major deviations from the protocol are brought to the attention of the Cohort Operations Committee.

Anthropometry equipment is calibrated frequently and results are recorded on an Anthropometry Equipment Calibration Log (Appendix 3.1.d). Scales are zero balanced daily and calibrated weekly, or when moved. Measuring tapes are checked monthly and replaced as needed. The number of above measurements are recorded on the 'Report on Use of Observation and Equipment Checklist' and sent to the Coordinating Center biannually.

Digit preference, systematic differences in location statistics, completion of checklists/logs according to schedule are analyzed by the Coordinating Center and reviewed by the Quality Control Committee. Refer to Manual 12 for a detailed description of quality assessment procedures.

3.1.6 Data Collection

The Anthropometry Form is collected by either the technician (observer) or recorder by direct data entry on a data entry screen (Appendix 3.1.b) or on a paper form for delayed data entry.

3.2 Dental Study

The ARIC Dental Study is an ancillary study to Visit 4, funded by the National Dental Institute, and jointly conducted by the University of North Carolina (UNC) School of Dentistry and current UNC ARIC Study investigators under the auspices of the ARIC Steering Committee. At the field centers, the dental study consists of dental screening and dental history interviews and a blood serum sample from all participants. An oral exam, based on a standardized study protocol performed by trained and certified dental hygienists, is done on all eligible cohort members to identify problems in dental hygiene (as a courtesy to participants); assess levels of plaque; collect and store crevicular fluid and plaque; record a gingival index; measure probing depth and cemento-enamel junction (CEJ), and record the extent of bleeding on probing.

The UNC School of Dentistry serves as an ARIC Study central agency for (1) the preparation of standardized protocols for the dental examination; (2) the creation and maintenance of a data entry system; (3) the training and certification of dental examiners and recorders; (4) the analysis of gingival and crevicular fluid and serum samples and (5) collecting, analyzing and transmitting study data to the ARIC Coordinating Center.

The specific aims of the ARIC Dental Study are to (1) determine the prevalence, extent, and severity of periodontal conditions in the ARIC population and describe the associations between those conditions and prevalent CHD, carotid artery wall thickness, and atherosclerotic risk factors, and (2) determine whether the local gingival crevicular fluid levels of prostaglandin E_2, thromboxane B_2 , interleukin-1B, and tumor necrosis factor-alpha are elevated in cases of severe carotid atherosclerosis, and whether elevated levels of these mediators are associated with atherosclerosis risk factors, including elevated serum lipid values and fibrinogen.

Although the dental study was implemented 4 to 6 months after the start-up of Visit 4, all cohort members are screened and recruited to participate in the dental study. The majority of ARIC participants are screened during their Contact Year 10 Annual Follow-up interview and Visit 4 scheduling telephone call. Those participants who were examined prior to the implementation of the Dental Study are recontacted, screened and offered the opportunity to return to the field center at a later date for the dental exam. The dental study serum sample is not drawn on participants returning to the field center for a dental exam.

3.2.1 Rationale

Periodontal diseases, which are chronic gram-negative infections, represent a possible risk factor for both atherosclerosis and thromboembolic events. Previous studies have demonstrated an association between periodontal disease severity and a risk for CHD and stroke. These associations may be due to a chronic, underlying inflammatory response that places an individual at higher risk for developing both periodontal disease and atherosclerosis.

3.2.2 Procedures

The protocol for administering the dental screening (Section 2.6) and history (Section 2.5) interviews is in Chapter 2; their respective data collection forms and question by question instructions are in Appendix 2.5 and 2.6.

A brief description of the procedures for collecting the dental study serum sample and completing its data collection form (LABB) is provided in Section 3.9 of this manual and Appendix 3.9. The Dental Study serum sample is drawn during the routine ARIC venipuncture, is processed along with the other ARIC blood samples and shipped to the UNC School of Dentistry according to the study protocol. Further details are provided in Manual 7 (Blood Collection and Processing).

The specific procedures for performing and collecting the data for the oral exam are described in separate manuals, The ARIC Dental Procedures Manual, and the Dental ARIC Data Entry System Users Manual, respectively. The Dental Study data collection forms and results report are located in the ARIC Dental Procedures Manual.

In general, the participant's eligibility and willingness to have a oral exam are established prior to the visit, and the oral exam is scheduled in advance, allowing the dental examiner to have the pre-packaged specimen data collection packets labelled and set out prior to the participant's arrival. The oral exam takes approximately half an hour and is conducted during the flexible component of the ARIC exam. See Table 2.3.

The oral exam is performed by a trained and ARIC certified dental examiner, usually a dental hygienist, and data and sample collection are collected by a trained and certified recorder who assists the dental examiner. Data collected in the Dental Study data entry system and samples are stored and shipped to the UNC School of Dentistry according to the procedures in the Dental ARIC Data Entry System Users Manual and the ARIC Dental Procedures Manual, respectively.

The participant's eligibility is confirmed by the hygienist prior to the oral exam by briefly reviewing the responses on the Dental Screening form (not re-administering the form) and determining whether an interim event(s) since the administration of the screening form now requires prophylactic antibiotic coverage.

The oral exam can be briefly interrupted when a participant is scheduled to have the 2 hour post-load glucose sample drawn during the time the oral exam is being done. The participant is escorted by a laboratory technician to the

venipuncture workstation (unless the dental workstation meets OSHA venipuncture regulations and the blood can be drawn according to the ARIC venipuncture protocol), the second OGTT sample is drawn, and the participant is returned to the dental workstation to complete the oral exam.

A Dental Study results report which summarizes the hygienist's findings and recommendations (if any) for further follow-up with a dentist is generated at the conclusion of the oral exam and given to study participants as a courtesy. ARIC participants are informed that the oral examination, like the interviews and procedures in the ARIC Study, is not the same as a dental examination performed by one's personal dentist, and does not provide diagnosis, treatment or medical advice.

3.2.3 Training

Training for the dental examiner and the dental recorder is done centrally at the UNC School of Dentistry. Training for new dental recorders can be done locally by certified dental examiners. Training, however, for dental examiners is always provided by the UNC School of Dentistry. Refresher courses are provided annually.

3.2.4 Certification

Certification is required for dental examiners. Certification is done by the Dental Study principal investigator (PI), based on reviews of data submitted on five people. Clinical exam data are reviewed for completeness and unusual patterns and entries. Samples are assayed in the laboratory to determine if cytokines are present and within expected parameters. Recertification is performed annually after the annual retraining sessions.

3.2.5 Quality Control

Quality control starts with the Dental Study computerized examination data entry system (DES), which directs the examination procedure, requires consistency throughout the exam, and allows only a certain range of entries to be made. When examination data are received at the Dental School, they are checked for completeness of the examination, expected patterns of entries, and the examinations are matched with the screening and history forms to look at acceptance rates and patterns of refusals and exclusions.

3.2.6 Data Collection

Data from the periodontal exam and sample storage and shipping procedures of dental study participants' samples are listed in their respective manuals of procedures. Data from the periodontal exam that are recorded in the Dental Study DES (the clinical exam form) are stored on diskette and shipped to the School of Dentistry every two weeks. Participant samples are stored at the field centers and also shipped to the School of Dentistry (separate location).

In contrast, screening and dental history data are collected on all participants. The Dental Screening and History forms are entered into the ARIC data entry system and transferred to the ARIC Coordinating Center, according to the ARIC study protocol.

3.3 Electrocardiogram

A resting 12-lead ECG is performed on each participant in Visit 4 using procedures and equipment identical to those employed in previous cohort examinations. Processing and coding at the Minnesota and EPICARE centers follow the same procedures used in the baseline visit. Full details are provided in Manual 5 of the ARIC Protocol.

3.3.1 Rationale

The main purpose of the electrocardiographic measurements is to provide information on (1) interim myocardial infarction; (2) changes in conduction pattern, ventricular hypertrophy and ischemia; (3) and other indicators of cardiac function. Hospital ECGs are also read and abstracted for all cohort participants hospitalized after their baseline visit, to determine if a cardiac end point event has occurred.

3.3.2 Procedures

Standard (12-lead) ECG operational procedures are provided in Manual 5, Electrocardiography, and the central training manual.

3.3.3 Training

Central training of senior field center technicians was initially performed in Visit 1. Training for new ECG technicians is provided centrally and by the senior certified ECG technician at each field center, with attention to (1) electrode placement, (2) skin preparation, (3) MAC PC menus and data entry, and (4) self-evaluation techniques for technical performance.

3.3.4 Certification

Certification is required for ECG technicians performing 12-lead ECGs. Requirements and procedures are listed in Manual 5 and summarized in Table 2.2. The EPICARE ECG Reading Center serves as the certifier. Recertification is performed bi-annually by the field center senior technician (January and July), but technician performance is monitored continuously by EPICARE with quarterly reports to the field centers.

3.3.5 Quality Assurance

To maintain certification each technician is required to perform a minimum of three (3) ECGs per week over a two-month period; quality grades for each 12-Lead ECG are reported by the EPICARE Center to each technician on an ongoing basis; an ECG quality control checklist is administered biannually (see Appendix Q of Manual 5).

Quality assurance of the ECG coding at each of the two central ECG reading facilities includes internal, and external quality control programs. These are detailed in manuals 5 (Electrocardiography) and 12 (Quality Control).

3.3.6 Data Collection

The standard electrocardiograph for the recording of 12-lead ECGs is the MAC PC Personal Cardiograph by Marquette Electronics, Inc. Data collection procedures are fully documented in Manual 5. Paper tracings are stored in the participant's folder. Electronic records of the 12-lead ECGs are transmitted daily by modem to the ECG Computer Center at EPICARE with next day verification of receipt to the field centers.

3.4 Heart Rate Variability

Heart rate variability (HRV) is collected on all ARIC Visit 4 participants, immediately after the 12-lead ECG or as soon as the participant has been supine for at least 10 minutes. In order to derive HRV indices, R-R interval data over a specified period (6 minutes) are collected and stored following a standardized protocol. These R-R interval data are processed at a central location by trained technicians to derive HRV indices from the R-R interval variations.

HRV data are collected on individuals regardless of fasting status or participation in the OGTT. However, for persons doing the OGT test, HRV data must be collected prior to the administration of the glucose load, i.e., 9HRV is never collected after the glucola is administered.

In all instances, the HRV technician verifies fasting status according to the ARIC QxQ instructions of the Fasting/Tracking form. This information is recorded on the HRV log and the HRV screen per instructions found in the HRV protocol manual.

3.4.1 Rationale

HRV has been used as a non-invasive measure of cardiac autonomic activity, and has been found to be associated with the prognosis of acute myocardial infarction in clinically-based studies.

3.4.2 Procedures

Standard HRV procedures are provided in a separate manual (Heart Rate Variability Data Collection Manual).

3.4.3 Training

Lead HRV technicians are centrally trained by the central HRV technician in conjunction with the ARIC Ultrasound Reading Center staff. Other ECG technicians and new staff are trained locally by the designated local expert at each field center.

3.4.4 Certification

Certification is based on the adequate performance of five procedures observed by the trainer. Retraining is conducted annually. Technician performance is monitored continuously, with deterioration of quality indices being brought to the attention of the technician by the Ultrasound Reading Center. Satisfactory performance over the course of one year leads to recertification.

3.4.5 Quality Control

Quality control procedures for technicians are described in the HRV Data Collection Manual. Quality control procedures for the reading center technicians are described in the HRV Data Processing Manual.

3.4.6 Data Collection

HRV data are collected using ART HRVECG system installed on a dedicated PC. Details are in the HRV Data Collection Manual. HRV data are backed up weekly and shipped to the Ultrasound Reading Center with the weekly shipment of the ultrasound tapes. A copy of the data is also stored on diskettes at the field centers.

3.5 Microalbuminuria study

A urine sample is collected on all ARIC participants at Visit 4 in order to perform assays for microalbuminuria. Procedures for the collection of the urine sample is provided below. Procedures for the processing, storage, and shipping of urine samples are provided in Manual 7. Instructions for completing the urine section of the Laboratory form (LABB, Appendix 3.6.c) are provided following the data collection form in Appendix 3.6.a.

3.5.1 Rationale

A primary focus of Visit 4 is the assessment of the putative association(s) of chronic inflammation to atherosclerosis and other aspects of coronary heart disease and stroke.

3.5.2 Procedures for Collecting the Urine Specimen

A urine sample is collected from each participant (preferably) at the beginning of the clinical exam. The specimen is divided into three separate sample tubes and frozen at the field centers until shipping. Aliquots for creatinine and albumin on each participant are shipped to the Minneapolis ARIC Field Center. The 50 ml conical tube (one per participant) for the hemostatic metabolites are shipped to the ARIC Hemostasis Laboratory.

3.5.2.1 Participant Instructions

After participants complete the reception work station activities and are taken to change clothes, they are informed about the urine collection by saying something like:

> "During your exam, we hope to collect a urine specimen. You may do that as you change clothes for the exam. Or, if you wish to do it later, please notify us when you need to use the bathroom."

The urine specimen is collected at the field center whenever the participant needs to void. If the participant has not voided by the time of the exit interview, the participant is asked to void at that time.

When the participant is ready to void, a specimen cup (labeled with his/her ID) and lid and a TIME VOIDED label are provided by the staff member working with the participant at that time. The participant is instructed to

1. void in the cup, filling it if possible, and place the lid securely on top of the container

2. record the time of voiding on the label, and

3. bring the specimen cup back to the staff member, OR

4. place the sample container in a refrigerator designated for urine samples, and report to a staff member that the specimen has been collected, depending on locally approved OSHA regulations.

Bathrooms are equipped with a wall clock and pencils for participants to use in recording the time of voiding on the label. The staff member verifies the participant has written the "time voided" on the label, and assesses the adequacy of the sample for processing. If insufficient, the participant is requested to void again in a clean container prior to leaving the field center. A note is made on the participant's Itinerary Sheet that a second sample is needed by the ARIC staff person who observes the placement of the participant's urine specimen in the refrigerator. A note can also be made on the participant's first sample that a second sample is needed. The optimal time for the collection of the second specimen is after the snack when the participant is changing back in to street clothes. The instructions for providing the urine sample are repeated to the participant at that time.

Prior to processing, the laboratory staff records whether a urine sample was obtained and transcribes the collection time of the urine void from the ID label onto each participant's LABORATORY (LABB) form (Appendix 3.6.a).

3.5.3 Training

Training in the provision of instructions to participants for the collection of urine specimens is provided centrally, or locally for new staff by a certified laboratory technician, the interviewer supervisor or study coordinator at each field center.

3.5.4 Certification

No certification is required.

3.5.5 Quality Control

Techniques and adherence to protocol are observed by Coordinating Center monitors; the quality of the urine specimens and missingness are monitored by the Quality Control Committee.

3.5.6 Data Collection

Information on the collection and processing of urine samples is recorded on the paper version of the Laboratory (LABB) form for delayed data entry. When the first urine sample is insufficient for processing, the participant is asked to provide a second sample, which is mixed with the first. The time of the urine sample, however, is recorded on the Laboratory form as the hour and minutes of the last voided specimen. The assessment of volume adequacy for the Laboratory form is made immediately prior to processing.

3.6 Oral Glucose Tolerance Test

In population surveys of middle-aged individuals, approximately 50% of diabetics and almost all individuals with impaired glucose tolerance will not have been diagnosed. Although measurement of fasting glucose identifies some diabetics (fasting glucose levels have been obtained on all ARIC participants at each clinical examination), this measurement alone misses approximately 75% of the population with abnormal glucose tolerance. The oral glucose tolerance test (OGTT) is the standard test to determine whether diabetes or a milder abnormality of glucose tolerance is present. The OGTT is necessary to document mild, asymptomatic abnormalities in glucose clearance. It is required to distinguish between individuals with normal glucose tolerance and those with abnormal glucose tolerance (who have not yet developed fasting hyperglycemia).

3.6.1 Rationale

Diabetes is a metabolic disease characterized by abnormally high blood sugar and an increased risk of several chronic complications, including heart, vascular, eye and kidney diseases. In the middle aged and the elderly, diabetes is associated with increased cardiovascular disease (CVD) and is an especially strong risk factor for heart disease in women. Many people with diabetes are asymptomatic, but remain at increased risk of complications. Impaired glucose tolerance is defined as an abnormal glucose tolerance level between normal and diabetes. People with impaired glucose tolerance also appear to have an increased risk of CVD, but little or no increased risk of eye and kidney disease.

Until a few years ago, larger doses of glucose were commonly administered during the OGTT and some individuals complained about the fluid volume and/or subsequent GI distress. During the last 10 years, the use of a lower dose of glucose has greatly reduced this problem. In a study performed by the National Institute of Aging, only 0.3% (3 per thousand) participants complained of side effects, all of which were mild and transient. Between 1990 and 1992, National Heart, Lung, and Blood Institute investigators have performed over 10,000 OGTTs, like those to be done in ARIC, with no serious

side effects and less than 0.5% of mild side effects. Because the ARIC study screens the individuals invited to take part in the OGTT, participants can be reassured that this is a safe, widely used, and informative test.

3.6.2 Procedures

The OGTT has several components which **are all fixed** within the context of the participant flow. Note that heart rate variability, and therefore ECG, as well as the fasting venipuncture must be done prior to administering the glucose load. And, the post glucose load venipuncture must be scheduled 2 hours, plus or minus 10 minutes, after ingestion (see below for details).

Participants are optimally scheduled at the field center by 10:30 am. Their eligibility and willingness to participate in the OGTT is determined during reception. The OGTT Screening Form (GTSB) is administered to all participants (see section 2.6). Persons taking medications to control their diabetes, those with prior surgery to remove part of the stomach or intestines, on kidney dialysis, and those declining to participate are excluded from the OGTT. Exclusion from OGTT (for either medical reasons or personal preference) is also marked on the Itinerary Sheet.

Before administering the glucose load, the technician verifies the participant's eligibility, as recorded on the OGTT Screening Form. Blood samples to measure participants' initial fasting blood sugar are drawn as part of the routine ARIC venipuncture. The glucose load (75 grams of glucola) is administered immediately following venipuncture. Two hours after the participant *began* to drink the glucola, a second blood sample is obtained for measurement of glucose and insulin. A snack is provided soon after the drawing of the two hour blood sample.

3.6.2.1 Venipuncture for Fasting Glucose Samples

Fasting glucose samples are drawn as part of the regular ARIC procedures. Detailed instructions are outlined in Manual 7. Either prior to or during venipuncture, the phlebotomist verifies the participant's eligibility to participate on the OGTT Administration Form. Administration of the glucola is scheduled immediately following venipuncture.

3.6.2.2 Administration of Glucose

All eligible participants receive a standard 75 gram glucose load as a flavored drink. Commercially available preparations for the OGTT made from 75 grams of glucose monohydrate only contain 68 grams of glucose, and are not to be used. The preferred means of serving the glucola to the participant is to remove the cap and serve the bottle with a straw. If requested by the participant, the contents can also be poured into a paper cup and served with or without a straw. Participants are instructed to consume the contents of the container (bottle or glass) in its entirety in less than 10 minutes. Most individuals consume the full amount in 3 to 5 minutes quite easily.

The timing for the 2 hour post load venipuncture begins as soon as the participant starts to drink the glucose solution. The time the participant *began* drinking the glucola is recorded in Item 1 of the Oral Glucose Tolerance Administration (GTAA) form (Appendix 3.6.a). (Instructions on how to complete the form are in Appendix 3.6.b.) The time the participant should have the 2 hour post load venipuncture is recorded on the Itinerary Form.

Study participants are encouraged to drink the full amount of glucola; otherwise they will not get the full benefit of the test. If the individual does not consume the full amount of glucola, the technician measures the residual amount and records it in Item 2 of the OGTT Administration (GTAA) form. The measurement of the residual glucola is not necessary if only a few drops are left. If the residual amount is 145 ml or more, the 2 hour blood

draw is NOT performed, and the OGTT Administration Form is completed accordingly. Based on the experience in many epidemiologic studies in the U.S. and elsewhere, this should be a very uncommon event.

3.6.2.3 Two Hour Post Glucose Load Venipuncture

The two hour blood sample is obtained for measurement of glucose and insulin two hours after the start of the test. The blood sample is drawn as close to the two hour time as possible. The phlebotomist records that the post-load blood glucose sample was drawn, and the actual time it was drawn (or the reason(s) for non-collection) in the OGTT Administration (GTAA) Form (Appendix 3.3.a).

Every scheduling effort is made to allow participants to go to the venipuncture work station for the 2 hour blood sample. The Itinerary Sheet needs to be checked frequently as a guide to scheduling interviews and procedures, especially towards the end of the examination. In a complex study such as ARIC, it is inevitable that some participants will be busy with other parts of the examination. If the participant is available within a 10 minute window of the scheduled 2 hour post-load venipuncture, the overlapping interview or procedure does not need to be rescheduled or interrupted. However if the 2 hour blood sample is due and the participant cannot come to the venipuncture work station within the 10 minute window, the phlebotomist, if possible, goes to the participant to obtain the sample.

3.6.2.4 Snack

OGTT study participants should neither drink nor eat anything in the period between the glucose administration and the 2-hour blood draw. After the post-load venipuncture, participants are given the regular snack, as soon as possible. OGTT study participants will have been reminded to ask their physicians whether they can postpone taking the medications they usually take first thing in the morning until they have their 2 hour post-load venipuncture (see Eligibility, above).

3.6.2.5 Documentation of Side Effects

If participants complain of any problems during the test, they should be reported to the Study Coordinator or the Study Nurse and documented on the field center's Incident Log. Based on previous studies similar to ARIC, side effects are very infrequent, and vomiting was reported only on 0.1 percent of tests (diarrhea is not a side effect of the OGTT). However, if vomiting has occurred, the 2-hour blood draw should not be done, and the reason for the incomplete test recorded as 'other' in Item 4 of the OGTT Administration (GTAA) Form (Appendix 3.3.a).

3.6.2.6 Readiness for Emergencies

Field centers keep on hand orange juice or equivalent, sugar-containing beverages at all times.

Participants with known or undiagnosed diabetes may develop low blood sugar or an "insulin reaction". If recognized promptly by clinic staff, it should be mild and easily treated with orange juice or a similar sugar containing beverage.

Hypoglycemia, or an abnormally low blood glucose level, occurs when there is an imbalance between the dose of hypoglycemic medications (in the treated diabetic) or the blood sugar level (in any person) and the person's food intake and activity level. However, treated diabetics are excluded from the OGTT. Classic symptoms include anxiety, tremor, palpitations, sweating, faintness, and hunger. If untreated, a further decrease in blood glucose may lead to confusion followed by loss of consciousness. Prolonged hypoglycemia

may precipitate angina pectoris or seizures.

It is important to remember that symptoms of hypoglycemia are variable and may be partially masked in older participants.

If a person displays any of these symptoms after ingesting the glucola and is able to take food orally, orange juice containing additional sugar should be given immediately and the clinic physician notified as soon as possible. When a hypoglycemic reaction occurs, the person is evaluated by medical staff prior to leaving the field center.

If an OGTT participant loses consciousness, hypoglycemia should be presumed until ruled out. **Severe hypoglycemic reactions are a medical emergency** and the person should be transported immediately to an emergency care facility.

3.6.3 Training

Training in the administration of the glucola, completion of the data entry form, blood drawing, processing, storage and shipping for laboratory technicians is provided centrally, or locally for new staff by a certified laboratory technician at each field center.

3.6.4 Certification

The lead technician is certified at central training by the central trainer; other technicians are certified either at central training or by the lead technician at the field center. Recertification is done bi-annually (January and July) by observation.

3.6.5 Quality Control

In addition to annual recertification authorized by the Hemostasis Laboratory, protocol adherence in the performance of each procedure is reviewed at least biannually by the lead technician and annually by Coordinating Center field center monitors. Deviations from protocol and possible remedial actions are discussed with study coordinators and staff at that time. Major deviations are brought to the attention of the Cohort Operations Committee.

3.6.6 Data Collection

Information on eligibility to participate in the OGTT is recorded on the Oral Glucose Tolerance Screening (GTSB) form, fasting status is recorded on the Fasting/Tracking (FTRD) form, the administration of the glucola is documented on the Oral Glucose Tolerance Administration (GTAA) form, and the collection and processing of the fasting and post-load blood samples is recorded on the Laboratory (LABB) form.

3.7 Sitting Blood Pressure

Sitting blood pressure is measured on all participants at each field center. It is measured in a resting state, and in contrast to the procedures in Visits 1-3, only two measurements are taken with a random zero sphygmomanometer. Data are recorded on the Sitting Blood Pressure (SBPD) form (Appendix 3.4.a).

3.7.1 Rationale

As one of the most powerful risk factors of cardiovascular disease, a measurement of sitting blood pressure is included in every clinic examination of the ARIC cohort. The procedures are the same used in previous examinations, except only two measurements are taken, as detailed in Manual 11 of the ARIC Protocol.

3.7.2 Procedures

Sitting blood pressure is a fixed component of the participant flow and is measured in conjunction with the anthropometric measurements and before the ECG and venipuncture (Table 2.3). Procedures for obtaining sitting blood pressure are found in Chapter 1 of Manual 11. Question by question instructions for completing the data collection form are in Appendix 3.4.c of this manual.

Guidelines for terminating the clinical exam and referring participants with abnormal blood pressures for clinical care or follow-up are listed in sections 4 (Medical Data Review) and 5 (Referrals and Review Guidelines) of this manual.

3.7.3 Training

Blood pressure technicians are trained centrally at the beginning of each examination. New technicians, hired after Visit 4 central training are trained locally by the designated local expert (Table 2.2). Refer to Manual 11 for further details.

3.7.4 Certification

Certification is required; criteria are listed in Manual 11. Recertification is performed biannually in January and July. Recertification criteria include:

1. Successful completion of double-stethoscope observation, semi-annually;

2. Semi-annual test with recertification tapes;

3. Absence of end digit preference for more than 6 months during one year;

4. Annual review by the central ARIC blood pressure trainer.

3.7.5 Quality Assurance

Detailed quality control procedures are provided in Manuals 11 and 12, and include periodic review by the Quality Control Committee of end digit preference, systematic differences between technicians in mean values, and completion of performance on checklists/logs. The observer checklist for observation of blood pressure techniques by (1) an observer, (2) by double stethoscoping, and (3) blood pressure training/certification tapes (Appendices in Manual 11) is completed biannually for each certified technician. Monitoring of certification status is conducted by the Coordinating Center.

3.7.6 Data Collection

The Sitting Blood Pressure Form is collected by direct data entry (Appendix 3.4.b) on screen unless the work station computer is disabled. A paper version of the form is available as backup.

3.8 Ultrasound

B-mode Ultrasound imaging of the carotid arteries is a core study measurement performed at each examination on all, or a sample of participants. It provides a non-invasive, standardized measurement of thickening of the intima-media area of the arterial wall, a marker of atherosclerosis. The presence of atherosclerotic lesions is also recorded. These measurements in ARIC make it possible to study the natural history of atherosclerosis, factors associated with its distribution in populations and temporal progression, in addition to its clinical manifestations as is the case for traditional studies of overt clinical disease.

3.8.1 Rationale

Thickening of the arterial wall, attributable to atherosclerotic arterial disease, precedes significant stenosis and clinical manifestations of coronary heart disease. Its prevalence in the study population and its change over time represent a dependent variable for major study questions in ARIC. These ultrasonographic indices of atherosclerosis are also collected to test their ability to predict incident cardiovascular events in the ARIC cohort. During Visit 4, the B-mode ultrasound examination consists of imaging of the carotid arteries in the neck, and monitoring of arterial blood pressure in the supine, seated and standing positions.

3.8.2 Procedures

Procedural and operational detail is provided in manuals 6-A (Ultrasound Scanning), 6-B (Ultrasound Reading).

3.8.3 Training

Central training for ARIC sonographers is provided by the Ultrasound Reading Center (URC), and described in Manual 6-A.

3.8.4 Certification

Certification of experienced sonographers is based on the ability to visualize arterial walls, consistent with the process average of all sonographers. Certification remains in effect as long as visualization is consistent with the overall sonographer process average, and protocol is adhered to.

New sonographers read training materials, observe certified sonographers, attend a central sonographer training course at the URC and practice scanning volunteers at their local field centers. Practice scans are reviewed by chief sonographers at the field centers. When practice scans conform to protocol and are approximately equivalent to the study average, the trainee produces videotapes of scans of volunteers, of the same ages as cohort members, for review at the URC by certified readers. Certification is conferred when the trainee's average number of paired points meet or exceed that of current certified sonographers.

3.8.5 Quality Assurance

Quality assurance of the ultrasound scan is supported by annual retraining of chief sonographers, visits by URC experts to field centers, a preventive maintenance program of the ultrasound equipment, monitoring by the URC of equipment performance, repeat scanning of a randomly selected arterial segment for each participant, periodic scans of the same individual by different sonographers, and monitoring of data at the URC and the Coordinating Center. The ultrasound system is monitored by scanning of tissue-equivalent phantoms on a schedule determined by the performance characteristics of the systems.

The URC monitors sonographer adherence to protocol, as well as the quality of arterial wall boundary images contributed by each sonographer. At the Coordinating Center periodic reports are prepared for the Quality Control Committee, to monitor the rate of success in the acquisition of data, comparability between repeated scans, by sonographer, by field center, and over time. Equivalent reports are prepared by the Coordinating Center to monitor ultrasound reader performance.

3.8.6 Data Collection

Data are collected on a Biosound Phase II scanner. A microcomputer assists the sonographer during the standardized examination sequence and data collection. The B-Mode examination is recorded on ½ inch SVHS videotape and

read at the URC. Participant ultrasound files and blood pressure files are sent to the URC[1].

3.9 Venipuncture

Blood collection and processing follow a standardized protocol and permits the standardized measurement of associations of atherosclerotic manifestations and new coronary heart disease with clinical chemistries, including glucose, and plasma lipid, lipoprotein cholesterol, and apolipoprotein levels and hemostatic factors which are known or suspected to be risk factors for CHD and stroke.

3.9.1 Rationale

The objective in ARIC continues to be having blood samples for various blood chemistries drawn and processed locally at each field center, but analyzed and reported by central laboratories. Because the venipuncture itself can affect study results, the need for strict interpretation of the standardized venipuncture methods outlined in manuals 7-9 is paramount.

3.9.2 Procedures

Venipuncture is performed in a fixed sequence in the participant flow (Table 2.3). The first venipuncture is performed after anthropometry, sitting blood pressure and ECG/HRV measurements, on all cohort members, regardless of their fasting status, and includes 3 plasma samples for the Lipid and Hemostasis laboratories; 2 serum samples for the Hemostasis and Dental laboratories; and an optional sample for a local Hematology laboratory (Figure 3.5). A second venipuncture is performed on OGTT participants, two hours after the administration of the glucose load. Detailed venipuncture, sample processing and shipping instructions are written in Manual 7.

3.9.2.1 Nonfasting Participants

Participants who have not met the ARIC fasting requirements (nothing by mouth except water, or one cup of black, unsweetened coffee or tea for the past 10 hours) are informed that because they have had something to eat or drink within the past 10 hours, it may not be possible to interpret some of their clinical chemistry values, but they are welcome to return to the field center at a later date fasting for a second venipuncture if there are no medical contraindications.

NOTE: persons who are non-fasting and indicate that they would like to be rescheduled for another blood draw are NEVER used as a QC blood phantom.

Persons who have not fasted for 10 hours, but who indicate that they would like to have an OGTT, have the regular ARIC panel drawn, and are also invited to return for a repeat blood draw in conjunction with the OGTT. See Manual 7 for instructions on completing a repeat blood draw on separate days.

3.9.3 Training

Prior to the first cohort visit, phlebotomists were trained centrally. Subsequently, technicians performing venipuncture and processing blood samples have been trained and certified locally by the chief ARIC laboratory technician. Refer to Manual 7 for further details.

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[1] No Heart Rate data collected in U.S. for V4; no backup tape created for V3 or V4

3.9.4 Certification

Recertification is required annually and is performed by the chief ARIC technician at the Central Hemostasis Laboratory or by designated trainer/certifiers from the ARIC field centers. Criteria are described in Manuals 7 and 12.

FIGURE 3.5

SAMPLE PROCESSING FLOW SHEET

Venipuncture time	0:00	GLUCOLA 0:00 - 0:15	0:10 - 0:25	0:30-0:45	0:40-0:55	0:45-0:60	<1:30	2:00

	Temperature after Venipuncture	Stage I	Stage II	Stage III	Draw Next Donors	Final Processing	Freeze	Packaging	Destination
Tube 1 Red and Gray 9.5 ml room temperature	Room temperature	Incubate at room temperature 30 minutes		Centrifuge 10 minutes at 4C 3000 x g		Aliquot serum into 5 white vials seal with white screw caps	5 white cap vials	5 white cap vials in 3" x 6" bag	Central Hemostasis
Tube 2 Blue tops 4.5 ml room temperature	Ice bath	Centrifuge 10 minutes at 4 C 3000 x g	Aliquot plasma into 3 blue micro sample tubes	Refrigerate			3 Blue micro sample tubes	3 blue tubes in 3" X 6" bag	Central Hemostasis Laboratory
Tube 3 & 4 Lavendar tops 10 ml room temperature	Ice bath	Centrifuge 10 minutes at 4 C 3000 x g	Aliquot plasma into 10 white vials seal with lavendar screw caps. Transfer buffy coats into 2 white vials; seal with brown screw caps.	Refrigerate			10 lavender cap vials 2 brown cap vials	10 lavender cap vials 2 brown cap vials in 3" x 6" bag	Central Lipid Laboratory
Tube 5 Red and gray 9.5ml room temperature	Room temperature	Incubate at room temperature 30 minutes		Centrifuge 10 minutes at 4C 3000 x g		Aliquot serum into 4 white vials with red screw caps	4 red cap vials	4 red cap vials into box	UNC Dental Laboratory
Tube 6 Lavender top 5 ml	Room temperature	Refrigerate	OPTIONAL COLLECTION AT FIELD CENTERS						Field Center Hematology Lab
Tube 7 2 hr OGTT Lavendar top 10 ml	Ice Bath	Centrifuge 10 minutes at 4 C 3000 x g	Aliquot plasma into 5 yellow micro sample tubes				5 yellow micro sample tubes	5 yellow micro sample tubes in 3" x 6" bag into 6x6 bag with lipids	Central Lipid Laboratory

3.9.5 Quality Assurance

Data quality monitoring includes periodic review by the Quality Control Committee of (1) tube filling time, (2) number of venipuncture attempts, and (3) selected markers of lack of adherence to protocol during phlebotomy and/or processing of specimens at the field center laboratory.

3.9.6 Data Collection

Blood collection and processing data are collected on a hard copy of the Laboratory (LABB) Form for delayed data entry into the ARIC DES. Notes reflecting blood drawing or processing problems are recorded in the comment section of the Laboratory form (Item 16), and on at the bottom of the laboratory shipping forms which is forwarded as hard copy to the central laboratories and Coordinating Center. Sample Inventory (SMPD) Forms (Appendix 2.3.b) are also completed for each participant documenting the collection (yes/no and collection date) of the lipid, hemostasis and dental study blood samples.

3.10 Snack

A light snack is scheduled as soon as possible after venipuncture for non-OGTT eligible participants, and after the second venipuncture for OGTT participants. Caffeine-free refreshments are provided, including decaffeinated coffee and tea. Menus are locally determined.

4.0 MEDICAL DATA REVIEW

Although it is made clear to all cohort participants in the informed consent and their providers of medical care in the cover letters for the final results report that the interviews and clinical exams which participants undergo are not a substitute for regular medical care, one of the benefits to participants is the summary of results distributed by the field center at the conclusion of, and also several weeks following, the clinical exam. At the end of the field center visit, participant interview and examination data are reviewed by the trained staff to provide the participant with a summary of study results for height, weight, sitting blood pressure and a preliminary report of the ECG (Appendix 4). Participants are reminded that their clinically relevant study data which are processed at the study's central reading centers and laboratories are not available for several weeks.

4.1 Rationale

From the perspective of the investigators, the primary objective of the medical data review is to safeguard participant safety. Clinical and interview data are reviewed with participants to confirm selected positive symptoms reported during the interviews/exams and to determine if these appear to warrant immediate (same day), urgent (same week) or routine medical follow-up. Conditions requiring emergency referral are dealt with as soon as observed and in general have been dealt with before the Medical Data Review takes place. For example, cardiac events, blood pressure readings $\geq$ 210/120 mm Hg and acute pattern abnormalities detected on the ECG are attended to as soon as observed. The ARIC physician is consulted, the clinic visit terminated, the person referred for immediate medical care, and a return visit to complete missed procedures and interviews is scheduled as appropriate. Persons with elevated blood pressures less than 210/120 mm Hg are referred to their source of medical care at the Medical Data Review following the guidelines shown in Table 4.2. Likewise, observations of an ECG abnormality identified as major in Table 5.1 are reviewed by an ARIC physician on call before the participant leaves the field center.

When clinically relevant laboratory data processed at the study's central agencies (laboratories and reading centers) have been received at the field centers, the data are again reviewed prior to producing summary reports for participants and their physicians. As part of this review, ARIC clinical personnel again may recommend follow-up if symptoms/conditions appear to warrant further medical attention.

At the field center, participants' clinically relevant Visit 4 data are reviewed at three levels. The first review takes place during the Medical Data Review (see below, section 4.3), which is conducted after all interviews and physical exams have been completed and data have been assembled as part of the Data Inventory step (section 3.11). The second and third levels of medical data review take place after data processed at the study's central agencies (Dental Study Laboratory, ECG Reading Center, Hemostasis Laboratory, Lipid Laboratory, and Ultrasound Reading Center) are returned to the field centers and are reviewed the study clinicians (Chapter 6, Physician Review) and summarized for inclusion in the final results reports (Chapter 7, Results Reporting) that are mailed to participants and their providers of medical care.

4.2 Data Inventory

The data inventory step initiates the last fixed component of the field center examination sequence (Table 2.3), and is done after all interviews and examination procedures have been completed in preparation for the Medical Data Review. Participant data are collected by various means during the course of Visit 4 and require summarization and placement in the participant's folder for nurse/clinician review.

4.2.1 Rationale

Although the ARIC study does not diagnose or treat any medical condition, the participant's safety is of paramount concern. Therefore, data collected during the examination that could indicate the need for immediate (same day), urgent (within one week) or routine (within one to two months or first convenient appointment) referral for medical care (Table 5.1) are put together into one document, the Medical Data Review Printout (Appendix 4.a), and reviewed with the participant prior to the completion of the examination. (Note: data required for emergent referrals are compiled as soon as the condition is observed, e.g., blood pressures in the range of very severe hypertension as listed in Table 4.1 and 4.2). Data inventory is the data management process by which the Medical Data Review Printout is produced.

4.2.2 Procedures

A staff person reviews the participant itinerary sheets to determine that all interviews and procedures have been completed, participants' folders to verify they contain the paper versions of the forms to be completed by ARIC staff, and participants' self-administered forms to determine completeness and whether assistance is required/requested. After completeness of examination and quality control procedures have been confirmed, participants are invited to change back into street clothes while the data are being prepared for the medical data review.

4.2.3 Training

At each field center the Data Coordinator and/or the Study Coordinator is responsible for training the personnel charged with data inventory, and the assembly of study materials for the Medical Data Review.

4.2.4 Certification

Certification for data inventory is the responsibility of the field center Data Coordinator at the beginning of Visit 4. No recertification is required, but staff performance is monitored by the study coordinator.

4.2.5 Quality Assurance

Quality assurance consists of observation by the supervisor and retraining or corrective action, as required.

4.2.6 Data Collection

Please refer to the Manual of Operations for Data Coordinators.

4.3 Procedures

Trained staff conducts the medical data review to

(1) summarize the results of selected measurements obtained during the exams/interviews,

(2) determine whether a reported stroke/TIA symptom(s) constitutes a possible cerebrovascular event(s),

(3) identify potential medical problems,

(4) answer participant questions.

Prior to the Visit 4 Medical Data Review, the participant's data are reviewed for positive findings during Visit 3 (i.e., alert values and referral letters), positive findings during any of the Annual Follow-up interviews

between Visit 3 and Visit 4 (such as positive Rose Angina, cardiac procedures or hospitalizations), or comments on the participant's current itinerary form made by interviewers or technicians. Visit 4 data from the following sources are then reviewed from the participant folder and the Medical Data printout (Appendix 4.a) with the participant:

1. Blood Pressure
   a. Historical data annotated on Itinerary Form and PIN;
   b. Abnormal values from previous exams on Alert/Referral Log;
   c. Current values on clinic visit report, prepared by DES;
   d. Use of antihypertensive medications;
   e. Physician diagnosis of hypertension reported by participant and date of most recent medical care.

2. Electrocardiogram
   a. Historical tracings filed in participant folders;
   b. Abnormal values from previous exams on Alert/Referral Log;
   c. Current tracing filed in participant's folder;
   d. ECG interpretation printed on tracing (optional by field center);
   e. Preliminary reading written on Clinic Visit Report.

3. Physician Diagnosed Medical Problems Reported by Participant
   a. Physician diagnosis of diabetes;
   b. Physician diagnosis of high cholesterol;
   c. Physician diagnosis of cancer.

4. Participant Reported Medical Conditions Consistent with:
   a. Uterine bleeding not associated with normal menstruation or hormone replacement therapy on Reproductive History form;
   b. Rose Questionnaire Angina on AFU or Health History forms;
   c. Physician diagnosed Stroke/TIA or symptoms consistent with TIA or stroke reported on TIA/Stroke form;
   d. Intermittent claudication reported on AFU form.

5. Invasive Cardiovascular Procedures
   a. Coronary bypass or other heart procedures on Health History form;
   b. Carotid endarterectomy or other arterial re-vascularization on Health History form;
   c. Balloon angioplasty at any site on Health History form.

6. Cardiac Diagnostic Procedures
   a. Echocardiogram on Health History form;
   b. ECG on Health History form;
   c. Treadmill or cardiac stress test on Health History form;
   d. Carotid artery ultrasound on Health History form;
   e. MRI of the brain on Health History form;
   f. CAT scan of the brain on Health History form.

7. Weight/height
   a. Historical data annotated on Itinerary Form and PIN;
   b. Current weight from Anthropometry form.
   c. Current height from Anthropometry form.

8. Demographics
   a. Date of birth and age from UPD form;
   b. Name/source of medical care from UPD form.

Responses to item 4 (uterine bleeding) of the Female Reproductive History form are followed-up as part of the Medical Data Review. If the response to Item 4 is either I, O, or D, the participant is asked if she has seen a physician for this. If the answer is no, a referral should take place. If the bleeding has occurred during the 6 months preceding the clinic visit, the participant is

encouraged to see her physician within one month, as a consult for this bleeding. If the bleeding has not recurred in the six months preceding the clinic visit, the participant is encouraged to mention the uterine bleeding to her physician at the next convenient appointment.

When the letter to the physician reporting the participant's study results is prepared, it should include mention of uterine bleeding and the referral made at the time of the participant's clinic visit.

Access to data from previous examinations (Visits 1-3) by field center staff during Visit 4 is limited to two purposes: (1) to prepare the Visit 4 folder, and (2) to conduct the medical data review. Data from previous exams should not be accessed for other purposes during the course of the Visit 4 exam to avoid the possibility of biasing the collection of new data.

The data coordinator, or staff member designated by the study coordinator to prepare participant folders, should be the only person accessing Visit 1-3 information prior to Visit 4. During folder preparation, the chart is reviewed for any incidents and special participant needs that may have been recorded during previous visits, as well as factors that could affect participant and staff safety (infectious disease, syncopal episodes, etc.) The latter is the only information from previous exams to be brought to the attention of the entire staff and is noted on the Visit 4 Participant Itinerary Sheet. The person performing the medical data review, however, has access to all previous ARIC findings relevant to the medical review, immediately prior to discussing the participant's clinic visit report (Appendix 4).

If during the course of the Visit 4 examination a participant asks about changes in his/her laboratory values/clinical procedures since any of the previous exams, staff members defer the questions to the Medical Data Review. A prototype response by ARIC staff is: "I do not have access to the results from your previous exams, but if you hold your questions until the completion of your visit, Ms/Mr. _____ will answer them." During the Medical Data Review, an attempt is made to address all questions that may arise. Care must be taken not to over-emphasize changes between visits, because some differences may be random variability or measurement error and in order not to 'intervene' on the cohort. Changes may be pointed out, but health education recommendations, are to be avoided unless contained in the referral guidelines.

The following guidelines are used for explaining study results from Visit 4 or for recommending medical follow-up on the results reported in the clinic visit report during Medical Data review.

1. Changes in height and weight from previous exams should be focused on weight gained or lost, e.g., more than 10% since Visit 3; decrease in height of greater than 2 cm.

2. The blood pressure readings, based on the average of the first and second measurements, are recorded on the Report on Blood Pressure and Recommendations graph (Figure 4.1) and medical follow-up recommendations (Tables 4.1 and 4.2) are discussed with the participant. As these recommendations apply specifically to newly diagnosed hypertension, the following statement has been added to the graph: "the scheduling of follow-up should be modified by reliable information about past blood pressure measurements, other cardiovascular risk factors, or target-organ disease" (The Fifth Report of the Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure. Arch Intern Med:153;154-183,1993). Because of the clinical judgment required to operationalize the referral guidelines of individuals with a previous history of high blood pressure, other CVD risk factors, or target-organ disease, the ARIC referral guidelines (Figure 4.1), adapted from the

fifth Joint National Committee recommendations, are followed for all participants, unless the participant's physician has recommended otherwise.

3. Action on ECG findings depends on the severity of the findings. The previously unrecognized appearances of a major abnormality warrants consultation with the ARIC medical staff and possible referral. In contrast, a previously referred ECG abnormality that demonstrates no change in Visit 4 in an asymptomatic participant does not warrant repeat referral. This decision is made by the ARIC physician who reviews the ECG tracings on a weekly basis.

4. It is unlikely that participants will ask about changes in other factors. However, these should also be considered in the context of measurement variability before labelling them real changes.

Table 4.1 Joint National Committee on Detection, Evaluation and Treatment of High Blood Pressure (JNC V): Blood Pressure Classifications for Adults Aged 18 and Older, Not Taking Antihypertensive Drugs

Category	Systolic (mm Hg)	Diastolic (mm Hg)
Normal	< 130	< 85
High normal	130-139	85-89
Hypertension		
Stage 1 (mild)	140-159	90-99
Stage 2 (moderate)	160-179	100-109
Stage 3 (severe)	180-209	110-119
Stage 4 (very severe)	≥ 210	≥ 120

Table 4.2. Medical Care Referral Guidelines for Blood Pressure, Based on Joint National Committee on Detection, Evaluation and Treatment of High Blood Pressure (JNC-V, 1993) Guidelines

Referral Classification	Examination Findings	Recommendation to Participant[1]	Explanation to Participant
Emergency Referral	SBP ≥ 260 or DBP ≥ 130	Transportation to emergency care facility. Stop exam and reschedule clinic visit.	Your BP is very high.
Immediate Referral	SBP 210-259 or DBP 120-129	Consult with ARIC MD. Refer to source of care immediately (today). Stop exam and reschedule clinic visit.	Your BP is very high.
Urgent Referral	SBP 180-209 or DBP 110-119	Consult with ARIC MD and proceed unless otherwise indicated. Refer to source of care within 1 week.	Your BP is high.
Routine Referral	SBP 160-179 or DBP 100-109 SBP 140-159 or DBP 90-99	Refer to source of care within 1 month. Refer to source of care within 2 month.	Your BP is elevated. Your BP is elevated.
No Referral	SBP 130-139 or DBP 85-89 SBP < 130[2] or DBP < 85[2]	Recheck in 1 year (no ARIC referral) Recheck in 2 years (no ARIC referral)	Your BP is high normal. Your BP is normal.

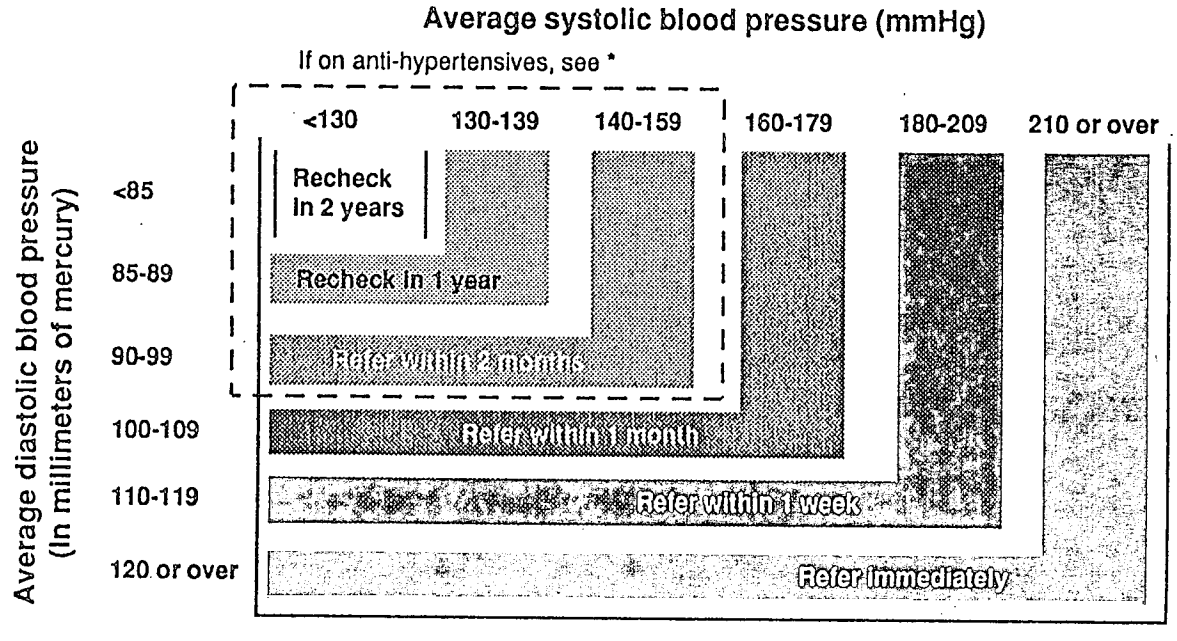
[1] If the systolic and diastolic categories are different, follow recommendations for the shorter time follow-up (e.g., 160/85 mm Hg should be evaluated or referred to source of care within 1 month).
[2] Unusually low readings should be evaluated for clinical significance.

Report on Your Blood Pressure and Follow-up Recommendations

(Based on the Fifth Report of the Joint National Committee on Detection, Evaluation, and treatment of High Blood Pressure)

Name:_____ Your blood pressure is:_____/_____ mmHg

Please follow the recommendation panel highlighted for you. Health Care Provider:_____



* If the participant is on anti-hypertensive treatment and blood pressures are in the range identified by the interrupted line, follow the schedule recommended by the participant's physician.

Appointment needed: Yes____ No____ Staff ID:_____

Appointment scheduled: _____ _____ Date: _____/_____/_____
(date) (time)

Figure 4.1 Report on Your Blood Pressure and Follow-up Recommendations

During the Medical Data Review, selected affirmative answers to the standardized questions in the interviews and exams are confirmed through additional, non-standardized, clinically-oriented questions. As part of the data inventory process, participant's responses to selected items with potential medical care impact or participant safety implications are printed by the networked DES on the Medical Data printout for ease of review before the Medical Data Review. The back-up procedure in case of computer failure or incomplete data collection is to identify such items on the paper forms. Relevant alert values and referral guidelines are listed in Chapter 5.1.

Symptoms of TIA or stroke which are reported to have occurred within the six months prior to the interview which appear to be cerebrovascular in nature are discussed with the field center medical director for recommendations on referral for medical care. A TIA/Stroke Worksheet is available to document (1) the presence of a noncerebrovascular cause which explains the symptom, (2) the impression as to whether the symptoms are indicative of a TIA or stroke since Visit 3, and (3) the most recent date of the putative event.

In summary, factual information (ARIC Clinic Visit 4 Report, Appendix 4.b) is given to participants about their results during the Medical Data Review, identifying abnormalities and recommending referral as needed, but avoiding medical advice about prognosis, prevention or therapy. Physician back-up is available at all times.

4.4 Training

Staff are trained for the Medical Data Review tasks by the ARIC medical director and/or field center principal investigator.

4.5 Certification

The local trainer is responsible for certification of the physician assistants, and nurse practitioners/clinicians responsible for medical data review.

4.6 Quality Assurance

The medical director of each ARIC field center is responsible for ensuring that the medical data review, referrals and reporting of results are done according to procedures in the ARIC protocol.

4.7 Data Collection

The study data generated during the Medical Data Review include confirmation of positive symptoms identified on the TIA/Stroke Form, and occasionally critically important notes. These data are stored as hard copy in the participant's folder, and referrals are coded on the Report/Referral Form (Appendix 5.c).

5.0 REFERRALS AND REVIEW GUIDELINES

5.1 Rationale

Participants are referred based on the guidelines for referral listed below. Prior to the Medical Data Review, a DES utility retrieves affirmative responses to key items indicative of hypertension, diabetes, ischemic heart disease, hypercholes-terolemia, cancer, uterine bleeding, chest pain on effort, congestive heart failure, TIA/stroke, and intermittent claudication. Guidelines for conducting the medical data review are provided in the Medical Data Review instructions.

Referrals for initial care, as well as follow-up care, can be made at the Medical Data Review or in subsequent communications. Uniform criteria for emergency, immediate, urgent and routine referrals have been established for use at all ARIC field centers, Section 5.1.2, and are summarized in Tables 4.2 and 5.1. Sources of medical care for participants who do not have a physician are identified by each field center in consultation with the representatives of the local medical community. All referrals are documented on a separate Report/Referral Form and the ARIC Alert/Referral Log, Appendices 5.c and 5.d, respectively.

5.2 Procedures

Referrals are made during the Medical Data Review or upon receipt of the study's clinically relevant data which follow the criteria listed below.

1. Emergency Referral. Transportation to the nearest emergency care facility is provided or an emergency squad is called.

2. Immediate Referral. The participant is urged to see his/her physician within one day.

   The nurse/clinician consults with the ARIC physician, and the participant's physician is called. The participant's physician is also sent a letter of explanation (Appendix 6.a)

3. Urgent Referral. The participant is asked to see his/her physician within one week.

   The nurse/clinician confirms the decision with the ARIC physician, and explains the reason(s) for an urgent referral to the participant. This usually occurs during the Medical Data Review, but can occur when alert values are returned to the field center from a central agency. The ARIC physician calls the participant's provider of care, and sends a referral letter. (Appendix 6.a and 6.b). Follow-up letters are also sent to the participant (Appendix 6.c,6.d).

4. Routine Referral. The participant is asked to see his/her physician within one month, or at the first convenient appointment.

   The nurse/clinician advises a visit to the participant's physician. A referral letter is sent to the participant (Appendix 7.e-h) and his/her physician (Appendix 7.b or 7.c) as a cover letter for the final results report.

5. No Referral. The study results are summarized for the participant and held for a routine results letter which are sent as cover letters for the final results report (Appendix 7.d).

Procedure/symptom specific guidelines are summarized in Table 5.1. Certain interview items or measurements (identified with an asterisk) require confirmation from additional questions during the Medical Data Review.

Referral guidelines for blood pressure differ based on a prior history of an elevated blood pressure during previous examinations. The reviewer determines the acuteness of the findings, and whether or not the condition is being monitored by the participant's physician. If the participant is aware of and being followed medically for a condition, judgement is exercised about whether to refer, and the degree of urgency. The types of participant and physician referral and normal results letters used for each of the five referral categories are summarized in Table 7.2; examples of the texts of these letters are provided in Appendices 6 and 7.

Table 5.1 Medical Care Referral Guidelines.

Referral Classification	Examination Findings	Recommendation to Participant	Explanation to Participant
IMMEDIATE REFERRAL	*SBP ≥ 210 mm Hg or DBP ≥ 120 mm Hg	See M.D. today.	BP very high.
	*Unstable angina	"	Your chest pains may be important
	*Neurologic symptoms in past week	"	Your symptoms may be important.
	*Other severe symptoms or findings	"	Your symptoms may be important.
URGENT REFERRAL	*Angina, stable but untreated/not being followed	See M.D. within a week.	Your chest pains may be important
	*Neurologic symptoms, untreated, one week to six months ago	"	Your symptoms may be important.
	*Acute congestive heart failure	"	Your symptoms may be important.
	*Other acute, but less severe symptoms	"	Your symptoms may be important.
	*SBP ≥ 180-209 mm Hg or *DBP ≥ 110-119 mm Hg	"	BP high.
ROUTINE REFERRAL	*Old MI (Rose Questionnaire), previously unrecognized	See M.D. within month or at first convenient appointment.	Your chest pain may be important.
	*Neurologic problem (stroke, TIA exam findings) >6 months ago, unrecognized	"	Your symptoms may be important.
	*Claudication, previously unrecognized	"	Your leg pain may be important.
	*Other symptoms or findings needing evaluation/not being followed	"	Your symptoms may be important.
	*Uterine bleeding; response I,O,D on Reproductive Hx form.	"	Your symptoms may be important.

* Interview items/measurements require confirmation during Medical Data Review

Table 5.1 Medical Care Referral Guidelines, continued

Referral Classification	Examination Findings	Recommendation to Participant	Explanation to Participant
ROUTINE REFERRAL	*SBP 160-179 mm Hg or DBP 100-109 mm Hg	See MD within one month.	BP elevated.
	*SBP 140-159 mm Hg or DBP 90-99 mm Hg	See MD within two months.	BP elevated.
NO REFERRAL	*Angina, stable on treatment/being followed	None.	Confirm only.
	*MI, previously documented	None.	Confirm only.
	*SBP 130-139 mm HG or DBP 85-89 mm Hg	Recheck in 1 year	Your reading is high normal.
	*SBP $\leq$ 140 mm Hg and DBP $\leq$ 90 mm Hg	Recheck in 2 years	Your reading was normal.
	Height, weight	None.	Report only.
ECG Findings Requiring Review by M.D. Before Participant leaves Field Center.	Acute pattern abnormalities MI, ischemia...)*	Per review by MD.	Would like to review with M.D.
	Any other ECG finding, alone or in conjunction with symptoms, causing concern.*		
Other ECG Findings or Normal ECG			A copy of the ECG will be sent to your physician with the other results.

* Interview items/measurements require confirmation during Medical Data Review

[1] 2nd or 3rd degree block, ventricular tachycardia, R on T, atrial fib/flutter with ventricular rate < 60 or > 110, sinus bradycardia < 50, sinus tachycardia > 110, PR interval > 0.26 sec.

6.0 PHYSICIAN REVIEWS

6.1 General Policies

The second level of medical data review is a review of the participant's data within one week of the visit by the field center medical staff. This procedure includes the information initially reviewed during the Medical Data Review; optional hematology results received from local laboratories; clinical chemistry, hemostasis or lipid alert values reported by telephone or electronic mail from one or more of the central laboratories; and ultrasound alert values if the URC ultrasound clinician has confirmed a finding meeting the criteria of an alert criteria.

This general medical review provides a medical staff interpretation of the study results and an overview of referrals and reports from the field center.

6.2 Procedures

The physician review is an ongoing activity at the field center. Once a week a physician reviews the data of participants seen in the preceding week. After examination of the participant's medical data review printout and ECG, the physician records the interpretation on the Medical Data Review printout and reviews the preliminary interpretation by the nurse/clinician. The physician also confirms the optional hematology results for alert values, and assumes responsibility for any referrals. Any referrals made during Medical Data Review are reviewed at this time.

7.0 RESULTS REPORTING

This activity concludes a process which extends over 4 to 8 weeks after the participant completes Visit 4. When all study results are received from the central laboratories, reading centers, and the Coordinating Center, they are summarized for final disposition by field center medical staff. Final summaries of study results are compiled, according to the criteria in section 5.1.2, and mailed to participants and physicians.

As alert values are returned from the central laboratories and reading centers, the medical staff reviews them and assumes responsibility for referrals (see Table 5.1). Routine results may bypass physician review until the final report is generated. The ARIC physician or clinic director reviews all letters and reports sent to participants and their physicians.

With participant approval, normal and abnormal results of the clinically relevant medical tests are reported to the participant's physician. Clinically relevant medical tests are differentiated from those with strictly research value as being of empirical value for diagnosis and/or treatment. Whenever the therapeutic implications of results are not known, a statement to that effect is included in the report to the physician. Copies of all reports and letters concerning examination results sent to participants and physicians are kept on file at the field center.

Reporting of Visit 4 values is made in the context of Visit 3 results. The alert values listed in Table 7.1 are reported with recommendations for medical follow-up. When a value is outside of the reference-range listed in Table 7.1, but falls in a "gray zone" (marginally outside of the reference range, but probably not clinically relevant) or is similar or identical to one that resulted in a referral at Visit 3 (an ECG for example), a referral in Visit 4 is not automatic and is only initiated at the discretion of the medical director. A copy of the abnormal study result, however, is included in the summary of results sent to the participant and his/her medical care provider.

All reports to participants or physicians are factual. If verification or follow-up is needed, the participant is advised to discuss the results with the provider of medical care. ARIC study personnel provide no specific medical advice or interpretation of results. This type of medical practice is felt to be the prerogative and responsibility of the participant's physician. Consistent with this policy, clear instructions are given to all ARIC staff to avoid interpreting study results.

Table 7.1 Laboratory Alert, and Normal Reference Values

Chemistries	Reference Ranges for ARIC Labs**	Gray Zone	Significant Range	Alert Values*
total cholesterol	<200 Desirable 200-239 mildly elevated ≥ 240 markedly elevated	200-204	205-244 ≥ 245	none
LDL	< 130	130-133	≥ 134	none
HDL	> 35	34-35	≤ 33	none
TG	< 220	220-223	224-1000	> 1000
creatinine	< 1.5 men < 1.4 women	none	1.5-2.5 1.4-2.5	> 2.5
fasting glucose	70-130	none	60-69 131-200	< 60 > 200
2 hour glucose	70-139	none	60-69 140-300	< 60 > 300

* Laboratory notifies field center; field center MD takes referral or notification action.

** Reference ranges are provided on ARIC reports to participant and their physician.

Even though ARIC is an observational study, the recommendation to participants for additional tests and procedures to be performed by participant's physician as a result of ARIC reporting is considered an acceptable and necessary consequence of study participation.

7.1 Overview of Results Reporting

Figure 7.1 (ARIC Referral/Notification Procedures) provides an overview of this process and illustrates the interface between the review of medical data, the referral process, and the notification of study results. The figure also illustrates that certain results are reported on a routine basis, whereas potentially abnormal study results are reported to participants and their physicians on an expedited basis.

The reports to the participant and/or the physician provide a minimum, standard set of study results. Reports to participants include a statement indicating either that all study results are within ranges considered normal, or that a study result requires confirmation or further investigation. Normal ranges and brief explanatory statements are provided. Physicians receive a letter of explanation (Table 7.2 and Appendices 6 and 7) and a copy of the participant's results report, and are thus aware of any results flagged as being outside of the ARIC reference range, and the wording and explanations provided to their patients.

The following is a review of results reporting procedures.

1. At reception, the Schedule of ARIC Results Reporting (Appendix 5.b) is reviewed with (and at local option, given to) the participant to describe the tests to be reported to the participant and the physician, and their timing.

2. At Medical Data Review, a Participant Medical Data Review Printout is generated summarizing findings for the Medical Data Review. Items flagged for review are automatically retrieved from the data base and printed on this form. The nurse/clinician conducts the Medical Data Review with the participant, as described in section 4.1. A pre-printed Summary of Visit 4 Report (Appendix 4.b) is filled in during the Medical Data Review and given to the participant to summarize the exam results which do not require processing by a central laboratory or reading center.

3. At the Medical Data Review, a referral may be necessary. Three levels of referral are designated: Immediate (same day), Urgent (within one week), Routine (within one to two months, depending on study guidelines), and the corresponding referral letters are sent to the participant's physician (Appendix 6). (Emergent referrals are made as soon as the condition is observed and are generally not held until the Medical Data Review). For immediate or urgent referrals, a phone call to the participant's provider of medical care may be made to facilitate the referral recommendation given to the participant.

4. Once a week, a physician review occurs during which the ARIC physician reviews participant data and interprets ECG tracings, as described in section 6.1.2. If an abnormality is detected at this time, a report or referral letter is sent to the participant and his/her physician (Appendix 7).

5. The central laboratories and reading centers send the field centers the clinically relevant study results 4-12 weeks after each participant's Visit 4 exam. If there are "alert values", the participant is notified using an Alert Value Referral Letter (Appendix 7.e and f) and the medical care provider is notified (Appendix 7.b and c). If there are no "alert values", normal results reports and cover letters indicating no

abnormal findings are sent to participants and their physicians if requested.

6. When all results are available, the Summary Report to the Participant and Physician and accompanying cover letters are generated. The types of cover letters are summarized in Table 7.2 and prototype letters are found in Appendix 7.

7. The field center director or a field center physician reviews all results and takes responsibility for letters before they are mailed. If the ARIC participant is also a participant in another medical research project, possible unblinding by reporting ARIC results is considered.

8. A record is kept of all alert values and referrals on the Report and Referral (REFB) form (Appendix 5.c) and on the Alert/Referral Log (Appendix 5.d) Copies of all referral letters and results reports are filed in participant folders.

Figure 7.1 ARIC Referral/Notification Procedures

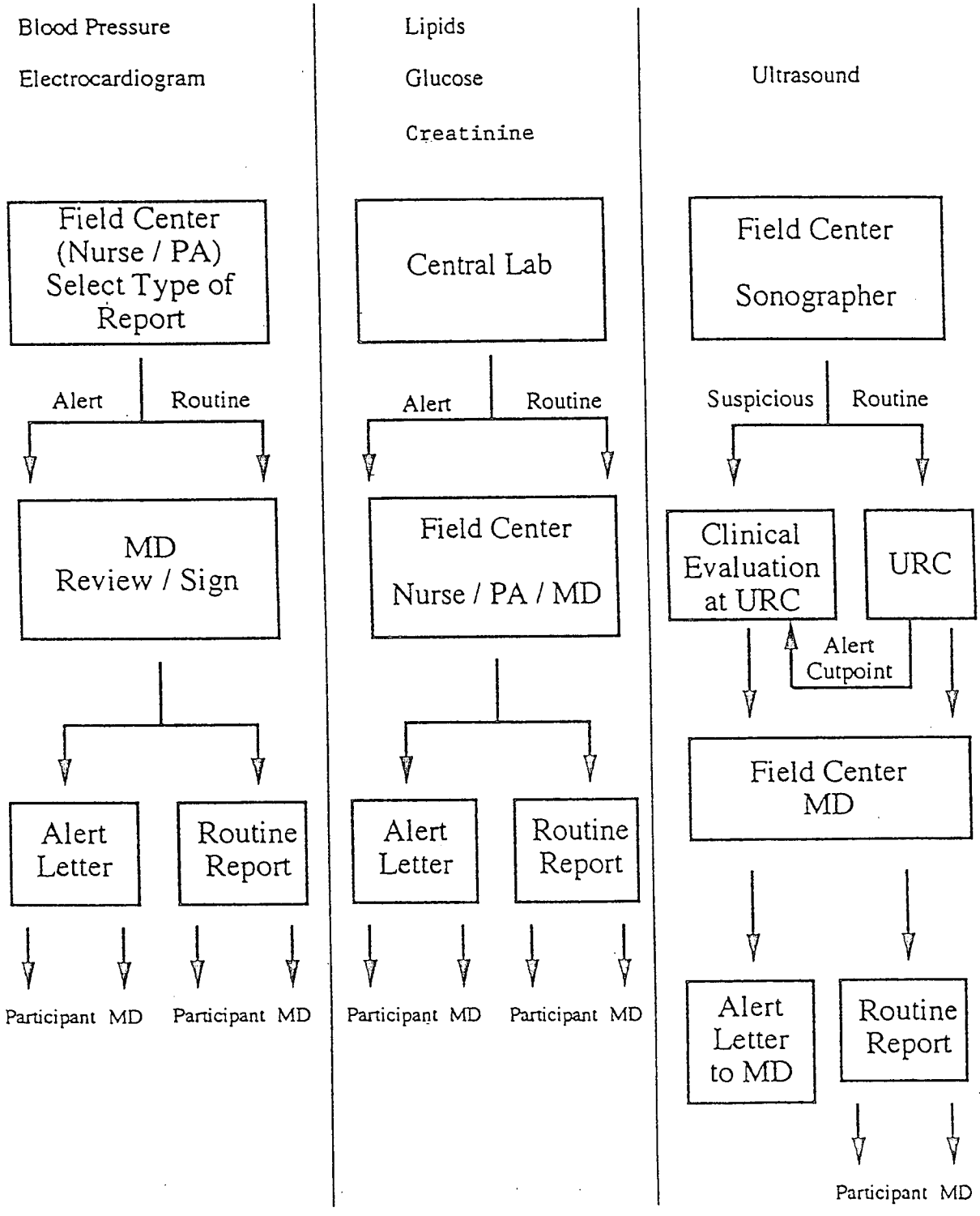


Table 7.2 Cover Letters for the Reports to Participants and Physicians

RECIPIENT	TYPE OF COVER LETTER FOR RESULTS REPORTS
	REFERRAL LETTERS FOR ALERT VALUES
Physician	a) referral post clinic visit
Participant	a) referral at clinic visit (N/A) b) referral post clinic visit (w/ MD) c) referral post clinic visit (no MD)
	COVER LETTERS FOR SUMMARY Visit 4 RESULTS REPORT
Physician	a) Normal results b) Abnormal results, no previous referral made c) Abnormal results, previous referral made
Participant a)	Normal results b) Abnormal results, no previous referral made c) Abnormal results, previous referral made d) Normal results, no MD designated e) Abnormal results, no MD designated
INSURANC.LTR	Study results sent to third party

7.2 Report of Ultrasound B-Mode Scan Measurements

The ARIC ultrasound examination is oriented toward the detection of early atherosclerotic changes in the arterial wall and does not provide clinical documentation of the extent of lesions which might be of medical importance. Portions of the internal carotid artery, which may have disease, are not visualized at all. Some of the early arterial changes documented for ARIC and non-lumen encroaching wall thickness are not, at present, of known medical value and are of research interest only. Such results are not routinely reported to the participant and his/her physician. In the process of obtaining consent, the participant is informed of this fact. Neither the ARIC ultrasound examination protocol, nor the training of the ARIC sonographers, provide an adequate capability to detect clinically significant arterial lesions in the study participants. If in the course of the highly standardized ultrasound scanning procedures a lesion(s) is found of potential clinical importance, the ARIC sonographer sends the study to the URC for expedited review by an expert neurologist. If a minimum residual lumen of 2 mm or less is present, and/or if in the opinion of the neurologist an ultrasound scan according to a clinical protocol is indicated, this is communicated to the field center as an alert value.

If during the reading process at the Ultrasound Reading Center an arterial wall thickness of 2 mm or more is found, the study is forwarded to the neurologist for evaluation. If a referral is recommended, field centers are notified to contact the study participant and their provider of medical care a letter signed by the medical director (Appendix 7.a-c). Records of this notification are kept at the Reading Center and the field center. The Ultrasound Reading Center's clinical expert reviews all studies identified in this manner, suspected to contain an alert value.

The medical and ultrasound experts of the ARIC Study agree that the alert value cutpoints criteria are consistent with local medical practice for each of the ARIC study communities. It is an explicit requirement of the participant safety criteria of the ARIC Study that this section of the protocol be reviewed periodically, and modified as needed according to advances in the state of the science and evolving medical practice.

7.3 Routine Notification of Study Results

Results of routine medical examinations, normal or abnormal, are reported to the participant and his/her physician, unless the participant has not identified a personal physician or has specifically asked to receive all study results. (Refer to Appendix 7 for prototype letters.) This is explained to the participant during the visit to the ARIC field center, and the participant is provided a schedule for results reporting.

7.3.1 Results routinely reported to the participant

Results reported to the participant during the clinic visit (ARIC CLINIC Visit 4 REPORT, Appendix 4.b) include current weight and weight at the previous examinations, current height and height at Visit 1 and 3, current blood pressure and blood pressure measurements from the previous examinations, a statement that the ECG tracing will be read for inclusion in the summary report, and a statement that only abnormalities on the carotid artery scan will be reported.

Within three months after Visit 4, the SUMMARY OF ARIC Visit 4 RESULTS FOR PARTICIPANTS AND THEIR PHYSICIANS (Appendix 5.a) is mailed to the participant. This report includes the following confirmed study results from Visit 4: weight and height; blood pressure; summary report of electrocardiogram; summary report of echocardiogram (Jackson participants); summary report of the retinal photograph of one eye for participants in the repeatability study at the beginning of Visit 4; B-scan ultrasound exam of the carotid arteries, and

blood tests (total, LDL and HDL- cholesterol values, triglycerides, creatinine, fasting glucose, and a 2 hour glucose for OGTT participants).

7.3.2 Results routinely reported to the physician

Participants' physicians receive a copy of the reports sent to their patients. In addition, physicians are notified of any important symptoms reported by the participant and they are provided with the participant's electrocardiogram.

7.3.3 Results Reported Only by Request

All other study measurements, i.e., those not routinely reported to participants and/or their physicians, are considered to be of research value only. If a participant requests them, these values are provided on an ad hoc basis.

On the rare occasion that a field center receives a request for a participant's study results from a third party medical care payor, a results report can be released according to the following steps.

1. A signed statement from the participant authorizing the release of ARIC study data to anyone other than the participant or his/her identified provider of medical care is required prior to the release of study data by the ARIC study. A copy of the request and the authorization for release of study data is kept in the participant's folder.

2. The report contains only the information that was released to the participant's physician (or the participant), i.e., an exact copy of the cover letter, the results report and the ECG tracing.

3. This information is sent with a cover letter (Appendix 7.i) from the field center's medical director stating that the ARIC study does not provide diagnostic services or treatment.

4. The information is sent directly to the third party with an exact copy to the study participant, indicating the date on which the information was sent.

7.3.4 Study Results Requiring Special Notification

The ARIC protocol identifies certain potentially abnormal findings that require expedited notification to the participant or his/her physician. These include flagged responses to the medical history questionnaire. These items, and the corresponding referral and notification criteria, are described in section 7.1. Similarly, "alert value" levels have been defined for the functional tests and laboratory measurements.

Laboratory and ultrasound results are not available at the time of the clinic visit. Local (and optional) hematology results are reviewed at the Field Center for alert values within several days of the clinic examination. Notification in response to an alert value in hematology results occurs after review of the participant's record. The central laboratory,the Ultrasound Reading Center, and the Fundus Photograph Reading Center notify field centers directly of "alert values". Notification of alert values to field centers is by telephone, electronic mail or FAX; confirmation and acknowledgment is required. The laboratory alert values are in Table 7.2.

8.0 PARTICIPANT SAFETY

The safety and welfare of the ARIC participants is protected by

(1) specific measures taken in the design or conduct of the examination for their safety;

(2) the mechanisms established for handling potential emergencies;

(3) routine notification of participants and their physicians regarding the results of the examination, and

(4) the procedures ARIC staff use to review all potentially medically important results and make the appropriate referrals.

An important factor in participants' welfare involves their expectations regarding the examination. If they believe the ARIC examination is a substitute for a clinical examination, delay in seeking needed medical care could occur. Therefore, the provision of adequate information is a requisite to the ARIC informed consent procedures (described in section 2.11).

8.1 Measures to Protect the Participant

Examination procedures which convey potential risk to participants include the fasting requirement, venipuncture, and measurement of postural changes in blood pressure. Methods by which participant risk is minimized (more fully described elsewhere in ARIC Manuals) include the following.

The possibility of hypoglycemia with a 12-hour fast is diminished by routine inquiry about reasons which should exempt the participant from fasting during the scheduling of Visit 4. Other medical conditions or dietary restrictions which may be incompatible with the snack provided in the clinic are also ascertained.

Hematomas or prolonged bleeding may result from venipuncture. These are usually avoided if well-trained technicians follow the procedures for blood drawing and take the precautions described in ARIC Manual 7. Prior to venipuncture, the participant is asked the question "Do you have any bleeding disorders?" If the participant answers affirmatively or is uncertain, he/she is asked about whether he/she has had blood drawn previously and if so, whether there were any problems such as swelling or continuing to bleed at the venipuncture site. If the answer to this question is "yes", the clinic supervisor is summoned to approve the venipuncture. Occasionally, with any participant, bleeding persists after venipuncture. Procedures described in Manual 7 are followed. If the measures taken have not stopped all bleeding within 30 minutes, and there is no obvious explanation for the prolonged bleeding, a medical referral is made. Also, the participant is instructed to seek medical care promptly if bleeding recurs after leaving the ARIC clinic.

Participants may experience syncope during the venipuncture. Methods for handling major and minor emergencies are described in sections 8.3.1. and 8.3.2, respectively.

The ARIC ultrasound exam involves no more ultrasound exposure than is usually the case when examining superficial arteries clinically. See ARIC Manual 6 for details. The American Institute for Ultrasound in Medicine has issued the following statement concerning the safety of ultrasound.

Safety Statement for Training and Research

> Diagnostic ultrasound has been in use for over 25 years. No confirmed adverse biological effects on patients resulting from this usage have ever been reported. Although no hazard has been identified that would preclude the prudent and conservative use of diagnostic ultrasound in education and research, experience from normal diagnostic practice may or may not be relevant to extended exposure times and altered exposure conditions. It is therefore considered appropriate to make the following recommendations: In those special situations in which examinations are to be carried out for purposes other than direct medical benefit to the individual being examined, the subject should be informed of the anticipated exposure conditions, and of how these compare with conditions for normal diagnostic practice.

Following the 45 minute ultrasound examination, the participant is asked to sit and then stand so that postural changes in blood pressure and pulse rate can be measured. These procedures are described in ARIC Manual 6.A (Ultrasound Scanning). The precautions against adverse effects of orthostatism are summarized here.

Before beginning, the procedures for measuring postural changes are explained to the participant. The participant is asked whether or not he or she ever feels faint on standing. If the question is answered in the affirmative, permission to make the measurement (postural change) is still sought. Should the person decline, the procedure is not performed. In the absence of a reason not to continue, however, the participant is asked if he or she is taking medications that produce light-headedness when standing (postural effects). When the postural changes are measured, the sonographer is positioned closely behind the person as a protective measure should he or she become faint. A sturdy chair is positioned close at hand so that the participant may sit down promptly should s/he feel the need. Furthermore, examinees are advised to notify staff immediately if not feeling well and to ask for the chair. Clinic staff are instructed to watch the participant for signs of distress. In the event that the participant faints, the procedures described below in Section 8.3.2 and in Manual 11 are followed.

8.2 Stopping Rules for Interviews and Procedures

Participant safety and comfort during the clinical examination are monitored throughout the clinic visit. Interviewers and technicians observe participants for signs of fatigue or physical and/or emotional discomfort. When any one of these conditions are observed, participants are offered the opportunity to discontinue the interview or procedure, and are given an opportunity to rest before being taken to the next work station. Persons incapable of completing all of the clinical exam are invited to change back into their street clothes and participate in the medical data review and reschedule the clinic exam on another day.

For persons with conditions which require emergency and immediate referrals, such as cardiac events, unstable angina, ECGs with acute pattern abnormalities or blood pressures $\geq$ 210/120 mm Hg (See Tables 4.2 and 5.1), the ARIC physician is consulted immediately, the clinic exam is terminated as soon as the condition is observed, and another appointment for Visit 4 rescheduled as appropriate. For blood pressures requiring referral within one week (SBP 180-209 mm Hg or DBP 110-119 mm Hg; the urgent referral category in Table 4.2), the ARIC physician is also consulted, and the clinic exam is either continued and the participant advised to seek medical care within one week or the clinic exam is terminated and rescheduled, based on the physician's recommendation. The termination of any interview or procedure is documented on the participant itinerary sheet.

8.3 Methods for Handling Emergencies

While all life threatening emergencies (e.g., acute MI) require immediate evaluation of the participant at an acute care facility, some emergency measures may be required in the clinic before departure (e.g., cardiac arrest). In addition, there are minor emergencies (hypotension, fainting, etc.) which may require treatment in the clinic only. Although most emergencies are of the less severe nature, ARIC Field Center clinics are prepared for both types.

8.3.1 Major emergencies

In a serious event the primary concern of the clinic staff is to implement pre-established procedures to get the participant to the nearest medical facility. All ARIC clinics are located within a few city blocks of a large, general, acute-care hospital. A staff person with certification in basic life support is on duty and physically present at every clinic session. Needed life support procedures are continued until emergency care arrives or the participant is transported to a hospital. Each ARIC clinic, depending on its location and staffing patterns, has specific emergency procedures, which define:

1. Who is in charge during the emergency.

2. Who is to administer treatments.

3. Who is to be notified.

4. What action clinic staff is to take.

5. Which reports are to be filed.

Each clinic has, in addition to trained personnel and emergency equipment, posted in a conspicuous place (e.g., the reception area): phone number of police and fire stations; ambulance services; and specific phone numbers or codes to alert medical teams, if applicable.

In each participant's folder, the name and phone number of his/her physician or usual source of health care and the home and work telephone numbers of one or more contact persons are available on the UPD form. Each field center clinic is required to have on site at all times during which participants are interviewed and examined either a physician, a physician assistant or a registered nurse.

All emergency situations are coordinated by the staff person designated, a priori, or by a physician if present. Each center has a designated physician on duty for each clinic session. If not physically present in clinic, he or she is within immediate reach by phone or paging system and within a short distance to the clinic. The physician duty roster is posted with the clinic secretaries and in the office of the nurse/clinician so that the name of the responsible physician is readily accessible. However, in no case is emergency referral and/or care deferred while staff is attempting to locate a clinic doctor.

ARIC staff are trained to carry out their specific responsibility during an emergency. Retraining is the responsibility of each field center, following institutional guidelines.

All emergencies, whether serious or minor, are documented. This requires filling out an institutionally-approved form identifying the type of emergency. This is done by the person in charge at the time, and all reports are co-signed by a clinic physician and are filed at each clinic.

8.3.2 Minor emergencies

The most common minor emergency is simple syncope (fainting) and near syncope. These events may occur during the postural blood pressure measurements or venipuncture. Management of simple syncope or near syncope is the same whether associated with measuring postural blood pressure changes or drawing blood.

Many syncopal episodes can be prevented if clinic staff are alert to early signs. In any situation in which syncope is likely, e.g., after the venipuncture, staff verify that the participant does not look or feel faint. If the participant looks faint or feels faint in the venipuncture area:

1. Have the person remain in the chair and sit with head between the knees or recline if the appropriate chair is used at the field center.

2. Crush an ampule of smelling salts and wave it under the participant's nose for a few seconds;

3. Provide the participant with a basin and a towel if he/she feels nauseous;

4. Have the participant stay in the chair until he/she feels better and the color returns.

If the participant continues to feel sick, recline the chair, place a cold wet towel on the back of the person's neck, and notify the supervisor. If a participant faints, he/she is cautiously lowered to the supine position on the floor and one attendant immediately calls for an in-house nurse/clinician to assist the patient. The remaining attendant raises the patient's legs above the plane of the body to increase venous return. Prior to this, the staff member momentarily palpates for a carotid pulse and checks to be sure the subject is breathing. If life support measures are needed, the procedures outlined in section 8.2.1 are followed.

8.4 Emergency Equipment

A basic first aid kit is maintained at each Field Center. The kit contains a reference guide of its contents, and is checked every year and immediately after each use. At each Field Center the Study Coordinator identifies a person responsible for this task.

APPENDIX

Manual 2. Cohort Procedures Components

Appendix

Table of Contents

NAME: **Appendix 1.1** ID: CONTACT YEAR: 10

Number of Previous Ultrasound Scans: 1

PARTICIPANT TRACING INFORMATION SHEET

Address:

Sex: Race:

Date of birth:

State of birth:

Social Security No:

Home Phone:

Driver's License No:

Other Phone:

Driver's License State:

Nickname:

Administrative:

Maiden Name:

Date of Baseline Visit:

Final Status:

Date of Visit 3:

Date Determined:

Date of Visit 4:

Contact Person 1:

Contact Person 2:

Physician:

Employer:

Appendix 1.2

Name: ID: CONTACT YEAR: 10

ARIC ANNUAL FOLLOW-UP VERSION F
VERIFICATION OF TRACING INFORMATION (UPD updated by: _____)

CURRENT DATA ON FILE	CORRECTIONS/CHANGES TO DATA
Name:	Name: _____
Mailing Address:	Mailing Address: _____ _____ _____ _____
Home Phone:	Home Phone: (____) ____-____
Other Phone:	Other Phone: (____) ____-____

NAME: _____ ID: _____ Contact Year: __

ARIC ANNUAL FOLOW-UP
VERIFICAITON OF TRACING INFORMATION (UPD updated by: ____)

CURRENT DATA ON FILE:

Name: _____

Mailing address:

_____

_____

Home Phone: (___) ___-____

Other Phone: (___) ___-____

Two People Who Are Likely To Know Your Address At All Times:

(1)
Name: _____

Mailing address:

_____

_____

Home Phone: (___) ___-____

Relation: _____

(1)
Name: _____

Mailing address:

_____

_____

Home Phone: (___) ___-____

Relation: _____

CORRECTIONS\CHANGES TO DATA:

Name: _____

Mailing Address:

_____

_____

Home Phone: (___) ___-____

Other Phone: (___) ___-____

(2)
Name: _____

Mailing Address:

_____

_____

Home Phone: (___) ___-____

Relation: _____

(2)
Name: _____

Mailing Address:

_____

_____

Home Phone: (___) ___-____

Relation: _____

ARIC
2060 Beach Street
Winston-Salem, NC 27103
(919) 777-3040

ATHEROSCLEROSIS RISK IN COMMUNITIES STUDY

FORSYTH CO. N CAROLINA | JACKSON MISSISSIPPI | SUBURBAN MINNEAPOLIS MINNESOTA | WASHINGTON CO. MARYLAND

1-
2-
3-

Dear 4-

It has been almost one year since you were contacted by the National Institutes of Health study, the medical research project of the University of [ ] in which you are participating. As explained at your first examination, the ARIC Study maintains annual contacts to monitor the health of its participants.

In the next few days, an ARIC Study interviewer will telephone you to obtain some brief information about your health in the past year. It would be helpful if you could have ready for the interviewer information about any hospitalizations or illnesses you may have had in the past year. The interview will take about 10 minutes.

If you think it will be difficult for us to reach you in the next week, please telephone the ARIC Study office at ___ - ____ so that we can make special arrangements for your interview.

We thank you again for your assistance in this research project.

Sincerely,

[Principal Investigator]

ARIC COHORT ANNUAL FOLLOW-UP

ID: _____ CONTACT YEAR: ___ FORM CODE: TRC VERSION: F 01/30/96

NAME: _____

RECORD OF CALLS AND SCHEDULING				
Day of Week/ Date (mm/dd/yy)	Time	Notes and Clinic Visit Information	Result Code*	Int ID
S M T W T F S / /	A P			
S M T W T F S / /	A P			
S M T W T F S / /	A P			
S M T W T F S / /	A P			
S M T W T F S / /	A P			
S M T W T F S / /	A P			
S M T W T F S / /	A P			
S M T W T F S / /	A P			
S M T W T F S / /	A P			
S M T W T F S / /	A P			
S M T W T F S / /	A P			
S M T W T F S / /	A P			
S M T W T F S / /	A P			
S M T W T F S / /	A P			

Appendix 1.5b

ARIC COHORT ANNUAL FOLLOW-UP

ID: _____ CONTACT YEAR: ____ FORM CODE: TRC VERSION: F 01/30/96

NAME: _____

CONTACT YEAR (____) DATE RANGE
Earliest: __/__/__ Target: __/__/__ Latest: __/__/__

CY 10 APPOINTMENT:
_____ ___/___/___ __:__
Day Date Time

RECORD OF CALLS AND SCHEDULING					
Day of Week/ Date (mm/dd/yy)	Time	Notes and Clinic Visit Information	Result Code*	App't Code**	Int ID
S M T W T F S / /	A P				
S M T W T F S / /	A P				
S M T W T F S / /	A P				
S M T W T F S / /	A P				
S M T W T F S / /	A P				
S M T W T F S / /	A P				
S M T W T F S / /	A P				

ANNUAL FOLLOW-UP QUESTIONNAIRE (AFUF screen 14 of 14)

*RESULT CODES (CIRCLE THE FINAL SCREENING RESULT CODE) **(AFUF item 46)**

01-No Action Taken
02-Tracing (Not yet contacted any source)
03-Contacted, Interview Complete
04-Contacted, Interview Partially Complete or Rescheduled
05-Contacted, Interview Refused
06-Reported Alive, Will Continue to Attempt Contact This Year
07-Reported Alive, Contact Not Possible This Year
08-Reported Deceased
09-Unknown
98-Does Not Want Any Further AFU Contact

** APPOINTMENT CODES **(AFUF item 47)**

00 Appointment scheduled (record date, time, and special needs).
01 Clinic examination completed.
02a Appointment deferred (by clinic staff).
02b Appointment pending due to sickness or other concerns/ condition of the participant.
03 Moved outside of the study area, will be contacted annually for follow-up.
04 Re-scheduled many times, unlikely to complete appointment.
05a Appointment refused, permanently incapacitated.
05b Appointment refused, other reasons.
06 Refused clinic visit and does not want any further contact
07 Unable to locate.
08 Deceased.

48. Does participant still live within official ARIC study boundaries? ..... ☐

Yes (Y) No (N) Unknown (U)

O.M.B. 0925-0281
exp. 09/30/98

ARIC
herosclerosis Risk in Communities

ANNUAL FOLLOW-UP QUESTIONNAIRE FORM

A-7

ID NUMBER: | | | | | | | | CONTACT YEAR: | | | FORM CODE: A F U VERSION: F 01/30/96

LAST NAME: | | | | | | | | | | | | | INITIALS: | | .

Public reporting burden for this collection of information is estimated to average 8 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: **PHS Reports Clearance Officer, Rm. 737-F, Humphrey Building, 200 Independence Ave., SW, Washington, D.C. 20201, ATTN: PRA (0925-0281).** Do not return the completed form to this address.

INSTRUCTIONS: This form should be completed during the interview portion of the participant's annual follow-up. ID Number, Contact Year, and Name must be entered above. Whenever numerical responses are required, enter the number so that the last digit appears in the rightmost box. Enter leading zeros where necessary to fill all boxes. If a number is entered incorrectly, mark through the incorrect entry with an "X". Code the correct entry clearly above the incorrect entry. For "multiple choice" and "yes/no" type questions, circle the letter corresponding to the most appropriate response. If a letter is circled incorrectly, mark through it with an "X" and circle the correct response.

ANNUAL FOLLOW-UP QUESTIONNAIRE (AFUF screen 1 of 14)

A. VITAL STATUS

1. Date of status determination: ..... | | | / | | | / | | |
Month Day Year

2. Final Status:
{Circle one below}

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

Contacted and alive	C	Phone	A	Go to Item 6, Screen 2
		Personal Interview	B	
		Letter	C	Go to Item 30, Screen 7
Contacted & Refused	F			Go to Item 41, Screen 11
Reported alive	R	Relative, spouse, acquaintance	D	Go to Item 30, Screen 7
		Employer information	E	
		Other	F	
Reported Deceased	D	Relative, spouse, acquaintance	G	Continue to Item 4
		Surveillance	H	
		Other (National Death Index)	I	
Unknown	U			Go to Item 41, Screen 11

ANNUAL FOLLOW-UP QUESTIONNAIRE (AFUF screen 2 of 14)

B. DEATH INFORMATION

4. Date of death:

		/			/		

Month Day Year

5. Location of death:

a. City/County

b. State:

After Item 5, skip to Item 30, Screen 7

C. GENERAL HEALTH

6. Now I will ask you some questions about your health since we last spoke with you; that is, since we last contacted you on (mm/dd/yy) until today. During that time, compared to other people your age, would you say that your health has been excellent, good, fair or poor?

Excellent E

Good G

Fair F

Poor P

ANNUAL FOLLOW-UP QUESTIONNAIRE (AFUF screen 3 of 14)

D. CHEST PAIN ON EFFORT

7. Since we last contacted you, have you had any pain or discomfort in your chest?..... Yes Y

No N

Go to Item 20, Screen 5

8. Do you get it when you walk uphill or hurry? ..... Yes Y

Go to Item 17, Screen 5

No N

Never hurries or walks uphill H

9. Do you get it when you walk at an ordinary pace on the level? ..... Yes Y

No N

10. What do you do if you get it while you are walking?

Stop or slow down S

Carry on C

{Record "Stop or slow down" if subject carries on after taking nitroglycerin}

Go to Item 17, Screen 5

11. If you stand still, what happens to it? ..... Relieved R

Go to Item 17, Screen 5

Not relieved N

ANNUAL FOLLOW-UP QUESTIONNAIRE (AFUF screen 4 of 14)

12. How soon?..... 10 minutes or less L

Go to Item 17, Screen 5 — More than 10 minutes M

13. Will you tell me where it was? {Record answer verbatim in space below. Then, circle Y or N for all areas.}

_____

_____

	Yes	No
a. Sternum (upper or middle)	Y	N
b. Sternum (lower)	Y	N
c. Left anterior chest	Y	N
d. Left arm	Y	N
e. Other	Y	N

13.f. Specify:

14. Do you feel it anywhere else?..... Yes Y
{If "Yes", record above} No N

15. Did you see a doctor because of this pain or discomfort? ..... Yes Y

No N

Go to Item 17, Screen 5

16. What did he say it was?

Angina A

Heart Attack H

Other Heart Disease D

Other O

ANNUAL FOLLOW-UP QUESTIONNAIRE (AFUF screen 5 of 14)

E. POSSIBLE INFARCTION

17. Since our last contact have you had a severe pain across the front of your chest lasting for half an hour or more? ..... Yes Y

No N

Go to Item 20

18. Did you see a doctor because of this pain? Yes Y

No N

Go to Item 20

19. What did he say it was?

Heart Attack H

Other Disorder O

F. INTERMITTENT CLAUDICATION

20. Since we last contacted you, have you had pain in either leg on walking? Yes Y

No N

Go to Item 29, Screen 7

21. Does this pain ever begin when you are standing still or sitting? ..... Yes Y

No N

Go to Item 29, Screen 7

ANNUAL FOLLOW-UP QUESTIONNAIRE (AFUF screen 6 of 14)

22. In what part of your leg do you feel it?
{If calves not mentioned, ask: Anywhere else?}

Pain includes calf/calves C

Pain does not include calf/calves N

→ Go to Item 29, Screen 7

23. Do you get it if you walk uphill or hurry? ..... Yes Y

→ Go to Item 29, Screen 7 — No N

Never hurries or walks uphill H

24. Do you get it if you walk at an ordinary pace on the level? .... Yes Y

No N

25. Does the pain ever disappear while you are walking? ..... Yes Y

→ Go to Item 29, Screen 7 — No N

26. What do you do if you get it when you are walking?

Stop or slow down S

→ Go to Item 29, Screen 7 — Carry on C

ANNUAL FOLLOW-UP QUESTIONNAIRE (AFUF screen 7 of 14)

27. What happens to it if you stand still?

Relieved R

→ Go to Item 29 — Not relieved N

28. How soon?

10 minutes or less L

More than 10 minutes M

G. STROKE/TIA

29. Since our last contact have you been told by a physician that you had a stroke, slight stroke, transient ischemic attack, or TIA? ..... Yes Y

No N

If "Yes", ensure that this event is included in the "HOSPITALIZATIONS" section, if appropriate.

H. HOSPITALIZATIONS

30. Were you (Was [name]) hospitalized for a heart attack since our last contact on (mm/dd/yy)? ..... Yes Y

No N

Unknown U

If "Yes", complete "HOSPITALIZATIONS" section.

ANNUAL FOLLOW-UP QUESTIONNAIRE (AFUF screen 8 of 14)

31. Have you stayed (Did [name] stay) overnight as a patient in a hospital for any other reason since our last contact? ..... Yes Y
No N
Unknown U

If "Yes", add to "HOSPITALIZATIONS" section. For DECEASED, REPORTED ALIVE, or CONTACTED BY LETTER statuses go to Item 41, screen 11.

I. FUNCTIONAL STATUS

"Next, I would like to find out whether you can do some physical activities without help. By 'without help,' I mean without the assistance of another person. These questions refer to the last 4 weeks."

32. Are you able to do heavy work around the house, like shoveling snow or washing windows, walls or floors, without help? ..... Yes Y
No N

33. Are you able to walk up and down stairs without help? ..... Yes Y
No N

34. Are you able to walk half a mile without help? That's about 8 ordinary blocks. .... Yes Y
No N

35.a. Are you able to go to work?

Go to Item 36a, Screen 9 — Yes Y
No N

Go to Item 37a, Screen 9 — Not Applicable A

b. Is a heart problem the main cause of your not being able to work?

Go to Item 37a, Screen 9 — Yes Y / No N / Unknown U

ANNUAL FOLLOW-UP QUESTIONNAIRE (AFUF screen 9 of 14)

36.a. During the past 4 weeks, have you missed work for at least half a day because of your health? ..... Yes Y
No N

Go to Item 37a

b. On how many days has this happened? {maximum 28}

[ ][ ] days

37.a. Are you able to do your usual activities, such as work around the house or recreation?

Go to Item 38a — Yes Y
No N

37.b. Is a heart problem the main cause of your being unable to do this (these) activity(ies)?

Go to Item 39a, Screen 10 — Yes Y / No N / Unknown U

38.a. During the past 4 weeks, have you had to cut down on your usual activities, (such as work around the house or recreation), for half a day or more because of your health?

Go to Item 39a, Screen 10 — Yes Y
No N

b. On how many days has this happened? {maximum 28}

[ ][ ] days

ANNUAL FOLLOW-UP QUESTIONNAIRE (AFUF screen 10 of 14)

39.a. Over the past year, have you lost more than 10 pounds?

	Yes	Y
Go to Item 40a	No	N
Go to Item 39c	Unknown	U

b. About how much lower is your weight now than a year ago?

[ ][ ][ ] pounds

c. Were you trying to lose this weight? ..... Yes Y

No N

Unknown U

40.a. Please tell me which of the following describes your current marital status:

{READ ALL CHOICES}

Go to Item 40c, Screen 11	Married	M
	Widowed	W
	Divorced	D
	Separated	S
Go to Item 40c, Screen 11	Never Married	N

b. When did you become (widowed/divorced/separated)?

During the last month A

More than 1 month ago, but during the last 6 months B

More than 6 months ago, but during the last year C

More than one year ago D

Don't know E

ANNUAL FOLLOW-UP QUESTIONNAIRE (AFUF screen 11 of 14)

40.c. Did someone [else] you were close to die in the past year? ..... Yes Y

Go to Item 41	No	N
	Don't Know	U

d. When did this person die?

During the last month A

More than 1 month ago, but during the last 6 months B

More than 6 months ago, but during the last year C

Don't know D

40.e. What was this person's relationship to you?

Mother	M
Father	F
Sister	S
Brother	B
Child	C
Other relative	R
Friend	D
Pet	P
Other	O

J. ADMINISTRATIVE INFORMATION

41. Code number of person completing this form:

ANNUAL FOLLOW-UP QUESTIONNAIRE (AFUF screen 12 of 14)

K. HOSPITALIZATIONS

For each time you were (he/she was) a patient over night in a hospital, I would like to obtain the reason you were (he/she was) admitted, the name 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/dd/yy of last contact)? [Fill in, probing as necessary. Abbreviations can be used for local hospitals. Probe for additional hospitalizations. For linkage, H indicates that the hospitalization was reported; N indicates that the hospitalization was fully sought by Surveillance, and not found.]

42.a. Hospital Reason:

_____

43.a. Hospital Name, City, and State:

_____

44.a. Month and Year: | | | / | | | (M M / Y Y)

45.a. Linkage Status: | | (H) or (N)

42.b. Hospital Reason:

_____

43.b. Hospital Name, City, and State:

_____

44.b. Month and Year: | | | / | | | (M M / Y Y)

45.b. Linkage Status: | | (H) or (N)

42.c. Hospital Reason:

_____

43.c. Hospital Name, City, and State:

_____

44.c. Month and Year: | | | / | | | (M M / Y Y)

45.c. Linkage Status: | | (H) or (N)

NAME: _____ ID NUMBER: | | | | | | | | Contact Year: | | |

ANNUAL FOLLOW-UP QUESTIONNAIRE (AFUF screen 13 of 14)

42.d. Hospitalization Reason:

_____

43.d. Hospital Name, City, and State:

_____

44.d. Month and Year: | | | / | | | (M M / Y Y) 45.d. Linkage Status: (H) or (N) | |

42.e. Hospitalization Reason:

_____

43.e. Hospital Name, City, and State:

_____

44.e. Month and Year: | | | / | | | (M M / Y Y) 45.e. Linkage Status: (H) or (N) | |

42.f. Hospitalization Reason:

_____

43.f. Hospital Name, City, and State:

_____

44.f. Month and Year: | | | / | | | (M M / Y Y) 45.f. Linkage Status: (H) or (N) | |

Appendix 1.7

INSTRUCTIONS FOR THE ANNUAL FOLLOW-UP TRACING FORM AND QUESTIONNAIRE, AFU, VERSION F, 01/30/96 PREPARED 11/25/96

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 vital status, and (3) document interim medical events which have occurred 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).

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" used 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 participants' cardiovascular health since their clinic visit, functional status and major life events, and a "Hospitalizations" section to record information on any hospitalizations. The questionnaire is completed on paper and then batch-entered into the local database.

Contact Year 10 AFU includes the scheduling of the fourth clinic visit. If the participant refuses or does not show for a visit in Contact Year 10, scheduling may also be attempted in Contact Years 11 or 12.

When contact is made with the participant or an informant, the interviewer attempts to determine the participant's present address (or residence immediately prior to death) to assist in ARIC surveillance activities. At the completion of the AFU interview, the location of the participant's residence is recorded as within the ARIC surveillance boundaries (YES), outside of the surveillance area (NO), or UNKNOWN in Item 48 at the bottom of the TRC form. For participants who have expired, the place of residence refers to the person's address immediately prior to death.

II. ANNUAL FOLLOW-UP PROCEDURES

A. Contacting Procedures and Rules

Either the Coordinating Center or the field center staff 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:

Contact Year	Earliest	Target	Latest
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
06	5/14/91	11/14/91	5/13/92
07	5/14/92	11/14/92	5/13/93
08	5/14/93	11/14/93	5/13/94
09	5/14/94	11/14/94	5/13/95
10	5/14/95	11/14/95	5/13/96
11	5/14/96	11/14/96	5/13/97
12	5/14/97	11/14/97	5/13/98

The initial call for annual contact is made no more than three weeks or so before the target date except in contact years 4, 7 and 10, in which the contact can be made up to 4 months earlier to aid clinic scheduling. Ideally, the contact takes place as closely as possible to the "Target" date. If for some reason contact is not made until after the "Latest" date, this contact is assigned to the following Contact Year. This procedure 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.

At the option of the field center, the first step in the contacting procedures in contact years in which a field center examination is to be scheduled can be 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, the Annual Follow-up (AFU) form, the accompanying question-by-question instructions, and an appointment calendar for scheduling Visit 4.

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 typically 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 a clinic appointment is to be scheduled with more than one respondent during a single call, 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 (TRC) is used to keep track of attempts to contact a participant and appointment scheduling. One line is used for each attempted contact, and a result code is assigned. Two types of TRC form (Record of Call form) are used, one for annual follow-up calls which lead to scheduling of a clinic visit and one for the remaining years. The TRC used in the first case contains two panels at the bottom of the form, one used to record Result Codes and one for Appointment Codes. TRC forms used during contact years which do not lead to appointments have a single panel, namely the Result Codes, as described below. Assigning the code at each contact is very important, as the code 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:

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

02: "Tracing" - Attempts are being made to locate the participant, but so far neither the participant nor another reliable source have been contacted.

*03: "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.

*04: "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.

*05: "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.

06: "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.

*07: "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.

*08: "Reported Deceased" - Reliable information indicates that the participant has died.

*09: "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.

*98 "Does Not Want Any Further Contact" - The participant has requested 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 calls to describe the nature of the refusal. The recruitment 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 by the study.

When the AFU has been successfully administered, or the supervisor determines that all contact efforts have been exhausted (see below), the final result code is circled in the RESULTS CODE BOX on the TRC form. This result code is subsequently entered as Item 46 in the data entry system of the Annual Follow-up form (AFUF). Item 47 (appointment code) is by-passed and Item 48 (live in ARIC boundaries) is completed.

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".

For Contact Year 10, or later contact years when Visit 4 is still outstanding, the appointment codes (with possible final codes indicated by *) are:

*00: Appointment scheduled.

01: Clinic examination completed.

02a: Appointment deferred (by clinic staff), e.g., needs Saturday clinic; school vacation; some other work conflict; etc.

02b: Appointment pending due to sickness or other concerns/condition of the participant. Typically needs a flag or date for re-contacting by staff.

*03: Moved outside of the study area (participant does not need to be recontacted to make an appointment, but will be contacted annually for follow-up.

*04: Re-scheduled many times, unlikely to complete appointment (but has not yet formally refused).

*05a Appointment refused, permanently incapacitated.

*05b Appointment refused, other reasons.

*06: Refused clinic visit and does not want any further contact by ARIC staff. Record reason for refusal for entry into a DES note log.

07: Unable to locate.

*08: Deceased.

In contact year 10, the final appointment code is circled in the APPOINTMENT CODE BOX at the bottom of the TRC form when the participant is successfully scheduled for a field center exam (i.e., appointment is scheduled and kept), a reason for inability to schedule is ascertained, or the supervisor determines that all efforts to schedule the appointment have been exhausted. This appointment code is subsequently entered as Item 47 in the data entry system of the Annual Follow-up form (AFUF), and Item 48 (live in ARIC boundaries) is completed.

2. Questionnaire

Once the participant is called, the interviewer begins by reading the following script:

INTRODUCTION: "Hello, this is (YOUR NAME) from the ARIC Study. May I please speak with (NAME(s) OF PARTICIPANT(s))?"

DETERMINE PARTICIPANT'S AVAILABILITY AND VITAL STATUS.

IF DECEASED, OFFER CONDOLENCES, AND THEN DETERMINE THE DATE AND LOCATION OF DEATH (STARTING WITH ITEM 4) AND CONTINUE WITH THE SECTION ON HOSPITALIZATIONS (Section H). AT END OF INTERVIEW, INFORM THE RESPONDENT OF THE POSSIBLE NEED FOR SOMEONE FROM THE ARIC STAFF TO CONTACT A FAMILY MEMBER LATER ON, AND ASK WHEN WOULD BE THE BEST TIME TO CALL.

WHEN PARTICIPANT IS ON THE LINE (CY11, CY12), READ: "Hello, this is (YOUR NAME) from the ARIC Study and I'm making our annual contact call. 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 (CY10), READ: "Hello, this is (YOUR NAME) from the ARIC study and I'm making our an annual contact call. I would like a few minutes of your time to find out about your health in the past year and 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:

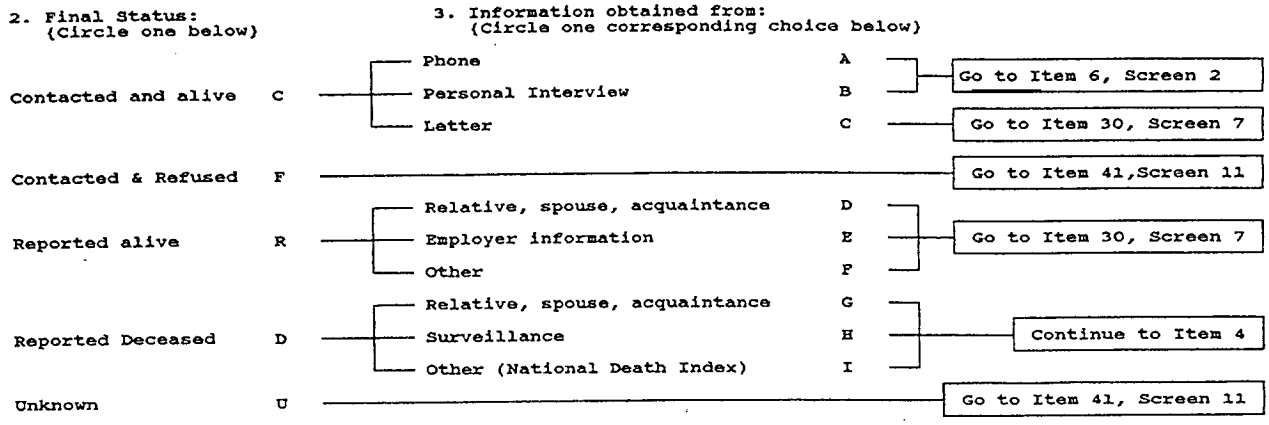
0	5	/	0	3	/	9	3
Month			Day			Year	

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 DURING THE PARTICIPANT'S CONTACT YEAR, 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:



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

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.

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 10 do not confuse this AFU status with refusing an appointment (code 05a and 05b 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 either 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 DURING THE SAME CONTACT YEAR WITHOUT WRITTEN AUTHORIZATION FROM THE COORDINATING CENTER. THEREFORE, A FINAL STATUS CODE SHOULD NOT BE ASSIGNED 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 3/5/87, and his "Latest" CY 02 date is 9/4/88. Record as:

Contact Year	Date of Status Determination	Status
2	9/4/88	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 02 was "Unknown," as determined on 6/28/88. His baseline visit was on 1/23/87. Record as:

Contact Year	Date of Status Determination	Status
3	6/28/88	U

3. It is Contact Year 2. The participant's baseline visit was on 2/24/87. His "Latest" date is 8/23/88. Neither the participant nor a reliable source can be located. Finally, on 8/25/88 (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:

Contact Year	Date of Status Determination	Status
2	8/23/88	U
3	8/25/88	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:

Contact Year	Date of Status Determination	Status
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 is a relative or an obituary. Take steps to begin a death investigation by initiating a Cohort Event Eligibility Form. Obtain as much information as possible from the informant on items 4 and 5. For example, if only the year and month of death are known, record them, (and not the day). Similarly, if the state is known, but not the city/county, record as much information as is available. Continue with Item 30, Section H (HOSPITALIZATIONS).

C. General Health

The time frame for the next set of questions in Sections C - G is since the last Annual Follow-up (AFU) call. Generally this is about 12 months. Exceptions to this could result from one or more missed AFU contacts. The most recent contact will rarely have been the last field center visit. It is important that the participant understand the time frame.

6. Read the question and the response categories verbatim, substituting the date on which the participant was most recently contacted (directly) where indicated.

D. Chest Pain on Effort

7. If the participant has reported chest pain during previous interviews, but none since the last contact, select NO and skip to Item 20; otherwise enter YES and continue with Items 8-16. These refer to the 'pain or discomfort in [the] chest' that the participant reported during the most recent (telephone) interview. 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, stair climbing, 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. 'It' refers to the pain/discomfort being described in Item 13. If there is a positive response to this question, select YES and also record the location of pain in item 13f.

15. 'Doctor' refers to a medical doctor in a clinic, hospital or private practice.

16. Read the question, but do not read the response categories. If there is more than one diagnosis, and heart attack is listed among the diagnoses, select 'H' (heart attack). If 'heart attack' is not given, but 'angina' and 'other heart disease' are, select 'A' (angina). If 'heart disease' and 'other' are both given, select 'D' (heart disease).

E. Possible Infarction

These three items refer to 'a severe pain across the front of [the] chest lasting for half an hour or more' which has occurred only since the last (telephone) contact.

17-19. Ask the questions exactly as printed. For the response to Item 17 to be positive, the pain must have been severe, located across the front of the chest, and have lasted for a minimum of half an hour. Refer to Item 15 for the definition of a 'doctor'. 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

The purpose of questions 30 and 31 is to determine whether it is necessary to complete the "Hospitalizations" section after the questionnaire has been completed. Generally, these questions are asked directly of the participant, but the participant or the interviewer can ask to have a spouse or more knowledgeable person in the household answer the questions on hospitalization. When direct contact is not made with the participant, but a reliable source of information has provided a status of "Reported alive" or "Reported deceased" in item 2, questions 30 and 31 may be asked of this source. If speaking with an informant, replace the words "Were you" with "Was ____(participant)". The term "hospitalized" includes staying overnight in any acute or chronic care facility which excludes nursing homes. Only inpatient care should be included, e.g., ER or outpatient visits not involving an overnight stay are coded as NO. If the participant or informant is unsure, doesn't know or can't provide information about the overnight hospitalization(s) for heart attack (Item 30) or other condition (Item 31), select the response category UNKNOWN.

30. Question 30 is intended to specifically enhance the participant's or informant's recall about cardiovascular-related hospitalizations. The term 'heart attack' refers to the person's admitting diagnosis or discharge diagnosis. For example, the response to Item 30 would be YES for a person admitted to a hospital overnight to rule out a suspected heart attack. Frequently, such a patient is discharged with a diagnosis of something other than a heart attack, for example, tachycardia (uneven heart rate) and esophageal reflux (indigestion). In other words, admissions to "rule out", as well as discharge diagnoses of a heart attack, are both coded YES.

31. This question asks the participant/informant to recall overnight hospitalizations in acute or chronic care facilities, such as hospitals, for any other condition.

If the response to Item 30 or 31 is positive, Section K (HOSPITALIZATIONS) can be administered prior to administering Section I (FUNCTIONAL STATUS).

I. Functional Status

Provide a transition statement such as, "Next I would like to find out whether you can do some physical activities without help. By 'without help,' I mean without the assistance of another person. These questions refer to the last 4 weeks."

This time frame is different from the previous section on hospitalizations. In general, you are trying to assess the participant's current functional status. This time period (i.e., the last 4 weeks rather than the day of the interview) has been chosen because we do not want to document decreases in functional ability that might be due to temporary conditions such as a headache, a cold or the flu, or a sprained ankle, etc. The intent of these questions is to record the individual's overall ability to perform the various activities covered (i.e., heavy work around the house, walk upstairs without assistance, walk half a mile, or work outside the home).

32. For this question, the examples are just guidelines. If a person can do any heavy work (not necessarily all of the things specified in the question), then record YES. Other examples of heavy work around the house could be "cutting the grass with a hand or power mower" (but not a riding lawn mower), or "painting walls or wallpapering."

33. The focus of the question is on the participant's ability to walk up and down stairs without the assistance of another person. If the participant says something like, "We have a ranch house, so I don't have to go up stairs," say that you want to know if he/she is able to walk up and down stairs. If the respondent is uncertain, code as NO.

34. Again, the emphasis is on the ability to do the activity, in this case, to walk half a mile. The concept of help in this item refers to persons helping. Therefore, the use of equipment would not be considered assistance and you would code YES for a participant who reported walking half a mile with the use of a cane. One, it keeps the definition consistent with those in Items 32 and 33. Two, it is assumed (and was the experience in Framingham) that anyone requiring either a second individual to assist ambulating or the use of a rehabilitative device (such as a three-pronged cane or walker) is not able to walk half a mile.

35. The focus of this question is whether the ability to work outside the home has been primarily compromised due to poor health (i.e., the participant is completely unable to engage in his or her occupation).

> If NO, determine if the poor health and the resultant disability were due to heart disease (Item 35.b). Regardless of the response, skip Item 36 and go to Item 37.a.
>
> If YES, go to Item 36.a.
>
> If the participant (1) does not work outside the home or (2) is not capable of working but would normally not be working outside the home (e.g., a homemaker, retired, or unemployed and not looking for work), code as NOT APPLICABLE, skip Item 36, and go to Item 37.a.

In 35.b., if asked about the meaning of "a heart problem," do not interpret nor offer a medical explanation, but rather let the participant decide whether s/he is "unable to work because of a heart condition or heart disease."

36. The focus of question 36.a is absence from work anytime within the four weeks prior to the interview for at least half a day (4 hours or more) because of personal illness. If this occurred (YES for Item 36.a), determine how many days the participant was absent from work (Item 36.b). The maximum number of days not worked is 28. The minimum is 1 because less than 4 hours of missed work would have been coded as NO in Item 36.a and Item 36.b would not have been asked. Therefore, 4 hours or more of missed work during a day is counted as 1; less than 4 hours is rounded down. For example, 3 days and 3 hours is entered as "03", whereas 3 days and 6 hours is entered as "04".

37. The focus of this question is to determine whether the ability to pursue one's normal activities around the house has been compromised by poor health.

> For example, you would code as NO a homemaker who is no longer able to clean house or perform the usual daily activities. If NO, determine if this is due to a heart problem (Item 37b), and go to Item 39, skipping Item 38. If asked about the meaning of "a heart problem," do not interpret nor offer a medical explanation, but rather let the participant decide whether s/he is "unable to work because of a heart condition or heart disease." If a participant indicates that s/he is able to carry on with the usual activities around the house but is not able to do his/her usual recreational activities -- such as bowling, walking, any form of recreational exercise -- code NO, determine in item 37.b if this is due to a heart problem, and go to item 39, skipping item 38.
>
> However, you would code as YES a retired brick layer (who is physically incapable of laying bricks) but who is able *to do his usual retirement activities* such as gardening or housework. Continue with Item 38a.

38. The focus of question 38.a is a reduction in the participant's usual activities (in contrast to a cessation of these activities in Item 37) during the four weeks prior to the interview because of poor health. The reduction in activities had to occur for at least half a day, i.e., 4 hours or more. If this occurred (YES for Item 38.a), determine on how many days the participant had to reduce his or her activity level (Item 38.b). The maximum number of days of reduced activity is 28. The minimum is 1 because less than 4 hours of reduced activity would have been coded as NO in Item 38.a and Item 38.b would not have been asked. Therefore, four hours or more of reduced activity during a day is counted as 1; less than 4 hours is rounded down. For example, 3 days and 3 hours is entered as "03", whereas 3 days and 6 hours is entered as "04".

39. The time frame for Item 39.a is 12 months prior to the interview. If the response is YES, ask how much lower the weight is now than one year ago (Item 39.b) and whether the participant was trying to lose weight (Item 39c). If more than 10 lbs were lost in the last 12 months (YES to Item 39.a), but more than 10 pounds were regained during the same time period, code '000' to indicate that the participant's current weight is not lower, but higher than it was a year ago.

If the response to Item 39.a is NO, go to Item 40.a.

If the participant doesn't know if more than 10 pounds have been lost during the last 12 months, enter 'U' for UNKNOWN, skip Item 39.b and determine if the unknown weight loss was intentional (Item 39.c).

40. The purpose of this question is to update marital status and to determine if one or more people close to the participant has died in the last 12 months.

Read Item 40.a and then all the response categories. If asked by the participant, the person is instructed to select the term which best describes his/her living situation, regardless of legal status. If the response is MARRIED or NEVER MARRIED, record the appropriate letter, skip Item 40b and go to Item 40.c. If the response is WIDOWED, DIVORCED, or SEPARATED, record the appropriate letter and determine how long ago the event took place (Item 40.b). Do not read the response categories, but probe if the participant's response is sufficiently unclear for you to select a category.

Read Item 40.c to all participants, inserting the word [*else*] if the participant lost his or her spouse (i.e., WIDOWED in Item 40.a) within the last year (Item 40.b).

If the response is YES, determine how long ago the person died. The time frame must be no more than 12 months ago. If the participant volunteers that more than one 'close' person died within the last 12 months, determine when the most recent death occurred.

If the participant volunteers that the deceased was a pet, code YES and replace the word "person" with the word "pet" in Item 40.d. Complete the response to Item 40e as Pet, but do not read the question out loud. If there were no deaths (NO or DON'T KNOW) within this time period, go to Item 41. If YES, determine how this person was related to the participant (Item 40.e). Do not read the response categories.

J. Administrative Information

41. The person at the clinic who has completed this form must enter his/her code number in the boxes provided.

3. Hospitalizations

A. Collection of data

If there was a positive response to Items 30 and/or 31, read the following script to the respondent/informant: 'For each time you were (he/she was) a patient over night in a hospital, I would like to obtain the reason you were (he/she was) admitted, the name and address of the hospital, and the date when you were discharged.' Abbreviations can be used for local hospitals.

42-44. 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 the (first) overnight stay, record the reason for the hospitalization (Item 42a), the hospital name, city, and state (Item 43a), and the discharge date (month and year) of the hospitalization (Item 44a). Probe for additional hospitalizations and follow the directions for the first hospitalization. There is space to complete 6 hospitalizations. If there are more than 6, record and enter the 6 most relevant to ARIC. List the others on a separate sheet, so all can be transmitted to surveillance. If the person was hospitalized overnight more than 6 times, select those with heart disease or stroke as reasons for hospitalization.

45. If any hospitalizations are reported, enter H beside the appropriate letter corresponding to each hospitalization. That is, if 3 hospitalizations are reported, enter H for items a, b, and c. Send a copy of the Hospitalizations page(s) or screen printouts to the surveillance supervisor and check the appropriate boxes for "Transmit to Surveillance." The surveillance staff will investigate each hospitalization. If a reported hospitalization cannot be found, the surveillance supervisor will notify the staff person responsible for annual follow-up, who then changes the "H" to "N". Be certain that the "H" changed corresponds exactly to the hospitalization in question (for example, if the second hospitalization is actually an outpatient visit, item b. H should become b. N).

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 insure 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 should be initiated. The hospitalizations sheet provides a check box to indicate that the information has been transmitted to the surveillance staff.

4. Verification of Tracing Information and Appointment Scheduling

A. Visit 4 Scheduling Not Needed

For AFU contacts for which a clinic visit is not being scheduled, choose the appropriate ending:

END (talking to participant): "Thank you very much for answering these questions. We will call you in about a year (see you at the clinic)." 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 4 Appointment

You may want to schedule all appointments in a household together. Below is a 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 (SECTION 5).

2. IF RESPONDENT IS UNWILLING TO SCHEDULE A CLINIC VISIT, INDICATE ON RECORD OF CALLS, AND VERIFY TRACING INFORMATION.

   "I'm sorry you are unwilling to come back for a fourth 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, SECTION 5.)

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 46 OF THE ANNUAL FOLLOW-UP FORM ON THE DES.

   Refer to page 5 for an explanation of the Appointment Code values. Refusal codes (05 and 06) should have the participant's reason for refusing entered into a notelog for item 46.

   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	IF YES
Since your appointment is at _____, you should begin fasting 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.	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 to ask you about your use of medicines, vitamins or supplements. This includes ALL medicines including: 1) prescription drugs from your physician or dentist; 2) prescription drugs you many have received from other people, such as friends or relatives; and 3) 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. Please bring in the bottles of any medications you have taken in the TWO weeks before your appointment. 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. INTRODUCE THE ORAL GLUCOSE TOLERANCE TEST

During the SCHEDULING OF VISIT 4, include the following in your description of ARIC procedures.

"In Visit 4 we will be adding new questions and procedures on diabetes and chronic infections to better understand how heart attacks and strokes develop.

For diabetes, we have added the oral glucose tolerance test. You drink 10 oz. of a flavored beverage that contains glucose, a type of sugar that is rapidly absorbed, and then we draw blood after 2 hours to see how well your body handles sugar. The results will be included in the final report to you and your physician. This test has been modified in recent years so that few people today ever have any discomfort after drinking the glucola. It is important for this test that you fast for the full 12 hours.

If you are taking medication to control diabetes, we will not do the oral glucose tolerance test. Please follow your regular schedule of medications and food intake. If, however, you have been told that you have high blood sugar or are controlling your blood sugar levels with diet, we would like to encourage you to have the oral glucose tolerance test. Of course, we will provide you and your doctor with these test results. Please feel free to discuss this with your doctor before your appointment with us.

This time we will not take photographs of your eyes nor will there be a lung function test.

f. RESOLVE ANY QUESTIONS OR CONCERNS.

"Do you have any questions?"

g. 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 only take 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."

5. Closing

NO ADDITIONAL INTERVIEWS	ADDITIONAL INTERVIEWS
"Thank you for your time. Good-bye."	"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

6. Update (UPD) 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, and phone number(s), as well as (except in CY10) 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 would be recorded as:

MAILING ADDRESS:	MAILING ADDRESS:
Highland View Apts.	_____
Apt. 73A	_____
3465 Highland Lane	_____
Chapel Hill, NC 27514	_____

ANY CHANGES TO TRACING INFORMATION MUST BE RECORDED ON THE UPD FORM IN THE VISIT 4 DATA MANAGEMENT SYSTEM.

Data should be updated on the UPD form as necessary immediately after the follow-up contact, but 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.

Appendix 1.8

ARIC
ATHEROSCLEROSIS RISK IN COMMUNITIES STUDY
FORSYTH CO. N. CAROLINA | JACKSON MISSISSIPPI | SUBURBAN MINNEAPOLIS MINNESOTA | WASHINGTON CO. MARYLAND

2060 Beach Street
Winston-Salem, NC 27103
(910) 777-3040

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2~
3~

Dear 4~

I would like to share some exciting news with you: ARIC is celebrating its 10-year anniversary, making it one of the longest studies of its kind. On behalf of the ARIC staff, and the many people who benefit from the knowledge gained in ARIC, I thank you for being a loyal participant. As a member of this ongoing study you contribute valuable information in our search for the causes and prevention of heart disease and stroke. Without dedicated people like you, this would not be possible.

Three years ago you were contacted for Clinic Visit 3 of the ARIC Study, and we are now pleased to invite you for your fourth visit. As before, your exam will include interviews, electrocardiogram, blood pressure measurements, and blood tests. For Visit 4 we will offer you a few new tests that we believe you will find both interesting and useful.

In the next few days you will get a call from our ARIC interviewer who will ask you a few questions and set up an appointment. **Please have your calendar available, with possible dates identified, to help us schedule a convenient date and time for your visit.** It would also be helpful if you could have ready any information about illnesses and hospitalizations you may have had during the past year. The telephone interview should last less than 15 minutes.

If you think it will be difficult for us to reach you in the next one or two weeks, please call the ARIC study office at 777-3067 to schedule a telephone interview, or to schedule an appointment for your fourth ARIC visit.

We do appreciate your contributions to this important study, and we are very glad to have you be part of ARIC.

Sincerely,

Pamela Williams
ARIC Field Supervisor

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6~

ATHEROSCLEROSIS RISK IN COMMUNITIES STUDY

FORSYTH CO. N. CAROLINA | JACKSON MISSISSIPPI | SUBURBAN MINNEAPOLIS MINNESOTA | WASHINGTON CO. MARYLAND

2060 Beach Street
Winston-Salem, NC 27103
(910) 777-3040

1~
2~
3~

Dear 4~:

It has been over three years since your physical examination by the ARIC Study. As explained at your first visit, the study conducts examinations every three years and contacts you by telephone each year to monitor the health of its participants.

This fourth examination is similar to your first three. It includes health interviews, an electrocardiogram (ECG), oral glucose tolerance testing, blood pressure measurements, blood tests, and an ultrasound picture of the arteries in your neck. The entire visit takes three and one-half to four hours.

Our interview staff has been trying to reach you by telephone to conduct a brief interview and to set up an appointment time for the examination. The telephone interview should take less than 10 minutes.

We will continue to try to reach you by telephone but it would be helpful if you could please **call the ARIC Study Office at 777-3067** to schedule a telephone interview, or to schedule an appointment for your third visit. Please leave a message if no one is available to talk to.

We **thank you again** for your participation in this important research project.

Sincerely,

Pamela M. Williams
ARIC Field Supervisor

5~
6~

ARIC
ATHEROSCLEROSIS RISK IN COMMUNITIES STUDY
FORSYTH CO. N. CAROLINA | JACKSON MISSISSIPPI | SUBURBAN MINNEAPOLIS MINNESOTA | WASHINGTON CO. MARYLAND

2060 Beach Street
Winston-Salem, NC 27103
(910) 777-3040

1~
2~
3~

Dear 4~

Recently you indicated that you did not wish to participate in the current ARIC examination. I appreciate all the time you have already given us both on the phone and in the ARIC clinic, and I assure you that we are very grateful. As you are aware, ARIC is one of the most important studies to help us understand how to prevent heart attacks and stroke, but we know that it is only possible because you have been willing to sacrifice some of your time and tell us about yourself.

Thank you again, and should you reconsider, we would be more than happy to hear from you. If your schedule permits we can offer a shorter exam visit (1 - 1 1/2 hrs). ARIC participants in Forsyth County have made this Field Center stand out from the rest. We are proud to be a part of the ARIC research staff that serves you.

Again, we are sad to lose you after so many years. If you should change your mind, please give me a call at (910) 777-3067. Any time you give us will be of much help to the study.

With best regards,

Pamela Williams
ARIC Recruitment Supervisor

5~
6~

TELEPHONE SCRIPT FOR AFU'S

This is _____ with Bowman Gray School of Medicine, on the ARIC Study. May I speak with _____.
(After getting cohort on telephone, VERIFY TRACING INFORMATION ON VERIFICATION SHEET FOR AFU 10. FOR ALL OTHER AFU'S, VERIFY, AS WELL, INFORMATION ON COHORT'S CONTACT NAMES ON TRACING FORM.

Complete AFU interview, thank cohort and remind them you will be contacting them in another year for updated information. **For AFU 10's, proceed to scheduling:**

After settling on date for clinic visit, remind them to **fast for twelve hours, taking nothing by mouth but water and essential medications unless they have a medical reason not to fast.**

Explain they will receive a packet in the mail a week before their scheduled appointment. The packet will contain their instruction sheet, a bag for medications - **all medication taken in the two weeks before their appointment, including prescription drugs, non-prescription drugs, over-the-counter medicines such as cold remedies, aspirin, vitamins, food supplements, etc.-** and the contact sheet to be brought in, updating the information on their contact people and doctor.

Remind them not to donate blood any time in the 7 days before the clinic appointment. If it becomes necessary to donate blood or plasma within 7 days of the appointment, ask them to call to reschedule.

Inform them of addition of two new procedures for visit 4. Tell them we will be doing urinalysis and oral glucose tolerance testing. Explain that we will ask them to give a urine specimen when they come in. We will be drawing your blood twice for the oral glucose tolerance test. For oral glucose tolerance test or OGTT we will ask them to drink a 12 oz orange flavored drink called glucola. We will then draw their blood again in two hours from the time the drink is consumed. They will not be given a snack or anything to drink until after the second blood draw. Diabetics on insulin and anyone who has had surgery to have a portion of their intestines removed cannot participate in OGTT. If they are diabetic on oral medication or diet controlled, they must first contact their physician for approval.

As we mentioned earlier, we have added a dental exam. This is just a simple examination of your mouth to see if there are any cavities, gum disease or spaces between your teeth and gums. It is not a regular dental cleaning. This is purely for research purposes.

Review date of clinic appointment; ask if they need transportation provided and ask them to be sure to call if they will be unable to keep appointment.

ARIC FORSYTH COUNTY ARIC NEWS
Fall 1996

ARIC Visit 4 in progress

Hello to all of our loyal ARIC participants. We are glad to bring this newsletter to you! We have lots of exciting information for you... so keep reading.

To date about 553 participants have returned to our clinic for their 4th ARIC examination. Several new tests are available during your visit, including a diabetes test (glucose tolerance test = GTT), a dental exam, and collection of information about your heart rate variability (HRV). The dental exam and HRV collection are just getting started but the diabetes test has been offered to all participants (who are not insulin dependent diabetics) and over 80% have participated. If you didn't get to participate in the dental exam.... don't worry... we will be calling you to schedule a convenient time for you to return for this. We thank you in advance for your support in this effort. More details on each of these areas are presented in articles throughout this newsletter.

Did I Hear You Right?

In the course of the phone call by ARIC staff prior to your Visit 4 examination, you will hear a new question from us: "*Would you like to have your teeth examined during your ARIC visit*" ? This may be a surprise to you. It was also a surprise to us to find out that there is a possible connection between dental cavities and gum disease, and hardening of the arteries, heart disease, and stroke. The reason is that chronic, low-grade infections and inflammation may predispose the body to hardening of the arteries, and possibly also to clot formation.

This is a very important question to answer, given that large numbers of people have a mild form of gum disease, which could actually represent a risk for heart disease. There is much interest in this question at present, both in this country and overseas, because it may represent a neglected link to heart disease and stroke, and one that can be prevented quite effectively.

To help answer this question, one needs a study such as ARIC. What would this mean to you? During your Visit 4 examination, we will invite you to have your teeth examined by a dental hygienist, who will be looking for cavities and gum disease. The hygienist will also take a few samples of saliva from around your teeth, and scrape off a little bit of plaque from one of your teeth. None of this should cause pain.

At the end of this examination, the hygienist will report back to you and/or your dentist any findings that should be followed up by a dentist. Persons who do not have any natural teeth (or implants) will not be asked to take part in the dental examination. However, all ARIC participants will be asked a few questions about their dental history.

If you have any questions about this part of the examination, please don't hesitate to ask.

Diabetes Test Update

Many of you are familiar with the oral glucose tolerance test (OGTT) for diabetes. We are offering this test to all eligible participants. After participants have their blood drawn they are asked to drink 10 oz. of a flavored beverage containing glucose. Glucose is a sugar readily absorbed into the blood stream. After 2 hours we measure your blood sugar level. This test tells you how well your body handles sugar. It can also help identify diabetes in people who have no symptoms.

If you are eligible, we hope you will join other ARIC participants who have participated in this valuable study. We typically keep you busy during your 2 hours between blood collection... but if you should finish early we do have a new TV/VCR complete with a collection of your favorite Andy Griffith tapes!!

Your Own Scientific Breakthroughs ▽ ▽ ▽ ▽ ▽ ▽ ▽

Most of us find it interesting and exciting to find out about a scientific breakthrough in the news. You may not be aware of it, but ARIC participants have already "made the news" on several scientific breakthroughs..

Some highlights from ARIC papers published in the scientific literature are listed here, as a few examples of what was accomplished with the information you contributed.

The food consumption you reported lead us to the conclusion that ...

△ Eating fish has a protective effect on lung function and chronic lung disease.

△ ARIC participants who have a diet higher in vegetable fats and/or lower in animal fats have less thickening of the artery wall in their neck.

Studies we did on the blood you gave helped us to discover that ...

△ High levels of fasting insulin measured in the blood samples of our non-diabetic ARIC participants were found more often in those who were overweight and had high blood pressure.

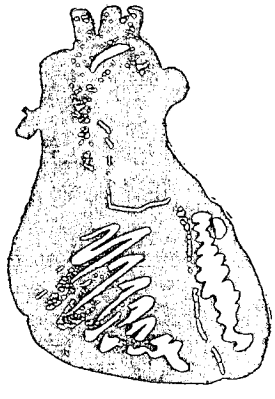
Many of you participated in a study on cerebral MRI (magnetic resonance imaging). From that study we observed that ...

△ Blood pressure levels are related to small strokes in the brain and a condition called white matter disease which can only be detected by MRI. As blood pressure went up the more frequently these effects were found to occur in the brain, both in persons who have high blood pressure and in those whose blood pressure is in the "normal" range.

These are only four of the many significant scientific findings that you have made possible by your participation.

From our heart to yours ...

♡ ⇨ ⇨ ⇨ ♡ ... ARIC thanks you!



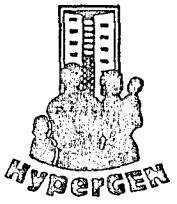
Don't Blink

The Retinal Photography Examination in ARIC's Visit 3 was a big success. More than 90% of the photographs taken were of very good quality. Thank you for your patience while these photographs were taken; some of you even agreed to help us out by having a photograph taken more than once.

The information from the eye photographs will help us understand how conditions such as high blood pressure and diabetes affect the small vessels in our body, not only in the eyes but also in the brain and in the kidneys. It will help us understand the relationships between strokes and patterns that can be seen in the vessels of the eye. We may even be able to identify people who are at higher risk of hardening of the arteries, heart attacks, and strokes by knowing their eye photograph results.

With your help, the ARIC study is making another important contribution in learning how to fight heart disease. If you have any questions about this important new area of research, don't hesitate to let us know. Write to us, or call us at your convenience at (910) 777-3040.

New HyperGEN Study



See brochure attached

This study will be performed at the ARIC clinic by our staff, on sibling pairs with high blood pressure. The visit lasts 2 to 2 1/2 hours. All will receive $20. We also invite all of the HyperGEN participants to receive an echocardiogram (TV picture of your heart). Each participant having an echocardiogram will receive a $10 Hanes Mall gift certificate. If you are interested, call us today at (910) 777-3044.

ECHOCARDIOGRAPHY is done using sound waves to make a TV picture of your heart. This picture can tell us about the size and shape of your heart, as well as the blood flow in your heart. This test will be offered to all HyperGEN participants immediately following their clinic visit. Hospital shuttle service will transport you to the ultrasound area at Baptist Hospital - and will return you to our clinic when you are finished. This examination takes 40 - 60 minutes and you will receive a $10 Hanes Mall gift certificate for participating. A brochure with additional details is available to all HyperGEN participants.

What is HRV?

HRV or heart rate variability is measured while you are fasting, after your ECG. As you know your heart beats a number of times each minute. Most of us assume that the amount of time between each beat is the same but researchers have learned that actually there is a great deal of variation in the amount of time between heart beats from a short time to a long time. In fact, healthy hearts typically have a great deal of variability. These time intervals are too small for us to detect when taking a pulse for example.... but a special computerized program can actually collect & show us these differences. The information from your heart is collected in very much the same way that your ECG is collected.

Currently we are not able to give you results of this test as they are for research purposes only. We will of course continue to update you with ARIC research articles in our lobby, and as soon as papers from the HRV data are published we will include them in our collection.

From us to you

♡ RECIPES FROM ARIC ♡

VEGETABLE SOUP — *Grady & Dee Posey*

1-1 1/2 lbs ground round - brown and add chopped onion (1 med.)
1 large bag Veg-all stew vegetables
2 cans diced tomatoes
1 small can tomato sauce
2 cups (16 oz.) tomato juice
3-5 potatoes (cubes)
1 small can corn or 1/2 bag frozen corn
4-5 beef boullion cubes
1 Tbsp. worchestershire

Mix all ingredients in crockpot or cook on the stove top; salt & pepper to taste.

PINEAPPLE CASSEROLE — *Kay Burke*

2 cans chunk pineapple, drained
1 cup sugar
1 cup grated sharp (any) cheese
6 Tsp. flour
1 stack Ritz crackers, crumbled
1 stick margarine, melted

Combine first 4 ingredients. Sprinkle crackers on top. Drizzle margarine over the crackers (or mix margarine and crackers first). Bake 30 minutes at 350°.

JAPANESE CHICKEN SALAD — *Amy Haire*

4 chicken breasts, cooked and chopped
1 large head lettuce, shredded
3 green onions, chopped
3 oz. (1 can) chow mein noodles
4 oz. sliced or slivered almonds
2 Tablespoons poppy seeds

Dressing: 4 Tblsps. sugar 1/2 cup oil
1/2 tsp. pepper 2 Tblsps. salt
4 Tblsps. vinegar (less if apple cider vinegar)

Mix dressing and set aside. Mix all other ingredients, except noodles. Right before serving, add noodles and pour on dressing. Mix well.
NOTE: Can omit chicken and use as regular salad.

THE ARIC STAFF APPLAUDS THE STUDY PARTICIPANTS

We find the ARIC participants of Forsyth County to be very cooperative and gracious during their visits to the clinic. We applaud your cooperative attitude while we administer the interviews and tests, and appreciate your willingness to participate in some of the extra studies with ARIC. We are very pleased to be able to work with you. Again, thank you!

Thank You . . . Thank You . . . Thank You

The ARIC staff would like to thank all of our loyal ARIC participants and their family members for their participation in the *Family Heart Study*.

LOST & FOUND

Occasionally earrings, eye glasses, jackets, medications, and other items are left in the clinic. If you are missing an item which you may have brought with you during your ARIC visit, please call (777-3040) or come by the clinic to check our lost and found items.

When we call . . .
Please say YES to your Visit 4!!

ADDRESS CORRECTION REQUESTED

ARIC
ATHEROSCLEROSIS RISK IN COMMUNITIES STUDY
2060 Beach Street
Winston-Salem, NC 27103
(910) 777-3040

Nonprofit Organization
U.S. Postage
PAID
Permit #177
Chapel Hill, NC 27599-1110

Dear _____ :

Thank you for agreeing to come to Visit 4 of the Atherosclerosis Risk in Communities (ARIC) Study. Your appointment has been scheduled for:

DAY_____ DATE ____/____/____ TIME ____:____A.M.

Please come to 2060 Beach Street. A map and parking directions are attached. **PLEASE READ THE FOLLOWING INSTRUCTIONS CAREFULLY.**

- **FASTING**
  Unless you have been instructed to the contrary, you should fast (NOTHING BY MOUTH EXCEPT WATER AND ESSENTIAL MEDICATION) for 12 hours before your appointment. A snack will be provided during your visit.

- **BLOOD DRAWING**
  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 us and reschedule your appointment.

- **SMOKING AND PHYSICAL ACTIVITY**
  Refrain from smoking or vigorous physical activity at least one hour before your appointment.

- **CLOTHING**
  Be prepared to change into a hospital gown after your arrival; bring or wear comfortable shoes or slippers that are easy to take on and off. Wear loose fitting underwear and leave necklaces at home.

- **MEDICATIONS**
  Be sure to bring all your medications in their original containers. Put these containers in the ARIC bag. This includes prescription, and non-prescription medications, including vitamins and aspirin.

- **GLASSES**
  If you normally wear glasses for reading, please bring them with you and keep them with your throughout the visit.

- **PHYSICIAN CONTACT**
  Please write down the name and address of your primary care physician on the Contact Information Sheet and bring with you to the ARIC clinic.

* **GLUCOSE TOLERANCE TEST**
If you choose to do this test you will not be offered any food or drink after you have consumed the glucola drink, until you have your second blood draw two hours later.

* **TRACKING INFORMATION**
On the enclosed Contact Information Sheet, please update the names, addresses and telephone numbers of two contact people to help us keep current on how to locate you in the future.

To help you move through the clinic on schedule, it is most important that you be on time for your appointment. Here is a list of activities for your visit.

Reception	Ultrasound
Urine Specimen	Interview
Blood Pressure Measurement	Electrocardiogram (ECG)
Blood Drawing	Snack
Glucose Tolerance Test	Dental Exam
Anthropometry (Body Measurement)	Medical Review

Total Exam Time - 4 hours

If you have any questions or a problem with your appointment, please call the clinic at 777-3067 between 8:00 a.m. and 5:00 p.m., Monday through Friday.

Appendix 1.10c

ARIC MEDICATION INSTRUCTIONS

PLEASE BRING WITH YOU TO THE ARIC FIELD CENTER ALL MEDICATIONS YOU HAVE USED WITHIN THE TWO WEEKS BEFORE YOUR APPOINTMENT: _____ TO _____

- Prescription Drugs from your physician
- Prescription Drugs you have been given by a friend or relative
- Non-prescription Drugs (over-the-counter medicines) that you obtained from a drug store, supermarket, or by mail, such as aspirin, cold remedies, vitamins, or the like

In order to be sure you have included everything, think about the past few weeks. Have you been ill or did you visit a physician or dentist who might have given you medication? For your convenience a list of typical medications or medical conditions requiring medications is presented below to help you remember any medications you may need to bring with you.

MEDICAL CONDITIONS

Allergies
Arthritis, joint problems, for example: cortisone-type medicine, anti-inflammatory drugs.
Birth control
Cancer
Constipation
Coughs and colds
Diabetes, for example: insulin
Fever
Flu, pneumonia
Headaches
Heart problems, angina or chest pain for ex: digitalis, nitroglycerin
High blood pressure
Hot flashes
Infections, for ex: penicillin, sulfas, other antibiotics
Lung problems, such as asthma, lung disease, emphysema, shortness of breath, wheezing
Menstrual problems
Nausea
Seizures
Skin problems
Thyroid
Tranquilizers
Ulcers, stomach problems, digestion
Vascular problems, blood thinning, for ex: dicumarol, coumadin
Vitamin or mineral supplements
Weight reduction

MEDICATIONS

Antacids: liquids, tablets
Antianxiety;antidepressants
Antihistamines
Appetite suppressants
Calcium supplements
Cholesterol lowering agents
Cough suppressants
Decongestants
Diet pills
Digestive Aids
Eye, ear or nose: drops, ointments, sprays
Fish oils
Hemorrhoidal suppositories
Herbs or folk remedies
Hormones
Iron or anemia medicines, for ex: Geritol
Laxatives
Mineral supplements
Muscle relaxants
Oral contraceptives
Pain relievers, for ex: Codeine, Darvon, Percodan, Tylenol #3/#4
Shots or pills to reduce water in the body
Sleeping pills
Steroids, cortisone: inhalants, ointments, pills, sprays

TAKE YOUR ESSENTIAL MEDICATION AS USUAL ON THE MORNING OF YOUR VISIT

CONTACT INFORMATION SHEET

YOUR NAME_____

We will again provide your doctor with results of your tests if you would like us to. Please fill out the information below and bring it with you to the clinic, so that we can update our records.

DOCTOR OR CLINIC NAME_____

ADDRESS_____

_____

TELEPHONE NUMBER_____

Since we will be contacting you for several more years, we would like to update our information to help us locate you in the future. Remember that all information is confidential and that anyone we might contact will be told only that we are trying to locate you for a health study.

Please complete the name, address, and telephone number of two close friends or relatives who you are likely to keep in touch with **(BUT WHO DO NOT LIVE WITH YOU)**, and who are not planning to move anytime soon. Thank you.

CONTACT PERSON 1

NAME_____

ADDRESS_____

_____

TELEPHONE NUMBER_____

CONTACT PERSON 2

NAME_____

ADDRESS_____

_____

TELEPHONE NUMBER_____

ATHEROSCLEROSIS RISK IN COMMUNITIES STUDY

FORSYTH CO. N. CAROLINA | JACKSON MISSISSIPPI | SUBURBAN MINNEAPOLIS MINNESOTA | WASHINGTON CO. MARYLAND

2060 Beach Street
Winston-Salem, NC 27103
(910) 777-3040

June 5, 1997

To Whom It May Concern:

Your employee,_____, has been a participant in an important medical research project called the Atherosclerosis Risk in Communities (ARIC) Study since December, 1989. This project is sponsored by the National Heart, Lung, and Blood Institute in only four communities nationwide. In Forsyth County, it is being sponsored by the Bowman Gray School of Medicine of Wake Forest University and The University of North Carolina at Chapel Hill. The purpose of the study is to better understand characteristics which may predispose people to heart or blood vessel disease.

The ARIC Study requires a three-and-one-half hour examination once every three years to collect the medical information. It is now time for _____ to have his/her exam. We hope you will allow your employee time off to complete this examination. His/Her participation is important to the study. If you have any further questions, you may call me at 910-777-3067.

Thank you.

Sincerely,

Pamela M. Williams
ARIC Field Supervisor

General Instructions For Completing Paper Forms

A. BACKGROUND

The Atherosclerosis Risk In Communities (ARIC) Study utilizes computer-assisted direct data entry as its primary mode of data collection. Nevertheless, the existence of paper forms is necessary for situations in which direct data entry is not possible. In such instances, data is collected on paper forms and then entered on the computer at some later time. The purpose of this document is to provide instructions for completing these paper forms. It should be read carefully prior to working with any forms. Specific sets of instructions associated with each form (QxQ's) should then be read for those forms which are of interest.

B. FORM STRUCTURE

Most of the paper forms in ARIC are designed to correspond exactly to the computer screens used for data entry. For this reason, forms are organized by "screen" instead of by "page". Thus, any item on a paper form may be located in the same position on the corresponding computer screen, and vice versa. In general, the first page of the paper form contains one screen, and subsequent pages contain two screens each. Most forms are structured as follows:

First page:

a. Form Title and OMB number
b. "Header" Information
    1. Participant's ID Number
    2. Contact Year
    3. Form Code (preassigned 3-letter code)
    4. Version (1-letter code and date)
    5. Participant's Last Name and Initials
c. OMB Statement
d. Summarized Instructions
e. First Screen of the Form

An example of a typical "first page" is given in Figure 1.

Following pages:

a. Form Title, Code, and Version
b. Successive Screens

On forms where two screens appear on the same page, both columns of the top screen should be completed in full before proceeding to the bottom screen. This order is illustrated in Figure 2.

Figure 1

Example of ARIC Form - First Page

O.M.B. 0925-0821
exp.

ARIC
Atherosclerosis Risk in Communities

FASTING/TRACKING FORM

ID NUMBER: | | | | | | | | | CONTACT YEAR: 0 7 FORM CODE: F T R VERSION: C 09/10/92

LAST NAME: | | | | | | | | | | | | | | | INITIALS: | | |

Public reporting burden for this collection of information is estimated to average 1 minutes, including time for reviewing instructions, gathering needed information and completing and reviewing the questionnaire. If you have comments regarding this burden, please send them to Attention: PRA Reports Clearance Officer, PHS, 721-B Hubert H. Humphrey Building, 200 Independence Avenue, SW, Washington, D.C. 20201, and to the Paperwork Reduction Project (0925-0281), Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, D.C. 20503.

INSTRUCTIONS: This form is completed during the participant's visit. ID Number, Contact Year and Name must be entered above. Whenever numerical responses are required, enter the number so that the last digit appears in the rightmost box. Enter leading zeroes where necessary to fill all boxes. On the paper form, if a number is entered incorrectly, mark through the incorrect entry with an "X". Code the correct entry clearly above the incorrect entry. For "multiple choice" questions, circle the letter corresponding to the most appropriate response. If a letter is circled incorrectly, mark through it with an "X" and circle the correct response.

FASTING/TRACKING FORM (FTRC screen 1 of 1)

1. Date of clinic visit 3:

		/			/		
month			day			year	

2. Date of fasting determination:

		/			/		
month			day			year	

3.a. Time: ..... | | | : | | |
h h : □ □

b. AM ..... A
PM ..... P

4. When was the last time you ate or drank anything except water?

a. Day last consumed: ..... Today T
Yesterday Y
Go to Item 6 ——— Before Yesterday B

4.b. Time last consumed: | | | : | | |
h h □ □

c. AM ..... A
PM ..... P

5. Computed fasting time: ..... __ __ hours

6. Have you given blood within the last 7 days? ..... Yes Y
No N

7. Method of data collection ..... Computer C
Paper P

8. Code number of person completing this form: ..... | | |

Figure 2

Example of ARIC Form - Page with Multiple Screens

TIA/STROKE FOSH (TIAD screen 2 of 30)

4. During this time, how many episodes of loss or changes in speech have you had?

1
2
3
4
5
6-20
More than 20, or frequent, intermittent events, too numerous to count

A
B
C
D
E
F
G

5. During this same time period, when did the earliest occur?

2

Within the last 6 months — A
Greater than 6 months, but less than 1 year ago — B
Greater than 1 year, but less than 2 years ago — C
Greater than 2 years, but less than 3 years ago — D
3 or more years ago — E

TIA/STROKE FOSH (TIAD screen 3 of 30)

6. How long did it (the longest episode) last?

3

Less than 30 seconds — A
At least 30 seconds, but less than 1 minute — B
At least 1 minute, but less than 3 minutes — C
At least 3 minutes, but less than 1 hour — D
At least 1 hour, but less than 6 hours — E
At least 6 hours, but less than 12 hours — F
At least 12 hours, but less than 24 hours — G
At least 24 hours — H

7. Did the (worst) episode come on suddenly? ..... Yes — Y
No — N

8. How long did it take for the symptoms to get as bad as they were going to get?

4

0-2 seconds (instantly) — A
At least 3 seconds, but less than 1 minute — B
At least 1 minute, but less than 1 hour — C
At least 1 hour, but less than 2 hours — D
At least 2 hours, but less than 24 hours — E
At least 24 hours — F

C. GENERAL INSTRUCTIONS FOR COMPLETING AND CORRECTING ITEMS ON THE FORMS

All items fall into two main categories: (1) fill in the boxes, and (2) multiple choice. Techniques for completing each of these types of items, as well as making corrections, are described below. A general rule is to record information only in the spaces provided (except for some error corrections).

1. Fill In The Boxes: Recording Information

When alphabetic information is required, print the response beginning in the leftmost box using capital letters. Punctuation may be included.

Example: If the participant's last name were O'Reilly, it should be entered as follows:

LAST NAME: | O | ' | R | E | I | L | L | Y | | | | |

If the response contains more characters than there are boxes, beginning with the first character enter as many characters as there are boxes.

Example: If the subject's last name were Hobgoodnotting, it should be entered as follows:

LAST NAME: | H | O | B | G | O | O | D | N | O | T | T | I |

Whenever numerical responses are required, enter the number so that the last digit appears in the rightmost box. Enter leading zeroes where necessary to fill all boxes. (This does not apply to the address section or to any item which combines alphabetic and numeric information. Such items should be treated as alphabetic.)

Example: If the participant's diastolic blood pressure were 96, it should be coded as:

Diastolic: ..... | 0 | 9 | 6 |

In some cases, numeric fields have a pre-printed number of decimal places. Also, it is possible that the QxQ instructions will specify the number of decimal places to be recorded. Instructions on how to round values to the expected number of decimal places are found in the QxQ instructions. When necessary, enter trailing zeros to fill the requested number of places to the right of the decimal point. Leading zeros may be needed so that all boxes to the left of the decimal are also filled.

Example with trailing zero: If the participant takes twelve vitamins per day, it should be recorded as:

Number per day: ..... | 1 | 2 | . | 0 |

Example with leading zero: If the participant takes two and one-half vitamins per day, it should be recorded as:

Number per day: ..... | 0 | 2 | . | 5 |

In most cases when dates are recorded, slashes ("/") are used as the separator characters for month, day, and year. These are usually pre-printed in the response field. The format to be used to record dates is indicated under the boxes. If not, the QxQ instructions will indicate which format and separator to use. ARIC uses the U.S. order for recording dates (month/day/year). The QxQ instructions may also contain information on how to handle partial dates. When necessary, use leading zeros within each date unit (month or day or year) so that each box is filled.

Example: Data collected on April 3, 1993 would be recorded as:

Date of data collection:..... | 0 | 4 | / | 0 | 3 | / | 9 | 3 |
m m d d y y

ARIC usually records time using a 12-hour clock, with AM or PM indicated separately. In most cases, colons (":") are used as the separator character for hours and minutes, and are typically pre-printed in the response field. The format to be used is indicated under the boxes. If not, the QxQ instructions will indicate which format and separator to use. When necessary, use leading zeros within each time unit (hour or minute) so that each box is filled. Note that midnight is recorded as 12:00 AM, and noon is recorded as 12:00 PM.

Example: A time of fasting determination of 8:05 in the morning is recorded as:

a. Time of fasting determination:..... | 0 | 8 | : | 0 | 5 |
h h m m

b. AM.....(A)

PM..... P

2. Fill In The Boxes: Correcting Mistakes

If a number or letter is entered incorrectly, mark through the incorrect entry with an "X". Code the correct entry clearly above the original incorrect entry.

Example: If the participant's systolic blood pressure was actually 130, but was incorrectly entered:

Systolic: ..... | 1 | 3 | 9 |

The correction would look like:

Systolic: ..... | 1 | 3 | 0 |

If a mistake is made, corrected, and then it is discovered that the correction is incorrect, make a second correction as shown below:

Systolic: ..... | 1 | 3 | 2 |

3. Fill In The Boxes: Unknown Or Inapplicable Information

If an item of this type (either alphabetic or numeric) *does not apply* to the subject being interviewed, leave it **blank**. For example, if the participant does not have an "other" phone number, that item is left blank. Similarly, if the form provides spaces for three measurements, but only two are taken, the third space is left blank.

If the item *does apply*, but the response is unknown, mark through the box(es) with two horizontal lines.

Example: The question "How old were you when you had your first heart attack?" is asked, but the participant does not recall how old he/she was. The question *does apply* because it has been established that the participant has had a heart attack, but the *answer to this question is not known*. In this case, the response would look like:

How old were you when you had your first heart attack? ..... | | |

4. Multiple Choice: Recording Information

In this type of question several alternatives are given for the answer, each having a corresponding letter. When it is decided which alternative is most appropriate, circle the corresponding letter in the space provided. Always circle one letter only.

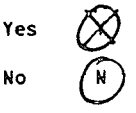
Example: If the participant indicates that they have never had chest pain or discomfort, the response would look like:

Have you ever had any pain
or discomfort in your chest? ..... Yes Y
No (N)

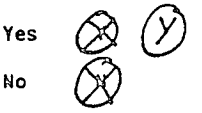
5. Multiple Choice: Correcting Mistakes

If a response is coded incorrectly, mark through the incorrectly coded response with an "X" and circle the correct response.

Example 1: The actual response is No, but Y was circled incorrectly. The correction looks like:



Example 2: If a mistake is made, corrected, and then it is discovered that the correction is incorrect, make a second correction as shown below:



D. COMPLETING "HEADER" INFORMATION

The following guidelines should be observed in filling out the "header" information located at the top of the first page on all forms:

ID NUMBER: Write in the participant's 7-digit ID. The first box contains the letter identifying the field center, followed by the 6-digit numeric portion of the ID number.

Example: ID NUMBER:

J	9	9	9	9	9	9

CONTACT YEAR: Fill in the appropriate contact year for the form. Use leading zeroes. Note: This item may be pre-coded on some forms.

LAST NAME: Code the response beginning in the leftmost box using capital letters. If the name contains more letters than there are boxes, beginning with the first letter enter as many letters as there are boxes. Punctuation (e.g., apostrophes and hyphens) and blanks may be

entered as part of the last name. Follow the guidelines and examples given above for alphabetic "fill in the boxes" items.

INITIALS: Record the participant's first initial in the first box and middle initial in the second box. If a female participant is married and uses a "maiden" name (father's surname) as a middle name, use that initial as the second initial. Otherwise, if the participant has more than one middle name, record only the first initial and the second initial. If there is no middle name, record the first initial in the first box and leave the second box blank.

Example 1: A participant's first initial is K, but he has no middle name. The entry would be as follows:

INITIALS: | K | |

Example 2: If the participant's full name is John Oscar Van Camp, Jr., and the participant specifies that his last name is "Van Camp", it should be entered as:

LAST NAME: | V | A | N | | C | A | M | P | | | | | INITIALS: | J | O |

E. SKIP PATTERNS ("Go to" Boxes)

Skip patterns occur in many multiple choice type items. Here, if a certain response is selected, it is necessary to skip over one or more items to the next applicable item. This is indicated by an arrow from the response which necessitates a skip to a box containing a "go to" statement. If that response is selected, the next item to be asked is the one indicated in the box. If the other response is selected, always proceed to the next item unless otherwise directed. The box will also indicate the screen containing the "go to" item if that item is not on the current screen.

Example: 7. Since we last contacted you,
have you had any pain
or discomfort in your chest? ..... Yes Y

No N

Go to Item 20,
Screen 5

In this case, if the response is "No", skip to item 20 on screen 5. If the response is "Yes", proceed to the next question, item 8.

Occasionally, a skip pattern will occur in a fill-in type item. In those instances, specific instructions are provided on the form. Again, if the skip criteria are not satisfied, continue with the next item.

A few items will trigger a skip regardless of the response. For these, follow the instructions on the form.

ATHEROSCLEROSIS RISK IN COMMUNITIES STUDY

PAPER FORMS VS DES

1. Recording Responses

Most of the questions in the ARIC forms have precoded responses. There are a few questions, however, that you must write in a response to the question. Some questions have precoded responses as well as an "other" category. If the respondent's answer does not fit into a precoded answer, you must specify the response. The recording practices below must be followed at all times to assure that the response recorded accurately reflects the respondent's answers and to assure the questionnaire data can be converted to machine-readable form.

* You must listen to what the respondent says and record the appropriate answer if the response satisfies the objective of the question.

* In recording answers to open-ended questions or "other" categories, print the response verbatim.

* Record the response immediately after it is given.

* Use a black ball point pen.

* Record in the white space below the questions any responses that "don't quite fit" in one of the response categories. Your notes will help the analysts in understanding points of confusion, difficulty, etc.

* Print or write legibly.

* If a respondent refuses to answer a question, write "refused" in the left margin beside the question.

* A single answer choice code must be circled in each question to represent the respondent's answer. The only deviation from this rule is for disease questions which are subdivided into several diseases and any answer code is to be circled for each disease listed.

Some of the question in the ARIC study ask about recall of events over time. You may assist the respondent without violating probing rules by working with him/her on math or pinpointing dates or events (such as age a parent was when diagnosed with a specific disease). Another way to help pinpoint more accurate information is to ask respondent to think about time of year or season when an event occurred.

* Right-justify and zero-fill to record numeric entries such as dates, minutes, hours, etc. An example of proper recording of an interview that began at 7:15 in the evening is:

2. 07 15 A
HOUR MINUTE P

* When alphabetic information is required in recording, print the response beginning in the left most box, using capital letters. Punctuation may be included. For example, if the participant's last name were O'Reilly, it should be entered as follows:

O'REILLY____

LAST NAME

If the response contains more characters than there are boxes, beginning with the first character, enter as many characters as there are boxes. You may use standard abbreviations. For example:

RESEACH_TRIANGLE_INST.

COMPANY NAME

Recording "Don't Know" responses--you have been provided with response codes of unknown or unsure for many "don't know" responses. For recording boxes, a "don't know" response should be recorded by marking through the box (es) with two horizontal lines as show in the following example:

25. How old is he? ENTER "99" FOR AGES 99 AND OLDER.

==

AGE

EXAMPLE 4

The response to the following question was "No" but the Y was circled incorrectly. The respondent then said that he/she did stay in the hospital overnight last year even though it was considered an outpatient procedure. Make the correction as follows:

11. Have you stayed overnight as a patent in a hospital during the past year?

Yes..... Y Y
No..... N

3. Instrument Conventions

Certain conventions are used consistently in the ARIC field instruments. Familiarity with these conventions will help you use the instrument with ease and confidence. Note that some of these conventions are not consistent with the clinic interview which uses direct data entry. Note also that italics in the right-hand margin of the HOM (RMS, HOM and IDN) are keying instructions which you should ignore.

OVERVIEW OF INTERVIEW SKILLS AND TECHNIQUES

I. **Interviewer bias - includes anything that creates a systematic difference between responses obtained by different interviewers.**

   A. Respondent's perception of the interviewer and his/ reaction to that perception.

   B. Interviewer's perception of the respondent and his/her reaction to that perception.

II. **Characteristics of a good interview**

   A. There is an appropriate atmosphere; friendly but business-like.

   B. The respondent is at ease. Interviewer should be able to put respondent at ease and ensure their confidentiality.

   C. Interviewer obtains the answer to the questions asked through the proper use of probes and does not interpret questions or try to argue.

   D. Interviewer gives only neutral responses to the respondent's answers and clarifies confusing responses but does not challenge an answer.

III. **Specific skills required for interviewers include the following:**

   A. Be able to ask questions at an even pace and in conversational tones.

   B. Know the question and response categories well enough to keep the interview flowing smoothly.

   C. Know when there are probes that can be used, and know how to use them. Understand when it is inappropriate to probe.

D. Be able to think as an interviewer, putting aside other roles (ECG tech, mother, father, etc.) for the period of the interview. FOCUS on the interview.

E. Be able to maintain a positive attitude about the interview so that the respondent feels that the interview is important.

F. Be able to keep some level of control over the interview process, i.e., by keeping the interview focussed on the specific question and not arguing with the respondent.

G. Ensure that data is coming from the respondent. Listen carefully and avoid being engaged in the answer. Often respondents will use a tack such as "What do you think?" or "Let me tell you about that so that you can help me with the answer." These attempts encourage the interviewer to be "helpful" and can result in bias by leading the respondent to an answer. Remember that you are the interviewer administering the interview, not the respondent being interviewed. We need the information on the respondent not on you.

H. Interviewers should dress professionally, be neat, pleasant looking. Additionally, they should be not too timid, but not too aggressive.

I. Eye contact with interviewers is very important but by the same token, it is not a good idea "to stare them down" or to act as though you do not believe their answers.

Appendix 2.2b

CONDUCTING THE INTERVIEW

I. The interviewer must help the respondent to feel at ease and comfortable with the interview. During the initial contact and throughout the interview, you should:

   A. Maintain a positive attitude.

   B. Repeat that any information the respondent gives you will be kept confidential if he/she appears to be apprehensive about providing information.

   C. Maintain control of the interview.

   D. Assume a non-judgmental, noncommittal, neutral approach to the respondent and the subject matter so that the sample member will feel comfortable answering the questions truthfully.

II. The process of asking the questions and recording responses correctly is crucial to obtaining useable, high-quality data. The following are standard practices used in interviewing situations which should be following.

   A. Ask the questions <u>using the exact words</u> printed in the questionnaire form

   B. Ask the questions in <u>the exact sequence</u> in which they appear or as instructed. If the questions are to be asked out of sequence, a skip instruction will appear beside the response categories (in the case of direct data entry, the system will skip automatically).

   C. Ask <u>every question specified</u> even when a respondent has seemingly provided the answer to the question when another was asked. The answer received in the context of one question may not be the same answer that will be received when the other question is asked.

D. If the answer to a question indicated that the respondent did not understand the intent of the question, repeat the question. Note here that repeating is done only when it appears that the respondent did not understand the question. Other techniques for probing are also listed in this paper.

E. Read the questions at a moderate speed, preferably at a pace of about two words per second. Remember that too slow will prolong the interview unnecessarily and too fast will mean opportunity for error. Although you have stated this question, 6,534 times, the respondent is hearing it for the first time.

F. Avoid suggesting answers to the respondent. As noted earlier, the respondents may try to get you to answer for them. Your job is to ask the questions, and then record his/her responses. Don't help them!

G. Read transition statements just as they are printed in the questionnaire. Transition statements are designed to inform the respondent of the nature of a question or a series of questions, to define a word, or to describe what is being asked for the question.

H. Sensitive questions should be asked in a neutral manner which should not differ from the normal professional flow of the interview. The respondent may be more comfortable if you avoid eye contact when asking sensitive questions.

III. There will be times when the interviewer needs to probe to obtain a more complete or more specific answer from a respondent. An interviewer should know the background of all questions (the information in the QxQ's) and why they are being asked. When the objective of a question is clear, the interviewer can judge whether a response is adequate or inadequate. In order to elicit complete, adequate answers, an interviewer often will need to use an appropriate neutral or nondirective probe. The important thing to remember when probing, is that an interviewer must not suggest answers or lead the respondent. General rules for probing follow.

A. The silent probe is one of the best. In a silent probe, the interviewer simply pauses or hesitates and looks to the respondent for an answer. An interviewer who is comfortable with the silence can usually elicit a good answer by silence.

B. Neutral questions or statements encourage a respondent to elaborate on an inadequate response. Examples of neutral probes are "What do you mean?," "Can you say some more about that?," "How do you mean?," "Tell me what you have in mind."

C. Clarification probes should be used when the response is unclear, ambiguous or contradictory. The interviewer should be careful not to appear to challenge the respondent when clarifying a statement and always use a neutral probe. Simply repeating what the respondent has just said is often an excellent probe in this situation. Hearing the response just given often stimulates the respondent to further thought.

D. Unless the form has a response of "Unknown," the "I don't know" response almost always requires a probe since this response can mean one of several things: (1) the respondent doesn't understand the question and say "don't know" to avoid saying he/she doesn't understand; (2) the respondent is thinking the question over and says "don't know" to fill the silence and gain time to think; (3) the respondent may be trying to evade the issue because he/she feels uninformed, is afraid of giving a wrong answer or the question seems to personal (4) the respondent may really not know.

Some of the questions in the ARIC study ask abut recall of events over time (smoking, medications, alcohol, etc.). You may assist the respondent without violating probing rules by working with him/her on math (such as calculating number of years the respondent did not smoke cigarettes) or pinpointing dates or events (such as age at which a parent was diagnosed with a specific disease). However, in the "helping" stages, an interviewer should not at any point suggest a date or number or any other specific information. The "helpfulness" needs to be in the form of neutral responses, i.e., "Can you recall the time of year that the event occurred?," "Please estimate the number of cigarettes that you smoked."

Standardized Interviewing Techniques

- Read Questions as Written
- Probe inadequte or ambiguous responses
- Record answers according to instructions
- Be interpersonally nonjudgmental about responses

Obstacles to Standardized Interviewing

- Inadequate instrument
- Inadequately trained respondent

Reasons Interviewers Fail to Standardize

- Goals in conflict - Truth vs. Standardization
- Goals of rapport in conflict with standardization
- Inadequate trained - failure to understand the role of the interviewer

PROBING TECHNIQUES

- SILENCE
- REPEAT THE QUESTION
- CLARIFY THE RESPONSE
- NEVER SUGGEST ANSWERS

TRAINING THE RESPONDENT

1. Introductory Script (one example)

I would like to read you a brief statement about how an interview such as this works. I am going to read you a set of questions exactly as they are worded so that every study respondent in ARIC is answering the same questions. You will be asked to answer two kinds of questions. Some times you will answer in your own words and other questions you will have a list of answers from which to choose. If at any time during the interview you are unclear about what is needed, please be sure to ask me.

2. When the interview begins, if the respondent fails to respond according to training, the interviewer should stop the interview and again state the conditions under which the questions are being ask.

SPECIFIC SITUATIONS

PROBLEM: Something about the sentence is not clear to the respondent or the answer they give is ambiguous.

INTERVIEWER:

I see what you are asking. I realize that sometimes these questions seem unclear to people even though they are written and carefully tested before they are in the field. Let me read the question for you again and you give me the best answer you can give.

PROBLEM: Respondent does not want to choose one of the answers.

INTERVIEWER:

I need you to pick an answer from one of the responses so that we can compare your responses with those of the many others in the study. I know that sometimes the answers are not exactly as you would like, but it is important that you respond with one of these answers.

PROBLEM: Respondent will not give an answer because it will only be a guess.

INTERVIEWER:

Well, we recognize the problem but we would like you to give your best estimate. Even though the answer may not be exactly right, no one is in a better position than you to make the estimate.

PROBLEM: A family member wants to help.

INTERVIEWER:

On factual questions, it is fine for you to have help, for example, with the dates of a hospitalization or the number of times that you have been in the hospital. But when it comes to feelings or opinions such as how you felt during the past week, it is important that you respond for yourself, based on what you think is best for you.

PROBLEM: Respondent asks the interviewer for help.

INTERVIEWER:

I would be happy to talk with you about the problem but we can do that after the interview is over. The reason is that in some cases when an interviewer discusses a question before hand, it changes in some manner how you may or may not respond to the question.

PROBLEM: Respondent does not seem to understand the "rules of the game," that is; the responses that they give do not match the response categories.

INTERVIEWER: The interviewer should review either the responses on the card or the types of responses that are required by the form with the respondent.

Appendix 2.3a V3 COHORT DES CXI

Move Save Cancel Problem Help Display Perm.Miss

ID: M122323 FORM: UPD VERSION: B CONTACT YEAR: 07
Search by ID Adding New Record

COHORT PARTICIPANT INVENTORY

Form	Year	Status	Form	Year	Status	Form	Year	Status
1. AFU	02	-	16. MSR	07	-			
2. AFU	03	-	17. PHX	07	-			
3. AFU	04	-	18. PNP	07	-			
4. AFU	05	-	19. REF	07	-			
5. AFU	06	-	20. REX	07	-			
6. AFU	07	-	21. RHX	07	-			
7. AFU	08	-	22. RPA	07	-			
8. AFU	09	-	23. SBP	07	-			
9. ANT	07	-	24. SNP	07	-			
10. CNF	07	-	25. TIA	07	-			
11. DTI	07	-	26. TIB	07	-			
12. FTR	07	-	27. UPD	07	-			
13. HHX	07	-	28. VEN	07	-			
14. MPR	07	-	29. VIT	07	-			
15. MSC	07	-						

Press any key to continue ...

(SMPD screen 1 of 1)

	SAMPLE TYPE	a. COLLECTED (Yes, No or Pending)	b. DATE OF COLLECTION (mm/dd/yy)	c. COMMENT
1.	Lipids	a~_	b~_____	c~_____
2.	Hemostasis	a~_	b~_____	c~_____
3.	ECG	a~_	b~_____	c~_____
4.	Ultrasound	a~_	b~_____	c~_____
5.	Urine (Minnesota)	a~_	b~_____	c~_____
6.	Urine (Hemostasis)	a~_	b~_____	c~_____
7.	Serum (UNC-Dental)	a~_	b~_____	c~_____
8.	Dental plaque	a~_	b~_____	c~_____

9~ Code number of person completing this form: ___ []

ARIC
Atherosclerosis Risk in Communities

Appendix 2.4a

COGNITIVE FUNCTION FORM

O.M.B. 0925-0281
exp. 09/30/98

ID NUMBER: | | | | | | | | CONTACT YEAR: | 1 | 0 | FORM CODE: | C | N | F | VERSION: C 01/30/96

LAST NAME: | | | | | | | | | | | | | INITIALS: | | |

PART A: DELAYED WORD RECALL

PLACE A CHECK IN THE COLUMN TO THE RIGHT OF EACH WORD AFTER THE PARTICIPANT HAS READ IT ALOUD AND USED IT IN A SENTENCE.

PLACE A CHECK IN THE 2ND COLUMN TO THE RIGHT OF EACH WORD AFTER THE PARTICIPANT HAS READ IT ALOUD AND USED IT IN A SENTENCE THE SECOND TIME.

AFTER THE COMPLETION OF THE DIGIT SYMBOL TEST, ASK THE PARTICIPANT TO RECALL THE 10 WORDS ORIGINALLY GIVEN:

CHECK OFF ALL THE WORDS RECALLED WITHIN 60 SECONDS.

	FIRST TIME	SECOND TIME	DELAYED WORD RECALL	
chimney	_____	_____	book	_____
salt	_____	_____	button	_____
harp	_____	_____	chimney	_____
button	_____	_____	finger	_____
meadow	_____	_____	flower	_____
train	_____	_____	harp	_____
flower	_____	_____	meadow	_____
finger	_____	_____	rug	_____
rug	_____	_____	salt	_____
book	_____	_____	train	_____

ID NUMBER: | | | | | | | | CONTACT YEAR: | 1 | 0 | FORM CODE: | C | N | F | VERSION: C 01/30/96

T NAME: | | | | | | | | | | | | | INITIALS: | | |

PART B: DIGIT SYMBOL SUBSTITUTION (DSS) TASK

10. DIGIT SYMBOL

1	2	3	4	5	6	7	8	9
—	⊥	⊐	L	⊔	O	^	X	=

SCORE

SAMPLES

⌐	1	3	7	2	4	8	2	1	3	2	1	4	2	3	5	2	3	1	4	5	6	3	1	4		
1	5	4	2	7	6	3	5	7	2	8	5	4	6	3	7	2	8	1	9	5	8	4	7	3		
6	2	5	1	9	2	8	3	7	4	6	5	9	4	8	3	7	2	6	1	5	4	6	3	7		
9	2	8	1	7	9	4	6	8	5	9	7	1	8	5	2	9	4	8	6	3	7	9	8	6		

ID NUMBER: | | | | | | | | CONTACT YEAR: | 1 | 0 | FORM CODE: | C | N | F | VERSION: C 01/30/96

LAST NAME: | | | | | | | | | | | | | INITIALS: | | |

PART B: DIGIT SYMBOL SUBSTITUTION (DSS) TASK

ID NUMBER: | | | | | | | | CONTACT YEAR: | 1 | 0 | FORM CODE: | C | N | F | VERSION: C 01/30/96

CNF SCORING SUMMARY

PART A: DELAYED WORD RECALL

ADD UP THE CHECK MARKS IN COLUMN 3, PART A AND ENTER THE TOTAL NUMBER OF RECALLED WORDS BELOW:

1. TOTAL WORDS RECALLED (CNFC, Part A): | | |

PART B: DIGIT SYMBOL SUBSTITUTION

APPLY THE DSS SCORING TEMPLATE TO THE RESPONSES ON PART B AND ENTER THE NUMBER OF CORRECT SYMBOLS BELOW:

2. TOTAL CORRECT SYMBOLS (CNFC, Part B): | | |

APPLY THE DSS SCORING TEMPLATE TO THE RESPONSES ON PART B AND ENTER THE NUMBER OF INCORRECT SYMBOLS BELOW:

3. TOTAL INCORRECT SYMBOLS (CNFC, Part B): | | |

PART C: WORD FLUENCY

ADD UP THE TOTAL NUMBER OF WORDS LISTED IN COLUMNS F, A, AND S ON PART C, AND ENTER THAT TOTAL BELOW:

4. TOTAL WORDS LISTED (CNFC, Part C): | | |

PART D: ADMINISTRATIVE INFORMATION

5. DATE OF DATA COLLECTION: | | | / | | | / | | |
   month day year

6. INTERVIEWER CODE NUMBER: | | | |

ID NUMBER: | | | | | | | | CONTACT YEAR: | 1 | 0 | FORM CODE: | C | N | F | VERSION: C 01/30/96

PART C: WORD FLUENCY TASK

START THE STOPWATCH. RECORD VERBATIM. DO NOT CORRECT ERRORS. IF THE PARTICIPANT STOPS, ENCOURAGE FURTHER RESPONSES. ALLOW 60 SECONDS FOR EACH LETTER. THE NEXT LETTER IS NOT GIVEN UNTIL THE ENTIRE 60-SECOND PERIOD HAS PASSED.

	F	A	S
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			
11.			
12.			
13.			
14.			
15.			
16.			
17.			
18.			
19.			
20.			

(CNFC screen 1 of 1)

CNF SCORING SUMMARY

PART A: DELAYED WORD RECALL

1~ TOTAL WORDS RECALLED: __

PART B: DIGIT SYMBOL SUBSTITUTION

2~ TOTAL CORRECT SYMBOLS: __

3~ TOTAL INCORRECT SYMBOLS: __

PART C: WORD FLUENCY

4~ TOTAL WORDS LISTED: __

PART D: ADMINISTRATIVE INFORMATION

5~ DATE OF DATA COLLECTION: _____
mm/dd/yy

6~ INTERVIEWER CODE NUMBER: ___

Appendix 2.4c

INSTRUCTIONS FOR THE COGNITIVE FUNCTION WORKSHEET
CNF, Version C, 01/30/96
PREPARED 02/05/96

I. GENERAL INSTRUCTIONS

1. Affix a participant ID label at the top of each page of the Cognitive Function (CNF) form, or complete the header information on all pages if labels are not available.

2. The CNF form is administered to participants at any point in the examination between the fixed components at the beginning and end of the field center visit.

3. Forms of participants who refuse to do the CNF activities are set to permanently missing in the DES.

4. The Digit Symbol Substitution Task (DSS) sheet remains unattached from the CNF form until completed by the participant.

5. Minimize extraneous noise in the testing environment as this may be distracting and affect test results.

6. The interviewer must sit quietly and minimize any movements to avoid distracting the participant.

7. Stopwatches/clocks are necessary to time all of the components of the cognitive function exam. The preferred option is a clock in clear view on the table or wall, allowing the interviewer to subtly glance at it to keep track of time. Hand-held chronometers can also be used. All efforts should be made to minimize the participant's awareness of the timing device to avoid producing anxiety and affecting test results.

8. Tape recorders cannot be used during the administration of the cognitive function forms.

9. Most participants will feel challenged; however, some will feel insecure and others possibly hostile. It is important for the interviewer's attitude to be friendly, non-threatening, reassuring and supportive throughout the tests. Interviewers should be sensitive to provide positive reinforcement at the end of each segment if appropriate.

10. Participants are often curious as to how well they did. Although scoring does not take place during the tests, the interviewer should reassure each participant who asks that he/she did as well as everybody else.

PART A: DELAYED WORD RECALL

11. READ TO PARTICIPANT:

> "This portion of the ARIC exam is to record your ability to remember words and symbols. It is like a word game or puzzle, but it is an important part of the exam."
>
> "I'm going to show you some words that I'd like you to remember. Please read along with me each word on the card, repeat the word out loud and then use it in a sentence which conveys the meaning of the word. Do not use words from a previous card in your sentence."

12. SAY EACH WORD AS YOU SHOW THE PARTICIPANT THE DELAYED WORD RECALL FLASH CARDS. This is to avoid problems with visually impaired or illiterate participants being treated differently.

Encourage the participants to form sentences that convey the meaning of the word. Offer suggestions or make corrections, if necessary, at any point during the procedure.

> For example, do not allow sentences like "The chimney is nice", but encourage statements like, "The smoke went up the chimney".

13. NO WORD LINKAGE IS ALLOWED. EACH SENTENCE MUST CONTAIN ONLY THE WORD ON THE CARD AND NOT INCLUDE PREVIOUS WORDS TO BE RECALLED.

SHOW THE CARDS, ONE AT A TIME.

If after repeating the first word the participant has difficulty constructing a sentence, PROVIDE THE FOLLOWING EXAMPLE:

> "The smoke went up the chimney."

14. PLACE A CHECK IN THE COLUMN TO THE RIGHT OF EACH WORD AFTER THE PARTICIPANT HAS READ IT ALOUD AND USED IT IN A SENTENCE. When all 10 words have been read and made into a sentence, ask the participant to REPEAT THE PROCESS. When repeating the list, the participant may use the same sentence or form a different sentence.

READ TO THE PARTICIPANT:

> "To help you to remember, we'll go through the words again. As before, I'll say each word aloud, you repeat after me and use it in a sentence. You may use the same sentence or make up a different one."

15. PLACE A CHECK IN THE 2ND COLUMN TO THE RIGHT OF EACH WORD AFTER THE PARTICIPANT HAS READ IT ALOUD AND USED IT IN A SENTENCE THE SECOND TIME.

16. When this process is completed, GO TO PART B: THE DIGIT SYMBOL TEST.

PART B: DIGIT SYMBOL SUBSTITUTION (DSS) TASK INSTRUCTIONS

17. DISCREETLY PICK UP THE STOPWATCH.

18. HAND THE PARTICIPANT A PENCIL WITHOUT AN ERASER. PLACE THE DIGIT SYMBOL FORM IN FRONT OF THE PARTICIPANT, POINT TO THE KEY ABOVE THE TEST ITEMS AND READ:

> "Next is a digit-symbol task. Look at these boxes. Notice that each has a number in the upper part and a mark or symbol in the lower part. Each number has its own mark."

19. POINT TO 1 AND ITS MARK, THEN TO 2 AND ITS MARK.

> "Now look down here where the boxes have numbers in the top part, but the squares at the bottom are empty."

20. POINT TO THE SAMPLE ITEMS.

> "You are to put in each of the empty squares the mark that should go there, like this:"

POINT TO THE FIRST SEVERAL SAMPLE SPACES.

> "Here is a 2; the 2 has this mark."

POINT TO THE FIRST SAMPLE ITEM, THEN TO THE MARK BELOW THE 2 IN THE KEY.

> "So I put it in this square, like this."

WRITE IN THE SYMBOL IN THE FIRST SAMPLE SQUARE. THEN SAY

> "Here is a 1; the 1 has this mark."

POINT TO THE SECOND SAMPLE ITEM, THEN TO THE MARK BELOW THE 1 IN THE KEY.

> "So I put it in this square."

WRITE IN THE SYMBOL IN THE SECOND SQUARE. THEN SAY

> "This number is 3; the 3 has this mark."

POINT TO THE THIRD SAMPLE ITEM, THEN TO THE MARK BELOW THE 3 IN THE KEY.

"So I put it in this square."

WRITE IN THE SYMBOL.

21. AFTER MARKING THE FIRST THREE SAMPLES ITEMS, SAY:

"Now you fill in the squares up to this heavy line."

22. NOTE: If the participant makes an error on a Sample item, correct the error immediately and review the use of the Key. Continue to help (if necessary) until the seven Sample items have been filled in correctly. Do not proceed with the test until the participant clearly understands the task. When the participant fills in a Sample item correctly, offer encouragement by saying

"Yes" or "Right,"

and finally,

"Yes, now you know how to do them."

23. During the Sample exercise, look to see if a left-handed participant blocks or partially blocks the Key when filling in the marks. If this occurs, place a separate Digit Symbol form next to the participant's worksheet on the participant's right-hand side so that the extra Key is aligned with the one blocked by the participant's hand. Have the participant use the separate Key to complete the Sample items and to take the actual test.

24. WHEN THE SAMPLE EXERCISE HAS BEEN COMPLETED SUCCESSFULLY SAY,

"When I tell you to start, you do the rest of them."

25. POINT TO THE FIRST TEST ITEM AND SAY,

"Begin here and fill in as many squares as you can, one after the other, without skipping any. Keep working until I tell you to stop. Go as fast as you can without making mistakes. If you make a mistake, do not erase. Mark over it with the correct symbol within the same box."

26. SWEEP ACROSS THE FIRST ROW WITH YOUR FINGER AND SAY,

"When you finish this line, go on to this one."

AND POINT TO THE FIRST ITEM IN ROW 2.

27. SAY "Go ahead,"

    AND BEGIN TIMING. NO SKIPS ARE ALLOWED. IF THE PARTICIPANT OMITS AN ITEM OR STARTS TO DO ONLY ONE TYPE (e.g., only the "1"s) SAY,

    "Do them in order. Don't skip any."

28. POINT TO THE FIRST ITEM OMITTED AND SAY,

    "Do this one next."

29. IF THE PARTICIPANT GETS TO THE END OF A LINE AND STOPS, SAY

    "Please go on to the next line."

30. GIVE NO FURTHER ASSISTANCE EXCEPT (IF NECESSARY) TO REMIND THE PARTICIPANT TO CONTINUE UNTIL INSTRUCTED TO STOP.

31. Timing must be precise on this test. AT THE END OF 90 SECONDS, SAY

    "That is all we have time for. Thank you. No one is able to do all of them."

32. AFTER THE COMPLETION OF THE DIGIT SYMBOL TEST, ASK THE PARTICIPANT TO RECALL THE 10 WORDS ORIGINALLY GIVEN AS FOLLOWS:

    "Please tell me the words that you recall from the first task when you were asked to read several words and use them in a sentence."

33. ONCE THESE INSTRUCTIONS HAVE BEEN GIVEN, START THE STOPWATCH. Use the stopwatch discreetly to avoid creating anxiety or a sense of time pressure.

34. USING PAGE 1, COLUMN 3 OF THE WORKSHEET, CHECK OFF ALL THE WORDS RECALLED WITHIN 60 SECONDS.

35. IF THE PARTICIPANT STOPS, ENCOURAGE FURTHER RESPONSES. This encouragement may be necessary because some participants may spontaneously report fewer words than they actually could recall with further effort. When the respondent indicates that he/she cannot remember any more words, or after 60 seconds, READ:

    "That will be fine. Thank you. Nobody is able to remember all these words."

PART C: WORD FLUENCY

36. EXPLAIN THE RULES TO THE PARTICIPANT AS FOLLOWS:

> "I will say a letter and you are to tell me all the different words you can think of beginning with that letter. Leave out proper names, names of places, or numbers. So, if I were to say 'T', you would not use 'Thomas', 'Tennessee', or 'ten', but such words as 'table' or 'take' would be fine. They should be different words, not the same word with different endings (for example, take, takes, and taking would be considered the same word, but take and took would be two.) Are you ready? Tell me words that start with __. Go ahead, I will tell you when to stop."

37. START STOPWATCH. RECORD VERBATIM. DO NOT CORRECT ERRORS.

38. If the participant cannot think of any more words, sit quietly by and wait 15 seconds. AFTER 15 SECONDS OF SILENCE ASK,

"Can you think of others that begin with the letter __?"

Do not stop the test until the entire 60 seconds is over.

39. If the participant repeats a word or makes an error (as an example, gives a name), simply say:

"That's okay; just go on."

Under no circumstances should you ever interrupt the exam to make a clarification.

40. While recording the words, if you cannot keep up with the words being listed and you miss a word, but are certain that the participant produced an acceptable answer, place an X on the line to indicate the participant should receive credit for the word.

41. Allow 60 seconds for each letter. The next letter is not given until the entire 60 second period has passed. At the end of the third letter, SAY:

"That is all we have to do. Thank you. You did well."

42. After the participant has left the room, proof all the responses for readability. Draw a single straight line through any duplicate responses. Clarify any words that may have been unclear during the time the test was being given. If you are unable to spell the word, write it out phonetically.

43. Check any ambiguous words in the dictionary only after the

participant has left the room.

II. CNF SCORING SUMMARY (WORKSHEET PAGE 4)

1. The score for DELAYED WORD RECALL is the total number of words recalled following the DSS and is equal to the number of words checked on Page 1, column 3. ENTER THAT NUMBER ON PAGE 4 OF THE CNF WORKSHEET, ITEM 1 (CNFC, Q.1)

2. Scoring of the DIGIT SYMBOL SUBSTITUTION (DSS) TEST is done after the participant has completed all three parts of the cognitive function interview. The DSS score is based on the number of symbols correctly coded in 90 seconds.

   For participants who are unable to understand or take the test, ENTER "=" IN BOTH SCORE BOXES ON PAGE 4 OF THE CNF WORKSHEET, ITEMS 2 AND 3 (CNFC, Q.2 AND Q.3).

   When part of the sample is attempted, but the participant refuses to complete the actual test, enter "=" for both scores, as above.

3. PLACE THE TEMPLATE OVER THE DSS TEST AND COUNT THE NUMBER OF CORRECT AND INCORRECT SYMBOLS. A figure is scored as correct if it is clearly identifiable as the keyed figure, even if it is drawn imperfectly or if it is a spontaneous correction of an incorrect figure.

   Give 1 point for each item filled in correctly. If there is more than one symbol in the box, and one of them is correct, give the participant credit. The seven Sample items are <u>not</u> included in the participant's score.

   Credit is not given for items completed out of sequence.

   Blank spaces between two completed items receive <u>no credit</u> towards the participant's scores. This rule is not in the WAIS-R manual. It is the responsibility of the interviewer to notice and correct skips. (Refer to step 24 on page 4.)

   If the "U" symbol is recorded as "V", give full credit.

4. ENTER THE NUMBER OF <u>CORRECT</u> SYMBOLS ON PAGE 4 OF THE CNF WORKSHEET, ITEM 2 (CNFC, Q.2). (Do not count blank spaces between two completed items.)

5. ENTER THE NUMBER OF <u>INCORRECT</u> SYMBOLS ON PAGE 4 OF THE CNF WORKSHEET, ITEM 3 (CNFC, Q.3). (Do not count blank spaces between two completed items.)

6. In scoring the Word Fluency test, no proper names are allowed.

Plurals or normal suffixes are not allowed and only "count" once (e.g., take, takes, taking). However a different form of the word, such as "took," can be counted in addition to take.

Words like someone, something, somebody can all be "counted" separately. Homonyms like "ant" and "aunt" can both be counted if given consecutively and the participant states it as two different words. If given apart, it will be assumed that the participant is simply being repetitious (unless specified to the contrary). Under no circumstances should the interviewer interrupt the exam to make a clarification.

7. Any foreign words in standard American usage found in your dictionary are acceptable. For example, "apropos" probably would count, whereas, "señorita" might not. Each center should have the same standard dictionary in clinic.

8. The score for the WORD FLUENCY TEST is the total acceptable number of words listed in all 3 columns of page 3 of the CNF Worksheet. ENTER THAT NUMBER ON PAGE 4 OF THE CNF WORKSHEET, ITEM 4 (CNFC, Q.4)

9. ENTER THE DATE OF DATA COLLECTION ON PAGE 4 OF THE CNF WORKSHEET, ITEM 5 (CNFC, Q.5).

10. ENTER THE CODE NUMBER OF THE INTERVIEWER WHO ADMINISTERED THIS FORM ON PAGE 4 OF THE CNF WORKSHEET, ITEM 6 (CNFC, Q.6).

ARIC
Atherosclerosis Risk in Communities

Appendix 2.5a

O.M.B. 0925-0281
exp. 09/30/98

DENTAL HISTORY FORM

ID NUMBER: | | | | | | | | CONTACT YEAR: | 1 | 0 | FORM CODE: | D | H | S | VERSION: A 07/24/96

LAST NAME: | | | | | | | | | | | | | INITIALS: | | |

Public reporting burden for this collection of information is estimated to average 3 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: **PHS Reports Clearance Officer, Rm. 737-F, Humphrey Building, 200 Independence Ave., SW, Washington, D.C. 20201, ATTN: PRA (0925-0281).** Do not return the completed form to this address.

INSTRUCTIONS: This form is completed during the participant's visit. ID Number, Contact Year and Name must be entered above. Whenever numerical responses are required, enter the number so that the last digit appears in the rightmost box. Enter leading zeroes where necessary to fill all boxes. On the paper form, if a number is entered incorrectly, mark through the incorrect entry with an "X". Code the correct entry clearly above the incorrect entry. For "multiple choice" questions, circle the letter corresponding to the most appropriate response. If a letter is circled incorrectly, mark through it with an "X" and circle the correct response.

DENTAL HISTORY FORM (DHSA screen 1 of 4)

1. Have you lost any of your natural teeth? .....Yes Y

   Go to Item 5, Screen 1. ——— No N

2. Did you lose any teeth because of:

	Yes	No	Unknown
a. Cavities	Y	N	U
b. Gum disease	Y	N	U
c. Accident	Y	N	U
d. Wisdom teeth pulled	Y	N	U
e. Extracted because of overcrowding	Y	N	U
f. Other	Y	N	U

3. Do you have false teeth? ..... Yes Y

   Go to Item 5, Screen 1. ——— No N

4. How old were you when you got your first false teeth? ..... | | | age

5. Have you ever noticed any of your teeth were loose? Do not include the times when you lost your baby teeth, had braces, or had a tooth hit and made loose..... Yes Y

   No N

   Unknown U

DENTAL HISTORY FORM (DHSA screen 2 of 4)

6.a. Have you ever had a root canal done? .... Yes Y

Go to Item 7. — No N

Unknown U

b. Did you have a root canal done on more than one tooth? ..... Yes Y

No N

Unknown U

7. Have you ever had a dental implant? ..... Yes Y

No N

8. How often did you brush your teeth yesterday?

Not at all ..... A

One time ..... B

Two times C

Three times or more ..... D

9. How often did you use dental floss last week?

Not at all ..... A

One time ..... B

Two times C

Three times or more ..... D

DENTAL HISTORY FORM (DHSA screen 3 of 4)

10. When was the last time you went to the dentist for any reason?

Within the last 6 months ..... A

6 months to less than 1 year ago ... B

1 to less than 2 years ago C

2 to less than 3 years ago ..... D

3 to less than 5 years ago ..... E

5 or more years ago ..... F

11. Would you say that you use a dentist on a regular basis, or do you only go when you are in discomfort or when you need something fixed?

Regular basis ..... A

Only when in discomfort ..... B

When something needs to be fixed C

Don't go to the dentist ..... D

Other ..... E

12. Do you have a dentist? ..... Yes Y

No N

DENTAL HISTORY FORM (DHSA Screen 4 of 4)

13. Date of collection: | | | / | | | / | | |

14. Method of data collection: ..... Computer C
Paper P

15. Code Number of person completing this form: ..... | | | |

(DHSA screen 1 of 4)

1~ Have you lost any of your natural teeth? _ []

Yes(Y) or No(N)*

2. Did you lose any teeth because of:

Yes(Y), No(N) or Unknown(U)

a~ Cavities _ []
b~ Gum disease _ []
c~ Accident _ []
d~ Wisdom teeth pulled _ []
e~ Extracted because of overcrowding _ []
f~ Other _ []

3~ Do you have any false teeth?

Yes(Y) or No(N)*

4~ How old were you when you first got your false teeth? __ [] age

5~ Have you ever noticed any of your teeth were loose? Do not include the times when you lost your baby teeth, had braces, or had a tooth hit and made loose. _ []

Yes(Y), No(N) or Unknown(U)

(DHSA screen 2 of 4)

6a~ Have you ever had a root canal done? _ []

Yes(Y), No(N)* or Unknown(U)*

b~ Did you have a root canal done on more than one tooth? _ []

Yes(Y), No(N) or Unknown(U)

7~ Have you ever had a dental implant? _ []

Yes(Y) or No(N)

8~ How often did you brush your teeth yesterday? _ []

Not at all (A)
One time (B)
Two times (C)
Three times or more (D)

9~ How often did you use dental floss last week? _ []

Not at all (A)
One time (B)
Two times (C)
Three times or more (D)

(DHSA screen 3 of 4)

10~ When was the last time you went to the dentist for any reason? _ ▯

Within the last 6 months	(A)
6 Months to less than 1 year ago	(B)
1 to less than 2 years ago	(C)
2 to less than 3 years ago	(D)
3 to less than 5 years ago	(E)
5 or more years ago	(F)

11~ Would you say that you use a dentist on a regular basis, or do you only go when you are in discomfort or when you need something fixed? _ ▯

Regular basis	(A)
Only when in discomfort	(B)
When something needs to be fixed	(C)
Don't go to the dentist	(D)
Other	(E)

12~ Do you have a dentist? _ ▯

Yes(Y) or No(N)

(DHSA screen 4 of 4)

13~ Date of collection: _____ ▯
mm/dd/yy

14~ Method of data collection: _ ▯

Computer(C) or Paper(P)

15~ Code number of person completing this form: ___ ▯

INSTRUCTIONS FOR THE DENTAL HISTORY FORM
DHS, VERSION A, 7/24/96
PREPARED 4/25/97

I. GENERAL INSTRUCTIONS

The Dental History form is administered to all ARIC participants, regardless of whether they are eligible for the dental examination. The form documents aspects of the participant's dental status which may be related to a history of chronic inflammation. It includes questions on the cause(s) of tooth loss, loose teeth, false teeth, root canal(s), dental implant(s), frequency of teeth brushing and flossing, and the use of dental care.

II. DETAILED INSTRUCTIONS FOR EACH ITEM

1. **Have you lost any of your natural teeth?** Natural teeth may be defined as the teeth you got as you were growing up. It DOES NOT refer to a person's baby teeth. A response of YES means the person has lost at least one natural tooth, for any reason, any time prior to the interview. If YES, continue with Item 2. If NO, go to Item 5.

2. **Did you lose any teeth because of:** Read the introductory phrase and all the causes listed in Items a-f. Record a response of YES, NO, or UNKNOWN for each reason. In general, the loss of any one tooth will be due to just one cause. The multiple causes are listed to cover the loss of more than one tooth. There may be exceptions. For example, when a participant reports both the loss of a natural tooth (teeth) because it rotted out and severe gum disease prior to the loss of that tooth, it may not be possible to determine which condition lead to the tooth's removal. In that case, you would select YES for both cavities (a) and gum disease (b). The exception to these guidelines for multiple causes is for wisdom teeth. When wisdom teeth (tooth) have been extracted, record YES for Item 2.d and NO for Item 2.e (even if due to overcrowding), unless teeth other than the wisdom teeth have also been pulled for overcrowding.

3. **Do you have false teeth?** A response of YES means the person has one or more artificial teeth that replace teeth which have been extracted (or lost due to an accident), such as a "plate", "bridge", "uppers" or "lowers". It does not refer to a "crown", "implant", or an "inlay". If NO, go to Item 5. If YES, continue with Item 4.

4. **How old were you when you got your first false teeth?** Read the question stressing the person's age when the "first" false teeth were received, especially if the person has reported receiving more than one set of false teeth. If the person cannot remember the exact age, ask for a best guess. The question can be repeated inserting the word "approximately" at the beginning of the sentence.

5. **Have you ever noticed any of your teeth were loose? Do not include the times when you lost your baby teeth, had braces, or had a tooth hit and made loose.** A response of YES means the person has had one or more natural (adult) teeth that were not securely held in place by the gums, and not as the result of an external cause, such as braces or trauma to the jaw.

6.a **Have you ever had a root canal done?** A root canal can be defined as a dental procedure to remove the tooth's nerve when the tooth has "died" or in preparation for an extensive filling, inlay or crown. A response of YES means the person has had at least one root canal performed on a natural (adult) tooth prior to the interview. Continue with Item 6.b. When the response is NO or UNKNOWN, go to Item 7.

6.b **Did you have a root canal done on more than one tooth?** Self explanatory.

7. **Have you ever had a dental implant?** A dental implant may be defined as an artificial tooth that is surgically implanted (placed) in the mouth by screwing the tooth into the jaw bone. It is very unlikely that a person with dental implants will be unaware of them, as the procedure requires lengthy surgery and recovery.

When an interviewer has been told explicitly by an ARIC participant that he or she has no natural teeth and no dental implants (this information can be obtained from several questions, such as Item 1, 3 or 7) the interviewer does not read Items 8 or 9 out load to the participant. However, the interviewer must enter a response of "A" (not at all) to both questions. For these two questions, "not at all" also means "not applicable". When an interviewer is not absolutely certain that the participant has no teeth to brush or floss, Items 8 and 9 are read.

8. **How often did you brush your teeth yesterday?** Read the question and select the response category which corresponds to the person's answer. Unless the person did not sleep before the ARIC exam (e.g., came directly from work), "yesterday" can be defined as the period of time the person was awake prior to retiring the night before the clinic exam.

9. **How often did you use dental floss last week?** If asked, "last week" refers to the six days immediately preceding the date the questionnaire is administered.

10. **When was the last time you went to the dentist for any reason?** Read the question and select the response category which corresponds to the person's answer. "Dentist" can be defined in terms of an individual practitioner or a clinical setting (facility) in which dentistry is practiced.

11. **Would you say that you use a dentist on a regular basis, or do you only go when you are in discomfort or when you need something fixed?** The response categories are based on the options offered in the question. A separate response category is provided for people who don't go to the dentist, or for those whose response fits other situations not listed above. Although the second and third options are not necessary mutually exclusive, the distinguishing characteristic between the two choices is that the

person is responding to the pain in option "B" in contrast to responding to the need to have dental work done (option "C"), regardless of the level of discomfort. If both options are applicable, select "B". If probing is required to differentiate between options "B" and "C", you can say "If you had to choose between the two, would you say that you only go to a dentist when you are in discomfort OR (pause) when you need something fixed?"

12. **Do you have a dentist?** "Dentist" can be defined in terms of an individual practitioner or a clinical setting (facility) in which dentistry is practiced. This question is asked to confirm the response of the people who reported seeing a dentist "on a regular basis" in Item 11. Do not go back and revise the response to Item 11 when the responses to Items 11 and 12 are inconsistent unless the participant specifically asks to do so.

13. **Date of data collection.** Using the standard date format, enter the date on which the form was administered.

14. **Method of data collection.** Select "C" if the data were directly entered into the data entry system or "P" if the data were recorded on the paper form for delayed data entry.

15. **Code number of person completing this form.** Enter the interviewer's ID code.

LIST OF IMMUNOSUPPRESSIVE DRUGS FOR ITEM 14 OF DENTAL SCREENING FORM

Prepared 3/19/97

AMCINONIDE (CYCLOCORT)

BECLOMETHASONE DIPROPIONATE (VANCERIL)

BETAMETHASONE DIPROPIONATE (Diprosone)

CHLORAMBUCIL (leukeran)

CORTISONE ACETATE (Cortone)

DESONIDE (Tridesilon)

DESOXIMETASONE (TOPICORT)

Diflorasone diacetate (FLORONE, MAXIFLOR)

FLUDROCORTISONE ACETATE (FLORINEF)

FLUOCINOLONE ACETONIDE (Synalar)

FLUOCINONIDE (Lidex, Topsyn)

FLUOROMETHOLONE (Oxylone)

FLURANDRENOLIDE USP (Cordan)

HALCINONIDE USP (Halog)

Hydrocortisone Acetate (Cortril, Orabase)

Hydrocortisone (Cortef, Texacort)

MELPHALAN (alkeran)

LIST OF IMMUNOSUPPRESSIVE DRUGS FOR ITEM 14 OF DENTAL SCREENING FORM (continued)

METHOTREXATE

Prednisolone (Meticorten)

Prednisone (DELTASONE)

Prednisone Phosphate (HYDELTRASOL or SAVACORT-S)

TAMOXIFEN

tamoxifen (NOLVADEX)

TRIAMCINOLONE ACETONIDE (Aristocort)

TRIAMCINOLONE ACETONIDE (MYCOLOG)

ARIC
Atherosclerosis Risk in Communities

Appendix 2.6a

DENTAL SCREENING FORM

O.M.B. 0925-0281
exp. 09/30/98

ID NUMBER: | | | | | | | | CONTACT YEAR: | 1 | 0 | FORM CODE: | D | S | R | VERSION: A 09/15/96

LAST NAME: | | | | | | | | | | | | | INITIALS: | | |

Public reporting burden for this collection of information is estimated to average 4 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: **PHS Reports Clearance Officer, Rm. 737-F, Humphrey Building, 200 Independence Ave., SW, Washington, D.C. 20201, ATTN: PRA (0925-0281).** Do not return the completed form to this address.

INSTRUCTIONS: This form is completed when scheduling Visit 4. ID Number, Contact Year and Name must be entered above. Whenever numerical responses are required, enter the number so that the last digit appears in the rightmost box. Enter leading zeroes where necessary to fill all boxes. If a number is entered incorrectly, mark through the incorrect entry with an "X". Code the correct entry clearly above the incorrect entry. For "multiple choice" and "yes/no" type questions, circle the letter corresponding to the most appropriate response. If a letter is circled incorrectly, mark through it with an "X" and circle the correct response.

DENTAL SCREENING FORM (DSRA Screen 1 of 3)

1.a Do you have ANY of your natural teeth? ..... Yes Y → Go to Item 2. / No N

1.b Do you have any dental implants? ..... Yes Y / No N → Exclude. Go to Item 15.

2. Has a dentist or a physician ever told you that you need to take antibiotics before every dental visit? ..... Yes Y → Exclude. Go to Item 3. / No N → Go to Item 4.

3. Why: _____
_____
_____
Exclude. Go to Item 15.

Has a doctor ever told you that you have any of the following?

4. congenital heart disease? Yes Y / No N / Unknown U → Exclude. Go to Item 15.

5. rheumatic heart disease? Yes Y / No N / Unknown U → Exclude. Go to Item 15.

6. a heart murmur from a defect in the structure of the heart? Yes Y / No N / Unknown U → Exclude. Go to Item 15.

7. an infection of the lining of the heart called endocarditis? Yes Y / No N / Unknown U → Exclude. Go to Item 15.

8. mitral valve prolapse? Yes Y / No N / Unknown U → Exclude. Go to Item 15.

9. Do you have a cardiac pacemaker? Yes Y / No N / Unknown U → Exclude. Go to Item 15.

DENTAL SCREENING FORM (DSRA Screen 2 of 3)

10.	Have you had a heart, kidney, or other organ transplant?	Yes No Unknown	Y N U	Exclude. Go to Item 15.
11.	Do you have a surgically implanted heart valve, stent, shunt or artificial joint?	Yes No Unknown	Y N U	Exclude. Go to Item 15.
12.	Are you on kidney dialysis?	Yes No Unknown	Y N U	Exclude. Go to Item 15.
13.	Have you had major surgery, radiation, or chemotherapy for cancer within the last 2 months?	Yes No Unknown	Y N U	Exclude. Go to Item 15.
14.	Are you taking prednisone or an immunosuppressive medication?	Yes No Unknown	Y N U	Exclude. Go to Item 15.

15. The participant meets an exclusion criterion from the screening interview?

Yes	Y	---->	EXCLUDE, read exclusion statement
No	N	---->	RECRUIT, read recruitment statement

EXCLUSION STATEMENT:

Because you (SELECT THE RELEVANT STATEMENT BELOW):

-- do not have any of your natural teeth

-- have been told by a dentist that you need to take antibiotics before every dental visit

-- have a medical condition that might require you to have antibiotics before a dental examination

it may not be useful or safe for you to participate in this portion of the study. However, we will be asking you some questions about your dental history as part of the ARIC visit. [GO TO ITEM 17.]

DENTAL SCREENING FORM (DSRA Screen 3 of 3)

RECRUITMENT STATEMENT:

You are eligible to take part in this new study on the effect of infections on heart disease. Read DESCRIPTION OF DENTAL EXAM. Do you have any questions?

[CONTINUE WITH ITEM 16.]

16. May I schedule you for the dental exam?

Yes	Y	---> READ REMINDER
No	N	---> EXCLUDE

****

17. Date of telephone interview: __ __/__ __/__ __

18. Code Number of person completing telephone interview: __ __ __

DESCRIPTION OF DENTAL EXAM for ITEM 16.

This portion of the study includes a simple examination of your mouth to see if there are any cavities, gum disease or spaces between your teeth and gums. We will also collect a little plaque and pick up some fluid from around your teeth. Most people find these procedures quite comfortable.

REMINDER FOR PARTICIPANTS SCHEDULED FOR DENTAL EXAM.

The usual procedure in ARIC is to send your doctor a copy of your results reports. If you would like us to send your dentist a copy of your dental exam report, please bring his or her name and address with you when you come for your appointment.

Appendix 2.6b

(DSRA screen 1 of 3)

1a~ Do you have ANY of your natural teeth? _ [ ]
Yes(Y)* or No(N)

b~ Do you have any dental implants? _ [ ]
Yes(Y) or No(N)*

2~ Has a dentist or a physician ever told you that you need to take antibiotics before every dental visit? _ [ ]
Yes(Y) or No(N)*

3~ Why:(*) _____ [ ]
_____
_____
[Exclude. Go to Item 15, Screen 2.]

Has a doctor ever told you that you have any of the following?
[Items 4 - 8]
Yes(Y)*, No(N) or Unknown(U)

4~ Congenital heart disease? _ [ ]

5~ Rheumatic heart disease? _ [ ]

6~ A heart murmur from a defect in the structure of the heart? _ [ ]

7~ An infection of the lining of the heart called endocarditis? _ [ ]

8~ Mitral valve prolapse? _ [ ]

9~ Do you have a cardiac pacemaker? _ [ ]
Yes(Y)*, No(N) or Unknown(U)

(DSRA screen 2 of 3)

[ITEMS 10-14]
Yes(Y)*, No(N) or Unknown(U)

10~ Have you had a heart, kidney or other organ transplant? _ [ ]

11~ Do you have a surgically implanted heart valve, stent, shunt or artificial joint? _ [ ]

12~ Are you on kidney dialysis? _ [ ]

13~ Have you had major surgery, radiation, or chemotherapy for cancer within the last 2 months? _ [ ]

14~ Are you taking prednisone or an immunosuppressive medication? _ [ ]

15~ The participant meets an exclusion criterion from the screening interview? _ [ ]
Yes(Y)* or No(N)*

15y_ [ ] **** EXCLUSION STATEMENT: *****
Because you (SELECT THE RELEVANT STATEMENT BELOW):
- do not have any of your natural teeth
- have been told by a dentist that you need to take antibiotics before every dental visit
- have a medical condition that might require you to have antibiotics before a dental examination

it may not be useful or safe for you to participate in this portion of the study. However, we will be asking you some questions about your dental history as part of the ARIC visit.

(DSRA screen 3 of 3)

15z_ [ ] RECRUITMENT STATEMENT:
You are eligible to take part in this new study on the effect of infections on heart disease. READ DESCRIPTION OF DENTAL EXAM. Do you have any questions?

[Continue with Item 16.]

16~ May I schedule you for the dental exam? _ [ ]

Yes(Y) -READ REMINDER or No(N)

17~ Date of telephone interview: _____ [ ]
mm/dd/yy

18~ Code number of person completing telephone interview: ___ [ ]

DESCRIPTION OF DENTAL EXAM -ITEM 16
This portion of the study includes a simple examination of your mouth to see if there are any cavities, gum disease or spaces between your teeth and gums. We will also collect a little plaque and pick up some fluid from around your teeth. Most people find these procedures quite comfortable.

REMINDER FOR PARTICIPANTS SCHEDULED FOR DENTAL EXAM.
The usual procedure in ARIC is to send your doctor a copy of your results reports. If you would like us to send your dentist a copy of your dental exam report, please bring his or her name and address with you when you come for your appointment.

INSTRUCTIONS FOR THE DENTAL SCREENING FORM
DSR, VERSION A, 9/15/96
PREPARED 5/5/97

I. GENERAL INSTRUCTIONS

The Dental Screening form is usually administered during the recruitment/scheduling call. It could also be administered at reception if eligibility to participate in the dental exam has not been established prior to the clinic visit. The purpose of the form is to determine whether an ARIC participant is eligible for the Dental Component of the exam. This includes identifying individuals who might be placed at risk were they to have a dental examination without the use of an antibiotic immediately prior to, and following a dental exam. These exclusion criteria are based on the American Heart Association guidelines for the identification of individuals at higher than acceptable risk of contracting endocarditis without the prophylactic use of antibiotics prior to any dental examination or procedure. ARIC participants who require this type of medication and express an interest in having the dental exam can be recruited into the study if they agree to take the antibiotics required for a dental examination. These antibiotics have to be prescribed by a dentist or physician, with knowledge of the date of the ARIC exam. (A special note is written on the Dental Exam Informed Consent for the person to acknowledge having an exclusion criterion and taking the required antibiotics).

The DENTAL SCREENING questions begin by determining whether the person has any teeth on which to observe the presence of periodontal disease or whether the person would be placed at risk if a dental examination were performed without coverage by an antibiotic. As soon as an exclusion criterion is identified, circle the appropriate response category and skip to Item 15. Select the YES category (the person meets an exclusion criterion), circle EXCLUDE and read the appropriate statement which explains to the person why it may not be useful or safe for participation in this portion of the study.

When a participant is uncertain about the need to have antibiotic medication prescribed for all dental exams or procedures or is uncertain whether he/she has one of the medical conditions listed in Items 4-14, the interviewer selects UNKNOWN, does NOT exclude the person, BUT encourages the person to contact his/her doctor or dentist and resolve the uncertainty prior to coming to the ARIC exam. In situations where it is unclear during the telephone interview that a participant meets an exclusion criterion, questions about eligibility should be discussed and resolved with the ARIC clinic physician before telling the person that she/he is not eligible to participate.

II. DETAILED INSTRUCTIONS FOR EACH ITEM DURING THE RECRUITMENT SCREENING CALL.

1.a **Do you have ANY of your natural teeth?** Natural teeth may be defined as the teeth you got as you were growing up. A response of YES means the person has at least one natural tooth visible above the gum line. If YES, continue with Item 2. A response of NO means there are no visible teeth, regardless of whether the roots are present, or the person is unsure as to whether there are any visible natural teeth. Continue with Item 1.b.

1.b **Do you have any dental implants?** Dental implants may be defined as replacement teeth that are surgically implanted (placed) in the mouth by a dentist. It is very unlikely that a person with dental implants will be unaware of having them, as these teeth are screwed into the jaw bone, a procedure which requires lengthy surgery and recovery. Persons who have no natural teeth, but have dental implants, can be evaluated for periodontal disease, and therefore are NOT excluded. If a person has dental implants, select YES and continue with Item 2. If the person has no natural teeth and no dental implants, select NO. This person is not eligible to have a periodontal examination. Go to Item 15, select YES, circle EXCLUDE, and read the first option in the EXCLUSION STATEMENT:

> "Because you
>
> -- do not have any of your natural teeth, it may not be useful or safe for you to participate in this portion of the study."

Indicate to the participant, however, that everyone will be asked questions about their dental history. Continue with Item 17.

2. **Has a dentist or a physician ever told you that you need to take antibiotics before every dental visit?** A response of YES means that the person has previously been told (time frame unspecified) by their dentist or a medical doctor that he/she should routinely take an antibiotic before any kind of dental exam or procedure. If YES, select YES. Ask why they were told to take an antibiotic, and record the reason in the space provided in Item 3. Note that it is not necessary that the reason for taking the antibiotic is included in the AHA guidelines. A positive response, for what ever reason, means the person is not eligible to have a periodontal exam. Go to Item 15, select YES, circle EXCLUDE, and read the second option in the EXCLUSION STATEMENT:

> "Because you
>
> -- have been told by a dentist that you need to take antibiotics before every dental visit

it may not be useful or safe for you to participate in this portion of the study."

Indicate to the participant, however, that everyone will be asked questions about their dental history. Continue with Item 17.

A response of NO means the person has not been told to take antibiotics before dental exams. Select NO, and skip to Item 4. Read the TRANSITION STATEMENT (Has doctor ever told you that you have any of the following?). If in doubt, also select UNKNOWN, BUT (1) ask the participant to check with his/her dentist or doctor before coming to the field center and (2) leave a note for the examiner that the participant is going to check with his/her dentist/doctor and that he/she will need to probe the response to this question when the form is re-administered at the field center.

4-8. **Has a doctor ever told you that you have any of the following?** Read the introductory portion of the question, stressing physician diagnosis (has a doctor) and the life time applicability of the question (ever told you), and then read each medical condition until the participant reports a positive condition or you complete the list. Circle the appropriate response. Participants who don't know if they have the condition are not excluded. However, (1) ask the participant to check with his/her doctor before coming to the field center and (2) leave a note for the examiner that the participant is going to check with his/her doctor and that he/she will need to probe the response to Item 2 when the form is re-administered at the field center. Definitions of the medical terms are printed in the table at the end of the instructions and may be read to participants if they are unclear as to whether they have the condition. A positive response (YES) requires the person (or a surrogate, such as a parent) to have been given the diagnosis by a physician. If there is a positive response, select YES. No further questions about exclusion criteria need to be administered. Go to ITEM 15. Select YES, circle EXCLUDE and read the third option in the EXCLUSION STATEMENT:

"Because you

-- have a medical condition that might require you to have antibiotics before a dental examination,

it may not be useful or safe for you to participate in this portion of the study."

Indicate to the participant, however, that everyone will be asked questions about their dental history. Continue with Item 17.

9. **Do you have a cardiac pacemaker?** Record the response. When the response is NO or UNKNOWN, continue with the next question. When the

response is positive, select YES, and go to Item 15. Select YES and circle EXCLUDE. Read the third option of the exclusion statement to the participant and indicate to the participant, however, that everyone will be asked questions about their dental history by the examiner. Continue with Item 17. In situations where it is unclear during the telephone interview that a participant meets an exclusion criterion, questions about eligibility should be discussed and resolved with the ARIC clinic physician before telling the person that she/he is not eligible to participate.

10. **Have you had a heart, kidney or other organ transplant?** Follow the procedures for Item 9.

11. **Do you have a surgically implanted heart valve, stent, shunt or artificial joint?** Follow the above procedures.

12. **Are you on kidney dialysis?** Follow the above procedures. Because of the skip rules, this question will not be asked if the person has had a kidney transplant.

13. **Have you had major surgery, radiation, or chemotherapy for cancer within the last 2 months?** The object of the question is to identify persons who have been treated for cancer within the past 2 months who might also need a prophylactic antibiotic for a dental exam or procedure. For example, persons who have had minor surgery to remove a skin cancer without adjuvant radiation or chemotherapy need not be excluded from the dental exam. However, all situations which involve questionable eligibility should be discussed and resolved with the clinic physician before telling the person that she/he is or is not eligible to participate.

14. **Are you taking prednisone or an immunosuppressive medication?** Because of the skip rules for persons with positive responses to organ transplants, artificial joints, or the treatment of cancer within the past 2 months, this question will not have to be asked of the majority of people who would most likely be taking medications to suppress their immune system. Participants who don't know if they are taking prednisone or other immunosuppressive medication are not excluded. A representative (but not inclusive) list of immunosuppressant medications is provided at the end of these instructions. You are only excluding people who take prednisone or other immunosuppressive medication(s) orally or by injection. For example, inhaled steroids, nose sprays with steroids, or topical medications, such as hydrocortisone creams, do NOT disqualify a person from having the dental examination. When a participant's response is positive, ask "How are you taking this medication?" to make sure that the route of administration is not topical. If the medication(s) in question is not on the list, (1) ask the participant to check with his/her doctor before coming to the field center and (2) leave a note for the dental examiner that the participant is going to check with his/her doctor. The participant's eligibility status should be resolved when

the dental examiner asks "since the time you agreed to participate in the dental examination, have you had any additional health problems or has your dentist told you that you need to take antibiotics before a dental appointment?"

15. **The participant meets one exclusion criterion from the screening interview?** In general, as soon as a participant meets an exclusion criterion, no more exclusion conditions are filled out. Select YES, circle EXCLUDE, read the relevant option of the exclusion statement to the participant, and indicate to the participant, however, that everyone will be asked questions about their dental history. Continue with Item 17. When participants are excluded for other medical conditions (e.g., an abnormal ECHO cardiogram), select YES, circle EXCLUDE, enter the reason in the notelog, and follow the regular procedures for persons who cannot be invited to have the dental exam. When no exclusion criteria are noted during the telephone interview, select NO, circle RECRUIT, read the recruitment statement, and answer any questions. Continue with Item 16.

    EXCEPTION: When a participant meets an American Heart Association exclusion criterion (items 2-14), AND REQUESTS the dental examination, the person can be recruited into the study if he/she agrees to take the antibiotics required for a dental examination. These antibiotics have to be prescribed by a dentist or physician, with knowledge of the date of the ARIC exam. (A special note is made on the Dental Exam Informed Consent for the person to acknowledge having an exclusion criterion and taking the required antibiotics). When this occurs,

    (1) the response to item 15 will be coded as RECRUIT (enter NO), even though one or more exclusion criteria are positive. Continue with Item 16.

    (2) Prepare a note for the ARIC receptionist and the dental hygienist that this person requires antibiotic treatment for a dental exam, but has indicated that he/she will obtain and take the requisite antibiotics. Special consent will have to be documented on the Dental Informed Consent form.

16. **May I schedule you for the dental exam?** This question is administered by the telephone interviewer after determining the participant's eligibility. Read the RECRUITMENT STATEMENTs which indicate eligibility (left hand side of DES Screen #3) and describes the dental exam (right hand side of DES Screen #3). When the participant agrees to participate, select YES, and continue by reading the script which requests the name and address of the person's dentist (right hand side of DES Screen #3). When the person does not agree to have a dental exam, select NO, (this automatically excludes the person from the study) and circle EXCLUDE. Complete Items 17 and 18 at the end of the telephone interview.

17. **Date of telephone interview:** Using the standard date format, enter the date on which the full (telephone) interview was conducted, usually during the recruitment/scheduling call. This field is not revised during the second (clinical) interview.

18. **Code number of person completing the telephone interview.** This field is completed only during the telephone interview.

SCRIPTS FOR SCHEDULING THE ARIC DENTAL EXAM

INTRODUCTION

At each of the ARIC visits we have included one or two procedures or interviews that explore some new questions on the causes of heart disease. In Visit 3 we took photographs of the veins and arteries in your eyes. At this visit we have added a very brief exam of your teeth and gums, because new studies suggest that cavities and gum disease may be related to heart disease. However, before we can ask you to take part in this study, I need to go over a few questions to make sure that this dental exam would be useful or safe.

COMPONENTS OF THE DENTAL EXAM

This portion of the study includes a simple examination of your mouth to see if there are any cavities, gum disease or spaces between your teeth and gums. We will also collect a little plaque (tartar) and pick up some fluid from around your teeth. Most people find these procedures to be quite comfortable.

RESULTS REPORTS

The usual procedure in ARIC is to send your doctor a copy of your results reports. If you would like us to send your dentist a copy of the dental exam report, please bring his or her name and address with you when you come for your appointment.

DEFINITIONS AND SYNONYMS OF MEDICAL TERMS

MEDICAL CONDITION	DEFINITION
CONGENITAL HEART DISEASE	Heart disease which is present since birth and which is diagnosed either at birth or early in a person's life.
RHEUMATIC HEART DISEASE	Damage to the heart valves caused by a strep infection, which can manifest itself from slight heart murmurs to pump failure of the heart.
HEART MURMUR FROM A DEFECT IN THE STRUCTURE OF THE HEART	Heart murmur due to problems of the heart valves or the arteries leaving the heart, (not what are often called "innocent" heart murmurs).
INFECTION OF THE LINING OF THE HEART, CALLED ENDOCARDITIS	no other synonyms available
MITRAL VALVE PROLAPSE	protrusion of the heart valve, called mitral, which causes some difficulties to the pumping function of the heart.
CARDIAC PACEMAKER	implanted electrical device used to trigger or regulate the heart beat
HEART/KIDNEY/OTHER ORGAN TRANSPLANT	no other synonyms
SURGICALLY IMPLANTED HEART VALVE, ARTIFICIAL JOINT, STENT or SHUNT	a stent is a device placed in an artery during angioplasty to help keep the artery from collapsing after surgery. A shunt is a mechanical device to bypass fluids, a "bypass".
PREDNISONE OR OTHER IMMUNOSUPPRESSIVE MEDICATION	If uncertain, have participant ask his/her doctor before the ARIC visit.

LIST OF IMMUNOSUPPRESSIVE DRUGS FOR ITEM 14 OF DENTAL SCREENING FORM

Prepared 3/19/97

AMCINONIDE (CYCLOCORT)

BECLOMETHASONE DIPROPIONATE (VANCERIL)

BETAMETHASONE DIPROPIONATE (Diprosone)

CHLORAMBUCIL (leukeran)

CORTISONE ACETATE (Cortone)

DESONIDE (Tridesilon)

DESOXIMETASONE (TOPICORT)

Diflorasone diacetate (FLORONE, MAXIFLOR)

FLUDROCORTISONE ACETATE (FLORINEF)

FLUOCINOLONE ACETONIDE (Synalar)

FLUOCINONIDE (Lidex, Topsyn)

FLUOROMETHOLONE (Oxylone)

FLURANDRENOLIDE USP (Cordan)

HALCINONIDE USP (Halog)

Hydrocortisone Acetate (Cortril, Orabase)

Hydrocortisone (Cortef, Texacort)

MELPHALAN (alkeran)

LIST OF IMMUNOSUPPRESSIVE DRUGS FOR ITEM 14 OF DENTAL SCREENING FORM (continued)

METHOTREXATE

Prednisolone (Meticorten)

Prednisone (DELTASONE)

Prednisone Phosphate (HYDELTRASOL or SAVACORT-S)

TAMOXIFEN

tamoxifen (NOLVADEX)

TRIAMCINOLONE ACETONIDE (Aristocort)

TRIAMCINOLONE ACETONIDE (MYCOLOG)

O.M.B. 0925-0281
exp. 09/30/98

A-107

ARIC
Atherosclerosis Risk in Communities

FASTING/TRACKING FORM

ID NUMBER: | | | | | | | | CONTACT YEAR: | 1 | 0 | FORM CODE: | F | T | R | VERSION: D 11/30/95

LAST NAME: | | | | | | | | | | | | | INITIALS: | | |

INSTRUCTIONS: This form is completed during the participant's visit. ID Number, Contact Year and Name must be entered above. Whenever numerical responses are required, enter the number so that the last digit appears in the rightmost box. Enter leading zeroes where necessary to fill all boxes. On the paper form, if a number is entered incorrectly, mark through the incorrect entry with an "X". Code the correct entry clearly above the incorrect entry. For "multiple choice" questions, circle the letter corresponding to the most appropriate response. If a letter is circled incorrectly, mark through it with an "X" and circle the correct response.

FASTING/TRACKING FORM (FTRD screen 1 of 1)

1. Date of clinic visit:

		/			/		

month day year

2. Date of fasting determination:

		/			/		

month day year

3.a. Time: ..... | | | : | | |

h h : m m

b. AM ..... A

PM ..... P

4. When was the last time you ate or drank anything except water?

a. Day last consumed: ..... Today T

Yesterday Y

Go to Item 6 ——— Before Yesterday B

4.b. Time last consumed: | | | : | | |

h h m m

c. AM ..... A

PM ..... P

5. Computed fasting time: ..... __ __ hours

6. Have you given blood within the last 7 days? ..... Yes Y

No N

7. Method of data collection ..... Computer C

Paper Form P

8. Code number of person completing this form: ..... | | | |

Appendix 2.7b

(FTRD screen 1 of 1)

1~ Date of clinic visit: _____ mm/dd/yy

2~ Date of fasting determination: _____ mm/dd/yy

3.a~ Time: _____ hh:mm

b~ AM (A) or PM (P) _

4. When was the last time you ate or drank anything except water?

a~ Day last consumed: _

Today (T)
Yesterday (Y)
Before Yesterday (B)*

b~ Time last consumed: _____ hh:mm

c~ AM (A) PM (P) _

5~ Computed fasting time: __ hours

6~ Have you given blood within the last 7 days? _

Yes (Y) NO (N)

7~ Method of data collection _

Computer (C) or Paper (P) Form

8~ Code number of person completing this form: ___

Appendix 2.7c

INSTRUCTIONS FOR THE FASTING/TRACKING FORM
FTR, VERSION D, 01/12/95
PREPARED 05/08/95

The Fasting/Tracking Form is completely filled out at the beginning of the participant's visit. Portions of this form may be updated (in the CHANGE mode of the data entry system) if the participant arrived at the field center having consumed anything other than water or black, unsweetened coffee or tea in the 8 hours prior to the beginning of the Visit 4 exam and agreed to return on another day for blood drawing in the fasting state.

The interviewer needs to be familiar with and understand the document entitled "General Instructions for Completing Paper Forms" prior to administering this form. ID Number, Contact Year, and Name are completed as described in that document.

1. Date of Clinic Visit 3. This is the official date of Visit 4. Enter the date on which the participant signs the Visit 4 Informed Consent Form. If the participant returns at a later date for venipuncture, this date is not changed. The information below on his/her fasting status, however, will be updated. To record the Visit 4 date, code in the numbers using leading zeroes where necessary to fill all spaces. For example, May 3, 1993 would be entered as:

0	5	/	0	3	/	9	3
Month			Day			Year	

2. Date of Fasting Determination. This is the date on which the participant's fasting is documented. This date may be updated if it were necessary for the participant to return to have fasting blood drawn. Enter the date using the standard date format, as described for Item 1.

3. Time. Enter the time of the reception.

4. When was the last time you ate or drank anything except water? Ask the question verbatim. Record the appropriate day in item (a), time in item (b), and AM or PM in item (c). Use midnight (12:00 am) as the strict cutoff between days. Note: If "Before Yesterday" is chosen in (a), skip to Item 6.

5. Computed Fasting Time. This item is calculated automatically when the Fasting/Tracking Form is entered directly on the computer. (As a way of denoting this on the paper form, lines are provided rather than boxes for recording the result.) To calculate the fasting time when

using the paper version of the form, use the "Fasting Time Computation Table," which can be found on the last page of these instructions, to determine the time. To use the table, look up the Time Last Consumed on the left hand column, and the current time (Time of Visit) along the top. The value in the body of the table corresponding to those two times is the number of hours fasted. Note that the "Time Last Consumed" is separated into "Yesterday" and "Today," and that all times are separated by "AM" and "PM." In addition, times are given in one-hour intervals. The top line in the table may be used whenever the Time Last Consumed is earlier than 7:00 PM. This is acceptable because, although the fasting time may not be accurate, it will not be less than the critical time of 12 hours.

Note: Computing fasting time using the table does not always provide the same result as the computer (due to a reduction in accuracy). However, any effect arising from this fact is believed to be negligible because (1) only a small number of cases would cross over the 12-hour critical time, and (2) even in such cases, ARIC procedures call for the completion of the visit regardless of fasting time.

For example, if the Time Last Consumed is 7:30 PM yesterday (in 7-7:59 PM interval) and the Time of Visit is 8:15 AM (in 8-8:59 AM interval), the fasting time is 13 hours.

6. Have you given blood within the last 7 days. Read the question. If the response is YES, determine whether the participant gave or donated a pint of blood/plasma in contrast to had blood samples drawn. Record YES only if "given blood" refers to the donation of a pint (or more) or whole blood or plasma, not a blood sample for diagnostic evaluation. Otherwise, record NO.

7. Record "C" if the form was completed on the computerized data entry system, or "P" if the paper form was used. If the form was completed partially on paper and partially on the computer, code as "Paper Form."

8. The person at the clinic who has completed this form must enter his/her code number in the boxes provided.

FASTING TIME COMPUTATION TABLE

Time Last Consumed	Time of Visit: AM 7-7:59	8-8:59	9-9:59	10-10:59	11-11:59	PM 12-12:59	1-1:59	2-2:59	3-3:59	4-4:59	5-5:59	6-6:59
Yesterday...												
Earlier	13	14	15	16	17	18	19	20	21	22	23	24
7-7:59	12	13	14	15	16	17	18	19	20	21	22	23
8-8:59	11	12	13	14	15	16	17	18	19	20	21	22
PM												
9-9:59	10	11	12	13	14	15	16	17	18	19	20	21
10-10:59	9	10	11	12	13	14	15	16	17	18	19	20
11-11:59	8	9	10	11	12	13	14	15	16	17	18	19
Today...												
12-12:59	7	8	9	10	11	12	13	14	15	16	17	18
1-1:59	6	7	8	9	10	11	12	13	14	15	16	17
2-2:59	5	6	7	8	9	10	11	12	13	14	15	16
3-3:59	4	5	6	7	8	9	10	11	12	13	14	15
4-4:59	3	4	5	6	7	8	9	10	11	12	13	14
5-5:59	2	3	4	5	6	7	8	9	10	11	12	13
AM												
6-6:59	1	2	3	4	5	6	7	8	9	10	11	12
7-7:59	0	1	2	3	4	5	6	7	8	9	10	11
8-8:59		0	1	2	3	4	5	6	7	8	9	10
9-9:59			0	1	2	3	4	5	6	7	8	9
10-10:59				0	1	2	3	4	5	6	7	8
11-11:59					0	1	2	3	4	5	6	7
12-12:59						0	1	2	3	4	5	6
1-1:59							0	1	2	3	4	5
2-2:59								0	1	2	3	4
PM												
3-3:59									0	1	2	3
4-4:59										0	1	2
5-5:59											0	1

ARIC
Atherosclerosis Risk in Communities

Appendix 2.8a

HEALTH HISTORY FORM

O.M.B. 0925-0281
exp. 09/30/98

ID NUMBER: | | | | | | | | CONTACT YEAR: | 1 | 0 | FORM CODE: | H | H | X | VERSION: D 12/01/95

LAST NAME: | | | | | | | | | | | | | INITIALS: | | |

Public reporting burden for this collection of information is estimated to average 2 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: **PHS Reports Clearance Officer, Rm. 737-F, Humphrey Building, 200 Independence Ave., SW, Washington, D.C. 20201, ATTN: PRA (0925-0281).** Do not return the completed form to this address.

INSTRUCTIONS: This form should be completed during the participant's visit. ID Number, Contact Year and Name must be entered above. Whenever numerical responses are required, enter the number so that the last digit appears in the rightmost box. Enter leading zeroes where necessary to fill all boxes. If a number is entered incorrectly, mark through the incorrect entry with an "X". Code the correct entry clearly above the incorrect entry. For "multiple choice" and "yes/no" type questions, circle the letter corresponding to the most appropriate response. If a letter is circled incorrectly, mark through it with an "X" and circle the correct response.

HEALTH HISTORY FORM (HHXD screen 1 of 8)

A. AFU CHEST PAIN CONFIRMATION

1. Did the participant report positive Rose angina in the Annual Follow-up call preceding this visit?..... Yes Y

   No N → Go to Item 4, Screen 2.

2. In the ARIC telephone call you mentioned having some pain or discomfort in your chest in the past year. Could you tell me where it was?

   Yes Y

   No-pain not recalled P → Go to Item 4, Screen 2.

   No-location not recalled L → Go to Item 3.

[DO NOT READ LOCATIONS]

	Yes	No
2.a. Sternum (upper or middle)	Y	N
b. Sternum (lower)	Y	N
c. Left anterior chest	Y	N
d. Left arm	Y	N
e. Other	Y	N

→ Go to Item 3.

Specify: _____

3. In the past two months has your chest discomfort either occurred more often, lasted longer when it occurs, or come on at rest? ..... Yes Y

   No N

HEALTH HISTORY FORM (HHXD screen 2 of 8)

B. INVASIVE PROCEDURES

4. Since your last ARIC visit, have you had surgery on your heart, or the arteries of your neck or legs, excluding surgery for varicose veins? ..... Yes Y

Go to Item 6, Screen 3. — No N

5. Did you have:

a. Coronary bypass: ..... Yes Y

No N

b. Other heart procedure: ..... Yes Y

Go to Item 5.c. — No N

Specify: _____

_____

c. Carotid endarterectomy: ..... Yes Y

Go to Item 5.e. — No N

5.d. Site: ..... Right R

Left L

Both B

e. Other arterial revascularization: ..... Yes Y

Go to Item 5.f. — No N

Specify: _____

_____

f. Any other type of surgery on your heart or the arteries of your neck or legs? ..... Yes Y

No N

HEALTH HISTORY FORM (HHXD screen 3 of 8)

6. Since your last visit to the ARIC clinic, have you had a balloon angioplasty on the arteries of your heart, neck, or legs? ..... Yes Y

Go to Item 8. — No N

7. Did you have:

a. Angioplasty of the coronary arteries: Yes Y

No N

b. Angioplasty in the arteries of your neck: ..... Yes Y

No N

c. Angioplasty of lower extremity arteries: ..... Yes Y

No N

8. Since your last visit to the ARIC clinic, have you had:

a. Heart catheterization: ..... Yes Y

No N

b. Carotid artery catheterization: ..... Yes Y

No N

c. Other arterial catheterization: ..... Yes Y

Go to Item 9.a., Screen 4. — No N

Specify: _____

_____

HEALTH HISTORY FORM (HHXD screen 4 of 8)

C. DIAGNOSTIC PROCEDURES

9. Since your last visit to the ARIC clinic, have you had any of the following procedures performed for a medical reason? Please do not include any procedures done for research studies or a fitness program.

	Yes	No
a. Echocardiogram:	Y	N
b. Electrocardiogram:	Y	N
c. Treadmill or cardiac stress test:	Y	N
Go to Item 9.e.		
d. Thallium scan of the heart:	Y	N
e. Holter monitor:	Y	N
f. Heart rhythm and conduction studies:	Y	N
g. Carotid ultrasound studies:	Y	N
h. MRI exam of the brain:	Y	N
i. CAT scan of the brain:	Y	N

HEALTH HISTORY FORM (HHXD screen 5 of 8)

D. HEAD INJURIES

10. Have you ever had a major head injury? That is, one that resulted in your losing consciousness, no matter how briefly, or that led you to see a physician or seek hospital care? .... Yes Y

Go to Item 11. — No N

a. How many times has this happened? ..... ☐

b. How many of these head injuries resulted in your losing consciousness, no matter how briefly? ..... ☐

10.c. In what year was your last head injury for which you lost consciousness or sought medical care? ..... 19☐☐

E. BLOOD TRANSFUSION

11. Have you ever received a blood transfusion? This includes whole or fresh blood or red blood cells, but NOT plasma or an IV without blood. ..... Yes Y

Go to Item 17, Screen 7. — No N; Unknown U

12. How many times have you received a blood transfusion? ..... ☐☐ times

HEALTH HISTORY FORM (HHXD screen 6 of 8)

13. How old were you when you had your first transfusion? ..... ☐☐ age

14. What was the reason for your first transfusion?

[SHOW RESPONSE CARD]

Injury (car accident, fall, etc.) ...	A
Childbirth	B
Bleeding ulcer	C
Surgery	D
Anemia	E
Other	F

15. Was the blood for your first transfusion:

[READ EACH RESPONSE CATEGORY]

	Yes	No	Unknown
a. Your own	Y	N	U
b. From a blood relative	Y	N	U
c. From a non-blood relative	Y	N	U
d. From a blood bank	Y	N	U

HEALTH HISTORY FORM (HHXD screen 7 of 8)

[READ ONLY IF MORE THAN 1 TRANSFUSION]

16. Was the blood for your other transfusions:

[READ EACH RESPONSE CATEGORY]

	Yes	No	Unknown
a. Your own	Y	N	U
b. From a blood relative	Y	N	U
c. From a non-blood relative	Y	N	U
d. From a blood bank	Y	N	U

17. Have you ever received any other blood products, such as clotting factors, white blood cells, platelets or plasma? ..... Yes Y; No N; Unknown U

F. WALKING/STANDING

18. Does the participant use a wheelchair, crutches or walker? ..... Yes Y; No N

→ Go to Item 20, Screen 8.

19. Does the participant walk with a cane? ..... Yes Y; No N

HEALTH HISTORY FORM (HHXD screen 8 of 8)

G. ADMINISTRATIVE INFORMATION

20. Date of data collection: ..... | | | / | | | / | | |
month day year

21. Method of data collection: ..... Computer C
Paper form P

22. Code number of person completing this form: ..... | | | |

(HHXD screen 1 of 8)

A. AFU CHEST PAIN CONFIRMATION

1~ Did the participant report positive Rose angina in the Annual Follow-up call preceding this visit? _ []

Yes (Y) or No (N)*

2~ In the ARIC telephone call you mentioned having some pain or discomfort in your chest in the past year. Could you tell me where it was? _ []

Yes	(Y)
No-pain not recalled	(P)*
No-location not recalled	(L)*

[DO NOT READ LOCATIONS.]

Yes (Y) or No (N)

2.a~ Sternum (upper or middle) _ []
b~ Sternum (lower) _ []
c~ Left anterior chest _ []
d~ Left arm _ []
e~ Other _ []
[If Yes specify on note log]

3~ In the past two months has your chest discomfort either occurred more often, lasted longer when it occurs, or come on at rest? _ []

Yes (Y) or No (N)

(HHXD screen 2 of 8)

B. INVASIVE PROCEDURES

4~ Since your last ARIC visit, have you had surgery on your heart, or the arteries of your neck or legs, excluding surgery for varicose veins? _ []
Yes (Y) or No (N)*

5. Did you have:
Yes (Y) or No (N)

a~ Coronary bypass: _ []

b~ Other heart procedure _ []
[If Yes, specify on note log]

c~ Carotid endarterectomy (N)*: _ []

5.d~ Site? _ []

Right	(R)
Left	(L)
Both	(B)

e~ Other arterial revascularization: _ []

Yes (Y)* or No (N)
[If Yes, specify on note log]

f~ Any other type of surgery on your heart or the arteries of your neck or legs? _ []

Yes (Y) or No (N)

(HHXD screen 3 of 8)

6~ Since your last visit to the ARIC clinic, have you had a balloon angioplasty on the arteries of your heart, neck, or legs? _

Yes (Y) or No (N)*

7. Did you have:

Yes (Y) or No (N)

a~ Angioplasty of the coronary arteries? _

b~ Angioplasty in the arteries of your neck? _

c~ Angioplasty of lower extremity arteries? _

8. Since your last visit to the ARIC clinic, have you had:

Yes (Y) or No (N)

a~ Heart catheterization: _

b~ Carotid artery catheterization: _

c~ Other arterial catheterization: _

[If Yes, specify on note log]

(HHXD screen 4 of 8)

C. DIAGNOSTIC PROCEDURES

9. Since your last visit to the ARIC clinic, have you had any of the following procedures performed for a medical reason? Please do not include any procedures done for research studies or a fitness program.

Yes (Y) or No (N)

a~ Echocardiogram: _

b~ Electrocardiogram: _

c~ Treadmill or cardiac stress test (N)*: _

d~ Thallium scan of the heart: _

9.e~ Holter monitor: _

f~ Heart rhythm and conduction studies: _

g~ Carotid ultrasound studies: _

h~ MRI exam of the brain: _

i~ CAT scan of the brain: _

(HHXD screen 5 of 8)

D. HEAD INJURIES

10~ Have you ever had a major head injury? That is, one that resulted in your losing conciousness, no matter how briefly, or that led you to see a physician or seek hospital care? _ [ ]

Yes(Y) or No(N)*

a~ How many times has this happened? _ [ ]

b~ How many of these head injuries resulted in your losing conciousness, no matter how briefly? _ [ ]

10.c~ In what year was your last head injury for which you lost consciousness or sought medical care? 19__ [ ]

E. BLOOD TRANSFUSION

11~ Have you ever received a blood transfusion? This includes whole or fresh blood or red blood cells, but NOT plasma or an IV without blood. _ [ ]

Yes(Y), No(N)* or Unknown(U)*

12~ How many times have you received a blood transfusion? __ [ ] times

(HHXD screen 6 of 8)

13~ How old were you when you had your first transfusion? __ [ ]

14~ What was the reason for your first transfusion? _ [ ]
[SHOW RESPONSE CARD]

Injury (car accident, fall, etc.)	(A)
Childbirth	(B)
Bleeding ulcer	(C)
Surgery	(D)
Anemia	(E)
Other	(F)

15. Was the blood for your first transfusion:

[READ EACH RESPONSE CATEGORY]

Yes(Y), No(N) or Unknown(U)

a~ Your own _ [ ]

b~ From a blood relative _ [ ]

c~ From a non-blood relative _ [ ]

d~ From a blood bank _ [ ]

(HHXD screen 7 of 8)

[READ ONLY IF MORE THAN 1 TRANSFUSION]

16~ Was the blood for your other transfusions:
[READ EACH RESPONSE CATEGORY]

Yes(Y), No(N) or Unknown(U)

a~ Your own _ [ ]

b~ From a blood relative _ [ ]

c~ From a non-blood relative _ [ ]

d~ From a blood bank _ [ ]

17~ Have you ever received any other blood products, such as clotting factors, white blood cells, platelets or plasma? _ [ ]

Yes(Y), No(N) or Unknown(U)

F. WALKING/STANDING

18~ Does the participant use a wheelchair, crutches or walker? _ [ ]

Yes (Y)* or No (N)

19~ Does the participant walk with a cane? _ [ ]

Yes (Y) or No (N)

(HHXD screen 8 of 8)

G. ADMINISTRATIVE INFORMATION

20~ Date of data collection: _____ [ ]
mm/dd/yy

21~ Method of data collection: _ [ ]

Computer (C) or Paper (P) Form

22~ Code number of person completing this form: ___ [ ]

Appendix 2.8c

INSTRUCTIONS FOR THE HEALTH HISTORY FORM
HHX, VERSION D, 12/01/95
PREPARED 02/12/96

I. GENERAL INSTRUCTIONS

The Health History form is administered by a study-certified physician's assistant, nurse/nurse practitioner, licensed practical nurse, or an equivalently trained field center staff member with a general understanding of the medical terms and diagnostic procedures referred to in this interview. Familiarity with and understanding of the document entitled "General Instructions for Completing Paper Forms" is necessary prior to administering this form. The participant's ID number, Contact Year and Name are completed in this form's header as described in that document.

II. DETAILED INSTRUCTIONS FOR EACH ITEM

A. Annual Follow-up (AFU) Chest Pain Confirmation

1. Section A refers to the reporting of chest pain by the participant during the most recent administration of the Annual Follow-up (AFU) form. Do not read Item 1 aloud. Item 1 is completed by the interviewer after reviewing the AFU form, which is filed in the participant's folder. "Positive Rose angina" is defined as the response code 'L' (10 minutes or less) to Item 12 in the AFU form. The response 'M' (more than 10 minutes) or no response (i.e., missing) is coded as NO in the HHX form, and the interviewer skips to Item 4. In general, the 'Annual Follow-up call preceding this visit' refers to the ninth AFU contact (CY10), the most recent contact in which the fourth ARIC examination (Visit 4) was scheduled. In every case, it refers to the most recent participant contact prior to the fourth ARIC examination.

2. "In the past year" refers to the 12 months immediately preceding the most recent Annual Follow-up interview. If the participant does not remember reporting chest pain, code 'P' and skip to Item 4.

   If the participant cannot locate the site of the reported pain (i.e., a negative response to 'Could you tell me where it was?") , code 'L' and skip to Item 3.

   To select YES, the participant must confirm having had chest pain and that the chest pain occurred within the 12 months prior to the AFU interview, and that the location can be identified. When the site of the pain can be identified, code 'Y', and respond YES or NO to each of the locations in items 2a-e.

To complete items 2a-e, ask the participant to point to the area or areas where the pain occurred. Areas other than those listed on the form should be specified on a note log after Item 2e. The areas are the interviewer's best approximation with the sternum divided into thirds, and the anterior chest to the left of the sternum and below the clavicle. The left arm includes the area below the clavicle and above the left hand. The left shoulder (clavicle and above), neck and jaw are coded as "other" (Item 2e).

3. Ask the question as written. Code YES for <u>any positive response to a reported change in the frequency, duration or onset at rest</u> of the chest pain which has occurred in the last two months prior to this interview compared to any previous episodes of chest pain. This includes terms, such as, "worse" or "more severe" chest discomfort or pain.

B. Invasive Procedures

4. The frame of reference for items 4-8 is the time period between the third and fourth ARIC examinations. If the third examination was missed, then the frame of reference is the time period between the second and fourth ARIC examinations.

Items 4 and 5 refer to "major" therapeutic surgery on the heart or the 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 <u>not</u> 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.

A table of standardized definitions and synonyms is provided at the end of the instructions. These definitions are read to participants who <u>request</u> the definition or a clarification of a procedure during the interview.

Code NO and skip to Item 6 if the participant denies surgery on the heart, or leg or neck arteries since the last ARIC visit.

5. The questions in Item 5 are not mutually exclusive. For example, when coding, a person who has had coronary bypass surgery may have also had another "open heart" procedure during the same operation, in which case YES is coded for both Items 5a and 5b.

Coronary bypass surgery (Item 5.a) is a procedure to improve blood supply to the heart muscle. This surgery is most often performed when narrow coronary arteries reduce the flow of oxygen-containing blood to the heart.

Examples of "other heart procedures" include: valve replacement, ventricular aneurysm resection, repair of aortic or ventricular stenosis, patent ductus closure, pacemaker, etc. Note that coarctation of the aorta would not be included here as an isolated surgical procedure. Specify the type of "other heart procedure(s)" in the note log following Item 5b.

The procedure "carotid endarterectomy" can be defined to the participant (if requested) as "surgery to restore blood flow in one or both of the arteries in your neck". If the participant does not report this procedure, continue with Item 5e. If the response is YES, identify the site(s) of the procedure in Item 5d. Identify all sites (Right, Left, or Both) on which the procedure was done.

With regard to the lower extremity, "other arterial revascularization" (item 5e) includes any procedure where additional blood flow is brought to an artery via a by-pass from a location elsewhere in the body. An example for the lower extremity is an ilio-femoral bypass procedure. A response of YES requires the specification of the procedure in the following note log.

If another type of surgery on the heart is reported, code YES for Item 5f. Examples of "other" could be resection of an aneurysm, removal or bypass of congenital malformations, or trauma surgery. A note log is not necessary.

6. Items 6 and 7 refer to balloon angioplasty only on the arteries of the heart, neck or legs. Balloon angioplasty is defined as a therapeutic procedure used to dilate (widen) narrowed arteries. A catheter with a deflated balloon on its tip is passed into the narrowed artery segment, the balloon inflated, and the narrow segment widened. To keep arteries from collapsing, stents (stainless-steel supports) can be inserted into the artery during angioplasty. "Legs" refers to the entire lower extremity (not just "below the knee", which is the restricted anatomical definition). Verify that the participant knows the difference between a catheterization and a balloon angioplasty procedure before recording a YES response. Catheterization is defined as a diagnostic procedure used to examine the arteries, veins or heart by introducing a thin tube (catheter) into a vein or artery.

7. Item 7 only documents balloon angioplasty of the coronary arteries (the two arteries arising from the aorta that arch down over the top of the heart, branch and provide blood to the heart muscle), the carotid arteries (the arteries in the neck), and the arteries in the lower extremities (the entire lower extremity, not just below the knee). Angioplasty with stents, or "stents" is generally performed for coronary artery angioplasty and are coded as YES in Item 7.a.

Balloon angioplasty of the renal arteries does not fit any of the categories for Item 7 and should not be recorded.

8. The overlap in items 7a and 8a, 7b and 8b, and 7c and 8c is deliberate. The primary distinction between the two sets of questions is the intent of the procedure. Angioplasties are generally <u>therapeutic</u> procedures, whereas "simple" catheterizations are <u>diagnostic</u> procedures, often performed prior to balloon angioplasty.

Heart catheterization involves introducing a thin tube (catheter) into a vein or artery and passing it into the heart.

Carotid artery catheterization involves introducing a thin tube (catheter) into the carotid artery in the neck.

If there is a positive response to "other arterial catheterization", code YES and specify the procedure in the following note log.

C. Diagnostic Procedures

9. Again, the time frame for Item 9 is the interval between the last and current ARIC examinations, not the last AFU interview. For a response to be YES, these procedures should have been done for a medical reason, and not as part of a research study (including ARIC) or a fitness program. These diagnostic procedures are used in ARIC analyses to indicate possible new cardiovascular disease since the last ARIC visit. In a clinical or medical setting, they would only be ordered by physicians to diagnose or rule out cardiovascular disease(s). In other settings, such as a research study or a physical fitness program, they are performed for reasons other than medical care. The response category is NO for a person who denies having had a procedure or who does not know whether a procedure has been performed and cannot provide any descriptive information which the interviewer can compare with the definitions on the chart of definitions and synonyms.

An echocardiogram (Item 9.a) is a diagnostic method in which pulses of sound are transmitted into the body and the echoes returning from the surfaces of the heart and other structures are electronically plotted and recorded to produce a "picture" of the heart's size, shape and movements.

An Electrocardiogram (ECG or EKG) is a graphic record of the electrical impulses produced by the heart. Item 9.b specifically refers to a <u>resting</u> ECG; do not include an ECG obtained while the person was on the treadmill or participating in other stress tests.

Item 9.c documents whether an ECG or other assessment of cardiac function was performed while the person exercised on a Treadmill (e.g., walking on a revolving platform) or performed other types of cardiac stress tests (e.g., a bicycle) which increased the heart rate. If the response is NO, skip to Item 9.e. If the response is YES, determine whether a thallium scan of the heart (Item 9.d) was performed.

A thallium scan of the heart (Item 9.d) is a diagnostic procedure in which a tracer is injected into the blood stream and imaged as it circulates through the heart.

A Holter monitor (Item 9.e) is a small, portable ECG which is worn by a patient for an extended period of time (usually 24 hours), frequently to measure cardiac arrhythmias (the irregular transmission of electrical impulses in the heart).

Heart rhythm and conduction studies (Item 9.f) sometimes called electrophysiologic testing, are invasive procedures to assess arrhythmias. The procedure is performed under local anesthesia. Temporary electrode catheters are placed through peripheral veins (and sometimes through arteries) into the heart using fluoroscopic guidance. The catheters are positioned in the atria, ventricles or both, and at strategic locations along the conduction system. Their purpose is to record cardiac electrical signals and "map" the spread of electrical impulses during each beat.

Carotid ultrasound studies (Item 9.g) are noninvasive diagnostic studies of the artery(ies) in the neck in which pulses of sound are transmitted into the neck and the echos returning form the surfaces of the artery and other structures are electronically plotted to produce a picture of a small segment of the artery, its walls, and any atherosclerosis (hardening of the arteries or plaque) that may be present. Do not count the previous procedure in ARIC or other research study examinations.

An MRI (magnetic resonance image) of the brain (Item 9.h) is a non-invasive diagnostic technique in which magnetic fields (in contrast to x-rays) are used to produce a picture of the brain which identifies areas of abnormality. The procedure is done while the person is placed in a long, cylindrical tube. Record YES, if the procedure was restricted to the brain or done as part of a more comprehensive MRI scan.

CAT scan (computerized tomography) of the brain (Item 9.i) is also a non-invasive diagnostic technique to produce an image of the brain, in which abnormalities can be identified. This scan, however, only requires the person to lie on a flat surface with the head placed in a donut like structure, in contrast to the MRI. Record YES, if this scan

was restricted to the brain, or done as part of a more comprehensive CT scan.

D. Loss of Consciousness

10. This question documents two types of head injury a person may have had any time prior to this ARIC visit: it includes a head injury (including any blow to the head, car accidents, falls, other trauma, etc.) that either (1) lead to loss of consciousness, regardless of the length of time, OR (2) that required medical follow-up. A positive response for head injury must meet at least one of the two criteria. The definition excludes spontaneous bleeding into the head or brain. If "No", skip to Item 11.

    Item 10.a refers to the head injury(ies) reported in the lead-in question which required either medical care or loss of consciousness. If greater than 9, record 9.

    Item 10.b focuses on only the head injuries reported in Item 10 in which there was LOSS OF CONSCIOUSNESS (being knocked out). If more than 6 are reported, please double check that all resulted in loss of consciousness. If more than 9 (very unlikely), record 9.

    Item 10.c again refers to the ORIGINAL DEFINITION of head injuries, i.e., a head injury that resulted in a LOSS OF CONSCIOUSNESS OR one that required MEDICAL CARE. If only one head injury is reported, enter the year it occurred. If more than one, enter the date of the MOST RECENT ONE.

E. Blood Transfusion

11. Blood transfusions are given for major blood loss (e.g., injury, childbirth, gastrointestinal bleeding, surgery, etc.) or for low red blood cell production (e.g., anemia). Note that this question refers to whole/fresh blood or red cells, but NOT plasma (blood fluid without red cells) or other intravenous (IV) solutions. If NO or UNKNOWN, go to Item 17.

12. This is the TOTAL NUMBER of blood transfusions, meeting the definition in Item 11. If the person cannot remember the exact number, ask for a best guess. A transfusion refers to the procedure, not the number of individual units of blood received. The number of transfusions reported in this question will govern the skip pattern for Item 16.

13. Record age at FIRST blood transfusion.

14. Read the question, stressing the choice is to be based on the <u>first</u> transfusion (if the person has received more than one transfusion), and show the participant the response card while reading the response categories.

15. Seek the source of blood for the first transfusion. There are four choices: "your own"; "from a blood relative"; "from a non-blood relative"; "from a blood bank". Some people donate their own blood, for example, before major surgery; some have relatives donate. It is important that the participant understands that two of the choices differentiate between genetic (biologically related) and non-genetic (related by marriage) relatives (blood relatives and non-blood relatives). For example, one's natural mother is a blood relative and one's step mother is a non-blood relative. Blood that comes from the Red Cross or a facility within a hospital is coded as "blood bank". It is possible that an individual received more than one type of blood during the first transfusion, e.g., two autologous (self-donated) units and one unit from a blood bank. Therefore, READ EACH RESPONSE CATEGORY to the participant and record an answer for each category.

16. THIS ITEM IS TRICKY! If the response to Item 12 was 1, go to Item 17. If the response to Item 12 was 2 or more, read Item 16 stressing "your other" transfusions, and the response categories. The definitions for the sources in the four response categories are the same as for Item 15. And, as in the previous question, the person could have received blood from all four sources, especially if there have been multiple transfusions during his/her lifetime.

17. This question is read to all participants. Other blood products, i.e., those not included in Items 11-16, are reported here. These, however, do NOT include intravenous (IV) transfusions of non-blood products.

F. Walking/Standing

18. The response is coded by the interviewer without asking the participant. A positive response skips the interviewer to Item 20.

19. The response is coded by the interviewer without asking the participant.

E. Administrative Information

20. Enter the date on which the participant completed this interview. Code in numbers using leading zeroes where necessary to fill all boxes. For example, May 3, 1995, would be entered as:

0	5	/	0	3	/	9	5
month			day			year	

21. Record "C" if the form was completed on the computerized data entry system, or "P" if the paper form was used. If the form was completed partially on paper and partially on the computer, code as "Paper Form."

22. The person at the clinic who has completed this form must enter his/her code number in the boxes provided.

ARIC
Atherosclerosis Risk in Communities

HEALTH AND LIFE PROFILE FORM

ID NUMBER: | | | | | | | | CONTACT YEAR: | | FORM CODE: H P C VERSION: B 12/06/95

LAST NAME: | | | | | | | | | | | | | | | INITIALS: | |

PUBLIC REPORTING BURDEN

Public reporting burden for this collection of information is estimated to average 1-2 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: **PHS Reports Clearance Officer, Rm. 737-F, Humphrey Building, 200 Independence Ave., SW, Washington, D.C. 20201, ATTN: PRA (0925-0281).** Do not return the completed form to this address.

GENERAL INSTRUCTIONS FOR COMPLETING FORM

INSTRUCTIONS: This questionnaire asks you to describe how you feel about your life and health. Please take your time to answer carefully. There are no "right" or "wrong" answers. We are interested in your feelings and opinions. For each of the following statements, please choose the one response that best describes you. Circle only one response for each question or statement. If you make a mistake, cross it out and circle the letter you want.

(CIRCLE ONLY ONE LETTER IN EACH ROW)

	ALMOST NEVER	SOMETIMES	OFTEN	ALMOST ALWAYS
1. I am quick tempered.....	A	B	C	D
2. I have a fiery temper.....	A	B	C	D
3. I am a hotheaded person.....	A	B	C	D
4. I get angry when I am slowed down by others' mistakes.....	A	B	C	D
5. I feel annoyed when I am not given recognition for doing good work.....	A	B	C	D
6. I fly off the handle.....	A	B	C	D
7. When I get angry, I say nasty things.....	A	B	C	D
8. It makes me furious when I am criticized in front of others.....	A	B	C	D
9. When I get frustrated, I feel like hitting someone.....	A	B	C	D
10. I feel infuriated when I do a good job and get a poor evaluation.....	A	B	C	D

THE END

For Administrative Use Only.

11. Date | | |/| | |/| | | 12. Administration (A,B,C,D) [ ] 13. Code [| |]

HEALTH AND LIFE PROFILE FORM (HPCB screen 1 of 3)

1. I am quick tempered. _ [ ]

Almost Never	(A)
Sometimes	(B)
Often	(C)
Almost Always	(D)
No Response	(E)

2. I have a fiery temper. _ [ ]

Almost Never	(A)
Sometimes	(B)
Often	(C)
Almost Always	(D)
No Response	(E)

3. I am a hotheaded person. _ [ ]

Almost Never	(A)
Sometimes	(B)
Often	(C)
Almost Always	(D)
No Response	(E)

4. I get angry when I am slowed down by others' mistakes. _ [ ]

Almost Never	(A)
Sometimes	(B)
Often	(C)
Almost Always	(D)
No Response	(E)

HEALTH AND LIFE PROFILE FORM (HPCB screen 2 of 3)

5. I feel annoyed when I am not given recognition for doing good work. _ [ ]

Almost Never	(A)
Sometimes	(B)
Often	(C)
Almost Always	(D)
No Response	(E)

6. I fly off the handle. _ [ ]

Almost Never	(A)
Sometimes	(B)
Often	(C)
Almost Always	(D)
No Response	(E)

7. When I get angry, I say nasty things. _ [ ]

Almost Never	(A)
Sometimes	(B)
Often	(C)
Almost Always	(D)
No Response	(E)

8. It makes me furious when I am criticized in front of others. _ [ ]

Almost Never	(A)
Sometimes	(B)
Often	(C)
Almost Always	(D)
No Response	(E)

HEALTH AND LIFE PROFILE FORM (HPCB screen 3 of 3)

9. When I get frustrated, I feel like hitting someone. _ ☐

Almost Never	(A)
Sometimes	(B)
Often	(C)
Almost Always	(D)
No Response	(E)

10. I feel infuriated when I do a good job and get a poor evaluation. _ ☐

Almost Never	(A)
Sometimes	(B)
Often	(C)
Almost Always	(D)
No Response	(E)

ADMINISTRATIVE INFORMATION

11. Date of data collection: _____ ☐
mm/dd/yy

12. Type of administration: _ ☐

Self Administered	(A)
Interviewer Administered	(B)
Both	(C)
Not Done	(D)

13. Code number of person reviewing/completing this form: ___ ☐

INSTRUCTIONS FOR THE HEALTH AND LIFE PROFILE FORM
HPC, Version B, 01/13/95
PREPARED 2/12/96

The HEALTH AND LIFE PROFILE FORM in Visit 4 repeats one portion of the form (Part C) which was originally administered during Visit 2. Part C is the Spielberger Trait Anger form and is designed to measure symptoms of anger. It is intended to be self administered, but if necessary, can be interviewer-administered. The paper version of the form is different from the data entry (DES) screens. The primary difference between the paper and screen versions, in addition to the obvious format differences, is the inclusion of a "don't know" response in the DES version to document that the participant did not complete either a single question or the entire questionnaire.

To preserve confidentiality, a single page cover sheet is stapled over the Health and Life Profile form and participants are encouraged to answer the questions in a private, quiet area at the field center.

The following introductory script serves as a prototype and should be adapted to meet the needs of the participant and field center.

> We next have a short questionnaire asking how you feel about your life and health. You may do this one by yourself.
>
> There are instructions on the first page of the form. (SHOW THE PARTICIPANT THE FIRST PAGE OF HPC FORM.) Will you be able to do these or would you like me to complete them with you?

If the participant needs assistance, skip to Section II.

I. SELF-ADMINISTRATION

VERIFY THAT THE FORM COVER SHEET HAS THE CORRECT ID LABEL. Provide overall instructions for completing the forms and indicate where you can be found if the participant has questions.

READ THE INTRODUCTORY SCRIPT.

> The Health and Life Profile has a total of 10 items that will go very quickly. There are 3 questions in small print at the bottom of the last page that you should ignore. These are filled out by ARIC staff.
>
> All statements ask you to circle the letter that matches the statement that best describes you. For each statement you have four choices: ALMOST NEVER; SOMETIMES; OFTEN; or ALMOST ALWAYS. (GO OVER HPC ITEM 1 AS AN EXAMPLE.) There are no right or wrong answers. We are only interested in your feelings and opinions.

> Please take your time to answer carefully. If you have any questions, I will be (INSERT YOUR WHEREABOUTS). I will check back with you in a few minutes to see how you are doing. If at anytime you feel you need my assistance, please let me know.

If the person has specific questions about the profile, provide neutral information only. Terms like "often" and "recently" are used frequently. Their definitions are left the participant's own preference or perception.

If the participant begins and then asks for assistance in completing part or all of the from, offer to complete the form with him/her. (See the instructions in Section II).

After allowing 20 minutes for the participant to complete the forms, a pre-assigned staff member checks in with the participant and decide if he/she needs assistance in completing the forms.

Field centers determine at what point in the exam the form is reviewed for completeness and what procedures should be implemented to assist the participant in completing them before the Exit Interview.

COLLECT THE FORM from the participant.

Scan the form for completeness. When the form is completed but there is one or more questions left blank, offer the participant the opportunity to complete them.

> I've noticed that there are one or more questions left blank. Would you like to do them or have you left them blank on purpose?

Depending on the answer, return the form to the participant and collect it after he/she has finished. Once the participant has answered all the questions he/she intends to, document the completions status of each form. This is done in two ways. (1) To document deliberately unanswered questions, write "no response " in the margin to the right of each unanswered question. (2) To document that the participant answered NO questions on a form, write "not done" in the margin to the right of the question "Type of Administration," located int he administrative section of that form (HPC, Item 12). Notes on the completion status of single questions or entire forms are later keyed into the data entry system.

The "For Administrative Use Only" section of each form is completed by the interviewer after the form has been reviewed for completeness. Item 11 is completed using the standard date format. Item 12 documents the type of administration. There are three response categories. "A" refers to total self-administration. "B" refers to total interviewer administration. "C" is entered if the administration of the form was a combination of self (A) and interviewer (B). "D" indicates the form was not answered by the participant, i.e., the form was not administered. Item 13 is the

code of the interviewer who explained the form to the participant, reviewed it for completeness or administered it.

II. INTERVIEWER ADMINISTERED

If the participant requests help with the form, offer to administer the paper version. As some items may be perceived as sensitive or embarrassing, statements and questions need to be read in a nonjudgmental tone.

The participant's literacy status and visual acuity should have been established during Visit 1 or at the Reception Station at the beginning of Visit 4 and documented on his/her itinerary form. Staff need to be sensitive to the participant's possible reluctance to admit (functional) illiteracy or deterioration of visual acuity since the last visit.

VERIFY THAT THE FORM COVER SHEET HAS THE CORRECT ID LABEL.

READ THE INTRODUCTORY SCRIPT

> This questionnaire asks you to describe how you feel about your life. There are no "right" or "wrong" responses. We are interested in your feelings and opinions. For the following statements, please choose the one response that best describes you.

GIVE HPC CARD 1 TO THE PARTICIPANT. After reading the response categories, ask if the participant would like to listen to the responses again. Read again, if appropriate - READ THE RESPONSE CATEGORIES (a) Almost never, (b) Sometimes (c) Often, and (d) Almost always. Then READ EACH STATEMENT on the form and CIRCLE the letter corresponding to the response or WRITE in the margin "No response" for later keying if the participant declines to select a response. RETRIEVE HPC CARD 1 and COMPLETE the administrative questions (items 11-13).

THANK THE PARTICIPANT AND TAKE HIM/HER TO THE NEXT WORKSTATION.

III. KEYING DATA FROM FORM HPC.

The HEALTH AND LIFE PROFILE form is keyed as soon as possible, preferably by the interviewer responsible for its completion. If the participant answered none of the questions on the form, the interviewer enters the header information and selects category "C" "Did Not Respond" to the question " type of administration" in the ADMINISTRATIVE SECTION (HPC: item 12). This is done in lieu of completing the "Did Not Respond" response for every field.

IV. SCORING OF THE HEALTH AND LIFE PROFILE QUESTIONNAIRE

The score for the Trait Anger (HPC) form will be calculated after the data have been sent to the Coordinating Center.

ARIC
Atherosclerosis Risk in Communities

Appendix 2.10a

INFLAMMATION FORM

O.M.B. 0925-0281
exp. 09/30/98

ID NUMBER: | | | | | | | | CONTACT YEAR: | 1 | 0 | FORM CODE: | I | N | F | VERSION: A 01/30/96

LAST NAME: | | | | | | | | | | | | | INITIALS: | | |

Public reporting burden for this collection of information is estimated to average 4 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: **PHS Reports Clearance Officer, Rm. 737-F, Humphrey Building, 200 Independence Ave., SW, Washington, D.C. 20201, ATTN: PRA (0925-0281).** Do not return the completed form to this address.

INSTRUCTIONS: This form should be completed during the participant's visit. ID Number, Contact Year and Name must be entered above. Whenever numerical responses are required, enter the number so that the last digit appears in the rightmost box. Enter leading zeroes where necessary to fill all boxes. If a number is entered incorrectly, mark through the incorrect entry with an "X". Code the correct entry clearly above the incorrect entry. For "multiple choice" and "yes/no" type questions, circle the letter corresponding to the most appropriate response. If a letter is circled incorrectly, mark through it with an "X" and circle the correct response.

INFLAMMATION FORM (INFA screen 1 of 6)

"A new part of ARIC will look at the effect infections may have on the development of hardening of the arteries.

Therefore, I would like to ask you the following questions about any infectious diseases you may have had."

1.a. Has a doctor ever told you that you have **hepatitis or jaundice?** ..... Yes Y

No N

Unknown U

Go to Item 2.a, Screen 2.

b. Have you had more than one episode of this in the past 10 years? ..... Yes Y

No N

Unknown U

c. Have you had at least one episode during the last 12 months? ..... Yes Y

No N

Unknown U

INFLAMMATION FORM (INFA screen 4 of 6)

6.a. Has a doctor ever told you that you have **bronchitis?** .... Yes Y

No N

Unknown U

Go to Item 7.a.

b. Have you had more than one episode of this in the past 10 years? ..... Yes Y

No N

Unknown U

c. Have you had at least one episode in the last 12 months? ..... Yes Y

No N

Unknown U

7.a. Has a doctor ever told you that you have **sinusitis or a sinus infection?** ..... Yes Y

No N

Unknown U

Go to Item 8, Screen 5.

b. Have you had more than one episode of this in the past 10 years? ..... Yes Y

No N

Unknown U

c. Have you had at least one episode in the last 12 months? ..... Yes Y

No N

Unknown U

INFLAMMATION FORM (INFA screen 5 of 6)

8. How many times have you had a **cold or a minor upper respiratory infection** in the last 10 years? .....

9. Have you ever had a **fever blister or cold sore** on your lips? ..... Yes Y

No N

Unknown U

Go to Item 10.

a. How many times have you had this in the last 10 years? .....

[If "00", go to Item 10.]

b. Have you had at least one episode in the last 12 months? ..... Yes Y

No N

Unknown U

10. Have you ever had **shingles,** also known as **herpes zoster?** ..... Yes Y

No N

Unknown U

Go to Item 11.

a. Have you had at least one episode of them in the last 12 months? ..... Yes Y

No N

Unknown U

11.a. Have you been **treated with antibiotics** during the last 10 years? ..... Yes Y

No N

Unknwon U

Go to Item 12, Screen 6.

b. Approximately how many times? .....

INFLAMMATION FORM (INFA screen 6 of 6)

12. Have your **gums bled while flossing or brushing your teeth** within the last two weeks? ..... Yes Y
No N
Unknown U

13.a. Has a dentist ever told you that you have **gum disease**? ..... Yes Y
No N
Unknown U

Go to Item 16.

b. How long ago were you told about this? ..... [ ][ ] years

14.a. Have you ever been treated for **gum disease**? ..... Yes Y
No N
Unknown U

Go to Item 16.

14.b. How long ago was this first treated? ..... [ ][ ] years

15. Have you ever had **gum surgery**? ..... Yes Y
No N
Unknown U

16. Date of data collection: ... [ ][ ]/[ ][ ]/[ ][ ]
m m / d d / y y

17. Method of data collection: ..... Computer C
Paper form P

18. Code number of person completing this form: ..... [ ][ ][ ]

INFLAMMATION FORM (INFA screen 2 of 6)

2.a. Has a doctor ever told you that you have **tuberculosis or TB?** ..... Yes Y

Go to Item 3.a. — No N; Unknown U

b. Was it diagnosed in the past 10 years? ..... Yes Y

Go to Item 3.a. — No N; Unknown U

c. In the last 12 months? ..... Yes Y; No N; Unknown U

3.a. Has a doctor ever told you that you have **arthritis?** ..... Yes Y

Go to Item 4.a, Screen 3. — No N; Unknown U

b. Have you had more than one episode or flare-up in the past 10 years? ..... Yes Y; No N; Unknown U

c. Have you had at least one episode in the last 12 months? ..... Yes Y; No N; Unknown U

INFLAMMATION FORM (INFA screen 3 of 6)

4.a. Has a doctor ever told you that you have a **urinary tract or kidney infection?** ..... Yes Y

Go to Item 5.a. — No N; Unknown U

b. Have you had more than one episode of this in the past 10 years? ..... Yes Y; No N; Unknown U

c. Have you had at least one episode in the last 12 months? ..... Yes Y; No N; Unknown U

5.a. Has a doctor ever told you that you have **pneumonia?** ..... Yes Y

Go to Item 6.a, Screen 4. — No N; Unknown U

b. Have you had more than one episode of this in the past 10 years? ..... Yes Y; No N; Unknown U

c. Have you had at least one episode in the last 12 months? ..... Yes Y; No N; Unknown U

Appendix 2.10b

(INFA screen 1 of 6)

"A new part of ARIC will look at the effect infections may have on the development of hardening of the arteries.

Therefore, I would like to ask you the following questions about any infectious diseases you may have had."

1.a~ Has a doctor ever told you that you have hepatitis or jaundice? _

Yes (Y), No (N)* or Unknown (U)*

b~ Have you had more than one episode of this in the past 10 years? _

Yes (Y), No (N) or Unknown (U)

c~ Have you had at least one episode during the last 12 months? _

Yes (Y), No (N) or Unknown (U)

(INFA screen 2 of 6)

2.a~ Has a doctor ever told you that you have tuberculosis or TB? _

Yes (Y), No (N)* or Unknown (U)*

b~ Was it diagnosed in the past 10 years? _

Yes (Y), No (N)* or Unknown (U)*

c~ In the last 12 months? _

Yes (Y), No (N) or Unknown (U)

3.a~ Has a doctor ever told you that you have arthritis? _

Yes (Y), No (N)* or Unknown (U)*

b~ Have you had more than one episode or flare-up in the past 10 years? _

Yes (Y), No (N) or Unknown (U)

c~ Have you had at least one episode in the last 12 months? _

Yes (Y), No (N) or Unknown (U)

(INFA screen 3 of 6)

4.a~ Has a doctor ever told you that you have a urinary tract or kidney infection? _

Yes (Y), No (N)* or Unknown (U)*

b~ Have you had more than one episode of this in the past 10 years? _

Yes (Y), No (N) or Unknown (U)

c~ Have you had at least one episode in the last 12 months? _

Yes (Y), No (N) or Unknown (U)

5.a~ Has a doctor ever told you that you have pneumonia? _

Yes (Y), No (N)* or Unknown (U)*

b~ Have you had more than one episode of this in the past 10 years? _

Yes (Y), No (N) or Unknown (U)

c~ Have you had at least one episode in the last 12 months? _

Yes (Y), No (N) or Unknown (U)

(INFA screen 4 of 6)

6.a~ Has a doctor ever told you that you have bronchitis? _

Yes (Y), No (N)* or Unknown (U)*

b~ Have you had more than one episode of this in the past 10 years? _

Yes (Y), No (N) or Unknown (U)

c~ Have you had at least one episode in the last 12 months? _

Yes (Y), No (N) or Unknown (U)

7.a~ Has a doctor ever told you that you have sinusitis or a sinus infection? _

Yes (Y), No (N)* or Unknown (U)*

b~ Have you had more than one episode of this in the past 10 years? _

Yes (Y), No (N) or Unknown (U)

c~ Have you had at least one episode in the last 12 months? _

Yes (Y), No (N) or Unknown (U)

(INFA screen 5 of 6)

8~ How many times have you had a cold or a minor upper respiratory infection in the last 10 years? __

9~ Have you ever had a fever blister or cold sore on your lips? _
Yes (Y), No (N)* or Unknown (U)*

a~ How many times have you had this in the last 10 years? __

[If "00", go to Item 10.]

b~ Have you had at least one episode in the last 12 months? _
Yes (Y), No (N) or Unknown (U)

10~ Have you ever had shingles, also known as herpes zoster? _

Yes (Y), No (N)* or Unknown (U)*

a~ Have you had at least one episode of them in the last 12 months? _

Yes (Y), No (N) or Unknown (U)

11a~ Have you been treated with antibiotics during the last 10 years? _

Yes (Y), No (N)* or Unknown (U)*

b~ Approximately how many times? __

(INFA screen 6 of 6)

12~ Have your gums bled while flossing or brushing your teeth within the last two weeks? _

Yes (Y), No (N) or Unknown (U)

13a~ Has a dentist ever told you that you have gum disease? _

Yes (Y), No (N)* or Unknown (U)*

b~ How long ago were you told about this? __ years

14a~ Have you ever been treated for gum disease? _

Yes (Y), No (N)* or Unknown (U)*

14b~ How long ago was this first treated? __ years

15~ Have you ever had gum surgery? _

Yes (Y), No (N) or Unknown (U)

16~ Date of data collection _____
mm/dd/yy

17~ Method of data collection _

Computer(C) or Paper(P) Form

18~ Code number of person completing this form ___

Appendix 2.10c

INSTRUCTIONS FOR THE INFLAMMATION FORM
INF, VERSION A, 01/30/96
PREPARED 05/05/97

I. GENERAL INSTRUCTIONS

The Inflammation form is administered by a study-certified nurse/nurse practitioner, licensed practical nurse or an equivalently trained field center staff member with a general understanding of the medical terms referred to in this interview. Familiarity with and understanding of the document entitled "General Instructions for Completing Paper Forms" is necessary prior to administering this form. The participant's ID number, Contact Year and Name are completed in this form's header as described in that document.

The Inflammation form collects information on the participant's prior history of a series of chronic infectious diseases, treatment with antibiotics, and history of periodontal disease. For most of the questions, the intent of this form is to document acquired infections that the participant is aware of from communication with his/her physician. The exceptions are colds and fever blisters/cold sores which often occur and are not diagnosed or treated by a physician. The time frame during which these conditions were diagnosed varies, requiring careful administration of each question. The exact wording and order of the questions should be followed to ensure standardization. Questions should not be skipped unless indicated by the skip pattern instructions.

The format of the majority of the questions on chronic infectious diseases starts with a lead-in question on a specific disease in which the time frame is a life time history and the disease must have been diagnosed by a physician. It is followed by a question on the frequency of episodes within the past 10 years and concludes with a question as to whether the person has had at least one episode in the 12 month's prior to the interview. Responses to lead-in questions of NO or UNKNOWN trigger a skip to the next disease.

A table of definitions and synonyms of many of the infectious diseases is provided for the use of the interviewer. Since most conditions require diagnosis by a physician, definitions of these conditions are not given to the participant unless clarification is specifically requested. The additional information in the table is provided to the interviewer in case the name of the diagnosis given by the physician does not match the exact term in the question, but does match the definition of the synonym.

II. DETAILED INSTRUCTIONS FOR EACH ITEM

The introductory script serves as a brief explanation to the participants as to why questions on a history of chronic infectious diseases and periodontal disease is being collected, and tangentially, why the periodontal exam is also being performed. In any observational study, care must be taken to encourage continued participation by providing reasonable explanations as to why questions or procedures are being introduced while taking care not to influence or bias participants' responses.

The form's introductory statement is read after verifying the participant's name. Do not define the terms, unless asked. The name of the disease should be familiar to the participant if the diagnosis has been made by the participant's physician.

1.a Read the question, stressing "has a doctor ever told you" and hepatitis or jaundice. The term "jaundice" is meant as a synonym for hepatitis and not for the unrelated jaundice which often occurs at birth. If, however, a participant reports hepatitis during childhood that was diagnosed by a physician (even if the knowledge of the diagnosis by a physician was obtained second hand from a parent), the information is applicable and informative. The same applies to the other infectious diseases. The time frame for this question is a life time history, i.e., any time prior to this interview. If the response is NO or UNKNOWN, select the appropriate response and go to Item 2. If YES, continue with part (b).

1.b Read the question, stressing "more than one" episode and "in the past 10 years". Record the response and continue with part (c).

1.c Read the question, stressing "at least one" episode during "the last 12 months".

2-7. Repeat the process for each of the diseases in items 2 through 7.

3. A positive response to Item 3.b requires more than one, distinct episode (flare-up) of arthritis. Code NO for persons reporting only one episode or constant, unvarying symptoms during the past 10 years. A positive response to 3.c requires at least one (distinct) episode of arthritis.

8. "Cold" is defined by the participant. If asked, the interviewer indicates that "flu-like symptoms" are a "cold", which includes a sore throat, if not accompanied by chills, aches, fever, or gastro-intestinal symptoms. If any of the latter are reported, the episode is not counted as a "cold". The occurrence of a cold or a minor upper respiratory infection is limited to the last 10 years. When participants cannot provide an accurate count, ask for a best guess. If more than 99, enter 99. The primary distinction between Item 7.a (sinusitis or a sinus infection) and Item 8.b (cold) is not the illness per se, but the requirement of a physician diagnosis for sinusitis.

9. Read the question stressing the time frame (life time history) and "fever blisters or cold sore". Note that this question does not require a physician's diagnosis. If NO or UNKNOWN, go to Item 10. If YES, continue with part (a).

9.a Read the question stressing the time frame, (in the past 10 years). When participants cannot provide an accurate count, ask for a best guess. If more than 99 (highly unlikely), enter 99.

9.b Read the question, stressing "at least one" episode during "the last 12 months".

10. Item 10 is the same format as Item 9, i.e., the interviewer needs to stress a life time history of a condition that does not have to have been diagnosed by a physician. If the response is NO or UNKNOWN, go to Item 11. If YES, continue with part (a).

10.a Read the question, stressing "at least one" episode during "the last 12 months".

11.a Read the question stressing the time frame (the last 10 years), and defining (if requested) antibiotics as a medication prescribed by a doctor to treat infections. The interviewer does not try to determine what is a relevant or legitimate use of an antibiotic in selecting a positive (YES) response. Both the use of an antibiotic to cure an infection or its prophylactic use (as in the case of heart transplants and hip replacements) is applicable. If the response is NO or UNKNOWN, go to Item 12. If YES, continue with part (b).

11.b The time frame refers to the last 10 years. The count concerns antibiotics and not the condition being treated. If the condition is treated with multiple courses of the same antibiotic, it is counted as one antibiotic for that condition. If a condition is treated with multiple antibiotics, the number of antibiotics for that condition is counted. For example, an episode of pneumonia treated with two, sequential courses of ampicillin is counted as "1". In contrast, an episode of pneumonia treated with two sequential courses of different antibiotics (ampicillin followed by tetracycline) is counted as "2". When participants cannot provide an accurate count, ask for a best guess. If more than 99 (highly unlikely), enter 99.

12. Items 12 - 15 focus on periodontal disease. Item 12 is a general question to ascertain whether the participant is currently experiencing bleeding gums. Read the question, stressing the time frame (within the past 2 weeks). If requested, bleeding gums can be defined as coloration of saliva when flossing or coloration of toothpaste when brushing the teeth. A positive response (YES) requires gum bleeding during (or as a result of) one or both activities, i.e., brushing the teeth or flossing. Brushing the gums is not considered brushing the teeth. For example, enter NO for persons who are edentulous, regardless of whether they are wearing dentures or practice good dental hygiene.

13.a Gum disease requires diagnosis by a dentist. The time frame is expanded to cover the participant's life time. If asked for clarification, "gum disease" refers to periodontal disease, such as receding gums, and not conditions due to medications or congenital abnormalities. Gum disease is an infection that causes the loss of support around the teeth, including the bone and support ligaments. It is associated with bleeding gums, gum recession (long teeth), and can lead to teeth that become loose or fall out. "Gingivitis" is used a lot on TV, especially in mouthwash commercials, and participants may tell you they have gingivitis. Even though gingivitis can lead to periodontal disease, by itself, it does not qualify as gum disease because it is too mild and comes and goes. If the response to the question is NO or UNKNOWN, go to Item 16. Thank the participant and indicate that this completes the

questions in this portion of the interview. If YES, continue with part (b).

13.b Record "1 to 12 months" or "1 year ago" as "01"; "13 to 24 months" or "2 years ago" as "02", etc. If the participant cannot provide an accurate number, ask for a best guess.

14.a Read the question, stressing the time frame (have you ever) and "gum disease". This refers to the positive statement in Item 13. If NO or UNKNOWN, go to Item 16. Thank the participant and indicate that this completes the questions in this portion of the interview. If YES, continue with part (b).

14.b Read the question, stressing the time frame, "first" treated. Record "1 to 12 months" or "1 year ago" as "01"; "13 to 24 months" or "2 years ago" as "02", etc. If the participant cannot provide an accurate number, ask for a best guess.

15. Read the question, stressing the time frame (have you ever) and "gum surgery". If asked for clarification, "gum surgery" refers to procedures to treat periodontal disease, and not procedures to repair trauma or other dental abnormalities.

16. Record the date on which the participant was seen in the field center. Enter numbers using leading zeroes where necessary to fill all boxes. For example, May 3, 1993 would be entered as:

05 / 03 / 93
month day year

17. Record "C" if the form was completed on the computerized data entry system, or "P" if the paper form was used. If the form was completed partially on paper and partially on the computer, enter as "paper form".

18. Enter the interviewer ID of the person administering the interview.

ARIC - VISIT 4

DEFINITIONS AND SYNONYMS FOR INFECTIOUS DISEASES - INFLAMMATION FORM

DEFINITIONS		SYNONYMS
INFA 1.a HEPATITIS	Acute (at times leading to chronic) inflammation of the liver. Can be of viral or toxic origin. Sometimes accompanied by yellow jaundice. Does not include jaundice at birth.	Jaundice
INFA 2.a TUBERCULOSIS	Chronic infection with tuberculosis bacillus, most often of the lungs	T.B.
INFA 3.a ARTHRITIS	Painful swelling of the joints; in adults most often chronic and degenerative.	
INFA 4.a URINARY TRACT INFECTION	Bacterial infection of the bladder (cystitis); or the kidney (pyelonephritis). The bladder infections are more common, and are usually accompanied by urgency, pain and/or burning sensations on voiding.	Kidney infection UTI
INFA 5.a PNEUMONIA	Bacterial or viral inflammation of a segment of the lung.	
INFA 6.a BRONCHITIS	Acute or chronic inflammation of the bronchial tree, usually accompanied by cough and expectation.	
INFA 7.a SINUSITIS	Inflammation of the sinus cavities around the nose, usually acute, accompanying an upper respiratory infection; can be chronic.	Sinus Infection

ARIC - VISIT 4
DEFINITIONS AND SYNONYMS FOR INFECTIOUS DISEASES - INFLAMMATION FORM

DEFINITIONS		SYNONYMS
INFA 8.a COLD	Upper respiratory infection or sore throat caused by the "common cold" virus; less severe or shorter duration than the "flu." Flu-like symptoms are a cold, unless accompanied by chills, fever, or gastro-intestinal symptoms.	Minor upper respiratory infection
INFA 9 FEVER BLISTER	Painful sores on the lips lasting a few days.	Cold sore
INFA 10.a SHINGLES	Viral infection (herpes zoster virus) leading to pain and sometimes small vesicles along nerve branches, usually on the trunk and less frequently other locations, such as the face. Not the same disease as "fever blisters".	Herpes zoster

ARIC
Atherosclerosis Risk in Communities

Consent Form Information

As you know, the Atherosclerosis Risk in Communities Study is a medical research project sponsored by the National Institutes of Health, conducted in four communities in the United States. It is known as the ARIC study and is authorized under 42USC 285b-3. The system of records which applies to ARIC is documented in the Federal Register, Vol. 60, No. 13, Friday, January 20, 1995, pages 4264-4266.

The purpose of the study is to learn more about the factors associated with heart diseases and hardening of the arteries. The information to be collected from this study will be used to add to our knowledge of risk factors for heart disease and may help to prevent premature deaths from heart attacks.

You are one of 4,000 people who have been selected at random (by chance) in Forsyth County by the Bowman Gray School of Medicine and the University of North Carolina at Chapel Hill to be a member of the ARIC Study.

If you agree to take part in this fourth examination of the study, you will be given a series of examinations similar to the ones you had during your previous ARIC exam. These include:

1. An interview to obtain information about your health, previous illnesses, hospitalizations, diet, your use of tobacco, alcohol, and medications.

2. An examination that will include measuring your blood pressure, heart rate, height and weight, and an electrocardiogram (ECG) which records the functioning of your heart.

3. An ultrasound examination that will take pictures of the arteries in your neck using sound waves.

4. The collection of 2½-3 ounces of blood from your arm while you are fasting for blood tests that will indicate whether you have high blood sugar, high cholesterol, and other conditions. A small sample of blood will be stored over time for possible future analyses, including genetic analyses.

5. A glucose tolerance test, such as the one used by your physician, to screen for diabetes.

As in the past ARIC clinic visits, these examinations will take about 3 hours to complete. The ARIC examination procedures are considered safe. There may be some slight discomfort during the blood drawing; however, we will have a skilled technician draw your blood. You will not be exposed to any X-rays. Ultrasound is now widely used in the evaluation of pregnancy and in other clinical applications. Your exposure to ultrasound in this examination will be no greater than a routine clinical examination. All of the tests are free of charge.

CONSENT FORM
ARIC
Atherosclerosis Risk in Communities

I have read the above and understand that I am invited to participate in the fourth examination of the ARIC study. I understand that the risks of participation are small. I understand that the benefits of taking part include possible early detection of diabetes, and heart and blood vessel problems that I may have. I also understand that my participation will add to our knowledge of risk factors for heart disease and may help to prevent premature deaths from heart attacks.

I agree to be contacted by ARIC study personnel once a year by phone or mail, and to answer questions about my health.

I authorize the ARIC study to obtain medical records from my physician and any hospitals where I might be admitted, and to contact my relatives if I die.

I understand that I am free to withdraw my consent and to stop taking part in this study at any time, without affecting any future relationship with the Bowman Gray School of Medicine. The procedures involved have been explained to me and understanding them fully I hereby consent to participate in the ARIC study.

_____ _____

Date Signature of Participant

_____

Printed Name of Participant

_____

Witness

Appendix 2.11b

INFORMED CONSENT
DENTAL ATHEROSCLEROSIS RISK IN COMMUNITIES STUDY

In addition to the ARIC examination, I am invited to take part in a research study to find out how chronic infections may affect the development of heart disease and hardening of the arteries (atherosclerosis). This includes several components:

(1) A medical history to determine whether there are any medical reasons for me not to participate or whether I am taking any medications which might affect the study results;

(2) Questions on my dental history;

(3) A brief dental exam to determine the extent of any gum (periodontal) disease I might have, and the collection of samples of fluid and plaque (tartar) from around my teeth.

The dental exam in ARIC is a portion of a standard periodontal (gum disease) exam which is routinely performed by dental hygienists for clinical purposes on thousands of patients every year. If my gums usually bleed when I brush my teeth, they may bleed a little during the examination. However, there should be no unusual pain or discomfort during the examination. As in ARIC, the oral examination is performed for research purposes only and no diagnoses nor treatment are provided.

The questions I will be asked about my dental history are similar to the questions I have been asked in the ARIC visits about my medical history. The dental exam is performed by a well-trained hygienist and take about 20 minutes. No other procedures will be required of me.

BENEFITS. The periodontal exam will be used to measure the amount of gum (periodontal) disease I have or have had. This includes an examination of my mouth and teeth to see if there are any cavities, gum disease or spaces between my teeth and gums. Although this exam is not a substitute for a complete examination given to people who go to a dentist seeking dental care, a summary of the observations and recommendations for follow-up care will be given to me at the end of the exam. The hygienist's report can also be sent to my dentist if I wish.

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RISKS. Persons who meet the American Heart Association guidelines for antibiotic coverage during a dental examination will not be eligible to participate in this study, unless they agree to have antibiotic treatment. I understand that I am not eligible to participate if I have been told by a doctor that I have one or more of the following conditions and am not treated with antibiotics for the purpose of this examination: congenital heart disease; rheumatic heart disease; an infection of the lining of the heart called endocarditis; mitral valve prolapse; a pacemaker, heart, lung, kidney or other organ transplant; or a surgically implanted heart valve, artificial joint, shunt or other body part. Further, I am not eligible if I have recently been treated for cancer within the last 2 months. To avoid exposing me to risk, a member of the ARIC staff has conducted an interview to identify any reason I should not have a dental exam, and I have, to the best of my ability, accurately answered each of these questions.

Having one of the above conditions, I am taking antibiotics for the dental exam. _____ (initials)

I understand that if any injury or illness occurs as a direct result of my participation in this study, the Bowman Gray School of Medicine will pay for medical treatment reasonably necessary to treat the injury or illness, up to a maximum of $25,000. Additional information may be obtained from the Medical Center's Director of Risk Insurance and Management (910) 748-3467. Questions about the rights of research subjects will be answered by the Chairman of the Clinical Research Practices Committee, Bowman Gray School of Medicine at (910) 748-4542. Questions about the study procedures will be answered by Dr. Gerardo Heiss or Mrs. Jeannette Bensen at (910) 777-3040.

My signature below indicates that I have read this statement and understand the study procedures, the risks, and the benefits. My participation is completely voluntary, and I am free to withdraw my consent and stop taking part at any time without affecting any future relationship with the rest of the ARIC study or with the Bowman Gray School of Medicine. The procedures have been explained to me, and understanding them fully, I hereby consent to participate in the ARIC Dental Study.

_____
PRINTED NAME

_____ _____
PARTICIPANT'S SIGNATURE DATE

_____ _____
WITNESS' SIGNATURE DATE

c:\aric\visit4\newforms\dentcnst.005:7/20/96:ccp

O.M.B. 0925-0281
exp. 09/30/98

ARIC
Atherosclerosis Risk in Communities

INFORMED CONSENT TRACKING FORM

A-153

ID NUMBER: | | | | | | | | CONTACT YEAR: | 1 | 0 | FORM CODE: | I | C | T | VERSION: A 07/18/96

LAST NAME: | | | | | | | | | | | | | INITIALS: | | |

Public reporting burden for this collection of information is estimated to average 0 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: **PHS Reports Clearance Officer, Rm. 737-F, Humphrey Building, 200 Independence Ave., SW, Washington, D.C. 20201, ATTN: PRA (0925-0281).** Do not return the completed form to this address.

INSTRUCTIONS: ID Number, Contact Year and Name must be entered above. Whenever numerical responses are required, enter the number so that the last digit appears in the rightmost box. Enter leading zeroes where necessary to fill all boxes. On the paper form, if a number is entered incorrectly, mark through the incorrect entry with an "X". Code the correct entry clearly above the incorrect entry. For "multiple choice" questions, circle the letter corresponding to the most appropriate response. If a letter is circled incorrectly, mark through it with an "X" and circle the correct response.

INFORMED CONSENT TRACKING FORM (ICTA screen 1 of 4)

A. INFORMED CONSENT

1. Type of consent: .... Full F → Go to Item 4.a., Screen 2.
   Partial P

2.a. Restrictions on use/storage of DNA? ..... Yes Y
   Go to Item 3.a. ← No N

b. Type of restriction on use/storage of DNA:

CVD research C
ARIC only ..... A
No use/storage of DNA ..... N
Other ..... O

Specify details of DNA restrictions:

_____
_____
_____
_____

3.a. Other restrictions placed on procedures or use of study data? ..... Yes Y
   Go to Item 4.a., Screen 2. ← No N

b. Type of restrictions on procedures or use of study data:

CVD research C
ARIC only ..... A
Other ..... O

Specify details of restrictions on procedures or use of study data:

_____
_____
_____
_____

INFORMED CONSENT TRACKING FORM (ICTA screen 2 of 4)

4.a. Restrictions on release of results to participant's physician? ..... Yes Y

Go to Item 5. ——— No N

b. Type of restriction placed on releasing ARIC results to the participant's physician:

Full restriction (release no results) .... F

Partial restriction ..... P

Specify details of restriction: _____

_____

_____

_____

5. Permission to access medical records? ... Yes Y

No N

Partial P

If partial, specify: _____

_____

_____

_____

B. ADMINISTRATIVE INFORMATION

6. Date of data collection: | | | / | | | / | | |

m m / d d / y y

7. Method of data collection: ..... Computer C

Paper Form P

8. Code number of person completing this form: ..... | | | |

INFORMED CONSENT TRACKING FORM (ICTA screen 3 of 4)

C. POST-VISIT CONSENT MODIFICATION

9.a. Consent changed? ..... Yes Y

Go to Item 12, Screen 4. ——— No N

b. Date of change? | | | / | | | / | | |

m m / d d / y y

10.a. Restrictions on use/storage of DNA? ..... Yes Y

Go to Item 11.a. ——— No N

b. Type of restriction on use/storage of DNA?

CVD research C

ARIC only ..... A

No use/storage of DNA ..... N

Other ..... O

Specify details of DNA restrictions:

_____

_____

_____

_____

11.a. Other restrictions placed on procedures or use of study data? ..... Yes Y

Go to Item 12, Screen 4. ——— No N

b. Type of restriction on procedures or use of study data:

CVD research C

ARIC only ..... A

Other ..... O

Specify details of restrictions on procedures or use of study data:

_____

_____

_____

_____

INFORMED CONSENT TRACKING FORM (ICTA screen 4 of 4)

12. Permission to access medical records? ..... Yes Y
No N
Partial P

If partial, specify: _____

_____

_____

_____

13.a. Withdrawal from study? ..... Yes Y
Go to Item 14. ——— No N

If "Yes", specify details of withdrawal request:

_____

_____

_____

_____

13.b. Date of withdrawal request: [ ][ ]/[ ][ ]/[ ][ ]
m m / d d / y y

14. Code number of person completing post-visit consent or withdrawal on this form: [ ][ ][ ]

(ICTA screen 1 of 4)

A. INFORMED CONSENT

1~ Type of consent: _ []
Full (F)* or Partial (P)

2a~ Restrictions on use/storage of DNA? _ []
Yes (Y) or No (N)*

b~ Type of restriction on use/storage of DNA: _ []

CVD research	(C)*
ARIC only	(A)*
No use/storage of DNA	(N)*
Other?	(O)*

[Specify details of DNA restrictions in notelog.]

3a~ Other restrictions placed on procedures or use of study data? _ []
Yes (Y) or No (N)*

b~ Type of restriction on procedures or use of study data: _ []

CVD research	(C)*
ARIC only	(A)*
Other?	(O)*

[Specify details of restrictions on procedures or use of study data in notelog.]

(ICTA screen 2 of 4)

4a~ Restrictions on release of results to participant's physician? _ []

Yes (Y) or No (N)*

b~ Type of restriction placed on releasing ARIC results to the participant's physician: _ []

Full restriction (Release no results)	(F)*
Partial restriction	(P)*

[Specify details of restriction in notelog.]

5~ Permission to access medical records? _ []

Yes (Y), No (N) or Partial (P)*

[If partial, specify in notelog.]

B. ADMINISTRATIVE INFORMATION

6~ Date of data collection: _____ []
mm/dd/yy

7~ Method of data collection: _ []

Computer (C) or Paper (P)

8~ Code number of person completing this form: (*) ___ []

(ICTA screen 3 of 4)

C. POST-VISIT CONSENT MODIFICATION

9.a~ Consent changed? _ ▯
Yes (Y) or No (N)*

b~ Date of change: _____ ▯
mm/dd/yy

10a~ Restrictions on use/storage of DNA? _ ▯
Yes (Y) or No (N)*

b~ Type of restriction on use/storage of DNA: _ ▯

CVD research	(C)*
ARIC only	(A)*
No use/storage of DNA	(N)*
Other?	(O)*

[Specify details of DNA restrictions in notelog.]

11a~ Other restrictions placed on procedures or use of study data? _ ▯
Yes (Y) or No (N)*

b~ Type of restriction on procedures or use of study data: _ ▯

CVD research	(C)*
ARIC only	(A)*
Other?	(O)*

[Specify details of restrictions on procedures or use of study data in notelog.]

(ICTA screen 4 of 4)

12~ Permission to access medical records? _ ▯

Yes (Y), No (N) or Partial(P)*

[If partial, specify in notelog.]

13a~ Withdrawal from study? _ ▯

Yes(Y)* or No(N)*

[If Yes, specify details of withdrawal request in notelog.]

13b~ Date of withdrawal request: _____ ▯
mm/dd/yy

14~ Code number of person completing post-visit consent or withdrawal on this form: ___ ▯

INSTRUCTIONS FOR THE INFORMED CONSENT TRACKING FORM ICTA, VERSION A, 07/18/96 PREPARED 08/21/96

I. GENERAL INSTRUCTIONS

This form is an internal form and is NOT administered to participants. The purpose of the form is to document and track in the ARIC central database the initial level of, and subsequent (if any) changes to, participants' restrictions on the use of their DNA or other study data by the ARIC investigators. Items 1-8 on the form are completed by an interviewer at the reception workstation, after participants have read and signed the informed consent form. Items 9 through 14 are completed when a participant notifies the study of a desire to either change his/her type of consent or access to medical records, or to withdraw from the study.

II. DETAILED INSTRUCTIONS FOR EACH ITEM

1. **Type of consent.** FULL consent means the informed consent document was signed and all conditions on the signature page and all procedures in the narrative description were agreed to. If FULL consent is obtained, continue with Item 4.a. PARTIAL consent means the document was signed, but restrictions were placed on one or more conditions on the signature page or in the description of the study.

2. **Restrictions on storage or use of DNA.** (Item 2.a.) NO means there are no restrictions on the use or storage of DNA and item 2.b is skipped. YES indicates that some type of DNA restriction was requested. (Item 2.b.) CVD RESEARCH means the participant has agreed to the storage and use of his/her DNA only in studies on cardiovascular diseases. ARIC ONLY is more limited and means the participant restricts the storage and use of his/her DNA to the ARIC Study. NO USE/STORAGE OF DNA is used to indicate absolute refusal of any DNA storage or DNA use. OTHER means that one of the above limitations on the use of DNA may have been requested AND/OR the participant has indicated ADDITIONAL/OTHER restrictions on the use of his/her DNA. List all of these restrictions under "specify", even if they include "CVD research" or "ARIC only".

3. **Other restrictions placed on procedures or use of study data.** (Item 3.a.) NO means that except for the use and storage of DNA or reporting of results to their physician, the participant has placed no other restrictions on his/her participation or the use of his/her study data. A NO response skips to Item 4.a. A YES response indicates that some other restriction has been requested. (Item 3.b.) CVD RESEARCH means the participant has agreed to the use of his/her study data only in studies on cardiovascular diseases. ARIC ONLY is more limited and means the participant restricts the use of his/her study data to only the ARIC Study. OTHER means that

one of the above limitations on the use of study data may have been requested AND/OR the participant has indicated ADDITIONAL/OTHER restrictions, either in the procedures or use of data. List all of these restrictions under "specify".

4. **Restrictions on release of results to participant's physician.** (Item 4.a.) NO indicates that no restrictions have been placed on the release of results to the participant's physician and item 4.b. is skipped. YES means that the participant has requested some type of restriction on reporting results to their physician. (Item 4.b.) FULL RESTRICTION means that no results are to be released to the participant's physician. PARTIAL RESTRICTION is used to indicate that some type of restriction less than full restriction has been placed on the release of results to the participant's physician. The details of the partial restriction need to be provided under "Specify".

5. **Permission to access medical records.** Select YES to indicate that ARIC has full permission to access the participant's medication records. NO indicates complete refusal to have ARIC staff access his/her medical records. PARTIAL means that some restriction less than full has been placed on ARIC staff accessing the participant's medication records. Details of the type of PARTIAL restriction are to be provided under "Specify".

6. **Date of data collection.** Using the standard date format, enter the date on which the informed consent document was administered and signed by the participant. This date is NOT changed when participants subsequently change their level of consent or withdraw from the study.

7. **Method of data collection.** Record "C" if the form is completed using direct data entry and "P" if the form is collected on paper for delayed data entry. If the form is completed partially on paper and partially on computer, select "P".

8. **Code number of person completing this form.** Enter the code number of the person completing the form.

Items 9-14 are only completed when participants subsequently contact the study and indicate one or more of the following:

a desire to change the original level of informed consent;

to revise the study's access to their medical records;

or to withdraw from the study.

It is possible that a change in the level of consent may not result in withdrawal from the study, or vice versa, withdrawal from the study may not *ipso facto* result in a revision of the restrictions placed on the use of study data in medical research. However, responses to all items in this section (Items 9-14) must be completed when participants recontact the study and request a revision of either status. Items 1-8 are not changed.

9. **Consent changed?** (Item 9.a.) Select YES or NO to indicate whether the participant requests any change in the previous type of informed consent. If no change is requested, select NO and go to Item 12. If a change is requested, enter the date on which the request was made in Item 9.b. using the standard date format and then SPECIFY the type of change(s) in Items 10 and 11.

10. **Restrictions on use/storage of DNA.** Follow the directions and definitions for Item 2.

11. **Other restrictions placed on procedures or use of study data.** Follow the directions and definitions in Item 3.

12. **Permission to access medical records.** Follow the directions and definitions in Item 5.

13. **Withdrawal from study.** (Item 13.a.) Select YES or NO to indicate whether the participant requests to be withdrawn from the ARIC Study. If NO, go to Item 14. If YES, provide details of the withdrawal under "specify". Document the date on which the request was made in Item 13.b.

14. **Code number of person completing the post-visit section of the form.** Enter the staff identification code of the person completing this portion of the form.

ARIC
Atherosclerosis Risk in Communities

Appendix 2.13a

MEDICAL HISTORY QUESTIONNAIRE

O.M.B. 0925-0281
exp. 09/30/98

A-161

ID NUMBER: | | | | | | | | CONTACT YEAR: | | | FORM CODE: | M | H | Q | VERSION: A 03/12/96

LAST NAME: | | | | | | | | | | | | | INITIALS: | | |

INSTRUCTIONS:

This questionnaire asks for information on your medical history. Please take your time and answer carefully. Mark only one response for each question or statement. For "multiple choice " and "yes/no" type questions, place an 'X' in the appropriate response box. If you make a mistake, black out that box and place an 'X' in the correct box.

1.a. Has a doctor ever told you that you had arthritis?	1.b. How old were you when you were first told you had arthritis?	1.c. Which type of arthritis was it?
☐ Yes →	_____ age	☐ Rheumatoid arthritis
☐ No (skip to Item 2.a.)		☐ Osteoarthritis
		☐ Don't Know
		(continue with Item 2.a.)
2.a. Has a doctor ever told you that you had hay fever?		2.b. Do you still have hay fever?
☐ Yes →		☐ Yes
☐ No (skip to Item 3.a.)		☐ No
		☐ Don't Know
		(continue with Item 3.a.)

3.a. Has a doctor ever told you that you had cataracts? ☐ Yes → ☐ No (skip to Item 4.a.)	3.b. How old were you when you were first told you had cataracts? _____ age (continue with Item 4.a.)	
4.a. Has a doctor ever told you that you had goiter or other thyroid diseases? ☐ Yes → ☐ No (skip to Item 5.a.)	4.b. How old were you when you were first told you had goiter or other thyroid diseases? _____ age	4.c. Do you still have goiter or other thyroid diseases? ☐ Yes ☐ No ☐ Don't Know (continue with Item 5.a.)
5.a. Has a doctor ever told you that you had lupus? ☐ Yes → ☐ No (skip to Item 6.a.)	5.b. How old were you when you were first told you had lupus? _____ age (continue with Item 6.a.)	

6.a. Has a doctor ever told you that you had gout? ☐ Yes → ☐ No (skip to Item 7.a.)	6.b. How old were you when you were first told you had gout? _____ age (continue with Item 7.a.)	
7.a. Has a doctor ever told you that you had stomach or duodenal ulcer? ☐ Yes → ☐ No (skip to Item 8.)	7.b. How old were you when you were first told you had stomach or duodenal ulcer? _____ age	7.c. Do you still have stomach or duodenal ulcer? ☐ Yes ☐ No ☐ Don't Know (continue with Item 8.)
8. Has a doctor ever told you that you had adenoma or polyp of the colon (large intestine)? ☐ Yes ☐ No (continue with Item 9.a.)		

9.a. Has a doctor **ever** told you that you had a blood clot in a leg (deep vein thrombosis)? This does not include varicose veins or phlebitis. ☐ Yes → ☐ No (skip to Item 10.a.)	9.b. How old were you when you were **first** told you had a blood clot in a leg? _____ age (continue with Item 10.a.)	
10.a. Has a doctor **ever** told you that you had a blood clot in your lungs (pulmonary embolus)? ☐ Yes → ☐ No (skip to Item 11.a.)	10.b. How old were you when you were **first** told you had a blood clot in your lungs? _____ age (continue with Item 11.a.)	
11.a. Has a doctor **ever** told you that you had Parkinson's disease? ☐ Yes → ☐ No (skip to Item 12.a.)	11.b. How old were you when you were **first** told you had Parkinson's disease? _____ age (continue with Item 12.a.)	

12.a. Has a doctor **ever** told you that you had gallstones?

☐ Yes →

☐ No (skip to Item 13.a.)

☐ Don't Know (skip to Item 13.a.)

12.b. Have you ever had medical treatment to dissolve or remove gallstones? Do not include surgery.

☐ Yes ☐ No ☐ Don't Know

(continue with Item 13.a.)

13.a. Have you ever had gallbladder surgery?

☐ Yes →

☐ No (skip to Item 14.a.)

☐ Don't Know (skip to Item 14.a.)

13.b. How old were you when you had gallbladder surgery?

_____ age

(continue with Item 14.a.)

14.a. Has a doctor **ever** told you that you had broken or fractured your hip?

☐ Yes →

☐ No (skip to Item 15.a.)

14.b. About how old were you when you fractured your hip for the first time?

_____ age

(continue with Item 15.a.)

15.a. Has a doctor **ever** told you that you had broken or fractured your wrist?

☐ Yes →

☐ No (skip to Item 16.a.)

15.b. About how old were you when you fractured your wrist for the first time?

_____ age

(continue with Item 16.a.)

16.a. Has a doctor **ever** told you that you had broken or fractured your spine?

☐ Yes →

☐ No (skip to Item 17.a.)

16.b. About how old were you when you fractured your spine for the first time?

_____ age

(continue with Item 17.a.)

17.a. Have you ever had <u>pain</u> in your hands? This also includes aching and stiffness. ☐ Yes → ☐ No (skip to Item 18.a.) ☐ Don't Know (skip to Item 18.a.)	17.b. Has this pain been present <u>on most days for at least 6 weeks</u>? ☐ Yes ☐ No ☐ Don't Know (continue with Item 18.a.)
18.a. Have you ever had <u>swelling</u> in your hands that hurt when the joint was touched? ☐ Yes → ☐ No (skip to Item 19.a.) ☐ Don't Know (skip to Item 19.a.)	18.b. Has this swelling been present <u>on most days for at least 6 weeks</u>? ☐ Yes ☐ No ☐ Don't Know (continue with Item 19.a.)
19.a. Have you ever had <u>stiffness</u> in your hands <u>when first getting out of bed in the morning?</u> ☐ Yes → ☐ No (skip to Item 20.a.) ☐ Don't Know (skip to Item 20.a.)	19.b. Has this stiffness been present <u>on most days for at least 6 weeks</u>? ☐ Yes ☐ No ☐ Don't Know (continue with Item 19.c.)
	19.c. How long after getting up and moving around does the morning stiffness last? ☐ less than 30 minutes ☐ 30 min. - 1 hour ☐ 1 - 3 hours ☐ more than 3 hours (continue with Item 20.a.)

20.a. Have you ever had pain in your knees? This also includes aching and stiffness.	☐ Yes → ☐ No (skip to Item 21.a.) ☐ Don't Know (skip to Item 21.a.)	20.b. Has this pain been present on most days for at least 6 weeks? ☐ Yes ☐ No ☐ Don't Know (continue with Item 21.a.)
21.a. Have you ever had swelling in your knees that hurt when the joint was touched?	☐ Yes → ☐ No (skip to Item 22.a.) ☐ Don't Know (skip to Item 22.a.)	21.b. Has this swelling been present on most days for at least 6 weeks? ☐ Yes ☐ No ☐ Don't Know (continue with Item 22.a.)
22.a. Have you ever had stiffness in your knees when first getting out of bed in the morning?	☐ Yes → ☐ No (skip to Item 23.a.) ☐ Don't Know (skip to Item 23.a.)	22.b. Has this stiffness been present on most days for at least 6 weeks? ☐ Yes ☐ No ☐ Don't Know (continue with Item 23.a.)
23.a. Have you ever had pain in your hips?	☐ Yes → ☐ No (skip to Item 24) ☐ Don't Know (skip to Item 24)	23.b. Has this pain been present on most days for at least 6 weeks? ☐ Yes ☐ No ☐ Don't Know (continue with Item 24.)

24. How many times a night do you usually get up to urinate (pass water)?

☐ None ☐ 1 ☐ 2 ☐ 3 or more times

[IF YOU ARE A MAN, PLEASE ANSWER ITEMS 25 AND 26]

25. Has the force of your urinary stream or water decreased over the years?

☐ Yes ☐ No

26. Have you ever had surgery for your prostate, not related to cancer?

☐ Yes ☐ No

This completes the Medical History Questionnaire. Thank you.

FOR ADMINISTRATIVE USE ONLY.

27. Date ☐☐/☐☐/☐☐ 28. Administration (A,B,C,D) ☐ 29. Code ☐☐☐

(MHQA screen 1 of 10)

1.a~ Has a doctor ever told you that you had arthritis? _ []

Yes (Y) or No (N)*

b~ How old were you when you were first told you had arthritis? __ [] age

c~ Which type of arthritis was it? _ []

Rheumatoid arthritis (R)
Osteoarthritis (O)
Don't Know (D)

2.a~ Has a doctor ever told you that you had hay fever? _ []

Yes (Y) or No (N)*

b~ Do you still have hay fever? _ []

Yes(Y), No(N) or Don't Know(D)

(MHQA screen 2 of 10)

3.a~ Has a doctor ever told you that you had cataracts? _ []

Yes(Y) or No(N)*

b~ How old were you when you were first told you had cataracts? __ [] age

4.a~ Has a doctor ever told you that you had goiter or other thyroid diseases? _ []

Yes (Y) or No (N)*

b~ How old were you when you were first told you had goiter or other thyroid diseases? __ [] age

4.c~ Do you still have goiter or other thyroid diseases? _ []

Yes (Y), No (N) or Don't Know (D)

5.a~ Has a doctor ever told you that you had lupus? _ []

Yes (Y) or No (N)*

b~ How old were you when you were first told you had lupus? __ [] age

(MHQA screen 3 of 10)

6.a~ Has a doctor ever told you that you had gout? _ ☐

Yes (Y) or No (N)*

b~ How old were you when you were first told you had gout? __ ☐ age

7.a~ Has a doctor ever told you that you had stomach or duodenal ulcer? _ ☐

Yes (Y) or No (N)*

b~ How old were you when you were first told you had stomach or duodenal ulcer? __ ☐ age

7.c~ Do you still have stomach or duodenal ulcer? _ ☐

Yes (Y), No (N) or Don't Know (D)

8~ Has a doctor ever told you that you had adenoma or polyp of the colon (large intestine)? _ ☐

Yes (Y) or No (N)

(MHQA screen 4 of 10)

9.a~ Has a doctor ever told you that you had a blood clot in a leg (deep vein thrombosis)? This does not include varicose veins or phlebitis. _ ☐

Yes (Y) or No (N)*

b~ How old were you when you were first told you had a blood clot in a leg? __ ☐ age

10.a~ Has a doctor ever told you that you had a blood clot in your lungs (pulmonary embolus)? _ ☐

Yes (Y) or No (N)*

10.b~ How old were you when you were first told you had a blood clot in your lungs? __ ☐ age

11.a~ Has a doctor ever told you that you had Parkinson's disease? _ ☐

Yes (Y) or No (N)*

b~ How old were you when you were first told you had Parkinson's disease? __ ☐ age

(MHQA screen 5 of 10)

12.a~ Has a doctor ever told you that you had gallstones? _ ☐

Yes (Y), No (N)* or Don't Know (D)*

b~ Have you ever had medical treatment to dissolve or remove gallstones? Do not include surgery. _ ☐

Yes (Y), No (N) or Don't Know (D)

13.a~ Have you ever had gallbladder surgery? _ ☐

Yes (Y), No (N)* or Don't Know (D)*

b~ How old were you when you had gallbladder surgery? __ ☐ age

14.a~ Has a doctor ever told you that you had broken or fractured your hip? _ ☐

Yes (Y) or No (N)*

b~ About how old were you when you fractured your hip for the first time? __ ☐ age

15.a~ Has a doctor ever told you that you had broken or fractured your wrist? _ ☐

Yes (Y) or No (N)*

b~ About how old were you when you fractured your wrist for the first time? __ ☐ age

(MHQA screen 6 of 10)

16.a~ Has a doctor ever told you that you had broken or fractured your spine? _ ☐

Yes (Y) or No (N)*

b~ About how old were you when you fractured your spine for the first time? __ ☐ age

17.a~ Have you ever had pain in your hands? This also includes aching and stiffness. _ ☐

Yes(Y), No(N)* or Don't Know(D)*

17.b~ Has this pain been present on most days for at least 6 weeks? _ ☐

Yes(Y), No(N) or Don't Know(D)

18.a~ Have you ever had swelling in your hands that hurt when the joint was touched? _ ☐

Yes(Y), No(N)* or Don't Know(D)*

b~ Has this swelling been present on most days for at least 6 weeks? _ ☐

Yes(Y), No(N) or Don't Know(D)

(MHQA screen 7 of 10)

19.a~ Have you ever had stiffness in your hands when first getting out of bed in the morning? _ ☐

Yes(Y), No(N)* or Don't Know(D)*

b~ Has this stiffness been present on most days for at least 6 weeks? _ ☐

Yes(Y), No(N) or Don't Know(D)

19.c~ How long after getting up and moving around does the morning stiffness last? _ ☐

Less than 30 minutes	(A)
30 minutes - 1 hour	(B)
1 - 3 hours	(C)
More than 3 hours	(D)

(MHQA screen 8 of 10)

20.a~ Have you ever had pain in your knees? This also includes aching and stiffness. _ ☐

Yes(Y), No(N)* or Don't Know(D)*

b~ Has this pain been present on most days for at least 6 weeks? _ ☐

Yes(Y), No(N) or Don't Know(D)

21.a~ Have you ever had swelling in your knees that hurt when the joint was touched? _ ☐

Yes(Y), No(N)* or Don't Know(D)*

21.b~ Has this swelling been present on most days for at least 6 weeks? _ ☐

Yes(Y), No(N) or Don't Know(D)

22.a~ Have you ever had stiffness in your knees when first getting out of bed in the morning? _ ☐

Yes(Y), No(N)* or Don't Know(D)*

b~ Has this stiffness been present on most days for at least 6 weeks? _ ☐

Yes(Y), No(N) or Don't Know(D)

(MHQA screen 9 of 10)

23.a~ Have you ever had pain in your hips? _ ☐

Yes(Y), No(N)* or Don't Know(D)*

b~ Has this pain been present on most days for at least 6 weeks? _ ☐

Yes(Y), No(N) or Don't Know(D)

24~ How many times a night do you usually get up to urinate (pass water)? _ ☐

None	(A)
1 time	(B)
2 times	(C)
3 or more times	(D)

[IF YOU ARE A MAN, PLEASE ANSWER ITEMS 25 AND 26]

25~ Has the force of your urinary stream or water decreased over the years? _ ☐

Yes (Y) or No (N)

26~ Have you ever had surgery for your prostate, not related to cancer? _ ☐

Yes (Y) or No (N)

(MHQA screen 10 of 10)

27~ Date of data collection: _____ ☐
mm/dd/yy

28~ Type of administration: _ ☐

Self Administered	(A)
Interviewer Administered	(B)
Both	(C)
Not Done	(D)

29~ Code number of person reviewing/ completing this form: ___ ☐

ARIC
Atherosclerosis Risk in Communities

Appendix 2.13c

O.M.B. 0925-0281
exp. 09/30/98

DEMONSTRATION QUESTIONNAIRE

ID NUMBER: TESTNAME XXXXXXXXXXX ID TEST ID ARIC XX CY

FORM CODE: M H Q

VERSION: A 01/31/96

LAST NAME: P A R T I C I P A N T

INITIALS: A B

INSTRUCTIONS:

This is a demonstration questionnaire to be explained by a field center interviewer. Typical instruction are: Please take your time and answer carefully. Mark only one response for each question or statement. For "multiple choice " and "yes/no" type questions, place an 'X' in the appropriate response box. If you make a mistake, black out that box and place an 'X' in the correct box. Some responses may require you to skip the next item and answer a later item.

1.a. Is this response correct? ☐ Yes → ☒ No (skip to Item 2.a.)	1.b. _____ age	
2.a. Is it raining? ☐ Yes ☒ No		

1.a. Is this response correct? ☒ Yes → ☒ No (skip to Item 2.a.)	1.b. 50 age	
2.a. Is it raining? ☐ Yes ☒ No		

This completes the Demonstration Questionnaire. Thank you.

FOR ADMINISTRATIVE USE ONLY.

25. Date ☐☐/☐☐/☐☐ 26. Administration (A,B,C,D) ☐ 27. Code ☐☐☐

Appendix 2.14a

ARIC
Atherosclerosis Risk in Communities

MEDICATION SURVEY FORM

O.M.B. 0925-0281
exp. 09/30/98

ID NUMBER: | | | | | | | | CONTACT YEAR: | 1 | 0 | FORM CODE: | M | S | R | VERSION: D 12/05/95

LAST NAME: | | | | | | | | | | | | | INITIALS: | | |

Public reporting burden for this collection of information is estimated to average 4 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: **PHS Reports Clearance Officer, Rm. 737-F, Humphrey Building, 200 Independence Ave., SW, Washington, D.C. 20201, ATTN: PRA (0925-0281).** Do not return the completed form to this address.

INSTRUCTIONS:

This form is completed in several stages by appropriately trained persons at the workstations identified for this purpose. If the paper form is used for data collection, data are keyed into the data entry system as soon as possible following its completion. ID number, participant name and contact year are entered above. Whenever numerical responses are required, enter the number so that the last digit appears in the rightmost box. Enter leading zeros where necessary to fill all boxes. If a number is entered incorrectly on a paper form, mark through the incorrect entry with an "X". Code the correct entry clearly above the incorrect entry. For "multiple choice" and "yes/no" type questions, circle the letter corresponding to the most appropriate response. If a letter is circled incorrectly, mark through it with an "X" and circle the correct response.

At the Reception station, verify that the medication bag is clearly identified with the participant's name. Do not open the medication bag or transcribe medications until the participant has signed the informed consent. The transcription section of Section B is completed while the participant proceeds with the visit. Medications are coded by trained field center personnel after the transcription and interview portions have been completed. Code numbers of the interviewer, transcriber and coder are recorded in the appropriate locations.

MEDICATION SURVEY FORM (MSRD screen 1 of 11)

A. RECEPTION

1. Did you bring all the medications you used in the past two weeks, or their containers?

Go to Section B and begin transcription while participant proceeds with clinic visit	Yes, all	Y
Go to Item 3; transcribe those medications which were brought at this time	Some of them	S
	No	N

2. Is this because you forgot, because you have not taken any medications at all in the last two weeks, or because you could not bring your medications?

Go to Item 25 Screen 6	Took no medications	T
	Forgot or was unable to bring medications	F

MEDICATION SURVEY FORM (MSRD screen 2 of 11)

"That's alright. Since the information on medications is so important, we would still like to ask you about it during the interview."

3. Could we follow up on this after the visit so that we can get the information from the (other) medication labels? (Explain follow-up options) ..... Yes Y

No or not applicable N

(Attempt to convert refusals; indicate on Itinerary Form)

Describe method of follow-up to be used: _____

MEDICATION SURVEY FORM (MSRD screen 3 of 11)

B. MEDICATION RECORDS

I. Transcription (Copy the NAME followed by the CONCENTRATION of each medication in the spaces below. (Continue on second line if needed)):

II. Interview (For each medication, circle the appropriate response to the following question):

RECORD NUMBER	a. MEDICATION NAME	b. CONCENTRATION	c. CODE NO.	d. "Did you take this medication in the past 24 hours?" YES (Y)/ NO (N) UNKNOWN (U)
4.				Y N U
5.				Y N U
6.				Y N U
7.				Y N U

MEDICATION SURVEY FORM (MSRD screen 4 of 11)

RECORD NUMBER	a. MEDICATION NAME	b. CONCENTRATION	c. CODE NO.	d. YES (Y)/ NO (N) UNKNOWN (U)
8.				Y N U
9.				Y N U
10.				Y N U
11.				Y N U
12.				Y N U
13.				Y N U
14.				Y N U
15.				Y N U
16.				Y N U
17.				Y N U
18.				Y N U
19.				Y N U
20.				Y N U

MEDICATION SURVEY FORM (MSRD screen 5 of 11)

21. Total number of medications in bag: ..... [ ][ ]

22. Number of medications unable to transcribe: ..... [ ][ ]

23. Code numbers of persons transcribing and coding medications:

a. Transcriber code number: ..... [ ][ ][ ]

b. Medication coder code number: ..... [ ][ ][ ]

c. Date of medication coding: ..... [ ][ ]/[ ][ ]/[ ][ ]
month day year

MEDICATION SURVEY FORM (MSRD screen 6 of 11)

C. INTERVIEW

"Now I would like to ask about a few specific medications."

24. Were any of the medications you took during the past two weeks for:
{If "Yes," verify that medication name is on medication record.}

	Yes	No	Unknown
a. High Blood Pressure	Y	N	U
b. High Blood Cholesterol	Y	N	U
c. Angina or Chest Pain	Y	N	U
d. Control of Heart Rhythm	Y	N	U
e. Heart Failure	Y	N	U
f. Blood Thinning	Y	N	U
g. Diabetes or High Blood Sugar	Y	N	U
h. Stroke	Y	N	U
i. Leg pain when walking	Y	N	U

25. During the past two weeks, did you take any aspirin, Alka-Seltzer, cold medicine or headache powder? ..... Yes Y

No N

Unknown U

Go to Item 28, Screen 7.

MEDICATION SURVEY FORM (MSRD screen 7 of 11)

26. How many days during the last two weeks did you take aspirin, or a medication that contains aspirin? ..... ☐☐ days

[Record 00 if participant did not take aspirin and go to Item 28.]

27. For what purpose are you taking aspirin? ..... Participant mentioned avoiding heart attack or stroke H
[DO NOT READ CHOICES]
Participant did not mention avoiding heart attack or stroke O

28. During the past two weeks, did you take any [other] medication for arthritis, fever, or muscle aches and pains, (or menstrual cramps)?..... Yes Y
(Read bracketed "other" unless no medications were reported; include parenthetical portion for females only)
No N
Unknown U

MEDICATION SURVEY FORM (MSRD screen 8 of 11)

"Next I would like to ask you about your regular use of aspirin alone or an aspirin containing medication, for example, aspirin+caffeine+codeine. By regular, I mean at least once a week for several months."

29. Are you NOW taking aspirin, or a medicine containing aspirin, on a regular basis? This does not include Tylenol nor Advil. ..... Yes Y

Go to Item 30, screen 10. — No N
Unknown U

a. What is the strength of aspirin in the pill? (Check the preparation, if available; otherwise - **SHOW RESPONSE CARD #1**).

Less than 300 mg (Baby) ..... A

300 - 499 mg (Regular) ..... B

500 mg or greater (Extra strength) C

Don't know ..... D

MEDICATION SURVEY FORM (MSRD screen 9 of 11)

29.b. How many days a week, on average, are you taking this medication? ..... ☐ days per week

c. How many pills are you taking per week, on average? ..... ☐☐ pills per week

d. For what purpose are you taking this medication?

Participant mentioned to avoid heart attack or stroke ..... H

Participant did not mention to avoid heart or attack or stroke ..... O

e. When did you start taking aspirin, or a medicine containing aspirin, on a regular basis? ..... ☐☐/☐☐

month year

MEDICATION SURVEY FORM (MSRD screen 10 of 11)

30. Except for aspirin or Tylenol, are you NOW taking other non-steroidal anti-inflammatory drugs or arthritis medicines on a regular basis? Examples include Ibuprofen, Advil, Nuprin, Motrin, Naprosyn, Feldene and Clinoril. ..... Yes Y

No N

Unknown U

Go to Item 31, Screen 11.

a. What is the brand name of the medicine? (Check the preparation, if available). ..... Ibuprofen or Advil I

Other O

b. If "Other", specify:

_____

c. How many pills per week are you taking, on average? ..... ☐☐ pills per week

d. When did you start taking _____ [insert name] on a regular basis? ..... ☐☐/☐☐

month year

MEDICATION SURVEY FORM (MSRD screen 11 of 11)

D. ADMINISTRATIVE INFORMATION

31. Date of data collection: ..... | | | / | | | / | | |
month day year

32. Method of data collection: ..... Computer C
Paper form P

33. Code number of person completing this form: ..... | | | |

Less than 300 mg (Baby) ..... A

300 - 499 mg (Regular) ..... B

500 mg or greater (Extra strength) C

Don't Know ..... D

Appendix 2.14b

(MSRD screen 1 of 11)

A. RECEPTION

1~ Did you bring all the medications you used in the past two weeks, or their containers? _

Yes, all	(Y)*
Some of them	(S)*
No	(N)

2~ Is this because you forgot, because you have not taken any medications at all in the last two weeks, or because you could not bring your medications? _

Took no medications	(T)*
Forgot or was unable to bring medications	(F)

(MSRD screen 2 of 11)

"That's alright. Since the information on medications is so important we would still like to ask you about it during the interview."

3~ Could we follow up on this after the visit so that we can get the information from the (other) medication labels? _
[EXPLAIN FOLLOW-UP OPTIONS]

Yes	(Y)
No or not applicable	(N)

[ATTEMPT TO CONVERT REFUSALS; INDICATE ON ITINERARY FORM]

[DESCRIBE METHOD OF FOLLOW-UP ON NOTE LOG]

(MSRD screen 3 of 11)

B. MEDICATION RECORDS
[GO TO ITEM 25, SCREEN 6 IF NONE]

I. Transcription (Copy the NAME followed by the CONCENTRATION of each medication in the spaces below. (Continue on second line if needed)):

II. Interview (For each medication, circle the appropriate response to the following question):

RECORD NUMBER	a. MEDICATION NAME	b. CONC.	c. CODE NO.	d. "Did you take this medication in the past 24 hours? YES (Y)/NO (N) UNKNOWN (U)
4.	a~_____	b~_____	c~_____	d~_
5.	a~_____	b~_____	c~_____	d~_
6.	a~_____	b~_____	c~_____	d~_
7.	a~_____	b~_____	c~_____	d~_

(MSRD screen 4 of 11)

B. MEDICATION RECORDS (continued)

RECORD NUMBER	a. MEDICATION NAME	b. CONC.	c. CODE NO.	d. YES (Y)/NO (N) UNKNOWN (U)
8.	a~_____	b~_____	c~_____	d~_
9.	a~_____	b~_____	c~_____	d~_
10.	a~_____	b~_____	c~_____	d~_
11.	a~_____	b~_____	c~_____	d~_
12.	a~_____	b~_____	c~_____	d~_
13.	a~_____	b~_____	c~_____	d~_
14.	a~_____	b~_____	c~_____	d~_
15.	a~_____	b~_____	c~_____	d~_
16.	a~_____	b~_____	c~_____	d~_
17.	a~_____	b~_____	c~_____	d~_
18.	a~_____	b~_____	c~_____	d~_
19.	a~_____	b~_____	c~_____	d~_
20.	a~_____	b~_____	c~_____	d~_

(MSRD screen 5 of 11)

21~ Total number of medications in bag: __

22~ Number of medications unable to transcribe: __

23. Code numbers of persons transcribing and coding medications:

a~ Transcriber code number: ___

b~ Medication coder code number: ___

c~ Date of medication coding: _____
mm/dd/yy

(MSRD screen 6 of 11)

C. INTERVIEW

"Now I would like to ask about a few specific medications."

24. Were any of the medications you took during the past two weeks for:

Yes (Y), No (N) or Unknown (U)
[If Yes, verify that medication name is on medication record]

a~ High Blood Pressure: _
b~ High Blood Cholesterol: _
c~ Angina or Chest Pain: _
d~ Control of Heart Rhythm: _
e~ Heart Failure: _
f~ Blood Thinning: _
g~ Diabetes or High Blood Sugar: _
h~ Stroke: _
i~ Leg pain when walking: _

25~ During the past two weeks, did you take any Aspirin, Alka-Seltzer, cold medicine, or headache powder? _

Yes (Y), No (N)* or Unknown (U)*

(MSRD screen 7 of 11)

26~ How many days during the last two weeks did you take aspirin, or a medication that contains aspirin? __ days
[Record 00 if participant did not take aspirin and go to Item 28]

27~ For what purpose are you taking aspirin? _

[DO NOT READ CHOICES]

Participant mentioned avoiding heart attack or stroke: H
Participant did not mention avoiding heart attack or stroke: O

28~ During the past two weeks, did you take any [other] medication for arthritis, fever, or muscle aches and pains, (or menstrual cramps)? _

Yes (Y), No (N) or Unknown (U)

[READ BRACKETED "OTHER" UNLESS NO MEDICATIONS WERE REPORTED; INCLUDE PARENTHETICAL PORTION FOR FEMALES ONLY]

(MSRD screen 8 of 11)

"Next I would like to ask you about your regular use of aspirin alone or an aspirin containing medication, for example, aspirin+caffeine+codeine. By regular, I mean at least once a week for several months."

29~ Are you NOW taking aspirin, or a medicine containing aspirin, on a regular basis? This does not include Tylenol nor Advil. _
Yes(Y) No(N)* Unknown(U)*

a~ What is the strength of aspirin in the pill? (Check the preparation, if available; otherwise - SHOW RESPONSE CARD #1). _

Less than 300 mg (Baby) ..... A

300 - 499 mg (Regular) ..... B

500 mg or greater (Extra strength) C

Don't know ..... D

(MSRD screen 9 of 11)

29.b~ How many days a week, on average, are you taking this medication? _ days per week

c~ How many pills are you taking per week, on average? __ pills per week

d~ For what purpose are you taking this medication? _

Participant mentioned to avoid heart attack or stroke: (H)

Participant did not mention to avoid heart or attack or stroke: (O)

e~ When did you start taking aspirin, or a medicine containing aspirin, on a regular basis? _____
mm/yy

(MSRD screen 10 of 11)

30~ Except for aspirin or Tylenol, are you NOW taking other non-steroidal anti-inflammatory drugs or arthritis medicines on a regular basis? Examples include Ibuprofen, Advil, Nuprin, Motrin, Naprosyn, Feldene and Clinoril. _

Yes(Y) No(N)* Unknown(U)*

a~ What is the brand name of the medicine? (Check the preparation, if available). _

Ibuprofen or Advil (I)*
Other (O)

b~ If "Other", specify:

_____

c~ How many pills per week are you taking, on average? __ pills per week

d~ When did you start taking [insert name] on a regular basis? _____
mm/yy

(MSRD screen 11 of 11)

D. ADMINISTRATIVE INFORMATION

31~ Date of data collection: _____ ▒▒
mm/dd/yy

32~ Method of data collection: _ ▒

Computer (C) or Paper (P) Form

33~ Code number of person completing this form: ___ ▒▒

Appendix 2.14c

INSTRUCTIONS FOR MEDICATION SURVEY FORM
MSR, VERSION D, 12/05/95
PREPARED 02/13/96

I. GENERAL INSTRUCTIONS

The purpose of the Medication Survey is to assess medication usage in the two weeks preceding the examination date. Information on both prescription and non-prescription drugs is ascertained. To obtain this information, the participant is asked prior to the clinic visit to bring to the field center all medications taken in the two-week period preceding Visit 4.

Interviewers require certification in interviewing techniques and familiarity with the data entry procedures for paper and electronic versions of the form (references: Data Entry System manual and the "General Instructions for Completing Paper Forms"). Transcribers and coders of medication information also require certification. Header information (ID Number, Contact Year, and Name) are completed in the format described in that document.

II. DETAILED INSTRUCTIONS FOR EACH ITEM

A. RECEPTION

MEDICATION SURVEY FORM (MSRD screen 1 of 11)

A. RECEPTION

1. Did you bring all the medications you used in the past two weeks, or their containers?

Go to Section B and begin transcription while participant proceeds with clinic visit	Yes, all	Y
Go to Item 3; transcribe those medications which were brought at this time	Some of them	S
	No	N

If the response is "Yes, all", go to Section B (MEDICATION RECORDS) and begin the transcription. This can take place at the reception station or while the participant proceeds with the clinic visit. As the participant delivers the medications, indicate where (and by whom) they will be returned before he/she leaves. Mention that medication names will be copied from the labels, and that if required, medications will be taken out of their container only in the presence of, and with approval of, the participant. Finally, indicate that a trained interviewer will later ask a few questions about each medication. Verify that the medications bag is clearly identified with the participant's name. Do not open the medications bag or transcribe medications until the participant has signed the informed consent.

If the response is "Some of them", go to Item 3 to make arrangements for those medications which were not brought; transcribe those medications which were brought in Section B (MEDICATION RECORDS).

If the response is "No", ask Item 2:

2. Is this because you forgot, because you have not taken any medications at all in the last two weeks, or because you could not bring your medications?.....Took no medications T

Forgot or was unable to bring medications F

Go to Item 25 Screen 6

If the response is "Took no medication" in the past two weeks, Section A ends here. Leave Section B (MEDICATION RECORDS) blank and skip to INTERVIEW, Section C (field or screen forward). Item 24 is left blank, and the interviewer continues administering Items 25-30, either at the reception or a subsequent workstation.

If the response is "Forgot or was unable to bring medications", reassure the respondent and ask Item 3:

3. Could we follow up on this after the visit so that we can get the information from the (other) medication labels? {Explain follow-up options} ..... Yes Y

No or not applicable N

Attempt to convert refusals; indicate on Itinerary Form}

Describe method of follow-up to be used: _____

If the participant agrees to follow-up, make arrangements for obtaining the information over the telephone. Describe the method of follow-up after Item 3 on the form. If the participant brought some medications, complete as much of Section B (MEDICATION RECORDS) as possible.

In case of deliberate omission to bring medications to the field center, the interviewer attempts participant conversion at the reception or a subsequent workstation. If participant conversion is to be attempted after reception, write a note to that effect on the Itinerary Sheet. Leave Section B (MEDICATION RECORDS) blank if no medications were brought in. Even if the participant declines to bring in (or provide medication names by telephone interview), attempt to complete as much of Section C (INTERVIEW) as possible. If the participant has not brought his/her medications, but remembers the names and concentration (strength) of all medications taken during the previous two weeks with confidence, the interviewer can make the judgement to record this information without a follow-up phone call.

B. MEDICATION RECORDS

Section B (MEDICATION RECORDS) is divided into three components to document information about each medication used by the participant: (1) Transcription, (2) Interview, and (3) Medication

Coding. Transcription includes recording in column (a) the name and in column (b) concentration (strength) of each medication used within the two weeks prior to the interview. The interview portion consists of determining and recording in column (d) whether the medication was taken within the last 24 hours. Medication Codes are looked up in General Product Information (GPI) section of the hard copy or DES version of the MEDISPAN Medication Dictionary and recorded in column (c). The transcription of the medication name (column a) and concentration (column b) is done by a trained transcriptionist prior to the interview with the participant or by an interviewer in conjunction with the administration of the questions in column (d). The coding of the medications from the DES medication dictionary can be done during the interview if the interviewer is certified in medication coding, or done later by a trained coder after the interview is completed.

Column (a). MEDICATION NAME & Column (b) CONCENTRATION

Open the medications bag and remove all medications. In column (a), transcribe the medication name (in BLOCK LETTERS if using a paper form), followed by the concentration in column (b), beginning with Item 4. Include all parts of the medication name and any numbers and/or letters that identify the strength (concentration). For keying purposes, the following format should be used when transcribing the medication name and concentration. For example:

Column (a)	Column (b)
AMPICILLIN	250 mg
AMPICILLIN LIQUID	125mg/5ml
NOSTRIL	½ %
ANACIN MAXIMUM STRENGTH	=====

Also copy any numbers and codes which follow or are part of the name. For example:

ANACIN-3	STUARTNATAL 1 + 1
ACEROLA C (100 MG)	ILETIN I NPH
TRIAMINIC12	S-K AMPICILLIN
OVRAL28	CALTRATE 600 + VITAMIN D
ORTHO-NOVUM 10/11-28	

If in doubt, it is preferable to add information that may be significant. This will help later in identifying (and coding) a medication.

To facilitate the recording process some standard abbreviations have been established.

A

Acetaminophen = APAP	Antibiotic = ANTIBIO
Aluminum = AL	Arthritic = ARTHR
Amitriptyline = AMITRIP	Aspirin = ASA
Antihistamine = ANTIHIST	Aspirin, Phenacetin and
Ammononium = AMMON	Caffeine = APC

B
Balanced Salt Solution = BSS Buffered = BUF

C
Caffeine = CAFF Chloride = CL
Calcium = CA Chlorpheniramine = CHLORPHEN
Capsules = CAP Codeine = COD
Carbonate = CARBON Compound = CPD or CMP or CMPD
Chewable = CHEW Concentrate = CON
Chlordiazepoxide = CHLORDIAZ

D
Decongestant = DECONG Diproprionate = DIPROP
Dextromethorphan = DM Docusate Sodium = DSS
Dioctylsodium Sulfosuccinate = DSS

E
Expectorant = EXP Extra = EX

F
Ferrous = FE Formula = FORM
Fluoride = F

G
Gluconate = GLUCON Guaifenesin = GG
Glyceryl Guacolate = GG

H
Hydrochloride = HCL Hydrocortisone = HC
Hydrochlorthiazide = HCTZ Hydroxide = HYDROX

I
Inhalation = INHAL Injection = INJ

J
Junior = JR

L
Laxative = LAX Long Acting = LA
Liquid = LIQ Lotion = LOT

M
Magnesium = MG Minerals = M
Maximum = MAX Multivitamins = MULTIVIT

N
Nitroglycerin = NTGN

O
Ointment = OINT Ophthalmic = OPTH

P
Penicillin = PCN
Pediatric = PED
Perphenazine = PERPHEN
Phenobarbital = PB
Phenylephrine = PE
Phenylpropanolamine = PPA
Potassium = K
Potassium Iodide = KI
Powder = PWD
Pyrilamine = PYRIL

R
Reliever = REL

S
Simethicone = SIMETH
Sodium = SOD
Solution = SOLN
Strength = STR
Suppository = SUPP
Suspension = SUSP
Sustained Action = SA
Sustained Release = SR
Syrup = SYR

T
Tablets = TAB
Theophyllin = THEOPH
Therapeutic = T
Time Disintegration = TD

V
Vaccine = VAC
Vitamin = VIT

W
With = W

Each drug name should be written out even if the same name or a portion of the name appeared in the previous drug. Do not use ditto marks (") to indicate a repeat of a previous item.

For this study we are not asking the strength or dose of the drug taken. Sometimes the drug name includes numbers or letters which could be mistaken for dosage. Having these numbers or letters as part of the drug name helps in selecting the appropriate code. Therefore, it is better to record all the information related to medication name and concentration on the form in a standard format. The following guidelines are offered for standardization.

Medication Name

* Print complete names using block capital letters.

* Record all identifying characters and numbers referring to concentration.

* Include as much identifying information as possible.

Sometimes the dosage form may appear to be part of the drug name since a few companies have trademarks for their dosage forms. For example, Enseals for enteric coated tablets and Kapseals or Pulvales for capsules. You may record these names as identifying information.

Combination Drugs

Combination medicines contain two or more drugs in a single pill or tablet. Some combination medicines such as Dyazide come in only one fixed combination (hydrochlorothiazide 25 mg and triamterene 50 mg); these combination medicines do not generally list a strength. Record DYAZIDE, in the space medication name and do not record anything for concentration.

Other combination medicines such as Inderide are available in more than one fixed dose combination (propranolol 40 mg and hydrochlorothiazide 25 mg; or propranolol 80 mg and hydrochlorothiazide 25 mg); these combination medicines generally list the strength as in "Inderide 40/25" or "Inderide 80/25." For these medicines, record INDERIDE, in the space for name, and "40/25" or "80/25" after the name as the concentration. For example:

Drugs containing two or more medications:

Example of fixed dosage:
Dyazide (hydrochlorothiazide and triamterene) code "DYAZIDE"

Examples of variable dosage:
Inderide 40/25 (40 mg Inderal, 25 mg hydrochlorothiazide) code "INDERIDE 40/25"

Inderide 80/25 (80 mg Inderal, 25 mg hydrochlorothiazide) code "INDERIDE 80/25"

* Do not record flavors of products and whether the preparations are sugar-free or sodium-free.

Concentration

Most drug concentrations are given in grams or milligrams. Record as written on the label using the abbreviations "gm" for grams and "mg" for milligrams. Rarely the dosage may be given in grains. Use the abbreviation "gr" for this.

When strength is not recorded as milligrams (mg) record all numbers, digits and characters used to denote concentration; this includes:

. - decimal point	gm = gram(s)
ml - milliliter	gr = grain(s)
/ml - per milliliter	mg = milligram
mEq - milliequivalents	
hr - hour	
/hr - per hour and	
% - percent	Note: When the abbreviation, "PC" (percent) is used, record percent symbol, "%".

SPECIFICS:

* Record strength of combination drugs where strength is separated by a "/" here.

* Liquid medicines concentration is often written in mg/ml (milligrams per milliliter). For example, Ampicillin 125 mg /5 ml, is recorded as: "AMPICILLIN 125 mg/5ml"

* Concentration for some medicines may be written as a percentage. For example: Alupent 0.6%, is recorded as: "ALUPENT 0.6%"

* Concentration for insulin is generally "U100" or 100 units per milliliter." This is often written as "100/ml" or "100U/ml." Record Insulin concentration as "U100" unless another strength is listed on the label.

NOTE: Do not record the quantity or number of pills/tablets dispensed.

If more than 17 medications are present or reported by the participant, only 17 medications are coded and keyed, selected according to the priorities described below. If it is necessary to defer the assignation of priorities for medications to be transcribed, the name and strength of each additional medication is recorded on the back of page 3 of the paper form, until 17 medication names are selected for transcription and coding. Medications may be prioritized during transcription by combining the transcription and interview components.

Prioritization is performed only if there are more than 17 medications and is based on the following algorithm: prescription medications first; then aspirin, aspirin-containing medications and anti-inflammatory preparations (aspirin, Alka-Seltzer, headache powders, cold medicine, medication for arthritis); followed by other over-the-counter preparations; and vitamins and food supplements last.

Example:

MEDICATION SURVEY FORM (MSRD screen 3 of 11)

B. MEDICATION RECORDS

I. Transcription (Copy the NAME followed by the CONCENTRATION of each medication in the spaces below. (Continue on second line if needed):

II. Interview (For each medication, circle the appropriate response to the following questions):

RECORD NUMBER	a. MEDICATION NAME & CONCENTRATION	b.	c. CODE NO.	d. "Did you take this medication in the past 24 hours?" YES (Y)/ NO (N) UNKNOWN (U)
4.	AMPICILLIN 125mg/5mL			Y N U

Once all names are transcribed, count the total number of different medications (including those which could not be transcribed) and enter this number in Item 21. Count the actual medications to determine the total. Do not refer to the record numbers on the screen or form. Set aside any containers which have no clear label and/or identification or medications without containers for later transcription by a trained interviewer. Add the number of these medications which you are unable to transcribe, and enter this number in Item 22. For example, if there were 7 medications in the bag, and you were able to transcribe 5 of them, items 21 and 22 would be completed as follows:

MEDICATION SURVEY FORM (MSRD screen 5 of 11)

21. Total number of medications in bag: 0 7

22. Number of medications unable to transcribe: 0 2

Open containers to examine medications only in the presence of the participant. If necessary, make a note on the form, and let the participant know that a trained interviewer will identify these medications with him/her. Enter your ARIC ID number in Item 23a (Transcriber code number). The ID number of the person coding the medication is entered in Item 23b. The date on which the medications are coded is entered in Item 23c. Return the medications to the carrier bag. If the interview portion has not been administered, place the Medication Survey paper form (if appropriate) in the medication bag and take the medication bag to the workstation in which the interview will be administered. If the interview portion of Section B has been administered, take the bag to a secure place at the physical exam workstation. AT NO TIME SHOULD THE MEDICATIONS BE LEFT UNATTENDED AT THE RECEPTION AREA.

Column (c). CODE NUMBER.

The six-digit medication code numbers are found in the hard copy or DES version of the Medication Dictionary which has been distributed to each Field Center. The drug names are listed in alphabetical order. Drug names that begin with a number, ditto ("), or a dash (-) are listed first. If a drug name is separated by a hyphen, the portion of the name preceding the hyphen is listed in alphabetical order.

If you encounter a drug name which is not in the dictionary, do not guess at a match. Simply set the status code to Q (questionable) so that the pharmacist at the Coordinating Center can develop a code number and update the dictionary.

For this study we are not interested in the actual strength of medication taken by the participant. Therefore, we have not included strength in the dictionary. Numbers that appear in the dictionary are used to differentiate between products. Before coding a drug entry, determine whether the numbers which are recorded are part of the name or are strength/concentration information. Numbers referring to strength/concentration are not used in the matching process.

Some drug products use a suffix to distinguish between combination products containing the same primary drug. For example:

Darvon = propoxyphene hydrochloride
Darvon N = propoxyphene napsylate
Darvon Cmpd = propoxyphene hydrochloride with aspirin and caffeine
Darvon with ASA = propoxyphene hydrochloride and aspirin

When coding a medication which contains more than one word, look for a match of the entire name in the dictionary. If the name matches, enter the corresponding code. If a complete match cannot be found, but the dictionary has a single entry for the ingredient(s) in the medication (usually the first word of the drug name), and there are no other entries containing this word, select the corresponding code. This occurs most often when:

- both the brand and generic name are transcribed, but only one is given in the dictionary;
- the form of the drug is transcribed, but not given in the dictionary;
- the seller's name is transcribed, but is not listed in the dictionary.

It is critical that the other words in the transcribed drug name do NOT involve additional ingredients.

Examples:

CORDARONE/AMIODARONE	not in the dictionary; code as AMIODARONE, which is listed.
DIMETAPP ELIXIR	not in the dictionary; code as DIMETAPP, which is listed.
ECKERD ALLERGY RELIEF TABS	not in the dictionary; code as ALLERGY RELIEF, which is listed.
TYLENOL NO. 3	not in the dictionary; cannot code, since "NO.3" could designate another ingredient; in fact, it designates codeine. It can be coded by searching for the abbreviation of tylenol's ingredient with codeine: APAP W CODEINE, which is in the dictionary.

In order to put drug names on the prescription label, pharmacists may use abbreviations. Unfortunately, these abbreviations are often not standardized. Some frequently used abbreviations, however, occur in the Medication Dictionary. For example:

APAP	=	acetaminophen	HC	=	hydrocortisone
ASA	=	aspirin	HCI	=	hydrochloride
CAFF	=	caffeine	HCTZ	=	hydrochlorothiazide
Cl	=	chloride	IV	=	intravenous
CMP	=	compound	K	=	potassium
COD	=	codeine	M	=	minerals
DM	=	dextromethorphan	SR	=	sustained release
Fl	=	fluoride	T	=	therapeutic
GG	=	glyceralguiacolate			

Column (d). USE IN PAST 24 HOURS

After the transcription of the medication name and concentration, or the verification of the accuracy of the transcription and its use within the last 2 weeks, the interviewer ascertains the use of each medication within the past 24 hours, while showing the participant each separate container. The following question is asked for each medication:

d. "Did you take this medication in the last 24 hours?"

If probing is required to assist the participant in remembering, the question may be repeated, specifying a time on the previous day. For example, "Have you taken this medication since 10:00 a.m. yesterday?"

RECORD NUMBER	a. MEDICATION NAME & CONCENTRATION	b. CODE NO.	c. YES (Y)/ NO (N) UNKNOWN (U)
4.	AMPICILLIN 125mg / 5ml		(Y) N U

Repeat this process for all medications, e.g., transcribe or verify the transcription of the medication/concentration and ask the question in column (d). Determine from Item 22 on the form at the end of Section B whether there are any medications in the bag for which the receptionist was unable to transcribe the name/concentration. These may include unmarked containers, loose pills, and containers with more than one medication. Ask the participant to open any unmarked containers, and to handle loose pills. With the participant's help and using a Physicians Desk Reference (PDR), attempt to identify these medications. If possible, enter the name and concentration, and ask if the medication was taken in the last 24 hours. If the medication cannot be identified, write UNKNOWN for the medication name and draw two horizontal lines through the boxes (enter "=" in the spaces) for the medication code number. If additional medications can be transcribed, adjust the total for Item 22, "Number of medications unable to transcribe:", accordingly. After this has been completed for all containers, prescriptions and medications in the bag, probe the participant on whether all medications taken in the previous two weeks are included. For any additional medications recalled by the participant, record the names and answer the questions with as much detail as possible. If there is any doubt, arrange for a phone call during which the participant can provide accurate information.

During the rest of the Medication Survey interview or during a subsequent interview, the participant may recall other medications or vitamins taken during the past two weeks. Their names and concentrations are transcribed in column (a and b, respectively) and last ingestion (use) is recorded in column (c) at this time, just as if they had been in the medication bag. However, the number of medications in the bag is not changed. This documents that information on some medications were provided from the participant's memory.

C. INTERVIEW

This portion of the Medication Survey is administered by the physician assistant/nurse clinician or a trained interviewer.

For Item 24, ask if medications were taken in the past two weeks for the nine listed reasons.

The following synonyms may be given in response to participant questions.

a. High blood pressure = hypertension
c. Angina or chest pain = heart pains
d. Control of heart rhythm = medicine for fast or irregular heart rate or heart beats
e. Heart failure = congestive heart failure, not heart attack
f. Blood thinning = anticoagulation
i. Leg pain when walking = claudication

Note: Stroke does not include TIA nor "slight strokes" which lasted less than 24 hours.

For example, if the participant had taken medication for high blood pressure and claudication and no other listed conditions, Item 24 would be coded as follows:

MEDICATION SURVEY FORM (MSRD screen 6 of 11)

C. INTERVIEW

"Now I would like to ask about a few specific medications."

24. Were any of the medications you took during the past two weeks for:
{If "Yes," verify that medication name is on medication record.}

	Yes	No	Unknown
a. High Blood Pressure	(Y)	N	U
b. High Blood Cholesterol	Y	(N)	U
c. Angina or Chest Pain	Y	(N)	U
d. Control of Heart Rhythm	Y	(N)	U
e. Heart Failure	Y	(N)	U
f. Blood Thinning	Y	(N)	U
g. Diabetes or High Blood Sugar	Y	(N)	U
h. Stroke	Y	(N)	U
i. Leg pain when walking	(Y)	N	U

If any of the conditions are answered affirmatively, be sure that the medication is recorded in Section B. The interviewer, however, cannot ask the participant to identify which medication was used to treat any of the conditions. For example, if the participant reported taking a medication to lower blood pressure during the last two weeks (Item 24.a), and no recognizable antihypertensive medications were recorded in Section B, the interviewer may probe to determine if the names of all medications taken during the last two weeks were recorded. If the person indicates that the names of all his/her medications have been transcribed, the interviewer cannot probe further to determine which medication was used to treat the high blood pressure.

Items 25-30 are asked of all participants, regardless of whether they reported taking any medications during the past two weeks or whether they brought any medication to the field center. This question is asked as worded. It may help to preface Item 25 with an explanation.

"I know you said you took no medications, but we include the next few questions as a memory jogger".

Although the primary purpose of Item 25 is to identify participants who are taking aspirin, the question is broadly constructed to include aspirin and other medications which may contain aspirin but are not necessarily labelled as aspirin, such as "Alka-Seltzer, cold medicine or headache powder". Therefore, this question may identify persons taking medications which do not include aspirin. With a positive response, continue with Item 26 and verify that the relevant information on the medication(s) was recorded in Items 4-20. If the response is NO or UNKNOWN, skip to Item 28.

Item 26 is narrower in scope and refers specifically to aspirin or aspirin-containing medications that have been taken within the two weeks preceding Visit 4. Record the number of days in this two week period (maximum of 14 days) that aspirin or aspirin-containing medications were taken. If no aspirin was taken, enter '00' and go to Item 28.

Ask Item 27 as written. Do not read the choices. If the participant mentions avoiding heart attack or stroke as part of his/her response, record "H." Individuals could be following the advice of their provider of medical care in doing this, or they could be acting on their own, based on information obtained through the media, friends or other sources. If the participant mentions "blood thinning" or avoiding blood clots as the reason for taking aspirin, record "H." If neither a heart attack or stroke is mentioned, record "O," even if the aspirin was prescribed by a physician.

Read Item 28 to all participants following the instructions provided at the end of the question, e.g., read the bracketed "other" if the response to Item 25 was positive and include "or menstrual cramps" for females only. The use of analgesic and anti-inflammatory medications that do not contain aspirin is verified because these (like aspirin) may affect some of the hemostasis tests. With a positive response, confirm whether the reported medications are transcribed in Section B.

Read Item 29 to all participants following the transition statement provided. We are after the current use (NOW) of aspirin or aspirin containing medication on a regular basis, regardless of the reason for its use. These medications do not include Tylenol, Advil, etc. Consult the list of Aspirin or Aspirin Containing Medications at the end of these instructions if in doubt. If asked by the participant, "regular" is defined as at least once a week for several months. If the response is "No" or "Unknown", skip to Item 30, Screen 18. When the response is Yes, continue by asking Item 29a.

a. Read the question and select the appropriate letter from the four response codes. Strength refers to the number of milligrams of aspirin per pill, not the total number of milligrams taken. (Buffered aspirin does not refer to strength, but to added ingredients.) The participant may offer

the actual milligrams, which can be categorized as shown in the responses. If the person can recall that the strength of the pill was not baby, but can't distinguish between regular and extra strength, code as regular, 'B'. If the participant does not remember at all, record "Don't Know".

b. Read the question. The purpose of this question is to document the number of days per week aspirin is taken. Record the typical frequency (i.e., "on average") of the aspirin that is used on a regular basis. If less than one day per week, record as zero. Round half days up to the next integer. The maximum number of days per week is 7.

c. Read the question. In contrast to part (b), the purpose of this question is to document the average number of aspirin tablets the person takes during a typical week. 'Pills' refers to both aspirin and aspirin containing medications, either in tablet or powder form. If >99, record as 99. If < 1, record as zero. If "half tablets" were used, divide the number of half tablets by 2 and round fractions up to the next integer. For example, record the use of 7 half tablets of aspirin per week as 04.

d. Read the question. Do not read the choices. If the participant mentions avoiding heart attack or stroke as part of his/her response, record "H." Individuals could be following the advice of their provider of medical care in doing this, or they could be acting on their own, based on information obtained through the media, friends or other sources. If the participant mentions "blood thinning" or avoiding blood clots as the reason for taking aspirin, record "H." If neither a heart attack or stroke is mentioned, record "O," even if the aspirin was prescribed by a physician. With a positive response to the initial Item 29, confirm whether the reported medication(s) is transcribed in section B.

e. Enter the year and month of the onset of regular use in 29.e. If the participant is unsure, ask for a best guess. If an estimate cannot be made, record "==" in the appropriate month or year field(s).

Read Item 30 as written. Question 30 parallels the aspirin question (Question 29) but documents the current, regular use of nonsteroidal anti-inflammatory drugs (NSAID). Item 30. excludes Tylenol and aspirin (as separate entities) and steroids. Nonsteroidal drugs are the most common non-aspirin treatments of arthritis. If the

participant is unsure about a medicine but mentions its name, quickly check the LIST OF NON-STEROIDAL ANTI-INFLAMMATORY DRUGS to decide. Note skip patterns. If participant answers YES, then continue by reading 30a.

a. If the response to 30a is Ibuprofen or Advil, record "I" and skip to 30.c. If the participant reports a different non-steroidal anti-inflammatory drug, then code "O" for Other and transcribe the name in Item 30.b

b. Do not ask this question; record the name based on the response to Item 30.a. If the preparation is available, use it to verify the response.

c. Read the question. The purpose of this question is to document the average number of NSAID tablets the person takes during a typical week. 'Pills' refers to tablets. If >99, record as 99. If < 1, record as zero. If "half tablets" were used, divide the number of half tablets by 2 and round fractions up to the next integer. For example, record the use of 7 half tablets of Ibuprofen per week as 04.

d. Read Item 30d inserting the brand name of the drug where indicated and record the month and year the participant began taking the drug on a regular basis.

D. ADMINISTRATIVE INFORMATION

31. Enter the date on which the participant was seen in the clinic. Code in numbers using leading zeroes where necessary to fill all boxes. For example, May 3, 1993, would be entered as:

0	5	/	0	3	/	9	3
month			day			year	

32. Record "C" if the form was completed on the computerized data entry system, or "P" if the paper form was used. If the form was completed partially on paper and partially on the computer, code as "Paper Form."

33. The person at the clinic who has completed this form must enter his/her code number in the boxes provided.

At the close of the interview, secure all medications in the carrier bag and return it to the participant or explain where he/she should pick it up before leaving. The medication bag must be stored in a secure location until it is returned to the participant. If data were collected on a paper form, place the form in the participant's folder.

O.M.B. 0925-0281
exp. 09/30/98

ARIC
Atherosclerosis Risk in Communities

ORAL GLUCOSE TOLERANCE SCREENING FORM

A-205

ID NUMBER: | | | | | | | | CONTACT YEAR: | 1 | 0 | FORM CODE: | G | T | S | VERSION: B 05/08/96

LAST NAME: | | | | | | | | | | | | | INITIALS: | | |

INSTRUCTIONS: This form is completed during the participant's visit. ID Number, Contact Year and Name must be entered above. Whenever numerical responses are required, enter the number so that the last digit appears in the rightmost box. Enter leading zeroes where necessary to fill all boxes. On the paper form, if a number is entered incorrectly, mark through the incorrect entry with an."X". Code the correct entry clearly above the incorrect entry. For "multiple choice" questions, circle the letter corresponding to the most appropriate response. If a letter is circled incorrectly, mark through it with an "X" and circle the correct response.

ORAL GLUCOSE TOLERANCE SCREENING FORM (GTSB Screen 1 of 3)

1. [REFER TO PIN SHEET; DO NOT READ TO PARTICIPANT.]

   Was participant treated for diabetes in Visit 3? ..... Yes Y
   No N

   [IF ITEM 1 IS "YES", EXCLUDE and SKIP TO EXCLUSION STATEMENT.]

2. Do you regularly take medication to control diabetes (high blood sugar)? ... Yes Y
   No N

   [IF ITEM 2 IS "YES", EXCLUDE and SKIP TO EXCLUSION STATEMENT.]

3. [REFER TO FASTING FORM; DO NOT READ TO PARTICIPANT]

   Has participant fasted at least 10 hours? ..... Yes Y
   No N

   [IF ITEM 3 IS "NO", EXCLUDE and SKIP TO EXCLUSION STATEMENT]

4. Have you had surgery to remove part of your stomach or small intestine? ..... Yes Y
   No N
   Unknown U

   [IF ITEM 4 IS "YES", EXCLUDE and SKIP TO EXCLUSION STATEMENT]

ORAL GLUCOSE TOLERANCE SCREENING FORM (GTSB Screen 2 of 3)

5. Are you on kidney dialysis? ..... Yes Y

No N

[IF Item 5 IS "YES", EXCLUDE and SKIP TO EXCLUSION STATEMENT.]

EXCLUSION STATEMENT

Because you (SELECT THE RELEVANT STATEMENT BELOW)

- are taking medication to control diabetes,
- have not been able to fast for 10 hours,
- have had part of your stomach removed,
- are on kidney dialysis,

it may not be useful or safe for you to participate in this portion of the study.

GO TO ITEM 7

ORAL GLUCOSE TOLERANCE SCREENING FORM (GTSB Screen 3 of 3)

6. Are you willing to participate in the glucose tolerance test? .... Yes Y

No N

7. Date of data collection: [ ][ ]/[ ][ ]/[ ][ ]

m m / d d / y y

8. Method of data collection: ..... Computer C

Paper P

9. Code number of person completing this form: [ ][ ][ ]

(GTSB screen 1 of 3)

1~ [REFER TO PIN SHEET; DO NOT READ TO PARTICIPANT]
Was participant treated for diabetes in Visit 3? _ []

Yes (Y)* or NO (N)

[IF "YES", EXCLUDE AND SKIP TO EXCLUSION STATEMENT]

2~ Do you regularly take medication to control diabetes (high blood sugar)? _ []

Yes (Y)* or No (N)

[IF "YES", EXCLUDE AND SKIP TO EXCLUSION STATEMENT.]

3~ [REFER TO FASTING FORM; DO NOT READ TO PARTICIPANT]
Has participant fasted at least 10 hours? _ []

Yes (Y) or NO (N)*

[IF "NO", EXCLUDE AND SKIP TO EXCLUSION STATEMENT.]

4~ Have you had surgery to remove part of your stomach or small intestine? _ []

Yes (Y)*, No (N) or Unknown (U)

[IF "YES", EXCLUDE AND SKIP TO EXCLUSION STATEMENT]

(GTSB screen 2 of 3)

5~ Are you on kidney dialysis? _ []

Yes (Y)* or No (N)

[IF "YES", EXCLUDE AND SKIP TO EXCLUSION STATEMENT]

*****

OZ~_ [] EXCLUSION STATEMENT
Because you (SELECT THE RELEVANT STATEMENT BELOW)
- are taking medication to control diabetes,
- have not been able to fast for 10 hours,
- have had part of your stomach removed,
- are on kidney dialysis,

it may not be useful or safe for you to participate in this portion of the study.

[GO TO ITEM 7]

*****

(GTSB screen 3 of 3)

6~ Are you willing to participate in the glucose tolerance test? _ []

Yes (Y) or No (N)

7~ Date of data collection: _____ []
mm/dd/yy

8~ Method of data collection: _ []

Computer (C) or Paper (P)

9~ Code number of person completing this form: ___ []

INSTRUCTIONS FOR THE ORAL GLUCOSE TOLERANCE SCREENING FORM
GTS, VERSION B, 05/08/96
PREPARED 04/09/97

I. GENERAL INSTRUCTIONS

The participant's eligibility and willingness to participate in the oral glucose tolerance test (OGTT) is determined during reception. Include the following in your description of ARIC procedures.

> "As we explained earlier, we have added a new test to detect diabetes even in people who have no symptoms. This is the oral glucose tolerance test. You drink 10 oz. of a flavored beverage that contains glucose, a type of sugar that is rapidly absorbed, and then we draw a small amount of blood after 2 hours to see how well your body handles sugar. The results will be included in the final report to you and your physician. This test has been modified in recent years so that few people today ever have any discomfort after drinking the glucola. Before you decide whether you do this, I need to ask you a few questions."

ADMINISTER THE FASTING FORM and then ADMINISTER THE OGTT SCREENING FORM

Review the PIN Sheet to determine whether the participant was being treated for diabetes at Visit 3. These persons are ineligible to participate in the OGTT. The appropriate exclusion statement is read to the participant and the OGTT Screening Form completed accordingly. Indicate on the Itinerary Form that the participant is ineligible for OGTT. Participants not treated for diabetes at Visit 3 are asked if they are currently taking medication to control diabetes or high blood sugar. These medications include insulin or oral hypoglycemics. The medications brought in to the field center are reviewed while the participant changes clothes. The appropriate exclusion statement is read to participants and the OGTT Screening Form is filled out accordingly. Indicate on the Itinerary Form that the participant is ineligible for OGTT.

If the participant will have fasted for LESS THAN 10 HOURS by the time glucose would be given after venipuncture, read the appropriate exclusion statement to the participant, and complete the administrative items. Indicate on the Itinerary Form that the participant is ineligible for OGTT. Note, the actual fasting status for OGTT will be calculated from the fasting time recorded on the Fasting/Tracking form and the time at which the glucose was administered recorded on the Oral Glucose Tolerance Administration form.

If the participant is eligible and agrees to participate, complete the administrative items and continue by saying:

"Thank you. The amount of sugar in the beverage you drink will break your fast and should keep you from feeling hungry. After you have your second blood work drawn, we will serve you a snack. However, please tell us if you feel faint or uncomfortable any time this morning. Do you have any questions?"

If the participant is eligible and does not agree to participate, complete the administrative items and continue by saying:

"That's okay. If you change your mind, let me know."

Continue with the rest of the reception.

II. DETAILED INSTRUCTIONS FOR EACH ITEM

1. **Was participant treated for diabetes in Visit 3?** Refer to the PIN sheet. Do not read the question to the person. If participant was a treated diabetic at Visit 3, select YES and begin and end the administration of this form by reading the EXCLUSION STATEMENT.

   Because you are taking medications to control diabetes, it may not be useful or safe for you to participate in this portion of the study.

   Complete items 7-9. Mark the Itinerary Sheet "NO OGTT".

   If the person was not taking medications to control diabetes or high blood sugar during Visit 3 (PIN sheet coded as NO), select NO and continue.

2. **Do you regularly take medication to control diabetes (high blood sugar)?** Read the question stressing "regularly" and "control diabetes". Include the parenthetical phrase (high blood sugar), if appropriate. If clarification is requested, medications to control diabetes include oral hypoglycemics and insulin. If participant reports regularly using medication to control diabetes, select YES and read the EXCLUSION STATEMENT regarding medications.

   Because you are taking medications to control diabetes, it may not be useful or safe for you to participate in this portion of the study.

   Complete items 7-9. Mark the Itinerary Sheet "NO OGTT".

   If the participant's response is NO, select NO and continue with Item 3.

   While the participant is changing, the medications brought in are reviewed

and the lack of oral hypoglycemics or insulin is verified. Participants who erroneously report not taking medication to control diabetes are informed by the staff member who meets them after changing that one of their medications is frequently used to control high blood sugar, and therefore, it would not be useful or safe for them to participate in the OGTT. The GTS form is corrected and the Itinerary Sheet marked "NO OGTT".

3. **Has participant fasted at least 10 hours?** Do not read the question out loud. Refer to Item 5 on the Fasting/Tracking Form. If fasting is less than 10 hours when the OGTT screening form is administered, estimate whether the fasting time will be less than 10 hours at the time the glucola would be administered after venipuncture. If the estimated fasting time will STILL be less than 10 hours immediately following venipuncture, select NO and read the EXCLUSION STATEMENT regarding fasting.

> Because you have not been able to fast for 10 hours, it may not be useful or safe for you to participate in this portion of the study.

Complete items 7-9. Mark the Itinerary Sheet "NO OGTT".

If the participant will have fasted for at least 10 hours by the time he/she is scheduled for venipuncture, select YES and go to Item 4.

4. **Have you had surgery to remove part of your stomach or small intestine?** Read question. The time frame is a life time history. If asked, "stomach stapling" is considered "surgery to remove part of your stomach" and the participant is not eligible for OGTT. Removal of part of the large intestine does NOT disqualify a person from participation; removal of all of the large intestine, or use of a colostomy, does result in exclusion from the OGTT. Participants who respond "no" or "don't know" to the question are eligible. If YES, read the EXCLUSION STATEMENT.

> Because you have had part of your stomach* removed, it may not be useful or safe for you to participate in this portion of the study.
>
> * If the exclusion is due to removal of part of the intestine, substitute "intestine" for the word "stomach".

Complete items 7-9. Mark the Itinerary Sheet "NO OGTT".

5. **Are you on kidney dialysis?** Read question. The time frame for the question is "current" kidney dialysis. Participants who respond "no" are

eligible. Participants who respond "YES" for any reason are excluded from the glucose tolerance test. If YES, read the EXCLUSION STATEMENT.

> Because you are on kidney dialysis, it may not be useful or safe for you to participate in this portion of the study.

Complete items 7-9. Mark the Itinerary Sheet "NO OGTT".

6. Read the question. If the participant asks, it might be helpful to indicate that this test has been used in many epidemiologic studies. The National Heart, Lung, and Blood Institute recently reported that after testing over 10,000 people, there were no serious side effects and less than 0.5% had mild side effects from the OGTT. If NO, thank the participant and indicate that this completes the questions for this section. Complete items 7-9. Mark the Itinerary Sheet "NO OGTT".

7. Enter the date on which the participant completed this interview. Code in numbers using leading zeroes where necessary to fill all boxes. For example, May 3, 1995 would be entered as:

0 5	/	0 3	/	9 5
month		day		year

8. Record "C" if form was completed on the computerized data entry system, or "P" if the paper form was used. If the form was completed partially on paper and partially on the computer, code as "Paper Form".

9. Enter the interviewer ID.

Appendix 2.16a

PARTICIPANT INFORMATION SHEET (PIN)

VERSION

Number of Previous Ultrasound Scans: 1

ID:

Diabetic Status: Unknown

Name:

Visit 3 Age:
Visit 1 DOB:

VISIT 1 INFORMATION

Visit 1 Date:
Visit 1 Weight:
Visit 1 Height:
Visit 1 SBP:
Visit 1 DBP:
Visit 1 Race:

VISIT 2 INFORMATION

Visit 2 Date:
Visit 2 Weight:
Visit 2 SBP:
Visit 2 DBP:

VISIT 3 INFORMATION

Visit 3 Date:
Visit 3 Weight:
Visit 3 Height:
Visit 3 SBP:
Visit 3 DBP:
Visit 3 Glucose:

REPRODUCTIVE HISTORY

POSITIVE ROSE ANGINA (FROM VISIT 4 CY AFU):

Comment: _____

Appendix 2.17a

ID NUMBER:_____

DATE __/__/__ TIME: ___:____

NAME:_____ CONTACT YEAR: 10

DATE OF BIRTH:___/___/___ AGE:___ SEX: M F RACE:____

CLINIC PROCEDURES	TIME STARTED	TIME COMPLETED	STAFF CODE#
MEDICATION BAG Y___ N___ BP MEDS _____ HEART TROUBLE _____ RECENT BLACKOUTS _____			
___ RECEPTION (CONST,UPD,FTR,GTS,)	__:__	__:__	____
CONSENT:____/COPY ____ TAPE YES _____ NO _____ TRT DIABETIC? (PIN): Y___ N ____ OGTT: Y ___ N ____ UA S___ I ____ LATER			
___ANTHRO..QC: Y__ N__.	__:__	__:__	____
___SBP.... ___/___ CUFF SIZE ____	__:__	__:__	____
___ECG/HRV	__:__	__:__	____
___VENIPUNCTURE...FAST TIME____.....	__:__	__:__	___
___GLUCOLA STARTED: ____:____ 2ND DRAW DUE: __:__			
___DENTAL ELIGIBLE Y/N ...	__:__	__:__	____
___ULTRASOUND.....	__:__	__:__	____
___INTERVIEWS CNF,HHX,MSR,PHX INF,DHX,TIA,TIB,RHX,SES, HPC,PAQ,MHQ	__:__	__:__	____
___MED DATA REVIEW(MD,TSR,REF,ECG)	__:__	__:__	____

SPECIAL NOTES:SCHEDULE DENTAL/HRV_____

ARIC
Atherosclerosis Risk in Communities

PERSONAL HISTORY FORM

O.M.B. 0925-0281
exp. 09/30/98

A-215

ID NUMBER: | | | | | | | | CONTACT YEAR: | 1 | 0 | FORM CODE: | P | H | X | VERSION: B 02/01/96

LAST NAME: | | | | | | | | | | | | | INITIALS: | | |

INSTRUCTIONS: This form should be completed during the participant's visit. ID Number, Contact Year and Name must be entered above. Whenever numerical responses are required, enter the number so that the last digit appears in the rightmost box. Enter leading zeroes where necessary to fill all boxes. If a number is entered incorrectly, mark through the incorrect entry with an "X". Code the correct entry clearly above the incorrect entry. For "multiple choice" and "yes/no" type questions, circle the letter corresponding to the most appropriate response. If a letter is circled incorrectly, mark through it with an "X" and circle the correct response.

PERSONAL HISTORY FORM (PHXB screen 1 of 8)

A. MEDICAL CARE

1. Please tell me if you usually go to one or more of the following sources of medical care when you want help with a health problem. By a 'health problem' I mean an illness, a medical question or concern, or a need for a test or treatment.

[SHOW RESPONSE CARD]

	Yes	No
a. Private physician	Y	N
b. HMO	Y	N
c. Walk-in clinic	Y	N
d. Regular clinic	Y	N
e. Hospital emergency room	Y	N
f. Other	Y	N

If "other", specify:

_____

2. To help pay for your medical care, do you NOW have:

[READ RESPONSE CATEGORIES]

	Yes	No	Unknown
a. Health insurance or a health plan, such as Blue Cross/Blue Shield or an HMO	Y	N	U
b. Medicare	Y	N	U
c. Medicaid	Y	N	U
d. Other	Y	N	U

PERSONAL HISTORY FORM (PHXB screen 2 of 8)

3. Have you seen a doctor, a physician's assistant or a nurse practitioner for any reason in the last 12 months? ..... Yes Y

No N

4. Have you ever been treated by a doctor for high blood pressure? ..... Yes Y

No N

Unknown U

5. Have you ever been treated by a doctor for high blood cholesterol? ..... Yes Y

No N

Unknown U

6. Has a doctor ever said you had any of the following?

	Yes	No	Unknown
a. Heart attack	Y	N	U
b. Heart failure or congestive heart failure	Y	N	U
c. Diabetes (sugar in the blood) ..	Y	N	U
d. Chronic lung disease, such as bronchitis, or emphysema ..	Y	N	U
e. Asthma	Y	N	U
f. Cancer	Y	N	U

Go to Item 7, Screen 3.

PERSONAL HISTORY FORM (PHXB screen 3 of 8)

6.g. Can you tell me in what part of the body the cancer was located?

h. And the date it was diagnosed?

month / year

i. Have you had another cancer? ..... Yes Y

No N

Unknown U

Go to Item 7.

j. Can you tell me in what part of the body the cancer was located?

6.k. And the date it was diagnosed?

month / year

B. Smoking

"The next series of questions asks about smoking."

7. Have you ever smoked cigarettes? [Code "NO" if less than 400 cigarettes in a lifetime.] ..... Yes Y

No N

Go to Item 12, Screen 5.

8. Do you now smoke cigarettes? ..... Yes Y

No N

Go to Item 11, Screen 4.

PERSONAL HISTORY FORM (PHXB screen 4 of 8)

9. When did you smoke your last cigarette?

Less than 2 months ago ..... A

At least 2 months ago, but less than 12 months ago ..... B

At least 12 months ago, but less than 24 months ago C

At least 24 months ago, but less than 36 months ago ..... D

More than 36 months ago ..... E

→ Go to Item 12, Screen 5.

10. Prior to quitting, how many cigarettes did you usually smoke per day?
[CODE "00" IF LESS THAN ONE PER DAY.]

☐☐ cigarettes per day

→ Go to Item 12, Screen 5.

11. How many cigarettes do you usually smoke per day now?
[CODE "00" IF LESS THAN ONE PER DAY.]

☐☐ cigarettes per day

PERSONAL HISTORY FORM (PHXB screen 5 of 8)

12. Please tell me if you have ever used the following?

	Yes	No
a. Pipe/cigars/cigarillos	Y	N
b. Chewing tobacco	Y	N
c. Snuff	Y	N
d. Nicotine gum that was prescribed by a doctor	Y	N
e. Nicotine patch that was prescribed by a doctor	Y	N

13. During the past year, about how many hours per week, on the average, were you in close contact with people when they were smoking? For example, in your home, in a car, at work or other close quarters .....

☐☐☐ hours

PERSONAL HISTORY FORM (PHXB screen 6 of 8)

C. ALCOHOL

"Next I am going to ask you about your consumption of wine, beer, and drinks made with hard liquor."

14. Have you ever consumed alcoholic beverages? ..... Yes Y

No N

Go to Item 21, Screen 8.

15. Do you presently drink alcoholic beverages? ..... Yes Y

No N

Go to Item 17.a, Screen 7.

16. When did you have your last alcoholic beverage?

- Less than 2 months ago ..... A
- At least 2 months ago, but less than 12 months ago ..... B
- At least 12 months ago, but less than 24 months ago C
- At least 24 months ago, but less than 36 months ago ..... D
- More than 36 months ago ..... E

GO ITEM 21, SCREEN 8.

PERSONAL HISTORY FORM (PHXB screen 7 of 8)

17.a. How many glasses of wine do you usually have per week? (4 oz. glasses; round down)

[ ][ ] per week

IF NONE, GO TO ITEM 18.a.

b. How many days in a week do you usually drink wine?

[ ] days

18.a. How many glasses, bottles, or cans of beer do you usually have per week? (12 oz. glasses, bottles, or cans, round down)

[ ][ ] per week

IF NONE, GO TO ITEM 19.a, Screen 8.

b. How many days in a week do you usually drink beer?

[ ] days

PERSONAL HISTORY FORM (PHXB screen 8 of 8)

19.a. How many drinks of hard liquor do you usually have per week? (1.5 oz. shots; round down)

☐☐ per week

IF NONE, GO TO ITEM 20.

b. How many days in a week do you usually drink hard liquor?

☐ days

20. During the past 24 hours, how many drinks have you had?

☐☐ drinks

D. ADMINISTRATIVE INFORMATION

21. Date of data collection: ..... ☐☐/☐☐/☐☐
month day year

22. Method of data collection: ..... Computer C
Paper form P

23. Code number of person completing this form: ..... ☐☐☐

(PHXB screen 1 of 8)

A. MEDICAL CARE

1. Please tell me if you usually go to one or more of the following sources of medical care when you want help with a health problem. By a 'health problem' I mean an illness, a medical question or concern, or a need for a test or treatment.
[SHOW RESPONSE CARD]
Yes (Y) or No (N)

a~ Private physician _
b~ HMO _
c~ Walk-in clinic _
d~ Regular clinic _
e~ Hospital emergency room _
f~ Other (If Yes, specify) _

2. To help pay for your medical care, do you NOW have:

[READ RESPONSE CATEGORIES]

Yes (Y), No (N) or Unknown (U)

a~ Health insurance or a health plan, such as Blue Cross/Blue Shield or an HMO _

b~ Medicare _

c~ Medicaid _

d~ Other _

(PHXB screen 2 of 8)

3~ Have you seen a doctor, a physician's assistant or a nurse practitioner for any reason in the last 12 months? _

Yes (Y) or No (N)

4~ Have you ever been treated by a doctor for high blood pressure? _

Yes (Y), No (N) or Unknown (U)

5~ Have you ever been treated by a doctor for high blood cholesterol? _

Yes (Y), No (N) or Unknown (U)

6. Has a doctor ever said you had any of the following?

Yes (Y), No (N) or Unknown (U)

a~ Heart attack _

b~ Heart failure or congestive heart failure _

c~ Diabetes (sugar in the blood) _

d~ Chronic lung disease, such as bronchitis, or emphysema _

e~ Asthma _

f~ Cancer (N*, U*) _

(PHXB screen 3 of 8)

6g~ Can you tell me in what part of the body the cancer was located?

_____

h~ And the date it was diagnosed?

_____
mm/yy

i~ Have you had another cancer? _

Yes (Y), No (N)* or Unknown (U)*

j~ Can you tell me in what part of the body the cancer was located?

_____

6k~ And the date it was diagnosed?

_____
mm/yy

B. Smoking

"The next series of questions asks about smoking."

7~ Have you ever smoked cigarettes? [Code "NO" if less than 400 cigarettes in a lifetime.] _

Yes (Y) or No (N)*

8~ Do you now smoke cigarettes? _

Yes (Y)* or No (N)

(PHXB screen 4 of 8)

9~ When did you smoke your last cigarette? _

Less than 2 months ago (A)

At least 2 months ago, but less than 12 months ago (B)

At least 12 months ago, but less than 24 months ago (C)

At least 24 months ago, but less than 36 months ago (D)

More than 36 months ago (E)*

10~ Prior to quitting, how many cigarettes did you usually smoke per day?

[CODE "00" IF LESS THAN ONE PER DAY.]

__ cigarettes per day

[GO TO ITEM 12, SCREEN 5]

11~ How many cigarettes do you usually smoke per day now?

__ cigarettes per day

[CODE "00" IF LESS THAN ONE PER DAY.]

(PHXB screen 5 of 8)

12. Please tell me if you have ever used the following?

Yes (Y) or No (N)

a~ Pipe/cigars/cigarillos _

b~ Chewing tobacco _

c~ Snuff _

d~ Nicotine gum that was prescribed by a doctor _

e~ Nicotine patch that was prescribed by a doctor _

13~ During the past year, about how many hours per week, on the average, were you in close contact with people when they were smoking? For example, in your home, in a car, at work or other close quarters?

___ hours

(PHXB screen 6 of 8)

C. ALCOHOL

"Next I am going to ask you about your consumption of wine, beer, and drinks made with hard liquor."

14~ Have you ever consumed alcoholic beverages? _

Yes (Y) or No (N)*

15~ Do you presently drink alcoholic beverages? _

Yes (Y)* or No (N)

16. When did you have your last alcoholic beverage? _

Less than 2 months ago (A)*

At least 2 months ago, but less than 12 months ago (B)*

At least 12 months ago, but less than 24 months ago (C)*

At least 24 months ago, but less than 36 months ago (D)*

More than 36 months ago (E)*

(PHXB screen 7 of 8)

17a~ How many glasses of wine do you usually have per week?
(4 oz. glasses; round down)

__ per week

[IF NONE, GO TO ITEM 18a.]

b~ How many days in a week do you usually drink wine?

_ days

18a~ How many glasses, bottles, or cans of beer do you usually have per week?
(12 oz. glasses, bottles, or cans, round down)

__ per week

[IF NONE, GO TO ITEM 19a, SCREEN 8.]

b~ How many days in a week do you usually drink beer?

_ days

(PHXB screen 8 of 8)

19a~ How many drinks of hard liquor do you usually have per week?
(1.5 oz. shots; round down)

__ per week

[IF NONE, GO TO ITEM 20.]

b~ How many days in a week do you usually drink hard liquor?

_ days

20. During the past 24 hours, how many drinks have you had?

__ drinks

D. ADMINISTRATIVE INFORMATION

21~ Date of data collection: _____
mm/dd/yy

22~ Method of data collection: _

Computer(C) or Paper(P) Form

23~ Code number of person completing this form ___

INSTRUCTIONS FOR THE PERSONAL HISTORY FORM
PHX, VERSION B, 12/01/95
REVISED 02/13/96

The Personal History Form (PHXB) collects current information on the participant's access to and use of medical care for general medical complaints and conditions related to cardiovascular disease, and updates information on smoking, passive smoking, and alcohol consumption since Visit 3. The exact wording and order of the questions are followed to ensure standardization. Questions are skipped only when indicated by the skip pattern instructions. Because of the unusual number of skip patterns in this form, greater than usual care needs to be taken by the interviewer to memorize the flow of the questions. Some of the questions on smoking and alcohol consumption may be considered sensitive and care must be taken to ask questions and record responses in a non-judgmental manner.

Interviewers are certified in general clinic interviewing and familiar with the ARIC data entry system (DES) and the "General Instructions for Completing Paper Forms" (in case the computer is down) prior to administering this form. Items in BRACKETS and/or CAPITAL LETTERS are instructions to the interviewer and are not read to the participant.

The HEADER (paper form) is completed by applying the long participant ID label and entering the participant's Name. THE QUESTIONS ARE READ CLEARLY USING THE EXACT WORDING ON THE FORM. The introductory and transitional scripts may deviate from the prototypes provided, but must include the same information.

A. Medical Care

Section A contains questions on the use of, payment for, and type of medical care services. The time frames for these questions vary and the questions need to be read, subtly stressing these differences. For instance, the source(s) of medical care (Item 1) refers to the participant's usual usage; the availability of medical care coverage (Item 2) refers to the participant's current coverage; and treatment for hypertension (Item 3) refers to the participant's lifetime.

1. The goal of the question is to document the participant's usual source(s) of medical care for a health problem, therefore, the question is read emphasizing "usually" and "source of medical care". The term "health problem" is defined as part of the question. Then each source of medical care is read; the response category (Yes or No) is not read aloud. Because participants may habitually use more than one source of medical care, *more than one category may have a positive response*. Definitions of the response categories are offered, only if the participant requests clarification. Show the participant the response card.

Private physician	A single physician who is routinely responsible for providing or overseeing a patient's medical care. The practice location of this physician is not important.
HMO	A health maintenance organization, i.e., a *prepaid medical care plan* in which a person may *or may not* be assigned to one physician (e.g., a private physician) from a group of physicians organized to provide preventive and curative medical care.
Walk-in clinic	An out-patient medical facility, which can be privately operated or part of a hospital, that provides emergent or routine medical care, but does not preschedule clinic appointments and does not provide patients with a regular physician.
Regular Clinic	An out-patient medical facility, which can be privately operated or part of a hospital, that preschedules appointments for patients (i.e., not a "walk-in" appointment) with available physicians (i.e., the patient does not have a "private" physician).
Hospital Emergency Room	A medical care facility in a hospital which is designed to provide emergent medical care, but can also provide follow-up care to individuals who have no other source of medical care.
Other	Any type of out- or in-patient medical care facility used by the participant to obtain routine medical care that is not described above.

2. The goal of this question is to document how participants currently pay for all or part of their medical care, excluding their own resources. This refers to private or public payment plans which pay for at least part of the participant's medical care, such as hospital, doctor, clinic, or surgeon's bills. It can include, but not be limited to, coverage for dental care. The four third party payment options are read aloud to the participant; the response categories (Yes, No or Unknown) are not. Types of coverage are not necessarily mutually exclusive, therefore, more than one option may have a positive response. Definitions of the types of medical payment plans are offered, only if the participant requests clarification. Read each response category and select the code (Y,N,U) which corresponds to the person's response.

Health insurance or health plan	Private (in contrast to public) payment plans for medical care, such as hospital, doctor, clinic or surgeon's bills.
Medicare	A government payment program for medical care, especially for the aged.
Medicaid	A government financed medical aid designed for those unable to afford regular medical service.
Other	Other government or private health care payment programs, such as veterans benefits, CHAMPUS, workman's compensation, etc., not described above.

3. Item 3 refers to any type of medical interaction (for a general check-up or a specific problem) with a medically trained health practitioner within the past 12 months. Family doctors, specialists, physician's assistants, nurse practitioners, hospitals, and clinics all apply. Dentists do not apply. If asked for clarification, tell the participant that chiropractors, herbalists and other allied health care professionals also do not apply.

4. This question assesses hypertension (high blood pressure) diagnosed and treated by a physician, anytime during the participant's life. Treatment refers to use of medications, prescribed by a physician,to lower high blood pressure.

A positive response (YES) indicates that the participant has received pharmacologic intervention under the direction of a physician, some time prior to Visit 4. The person does not have to, but could, be taking the antihypertensive medication now. A negative response (NO) indicates (1) a physician never prescribed pharmacologic treatment for high blood pressure, (2) the participant did not comply with the treatment recommendations; (3) or the participant was never told by a physician that he/she has high blood pressure. An unsure response (UNKNOWN) indicates the participant either does not know he/she is hypertensive or has ever received antihypertensive medication.

5. The goal of Item 5 and the definitions of the response categories are similar to that of Item 4 except that it deals with the diagnosis and treatment of hypercholesterolemia (high blood cholesterol) anytime during the participant's life.

6. Enter YES, NO or UNSURE for each item that identifies a specific condition (8a-f,i). A response is positive only if the condition was diagnosed by a physician. NO is coded if (1) the respondent was told by a doctor that he/she did not have the condition specified, (2) was never told by a doctor that he/she had the condition, or (3) was never tested for the condition. UNKNOWN is recorded if the respondent is not sure that the doctor said he/she had this condition. The code of UNKNOWN is most frequently used when the respondent cannot remember accurately what the doctor said. Do not define the condition for the respondent. Do not define the condition yourself based on the respondent's answer. Record ambiguous responses as UNKNOWN and enter the text of the response in a note log. Follow the skip patterns closely for responses of NO or UNKNOWN.

6. a-e. A positive response to each of these conditions (heart attack, congestive heart failure, diabetes, and chronic lung disease and asthma) requires diagnosis by a physician. The time frame is any time prior to this examination.

6.f If the response to Item 6.f is NO or UNSURE, go to Item 7. If the response is YES, ask what part of the body was affected and record the site (Item 6.g) and date of diagnosis (Item 6.h). Ask if the participant has had multiple diagnoses of cancer (Item 6.i). If NO or UNSURE, go to Item 7. If YES, record the site (Item 8.j) and date of diagnosis (Item 8.k). NOTE: Space is provided for recording information on only two cancers. If the participant reports more than two, record the location and date of the two earliest diagnoses. Do not probe to determine whether these diagnoses represent two separate malignancies or a malignancy and its recurrence.

B. Smoking

The questions in this section on smoking habits are adapted from the NHLBI Epidemiology Standardization Project. The purpose of its use at Visit 4 is to update the information on smoking patterns obtained during the previous examinations and to quantify lifetime passive exposure to smoke from cigarettes during the past 12 months. Begin administering this section of the form with the introductory statement.

7. The focus of this question is to measure the participant's lifetime cigarette smoking habits, i.e., *'Have you ever...?'* Code NO if the participant smoked less than 400 cigarettes over his/her lifetime. Most US cigarettes are and have been sold in packages containing 20 cigarettes. Therefore, 400 cigarettes will usually be equivalent to 20 packs of cigarettes or two cartons. If NO, go to item 12.

8. "Now" refers to within the last month, i.e., the last 4 weeks prior to the interview. If YES, go to Item 11.

9. Do not read the responses. If the last cigarette was smoked more than 36 months (Item 9e), go to Item 12. (If the participant quit smoking more than 36 months ago, consumption patterns will have been documented at Visit 3 and the data do not need to be collected again.)

10. PROBE if the response does not allow you to easily estimate the number of cigarettes smoked on the average day. You are looking for the usual number of cigarettes smoked per day over the entire lifetime of smoking. Usual is defined as the amount smoked for the longest time period. CODE 00 if the average number of cigarettes smoked is less than one per day, skip Item 11, and continue with Item 12.

11. As in Item 10, the question refers to the daily number of cigarettes smoked on an average day, but the time frame is restricted to the last month. You are looking for the usual number of cigarettes smoked per day during the past month. CODE 00 if the average number of cigarettes smoked is less than one per day.

12. This question covers lifetime smoking habits. Note that the use of nicotine gum or a patch must have been prescribed by a doctor.

    The introductory clause is read and then the four types of tobacco products other than cigarettes, pausing between the types, to allow the participant to respond to each category.

    Please tell me if you have ever used the following:

a. a pipe, cigars or cigarillos?
{pause; code the response}

b. chewing tobacco?
{pause; code the response}

c. snuff?
{pause; code the response}

d. nicotine gum that was prescribed by a doctor?
{pause; code the response}

e. nicotine patch that was prescribed by a doctor?
{pause; code the response}

13. The goal of this question is to obtain information on passive exposure to cigarette smoke (excluding cigars, pipes and cigarillos, etc.) in any type of close quarters (car, home, public transportation, work, etc.) during the past 12 months. RECORD the number of hours in the typical week over the past year, in contrast to an atypical situation, such as holidays or short-term smoking house guests.

C. Alcohol Consumption

The goal of the questions on alcohol consumption is to identify current vs previous vs non-drinkers, and to document current consumption patterns of participants who report that they currently consume alcoholic beverages. Frequency of alcohol consumption is determined as usual weekly intake. The serving sizes are different for beer, wine, and hard liquor. Serving sizes are "12 oz. bottles or cans of beer", "4 oz. glasses of wine", and "1½ ounce shots of hard liquor".

14. The goal of Item 14 is to determine whether or not a participant has ever consumed alcoholic beverages during his/her life. Persons who report never having consumed alcohol are not asked any more questions in this section, and the interviewer completes Items 21-23 in the Administrative Section.

15. "Presently" is defined by the participant. If the response is "NO", continue with Item 16. If the response is "YES", continue with Question 17.

16. The goal of the question is to document when the participant who reported he/she is no longer a current drinker (Item 15=No) last consumed an alcoholic beverage. The response categories are not read, but selected by the interviewer, based on the participant's response. Regardless of the response category selected, this question terminates the administration of the Personal History Form and the interviewer completes Items 21-23 in the Administrative Section.

The next three questions (Items 17-19) assess the amount of wine, beer and hard liquor consumed weekly (part a) and the number of days per week the alcoholic beverage(s) is consumed (part b) for participants who are current drinkers (Item 15=Yes). *Per week* includes weekends. If the participant answers in terms of drinks per month, divide by four to derive the weekly intake. If the number of drinks is "half a drink" or less, record "00". If the person does not drink the beverage being discussed (i.e., wine, beer or hard liquor), enter '00' and skip to the next set of questions. For example, if wine is not consumed, enter '00' in Item 17a, skip Item 17b and continue with the questions about beer (Item 18a). If the number of drinks is more than 99 record as "99".

17.a Wine is measured in 4 ounce glasses, rounding down; adjust the number of glasses reported as necessary to accommodate different sized containers. In addition to table wines, *wine* includes wine coolers, and "sweet wines". The period of reference is a seven day week, which includes weekends. If wine is not consumed, go to Item 18a.

17.b The focus of this question is the participant's habitual drinking pattern. The number of days the beverage is consumed per week should be consistent with the number of reported drinks per week in the previous item.

18.a Non-alcoholic beer is not considered a beer in this question. Beer (at any other alcoholic content) is measured as a 12 ounce glass, bottle or can, rounding down. The period of reference is a seven day week, which includes weekends. If beer is not consumed, go to Item 19a.

18.b The focus of this question is the participant's habitual (usual) drinking pattern. The number of days the beverage is consumed per week should be consistent with the number of reported drinks per week in the previous item.

19.a Hard liquor is measured in 1½ ounce shots, rounding down; adjust the number reported as necessary to accommodate different sized containers. Refer to the Alcohol Consumption by the Drink Conversion Table if necessary. Hard liquor also includes cordials and 'liqueurs'. The period of reference is a seven day week, which includes weekends. If hard liquor is not consumed, go to Item 20.

19.b The focus of this question is the participant's habitual (usual) drinking pattern.

20. The number of *drinks* includes all the wine, beer and hard liquor consumed within the 24 hours prior to the interview. Use the measurement criteria in items 17-19, i.e., 4 ounces for wine, 12 ounces for beer and 1½ ounces for hard liquor.

ALCOHOL CONSUMPTION BY THE DRINK CONVERSION TABLE

BEVERAGE	SERVING SIZE	CONTAINER/SERVINGS
WINE	1 glass = 4 oz	Fifth = 6 (4 oz) glasses
coolers	1 glass = 4 oz	1 (12 oz) bottle = 3 (4 oz) glasses
BEER	1 can/bottle = 12 oz	Pony (7 oz) = < 1 serving Regular can (12 oz) = 1 serving Tall can (16 oz) > 1 serving
HARD LIQUOR (SPIRITS)	1 shot = 1.5 oz	Pint bottle = 11 (10.67) shots 375 ml bottle = 11 shots Fifth = 21 shots 750 ml bottle = 16 shots Quart = 21 shots

D. Administrative Information

21. Enter the date on which the participant was seen in the clinic. Code in numbers using leading zeroes where necessary to fill all boxes. For example, May 3, 1993, would be entered as:

0	5	/	0	3	/	9	3

month day year

22. Record "C" if the form was completed on the computerized data entry system, or "P" if the paper form was used. If the form was completed partially on paper and partially on the computer, code as "Paper Form."

23. The person at the clinic who has completed this form must enter his/her code number in the boxes provided.

ARIC
Atherosclerosis Risk in Communities

Appendix 2.19a

PHYSICAL ABILITY QUESTIONNAIRE

O.M.B. 0925-0281
exp. 09/30/98

ID NUMBER: | | | | | | | | CONTACT YEAR: | | | FORM CODE: P A Q VERSION: A 02/01/96

LAST NAME: | | | | | | | | | | | | | INITIALS: | |

INSTRUCTIONS:

This questionnaire asks for information on your physical abilities. Below is a list of activities with which some people have difficulty because of a health or physical reason. Please mark an 'X' in the correct box to indicate whether you have no difficulty, some difficulty, much difficulty, or are unable to do these activities at all when you are by yourself and without the use of aids. DO NOT INCLUDE TEMPORARY CONDITIONS LIKE BROKEN LIMBS. Mark only one response for each question or statement. If you make a mistake, black out that box and place an 'X' in the correct box.

	No Difficulty	Some Difficulty	Much Difficulty	Unable To Do	Don't Know or Do Not Do
1. Walking for a quarter of a mile (that is about 2 or 3 blocks)?	☐	☐	☐	☐	☐
2. Walking up 10 steps without resting?	☐	☐	☐	☐	☐
3. Stooping, crouching, or kneeling?	☐	☐	☐	☐	☐
4. Lifting or carrying something as heavy as 10 pounds?	☐	☐	☐	☐	☐

	No Difficulty	Some Difficulty	Much Difficulty	Unable To Do	Don't Know or Do Not Do
5. Doing chores around the house (like vacuuming, sweeping, dusting, or straightening up)?	☐	☐	☐	☐	☐
6. Preparing your own meals?	☐	☐	☐	☐	☐
7. Managing your money (such as keeping track of your expenses or paying bills)?	☐	☐	☐	☐	☐
8. Walking from one room to another on the same level?	☐	☐	☐	☐	☐
9. Standing up from an armless straight chair?	☐	☐	☐	☐	☐
10. Getting in or out of bed?	☐	☐	☐	☐	☐
11. Eating, including holding a fork, cutting food, or drinking from a glass?	☐	☐	☐	☐	☐
12. Dressing yourself, including tying shoes, working zippers, and doing buttons?	☐	☐	☐	☐	☐

13. Because of any impairment or health problem, do you need the help of other persons for personal care needs such as eating, bathing, dressing or getting around your home?	☐ Yes ☐ No
14. Because of any impairment or health problem, do you need the help of other persons in handling routine needs, such as everyday household chores, doing necessary business, shopping, or getting around for other purposes?	☐ Yes ☐ No
15. Do you usually use any device to help you get around such as a cane, wheelchair, crutches or walker?	☐ Yes ☐ No
16. Do you usually use any special eating utensils?	☐ Yes ☐ No
17. Do you usually use any aids or devices to help you dress (such as button hooks, zipper pulls, long-handled shoe horn, etc.)?	☐ Yes ☐ No ☐ Don't Know

This completes the Physical Ability Questionnaire. Thank you.

FOR ADMINISTRATIVE USE ONLY.

18. Date ☐☐/☐☐/☐☐ 19. Administration (A,B,C,D) ☐ 20. Code ☐☐☐

(PAQA screen 1 of 5)

1~ Walking for a quarter of a mile (that is about 2 or 3 blocks)? _ []

No Difficulty	(A)
Some Difficulty	(B)
Much Difficulty	(C)
Unable to do	(D)
Don't know or Do not do	(E)
No Response	(F)

2~ Walking up 10 steps without resting? _ []

No Difficulty	(A)
Some Difficulty	(B)
Much Difficulty	(C)
Unable to do	(D)
Don't know or Do not do	(E)
No Response	(F)

3~ Stooping, crouching, or kneeling? _ []

No Difficulty	(A)
Some Difficulty	(B)
Much Difficulty	(C)
Unable to do	(D)
Don't know or Do not do	(E)
No Response	(F)

4~ Lifting or carrying something as heavy as 10 pounds? _ []

No Difficulty	(A)
Some Difficulty	(B)
Much Difficulty	(C)
Unable to do	(D)
Don't know or Do not do	(E)
No Response	(F)

(PAQA screen 2 of 5)

5~ Doing chores around the house (like vacuuming, sweeping, dusting, or straightening up)? _ []

No Difficulty	(A)
Some Difficulty	(B)
Much Difficulty	(C)
Unable to do	(D)
Don't know or Do not do	(E)
No Response	(F)

6~ Preparing your own meals? _ []

No Difficulty	(A)
Some Difficulty	(B)
Much Difficulty	(C)
Unable to do	(D)
Don't know or Do not do	(E)
No Response	(F)

7~ Managing your money (such as keeping track of your expenses or paying bills)? _ []

No Difficulty	(A)
Some Difficulty	(B)
Much Difficulty	(C)
Unable to do	(D)
Don't know or Do not do	(E)
No Response	(F)

8~ Walking from one room to another on the same level? _ []

No Difficulty	(A)
Some Difficulty	(B)
Much Difficulty	(C)
Unable to do	(D)
Don't know or Do not do	(E)
No Response	(F)

(PAQA screen 3 of 5)

9~ Standing up from an armless straight chair? _ []

No Difficulty	(A)
Some Difficulty	(B)
Much Difficulty	(C)
Unable to do	(D)
Don't know or Do not do	(E)
No Response	(F)

10~ Getting in or out of bed? _ []

No Difficulty	(A)
Some Difficulty	(B)
Much Difficulty	(C)
Unable to do	(D)
Don't know or Do not do	(E)
No Response	(F)

11~ Eating, including holding a fork, cutting food, or drinking from a glass? _ []

No Difficulty	(A)
Some Difficulty	(B)
Much Difficulty	(C)
Unable to do	(D)
Don't know or Do not do	(E)
No Response	(F)

12~ Dressing yourself, including tying shoes, working zippers, and doing buttons? _ []

No Difficulty	(A)
Some Difficulty	(B)
Much Difficulty	(C)
Unable to do	(D)
Don't know or Do not do	(E)
No Response	(F)

(PAQA screen 4 of 5)

13~ Because of any impairment or health problem, do you need the help of other persons for personal care needs such as eating, bathing, dressing or getting around in your home? _ []

Yes(Y), No(N) or No Response(R)

14~ Because of any impairment or health problem, do you need the help of other persons in handling routine needs, such as everyday household chores, doing necessary business, shopping, or getting around for other purposes? _ []

Yes(Y), No(N) or No Response(R)

15~ Do you usually use any device to help you get around such as a cane, wheelchair, crutches, or walker? _ []

Yes(Y), No(N) or No Response(R)

16~ Do you usually use any special eating utensils? _ []

Yes(Y), No(N) or No Response(R)

(PAQA screen 5 of 5)

17~ Do you usually use any aids or devices to help you dress (such as button hooks, zipper pulls, long-handle shoe horn, etc.)? _ ☐

Yes	(Y)
No	(N)
Don't Know	(D)
No Response	(R)

ADMINISTRATIVE INFORMATION

18~ Date of data collection: _____ ☐
mm/dd/yy

19~ Type of administration: _ ☐

Self Administered	(A)
Interviewer Administered	(B)
Both	(C)
Not Done	(D)

20~ Code number of person reviewing/ completing this form: ___ ☐

ARIC
Atherosclerosis Risk in Communities

Appendix 2.20a

SOCIOECONOMIC STATUS FORM

O.M.B. 0925-0281
exp. 09/30/98

ID NUMBER: | | | | | | | | CONTACT YEAR: | 1 | 0 | FORM CODE: | S | E | S | VERSION: A 01/11/96

LAST NAME: | | | | | | | | | | | | | INITIALS: | | |

Public reporting burden for this collection of information is estimated to average 4 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: **PHS Reports Clearance Officer, Rm. 737-F, Humphrey Building, 200 Independence Ave., SW, Washington, D.C. 20201, ATTN: PRA (0925-0281).** Do not return the completed form to this address.

INSTRUCTIONS: This form should be completed during the participant's visit. ID Number, Contact Year and Name must be entered above. Whenever numerical responses are required, enter the number so that the last digit appears in the rightmost box. Enter leading zeroes where necessary to fill all boxes. If a number is entered incorrectly, mark through the incorrect entry with an "X". Code the correct entry clearly above the incorrect entry. For "multiple choice" and "yes/no" type questions, circle the letter corresponding to the most appropriate response. If a letter is circled incorrectly, mark through it with an "X" and circle the correct response.

SOCIOECONOMIC STATUS FORM (SESA screen 1 of 9)

"Some studies suggest that the experiences we have in early life may be related to the occurrence of illness throughout our lives. The following questions are designed to assess some of your current and early life experiences. We realize that many of these refer to events that happened a long time ago. Please try to remember and answer as best you can. We will start our questions, however, by updating the information you have previously given us on your marital and occupational status."

A. PARTICIPANT

1. Please tell me which of the following describes your current marital status

[READ ALL CHOICES]

Married ..... M

Widowed ..... W

Divorced ..... D

Separated ..... S

Never Married ..... N

SOCIOECONOMIC STATUS FORM (SESA screen 2 of 9)

2. Since your last ARIC visit, have you changed your occupation, stopped working, or retired?

Yes Y

No N → Go to Item 6, Screen 4.

3. I would like you to look at this card while I read it to you. Please tell me the letter which best describes your CURRENT employment status.

[HAND RESPONSE CARD 1 TO PARTICIPANT AND READ EACH CATEGORY ALOUD.]

Homemaking, not working outside the home ..... A → Go to Item 6, Screen 4.

Employed at a job for pay, either full or part-time ..... B

Employed, but temporarily away from my regular work C

Unemployed, looking for work ..... D

Unemployed, not looking for work ..... E → Go to Item 5, Screen 3.

Retired from my usual occupation and not working ..... F

Retired from my usual occupation, but working for pay ..... G

SOCIOECONOMIC STATUS FORM (SESA screen 3 of 9)

4. Did you retire because of health reasons? .....

Yes Y

No N → Go to Item 6, Screen 4.

5. Please look at the categories on the card and tell me the letter that best describes your current or most recent occupation. If you cannot decide, tell me your occupation and we can decide together.

[HAND RESPONSE CARD 2 TO RESPONDENT AND READ ALOUD (if necessary)]

Homemaker ..... A

Technician, sales or clerical ..... B

Mechanic, repairman, construction worker or craftsman C

Service: hairdresser, domestic, restaurant, security ..... D

Management, professional ..... E

Farming, forestry, fishing ..... F

Driver, machine operator, sanitation, laborer ..... G

Unknown ..... H

SOCIOECONOMIC STATUS FORM (SESA screen 4 of 9)

6. Please look at this card. Which of these income groups represents your total combined family income for the past 12 months? Include income from all sources such as wages, salaries, social security or retirement benefits, help from relatives, rent from property, and so forth. Please tell me the letter only.

[HAND RESPONSE CARD 3 TO RESPONDENT AND READ ALOUD (if necessary)]

Under $5,000	A
$5,000 - $7,999	B
$8,000 - $11,999	C
$12,000 - $15,999	D
$16,000 - $24,999	E
$25,000 - $34,999	F
$35,000 - $49,999	G
$50,000 - $74,999	H
$75,000 - $99,999	I
$100,000 and over	J
Refused	R

SOCIOECONOMIC STATUS FORM (SESA screen 5 of 9)

7. On the average, how many people lived in your house during the last 12 months? ..... ☐☐

"Now I would like to ask you some questions about when you were a baby."

8. Were you a premature baby, that is were you born a month or more early? ..... Yes Y / No N / Unknown U

How much did you weigh at birth?

a. ☐☐ pounds b. ☐☐ ounces ——— Go to Item 9.

[If Unknown, enter == == and continue with Item 8c.]

8.c. Do you believe your birth weight was low, that is less than 5 1/2 pounds, medium, that is 5 1/2 to 9 pounds, high, that is over 9 pounds?

[HAND RESPONSE CARD 4 TO RESPONDENT AND READ ALOUD (if neccessary)]

Low, less than 5 1/2 pounds	L
Medium, 5 1/2 to 9 pounds	M
High, over 9 pounds	H
Unknown	U

9. Were you a twin? ..... Yes Y / No N / Unknown U

SOCIOECONOMIC STATUS FORM (SESA screen 6 of 9)

10. Now I would like you to think about the kind of jobs you had when you were younger. Please look at the categories on the card and tell me the letter that best describes your type of occupation when you were between 25 and 45 years of age. If you cannot decide or if you had many different kinds of jobs, describe the jobs you had and we can decide together.

a. Occupation for the longest time period ..... ☐

b. Occupation for the next longest time period ..... ☐ [If only one occupation, enter X in 10.b.]

[HAND RESPONSE CARD 2 TO RESPONDENT AND READ ALOUD (if necessary)]

Homemaker	A
Technician, sales or clerical	B
Mechanic, repairman, construction worker or craftsman	C
Service: hairdresser, domestic, restaurant, security	D
Management, professional	E
Farming, forestry, fishing	F
Driver, machine operator, sanitation, laborer	G
Unknown	H

SOCIOECONOMIC STATUS FORM (SESA screen 7 of 9)

B. PARENTS

[For Items 11 and 13, HAND RESPONSE CARD 5 TO RESPONDENT AND READ ALOUD (if necessary) AFTER READING THE QUESTIONS.]

11. I would like to ask you about your parents' education. Please look at this card and tell me the letter which best describes your natural mother's and your natural father's level of education when you were born.

a. Natural mother's education ..... ☐

b. Natural father's education ..... ☐

[RESPONSES FOR ITEMS 11. a - b]

Never went to school	A
Grades 1 to 3	B
Grades 4 to 8	C
Grades 9 to 11	D
Grade 12	E
GED	F
One or more years of Vocational or Professional School after High School	G
One or more years of College	H
One or more years of Graduate or Professional School after College	I
Unknown	U

12. Were you raised up to age 5 by anyone other than your natural parents? ..... Yes Y

No N

Go to Item 14, Screen 9

SOCIOECONOMIC STATUS FORM (SESA screen 8 of 9)

13. Now I would like to ask you about the education of the adults who took care of you when you were very young. Think about the two most important adults in your home between the time you were born and age 5. Please look at this card and tell me the letter which best describes their level of education during this time period.

a. First adult's highest level of education ..... ☐

b. Second adult's highest level of education ..... ☐

[If only one adult lived in the home, enter X in 13.b.]

[RESPONSES FOR ITEMS 13. a - b]

Never went to school	A
Grades 1 to 3	B
Grades 4 to 8	C
Grades 9 to 11	D
Grade 12	E
GED	F
One or more years of Vocational or Professional School after High School	G
One or more years of College	H
One or more years of Graduate or Professional School after College ..	I
Unknown	U

SOCIOECONOMIC STATUS FORM (SESA screen 9 of 9)

C. ADMINISTRATIVE INFORMATION

14. Date of data collection: ..... ☐☐/☐☐/☐☐
month day year

15. Method of data collection: ..... Computer C
Paper P

16. Code Number of person completing this form ..... ☐☐☐

(SESA screen 1 of 9)

"Some studies suggest that the experiences we have in early life may be related to the occurrence of illness throughout our lives. The following questions are designed to assess some of your current and early life experiences. We realize that many of these refer to events that happened a long time ago. Please try to remember and answer as best you can. We will start our questions, however, by updating the information you have previously given us on your marital and occupational status."

A. PARTICIPANT

1~ Please tell me which of the following describes your current marital status _ [MSTAT]

[READ ALL CHOICES]

Married	(M)
Widowed	(W)
Divorced	(D)
Separated	(S)
Never Married	(N)

(SESA screen 2 of 9)

2~ Since your last ARIC visit, have you changed your occupation, stopped working, or retired? _ [CHGOCC]

Yes (Y) or No (N)*

3~ I would like you to look at this card while I read it to you. Please tell me the letter which best describes your CURRENT employment status. _ [EMPSTAT]

[HAND RC 1 TO PARTICIPANT AND READ EACH CATEGORY ALOUD.]

Homemaking, not working outside the home	(A)*
Employed at a job for pay, either full or part-time	(B)*
Employed, but temporarily away from my regular work	(C)*
Unemployed, looking for work	(D)*
Unemployed, not looking for work	(E)*
Retired from my usual occupation and not working	(F)
Retired from my usual occupation, but working for pay	(G)

(SESA screen 3 of 9)

4~ Did you retire because of health reasons? _

Yes (Y)* or No (N)*

5~ Please look at the categories on the card and tell me the letter that best describes your current or most recent occupation. If you cannot decide, tell me your occupation and we can decide together. _

[HAND RC 2 TO RESPONDENT AND READ ALOUD (if necessary)]

Homemaker	(A)
Technician, sales or clerical	(B)
Mechanic, repairman, construction worker or craftsman	(C)
Service: hairdresser, domestic, restaurant, security	(D)
Management, professional	(E)
Farming, forestry, fishing	(F)
Driver, machine operator, sanitation, laborer	(G)
Unknown	(H)

(SESA screen 4 of 9)

6~ Please look at this card. Which of these income groups represents your total combined family income for the past 12 months? Include income from all sources such as wages, salaries, social security or retirement benefits, help from relatives, rent from property, and so forth. Please tell me the letter only. _

[HAND RC 3 TO RESPONDENT AND READ ALOUD (if necessary)]

Under $5,000	(A)
$5,000 - $7,999	(B)
$8,000 - $11,999	(C)
$12,000 - $15,999	(D)
$16,000 - $24,999	(E)
$25,000 - $34,999	(F)
$35,000 - $49,999	(G)
$50,000 - $74,999	(H)
$75,000 - $99,999	(I)
$100,000 and over	(J)
Refused	(R)

(SESA screen 5 of 9)

7~ On the average, how many people lived in your house during the last 12 months? __

"Now I would like to ask you some questions about when you were a baby."

8~ Were you a premature baby, that is were you born a month or more early? _
Yes (Y), No (N) or Unknown (U)

How much did you weigh at birth?
[If unknown, enter "== ==" and continue with Item 8c.]

a~ __ pounds b~ __ ounces
[GO TO ITEM 9.]

8.c~ Do you believe your birth weight was low, that is less than 5 1/2 pounds, medium, that is 5 1/2 to 9 pounds, high, that is over 9 pounds? _

[HAND RC 4 TO RESPONDENT AND READ ALOUD (if necessary)]

Low, less than 5 1/2 pounds	(L)
Medium, 5 1/2 to 9 pounds	(M)
High, over 9 pounds	(H)
Unknown	(U)

9~ Were you a twin? _
Yes (Y), No (N) or Unknown (U)

(SESA screen 6 of 9)

10. Now I would like you to think about the kind of jobs you had when you were younger. Please look at the categories on the card and tell me the letter that best describes your type of occupation when you were between 25 and 45 years of age. If you cannot decide or if you had many different kinds of jobs, describe the jobs you had and we can decide together.

a~ Occupation for the longest time period: _
b~ Occupation for the next longest time period: _
[If only one occupation, enter X in 10.b.]
[HAND RC 2 TO RESPONDENT AND READ ALOUD (if necessary]

Homemaker	(A)
Technician, sales or clerical	(B)
Mechanic, repairman, construction worker or craftsman	(C)
Service: hairdresser, domestic, restaurant, security	(D)
Management, professional	(E)
Farming, forestry, fishing	(F)
Driver, machine operator, sanitation, laborer	(G)
Unknown	(H)

(SESA screen 7 of 9)

B. PARENTS

[For Items 11 and 13, HAND RC 5 TO RESPONDENT AND READ ALOUD (if necessary) AFTER READING THE QUESTIONS.]

11. I would like to ask you about your parents' education. Please look at this card and tell me the letter which best describes your natural mother's and your natural father's level of education when you were born.

a~ Natural mother's education _

b~ Natural father's education _

[RESPONSES FOR ITEMS 11. a -b]

Never went to school	(A)
Grades 1 to 3	(B)
Grades 4 to 8	(C)
Grades 9 to 11	(D)
Grade 12	(E)
GED	(F)
One or more years of Vocational or Professional School after H.S.	(G)
One or more years of College	(H)
One or more years of Graduate or Professional School after College	(I)
Unknown	(U)

12~ Were you raised up to age 5 by anyone other than your natural parents? _
Yes (Y) or No (N)*

(SESA screen 8 of 9)

13. Now I would like to ask you about the education of the adults who took care of you when you were very young. Think about the two most important adults in your home between the time you were born and age 5. Please look at this card and tell me the letter which best describes their level of education during this time period.

a~ First adult's highest level of education _

b~ Second adult's highest level of education _
[If only one adult lived in the home, enter X in 13.b.]

[RESPONSES FOR ITEMS 13. a - b]

Never went to school	(A)
Grades 1 to 3	(B)
Grades 4 to 8	(C)
Grades 9 to 11	(D)
Grade 12	(E)
GED	(F)
One or more years of Vocational or Professional School after H.S.	(G)
One or more years of College	(H)
One or more years of Graduate or Professional School after College	(I)
Unknown	(U)

(SESA screen 9 of 9)

C. ADMINISTRATIVE INFORMATION

14~ Date of data collection: _____
mm/dd/yy

15~ Method of data collection: _

Computer (C) or Paper (P) Form

16. Code Number of person completing this form ___

Appendix 2.20c

INSTRUCTIONS FOR THE SOCIOECONOMIC STATUS FORM
SES, VERSION A, 12/01/95
REVISED 02/06/96

I. General Instructions

Because strong associations between morbidity and mortality and an individual's socioeconomic status (SES) have been observed in many epidemiologic studies, ARIC is expanding the data it collects on SES to include different time periods in each participant's life, beginning with infancy. The first portion of the Socioeconomic Status form updates each participant's current marital status, employment/retirement status, occupation if it has changed since Visit 3, and annual household income for the 12 months prior to Visit 4. These questions are repeated from previous interviews. Subsequent sections collect information which may help classify each participant's socioeconomic status at birth and between ages 25 to 45.

Interviewers are certified in general clinic interviewing and familiar with the ARIC data entry system (DES) and the "General Instructions for Completing Paper Forms" (in case the computer is down) prior to administering this form. Items in BRACKETS and/or CAPITAL LETTERS are instructions to the interviewer and are not read to the participant.

COMPLETE THE HEADER (paper form) by applying a long participant ID label and entering the participant's Name. READ THE QUESTIONS CLEARLY USING THE EXACT WORDING ON THE FORM. The introductory and transitional scripts may deviate from the prototypes provided, but must include the same information.

II. Detailed Instructions for Each Item

A. Occupation

This section updates occupational information on participants who have changed their occupation since Visit 3. In addition, annual family income information is collected on everyone.

1. The purpose of this question is to update marital status. Read Item 1 and then all the response categories. Record the appropriate letter. If asked by the participant, the person is instructed to select the term which best describes his/her living situation, regardless of legal status.

[READ ALL CHOICES]

Married.....A
Widowed.....W
Divorced.....D
Separated.....E
Never Married.....F

2. This item identifies the participants who have changed their occupation, stopped working or retired since Visit 3. Go to Item 6 for persons who have not changed their employment status.

3. GIVE RESPONSE CARD No. 1 to the participant, read Item 3 and (if necessary) READ ALL THE RESPONSES. If the participant selects category A (*homemaking, not working outside the home*), go to Item 6. If the respondent is both a homemaker and retired, the items on retirement (response F or G) take precedence. Response B, "employed at a job for pay, either full or part time," includes those who are self-employed and working at home, but not "homemaker" or "mother" (Response A). Skip to Item 5 if response is B-E. Continue with Item 4 if the response is F or G. RETRIEVE THE RESPONSE CARD.

[READ ALL CHOICES (if necessary)]

Homemaking, not working outside the home.....A

Employed at a job for pay, either full or part-time...B
Employed, but temporarily away from my regular work...C
Unemployed, looking for work.....D
Unemployed, not looking for work.....E

Retired from my usual occupation and not working.....F
Retired from my usual occupation but working for pay..G

4. Read Item 4. "Health reasons" refer to the participant's personal health and not the health of someone the participant needs to take care of.

5. GIVE THE RESPONSE CARD No. 2 TO THE PARTICIPANT, read Item 5, and (if necessary) READ ALL RESPONSES. If the respondent holds (held) more than one job, record the occupation for the job for the most hours worked per week. If two jobs were held and he or she works(ed) the same number of hours on each, record the information on the job held for the longest period of time.

Occupational data can be very hard to code. If the participant can not decide which response is appropriate, then probe to obtain the participant's occupation, and help him/her decide what response is appropriate.

[READ ALL CHOICES (if necessary)]

Homemaker.....A
Technician, sales or clerical.....B
Mechanic, repairman, construction worker or craftsman.....C
Service: hairdresser, domestic, restaurant, security.....D
Management, professional.....E
Farming, forestry, fishing.....F
Driver, machine operator, sanitation, laborer.....G
Unknown.....H

6. GIVE THE RESPONSE CARD No. 3 TO THE PARTICIPANT, read Item 6, and (if necessary) READ ALL RESPONSES. This question is asked of all participants and covers the entire family's income, not just what is earned by the individual. Read the question as written and ask the person to look at the income categories on the response card. Hand the response card to the person. Ask the person to select the letter which best represent his or her total family income.

[READ ALL CHOICES (if necessary)]

Under $5,000.....A
$5,000 - $7,999.....B
$8,000 - 11,999.....C
$12,000 - $15,999.....D
$16,000 - $24,999.....E
$25,000 - $34,999.....F
$35,000 - $49,999.....G
$50,000 - $74,999.....H
$75,000 - $99,999.....I
$100,000 and over.....J

7. Read Item 7 to the participant. The purpose of this question is to determine how many people were supported by the annual family income. If the number of persons in the household varied over the last 12 months, assist the respondent in determining the <u>average</u> number of inhabitants.

8. Read the transition statement between Items 7 and 8 and then read Item 8. "Premature" is defined in the question and, if clarification is requested, can be further defined as "less than 36 weeks gestation" or "at least 4 weeks premature".

Continue with parts (a) and (b). For participants who remember their full birth weight, fill in the pounds and ounces and go to Item 9. For those who remember their birth weight in pounds, enter the pounds in part (a) and fill in the ounces, part (b), with "==" , and go to Item 9. If the participant does not know the total or approximate weight,

enter "==" in both the pounds and ounces fields and continue with Item 8.c.

Read Item 8.c and the response categories while handing the participant Response Card No. 4. Ask participants to select the category that best describes their birth weight.

9. Read the question to all participants. Even though the question and response categories refer only to twins, the intent of the question is to identify multiple births. If the respondent replies YES or indicates that he/she is from a multiple birth (triplets, quadruplets, etc.), code the response as YES.

10. The purpose of Item 10 is to describe the type or category of occupation that was held for the longest period of time when the participant was between the ages of 25 and 45 years. Although most participants will have held more than one job between the ages of 25 and 45, many of these jobs will be in the same category. Part (b) is only completed if the participant held jobs in different occupational categories.

GIVE THE RESPONSE CARD No. 2 TO THE PARTICIPANT, read the introduction to Item 10 and Item 10.a. Next (if necessary) READ ALL RESPONSES. These are the same occupation categories that are used in Item 5. Enter the category which best describes the job(s) held between the ages of 25 and 45.

If the participant can not decide which occupational category is most appropriate, ask him/her to identify the job and select the occupation category from the occupation category dictionary.

If the participant indicates that he/she has had more than one job, AND these jobs fall into more than one occupational classification, ask the participant to identify the one held for the longest time and enter this category in 10.a. Code the occupational category of the other type of job in 10.b.

[READ ALL CHOICES (if necessary)]

Homemaker.....A
Technician, sales or clerical.....B
Mechanic, repairman, construction worker or craftsman.....C
Service: hairdresser, domestic, restaurant, or security.....D
Management, professional.....E
Farming, forestry, fishing.....F
Driver, machine operator, sanitation, or laborer.....G
Unknown.....H

B. PARENTS

11. The purpose of Item 11 is to determine the education completed by a participant's natural (biologic) mother (11.a.) and natural father (11.b.) at the time of the participant's birth. HAND RESPONSE CARD No. 4 TO PARTICIPANT, read the introduction to Item 11 and Item 11.a. Next (if necessary) READ ALL RESPONSES. Once the participant has answered Item 11.a, read Item 11.b. and (if necessary) READ ALL RESPONSES.

[READ ALL CHOICES (if necessary)]

Never went to school.....A

Grades 1 to 3.....B
Grades 4 to 8.....C
Grades 9 to 11.....D
Grade 12.....E

GED.....F

One or more years of Vocational or Professional School after High School.....G

One or more years of College.....H

One or more years of Graduate or Professional School after College.....I

Unknown .....U

GED refers to a high school Graduate Equivalency Diploma. It is awarded by the testing organization rather that a high school.

Vocational, trade or technical training is outside the formal high school, college, or graduate school sequence (although it may be obtained at a 2 or 4 year college) and is designed to give the respondent job skills. It does not include courses taken for personal enrichment but does include technical school, trade school or non-degree nursing schools. We are interested in the usual number of years required for a particular technical course even if it took the respondent a shorter or longer time to complete.

12. The purpose of Item 12 is to identify participants who were raised from birth to age 5 by persons other than their natural parents. The response is NO if at least one of the natural parents had primary responsibility for the participant's care for the majority of the time between the participant's birth and age 5. If NO, thank the participant and indicate that there are no

more questions in this portion of the interview. Complete the administrative section according to standard procedures.

If the response is YES, for example, participants who were adopted, or raised by a family member other than their natural parents, enter YES and continue with Item 13.

13. The purpose of Item 13 is to record the education level of the people who raised the participant between birth and age 5 if parenting was not provided by at least one natural parent. Ask the participant to think about the two most important adults in his/her home between birth and age 5. HAND RESPONSE CARD No. 4 TO PARTICIPANT, read Item 13. Record the highest level of education attained by the first surrogate parent in Item 13.a. If the participant was raised by a second surrogate parent, enter his/her level of education in Item 13.6. If the participant was raised by only one surrogate parent during this time period, enter an "X" in Item 13.b.

C. Administrative Information

14. Enter the date on which the participant was seen in the clinic. Code in numbers using leading zeroes where necessary to fill all boxes. For example, May 3, 1993, would be entered as:

0	5	/	0	3	/	9	3
month			day			year	

15. Record "C" if the form was completed on the computerized data entry system, or "P" if the paper form was used. If the form was completed partially on paper and partially on the computer, code as "Paper Form."

16. The person at the clinic who has completed this form must enter his/her code number in the boxes provided.

ARIC
Atherosclerosis Risk in Communities

Appendix 2.21a

TIA/STROKE FORM

O.M.B. 0925-0281
exp. 09/30/95

ID NUMBER: | | | | | | | | CONTACT YEAR: | 1 | 0 | FORM CODE: | T | I | A | VERSION: E 12/01/95

LAST NAME: | | | | | | | | | | | | | INITIALS: | | |

Public reporting burden for this collection of information is estimated to average 7-10 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: **PHS Reports Clearance Officer, Rm. 737-F, Humphrey Building, 200 Independence Ave., SW, Washington, D.C. 20201, ATTN: PRA (0925-0281).** Do not return the completed form to this address.

INSTRUCTIONS: This form is completed during the interview portion of the participant's visit. ID Number, Contact Year, and Name must be entered above. Whenever numerical responses are required, enter the number so that the last digit appears in the rightmost box. Enter leading zeroes where necessary to fill all boxes. If a number is entered incorrectly on the paper form, mark through the incorrect entry with an "X". Code the correct entry clearly above the incorrect entry. For "multiple choice" and "yes/no" type questions, circle the letter corresponding to the most appropriate response. If a letter is circled incorrectly, mark through it with an "X" and circle the correct response.

TIA STROKE FORM (TIAE screen 1 of 14)

A. MEDICAL HISTORY

1. Since the last ARIC visit, have you been told by a physician that you had a stroke, slight stroke, transient ischemic attack or TIA?

Yes Y

Go to Item 3. — No N

2. During this time, when did the (first) stroke or TIA occur?

a. | | month, b. | | year

B. SUDDEN LOSS OR CHANGE OF SPEECH

3. Since the last ARIC visit, have you had any sudden loss or changes in speech? ..... Yes Y

No N

Go to Item 10, Screen 6 — Don't know D

TIA/STROKE FORM (TIAE screen 2 of 14)

4. During this time, how many episodes of loss or changes in speech have you had?

1	A
2	B
3	C
4	D
5	E
6-20	F
More than 20, or frequent, intermittent events, too numerous to count	G

5. During this same time period, when did the earliest occur?

Within the last 6 months	A
Greater than 6 months, but less than 1 year ago	B
Greater than 1 year, but less than 2 years ago	C
Greater than 2 years, but less than 3 years ago	D
3 or more years ago	E

TIA/STROKE FORM (TIAE screen 3 of 14)

6. How long did it (the longest episode) last?

Less than 30 seconds	A
At least 30 seconds, but less than 1 minute	B
At least 1 minute, but less than 3 minutes	C
At least 3 minutes, but less than 1 hour	D
At least 1 hour, but less than 6 hours	E
At least 6 hours, but less than 12 hours	F
At least 12 hours, but less than 24 hours	G
At least 24 hours	H

7. Did the (worst) episode come on suddenly?

Yes	Y
No	N

a. How long did it take for the symptoms to get as bad as they were going to get?

0-2 seconds (instantly)	A
At least 3 seconds, but less than 1 minute	B
At least 1 minute, but less than 1 hour	C
At least 1 hour, but less than 2 hours	D
At least 2 hours, but less than 24 hours	E
At least 24 hours	F

TIA/STROKE FORM (TIAE screen 4 of 14)

8. Do any of the following describe your change in speech?

{READ ALL CHOICES}

	Yes	No	Don't Know
a. Slurred speech like you were drunk.	Y	N	D
b. Could talk but the wrong words came out.	Y	N	D
c. Knew what you wanted to say, but the words would not come out.	Y	N	D

9. While you were having your (worst) episode of change in speech, did any of the following occur?

{INCLUDE ALL THAT APPLY}

a. Numbness or tingling ..... Yes Y

No N

Go to Item 9.c, Screen 5

b. Did you have difficulty on:

{READ ALL CHOICES}

The right side only R

The left side only L

Both sides B

TIA/STROKE FORM (TIAE screen 5 of 14)

9.c. Paralysis or weakness ..... Yes Y

No N

Go to Item 9.e.

d. Did you have difficulty on:

{READ ALL CHOICES}

The right side only R

The left side only L

Both sides B

e. Lightheadedness or dizzy spells ..... Yes Y

No N

9.f. Blackouts or fainting ..... Yes Y

No N

g. Seizures or convulsions ..... Yes Y

No N

h. Headache ..... Yes Y

No N

TIA/STROKE FORM (TIAE screen 6 of 14)

9.i. Visual Disturbances ..... Yes Y

No N

Go to Item 10.

j. Did you have:

{READ ALL CHOICES UNTIL A POSITIVE RESPONSE IS GIVEN}

Double vision	A
Vision loss in right eye only	B
Vision loss in left eye only	C
Total loss of vision in both eyes	D
Trouble in both eyes seeing to the right	E
Trouble in both eyes seeing to the left	F
Other	G

If "Other," specify:

_____

C. SUDDEN LOSS OF VISION

10. Since the last ARIC visit, have you had any sudden loss of vision, complete or partial? ..... Yes Y

No N

Don't Know D

Go to Item 17, Screen 10

TIA/STROKE FORM (TIAE screen 7 of 14)

11. During this time, how many episodes of loss of vision have you had?

1	A
2	B
3	C
4	D
5	E
6-20	F
More than 20, or frequent, intermittent events, too numerous to count	G

12. During this same time period, when did the earliest occur?

Within the last 6 months	A
Greater than 6 months, but less than 1 year ago	B
Greater than 1 year, but less than 2 years ago	C
Greater than 2 years, but less than 3 years ago	D
3 or more years ago	E

TIA/STROKE FORM (TIAE screen 8 of 14)

13. How long did it (the longest episode) last?

Less than 30 seconds	A
At least 30 seconds, but less than 1 minute	B
At least 1 minute, but less than 3 minutes	C
At least 3 minutes, but less than 1 hour	D
At least 1 hour, but less than 6 hours	E
At least 6 hours, but less than 12 hours	F
At least 12 hours, but less than 24 hours	G
At least 24 hours	H

14. Did the (worst) episode come on suddenly? ..... Yes Y

No N

a. How long did it take for the symptoms to get as bad as they were going to get?

0-2 seconds (instantly)	A
At least 3 seconds, but less than 1 minute	B
At least 1 minute, but less than 1 hour	C
At least 1 hour, but less than 2 hours	D
At least 2 hours, but less than 24 hours	E
At least 24 hours	F

TIA/STROKE FORM (TIAE screen 9 of 14)

15. During the (worst) episode, which of the following parts of your vision were affected?

{READ ALL CHOICES}

Only the right eye	R
Only the left eye	L
Both eyes	B

Go to Item 16.

a. Did you have:

{READ ALL CHOICES UNTIL A POSITIVE RESPONSE IS GIVEN}

Total loss of vision	B
Trouble seeing to the right	R
Trouble seeing to the left	L
Other vision difficulties	O

16. While you were having your (worst episode of) loss of vision, did any of the following occur?

{INCLUDE ALL THAT APPLY}

a. Speech disturbance ..... Yes Y

No N

b. Numbness or tingling ..... Yes Y

No N

Go to Item 16.d, Screen 10

c. Did you have difficulty on:

{READ ALL CHOICES}

The right side only	R
The left side only	L
Both sides	B

TIA/STROKE FORM (TIAE screen 10 of 14)

16.d. Paralysis or weakness ..... Yes Y

Go to Item 16.f — No N

e. Did you have difficulty on:

(READ ALL CHOICES)

The right side only R

The left side only L

Both sides B

f. Lightheadedness or dizzy spells ..... Yes Y

No N

g. Blackouts or fainting ..... Yes Y

No N

16.h. Seizures or convulsions ..... Yes Y

No N

i. Headache ..... Yes Y

No N

D. DOUBLE VISION

17. Since the last ARIC visit, have you had a sudden spell of double vision? ..... Yes Y

Go to Item 22j., Screen 14. — No N

Don't Know D

a. If you closed one eye, did the double vision go away? ..... Yes Y

Go to Item 22j., Screen 14. — No N

Don't Know D

TIA/STROKE FORM (TIAE screen 11 of 14)

18. During this time, how many episodes of double vision have you had?

1 ..... A

2 ..... B

3 C

4 ..... D

5 ..... E

6-20 ..... F

More than 20, or frequent, intermittent events, too numerous to count ..... G

19. During the same time period, when did the earliest occur?

Within the last 6 months A

Greater than 6 months, but less than 1 year ago B

Greater than 1 year, but less than 2 years ago C

Greater than 2 years, but less than 3 years ago D

3 or more years ago E

TIA/STROKE FORM (TIAE screen 12 of 14)

20. How long did it (the longest episode) last?

Less than 30 seconds	A
At least 30 seconds, but but less than 1 minute	B
At least 1 minute, but less than 3 minutes	C
At least 3 minutes, but less than 1 hour	D
At least 1 hour, but less than 6 hours	E
At least 6 hours, but less than 12 hours	F
At least 12 hours, but less than 24 hours	G
At least 24 hours	H

21. Did the (worst) episode come on suddenly? ..... Yes Y

No N

a. How long did it take for the symptoms to get as bad as they were going to get?

0-2 seconds (instantly)	A
At least 3 seconds, but less than 1 minute	B
At least 1 minute, but less than 1 hour	C
At least 1 hour, but less than 2 hours	D
At least 2 hours, but less than 24 hours	E
At least 24 hours	F

TIA/STROKE FORM (TIAE screen 13 of 14)

22. While you were having your (worst episode of) double vision, did any of the following occur?

{INCLUDE ALL THAT APPLY}

a. Speech disturbances ..... Yes Y

No N

22.b. Numbness or tingling ..... Yes Y

No N

Go to Item 22.d, Screen 14

22.c. Did you have difficulty on:

{READ ALL CHOICES}

The right side only	R
The left side only	L
Both sides	B

TIA/STROKE FORM (TIAE screen 14 of 14)

22.d. Paralysis or weakness ..... Yes Y

No N

Go to Item 22.f

e. Did you have difficulty on:

{READ ALL CHOICES} The right side only R

The left side only L

Both sides B

f. Lightheadedness or dizzy spells ..... Yes Y

No N

g. Blackouts or fainting ..... Yes Y

No N

22.h. Seizures or convulsions ..... Yes Y

No N

i. Headache ..... Yes Y

No N

E. ADMINISTRATIVE INFORMATION

j. Date of data collection: | | | / | | | / | | |

Month Day Year

k. Method of data collection ..... Computer C

Paper form P

l. Code number of person completing this form: ..... | | | .

TIA/STROKE FORM (TIBE screen 1 of 16)

F. SUDDEN NUMBNESS OR TINGLING

23. Since the last ARIC visit, have you had any sudden numbness, tingling, or loss of feeling on one side of your body? ..... Yes Y

No N

Don't Know D

Go to Item 32, Screen 6.

24. Did the feeling of numbness or tingling occur only when you kept your arms or legs in a certain position?

Yes Y

No N

Don't Know D

Go to Item 32, Screen 6.

25. During this time, how many episodes of numbness, tingling, or loss of sensation have you had?

1 ..... A

2 ..... B

3 C

4 ..... D

5 ..... E

6-20 ..... F

More than 20, or frequent, intermittent events, too numerous to count ..... G

TIA/STROKE FORM (TIBE screen 2 of 16)

26. During this same time period, when did the earliest occur?

Within the last 6 months A

Greater than 6 months, but less than 1 year ago B

Greater than 1 year, but less than 2 years ago C

Greater than 2 years, but less than 3 years ago D

3 or more years ago E

27. How long did it (the longest episode) last?

Less than 30 seconds A

At least 30 seconds, but less than 1 minute B

At least 1 minute, but less than 3 minutes C

At least 3 minutes, but less than 1 hour D

At least 1 hour, but less than 6 hours E

At least 6 hours, but less than 12 hours F

At least 12 hours, but less than 24 hours G

At least 24 hours H

TIA/STROKE FORM (TIBE screen 3 of 16)

28. Did the (worst) episode come on suddenly? ..... Yes Y

No N

a. How long did it take for the symptoms to get as bad as they were going to get?

0-2 seconds (instantly) A

At least 3 seconds, but less than 1 minute B

At least 1 minute, but less than 1 hour C

At least 1 hour, but less than 2 hours D

At least 2 hours, but less than 24 hours E

At least 24 hours F

29. During the (worst) episode, which part or parts of your body were affected?

{READ ALL CHOICES}

	Yes	No	Don't Know
a. Left arm or hand	Y	N	D
b. Left leg or foot	Y	N	D
c. Left side of face	Y	N	D
d. Right arm or hand	Y	N	D
e. Right foot or leg	Y	N	D
f. Right side of face	Y	N	D
g. Other	Y	N	D

TIA/STROKE FORM (TIBE screen 4 of 16)

30. During this episode, did the abnormal sensation start in one part of your body and spread to another, or did it stay in the same place?

In one part and spread to another ..... S

Stayed in one part ..... O

Don't Know ..... D

31. While you were having your (worst) episode of numbness, tingling or loss of sensation, did any of the following occur?

{INCLUDE ALL THAT APPLY}

a. Speech disturbance ..... Yes Y

No N

TIA/STROKE FORM (TIBE screen 5 of 16)

31.b. Paralysis or weakness ..... Yes Y

No N

Go to Item 31.d.

c. Did you have difficulty on:

{READ ALL CHOICES}

The right side only R

The left side only L

Both sides B

d. Lightheadedness or dizzy spells ..... Yes Y

No N

e. Blackouts or fainting ..... Yes Y

No N

31.f. Seizures or convulsions ..... Yes Y

No N

g. Headache ..... Yes Y

No N

h. Pain in the numb or tingling arm, leg or face ..... Yes Y

No N

TIA/STROKE FORM (TIBE screen 6 of 16)

31.i. Visual Disturbances ..... Yes Y

No N

Go to Item 32.

j. Did you have:

{READ ALL CHOICES UNTIL A POSITIVE RESPONSE IS GIVEN}

Double vision A

Vision loss in right eye only B

Vision loss in left eye only C

Total loss of vision in both eyes D

Trouble in both eyes seeing to the right E

Trouble in both eyes seeing to the left F

Other G

If "Other," specify:

_____

G. SUDDEN PARALYSIS OR WEAKNESS

32. Since the last ARIC visit, have you had any sudden episodes of paralysis or weakness on one side of your body? ..... Yes Y

No N

Don't Know D

Go to Item 40, Screen 11.

TIA/STROKE FORM (TIBE screen 7 of 16)

33. During this time, how many episodes of paralysis or weakness have you had?

1	A
2	B
3	C
4	D
5	E
6-20	F
More than 20, or frequent, intermittent events, too numerous to count	G

34. During this same time period, when did the earliest occur?

Within the last 6 months	A
Greater than 6 months, but less than 1 year ago	B
Greater than 1 year, but less than 2 years ago	C
Greater than 2 years, but less than 3 years ago	D
3 or more years ago	E

TIA/STROKE FORM (TIBE screen 8 of 16)

35. How long did it (the longest episode) last?

Less than 30 seconds	A
At least 30 seconds, but less than 1 minute	B
At least 1 minute, but less than 3 minutes	C
At least 3 minutes, but less than 1 hour	D
At least 1 hour, but less than 6 hours	E
At least 6 hours, but less than 12 hours	F
At least 12 hours, but less than 24 hours	G
At least 24 hours	H

36. Did the (worst) episode come on suddenly?

Yes	Y
No	N

a. How long did it take for the symptoms to get as bad as they were going to get?

0-2 seconds (instantly)	A
At least 3 seconds, but less than 1 minute	B
At least 1 minute, but less than 1 hour	C
At least 1 hour, but less than 2 hours	D
At least 2 hours, but less than 24 hours	E
At least 24 hours	F

TIA/STROKE FORM (TIBE screen 9 of 16)

37. During this episode, which part or parts of your body were affected?

{READ ALL CHOICES}

	Yes	No	Don't Know
a. Left arm or hand	Y	N	D
b. Left leg or foot	Y	N	D
c. Left side of face	Y	N	D
d. Right arm or hand	Y	N	D
e. Right foot or leg	Y	N	D
f. Right side of face	Y	N	D
g. Other	Y	N	D

38. During this episode, did the paralysis or weakness start in one part of your body and spread to another, or did it stay in the same place?

Started in one part and spread to another	S
Stayed in one part	O
Don't Know	D

39. While you were having your worst episode of paralysis or weakness, did any of the following occur?
{INCLUDE ALL THAT APPLY}

a. Speech disturbances ..... Yes Y
No N

TIA/STROKE FORM (TIBE screen 10 of 16)

39.b. Numbness or tingling ..... Yes Y
No N

Go to Item 39.d.

c. Did you have difficulty on:

{READ ALL CHOICES}

The right side only	R
The left side only	L
Both sides	B

d. Lightheadedness or dizzy spells ..... Yes Y
No N

39.e. Blackouts or fainting ..... Yes Y
No N

f. Seizures or convulsions ..... Yes Y
No N

g. Headache ..... Yes Y
No N

h. Pain in the weak arm, leg or face ..... Yes Y
No N

TIA/STROKE FORM (TIBE screen 11 of 16)

39.i. Visual Disturbances ..... Yes Y

No N

Go to Item 40.

j. Did you have:

{READ ALL CHOICES UNTIL A POSITIVE RESPONSE IS GIVEN}

Double vision	A
Vision loss in right eye only	B
Vision loss in left eye only	C
Total loss of vision in both eyes	D
Trouble in both eyes seeing to the right	E
Trouble in both eyes seeing to the left	F
Other	G

If "Other," specify:

_____

H. SUDDEN SPELLS OF DIZZINESS OR LOSS OF BALANCE

40. Since the last ARIC visit, have you had any sudden spells of dizziness, loss of balance, or sensation of spinning? ..... Yes Y

No N

Don't Know D

Go to Item 47, Screen 16

41. Did the dizziness, loss of balance or spinning sensation occur only when changing the position of your head or body?

Yes Y

No N

Don't Know D

Go to Item 47, Screen 16

TIA/STROKE FORM (TIBE screen 12 of 16)

42. While you were having your (worst) episode of dizziness, loss of balance or spinning sensation, did any of the following occur? {INCLUDE ALL THAT APPLY}

a. Speech disturbances ..... Yes Y

No N

42.b. Paralysis or weakness ..... Yes Y

No N

Go to Item 42.d, Screen 13

c. Did you have difficulty on:

{READ ALL CHOICES}

The right side only	R
The left side only	L
Both sides	B

TIA/STROKE FORM (TIBE screen 13 of 16)

42.d. Numbness or tingling ..... Yes Y

No N

Go to Item 42.f.

e. Did you have difficulty on:

{READ ALL CHOICES}

The right side only R

The left side only L

Both sides B

f. Blackouts or fainting ..... Yes Y

No N

42.g. Seizures or convulsions ..... Yes Y

No N

h. Headache ..... Yes Y

No N

TIA/STROKE FORM (TIBE screen 14 of 16)

42.i. Visual Disturbances ..... Yes Y

No N

Go to Item 43.

j. Did you have:

{READ ALL CHOICES UNTIL A POSITIVE RESPONSE IS GIVEN}

Double vision A

Vision loss in right eye only B

Vision loss in left eye only C

Total loss of vision in both eyes D

Trouble in both eyes seeing to the right E

Trouble in both eyes seeing to the left F

Other G

If "Other," specify:

_____

43. During this time, how many episodes of dizziness, loss of balance or spinning sensation have you had?

1 ..... A

2 ..... B

3 C

4 ..... D

5 ..... E

6-20 ..... F

More than 20, or frequent, intermittent events, too numerous to count ..... G

TIA/STROKE FORM (TIBE screen 15 of 16)

44. During this time period, when did the earliest occur?

Within 6 months	A
Greater than 6 months, but less than 1 year ago	B
Greater than 1 year, but less than 2 years ago	C
Greater than 2 years, but less than 3 years ago	D
3 or more years ago	E

45. How long did it (the longest episode) last?

Less than 30 seconds	A
At least 30 seconds, but but less than 1 minute	B
At least 1 minute, but less than 3 minutes	C
At least 3 minutes, but less than 1 hour	D
At least 1 hour, but less than 6 hours	E
At least 6 hours, but less than 12 hours	F
At least 12 hours, but less than 24 hours	G
At least 24 hours	H

TIA/STROKE FORM (TIBE screen 16 of 16)

46. Did the (worst) episode come on suddenly? ..... Yes Y

No N

a. How long did it take for the symptoms to get as bad as they were going to get?

0-2 seconds (instantly)	A
At least 3 seconds, but less than 1 minute	B
At least 1 minute, but less than 1 hour	C
At least 1 hour, but less than 2 hours	D
At least 2 hours, but less than 24 hours	E
At least 24 hours	F

I. ADMINSITRATIVE INFORMATION

47. Date of data collection: [ ][ ]/[ ][ ]/[ ][ ]

Month Day Year

48. Method of data collection ..... Computer C

Paper form P

49. Code number of person completing this form: ..... [ ][ ][ ]

Appendix 2.21b

(TIAE screen 1 of 14)

A. MEDICAL HISTORY

1~ Since the last ARIC visit, have you been told by a physician that you had a stroke, slight stroke, transient ischemic attack or TIA? _

Yes (Y) or No (N)*

2. During this time, when did the (first) stroke or TIA occur?

a~ __ month, b~ __ year

B. SUDDEN LOSS OR CHANGE OF SPEECH

3~ Since the last ARIC visit, have you had any sudden loss or changes in speech? _

Yes (Y), No (N)* or Don't Know (D)*

(TIAE screen 2 of 14)

4~ During this time, how many episodes of loss or changes in speech have you had? _

1	(A)
2	(B)
3	(C)
4	(D)
5	(E)
6-20	(F)
More than 20, or frequent, intermittent events, too numerous to count.	(G)

5~ During this same time period, when did the earliest occur? _

Within the last 6 months	(A)
Greater than 6 months, but less than 1 year ago	(B)
Greater than 1 year, but less than 2 years ago	(C)
Greater than 2 years, but less than 3 years ago	(D)
3 or more years ago	(E)

(TIAE screen 3 of 14)

6~ How long did it (the longest episode) last? _

Less than 30 seconds (A)
At least 30 seconds, but less than 1 minute (B)
At least 1 minute, but less than 3 minutes (C)
At least 3 minutes, but less than 1 hour (D)
At least 1 hour, but less than 6 hours (E)
At least 6 hours, but less than 12 hours (F)
At least 12 hours, but less than 24 hours (G)
At least 24 hours (H)

7~ Did the (worst) episode come on suddenly? _
Yes (Y) or No (N)

a~ How long did it take for the symptoms to get as bad as they were going to get? _

0-2 seconds (instantly) (A)
At least 3 seconds, but less than 1 minute (B)
At least 1 minute, but less than 1 hour (C)
At least 1 hour, but less than 2 hours (D)
At least 2 hours, but less than 24 hours (E)
At least 24 hours (F)

(TIAE screen 4 of 14)

8. Do any of the following describe your change in speech?

Yes (Y), No (N) or Don't Know (D)

{READ ALL CHOICES}

a~ Slurred speech like you were drunk. _

b~ Could talk but the wrong words came out. _

c~ Knew what you wanted to say, but the words would not come out. _

9. While you were having your (worst) episode of change in speech, did any of the following occur?

{INCLUDE ALL THAT APPLY}

a~ Numbness or tingling: _
Yes (Y) or No (N)*

b~ Did you have difficulty on: _

{READ ALL CHOICES}

The right side only (R)
The left side only (L)
Both sides (B)

(TIAE screen 5 of 14)

9.c~ Paralysis or weakness? _
Yes (Y) or No (N)*

d~ Did you have difficulty on: _

{READ ALL CHOICES}

The right side only (R)
The left side only (L)
Both sides (B)

e~ Lightheadedness, or dizzy spells? _
Yes (Y) or No (N)

9.f~ Blackouts or fainting? _
Yes (Y) or No (N)

g~ Seizures or convulsions? _
Yes (Y) or No (N)

h~ Headache? _
Yes (Y) or No (N)

(TIAE screen 6 of 14)

9.i~ Visual disturbances? _
Yes (Y) or No (N)*

j~ Did you have? _

{READ UNTIL POSITIVE RESPONSE GIVEN}

Double vision (A)
Vision loss in right eye only (B)
Vision loss in left eye only (C)
Total loss of vision in both eyes (D)
Trouble in both eyes seeing to the right (E)
Trouble in both eyes seeing to the left (F)
Other (Specify) (G)*

C. SUDDEN LOSS OF VISION

10~ Since the last ARIC visit, have you had any sudden loss of vision, complete or partial? _

Yes (Y), No (N)* or Don't Know (D)*

(TIAE screen 7 of 14)

11~ During this time, how many episodes of loss of vision have you had? _ [ ]

1	(A)
2	(B)
3	(C)
4	(D)
5	(E)
6-20	(F)
More than 20, or frequent, intermittent events, too numerous to count	(G)

12~ During this same time period, when did the earliest occur? _ [ ]

Within the last 6 months	(A)
Greater than 6 months, but less than 1 year ago	(B)
Greater than 1 year, but less than 2 years ago	(C)
Greater than 2 years, but less than 3 years ago	(D)
3 or more years ago	(E)

(TIAE screen 8 of 14)

13~ How long did it (the longest episode) last? _ [ ]

Less than 30 seconds	(A)
At least 30 seconds, but less than 1 minute	(B)
At least 1 minute, but less than 3 minutes	(C)
At least 3 minutes, but less than 1 hour	(D)
At least 1 hour, but less than 6 hours	(E)
At least 6 hours, but less than 12 hours	(F)
At least 12 hours, but less than 24 hours	(G)
At least 24 hours	(H)

14~ Did the (worst) episode come on suddenly? _ [ ]
Yes (Y) or No (N)

a~ How long did it take for the symptoms to get as bad as they were going to get? _ [ ]

0-2 seconds (instantly)	(A)
At least 3 seconds, but less than 1 minute	(B)
At least 1 minute, but less than 1 hour	(C)
At least 1 hour, but less than 2 hours	(D)
At least 2 hours, but less than 24 hours	(E)
At least 24 hours	(F)

(TIAE screen 9 of 14)

15~ During the (worst) episode, which of the following parts of your vision were affected? _

{READ ALL CHOICES}

Only the right eye (R)*
Only the left eye (L)*
Both eyes (B)

a~ Did you have: _

{READ UNTIL POSITIVE RESPONSE GIVEN}

Total loss of vision (B)
Trouble seeing to the right (R)
Trouble seeing to the left (L)
Other vision difficulties (O)

16. While you were having your (worst episode of) loss of vision, did any of the following occur?

{INCLUDE ALL THAT APPLY}

a~ Speech disturbance? _
Yes (Y) or No (N)

b~ Numbness or tingling? _
Yes (Y) or No (N)*

c~ Did you have difficulty on: _

{READ ALL CHOICES}

The right side only (R)
The left side only (L)
Both sides (B)

(TIAE screen 10 of 14)

16.d~ Paralysis or weakness? _
Yes (Y) or No (N)*

e~ Did you have difficulty on: _
{READ ALL CHOICES}

The right side only (R)
The left side only (L)
Both sides (B)

f~ Lightheadedness or dizzy spells? _
Yes (Y) or No (N)

g~ Blackouts or fainting? _
Yes (Y) or No (N)

16.h~ Seizures or convulsions? _
Yes (Y) or No (N)

i~ Headache? _
Yes (Y) or No (N)

D. DOUBLE VISION

17~ Since the last ARIC visit, have you had a sudden spell of double vision? _

Yes (Y), No (N)* or Don't Know (D)*

a~ If you closed one eye, did the double vision go away? _

Yes (Y), No (N)* or Don't Know (D)

(TIAE screen 11 of 14)

18~ During this time, how many episodes of double vision have you had? _ [2]

1	(A)
2	(B)
3	(C)
4	(D)
5	(E)
6-20	(F)
More than 20, or frequent, intermittent events, too numerous to count.	(G)

19~ During this same time period, when did the earliest occur? _ [2]

Within the last 6 months	(A)
Greater than 6 months, but less than 1 year ago	(B)
Greater than 1 year, but less than 2 years ago	(C)
Greater than 2 years, but less than 3 years ago	(D)
3 or more years ago	(E)

(TIAE screen 12 of 14)

20~ How long did it (the longest episode) last? _ [2]

Less than 30 seconds	(A)
At least 30 seconds, but less than 1 minute	(B)
At least 1 minute, but less than 3 minutes	(C)
At least 3 minutes, but less than 1 hour	(D)
At least 1 hour, but less than 6 hours	(E)
At least 6 hours, but less than 12 hours	(F)
At least 12 hours, but less than 24 hours	(G)
At least 24 hours	(H)

21~ Did the (worst) episode come on suddenly? _ [1]
Yes (Y) or No (N)

a~ How long did it take for the symptoms to get as bad as they were going to get? _ [2]

0-2 seconds (instantly)	(A)
At least 3 seconds, but less than 1 minute	(B)
At least 1 minute, but less than 1 hour	(C)
At least 1 hour, but less than 2 hours	(D)
At least 2 hours, but less than 24 hours	(E)
At least 24 hours	(F)

(TIAE screen 13 of 14)

22. While you were having your (worst episode of) double vision, did any of the following occur?

{INCLUDE ALL THAT APPLY}

a~ Speech disturbances? _
Yes (Y) or No (N)

22.b~ Numbness or tingling? _
Yes (Y) or No (N)*

c~ Did you have difficulty on: _

{READ ALL CHOICES}

The right side only (R)
The left side only (L)
Both sides (B)

(TIAE screen 14 of 14)

22.d~ Paralysis or weakness? _
Yes (Y) or No (N)*

e~ Did you have difficulty on: _

{READ ALL CHOICES}

The right side only (R)
The left side only (L)
Both sides (B)

f~ Lightheadedness or dizzy spells? _
Yes (Y) or No (N)

g~ Blackouts or fainting? _
Yes (Y) or No (N)

22.h~ Seizures or convulsions? _
Yes (Y) or No (N)

i~ Headache? _
Yes (Y) or No (N)

E. ADMINISTRATIVE INFORMATION

j~ Date of data collection: _____
mm/dd/yy

k~ Method of data collection: _

Computer (C) or Paper (P) Form

l~ Code number of person completing this form: ___

(TIBE screen 1 of 16)

F. SUDDEN NUMBNESS OR TINGLING

23~ Since the last ARIC visit, have you had any sudden numbness, tingling, or loss of feeling on one side of your body? _ [1]

Yes (Y), No (N)* or Don't know (D)*

24~ Did the feeling of numbness or tingling occur only when you kept your arms or legs in a certain position? _ [1]

Yes (Y)*, No (N) or Don't know (D)

25~ During this time, how many episodes of numbness, tingling or loss of sensation have you had? _ [2]

1	(A)
2	(B)
3	(C)
4	(D)
5	(E)
6-20	(F)
More than 20, or frequent, intermittent events, too numerous to count.	(G)

(TIBE screen 2 of 16)

26~ During this same time period, when did the earliest occur? _ [2]

Within the last 6 months	(A)
Greater than 6 months, but less than 1 year ago	(B)
Greater than 1 year, but less than 2 years ago	(C)
Greater than 2 years, but less than 3 years ago	(D)
3 or more years ago	(E)

27~ How long did it (the longest episode) last? _ [2]

Less than 30 seconds	(A)
At least 30 seconds, but less than 1 minute	(B)
At least 1 minute but less than 3 minutes	(C)
At least 3 minutes, but less than 1 hour	(D)
At least 1 hour but less than 6 hours	(E)
At least 6 hours but less than 12 hours	(F)
At least 12 hours but less than 24 hours	(G)
At least 24 hours	(H)

(TIBE screen 3 of 16)

28~ Did the (worst) episode come on suddenly? _
Yes (Y) or No (N)

a~ How long did it take for the symptoms to get as bad as they were going to get? _

0-2 seconds (instantly)	(A)
At least 3 seconds, but less than 1 minute	(B)
At least 1 minute, but less than 1 hour	(C)
At least 1 hour, but less than 2 hours	(D)
At least 2 hours, but less than 24 hours	(E)
At least 24 hours	(F)

29. During the (worst) episode, which part or parts of your body were affected?

{READ ALL CHOICES}

Yes (Y), No (N) or Don't know (D)

a~ Left arm or hand _
b~ Left leg or foot _
c~ Left side of face _
d~ Right arm or hand _
e~ Right foot or leg _
f~ Right side of face _
g~ Other _

(TIBE screen 4 of 16)

30~ During this episode, did the abnormal sensation start in one part of your body and spread to another, or did it stay in the same place? _

In one part and spread to another	(S)
Stayed in one part	(O)
Don't Know	(D)

31. While you were having your (worst) episode of numbness, tingling or loss of sensation, did any of the following occur?

{INCLUDE ALL THAT APPLY}

a~ Speech disturbance? _
Yes (Y) or No (N)

(TIBE screen 5 of 16)

31.b~ Paralysis or weakness? _
Yes (Y) or No (N)*

c~ Did you have difficulty on: _

{READ ALL CHOICES}

The right side only (R)
The left side only (L)
Both sides (B)

d~ Lightheadedness or dizzy spells? _
Yes (Y) or No (N)

e~ Blackouts or fainting? _
Yes (Y) or No (N)

31.f~ Seizures or convulsions? _
Yes (Y) or No (N)

g~ Headache? _
Yes (Y) or No (N)

h~ Pain in the numb or tingling arm, leg or face? _
Yes (Y) or No (N)

(TIBE screen 6 of 16)

31.i~ Visual disturbances? _
Yes (Y) or No (N)*

j~ Did you have: _

{READ UNTIL POSITIVE RESPONSE GIVEN}

Double vision (A)
Vision loss in right eye only (B)
Vision loss in left eye only (C)
Total loss of vision in both eyes (D)
Trouble in both eyes seeing to the right (E)
Trouble in both eyes seeing to the left (F)
Other (Specify) (G)*

G. SUDDEN PARALYSIS OR WEAKNESS

32~ Since the last ARIC visit, have you had any sudden episodes of paralysis or weakness on one side of your body? _

Yes (Y), No (N)* or Don't know (D)*

(TIBE screen 7 of 16)

33~ During this time, how many episodes of paralysis or weakness have you had? _

1	(A)
2	(B)
3	(C)
4	(D)
5	(E)
6-20	(F)
More than 20, or frequent, intermittent events, too numerous to count.	(G)

34~ During this same time period, when did the earliest occur? _

Within the last 6 months	(A)
Greater than 6 months, but less than 1 year ago	(B)
Greater than 1 year, but less than 2 years ago	(C)
Greater than 2 years, but less than 3 years ago	(D)
3 or more years ago	(E)

(TIBE screen 8 of 16)

35~ How long did it (the longest episode) last? _

Less than 30 seconds	(A)
At least 30 seconds, but less than 1 minute	(B)
At least 1 minute, but less than 3 minutes	(C)
At least 3 minutes, but less than 1 hour	(D)
At least 1 hour, but less than 6 hours	(E)
At least 6 hours, but less than 12 hours	(F)
At least 12 hours, but less than 24 hours	(G)
At least 24 hours	(H)

36~ Did the (worst) episode come on suddenly? _
Yes (Y) or No (N)

a~ How long did it take for the symptoms to get as bad as they were going to get? _

0-2 seconds (instantly)	(A)
At least 3 seconds, but less than 1 minute	(B)
At least 1 minute, but less than 1 hour	(C)
At least 1 hour, but less than 2 hours	(D)
At least 2 hours, but less than 24 hours	(E)
At least 24 hours	(F)

(TIBE screen 9 of 16)

37. During this episode, what part or parts of your body were affected?

{READ ALL CHOICES}

Yes (Y), No (N) or Don't know (D)

a~ Left arm or hand _
b~ Left leg or foot _
c~ Left side of face _
d~ Right arm or hand _
e~ Right foot or leg _
f~ Right side of face _
g~ Other _

38~ During this episode, did the paralysis or weakness start in one part of your body and spread to another, or did it stay in the same place? _

Started in one part and spread to another (S)
Stayed in one part (O)
Don't Know (D)

39. While you were having your (worst) episode of paralysis or weakness, did any of the following occur? {INCLUDE ALL THAT APPLY}

a~ Speech disturbances? _
Yes (Y) or No (N)

(TIBE screen 10 of 16)

39.b~ Numbness or tingling? _
Yes (Y) or No (N)*

c~ Did you have difficulty on: _

{READ ALL CHOICES}

The right side only (R)
The left side only (L)
Both sides (B)

d~ Lightheadedness or dizzy spells? _
Yes (Y) or No (N)

39.e~ Blackouts or fainting? _
Yes (Y) or No (N)

f~ Seizures or convulsions? _
Yes (Y) or No (N)

g~ Headache? _
Yes (Y) or No (N)

h~ Pain in the weak arm, leg or face? _
Yes (Y) or No (N)

(TIBE screen 11 of 16)

39.i~ Visual disturbances? _
Yes (Y) or No (N)*

j~ Did you have: _

{READ UNTIL POSITIVE RESPONSE GIVEN}

Double vision	(A)
Vision loss in right eye only	(B)
Vision loss in left eye only	(C)
Total loss of vision in both eyes	(D)
Trouble in both eyes seeing to the right	(E)
Trouble in both eyes seeing to the left	(F)
Other (Specify)	(G)*

H. SUDDEN SPELLS OF DIZZINESS OR LOSS OF BALANCE

40~ Since the last ARIC visit, have you had any sudden spells of dizziness, loss of balance, or sensation of spinning? _

Yes (Y), No (N)* or Don't know (D)*

41~ Did the dizziness, loss of balance or spinning sensation occur only when changing the position of your head or body? _

Yes (Y)*, No (N) or Don't know (D)

(TIBE screen 12 of 16)

42. While you were having your (worst) episode of dizziness, loss of balance or spinning sensation, did any of the following occur?

{INCLUDE ALL THAT APPLY}

a~ Speech disturbances? _
Yes (Y) or No (N)

42.b~ Paralysis or weakness? _
Yes (Y) or No (N)*

c~ Did you have difficulty on: _

{READ ALL CHOICES}

The right side only	(R)
The left side only	(L)
Both sides	(B)

(TIBE screen 13 of 16)

42.d~ Numbness or tingling? _
Yes (Y) or No (N)*

e~ Did you have difficulty on: _

{READ ALL CHOICES}

The right side only	(R)
The left side only	(L)
Both sides	(B)

f~ Blackouts or fainting? _
Yes (Y) or No (N)

42.g~ Seizures or convulsions? _
Yes (Y) or No (N)

h~ Headache? _
Yes (Y) or No (N)

(TIBE screen 14 of 16)

42.i~ Visual disturbances? _
Yes (Y) or No (N)*

j~ Did you have? _

{READ UNTIL POSITIVE RESPONSE GIVEN}

Double vision	(A)
Vision loss in right eye only	(B)
Vision loss in left eye only	(C)
Total loss of vision in both eyes	(D)
Trouble in both eyes seeing to the right	(E)
Trouble in both eyes seeing to the left	(F)
Other (Specify)	(G)*

43~ During this time, how many episodes of dizziness, loss of balance or spinning sensation have you had? _

1	(A)
2	(B)
3	(C)
4	(D)
5	(E)
6-20	(F)
More than 20, or frequent, intermittent events, too numerous to count.	(G)

(TIBE screen 15 of 16)

44~ During this time period, when did the earliest occur? _

- Within 6 months (A)
- Greater than 6 months, but less than 1 year ago (B)
- Greater than 1 year, but less than 2 years ago (C)
- Greater than 2 years, but less than 3 years ago (D)
- 3 or more years ago (E)

45~ How long did it (the longest episode) last? _

- Less than 30 seconds (A)
- At least 30 seconds, but less than 1 minute (B)
- At least 1 minute, but less than 3 minutes (C)
- At least 3 minutes, but less than 1 hour (D)
- At least 1 hour, but less than 6 hours (E)
- At least 6 hours, but less than 12 hours (F)
- At least 12 hours, but less than 24 hours (G)
- At least 24 hours (H)

(TIBE screen 16 of 16)

46~ Did the (worst) episode come on suddenly? _
Yes (Y) or No (N)

a~ How long did it take for the symptoms to get as bad as they were going to get? _

- 0-2 seconds (instantly) (A)
- At least 3 seconds, but less than 1 minute (B)
- At least 1 minute, but less than 1 hour (C)
- At least 1 hour, but less than 2 hours (D)
- At least 2 hours, but less than 24 hours (E)
- At least 24 hours (F)

I. ADMINISTRATIVE INFORMATION

47~ Date of data collection: _____
mm/dd/yy

48~ Method of data collection: _
Computer (C) or Paper (P) Form

49~ Code number of person completing this form: ___

Appendix 2.21c

INSTRUCTIONS FOR THE TIA/STROKE FORM
TIA/STROKE, VERSION E, 01/17/95
PREPARED 05/05/95

I. GENERAL INSTRUCTIONS

The TIA/Stroke form is completed during the participant's baseline visit and subsequent clinic exams. The interviewer must be certified and understand the "General Instructions for Completing Paper Forms" and the "DES Training Manual" prior to administering the form. Participant ID number, Contact Year and Name are completed as described in these documents. The interview is conducted using direct data entry unless there is a system failure, in which case data are initially recorded on the paper form for delayed data entry.

Due to the length of the TIA/Stroke Version E (TIAE) paper form, it was necessary to split the single paper form into two data entry forms (TIAE and TIBE). Because the data for Parts A and B are stored in the central data base as two separate data sets, administrative information is collected twice, once at the end of Section D (Double Vision) and again at the end of Section G (Sudden Spells of Dizziness, Loss of Balance).

II. GENERAL DEFINITIONS

The goal of the TIA/Stroke From is to determine whether the participant has had a physician-diagnosed stroke or transient ischemic attack (TIA) or symptoms of a stroke or transient ischemic attack (TIA) since the third exam (Visit 3). The reference period for the administration of Version E of the TIA/Stroke form is the interim between the previous and current exam, generally about 3 years. The lead-in question to each section is worded "Since the last ARIC visit". Throughout the questions, the words "sudden" and "suddenly" should be taken to mean what the participant perceives suddenly to be.

A stroke generally includes one or more of the following symptoms which begin suddenly: (1) loss or change of speech, (2) loss of vision, (3) double vision, (4) numbness or tingling on one side of the body, (5) paralysis or weakness on one side of the body, or (6) spells of dizziness or loss of balance. Therefore, a series of questions are asked for each symptom to determine whether an event took place, its duration, and its location, e.g., right carotid, left carotid or vertebrobasilar.

TIA is considered to be a slight (light) stroke where the same patterns of symptoms occur as in a stroke; the major difference in the definition is the duration of the symptoms, i.e., less than 24 hours.

III. DETAILED INSTRUCTIONS

A. MEDICAL HISTORY

1. Emphasize to the participant that the stroke/TIA must have been diagnosed by a physician since the last ARIC visit. Light (minor or small) stroke is a synonym for TIA.

2. Emphasize "During this time" which refers to the period since the last ARIC visit. Use standard date format. Enter "==" for unknown month or year.

B. LOSS OR CHANGE IN SPEECH

3. Emphasize "Since the last ARIC Visit" and sudden onset of loss or changes of speech. Enter Y, N or D. If NO or DON'T KNOW, skip to SECTION C, Item 10.

4. DO NOT READ RESPONSES. PROBE to select the appropriate category for a response of more than one episode.

5. The objective for this question is to begin collecting incidence data by documenting when the first (or only) episode occurred since the previous ARIC visit. READ THE QUESTION BUT DO NOT READ THE RESPONSES. Select the response category using the current visit as the reference point and counting backwards.

6. Replace "it" with the parenthetical phrase if more than one episode was previously reported. DO NOT READ THE RESPONSE CATEGORIES; probe to select appropriate category.

7. Use the parenthetical phrase if more than one episode was previously reported. If asked, WORST can be defined in terms of severity, intensity or association with other symptoms.

7a. READ QUESTION. DO NOT READ RESPONSES. Probe to select duration category.

8. READ THE QUESTION AND ALL RESPONSE CATEGORIES. Enter Y, N or D for each response.

9. READ THE QUESTION AND ALL RESPONSES. Responses are not mutually exclusive. Stress that the symptoms must have occurred at the same time as the (worst) episode described in Item 7. Note the skip patterns for responses to Items a, c and i.

C. SUDDEN LOSS OF VISION

10. Emphasize "Since the last ARIC Visit" and sudden onset of loss of vision. Enter Y, N or D. If NO or DON'T KNOW, skip to SECTION D, Item 17.

11. DO NOT READ RESPONSES. PROBE to select the category for a response of more than one episode.

12. DO NOT READ RESPONSES. Select the response category using the current visit as the reference point and counting backwards.

13. Use parenthetical phrase if multiple events were reported. DO NOT READ RESPONSES, but probe to select appropriate category.

14. Use parenthetical phrase if multiple events were reported. WORST is defined by the respondent in terms of severity, intensity or association with other symptoms. Enter Y or N.

14a. READ QUESTION. DO NOT READ RESPONSES. Probe to select duration category.

15. READ QUESTION using parenthetical expression if multiple events were reported. READ ALL 3 CHOICES before eliciting a response. The key word in the responses is ONLY. If R or L, go to Item 16.

15a. READ QUESTION AND EACH CATEGORY UNTIL THERE IS A POSITIVE RESPONSE, THEN STOP.

16. READ THE QUESTION AND ALL RESPONSES. Responses are not mutually exclusive. Stress that the symptoms must have occurred at the same time as the (worst) episode described in Item 14. Note the skip patterns for Items b and d.

D. SUDDEN ONSET OF DOUBLE VISION

17. Emphasize "Since the last ARIC Visit" and sudden onset of double vision. Enter Y, N or D. If NO or DON'T KNOW, skip to Item 22j.

17a. READ QUESTION AND ENTER Y, N, OR D. If NO or DON'T KNOW, skip to Item 22j.

18. DO NOT READ RESPONSES. PROBE to select the category for a response of more than one episode.

19. DO NOT READ RESPONSES. Select the response category using the current visit as the reference point and counting backwards.

20. Use parenthetical phrase if multiple events were reported. DO NOT READ RESPONSES, but probe to select appropriate category.

21. Use parenthetical phrase if multiple events were reported. WORST is defined by the respondent in terms of severity, intensity or association with other symptoms. Enter Y or N.

21a. READ QUESTION. DO NOT READ RESPONSES. Probe to select duration category.

22. READ THE QUESTION AND ALL RESPONSES. Responses are not mutually exclusive. Stress that the symptoms must have occurred at the same time as the (worst) episode described in Item 21. Note the skip patterns for responses to Items b and d.

22j. Because the form is divided into two parts, complete the administrative information (Items 22j-l) before continuing with Item 23.

Enter the date on which the participant was seen in the clinic. Code in numbers using leading zeroes where necessary to fill all boxes. For example, May 3, 1993, would be entered as:

0	5	/	0	3	/	9	3
month			day			year	

22k. Record "C" if the form was completed on the computerized data entry system, or "P" if the paper form was used. If the form was completed partially on paper and partially on the computer, code as "Paper Form."

22l. The person at the clinic who has completed this form must enter his/her code number in the boxes provided.

E. SUDDEN NUMBNESS OR TINGLING

23. Emphasize "Since the last ARIC Visit" and sudden onset of numbness or tingling. Enter Y, N or D. If NO or DON'T KNOW, skip to SECTION F, Item 32.

24. READ QUESTION AND ENTER Y, N, OR D. If Y, skip to SECTION F, Item 32.

25. DO NOT READ RESPONSES. PROBE to select the category for a response of more than one episode.

26. DO NOT READ RESPONSES. Select the response category using the current visit as the reference point and counting backwards.

27. Use parenthetical phrase if multiple events were reported. DO NOT READ RESPONSES, but probe to select appropriate category.

28. Use parenthetical phrase if multiple events were reported. WORST is defined by the respondent in terms of severity, intensity or association with other symptoms. Enter Y or N.

28a. READ QUESTION. DO NOT READ RESPONSES. Probe to select duration category.

29. READ THE QUESTION AND ALL RESPONSES. This episode should be the same one described in the previous question, Item 28. Responses are not mutually exclusive. Enter Y, N, or D for each response to Items a-g.

30. Referring to the previous episode (Items 28 and 29), READ QUESTION. SELECT one category based on the response.

31. READ THE QUESTION AND ALL RESPONSES. Responses are not mutually exclusive. Stress that the symptoms must have occurred at the same time as the (worst) episode described in Items 28-30. Note the skip patterns for responses to Items b and i.

F. SUDDEN PARALYSIS AND WEAKNESS

32. Emphasize "Since the last ARIC Visit" and sudden onset of paralysis and weakness. Enter Y, N or D. If NO or DON'T KNOW, skip to SECTION G, Item 40.

33. DO NOT READ RESPONSES. PROBE to select the category for a response of more than one episode.

34. DO NOT READ RESPONSES. Select the response category using the current visit as the reference point and counting backwards.

35. Use parenthetical phrase if multiple events were reported. DO NOT READ RESPONSES, but probe to select appropriate category.

36. Use parenthetical phrase if multiple events were reported. WORST is defined by the respondent in terms of severity, intensity or association with other symptoms. Enter Y or N.

36a. READ QUESTION. DO NOT READ RESPONSES. Probe to select duration category.

37. READ THE QUESTION AND ALL RESPONSES. This episode should be the same one described in the previous question, Item 36. Responses are not mutually exclusive. Enter Y, N, or D for each response to Items a-g.

38. Referring to the previous episode (Items 36 and 37), READ QUESTION. SELECT one category based on the response.

39. READ THE QUESTION AND ALL RESPONSES. Responses are not mutually exclusive. Stress that the symptoms must have occurred at the same time as the (worst) episode described in Items (36-38). Note the skip patterns for responses to Items b and i.

G. SUDDEN SPELLS OF DIZZINESS OR LOSS OF BALANCE

40. Emphasize "Since the last ARIC Visit" and sudden onset of dizziness or loss of balance. Enter Y, N or D. If NO or DON'T KNOW, skip to SECTION H, Item 47.

41. READ QUESTION AND ENTER Y, N, OR D. If Y, skip to SECTION H, Item 47.

42. READ THE QUESTION AND ALL RESPONSES. Responses are not mutually exclusive. Stress that the symptoms must have occurred at the same time as the (worst) episode described in Item 40. Note the skip patterns for responses to Items b, d and i.

43. DO NOT READ RESPONSES. PROBE to select the category for a response of more than one episode.

44. DO NOT READ RESPONSES. Select the response category using the current visit as the reference point and counting backwards.

45. Use parenthetical phrase if multiple events were reported. DO NOT READ RESPONSES, but probe to select appropriate category.

46. Use parenthetical phrase if multiple events were reported. WORST is defined by the respondent in terms of severity, intensity or association with other symptoms. Enter Y or N.

46a. READ QUESTION. DO NOT READ RESPONSES. Probe to select duration category.

H. ADMINISTRATIVE INFORMATION

47. Enter the date on which the participant was seen in the clinic. Code in numbers using leading zeroes where necessary to fill all boxes. For example, May 3, 1993, would be entered as:

0	5	/	0	3	/	9	3
month			day			year	

48. Record "C" if the form was completed on the computerized data entry system, or "P" if the paper form was used. If the form was completed partially on paper and partially on the computer, code as "Paper Form."

49. The person at the clinic who has completed this form must enter his/her code number in the boxes provided.

Appendix 2.22a

(UPDB screen 1 of 5)

A. VERIFICATION OF IDENTIFYING INFORMATION

1. a~ Title: ____ b~ First Name: _____

   c~ Middle Name: _____ d~ Last Name: _____

2. Mailing Address: a~ _____
   b~ _____
   c~ _____

   d~ City: _____ e~ State: __ f~ Zip Code: _____

3~ Home Phone Number: _____ 4~ Other Phone Number: _____
   area-###-#### area-###-####

5~ If missing, request Social Security Number: _____
   {Show disclosure statement} ###-##-####

6~ Administrative use: _____

(UPDB screen 2 of 5)

B. CONTACT PERSON 1

Display field help

{~~Press Esc-2~~ to produce explanatory statement before proceeding.}

7. a~ Title: ____ b~ First Name: _____

   c~ Last Name: _____

8. Mailing Address:

   a~ _____
   b~ _____
   c~ _____

   d~ City: _____ e~ State: __ f~ Zip Code: _____

9~ Telephone: _____ 10~ Relationship: _____
   area-###-####

(UPDB screen 3 of 5)

C. CONTACT PERSON 2

11. a~ Title: ____ [] b~ First Name: _____ []

c~ Last Name: _____ []

12. Mailing Address:

a~ _____ []
b~ _____
c~ _____

d~ City: _____ [] e~ State: __ [] f~ Zip Code: _____ []

13~ Telephone: _____ []
area-###-####

14~ Relationship: _____ []

(UPDB screen 4 of 5)

D. PHYSICIAN INFORMATION

15. a~ First Name: _____ []

b~ Last Name: _____ []

16. a~ Clinic/Building: _____ []

Mailing Address:

b~ _____ []
c~ _____

d~ City: _____ [] e~ State: __ [] f~ Zip Code: _____ []

(UPDB screen 5 of 5)

E. ADMINISTRATIVE INFORMATION {Show and explain Results Reporting Sheet.}

17~ Our usual procedure is to send results to you and your physician as shown on this sheet. _ []

{Enter "U" unless participant has no personal physician or volunteers that this procedure is not satisfactory. If no physician, enter "T". If participant requests another procedure, offer those given below.}

Usual procedure (detailed results to physician, summary to participant)	U
Detailed results to participant, but not to physician	T
Detailed results to both participant and physician	B

18~ Date of data collection/update: _____ []
mm/dd/yy

19~ Code number of person completing/updating this form: ___ []

INSTRUCTIONS FOR THE UPDATE FORM
UPD, VERSION B 11/17/92
Prepared 05/08/95

The UPDATE form is administered during Reception and updated based on Annual Follow-up calls. The form confirms the participant's demographic data and updates the tracking data which may have been collected up to three years ago. Unlike other forms which are completed during Visit 4, this form already contains data retrieved from the study's central database. An Update Form must be present in the local database in order for other Visit 4 forms to be added for this participant. If one is not already present on the local database, it must be added prior to adding other forms. When the form is administered using the computerized version of the UPDATE form, it is entered in the CHANGE mode of the data entry system.

If a paper form should be needed, print the Update Form from the local database.

INTRODUCTION OF THE FORM

"I would like to verify some of the information we have collected from you over the telephone."

A. VERIFICATION OF IDENTIFYING INFORMATION

1.(a-d) Read the participant's title, first, middle and last name. If there is a question as to spelling of any of the names, verify the spelling.

2.(a-f) Read the mailing address to the participant, indicating that you need the mailing address and not the participant's residence, and verify its accuracy.

3. Confirm the home telephone number.

4. Confirm the "other" telephone number. If none is (has been) given, ask if there is another telephone number where the participant could be reached.

Prior to Visit 4 the participant was asked to fill out an information sheet with the names and addresses of two contact persons, the primary care physician, and his/her social security number. Ask if he/she brought in the information sheet and offer to review it together while updating the next few questions.

5. The Social Security Number is requested only if it is missing. Show the participant the SOCIAL SECURITY DISCLOSURE STATEMENT and ask if he/she is willing to provide the number.

6. This item is for field center administrative use. Information such as winter residences or patient numbers can be entered here.

B. CONTACT PERSON 1

7 - 10 Read the name, address, telephone number and relationship of the first contact person on the form to the participant. Ask if any of it needs to be updated.

C. CONTACT PERSON 2

11 - 14 Repeat the procedure for the second contact person. Read the name, address, telephone number and relationship of the second contact person on the form to the participant. Ask if any of it needs to be updated.

D. PHYSICIAN INFORMATION

15.(a-b) Read the first and last names of the participant's physician. If there is a question as to spelling of any of the names, verify the spelling. If the participant has changed physicians, enter the new name.

16.(a) Read the Clinic/Building name to the participant and verify its accuracy or ask if there is one if the field is empty.

16.(b-f) Read the mailing address to the participant, and verify its accuracy. If the participant changed physicians, enter the new address.

E. ADMINISTRATIVE INFORMATION

Show and explain to the participant a blank copy of the Results Reporting Sheet that he/she will receive after Visit 4 and then read Item 17. Do not read the responses.

17. This question is asked regardless of whether or not a response is already present from Visit 3 data. Enter "U" unless the participant volunteers that this procedure is not satisfactory or has no personal physician. If no personal physician, enter "T". If the participant requests another procedure, offer only those listed on the screen (paper form).

18. During each data entry session in which the Update Form is verified or modified (either during the clinic visit or from Annual Follow-Up contact) the date field us updated. Code in numbers using leading zeroes where necessary to fill all boxes. For example, May 3, 1993, would be entered as:

0	5	/	0	3	/	9	3
month			day			year	

19. The person at the clinic who has performed the interview and completed or updated the form must enter his/her code number.

ARIC
Atherosclerosis Risk in Communities

Appendix 3.1a

ANTHROPOMETRY FORM

O.M.B. 0925-0281
exp. 09/30/98

ID NUMBER: | | | | | | | | CONTACT YEAR: | 1 | 0 | FORM CODE: | A | N | T | VERSION: D 12/05/95

LAST NAME: | | | | | | | | | | | | | INITIALS: | | |

Public reporting burden for this collection of information is estimated to average 4 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: **PHS Reports Clearance Officer, Rm. 737-F, Humphrey Building, 200 Independence Ave., SW, Washington, D.C. 20201, ATTN: PRA (0925-0281).** Do not return the completed form to this address.

INSTRUCTIONS:
This form should be completed during the participant's visit. ID Number and Name must be entered above. Whenever numerical responses are required, enter the number so that the last digit appears in the rightmost box. Enter leading zeroes where necessary to fill all boxes. If a number is entered incorrectly, mark through the incorrect entry with an "X". Code the correct entry clearly above the incorrect entry.

ANTHROPOMETRY (ANTD screen 1 of 3)

A. HEIGHT AND WEIGHT

1. Standing height (to the nearest cm, rounding down): ..... | | | | cm

2. Weight (to the nearest lb, rounding down): ..... | | | | lb

B. BODY SIZE

3. Girths (to the nearest cm, rounding down)

a. Waist: ..... | | | | cm

b. Hip: ..... | | | | cm

4. [DO NOT ASK]

Gender of Participant ..... Male M

Go to Item 9, Screen 3 — Female F

ANTHROPOMETRY (ANTD screen 2 of 3)

C. TECHNICIAN ASSESSMENT OF HAIR LOSS

"As part of the study, we are trying to classify the hair pattern on the heads of our male participants. Some recent studies have suggested that there may be an association between hair pattern and heart disease in men. The ARIC study would like to contribute to this research, with your help."

"To do this, I need to observe your head from three different angles and compare your hair pattern to a series of figures. Is this OK with you? Could you please turn to the right? And to the left? Thank you. Now, so that I can see the top of your head, please touch your chin to your chest."

5.a. Participant agrees to participate? ... Yes Y

Go to Item 9, Screen 3. ——No N

5.b. [DO NOT ASK. REFER TO THE HAIR LOSS CHART.]

Which figure most closely resembles the participant's hair pattern? ..... ☐☐

[Record "13" for bald]

D. HISTORY OF HAIR LOSS

6.a. Have you ever experienced hair loss or a receding hair line? .....Yes Y

Go to Item 9, Screen 3 ——No N

ANTHROPOMETRY (ANTD screen 3 of 3)

6.b. Approximately at what age did you begin to lose hair?

[SHOW RESPONSE CARD 1]

Less than 30 ..... A

30-39 ..... B

40-49 C

50-59 ..... D

60-69 ..... E

70 or older ..... F

Didn't lose hair .... G—— Go to Item 9.

7. Have you ever received or used any treatment for baldness, such as hair implantation or a medication prescribed by a doctor? ..... Yes Y

No N

Unknown U

8. Have you recently received chemotherapy (drug therapy for cancer)? ..... Yes Y

No N

Unknown U

E. ADMINISTRATIVE INFORMATION

9. Date of data collection: ..... ☐☐/☐☐/☐☐

month day year

10. Method of data collection: ..... Computer C

Paper form P

11. Code number of person completing this form: ..... ☐☐☐

Appendix 3.1b

(ANTD screen 1 of 3)

A. HEIGHT AND WEIGHT

1~ Standing height (to the nearest cm, rounding down): ___ cm

2~ Weight (to the nearest lb, rounding down): ___ lb

B. BODY SIZE

3. Girths (to the nearest cm, rounding down)

a~ Waist: ___ cm

b~ Hip: ___ cm

4~ [DO NOT ASK]
Gender of Participant _

Male (M) or Female (F)*

(ANTD screen 2 of 3)

C. TECHNICIAN ASSESSMENT OF HAIR LOSS

"As part of the study, we are trying to classify the hair pattern on the heads of our male participants. Some recent studies have suggested that there may be an association between hair pattern and heart disease in men. The ARIC study would like to contribute to this research, with your help."

"To do this, I need to observe your head from three different angles and compare your hair pattern to a series of figures. Is this OK with you? Could you please turn to the right? And to the left? Thank you. Now, so that I can see the top of your head, please touch your chin to your chest."

5.a~ Participant agrees to participate? _
Yes (Y) or No (N)*

5.b~ [DO NOT ASK. REFER TO THE HAIR LOSS CHART.]

Which figure most closely resembles the participant's hair pattern? __

[Record '13' for bald]

D. HISTORY OF HAIR LOSS

6.a~ Have you ever experienced hair loss or a receding hair line? _
Yes (Y) or No (N)*

(ANTD screen 3 of 3)

6.b~ Approximately at what age did you begin to lose hair? _ [ ]

[SHOW RC 1]

Less than 30	(A)
30-39	(B)
40-49	(C)
50-59	(D)
60-69	(E)
70 or older	(F)
Didn't lose hair	(G)*

7~ Have you ever received or used any treatment for baldness, such as hair implantation or a medication prescribed by a doctor? _ [ ]

Yes (Y), No (N) or Unknown (U)

8~ Have you recently received chemotherapy (drug therapy for cancer)? _ [ ]

Yes (Y), No (N) or Unknown (U)

E. ADMINISTRATIVE INFORMATION

9~ Date of data collection: _____ [ ]
mm/dd/yy

10~ Method of data collection: _ [ ]

Computer (C) or Paper (P) Form

11~ Code number of person completing this form: ___ [ ]

INSTRUCTIONS FOR THE ANTHROPOMETRY FORM
ANT, VERSION D, 12/05/95
PREPARED 02/06/96

I. GENERAL INSTRUCTIONS

The Anthropometry form is completed during the participant's clinic visit to record the results of that procedure. The technician must be certified to perform each of the anthropometric measurements and should have a working knowledge of the anthropometry procedures documented in Manual 2, Cohort Component Procedures for the Fourth Examination. The technician also should be familiar with and understand the document titled "General Instructions for Completing Paper Forms" prior to completing this form. ID Number, Contact Year, and Name should be completed as described in that document.

II. DETAILED INSTRUCTIONS FOR EACH ITEM

Anthropometry is performed before the clinic snack, or oral glucose tolerance test and after offering the participant an opportunity to empty the bladder.

1. When measuring standing height, be sure that the participant's head is in the Frankfort horizontal plane as described in the Manual of Operations. Record the height to the nearest centimeter using leading zeroes if necessary. If height is between the centimeter marks, round down to the nearest whole number.

2. Weight is taken with minimal clothing. Record results to the nearest pound, rounding down.

3. Girth measurements are taken against the skin or over lightweight non-constricting underwear, at the discretion of the field center.

3a. (Waist) Ask the participant to stand with the feet apart and weight equally distributed while the waist is measured. Place the tape horizontally at the level of the umbilicus (navel). Record the results to the nearest centimeter, rounding down.

3b. (Hip) The objective here is to measure the maximal circumference of the gluteal (hip) muscles. Refer to the anatomic figure in Manual 2 for the proper placement of the measuring tape. The measuring tape must be kept horizontal throughout this procedure. Record the results to the nearest centimeter, rounding down.

4. Record the gender of the participant. Do not ask the participant this question. If the participant is male, then continue; if the participant is female, go to Item 9.

C. Technician Assessment of Hair Loss

The attached series of figures is a scale for classifying male pattern baldness, regardless of ethnicity. After observing the participant's head from three angles (right side, left side and top), decide which figure most closely resembles the participant's hair pattern. You should aim at identifying the "natural" pattern, not the cosmetic appearance. For example, vertex baldness (top of the head) may sometimes be "disguised" by cosmetic combing. Try to identify the "natural" hair pattern, but don't ask the participant to re-comb his hair. Unless the participant voluntarily tells you that he has a toupee, do not probe. Select the more severe hair loss pattern when classifying hair patterns obscured by cosmetic combing, but select the less severe figure when deciding between two figures that don't clearly differentiate what is observed. If the participant expresses discomfort about this component of the exam, do not proceed. We do not want to embarrass any one.

The following prototype script can be used as an explanation:

> "As part of the study, we are trying to classify the hair pattern on the heads of our male participants. Some recent studies have suggested that there may be an association between hair pattern and heart disease in men. The ARIC study would like to contribute to this research with your help.
>
> To do this, I need to observe your head from three different angles and compare your hair pattern to a series of figures. Is this okay with you? Could you please turn to the right? And to the left. Thank you. Now, so that I can see the top of your head, please touch your chin to your chest."

5.a Record whether or not the person agrees to participate. If he declines, thank him, skip to Item 9, and complete the interview. If he agrees, select YES and ...

5.b Ask the person to turn his head to the right, to the left, and then to touch his chin to his chest. Refer to the hair loss chart and record the figure which most closely resembles the participant's hair pattern. When the hair pattern is substantially different on the right and left sides (due to cosmetic combing or other reasons) or hair loss is partially obscured at the vertex from cosmetic combing, select the figure which resembles the more severe pattern. In contrast, if you really can't decide between two figures (i.e., neither one is better), select the less severe figure. Record "13" if the participant is (totally) bald, i.e., he has no hair on his head, even if the hair loss is due to other than natural causes (e.g., shaving).

6.a Read Item 6.a to the men who have agreed to participate and circle the appropriate letter. The question covers the man's lifetime experience (Have you ever ...), so it is possible that previous hair loss is no longer visible, for example, if hair loss was due to chemotherapy. The response is positive if the participant reports either hair loss or a receding hair line. Record answer and follow skip pattern.

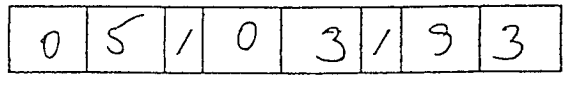
6.b In this question we are looking for the approximate age (in decades) when the participant first began to lose his hair. If asked, loss of hair can be defined as thinning of the hair, or loss of hair resulting in a change in the pattern of hair distribution on the head (such as a receding hair line), whichever started first. READ the response card to the participant and ask him to select the letter for the decade in which hair loss began. Note, the last category (G) is not printed on the response card. If the participant denies any thinning or loss of hair, code "G" and go to Item 9, even if you noticed hair loss during the examination. If the person is unsure when the hair loss began, ask for a best guess. Option "G" (denial of hair loss) is not printed on the response card shown to the participant, but can be used by the technician.

7. Again, the time frame for this question (Have you ever) is any time prior to the interview. Examples of "treatment for baldness" (or thinning hair) are given in the question. There may be others. We are looking for any type of treatment that is meant to stimulate hair growth (medication) or replace hair (implantation). Note that this does not include hair pieces.

8. The time frame for this question (Have you recently) is any time within the last 6 months. In the rare case where drug therapy resulting in hair loss was taken for a disease or condition other than cancer, code the answer as YES. If unsure, discuss the participant's response with the clinic physician and complete the form later. If the participant is unsure, code the response as UNKNOWN.

E. Administrative Information

9. Enter the date the participant was seen in the clinic. Code in numbers using leading zeroes where necessary to fill all boxes. For example, May 3, 1993, would be entered as:



10. Record "C" if the form was completed on the computerized data entry system, or "P" if the paper form was used. If the form was completed partially on paper and partially on the computer, code as "Paper Form."

11. The person at the clinic who has completed this form must enter his/her code number in the boxes provided.

Appendix 3.1d

ARIC

CHECKLISTS FOR ANTHROPOMETRY MEASUREMENTS

ARIC Field Center: _____

Date of Visit: _____

Technician: _____ I.D.#_____

Supervisor: _____ I.D.#_____

This booklet contains a checklist for each anthropometry measurement and equipment calibration. The purpose of these checklists is to help train technicians to take uniform and accurate measurements using calibrated measuring equipment. Each checklist leads you through a series of steps to obtain and to record a measurement. All measurements are done on the right side, unless the limb is missing, atrophied or injured.

	Item	Yes	No
A.	Anthropometry is done BEFORE the snack.	___	___
B.	Prepare participant for anthropometry: (May be done by the receptionist or technician).		
1)	If the participant is wearing any nylon hose other than knee highs, the participant is instructed to remove hose.	___	___
2)	Participant is wearing light-weight, non-constricting underwear.	___	___
3)	Participant is wearing scrub suit.	___	___
4)	Participant has removed shoes.	___	___
5)	Participant has emptied bladder.	___	___

Appendix 3.1e

ARIC

ANTHROPOMETRY EQUIPMENT CALIBRATION LOG

Mail original to Coordinating Center on Friday afternoons. Keep photocopy in Field Center.

Week of _____ (Monday's date) Field Center _____

DAILY CHECKS (at beginning of day)

	M	T	W	Th	F
1.a. Scales Read Zero	___	___	___	___	___

WEEKLY CHECKS

1. Scales

A. Calibration check of scales with 50 lb weight

Date _____

Time _____

Reading of scales with 50 lb weight _____

If reading outside of 49.5 to 50.5 range, scale should be serviced.

If service is REQUESTED, give Time _____ Date _____

RECALIBRATION by independent service technician Time _____ Date _____

B. Repeat calibration because of moving scales

Scales moved: 1. Date _____ 2. Date _____

Time _____ Time _____

Calibration: 1. Date _____ 2. Date _____

Time _____ Time _____

ARIC

ANTHROPOMETRY EQUIPMENT CALIBRATION LOG (cont.)

2. Height Rule

   a. Touches hard-surfaced platform on which measures are done _____

   b. Perpendicular to floor _____

MONTHLY CHECKS

1. Check Measuring Tape: Date _____

   a. Excess wear or damage found (Y or N) _____

   b. Height above floor (to nearest cm) on height rule of the 30 cm mark of the tape when the zero mark of the tape is aligned with the 150 cm mark of the height rule _____

      Note: If this measure is outside the 119.5-120.5 cm range, the tape should be replaced.

   c. Height above floor (to nearest cm) on height rule of the 100 cm mark of the tape, with the tape aligned as above. _____

      Note: If this measure is outside the 49.5-50.5 cm range, the tape should be replaced.

   d. Tape replaced (Y or N) ____ Date replaced _____

      Time replaced _____

Technician doing weekly check:

ID# _____ Signature _____ Date _____

Appendix 3.1f

ARIC

CHECKLIST FOR HEIGHT MEASUREMENT

	ITEM	YES	NO
1.	Participant is prepared.	___	___
2.	Procedure is explained to participant.	___	___
3.	Participant's spine and heels are placed against the wall.	___	___
4.	Participant's eye to ear plane is horizontal (ie.,Frankfurt plane).	___	___
5.	Measurement is taken with triangle or measuring block.	___	___
6.	Recording is completed.	___	___
7.	Data are recorded accurately to the nearest centimeter, rounding down.	___	___

Technician: _ _ _ cm

Supervisor: _ _ _ cm

8. Other: _____

Comments:

_____

_____

_____

Appendix 3.1g

ARIC

CHECKLIST FOR WEIGHT MEASUREMENT

ITEM	YES	NO
A. PROCEDURE		
1. Participant prepared and procedure explained	___	___
2. Position of participant on center of scale	___	___
3. Balance achieved	___	___
4. Recordings completed	___	___
5. Data recorded accurately to the pound, rounding down	___	___
Technician: _ _ _ lbs		
Supervisor: _ _ _ lbs		
6. Other _____	___	___

Comments:

_____

_____

_____

ARIC

CHECKLIST FOR MAXIMAL WAIST MEASUREMENT

ITEM	YES	NO
1. Subject stands erect, yet relaxed, with weight equally distributed on both feet.	___	___
2. Measuring tape is placed around subject's waist at the level of the umbilicus (navel).	___	___
3. Recorder or another observer verifies horizontal position of tape, both front and back of the subject, or uses mirror to check tape.	___	___
4. Subject takes a normal breath and gently exhales holding breath in a relaxed manner at the end of exhalation.	___	___
5. Tape is horizontal and snug, but not tight enough to compress tissue. (Invert tape, if needed, to insure reading edge of tape is snug to skin for measurement).	___	___
6. Reading is recorded to the nearest centimeter, rounding down, at point of relaxed end exhalation.	___	___

Technician: _ _ _ cm

Supervisor: _ _ _ cm

Comments: _____

_____

_____

ARIC

CHECKLIST FOR MAXIMAL HIP CIRCUMFERENCE MEASUREMENT

ITEM	YES	NO
1. Subject stands erect, yet relaxed, with weight equally distributed on both feet and feet together.	___	___
2. Measuring tape is placed horizontally and level around the subject's gluteal muscles (hips) at the level of maximal protrusion of the gluteal muscles. Verify this position by passing the tape above and below the observed maximum.	___	___
3. Recorder or another observer verifies horizontal position of tape, both front and back of the subject, or uses a mirror to check tape.	___	___
4. Tape is horizontal and snug, but not tight enough to <u>compress</u> tissue. (Invert tape, <u>if needed</u>, to insure reading the edge of tape is snug to the skin for measurement.	___	___
5. The measurement is made at the participant's side.	___	___
6. Tape is read to the centimeter, rounding down.	___	___

Technician: _ _ _ cm

Supervisor: _ _ _ cm

Comments: _____

_____

_____

Appendix 3.1j

ARIC

REPORT ON USE OF OBSERVATION AND EQUIPMENT CHECKLISTS

ARIC Field Center: _____

Date: ____/____/____ (Month/Day/Year)

Biannually: ____ January ____ July (19 __ __)

This form should be completed biannually and sent to the Coordinating Center (by the end of each January and July).

Form Type	Observer ID	Observed ID	Date (MM/DD/YY)
Anthropometry			
BP Observation			

ARIC

REPORT ON USE OF OBSERVATION AND EQUIPMENT CHECKLISTS (cont'd)

Form Type	Observer ID	Observed ID	Date (MM/DD/YY)
BP Tape Test			
BP Double Stethoscoping			
Venipuncture			

ARIC

REPORT ON USE OF OBSERVATION AND EQUIPMENT CHECKLISTS (cont'd)

ECG			

ARIC

REPORT ON USE OF OBSERVATION AND EQUIPMENT CHECKLISTS (cont'd)

Individual checklist for equipment should be filled weekly or monthly, according to the requirement of the checklist, and kept in the Field Center.

Key: N = Expected total number of checks needed;
n = Number of checks done;
% = % of checks done.

Checklist	Frequency	N	n	%
Anthropometry Equipment Calibration Log				
(1) Scale Read Zero	Daily			
(2) Weight Scales	Weekly			
(3) Height Rule	Weekly			
(4) Measuring Tape	Monthly			
Sitting Blood Pressure Monthly Log for BP Station	Weekly Monthly			

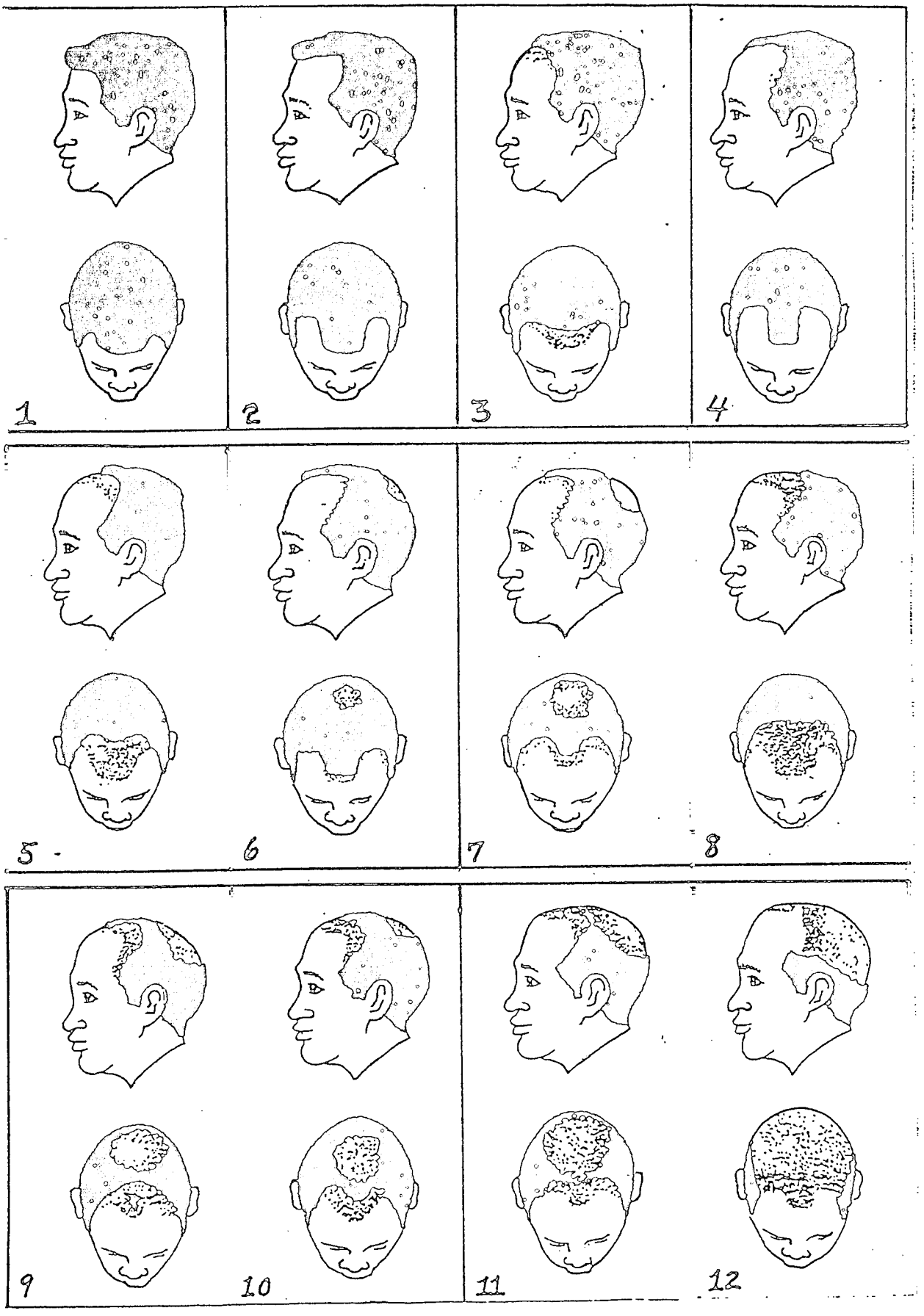
Appendix 3.1k

Body Size Measurements: Body Height in Centimeters and Inches[1]

Centimeters	Inches
122.0	48
124.5	49
127.0	50
129.5	51
132.0	52
134.5	53
137.0	54
139.5	55
142.0	56
145.0	57
147.5	58
150.0	59
152.5	60
155.0	61
157.5	62
160.0	63
162.5	64
165.0	65
167.5	66
170.0	67
172.5	68
175.0	69
178.0	70
180.5	71
183.0	72
185.5	73
188.0	74
190.5	75
193.0	76
195.5	77
198.0	78
200.5	79
203.0	80
205.5	81

[1] 1 inch = 2.54 centimeters; 1 centimeter = .39 inches

Hamilton Scale of Male Pattern Baldness



Appendix A

Creatinine and Albumin: Box Logging Form, Laboratory Form, and Shipping Sheet

For each box of stored creatinine and albumin samples, record on the Box Logging Form the location of the two specimens for each ID. Write the box number at the top. Write or insert an ID label for each participant whose sample is stored. Put these in a notebook until specimens are shipped.

Complete and key the LABORATORY Form for each participant.

When shipping, complete the Shipping Sheet as follows:

1. Enter the field center, date and time shipment was packed and sealed at the field center.

2. Enter the number of boxes in this shipment and their numbers.

3. Add any remarks and tech ID.

Send with the shipment a photocopy of the Shipping Sheet with one copy of each Box Logging Form corresponding to this Sheet. The laboratory will FAX back the Shipping Sheet as a confirmation.

Hemostasis Sample: Logging Form, and Shipping Sheet

When shipping, complete the Shipping Sheet as follows:

1. Enter the field center, date and time shipment was packed and sealed at the field center.

2. Enter the number of bags in this shipment and their numbers.

3. Add any remarks and tech ID.

Send with the shipment a photocopy of the Shipping Sheet with one copy of each Logging Form corresponding to this Sheet.

ARIC

URINE BOX and POSITION LOGGING FORM

BOX NUMBER:_____

POSITION	ID	POSITION	ID	POSITION	ID
01-02		29-30		57-58	
03-04		31-32		59-60	
05-06		33-34		61-62	
07-08		35-36		63-64	
09-10		37-38		65-66	
11-12		39-40		67-68	
13-14		41-42		69-70	
15-16		43-44		71-72	
17-18		45-46		73-74	
19-20		47-48		75-76	
21-22		49-50		77-78	
23-24		51-52		79-80	
25-26		53-54		81	EMPTY
27-28		55-56			

Appendix 3.2c

ARIC

URINE SHIPPING SHEET

To: Carolyne Campbell, Minneapolis ARIC Field Center

From: (circle one): F J M W

A. Field Center Package date and time

1.a. Date: [ ][ ]/[ ][ ]/[ ][ ]
M M / D D / Y Y

b. Time: [ ][ ]:[ ][ ]
H H M M

2. Number of boxes enclosed: (attach all box logs)

[ ][ ] boxes

3. Remarks: _____

_____

_____

4. Field Center Technician ID: [ ][ ][ ]

3. Arrival at lab

5.a. Date: [ ][ ]/[ ][ ]/[ ][ ]
M M / D D / Y Y

b. Time: [ ][ ]:[ ][ ]
H H M M

5. Remarks: _____

_____

_____

. Laboratory Technician Initials: [ ][ ][ ]

LAB: TO CONFIRM ARRIVAL, FAX THIS FORM BACK TO FIELD CENTER

Appendix 3.2d

ARIC

URINE-HEMOSTASIS LOGGING FORM

NUMBER OF BAGS:_____

ID	ID	ID

Appendix 3.2e

ARIC

URINE SHIPPING SHEET

To: Nena Aleksic, ARIC Central Hemostasis Laboratory

From: (circle one): F J M W

A. Field Center Package date and time

1.a. Date: ☐☐/☐☐/☐☐ (M M / D D / Y Y)

b. Time: ☐☐:☐☐ (H H M M)

2. Number of bags enclosed: (attach all logs)

☐☐ bags

3. Remarks: _____

_____

_____

4. Field Center Technician ID: ☐☐☐

5. Arrival at lab

5.a. Date: ☐☐/☐☐/☐☐ (M M / D D / Y Y)

b. Time: ☐☐:☐☐ (H H M M)

6. Remarks: _____

_____

_____

7. Laboratory Technician Initials: ☐☐☐

LAB: TO CONFIRM ARRIVAL, FAX THIS FORM BACK TO FIELD CENTER

APPENDIX B

REAGENT PREPARATION

3N HCL

3N HCL should be available for purchase; no additional preparation should be necessary.

3N Sodium Hydroxide (NaOH) from 5N NaOH

In a 100 ml volumetric flask, add 60 ml of 5N NaOH to approximately 30 ml of distilled water. Cover, mix, and fill to the line with distilled water. Remix. The solution is stable for one year at room temperature in a plastic bottle.

*** NOTE ***

REAGENT PREPARATION CAN BE ARRANGED THROUGH A LOCAL MEDICAL OR RESEARCH LABORATORY, OR A COMMERCIAL LABORATORY WITH GOOD QUALITY CONTROL STANDARDS, OTHERWISE, IF MIXED IN THE ARIC FIELD CENTER LABORATORY,

REAGENT PREPARATION MUST BE DONE IN A FUME HOOD WEARING APPROPRIATE EYE AND SKIN PROTECTION.

LABEL ALL REAGENTS APPROPRIATELY WITH NAME AND CONCENTRATION OF SOLUTION, DATE OF PREPARATION, EXPIRATION DATE, AND NAME OF PERSON PREPARING THE SOLUTION.

L AND NaOH ARE CORROSIVE AGENTS AND MUST BE LABELED AS SUCH !!!

Appendix 3.2g

APPENDIX C

SUPPLY LIST FOR URINE COMPONENT

CATALOG NUMBER	DESCRIPTION
	CURTIN MATHESON SCIENTIFIC, INC.
057-125	5 ML TRANSFER PIPETS (graduated to .25 ml) (PK/500)
366-385	50 mL CLEAR POLYPROPYLENE CENTRIFUGE TUBE, PLUG SEAL (SCREW) CAP (Corning)
024-990	10 OZ POLYSTYRENE, NONSTERILE SPECIMEN CONTAINER (CS/500)
024-991	POLYSTYRENE LIDS (for specimen containers) (CS/500)
	SARSTEDT, INC.
60.549-001	3.5 ML POLYPROPYLENE SCREW CAP TUBE (CS/1000)
	FISHER SCIENTIFIC
14-850-10G	pH PAPER (pH RANGE 3.0-7.5) (CS/10)
08-570-21D	100 ML GRADUATED CYLINDER (CS/8)
	BAXTER DIAGNOSTICS, INC.
R3890-7	FIBERBOARD BOX AND COVER (3" x 5-1/4" x 5-1/4")
R3894-7	BOX DIVIDER (81 vial size)

APPENDIX C (continued)

URINE SUPPLIES

VENDORS

Baxter Diagnostics, Inc.
1210 Waukegan Road
MP82
McGaw Park, IL 60085

Phone: (800) 234-5227

Curtin Matheson Scientific, Inc.
2 North Point Drive
Suite 300
Houston, TX 77060

Phone: (800) 650-0650 (industrial)

Curtin Matheson Scientific, Inc.
955 Cobb Place Blvd.
Kennesaw, GA 30144-6802

Phone: (800) 241-7670 (biomedical)
FAX: (404) 590-9014

Fisher Scientific
711 Forbes Avenue
ttsburgh, PA 15219-4785

Phone: (800) 766-7000
FAX: (800) 926-1166

Sarstedt, Inc.
P.O. Box 468
Newton, NC 28658-0468

Phone: (800) 257-5101
FAX: (704) 564-4003

APPENDIX C (continued)

GENERAL SUPPLIES

General Supplies

Droppers
Disposable gloves
Glass stirring rods
Liqui-Nox
Distilled water

Shipping Supplies

Dry ice
Biohazard labels
Insulated shipping containers

Appendix 3.3a

O.M.B. 0925-0281
exp. 09/30/98

ARIC
Atherosclerosis Risk in Communities

ORAL GLUCOSE TOLERANCE ADMINISTRATION FORM

ID NUMBER: | | | | | | | | CONTACT YEAR: | 1 | 0 | FORM CODE: | G | T | A | VERSION: A 01/26/96

LAST NAME: | | | | | | | | | | | | | INITIALS: | | |

INSTRUCTIONS: This form is completed during the participant's visit. ID Number, Contact Year and Name must be entered above. Whenever numerical responses are required, enter the number so that the last digit appears in the rightmost box. Enter leading zeroes where necessary to fill all boxes. On the paper form, if a number is entered incorrectly, mark through the incorrect entry with an "X". Code the correct entry clearly above the incorrect entry. For "multiple choice" questions, circle the letter corresponding to the most appropriate response. If a letter is circled incorrectly, mark through it with an "X" and circle the correct response.

ORAL GLUCOSE TOLERANCE ADMINISTRATION FORM (GTAA Screen 1 of 2)

[CONFIRM ELIGIBILITY FOR OGTT.]

1. a. Time participant **began** drinking glucola: ..... | | | : | | |
h h : m m

b. AM ..... A
PM ..... P

2. Amount of glucola NOT consumed. ..... | | | | ml

IF FULL AMOUNT CONSUMED, RECORD "000" AND RECORD TIME FOR DRAWING 2 HOUR SAMPLE ON ITINERARY SHEET. IF 145 ml OR MORE, DO NOT DRAW 2 HOUR BLOOD SAMPLE.

3. a. Time of 2 hour blood sample: | | | : | | |
h h : m m

[IF NOT DRAWN, RECORD "00:00" and GO TO ITEM 4]

b. AM ..... A
PM ..... P
→ Go to Item 5, Screen 2.

4. Reason for non-collection of 2 hour blood sample?

50% or less of glucola consumed ..... A
Venipuncture failure ..... B
Refusal C
Other ..... D

ORAL GLUCOSE TOLERANCE ADMINISTRATION FORM (GTAA Screen 2 of 2)

5. Date of data collection: | | | / | | | / | | |
m m / d d / y y

6. Method of data collection: ..... Computer C
Paper P

7. Code number of phlebotomist drawing 2 hour glucose sample: | | | |

Appendix 3.3b

(GTAA screen 1 of 2)

[CONFIRM ELIGIBILITY FOR OGTT.]

1.a~ Time participant began drinking glucola: _____ hh:mm

b~ AM (A) or PM (P) _

2~ Amount of glucola NOT consumed? ___ ml

[IF FULL AMOUNT CONSUMED, RECORD "000" AND RECORD TIME FOR DRAWING 2 HOUR SAMPLE ON ITINERARY SHEET. IF 145 ml OR MORE, DO NOT DRAW 2 HOUR BLOOD SAMPLE.]

3.a~ Time of 2 hour blood sample: _____ hh:mm

[IF NOT DRAWN, RECORD "00:00" and GO TO ITEM 4]

b~ AM (A)* or PM (P)* _

4~ Reason for non-collection of 2 hour blood sample? _

50 percent or less of glucola consumed	(A)
Venipuncture failure	(B)
Refusal	(C)
Other	(D)

(GTAA screen 2 of 2)

5~ Date of data collection: _____ mm/dd/yy

6~ Method of data collection: _

Computer (C) or Paper (P)

7~ Code number of phlebotomist drawing 2 hour glucose sample: ___

O.M.B. 0925-0281
exp. 09/30/98

ARIC
Atherosclerosis Risk in Communities

SITTING BLOOD PRESSURE FORM

ID NUMBER: | | | | | | | | CONTACT YEAR: | 1 | 0 | FORM CODE: | S | B | P | VERSION: D 12/01/95

LAST NAME: | | | | | | | | | | | | | INITIALS: | | |

Public reporting burden for this collection of information is estimated to average 9 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: **PHS Reports Clearance Officer, Rm. 737-F, Humphrey Building, 200 Independence Ave., SW, Washington, D.C. 20201, ATTN: PRA (0925-0281).** Do not return the completed form to this address.

INSTRUCTIONS: This form should be completed during the participant's visit. ID Number, Contact Year, and Name must be entered above. Whenever numerical responses are required, enter the number so that the last digit appears in the rightmost box. Enter leading zeroes where necessary to fill all boxes. If a number is entered incorrectly, mark through the incorrect entry with an "X". Code the correct entry clearly above the incorrect entry. For "multiple choice" and "yes/no" type questions, circle the letter corresponding to the most appropriate response. If a letter is circled incorrectly, mark through it with an "X" and circle the correct response.

SITTING BLOOD PRESSURE FORM (SBPD screen 1 of 3)

A. TEMPERATURE

1. Room Temperature (degrees centigrade): | | |

B. TOBACCO AND CAFFEINE USE

2. Have you smoked or used chewing tobacco, nicotine gum or snuff today or do you wear a nicotine patch? ..... Yes Y
   No N

   Go to Item 4

3. How long ago did you last smoke or last use chewing tobacco or snuff?

   a. | | hours, b. | | minutes

4. Have you had any caffeinated beverages, such as coffee, tea, or colas, or any chocolate today? ..... Yes Y
   No N

   Go to Item 6 Screen 2

5. How long ago did you last have any caffeinated beverage, or chocolate?

   a. | | hours, b. | | minutes

SITTING BLOOD PRESSURE FORM (SBPD screen 2 of 3)

C. PRELIMINARY MEASUREMENTS

6. Right Arm Circumference (cm): ..... [ ][ ]

7. Cuff Size:

(arm circumference in brackets)

Pediatric (under 24 cm)	P
Regular Arm (24-32 cm)	R
Large Arm (33-41 cm)	L
Other	O

8. Heart Rate (30 seconds): ..... [ ][ ]

9.a. Time of Day: ..... [ ][ ]:[ ][ ]
h h m m

b. AM or PM: ..... AM A
PM P

10. Pulse Obliteration Pressure: ..... [ ][ ][ ]

11. Maximum Zero: ..... [ ][ ]

\+ 3 0

12. Peak Inflation Level
(Computation--Item #10 + Item #11 + 30): ___ ___ ___

D. FIRST BLOOD PRESSURE MEASUREMENT

13. Systolic: ..... [ ][ ][ ]

14. Diastolic: ..... [ ][ ][ ]

15. Zero Reading: ..... [ ][ ]

SITTING BLOOD PRESSURE FORM (SBPD screen 3 of 3)

E. SECOND BLOOD PRESSURE MEASUREMENT

16. Systolic: ..... [ ][ ][ ]

17. Diastolic: ..... [ ][ ][ ]

18. Zero Reading: ..... [ ][ ]

F. COMPUTED NET AVERAGE OF FIRST AND SECOND BLOOD PRESSURE MEASUREMENTS

19. Systolic: ..... ___ ___ ___

20. Diastolic: ..... ___ ___ ___

G. ADMINISTRATIVE INFORMATION

21. Date of data collection: [ ][ ]/[ ][ ]/[ ][ ]
month day year

22. Method of Data Collection: ..... Computer C
Paper Form P

23. Code number of person completing this form: ..... [ ][ ][ ]

ID: _____ CONTACT YEAR: 10 FORM CODE: SBP VERSION: D 12/01/95

WORKSHEET FOR COMPUTING AVERAGE OF 1ST AND 2ND READINGS (ITEMS 19 AND 20)

	SYSTOLIC	DIASTOLIC
First Measurement	___ ___ ___ (#13)	___ ___ ___ (#14)
1st Zero Reading	— ___ ___ (#15)	— ___ ___ (#15)
First Corrected	___ ___ ___	___ ___ ___
Second Measurement	___ ___ ___ (#16)	___ ___ ___ (#17)
2nd Zero Reading	— ___ ___ (#18)	— ___ ___ (#18)
Second Corrected	___ ___ ___	___ ___ ___
Average Corrected	___ ___ ___ (#19)	___ ___ ___ (#20)

(SBPD screen 1 of 3)

A. TEMPERATURE

1~ Room Temperature (degrees centigrade): __ []

B. TOBACCO AND CAFFEINE USE

2~ Have you smoked or used chewing tobacco, nicotine gum or snuff today or do you wear a nicotine patch? _ []

Yes (Y) or No (N)*

3. How long ago did you last smoke or last use chewing tobacco or snuff?

a~ __ []hours, b~ __ []minutes

4~ Have you had any caffeinated beverages, such as coffee, tea or colas, or any chocolate today? _ []

Yes (Y) or No (N)*

5. How long ago did you last have any caffeinated beverage, or chocolate?

a~ __ []hours, b~ __ []minutes

(SBPD screen 2 of 3)

C. PRELIMINARY MEASUREMENTS

6~ Right Arm Circumference (cm): __ []

7~ Cuff Size: _ []
{arm circumference in brackets}

Pediatric {under 24 cm} (P)
Regular Arm {24-32 cm} (R)
Large Arm {33-41 cm} (L)
Other (O)

8~ Heart Rate (30 seconds): __ []

9.a~ Time of Day: _____ []
hh:mm

b~ AM (A) or PM (P): _ []

10~ Pulse Obliteration Pressure: ___ []

11~ Maximum Zero: __ []

12~ Peak Inflation Level {Computation Item #10 + Item #11 + 30}: ___ []

D. FIRST BLOOD PRESSURE MEASUREMENT

13~ Systolic: ___ []

14~ Diastolic: ___ []

15~ Zero Reading: __ []

(SBPD screen 3 of 3)

Item 12 Peak Inflation Level: ___ []

E. SECOND BLOOD PRESSURE MEASUREMENT

16~ Systolic: ___ []

17~ Diastolic: ___ []

18~ Zero Reading: __ []

F. COMPUTED NET AVERAGE OF FIRST AND SECOND BLOOD PRESSURE MEASUREMENTS

19~ Systolic: ___ []

20~ Diastolic: ___ []

G. ADMINISTRATIVE INFORMATION

21~ Date of data collection: _____ []
mm/dd/yy

22~ Method of Data Collection: _ []

Computer (C) or Paper (P) Form

23~ Code number of person completing this form: ___ []

INSTRUCTIONS FOR THE SITTING BLOOD PRESSURE FORM
SBP, VERSION D, 05/17/95
PREPARED 06/10/95

I. GENERAL INSTRUCTIONS

The Sitting Blood Pressure Form is completed during the participant's clinic visit. The technician must be certified and should have a working knowledge of the ARIC Blood Pressure Manual of Procedures. He/she should also be familiar with and understand the document titled "General Instructions For Completing Paper Forms" prior to completing this form. ID Number, Contact Year, and Name are completed as described in that document.

There should be no exertion, eating, smoking, or exposure to cold for half an hour before recording blood pressure. It is also important that the subject have no change of posture for five minutes before recording blood pressure.

Blood pressure is measured twice using a random zero sphygmomanometer. The detailed instructions below for the administration of the Sitting Blood Pressure Form should be reviewed in combination with the instructions for performing the measurements in Manual 2, Cohort Component Procedures, and in Manual 11, Sitting Blood Pressure.

II. DETAILED INSTRUCTIONS FOR VARIOUS QUESTIONS

A. TEMPERATURE

1. Record the room temperature in degrees centigrade. A thermometer is read and the temperature recorded each time the procedure is initiated to note fluctuations.

B. TOBACCO AND CAFFEINE USE

2. Ask the question as written. Use of any type of smoking materials, chewing tobacco, snuff, nicotine gum, etc. ~~within the last 4 hours~~ today or the current use of a nicotine patch should be noted. If none were used, skip to item 4.

3. Ask about the most recent time. The question is phrased "How long ago..." instead of "At what time..." in order to make it easier for the participant to answer. Record the answer in the same way.~~, noting it must be 4 hours or less.~~ If the participant is wearing a nicotine patch, record '0' hours (item 3a) and '00' minutes (item 3b). If unknown, mark through the boxes with two horizontal lines.

4-5. Ask the questions as written, following the same procedures given for items 2 and 3 above.

C. PRELIMINARY MEASUREMENTS

6. Measure right arm circumference once according to the Manual of Procedures. Record to the nearest centimeter.

7. Cuff size is determined by the arm circumference measurement in item 6. The appropriate size for a given arm circumference is given below, and also appears on the form itself.

Arm Circumference	Cuff Size
under 24 cm	Pediatric
24-32 cm	Regular Arm
33-41 cm	Large Arm
over 41 cm	Thigh (record as "other")

8. Instruct the participant to sit quietly, without changing his/her posture, while keeping both feet flat on the floor, for five minutes while you step out of the room. Start a timer, and return promptly after 5 minutes have elapsed. After the participant has sat quietly for five minutes, measure the heart rate for 30 seconds (do not count for 15 seconds and multiply by two) and record the number in the spaces available.

9. After recording the heart rate, enter the time. ~~you return to the workstation and begin measuring heart rate~~ A five minute wait with no change of posture must precede the first blood pressure measurement.

10-11. Record as described in the Manual of Procedures.

12. Calculate peak inflation level as "pulse obliteration pressure" + "maximum zero" + 30. This item is calculated automatically when the form is entered on the computer. (As a way of denoting this on the paper form, lines are provided rather than boxes for recording the result.)

D. FIRST BLOOD PRESSURE MEASUREMENT

13-14. Measure and record systolic and diastolic blood pressures as described in the Manual of Procedures. Right justify, using leading zeroes if necessary.

15. Record the zero reading.

NOTE: Do not calculate net blood pressure at this time.

E. SECOND BLOOD PRESSURE MEASUREMENTS

16-18. Repeat as in 13-15 above.

F. COMPUTED NET AVERAGE OF FIRST AND SECOND BLOOD PRESSURE MEASUREMENTS

19-20. Average systolic (item 19) and diastolic (item 20) blood pressures are calculated automatically when the form is entered on the computer. (As a way of denoting this on the paper form, lines are provided rather than boxes for recording the result.) When the paper form is being used, the average of the first and second readings for systolic and diastolic pressure must be calculated using a hand calculator. Use the worksheet at the end of the form to calculate items 19 and 20. Items 13-18 are transcribed onto that worksheet in the specified spaces. The "corrected" readings are calculated as the measurement itself minus the corresponding zero reading. These (first and second corrected) are then averaged to obtain the average corrected systolic and average corrected diastolic pressures. An example is given below.

H. ADMINISTRATIVE INFORMATION

21. Enter the date on which the participant was seen in the clinic. Code in numbers using leading zeroes where necessary to fill all boxes. For example, May 3, 1993, would be entered as:

0	5	/	0	3	/	9	3
month			day			year	

22. Record "C" if the form was completed on the computerized data entry system, or "P" if the paper form was used. If the form was completed partially on paper and partially on the computer, code as "Paper Form."

23. The person at the clinic who has completed this form must enter his/her code number in the boxes provided.

EXAMPLE:

WORKSHEET FOR COMPUTING AVERAGE OF 1ST AND 2ND READINGS (ITEMS 19 AND 20)

	SYSTOLIC	DIASTOLIC
First Measurement	142 (#13)	100 (#14)
1st Zero Reading	-18 (#15)	-18 (#15)
First Corrected	124	082
Second Measurement	138 (#16)	100 (#17)
2nd Zero Reading	-22 (#18)	-22 (#18)
Second Corrected	116	078
Average Corrected	120 (#19)	080 (#20)

O.M.B. 0925-0281
exp. 09/30/98

ARIC
Atherosclerosis Risk in Communities

LABORATORY FORM

A-339

ID NUMBER: | | | | | | | | CONTACT YEAR: | 1 | 0 | FORM CODE: | L | A | B | VERSION: B 03/26/96

LAST NAME: | | | | | | | | | | | | INITIALS: | | |

INSTRUCTIONS: This form should be completed on paper during the participant's visit.

A. MEDICAL HISTORY

1. Has a doctor ever said you had any of the following?

a. Kidney stones? ..... Yes Y
No N
Unknown U

b. Any other kidney disease, apart from a temporary infection? ..... Yes Y
No N
Unknown U

Go to Item 2.

c. Have you ever had a kidney transplant or been treated with dialysis for more than 6 months? .. Yes Y
No N

B. FASTING BLOOD DRAWING

2. Do you have any bleeding disorders? ..... Yes Y
No N
Unknown U

If Yes, specify in Item 16, Page 3.

3. Date of blood drawing: ..... | | | / | | | / | | |
month / day / year

4.a. Time of fasting blood drawing: ..... | | | : | | |
h h : m m

b. AM or PM: ..... AM A
PM P

5. Was fasting blood drawn before the glucola/snack? ..... Yes Y
No N

6. Number of venipuncture attempts: ..... ☐

7. Was the tourniquet reapplied? ..... Yes Y
No N

8. Phlebotomist ID: ..... ☐☐☐

C. BLOOD PROCESSING

9.a. Time at which specimen tubes 2-4 were spun: ☐☐:☐☐
h h : m m

b. AM or PM: ..... AM A
PM P

10.a. Time at which specimen Tube 1 was spun: ☐☐:☐☐
h h : m m

b. AM or PM: ..... AM A
PM P

11.a. Time at which specimen tubes 1-4 were placed in freezer: ☐☐:☐☐
h h : m m

b. AM or PM: ..... AM A
PM P

12.a. Time at which specimen Tube 6 was spun: ..... ☐☐:☐☐
h h : m m

b. AM or PM ..... AM A
PM P

13.a. Time at which specimen Tube 6 was placed in the freezer? ..... ☐☐:☐☐
h h : m m

b. AM or PM ..... AM A
PM P

14. Technician ID for fasting samples: ..... [ ][ ][ ]

15. Code number of technician processing post-glucose load samples: ..... [ ][ ][ ]

16. Comments on blood drawing/processing: ..... Yes Y
No N

If Yes, Specify: _____

D. URINE SAMPLE

17. Urine sample collected? ..... Yes Y
Go To Item 25. ——— No N

18. Date of urine sample: ..... [ ][ ]/[ ][ ]/[ ][ ]
m m / d d / y y

19.a. Time of urine sample: ..... [ ][ ]:[ ][ ]
h h : m m

b. AM or PM ..... AM A
PM P

20. Volume adequate for processing? ..... Yes Y
Go To Item 25. ——— No N

21. Creatinine/Albumin RECORD box number. ..... [ ][ ][ ]

22.a. Creatinine vial processed? ..... Yes Y
Go To Item 23.a. ——— No N

b. Creatinine POSITION number. ..... [ ][ ]

23.a. Albumin vial processed? ..... Yes Y
Go To Item 24. ——— No N

b. Albumin POSITION number. ..... [ ][ ]

24. Hemostasis vial processed? ..... Yes Y
No N

25. Technician ID for urine samples. ..... [ ][ ][ ]

Appendix 3.5b

(LABB screen 1 of 4)

A. MEDICAL HISTORY

1. Has a doctor ever said you had any of the following?

a~ Kidney stones? _ ☐

Yes (Y), No (N) or Unknown (U)

b~ Any other kidney disease, apart from a temporary infection? _ ☐

Yes (Y), No (N)* or Unknown (U)*

c~ Have you ever had a kidney transplant or been treated with dialysis for more than 6 months? _ ☐
Yes (Y) or No (N)

B. FASTING BLOOD DRAWING

2~ Do you have any bleeding disorders? _ ☐

Yes (Y), No (N) or Unknown (U)

3~ Date of blood drawing: _____ ☐
mm/dd/yy

4.a~ Time of fasting blood drawing: _____ ☐
hh:mm

b~ AM (A) or PM (P) _ ☐

(LABB screen 2 of 4)

5~ Was fasting blood drawn before the glucola/snack? _ ☐

Yes (Y) or No (N)

6~ Number of venipuncture attempts: _ ☐

7~ Was the tourniquet reapplied? _ ☐

Yes (Y) or No (N)

8~ Phlebotomist ID: ___ ☐

C. BLOOD PROCESSING

9.a~ Time at which specimen tubes 2-4 were spun: _____ ☐
hh:mm

b~ AM (A) or PM (P) _ ☐

10.a~ Time at which specimen Tube 1 was spun: _____ ☐
hh:mm

b~ AM (A) or PM (P) _ ☐

(LABB screen 3 of 4)

11.a~ Time at which specimen tubes 1-4 were placed in the freezer? _____ ☐
hh:mm

b~ AM (A) or PM (P) _ ☐

12.a~ Time at which specimen Tube 6 was spun: _____ ☐
hh:mm

b~ AM (A) or (PM) _ ☐

13.a~ Time at which specimen Tube 6 was placed in the freezer? _____ ☐
hh:mm

b~ AM (A) or PM (P) _ ☐

14~ Technician ID for fasting samples: ___ ☐

15~ Code number of technician processing post-glucose load samples: ___ ☐

16~ Comments on blood drawing/processing: _ ☐

Yes (Y) or No (N)
[IF YES, RECORD ON NOTE LOG]

D. URINE SAMPLE

17~ Urine sample collected? _ ☐

Yes (Y) or No (N)*

(LABB screen 4 of 4)

18~ Date of urine sample: _____ ☐
mm/dd/yy

19.a~ Time of urine sample: _____ ☐
hh:mm

b~ AM (A) or PM (P) _ ☐

20~ Volume adequate for processing? _ ☐

Yes (Y) or No (N)*

21~ Creatinine/Albumin RECORD box number: ___ ☐

22.a~ Creatinine vial processed? _ ☐

Yes (Y) or No (N)*

b~ Creatinine POSITION number: __ ☐

23.a~ Albumin vial processed? _ ☐

Yes (Y) or No (N)*

b~ Albumin POSITION number: __ ☐

24~ Hemostasis vial processed? _ ☐

Yes (Y) or No (N)

25~ Technician ID for urine samples: ___ ☐

Appendix 3.5c

INSTRUCTIONS FOR LABORATORY FORM
LAB, VERSION B, 03/26/96
PREPARED 05/16/97

I. GENERAL INSTRUCTIONS

The LABORATORY Form is completed during the participant's clinic visit to record information on the collection and processing of blood and urine samples. Technicians performing venipuncture and processing blood and urine samples must be certified and should have a working knowledge of the relevant Manuals of Operations. Technicians should also be familiar with and understand the document entitled "General Instructions for Completing Paper Forms" prior to completing this form. ID Number, Contact Year, and Name should be completed, as described in that document, prior to the arrival of the participant.

II. SPECIFIC INSTRUCTIONS

A. MEDICAL HISTORY

1.a The set of questions of kidney disease are repeated from the AFU Medical History form to update information that was collected previously. A positive response requires a physician diagnosis. The time frame is anytime prior to this interview. Read the question. It should not be necessary to define kidney stones. Continue with item 1.b.

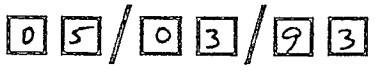
1.b Examples of other kidney (renal) diseases are kidney failure, diabetic kidney disease. If NO or UNKNOWN, go to Item 2. If YES, continue with Item 1.c.

1.c Read question and record response.

B. FASTING BLOOD DRAWING

2. If the participant has a bleeding disorder, consult with the field center physician, physician assistant or nurse practitioner before proceeding with the venipuncture. If the participant does not know whether he/she has a bleeding disorder, offer the explanation, "If you have a bleeding disorder you would have symptoms like excessive nose bleeds, or very easy bruising, or problems with bleeding after tooth extractions, or any type of surgery." If the participant is still unsure, consult with field center medical personnel before going on. Specify any bleeding disorders as briefly as possible in Item 16.

3. Note the date of blood drawing on the form. Code in numbers using leading zeros where necessary to fill all fields. For example, May 3, 1993 would be entered as shown below:



month day year

If the participant is rescheduled for another day, the actual date when blood is drawn should be entered.

4. Note the time of venipuncture on the form. This is the time when the vein is punctured. Fill in the fields using leading zeroes where necessary and indicate AM or PM.

5. Check the participant's Itinerary Sheet, or ask the participant if he/she has had the glucola or the clinic snack.

6. Include all venipuncture attempts by all phlebotomists. The same technician should not attempt a venipuncture more than twice.

7. Do not reapply the tourniquet during tubes #2 - #4. Only reapply the tourniquet after tube #4, and only if this is necessary to spare the participant another stick. Specify if a tourniquet reapplication occurred in Item 16.

8. The phlebotomist who performed the fasting blood drawing procedure enters his/her code number in the fields provided. If more than one phlebotomist attempts to draw the blood, enter the code of the first phlebotomist.

C. BLOOD PROCESSING

9. Note the time at which the centrifuge containing tubes 2-4 began to spin. Fill in the fields using leading zeroes where necessary and indicate AM or PM.

10. Note the time at which the centrifuge containing tube #1 began to spin. Fill in the fields using leading zeroes where necessary and indicate AM or PM.

11. Note the time at which samples from tubes 1-4 were placed in the freezer. Fill in the fields using leading zeroes where necessary and indicate AM or PM.

12. Note the time at which the centrifuge containing Tube 6 began to spin. Fill in the fields using leading zeroes where necessary and indicate AM or PM.

13. Note the time at which the sample from Tube 6 was placed in the freezer. Fill in the fields using leading zeroes where necessary and indicate AM or PM.

14. Enter the code number of the technician who began processing the fasting blood samples (tubes 1-4).

15. Enter the code number of the technician who processed the 2 hour post-glucose load sample (tube 6).

16. Include any clarifications or other information relevant to the assays being performed that are not included in the Fasting/Tracking Form (FTR), Medication Survey Form (MSR), or the Health History Form (HHX). This information will be keyed into the Venipuncture DES record. Be as clear and concise as possible.

D. URINE SAMPLE

17. Indicate whether a urine sample was collected. Urine samples that have remained at room temperature for more than 4 hours, or are not processed and placed in the freezer within 12 hours of collection must be discarded. In that case, enter NO and an explanatory note log. If the response category is NO, go to Item 25 and enter your technician ID. If YES, continue.

18. Enter the date on which the urine sample was collected using the standard date format.

19. Transcribe from the participant ID or TIME label on the urine sample container time (in hours and minutes) at which the urine sample was voided. Fill in the fields using leading zeroes where necessary and indicate AM or PM. If the participant voided twice, transcribe the latest time.

20. If urine sample is small, split between the creatinine and albumin vials. If sample is too small to process, select NO and go to Item 25.

21. Enter the RECORD (storage and shipping) BOX Number for the creatinine and albumin samples.

22. If the creatinine sample cannot be processed, select NO (Item 22.a) and go to Item 23.a. If creatinine is processed, record YES (Item 22.a) and the POSITION number of the creatinine aliquot vial in the storage and shipping box (Item 22.b).

23. If the albumin sample cannot be processed, select NO (Item 23.a) and go to Item 24. If albumin is processed, record YES (Item 23.a) and the POSITION number of the albumin aliquot vial in the storage and shipping box (Item 23.b).

24. If the urine sample for the Hemostasis Laboratory cannot be processed, select NO. If this urine sample is processed, select YES. Continue with Item 25.

25. Enter the code number of the technician who processed the urine samples.

MEDICAL DATA REVIEW PRINTOUT FOR ARIC VISIT 4

1. NAME (UPDB1B,C,D):
2. ID NUMBER:
3. DATE OF BIRTH (V1CORBIR):
4. DATE OF VISIT (FTRD1):
5. AGE IN YEARS (V1CORBIR,FTRD1):
6. PHYSICIAN NAME (UPDB15A,B): RICHARD HEDRICK
7. HEIGHT (ANTD1): CM FEET INCHES
8. WEIGHT (ANTD2): POUNDS

.....

9. AVERAGE SITTING BP (SBPD19/SBPD20): /
10. PARTICIPANT CURRENTLY TAKING ANTIHYPERTENSIVES (MSRD24A)?

.....

11. M.D. EVER SAID YOU HAD DIABETES (PHXB6C)?
12. M.D. EVER SAID YOU HAD CANCER (PHXB6F)?
13. [FOR FEMALES ONLY] UTERINE BLEEDING (RHXC4):

.....

14. HISTORY CONSISTENT WITH:

    A. ROSE QUESTIONNAIRE ANGINA:
    REPORTED SEEING AN M.D. BECAUSE OF CHEST PAIN, DURING LATEST AFU (AFUF15):
    IF YES, DATE OF PERTINENT AFU CALL (AFUF1 MM/YY):
    RECALLED CHEST PAIN/DISCOMFORT FROM LAST AFU CALL (HHXD2):
    HAS CHEST DISCOMFORT WORSENED IN THE PAST 2 MONTHS (HHXD3)?

    B. RECOGNIZED TIA OR STROKE:
    STROKE/TIA REPORTED DURING LATEST AFU (AFUF29)?
    IF YES, DATE OF PERTINENT AFU CALL (AFUF1 MM/YY):
    SINCE LAST VISIT, TOLD BY M.D. YOU HAD STROKE OR TIA (TIAE1)?
    DURING THIS TIME, DATE FIRST OCCURRED (TIAE2 MM/YY): /

    C. INTERMITTENT CLAUDICATION:
    CLAUDICATION REPORTED ON LATEST AFU (AFUF28=L):
    IF YES, DATE OF AFU CALL (AFUF1 MM/YY):

15. INVASIVE CARDIOVASCULAR PROCEDURE:

A. SINCE LAST VISIT, HAD HEART OR ARTERIAL SURGERY (HHXD4)?
CORONARY BYPASS (HHXD5A)?
OTHER HEART PROCEDURE (HHXD5B)?
(IF YES, SEE NOTE LOG)
CAROTID ENDARTERECTOMY (HHXD5C)?
SITE (HHXD5D)?
OTHER ARTERIAL REVASCULARIZATION (HHXD5E)?
BALLOON ANGIOPLASTY (HHXD6)?
ANGIOPLASTY OF CORONARY ARTERY (HHXD7A)?
ANGIOPLASTY OF NECK ARTERY (HHXD7B)?
ANGIOPLASTY OF LEG ARTERY (HHXD7C)?
CARDIAC CATHETERIZATION (HHXD8A)?
CAROTID ARTERY CATHETERIZATION (HHXD8B)?
OTHER ARTERIAL REVASCULARIZATION (HHXD8C)?
(IF YES, SEE NOTE LOG)

16. DIAGNOSTIC PROCEDURES:

SINCE LAST VISIT, HAD ECHOCARDIOGRAM (HHXD9A)?
ECG (HHXD9B)?
TREADMILL OR CARDIAC STRESS TEST (HHXD9C)?
CAROTID ULTRASOUND (HHXD9G)
MRI OF THE BRAIN (HHXD9H)?
CAT SCAN OF THE BRAIN (HHXD9I)?

.....

17. ECG: READ TRACING.

A. SIGNIFICANT FINDINGS IN PRELIMINARY INTERPRETATION:

_____

_____

_____

B. DIFFERENCES FROM PREVIOUS TRACING(S) ? NO _____ YES _____

IF YES, VISIT(S) __ __ __ SUMMARIZE _____

_____

C. WAS A PHYSICIAN NOTIFIED ? _____ NO _____ YES

IF YES, PHYSICIAN'S NAME _____ DATE _____/_____/_____

.....

18. M.D. REVIEW

M.D.'S INTERPRETATION OF ECG:

A. SUMMARY OF SIGNIFICANT FINDINGS _____

_____

_____

B. DIFFERENCES FROM PREVIOUS TRACING(S) ?

NO _____ YES _____ IF YES, SUMMARIZE _____

_____

19. OTHER SIGNIFICANT FINDINGS?

NO _____ YES _____ IF YES, SUMMARIZE _____

_____

20. WAS A REFERRAL MADE ? NO _____ YES _____

IF YES, SPECIFY ON REPORT AND REFERRAL FORM

---

21. CODE OF PERSON COMPLETING MEDICAL DATA REVIEW: ___ ___ ___

22. DATE OF MED. DATA REVIEW:

_____/_____/_____
MM DD YY

23. CODE OF M.D. REVIEWING THIS FORM: ___ ___ ___

24. DATE OF REVIEW BY M.D.:

_____/_____/_____
MM DD YY

Appendix 4b

ATHEROSCLEROSIS RISK IN COMMUNITIES

ARIC CENTER VISIT 4 REPORT

Last Name: Initials:

Date of visit: ARIC ID:

This is a summary of results of your ARIC exam today

Current Weight: pounds	Current Height: ft. in. (cm)
Visit 3 ( ) Weight: pounds	Visit 3 Height: ft. in. (cm)
Visit 2 ( ) Weight: pounds	
Visit 1 ( ) Weight: pounds	Visit 1 Height: 5 ft. 9 in. (176 cm)

Current Blood Pressure: / mm Hg (Averages of 2 measurements)

Visit 3 Blood Pressure: / mm Hg

Visit 2 Blood Pressure: / mm Hg

Visit 1 Blood Pressure: / mm Hg

The attached chart has been marked to show your blood pressure results. Please read it carefully and follow the recommendations highlighted for you.

Electrocardiogram: An ARIC physician will review your electrocardiogram and a copy will be sent to your physician with the rest of your results.

Ultrasound: If you had ultrasound today, portions of the arteries in your neck were video taped using ultrasound. Your study will be sent to our ultrasound reading center where measurements will be made. We will contact you if these measurements show that a blockage exists.

Other findings: ___ None ___ Yes, please make an appointment:

___ immediately ___ within one week ___ within 1 month or at first convenient appointment,

to discuss: _____

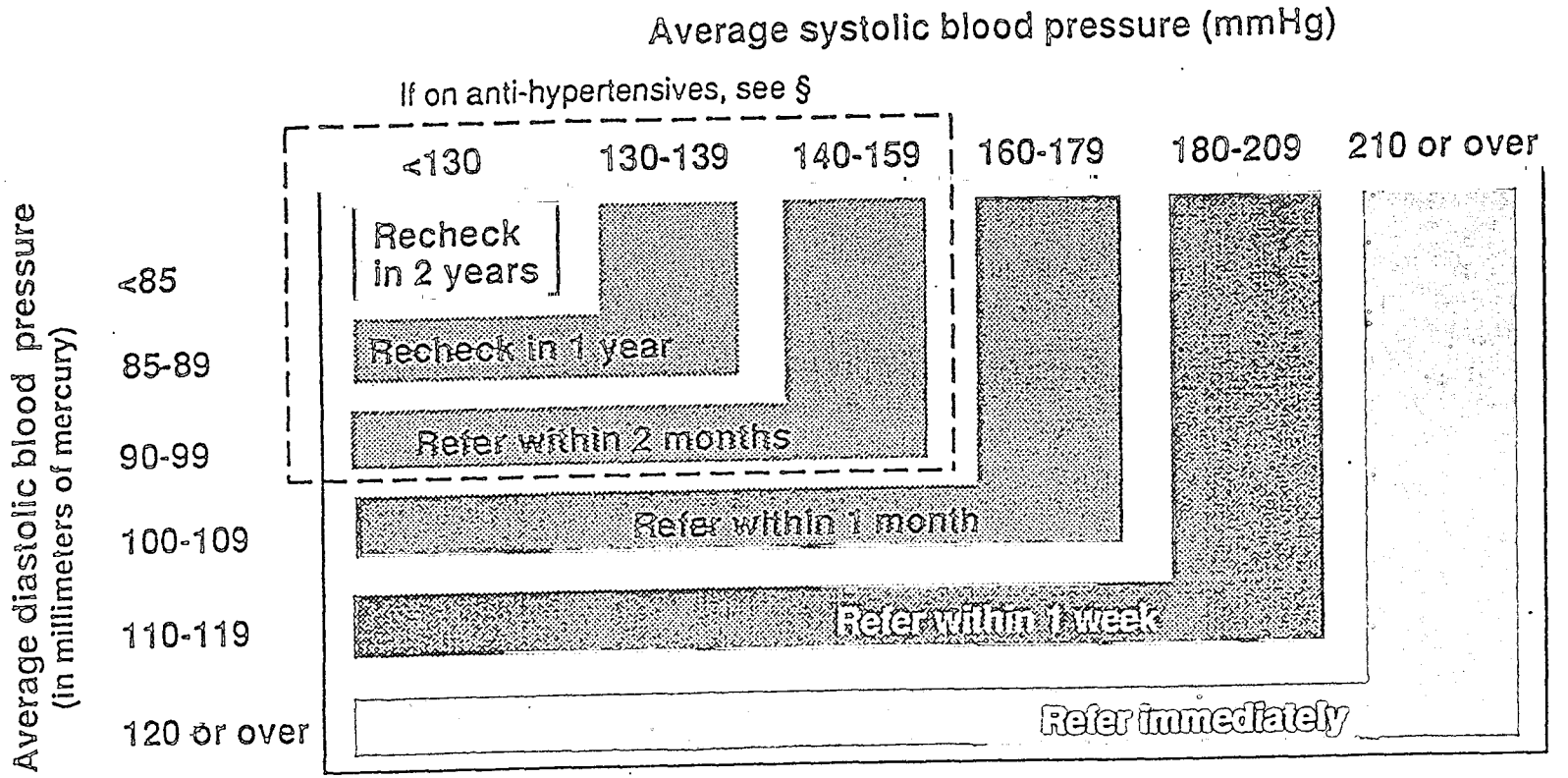
Staff Name and Signature _____ Date _____

Report on Your Blood Pressure and Follow-up Recommendations

(Based on the Fifth Report of the Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure)

Name: Your blood pressure is: ____/____ mmHg

Please follow the recommendation panel highlighted for you. Health Care Provider: _____



§If the participant is on anti-hypertensive treatment and blood pressures are in the range identified by the interrupted line, follow the schedule recommended by the participant's physician.

Appointment needed: Yes No Staff ID _____

Appointment Scheduled: _____ (date) _____ (time) Date ____/____/____

Appendix 5a

Atherosclerosis Risk in Communities

ARIC VISIT 4 RESULTS FOR PARTICIPANTS AND THEIR PHYSICIANS

Participant's name: pt full name~

Date of visit to the ARIC center: dov~

Birth date: dob~ Our Reference (ARIC ID): aric #~

These are the results of your ARIC Visit 4 examination:

Weight: wt~ pounds Height: htft~ ft. htin~ in. (htcm~ cm)

Blood Pressure: sbp~ mm Hg (Average of 2 measurements).
systolic diastolic

* If on antihypertensive medication, and SBP <160 and DBP <100:

  "If you are being treated for high blood pressure, your physician may have given you a schedule for your next check-up. Please follow that schedule. Attached are national guidelines for action on blood pressure, for your information."

* If NOT on antihypertensive tx, SBP <130 and DBP <85:

  "Your blood pressure was normal. Please recheck it in two years"

* If NOT on antihypertensive tx, SBP 130-139 and DBP 85-89:

  "Your blood pressure was high normal. Please recheck it in one year."

* If NOT on antihypertensive tx, SBP 140-159 or DBP 90-99; choose SBP or DBP, whichever falls in the higher category.

  "Your reading was elevated. At the time of your ARIC visit, we indicated that you should have your blood pressure checked within two months by a physician."

* If SBP 160-179 or DBP 100-109; choose SBP or DBP, whichever falls in the higher category.

  "Your reading was elevated. At the time of your ARIC visit, we indicated that you should have your blood pressure checked within a month by a physician."

* If SBP 180-209 or DBP 110-119; choose SBP or DBP, whichever falls

in the higher category.

"Your reading was clearly and importantly elevated. At the time of your ARIC visit we indicated that you should see your physician within one week, to determine whether treatment should be started or changed. If you have not done so already, please see your physician soon."

* If SBP≥ 210 or DBP≥120; choose SBP or DBP, whichever falls in the higher category.

"Your blood pressure reading was very high. At the time of your ARIC visit we indicated that you must see your physician at the earliest opportunity to confirm this finding. If you have not done so already, please see your physician at once."

Electrocardiogram:

A. Normal ECG, participant has physician:

"Your electrocardiogram is normal or has insignificant findings. Your electrocardiogram has been sent to your physician with a copy of this report."

B. Normal ECG, participant does not have a physician:

"Your electrocardiogram is normal or has insignificant findings. Your electrocardiogram is enclosed."

C. Abnormal ECG, has physician:

"Your electrocardiogram has an abnormal finding but shows no significant changes since your last ARIC visit. Your electrocardiogram has been sent to your physician with a copy of this report."

D. Abnormal ECG, participant does not have a physician:

"Your electrocardiogram has an abnormal finding but shows no significant changes since your last ARIC visit. Your electrocardiogram is enclosed."

E. Some changes since previous visit, participant has physician:

"Your electrocardiogram indicates some changes since your last ARIC visit, but there is no need for you to see your physician unless s/he requests it. Your electrocardiogram has been sent to your physician."

F. Some changes since previous visit, participant does not have a physician:

"Your electrocardiogram indicates some changes since your last ARIC visit, but there is no need for you to see your physician at this

time. Your electrocardiogram is enclosed."

G. Important changes on ECG, participant has physician:

"Your electrocardiogram shows some findings not seen in your last ARIC visit. Please check these results with your physician if you have not already done so. Your electrocardiogram has been sent to your physician."

H. Important changes on ECG, participant does not have a physician:

"Your electrocardiogram shows some findings not seen in your last ARIC visit. Please check these results with a physician if you have not already done so. Your electrocardiogram is enclosed."

B-Scan Ultrasound examination of the arteries:

* If not done in Visit 4:

"Your ultrasound examination was done during your ARIC Visit 3 clinic visit."

* If Routine (no alert values):

"The ARIC study performs a limited ultrasound examination of portions of the carotid arteries (blood vessels in the neck). We found no blockage in the artery segments examined. We consider blockage to be present if the opening of an artery is reduced to 2 millimeters or less."

* If Alert:

"We have previously sent a report suggesting that you see your doctor about a finding noted in your ultrasound examination of the arteries in the neck."

* If the ultrasound has not been received by xx weeks of the visit date:

"The ARIC study performs a limited ultrasound examination of portions of the carotid arteries (blood vessels in the neck). We have not yet received the results of your ultrasound examination from the Ultrasound Reading Center. This report will be sent to you by separate letter when available. We apologize for the delay."

* If the ultrasound has not been received by xx weeks of the visit date and ultrasound is to be reported unless abnormal:

"The ARIC study performs a limited ultrasound examination of portions of the carotid arteries (blood vessels in the neck). We have not yet received the results of your ultrasound examination from the Ultrasound Reading Center. As soon as we have this report we will contact you if any blockage of the artery is found. We consider blockage to be present if the opening of an artery is

reduced to 2 millimeters or less. Unless you hear from us you can assume that no abnormality was detected in the ultrasound scan."

aric #~

Blood Tests	Your Value	Reference Range
Total Cholesterol (mg/dL)	chol~	Less than 200: Desirable 200 - 239: Mildly elevated 240 or more: Markedly elevated
LDL cholesterol (mg/dL)	ldl~	less than 130
Total HDL cholesterol (mg/dL)	hdl~	greater than 35
Triglycerides (mg/dL)	trig~	less than 220
Creatinine (mg/dL)	creat~	Males 0.5 to 1.4 Females 0.5 to 1.1
Fasting Glucose (mg/dL)	fast gluc~	70 - 130
Two-Hour Post Glucose Load (mg/dL) (75 grams of oral glucose)	2-hr gluc~	70 - 140

Total cholesterol, LDL-cholesterol and triglycerides are the major fats in your bloodstream. High density lipoprotein (HDL) cholesterol is also a blood fat that appears to protect against hardening of the arteries. The level of Creatinine in your blood is an indirect measure of your kidney function. Glucose is your blood sugar and is altered in conditions such as diabetes. The glucose load test is used to detect diabetes, by drinking a known amount of glucose while fasting, and measuring the blood glucose level two hours later.

8. If All chemistries are in the reference range:

   "Your blood test results are all normal."

9. If Some in the Gray Zone but not significant:

   "Your blood test results show no significant abnormalities."

10. If Some in the significant range:

    "Your results show at least one value outside of the usual range, identified by an asterisk (*). You may want to check with your physician about this."

11. If Alert values:

"Your results show a value outside of the usual range, identified by double asterisks (**). You should check with your physician about this soon, if you have not already done so."

12. If Alert value(s) and one or more (non-alert) values outside the reference range:

"Your results show a value outside of the usual range, identified by double asterisks (**). You should check with your physician about this soon, if you have not already done so. In addition, your results show at least one value slightly outside of the usual range, identified by an asterisk (*). You may want to check with your physician about this."

Appendix 5b

ATHEROSCLEROSIS RISK IN COMMUNITIES STUDY

FORSYTH CO. N. CAROLINA | JACKSON MISSISSIPPI | SUBURBAN MINNEAPOLIS MINNESOTA | WASHINGTON CO. MARYLAND

2060 Beach Street
Winston-Salem, NC 27103
(910) 777-3040

SCHEDULE FOR REPORTING YOUR ARIC RESULTS

AT THE END OF YOUR CLINIC VISIT YOU WILL RECEIVE A SUMMARY OF:

HEIGHT AND WEIGHT
BLOOD PRESSURE
ELECTROCARDIAGRAM (PRELIMINARY REPORT)

YOUR TESTS WILL BE SENT TO SPECIALIZED LABORATORIES FOR MEASUREMENTS AND INTERPRETATIONS. APPROXIMATELY 10 TO 12 WEEKS AFTER YOUR VISIT DATE, A FULL SUMMARY WILL BE REPORTED TO YOU AND YOUR PHYSICIAN. IT WILL INCLUDE THE FOLLOWING:

HEIGHT AND WEIGHT
BLOOD PRESSURE
ELECTROCARDIAGRAM

BLOOD TESTS:
TOTAL CHOLESTEROL, LDL CHOLESTEROL, HDL CHOLESTEROL, TRIGLYCERIDES, RESULTS OF GLUCOSE TOLERANCE TEST, CREATININE, AND HEMATOLOGY WHICH INCLUDES: HEMOGLOBIN (HGB)
HEMATOCRIT (HCT)
WBC

ARIC
Atherosclerosis Risk in Communities

REPORT AND REFERRAL FORM

O.M.B. 0925-0281
exp. 09/30/98

ID NUMBER: | | | | | | | | CONTACT YEAR: | 1 | 0 | FORM CODE: | R | E | F | VERSION: D 05/22/97

LAST NAME: | | | | | | | | | | | | | INITIALS: | | |

INSTRUCTIONS: This form should be completed during the participant's visit. ID Number, Contact Year, and Name must be entered above. Whenever numerical responses are required, enter the number so that the last digit appears in the rightmost box. Enter leading zeroes where necessary to fill all boxes. If a number is entered incorrectly, mark through the incorrect entry with an "X". Code the correct entry clearly above the incorrect entry. For "multiple choice" and "Yes/No" type questions, circle the letter corresponding to the most appropriate response. If a letter is circled incorrectly, mark through it with an "X" and circle the correct response.

REPORT AND REFERRAL FORM (REFD screen 1 of 1)

A. VISIT 4 CLINIC EXAMINATION

1. Referral/alert made at Visit 4? ..... Yes Y
   No N
   → Go to Item 3

2. Was a referral made for:

	Yes	No	Not Done
a. Blood pressure	Y	N	U
b. ECG	Y	N	U
c. TIA/stroke in last 6 months	Y	N	U
d. Ultrasound	Y	N	U
e. Fasting Glucose	Y	N	U
f. Oral Glucose Tolerance Test	Y	N	U
g. Lipids	Y	N	U
h. Other chemistries	Y	N	U
i. Other conditions, please specify below.	Y	N	U

j. _____

B. ADMINISTRATIVE INFORMATION

3. Date of data collection: ..... | | | / | | | / | | |
   month day year

4. Method of data collection: ..... Computer C
   Paper form P

5. Code number of person completing this form: ..... | | | |

6. Outcome of Ultrasound:
   Normal ..... N
   Abnormal ..... A
   Not Done ..... U
   Delayed ..... D

7. Outcome of ECG review:
   Normal ..... N
   Abnormal but Unchanged ..... A
   Changed but Insignificant I
   Abnormal/Significant change .. S
   Not Done ..... U

ARIC
Atherosclerosis Risk in Communities

ARIC ALERT/REFERRAL LOG

O.M.B. 0925-0281
exp. 10/31/95

A-360

ID NUMBER: | | | | | | | | CONTACT YEAR: | | | FORM CODE: A L T VERSION: B 11/17/92

LAST NAME: | | | | | | | | | | | | INITIALS: | | |

Date Received: ___/___/___ mm dd yy

Alert Value: Item: _____ Value: _____

Referral/Action: __No __Yes > __Immediate __Urgent __Routine

Date of Action: ___/___/___ mm dd yy

Notes _____

Initials: __ __ __

Date Received: mm ___/___/___ ~~dd~~ yy

Alert Value: Item: _____ Value: _____

Referral/Action: __No __Yes > __Immediate __Urgent __Routine

Date of Action ___/___/___ mm dd yy

Notes _____

Initials: __ __ __

Date Received: ___/___/___ mm ~~dd~~ yy

Alert Value: Item: _____ Value:

Referral/Action: __No __Yes > __Immediate __Urgent __Routine

Date of Action ___/___/___ mm dd yy

Notes _____

Initials: __ __ __

Date Received: ___/___/___ mm ~~dd~~ yy

Alert Value: Item: _____ Value:

Referral/Action: __No __Yes > __Immediate __Urgent __Routine

Date of Action ___/___/___ mm dd yy

Notes _____

Initials: __ __ __

Participant called on __/__/__ Call taken by __ __ __. Notes _____

Participant called on __/__/__ Call taken by __ __ __. Notes _____

Ppt's MD called on __/__/__ Call taken by __ __ __. Notes _____

ARIC called Ppt. on __/__/__ Call made by __ __ __. Notes _____

ARIC called Ppt's MD __/__/__ Call made by __ __ __. Notes _____

Appendix 5d

(REFD screen 1 of 1)

A. VISIT 4 CLINIC EXAMINATION

1~ Referral/alert made at Visit 4? _ []
Yes (Y) or No (N)*

2. Was a referral made for:
Yes (Y), No (N) or Not Done (U)

a~ Blood pressure _ []
b~ ECG _ []
c~ TIA/stroke in last 6 months _ []
d~ Ultrasound _ []
e~ Fasting Glucose _ []
f~ Oral Glucose Tolerance Test _ []
g~ Lipids _ []
h~ Other chemistries _ []
i~ Other conditions,
please specify below _ []
j~ _____ []

B. ADMINISTRATIVE INFORMATION

3~ Date of data collection: _____ []
mm/dd/yy

4~ Method of data collection: _ []
Computer (C) or Paper (P) Form

5~ Code number of person
completing this form: ___ []

6~ Outcome of Ultrasound: _ []
Normal(N) Abnormal(A)
Not Done(U) Delayed(D)

7~ Outcome of ECG review: _ []
Normal(N) Abnormal but Unchanged(A)
Changed but Insignificant(I)
Abnormal/Significant change(S)
Not done(U)

Appendix 5f

INSTRUCTIONS FOR THE REPORT AND REFERRAL FORM AND THE ALERT/REFERRAL LOG
REF, VERSION D, 05/22/97
ALT, VERSION A, 11/17/92
PREPARED 06/20/97

I. GENERAL INSTRUCTIONS FOR REPORT/REFERRAL FORM

The purpose of this form is to keep a record -- at each field center and in the collaborative ARIC data base -- of notifications to ARIC participants of alert values, and/or study results which led to a medical referral. These alert values and referrals are those defined in the study protocol and are standardized throughout the study. Changing a referral value or alert action requires a revision of the ARIC study protocol, and approval by the Steering Committee. However, referrals of ARIC study participants to their provider of medical care occur also for conditions not contemplated in the study protocol, and based on the clinical judgement of the ARIC physician assistant/nurse clinician, after review by the ARIC physician or medical director. These types of referrals are also recorded on this form, under "other conditions".

Alert values reported to the field center result in expedited notification to the participant and the provider of care, and these values/actions are recorded on this form. If any emergent or urgent referrals were made at the time of the examination, these too are recorded on this form. Once the majority of the reports and study results have been obtained from the local laboratory, the central laboratory and the central reading agencies (ECG, ultrasound), a final report to the participant and provider of medical care are printed, and mailed. A summary of the medical alerts and referrals which have resulted from a participant clinic visit is collected on the Report and Referral Form. The optimal time to fill out and/or key in the Report and Referral Form is once the majority of the results have been received at the field center and a final report to the study participant is prepared.

At the time of preparing the final report on study results to the participant, not only are the possible alerts and referrals for the current visit reviewed -- in order to select the appropriate letter and report to the participant -- but study results from the prior visits are also examined to determine whether any values have changed by a reportable amount (see study protocol).

A new response category (Delayed) has been added to the response categories for ultrasound studies on the Report and Referral Form to permit the provisional documentation of a delay in its receipt when all other study results have been received and a participant results report would routinely be prepared. This information in turn triggers the inclusion of the paragraph in the results report which informs participants that there has been a delay in the receipt of their ultrasound results and they will be notified only if there is an abnormal finding.

In addition to tracking alerts and referrals the Report and Referral Form is used to record

medical and safety events. Occasionally a participant may report the onset of symptoms while at the field center, or other medical or safety events may occur (such as falling). These are annotated on the Report and Referral Form to allow tracking by the data entry system (DES). The event is recorded in the notelog for Item 1 whenever a participant experiences a medical or safety event at the field center, or contacts the field center to report a symptom occurring shortly after the clinic examination. See Section II for specific instructions.

II. DETAILED INSTRUCTIONS FOR EACH ITEM IN REPORT AND REFERRAL FORM

A. VISIT 4 CLINIC EXAMINATION

1. **Referral/alert made at this time?** Item 1 is a summary of Visit 4 referrals and/or alerts. Record YES if either an alert value or a medical referral has been given or sent to the participant and/or sent to his/her provider of medical care. No distinction is made on this form between an alert or medical referral, the time at which it was made (i.e., during the Medical Data Review or in a subsequent results report), nor is any difference made between the degree of urgency indicated on the medical referral. "At this time" refers to the time when the field center physician assistant/nurse has determined that all study results have been received for the participant, from all laboratories and central reading agencies. If no routine reporting of results is expected from a central reading agency, "at this time" implies that sufficient time has elapsed for the receipt of any possible alert notifications from that agency for this participant.

   If any referral and/or alert notifications were made for Visit 4, or are being made at this time, record YES, and continue with Item 2. Otherwise, record NO and complete the administrative items (Items 3-7) in Section B.

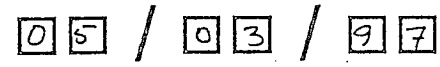
   When medical or safety incidents occur, attach a notelog to Item 1. In this notelog, provide as much detail and clarifying information as possible. If you are uncertain as to whether or not a particular circumstance should be recorded as a medical or safety issue, enter the information. Please note that this process is independent of the Report and Referral system, and one should err on the side of completeness. The notelog can be attached to Item 1 regardless of whether the response to this item is "yes" or "no". Since item 1 on REF can trigger a skip, care should be taken to verify that the notelog is entered for Item 1, and not another item.

2. **Was a referral made for ..."** In recording the type of referral and/or alert in items 2.a through 2.l, answer YES, NO or NOT DONE for every type of report. For this purpose, consider an alert or medical referral as any notification in a letter, phone call, or report calling the participant's or his/her physician's attention to a value measured in the clinic, in a local laboratory, or in a central reading agency/laboratory, and identifying it as a value which is either outside of the expected range or requiring follow-up and/or treatment. Typically, medical referrals by the ARIC Study suggest that a measurement should be repeated (within a

recommended period of time) or brought to the attention of the participant's physician for verification and/or follow-up. This constitutes a medical referral to be recorded on this form, for the specific type of study result listed under 2.a through 2.h. Part I (other conditions) serves to record any examination or laboratory findings not contemplated in the study protocol referral guidelines, which prompted a notification of the participant and/or his/her physician. Specifically included under (part I) are referrals due to uterine bleeding.

B. ADMINISTRATIVE INFORMATION

3. **Date of data collection.** Enter the date on which this referral form is being completed. Code in numbers using leading zeroes where necessary to fill all boxes. For example, May 3, 1997, would be entered as:



month day year

4. **Method of data collection.** Record "C" if the form was completed on the computerized data entry system, or "P" if the paper form was used. If the form was completed partially on paper and partially on the computer, code as "Paper Form."

5. **Code number of person completing this form.** The person at the clinic who has completed this form must enter his/her code number in the boxes provided.

6. **Outcome of Ultrasound** scan. Record the result of the participant's Visit 4 ultrasound scan ("N" for normal, "A" for abnormal) as soon as the report is received from the Ultrasound Reading Center. Record "U" when no scan was performed, or "D" for delayed receipt if the ultrasound reading is not available when the REF form is keyed and the results report is generated. The outcome status of the ultrasound study (Item 6), and if the study is abnormal, the referral/alert status (Item 1) and the referral indicator (Item 2) are revised in the DES update mode when the result is received from the Ultrasound Reading Center . Note that it is not possible for the URC to compare the results from the Visit 4 ultrasound exam with those from a previous exam, as is indicated in the "abnormal" results letter that is sent to the participant and his/her physician.

7. **Outcome of ECG Review.** Record the results of the participant's Visit 4 ECG after it has been reviewed by the ARIC clinician responsible for this review. Abnormal ECG tracings are compared with prior ECG tracings and results prior to being reported to the participant and his/her physician. A "U" is recorded when a participant does not have an ECG. Normal ECGs are coded as "N". There are three codes for abnormal ECGs. The selection is based on the advice of the ARIC clinician: "A" for abnormal, but unchanged from a previous tracing; "I" for abnormal or changed, but clinically insignificant in the opinion of the ARIC clinician; and "S" for abnormal that represents an abnormality that is new at Visit 4 or is a significant and clinically relevant change from a previous ARIC ECG.

III. ARIC ALERT/REFERRAL LOG

This log helps the ARIC field center clinician to keep track of alert values received after a participant's clinic visit; to record the action taken and the date of this action, as well as to identify the individual who is responsible for the course of action taken. This portion of the alert/referral log has been used during cohort Visits 1-3, and has not been revised. The information recorded on this log reflects the transactions by the ARIC field center clinician, consultations with the ARIC physician and/or medical director, and also serves to record notes of relevance to this process. These notes are often consulted when a participant calls to request results and/or clarification on results, and/or when the field center clinicians interact with the community practitioners and other providers of medical care of ARIC participants.

This alert/referral log is kept in the participant's file folder and is retrieved when results and/or alert values are received; when reports and/or letters to participants and their physicians are prepared; when the data are entered on the Report and Referral Form (screen); and when phone calls require a quick overview of the participant's medical information and the actions taken. The latter has been taken into consideration by expanding the record of phone calls at the bottom of the alert/referral log, for the convenience of the ARIC clinicians.

Appendix 6a

date~

md full name~
md address~

Dear Dr. md last name~:

We saw your patient, pt full name~, in the ARIC Study clinic on visit date~. During the course of our evaluation, the following problems were identified which we believe need attention:

md finding~

The ARIC Study does not provide diagnoses, medical advice, nor treatment. We have recommended to mr./mrs. last name~ that he/she~ contact you within three weeks to determine how to follow up on these results.

Should you have any questions, please feel free to contact us at 777-3040. A full report with results of our tests will be forwarded when available.

Sincerely,

Carolyn Pedley, MD
Medical Director

date~

pt full name~
pt address~

Dear mr./mrs. last name~:

Since your examination at the ARIC Study on visit date~ we have obtained some results of your studies. Your pt finding~ revealed a finding which should be discussed with your physician.

According to your instructions during the ARIC visit we have forwarded a copy of these results to Dr. md last name~. We suggest that you contact him/her~ within three weeks to determine how to follow up on these results.

Should you have any questions, please feel free to contact us at 777-3040. A full report with results of our tests will be forwarded when available.

Sincerely,

Carolyn Pedley, MD
Medical Director

Appendix 6c

date~

pt full name~
pt address~

Dear mr./mrs. last name~:

Since your examination at the ARIC Study clinic on visit date~ we have obtained some results of your studies. Your pt finding~ revealed a finding which should be discussed with a physician.

Because the ARIC Study does not provide any clinical diagnosis nor treatment, we offer to send all relevant information to participants' usual sources of medical care. During your ARIC Study visit you indicated that we should send these results to you.

We encourage you to consult your physician or usual source of medical care. If you do not have a personal physician or do not know where to find one we suggest that you call Health On Call at 716-2255 or Health Connections at 760-0122.

Should you have any questions, please feel free to contact us at 777-3040. A full report with results of our tests will be forwarded when available.

Sincerely,

Carolyn Pedley, MD
Medical Director

date~

md full name~
md address~

Dear Dr. md last name~:

pt full name~, a patient of yours, is a participant in the ARIC Study and was seen at our Field Center on visit date~. Attached to this letter is a report of the results of this examination.

The ARIC Study routinely offers to send all clinically relevant data to the participant's physician. Mr./Mrs. last name~ has indicated that we should send these results to you. We also mailed a letter to Mr./Mrs. last name~ to report that no abnormalities were found for any items covered by the ARIC Study examination, and that the enclosed results were sent to you.

The ARIC Study examination procedures are designed exclusively for epidemiologic research. Our study procedures do not substitute for a clinical examination, nor does the study provide any diagnosis or treatment. If a condition or laboratory test result is found that required diagnostic confirmation or possible treatment, the study participant is referred to pt his/her~ usual source of medical care.

As part of the ARIC Study follow-up protocol, Mr./Mrs. last name~ has agreed to be contacted by phone once a year. During this brief telephone interview, we will inquire about pt his/her~ general health, as well as any cardiovascular symptoms and hospitalizations during the year.

Thank you for your cooperation.

Sincerely,

Carolyn Pedley, MD
Medical Director

Enclosures

Appendix 7b

date~

md full name~
md address~

Dear Dr. md last name~:

pt full name~, a patient of yours, is a participant in the ARIC Study and was seen at our Field Center on visit date~. Attached to this letter is a report of the results of this examination. We have indicated on the report the results we consider to be outside the normal range.

The ARIC Study routinely offers to send all clinically relevant data to the participant's physician. Mr./Mrs. last name~ has indicated that we should send these results to you. We have mailed a letter to Mr./Mrs. last name~ to report that one or more abnormal findings were noted during the ARIC Study examination and reported to you. We have also suggested that Mr./Mrs. last name~ contact you to determine if these findings need further study.

The ARIC Study examination procedures are designed exclusively for epidemiologic research. Our study procedures do not substitute for a clinical examination, nor does the study provide any diagnosis or treatment. If a condition or laboratory test result is found that requires diagnostic confirmation or possible treatment, the study participant is referred to pt his/her~ usual source of medical care.

As part of the ARIC Study follow-up protocol, Mr./Mrs. last name~ has agreed to be contacted by phone once a year. During this brief telephone interview we will inquire about pt his/her~ general health, as well as any cardiovascular symptoms and hospitalizations during the year.

Thank you for your cooperation.

Sincerely,

Carolyn Pedley, MD
Medical Director

Enclosure

date~

md full name~
md address~

Dear Dr. md last name~:

We saw your patient, pt full name~, in the ARIC Study center on visit date~. During the course of the B-mode ultrasound examination of the carotid arteries the enclosed findings were identified, which we believe need attention. Also enclosed is a copy of the letter we sent to your patient.

The ARIC Study does not provide diagnoses, medical advice, nor treatment. We have recommended to mr./mrs. last name~ that pt he/she~ contact you to determine how to follow up on these results.

Should you have any questions, please feel free to contact us at 777-3040. A full report with results of our tests will be forwarded when available.

Sincerely,

Carolyn Pedley, MD
Medical Director

date~

md full name~
md address~

Dear Dr. md last name~:

pt full name~, a patient of yours, is a participant in the ARIC Study and was seen at our Field Center on visit date~. Attached to this letter is our final report of the results of this examination. We have indicated on the report the results we consider to be outside the normal range.

The ARIC Study routinely offers to send all clinically relevant data to the participant's physician. Mr./Mrs. last name~ has indicated that we should send these results to you, and we have already reported to you about the previous referral~. We are now sending a final report indicating possible abnormal findings to Mr./Mrs. last name~, reminding pt him/her~ to contact you if pt he/she~ has not already done so.

The ARIC Study examination procedures are designed exclusively for epidemiologic research. Our study procedures do not substitute for a clinical examination, nor does the study provide any diagnosis or treatment. If a condition or laboratory test result is found that requires diagnostic confirmation or possible treatment, the study participant is referred to pt his/her~ usual source of medical care.

As part of the ARIC Study follow-up protocol, Mr./Mrs. last name~ has agreed to be contacted by phone once a year. During this brief telephone interview we will inquire about pt his/her~ general health, as well as any cardiovascular symptoms and hospitalizations during the year.

Thank you for your cooperation.

Sincerely,

Carolyn Pedley, MD
Medical Director

Enclosure

date~

pt full name~
pt address~

Dear Mr./Mrs. last name~:

Thank-you for taking part in the ARIC Study examination at our Field Center on visit date~. We appreciate your willingness to continue participating in this important study.

The results of your examination are summarized on the attached sheet. We are glad to report that no abnormalities were found among these measurements.

Because the ARIC Study does not provide any clinical diagnosis nor treatment, we offer to send all relevant information to participants' usual sources of medical care. According to your instructions during the ARIC Study visit, we have mailed these results to md full name~, for md his/her~ review.

Our staff will continue to call you once every year to stay in touch. Thank you again for being a member of the ARIC Study.

Sincerely,

Carolyn Pedley, MD
Medical Director

Enclosure

Appendix 7e

date~

pt full name~
pt address~

Dear Mr./Mrs. last name~:

Thank you for taking part in the ARIC Study examination at our Field Center on visit date~. We appreciate your willingness to join us in this important study.

The results of your examination are summarized on the attached sheet. One or more of the measurements, as shown on the sheet, ought to be reviewed by your physician to determine whether these findings should be studied further.

According to your instructions during the ARIC Study visit, we have mailed these results to Dr. md last name~. Because the ARIC Study does not provide any clinical diagnosis nor treatment, we suggest that you contact Dr. md last name~ to determine if the findings need further study.

Our staff will continue to call you once every year to stay in touch. Thank you again for being a member of the ARIC Study.

Sincerely,

Carolyn Pedley, MD
Medical Director

Enclosure

date~

pt full name~
pt address~

Dear mr./mrs. last name~:

Since your examination at the ARIC Study on visit date~ we have obtained additional results of your studies. The evaluation of your ultrasound study at our reading center revealed a finding which should be discussed with your physician.

(Alert for lumen narrowing to 2 mm or less)

A narrowing of the blood vessel(s) in your neck was found in the location from URC report~ artery. Such narrowing is most often associated with atherosclerosis (hardening of the arteries). While some narrowing is found in many people, the amount of narrowing identified in your study was greater than expected (residual lumen of 2 mm or less). We recommend that you consult with your physician to determine whether further evaluation or treatment is necessary.

(Alert for wall thickness of 2 mm or greater)

Thickening of the wall of the blood vessel(s) in your neck was found in the location from URC report~ artery. Such wall thickening is most often associated with atherosclerosis (hardening of the arteries). While some artery wall thickening is found in many people, the thickness found in your study was 2 mm or greater. Approximately 3 percent of the population have artery walls this thick. We suggest that you consult with your physician to determine whether further evaluation or treatment is necessary.

According to your instructions during the ARIC visit, we have forwarded a copy of these results to Dr. md last name~.
Should you have any questions, please feel free to contact us at 777-3040. A full report with results of our tests will be forwarded when available.

Sincerely,

Appendix 7f

date~

pt full name~
pt address~

Dear Mr./Mrs. last name~:

Thank you for taking part in the ARIC Study examination at our Field Center on visit date~. We appreciate your willingness to join us in this important study.

The results of your examination are summarized on the attached sheet. One or more of the measurements, as shown on the sheet, ought to be reviewed by your physician to determine whether these findings should be studied further.

According to your instructions during the ARIC Study visit, we have mailed these results to Dr. md last name~, and we have already reported to you and to Dr. md last name~ about the previous referral~. We are now sending a final report.

Because the ARIC Study does not provide any clinical diagnosis nor treatment, we suggest that you contact Dr. md last name~ to determine if the findings need further study.

Our staff will continue to call you once every year to stay in touch. Thank you again for being a member of the ARIC Study.

Sincerely,

Carolyn Pedley, MD
Medical Director

Enclosure

date~

pt full name~
pt address~

Dear Mr./Mrs. last name~:

Thank you for taking part in the ARIC Study examination at our Field Center on visit date~. We appreciate your willingness to join us in this important study.

Because the ARIC Study does not provide any clinical diagnosis nor treatment, we offer to send any relevant information to participants' usual sources of medical care. During your ARIC Study visit you indicated that we should send these results to you.

The results of your examination are summarized on the attached sheet. No abnormalities were found during the ARIC Study examination and the laboratory results are in the range considered normal. If you find that the attached report is not clear, please call us at 919-777-3040.

Our staff will continue to call you once every year to stay in touch. Thank you again for being a member of the ARIC Study.

Sincerely,

Carolyn Pedley, MD
Medical Director

Enclosure

Appendix 7h

date~

pt full name~
pt address~

Dear Mr./Mrs. last name~:

Thank you for taking part in the ARIC Study examination at our Field Center on visit date~. We appreciate your willingness to join us in this important study.

The results of your examination are summarized on the attached sheet. We have identified the results which are possibly abnormal. In most instances such a result does not mean that a medical problem exists. However, we believe that the enclosed report should be reviewed by a physician to determine whether these results should be confirmed or studied further.

Because the ARIC Study does not provide any clinical diagnosis nor treatment, we offer to send all relevant information to participants' usual sources of medical care. During your ARIC Study visit you indicated that we should send these results to you. We encourage you to consult your physician or usual source of medical care, to alert them to those results that we have highlighted for verification. If you do not have a personal physician or do not know where to find one we suggest that you call Health On-Call at 716-2255 or Health Connections at 760-0122.

Our staff will continue to call you once every year to stay in touch. Thank you again for being a member of the ARIC Study.

Sincerely,

Carolyn Pedley, MD
Medical Director

Enclosure

date~

pt full name~
pt address~

Dear mr./mrs. last name~:

Since your examination at the ARIC Study on visit date~ we have obtained additional results of your studies. The evaluation of your ultrasound study at our reading center revealed a finding which should be discussed with your physician.

(Alert for lumen narrowing to 2 mm or less)

A narrowing of the blood vessel(s) in your neck was found in the location from URC report~ artery. Such narrowing is most often associated with atherosclerosis (hardening of the arteries). While some narrowing is found in many people, the amount of narrowing identified in your study was greater than expected (residual lumen of 2 mm or less). We recommend that you consult with your physician to determine whether further evaluation or treatment is necessary.

(Alert for wall thickness of 2 mm or greater)

Thickening of the wall of the blood vessel(s) in your neck was found in the location from URC report~ artery. Such wall thickening is most often associated with atherosclerosis (hardening of the arteries). While some artery wall thickening is found in many people, the thickness found in your study was 2 mm or greater. Approximately 3 percent of the population have artery walls this thick. We suggest that you consult with your physician to determine whether further evaluation or treatment is necessary.

If you do not have a personal physician or do not know where to find one we suggest that you call Health On Call at 716-2255 or Health Connections at 760-0122.

Should you have any questions, please feel free to contact us at 777-3040. A report from our Ultrasound Reading Center is attached.

Sincerely,

date~

name of company/recipient~
address of company/recipient~

Dear Sir:

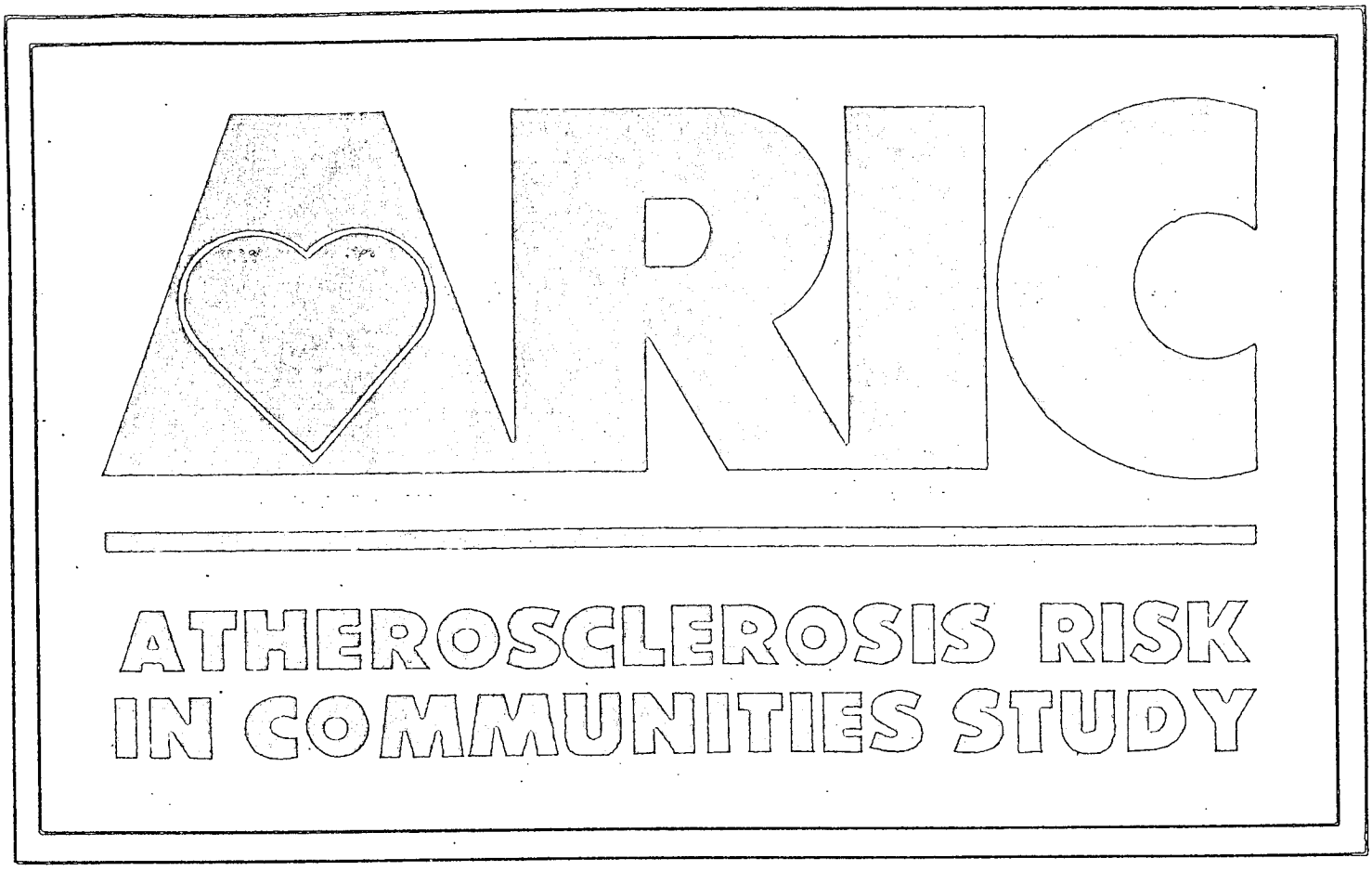
The enclosed information is provided to name of company/recipient~, per a written request dated date of request~ and signed by name of participant~, an ARIC study participant. This is a copy of the information provided on date of results report~ to name of participant~ and his/her~ provider of medical care.

The enclosed report represents part of the study results obtained during the ARIC clinic visit on date of exam~. The ARIC study does not offer medical diagnoses nor treatment. Any findings of medical relevance are, however, shared with the study participant and his/her physician. The additional information collected by the ARIC study represents data of research interest only.

Sincerely,

Carolyn Pedley, MD

c: name of participant~



Manual 14A
Retinal Photography

The National Heart, Lung, and Blood Institute
of the National Institutes of Health

Atherosclerosis Risk in Communities Study Protocol

Manual 14a

Retinal Photography

Visit 3

Version 1.0

August 1995

For Copies, Please Contact
ARIC Coordinating Center
Department of Biostatistics (CSCC)
University of North Carolina
CB# 8030, Suite 203, NationsBank Plaza
137 E. Franklin Street
Chapel Hill, NC 27514

FOREWORD

This manual, entitled Retinal Photography is one of a series of protocols and manuals of operation for the Atherosclerosis Risk in Communities (ARIC) Study. The complexity of the ARIC Study requires that a sizeable number of procedures be described, thus this rather extensive list of materials has been organized into the set of manuals listed below. Manual 1 provides the background, organization, and general objectives of the ARIC Study. Manuals 2 and 3 describe the operation of the Cohort and Surveillance Components of the study. Detailed Manuals of Operation for specific procedures, including those of reading centers and central laboratories, make up Manuals 4 through 11 and 13 through 15. Manual 12 on Quality Assurance contains a general description of the study's approach to quality assurance as well as the details for quality control for the different study procedures.

ARIC Study Protocols and Manuals of Operation

MANUAL	TITLE
1	General Description and Study Management
2	Cohort Component Procedures
3	Cohort and Community Surveillance
4	Pulmonary Function Assessment - (Retired)
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Manual 14a: Retinal Photography

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1.0 INTRODUCTION

The Atherosclerosis Risk in Communities (ARIC) Study is an epidemiological research study of the major factors contributing to the occurrence and trend of cardiovascular disease in middle-aged (age 35-74) adults in the United States and has two main objectives: (1) to investigate factors associated with both atherosclerosis and incidence of clinical cardiovascular disease, and (2) to measure coronary heart disease (CHD) occurrence and trends and relate them to community levels of risk factors, medical care and atherosclerosis.

The study will examine 14,500 subjects including men, women, blacks and whites. Examinations will be conducted in four US communities located in Forsyth County, North Carolina, Jackson, Mississippi, suburbs of Minneapolis, Minnesota and Washington County, Maryland. Follow-up examinations will be performed on the subjects remaining from the 4,000 persons (aged 45-64 at first examination) originally selected to represent each community.

Fundus photographs will be used to evaluate changes in the retinal vasculature (presumed to be related to hypertension and/or arteriolar sclerosis) that may be prognostic for various cardiovascular outcomes. Generalized and focal narrowing of arterioles and changes in arterio-venous (A/V) crossings will be evaluated. Although rare, signs of "malignant" hypertension (hemorrhages and micronaneurysms, "cotton wool spots," and swelling of the optic nervehead) will also be assessed. Other significant retinal conditions will be noted, such as diabetic retinopathy or vascular occlusions.

One 45 degree non-mydriatic (i.e., not requiring pharmacologic dilation of the pupil) retinal photograph will be taken of one eye of each of the 14,500 subjects. The photographs will be sent to the ARIC Retinal Reading Center for assessment of retinal status.

2

2.0 EQUIPMENT AND SUPPLIES

2.1 The Canon CR-45UAF Camera

A Canon non-mydriatic, auto-focus fundus camera with 35mm camera back will be used for this project. (A Polaroid camera attachment will be used during the training session to provide instant photo quality feedback.) The camera is mounted on a motorized instrument table to allow optimum alignment. Both photographer and subjects have pneumatically adjustable stools, the latter with a back rest.

The Retinal Reading Center has made one modification to the camera, the attachment of an aligning mask to the viewing monitor. The tranparent mask has two circles, labeled R and L, within which the photographer centers the optic disc of the right or left eye, respectively. The mask is taped to the monitor screen. It is easiest to attach the mask with the camera on and the external viewing function engaged. With the external viewing function engaged, the central viewing circles (used to align the pupil during photography) are visible and can be used to center the mask. The mask should be positioned with the right and left (R and L) circles equidistant from the viewing circles, and with the centers of the mask circles about 2 millimeters higher than the center of the concentric viewing circles. It is important to position the mask in relation to the viewing circles and NOT in relation to the edges of the monitor.

Additional transparent grids are available from Rose Brothers at the ARIC Retinal Reading Center, 610 North Walnut Street, Madison, WI 53705.

2.2 Supplies

Supplies can be divided into two categories: one-time purchases, and those bought on a repeat basis. One-time purchases include the Canon CR-45UAF fundus camera, adjustable table, two stools, and a camera cleaning kit containing a brush and air bulb for dust and lint removal.

A list of supplies that need to be reordered on a repeat basis follows:

(a) Slide film Kodak Professional Ektachrome 100 EPN, 36 exposure, is required.
(b) Photographic lens tissue
(c) Lens cleaning fluid (supplied by the Canon representatives)
(d) Kleenex tissues
(e) Spare view, flash and split lamps
(f) Bardes, side-loading, clear plastic slide mounting pages,#62022C, Bardes Products, Inc., 5245 West Clinton Avenue, Milwaukee, WI 53223
(g) Film roll processing labels (1" X 2")

2.2.1 Inventory

An inventory of supplies for each of 4 study centers, assuming an average of 3,625 subjects per center, follows:

(a)	36 Exp.Prof. Ektachrome 100 film	101 rolls (minimum)
(b)	Lens tissue	500 sheet package
(c)	Lens fluid	1 8oz. bottle
(d)	Facial tissues	10 boxes (200 tissues/box)
(e)	Spare lamps	1 flash, view and split
(f)	Film roll labels	101 (minimum)
(g)	Bardes plastic slide pages	362 20-pocket pages

2.3 Equipment Set-up

2.3.1 Daily Set-up Procedure

The camera dust cover and lens cap should be removed at the beginning of the day and the lens inspected and cleaned (see section 2.4.1) as necessary. Dust is the greatest enemy, producing the majority of artifacts on the photographs. When the camera is not in use, the lens cap should be in place and the special dust cover must remain on the camera. The 35mm camera back should be checked for sufficient battery power (see page 26 of the Operations Manual) and the film counter should be checked to be certain that the camera is loaded with film before beginning photography.

2.4 Care and Maintenance of Equipment

2.4.1 Lens and Camera Body Care

Before each photograph, the camera lens must be inspected and, if dirty, cleaned with the brush and air bulb to remove debris. Should more extensive cleaning of the lens be required, the lens can be fogged with your breath or moistened with absolute alcohol and then tissue should be used in a circular polishing motion until no dirt or oily film is visible on the lens when it is viewed from the front with the alignment lens removed and the view lamp on and turned up to its maximum intensity (see page 42 in the Operation Manual). The body of the camera should be kept clean and free of dirt with a soft cloth and water or a common spray cleaner like 409. The headrest may be cleaned with alcohol. The inside of the 35mm camera back is inspected for dirt and film fragments each time the film is changed. The air bulb or a puff of air is used to clean inside the camera back. The infra-red mirror relay lens assembly is cleaned as necessary to remove dirt or dust when seen on the display monitor. While these specks do not affect final photo quality, they are distracting and should be removed.

2.4.2 Instrument Table and Stools

The instrument table and stools can be kept clean by wiping with a common spray cleaner and a soft cloth. Occasionally the castors on the table and stools may squeak requiring a drop of light oil. The electric motor on the table requires no lubrication. The motor is protected by fuses that may need replacing should excessive current blow them out.

2.4.3 Flash, View and Split Lamp Concerns

It is anticipated that the flash, view and split lamps will fail at some point. Remember to keep all oil from your fingers off these lamps during replacement. The view and split lamp should last approximately one to two years and are easily replaced as needed. The flash lamp has a life of at least 5,000 flashes, enough to complete the study. Since the view and split lamps are relatively inexpensive bulbs, one spare for each should be ordered from Canon and kept at the field center. The flash lamp is expensive, and can be ordered from Canon when needed for overnight delivery.

As the flash lamp ages, the light output can diminish, producing progressively darker photographs. This can temporarily be over-ridden by an adjustment of the transformer output, though ultimately the lamp should be replaced. The decision to replace the lamp, due to dark photos, will be made with the Photography Consultant following routine review of processed photographs. The flash lamp requires careful handling during installation (the burnt out lamp may be hot, and the new lamp must be properly aligned), thus replacement should be attempted only by field center staff who have been trained to do this.

2.4.4 Film Concerns

The most consistent exposure will be obtained using a professional grade slide film such as Professional Ektachrome 100 (EPN). Professional grade films must be stored at a temperature of 55° F or lower. A conventional refrigerator is the perfect storage container for the Professional Ektachrome. Please remove the film from refrigeraton at least 1 hour (but no more than 24 hours) to allow it to warm to room temperature before use. This warming is necessary to prevent condensation inside the camera or film tearing which can occur when the film is cold.

You may also freeze this film if refrigerator space is at a premium. In this case, please be sure to remove any rolls at least 3 hours before use to allow ample time for the film to reach room temperature. During this time it is best to leave the frozen film in its plastic storage container to prevent condensation.

It is not necessary to refrigerate the film after exposure. Film should be developed promptly after the last exposure is taken.

2.4.5 Camera Malfunctions or Errors

Since the camera requires virtually no other maintenance, any malfunction will need to be investigated first by the examiners at each center and, when necessary, via telephone with the Retinal Reading Center Photography Consultant. Trouble-shooting tests can be performed in consultation with the consultant to diagnose any malfunction. Some camera malfunctions or photographer errors are not evident during photography and will only be discovered after examination of the processed films. This includes camera flash synchronization, transformer power settings, problems with a dirty objective lens or film loading problems. For this reason, prompt processing

of the film is important. A telephone link should be available between the photographers and the Photography Consultant at all times should a malfunction be discovered during the photography or following processing, or should the photographers have a problem or question needing immediate attention. The Photography Consultant, Michael Neider, can be reached at 608-263-9858 at the University of Wisconsin-Madison, Wisconsin. If he is not personally available, contact Ms. Rosemary Brothers (608-263-6976) instead. Service information can also be obtained directly from Canon USA in Itasca, Illinois or Lake Success, New York. Our contacts there are Tom Penkala, Canon USA, 100 Park Blvd., Itasca, IL 60143-2693, telephone number: 708-250-6230 or Ron Kaiser, Canon USA, 1 Canon Plaza, Lake Success, NY 11042-1113, telephone number: 516-328-4645.

3.0 EXAMINATION PROTOCOL

All subjects will have one 45-degree photograph taken of one eye. The eye to be photographed will be selected based on the subject's 6-digit ID number, excluding the check digit. When the ID number is even, the right eye will be photographed, and when it is odd, the left eye will be photographed. If the eye specified by this algorithm is considered too difficult to photograph with adequate photographic quality, the fellow eye should be photographed instead, and an explanatory note entered in the photography log. Conditions falling into this category are (based upon the technician's judgement): eye missing, inability to dilate at least 4 mm, inability to fixate adequately for proper photographic field definition, and opacities of the media preventing a reasonably clear view of the retinal vasculature.

3.1 Subject Exclusion

The photographer will attempt photography on subjects with poor visual acuity who may be unable to direct their gaze so that their nerve is properly positioned in the field alignment circle (as may be the case where both eyes are blind or when the subject is deaf and communication with them is impossible). In these cases, the photographer should get the best field definition possible remembering that it is better to have the nerve closer to the center of the picture than off too close to the edge. Additionally, the optic nerve can be displaced up or down by about 1/2 DD (disc diameter) and still provide useful information. If, in the photographer's judgement, no acceptable photograph can be taken, the subject will be excused from photography.

The photographer should attempt photography on those subjects who are physically disabled, provided that they can be comfortably positioned at the camera. To facilitate this, the subject may remain in a wheel chair positioned before the motorized camera table lowered to the appropriate height. Care should be taken when lowering the camera table to avoid pressing against the subjects legs. If, in the photographer's estimation, the subject can not be comfortably positioned, no photography will be performed.

3.2 Pre-examination Procedure

Before attempting photography, the photographer should become very familiar with the camera through a training session and by learning the terminology on pages 3 - 4 and 24 of the camera Operation Manual. The following protocol uses terminology from the Operation Manual and it is recommended that the entire manual be reviewed by each photographer performing photography.

The retinal camera should remain covered when not in use. <u>High humidity or temperatures must be avoided.</u> Dusty conditions mean that the camera will need frequent cleaning. The objective lens should be checked and cleaned with the air bulb if necessary <u>before each subject is photographed</u>. A more extensive cleaning is required to remove grease, smudges or stubborn spots from the lens. This cleaning requires removal of the lens "boot" and external

alignment lamp ring and should be referred to the chief photographer at each field center.

3.2.1 Subject Explanation and Informed Consent

Photography begins with a complete explanation of the procedure by the photographer. A Polaroid print may be useful to show what the optic nerve and retina looks like. It is important to reassure the subject that no retinal damage is caused by this procedure. The camera flash is bright and the subject should know when to expect a flash. The pictures will include the macula (area of central vision) and it is normal to experience a blue or red tint to vision immediately following the flash. This disappears within five to seven minutes. No dilation drops will be used for this examination, and the eyes will not be touched. A sample script of a typical retinal photography explanation (suitable for use as written material for deaf or interested subjects) follows:

> We will be taking a photograph of the inside of the back of one of your eyes (the retina) so we can study the blood vessels and look for any unusual changes. We will not be touching your eyes or be giving you any eye drops to take the picture. Instead, you will be asked to sit in a darkened room before a special camera with your chin in a chin rest. We darken the room so that your pupils will dilate and we can align and focus the camera on your retina. While your pupils are dilating, we may ask you some questions about your vision and the health of your eyes. During the aligning process you will only be aware of some small red lights and a blinking green light visible in the camera lens. We will ask you to follow the blinking green as we move it. Just before we take the picture, we will ask you to blink your eyes and then open them real wide. The camera will flash a bright flash from within the camera lens as the picture is taken.
>
> Just after the picture is taken, you may see a blue or red circular spot before the eye photographed. This will disappear within 5-7 minutes and causes no permanent damage to the eye. Please remember that we are taking only one picture (not an x-ray) of a small portion of one of your eyes and that this picture will not substitute as an eye examination. You will certainly be notified should we notice anything requiring immediate attention. Please continue to see your eye doctor on a regular basis for your complete eye examinations.

3.2.2 Completing the Retinal Artery Examination Form

Before photographing the subject, the photographer completes the first part of the ARIC Retinal Artery Examination Form (Example 5), which concerns the subject's ophthalmic history. The second part of the form records the circumstances of the photographic session, and can only be completed as the session begins. Part of the form can be completed while the subject becomes sufficiently dilated to be photographed. This will depend upon adequacy of ambient light for the photographer (to be able to read questions and record answers) and upon the time required to answer the questions.) In particular, if the assigned eye cannot be photographed for a reason gathered during the

ophthalmic history (e.g., that eye has been enucleated) or for a reason that emerges during the first part of the session (the assigned eye does not dilate sufficiently well to be photographed), the photographer indicates that the other eye has been selected and the reason for departing from the assignment. For logistical reasons, this form will be completed as a paper form, and later entered into the computer system.

3.2.3 Preparing the Camera

The video display is activated when the power switch on the side of the main unit is turned on. If no photography or switch operations are performed for 10 minutes, a power saving mode is activated, turning the lamps and display off to prevent unnecessary wear. During this power saving mode a "ready" lamp blinks on the monitor. Pressing any button below the arrows under the monitor, the joystick trigger, or the alignment button will reactivate the system.

Notice that three vertical arrows blink on the monitor when the main unit is switched on. This indicates the system is charging up. Do not take photographs until the blinking stops, indicating a fully charged flash. Pictures taken before the flash is fully charged will be severely underexposed.

The current date and subject ID number are displayed in the upper left-hand corner of the monitor. The camera contains an internal clock and the date will automatically change each day. The photographer must manually change the date if this clock should fail or if the camera is left unplugged for a long period of time. The date and time display is changed through Menu 3. The date format will read Month-Day-Year. The "Time Set" screen is used to adjust the current date and correct time. The camera is capable of recording a six-digit subject ID number (the ARIC ID with the field center number truncated), accessed through Menu 3, which must be reset for each subject photographed. Once properly entered into the camera, the number will appear below the date on the monitor. This number must be checked and adjusted before each subject is photographed because this information is recorded on each slide and will become a permanent part of the data slides and will become the primary identifier for each picture.

The 35mm camera body should be attached to the main unit and loaded with a fresh roll of Professional Ektachrome 100 EPN color slide film (36 exposures). The photographer needs to check that film is indeed loaded in the camera at the beginning of each photography session. The frame counter on the top of the camera will indicate the number of exposures taken. After 36 pictures are taken, the camera automatically rewinds the film. If the film needs to be removed before 36 exposures have been taken, a manual rewind button on the 35mm camera back (page 30 of the Operations Manual) needs to be depressed.

To load the camera, open the camera by sliding the camera latch down while pressing in on the cover lock button. Insert the new film cartridge in the left side and thread the film across the shutter to the right side, making sure that the film leader is aligned with the orange index mark. Be careful not to poke the shutter blades with a finger because damage to the blades can

easily occur. Take up any slack in the film by sliding excess film back into the cartridge. Close the back; the camera automatically threads the film and advances the film and counter to the number one exposure position. A blinking "check film back" warning on the monitor or blinking film marks on the camera back LCD display indicates the film is not loaded properly. In this case, reload the film. When the film is properly loaded, the camera back "reads" the film speed and automatically adjusts the flash output. At this point the photographer must press the "DSP" (for "display") button below the monitor to confirm that the following settings are correct:

```
BACK : RE 100 45          (35mm EOS body, 100 ASA, 45-degree field)
AF   : ON                 (autofocus on)
AE   : ON                 (autoexposure on)
BLINK: OFF                (blink detector off)
SPLIT : IN                (split focus detector in)
NO   : H 000001           (6-digit ARIC subject ID[1])
DATE : MM-DD-YY 12:00
```

The photographer will keep a manual film log on the ARIC Retinal Photography Log Form (example 1) kept in the camera room. This log file will include: film roll number, date, photographer ID number, subject name, subject ID number, eye photographed, and a comments section. Each roll of film will be assigned a unique roll number and will contain photographs of 36 subjects. Once a roll is completely exposed, it is removed from the camera and identified with a film roll number label for identification during processing and mounting.

3.3 Subject Photography

3.3.1 Subject Positioning and ID Entry

The subject and photographer are seated on the appropriate sides of the retinal camera. The subject is positioned so that he/she is comfortable with chin and forehead in the headrest. Chin height should be adjusted so that the eyes are approximately level with the height adjustment mark on the face rest pole. The room is darkened to the level where a newspaper can barely be read (equal to about 5 lux) and the camera room door is closed. The only light in the room should come from the display monitor. If a red lamp is used to aid the examiner during administration of the questionnaire, it must be turned off when photography is performed. While the subject begins to dilate, the photographer enters the last six digits of the subject ID (minus the prefix identifying the field center) into the camera via the number pad on the control panel, so that this can be imprinted at the edge of the photographic frame along with the date when the photograph is taken. After the number is entered, the photographer pushes pushes the "DSP" button (explained above) to

[1]The "H" before the subject ID number stands for "Hold," i.e., the camera holds the number until it is changed to another (rather than "C" for counting up automatically after each exposure). This letter is not available to be set to the code for the ARIC field center.

display the current camera values on the monitor, so that accuracy of subject ID entry can be checked.

3.3.2 Pupil Size and Alignment

The camera stage holding knob is unlocked, the alignment switch is turned on and the stage is moved to center the eye to be photographed horizontally and the height adjustment ring is used to position the eye vertically. The pupil should appear on the TV screen coincident with the central circle on the monitor. The camera joystick is moved forward or back until the pupil appears perfectly round. At this point, proper external alignment has been achieved. A pupil larger than the central 4mm circle on the monitor is required for adequate photography. If the eye assigned for photography does not dilate to at least 4mm after a 5-minute waiting period, the fellow eye should be examined for pupillary dilation as well. If dilation of the fellow eye is larger, the photographer will photograph it instead of the selected eye.

3.3.3 Fellow Eye Selection

For methodological reasons (approximately random and equal inclusion of right and left eyes) photography should be performed in the assigned eye whenever possible. The fellow eye should be selected only if characteristics of the assigned eye prevent a reasonably clear view of the retina. Such factors include poor pupillary dilation, as specified above, and substantial media opacities, including lens cataract, corneal irregularities, and opacities in the vitreous (e.g, vitreous hemorrhage). Assymetry of any other type (e.g., the fellow eye has more or less retinal pathology than the assigned eye) should be ignored when selecting the eye to be photographed. If the fellow eye is selected, an explanatory note must be written in the Photography Log Form.

3.3.4 Photography Through Small Pupils

The photographer will experience much more difficulty attempting photography through small (less than 4mm) pupils because all of the camera light doesn't enter thru the smaller pupil. This usually results in uneven illumination (seen as dark shadows) on the monitor. In this situation, the photographer must make careful camera adjustments to position the shadows as far away from the optic nerve as possible.

A small percentage of participants' eyes don't dilate the minimum 4mm required for adequate photography. Certain medication may prevent any dilation and the pupil size observed on the monitor may be 1-2mm, inadequate for the photographer to appreciate any retinal landmarks on the viewing monitor.

If no landmarks are visible, the photographer should adjust the camera slightly to position the corneal reflection dots slightly above or below their optimum position. This technique allows a portion of the illumination light (which falls on the iris when the pupil is small) to enter the eye. If any retinal landmarks become visible with this technique, a picture should be taken. However, if no retinal landmarks are visible, which is often the case

when dilation is less than 1.5mm, no picture is taken and the fellow eye is examined for dilation instead.

3.3.5 Exposure Compensations for Dark or Light Retinas

Photography of darkly pigmented retinas (black or Asian) will require increased flash output to avoid underexposed pictures. The photographer will press the "RE N" button under the main screen until a "+" appears in place of the "N" thus indicating a 1/3 f-stop increase in exposure. Photography of lightly pigmented retinas (blond, albino or Scandinavian) will require decreased flash output to avoid overexposed pictures. The photographer will press the "RE N" button on the main screen until a "-" appears in place of the "N" indicating a 1/3 f-stop decrease in exposure.

3.3.6 Internal Eye Alignment

Once proper external pupil alignment is achieved, the alignment switch is pressed to provide a view of the fundus, split focusing lines, corneal reflection dots, and the fixation light. If no split lines are seen, the height or left/right adjustment is improper, the "SPLT" (split lines) setting is set to "Out" (Menu 1), or the diopter compensating slider is pulled out. The split lines may fade in and out if the pupil is too small, the alignment of the camera is not centered on the pupil, or if the eyelashes or lids eclipse the light. If no corneal reflection dots are seen, the forward/backward adjustment is improper. The best photographs are obtained when the eye is well dilated, fixation is on the target; and lids and lashes are held wide open.

3.3.7 Focus with High Myopia or Hyperopia

The diopter compensation slide should be set to the "0" position for most eyes. This is the only setting in which the auto-focus mechanism works and allows photography of eyes with refractions between -12 and +15 diopters. In the event that the eye photographed falls outside this range and auto-focus cannot be achieved, as in the case of aphakia or high myopia, the diopter compensation slider must be adjusted for the clearest focus to the "+" or "-" position and the focusing knob is then turned manually to provide the sharpest image on the monitor. This can be facilitated by obtaining a brighter retinal image on the monitor by increasing the view light intensity. The normal setting for the view light intensity adjustment is approximately 4.

Standard TV monitor functions can be adjusted for the photographer's viewing comfort (including contrast and brightness) by opening the access door below the TV monitor. These are standard controls similar to those found on a home TV set and only effect viewing; they do not effect final photo quality.

3.3.8 Alignment, Focus and Proper Fixation

While viewing the fundus image on the screen, the photographer carefully adjusts the internal fixation target lever to position the optic nervehead (also called the optic disc) correctly on the screen. To facilitate consistent position of the optic disc, an aligning mask with two circles has

been added to the monitor. When the right eye is correctly positioned on the monitor, the disc falls into the right-hand circle. When the left eye is correctly positioned on the monitor, the disc falls into the left-hand circle. These aligning masks are provided by the Retinal Reading Center and, when properly attached to the monitor, they position the optic nerve centered from top to bottom and the nasal edge of the optic nerve falls between 1.50-2.00DD from the nasal edge of the photograph. If the photographer experiences difficulty placing the optic disc within the proper circle, it is preferable to have the disc shifted towards the center of the photographic field. Final confirmation of proper mask position is made at the Reading Center by measuring the optic nerve position on processed slides (not on the monitor).

Any fine adjustment of subject fixation is made by moving the fixation lever and instructing him/her to look into the lens of the camera at the green target light. In the event that the subject sees no fixation light with the eye being photographed, the photographer must carefully instruct the subject to make micro movements (fine movements up, down, left or right) until the disc falls into the appropriate circle.

Once the fixation is confirmed, the photographer must constantly adjust and position the camera to maintain the correct position of the corneal reflection dots. It is important that these dots be properly positioned at the three and nine o'clock positions before the picture is taken. This will ensure the correct distance from the eye and will allow a sharp image to be produced on the film. Focus is done automatically but should be confirmed by the photographer by assessing image sharpness and by checking the auto focus confirmation indicator (see page 18 of the Operation Manual) on the monitor.

3.3.9 Focusing Manually When The Auto-Focus Mechanism Doesn't Lock

When the auto-focus mechanism focuses the camera on the retina, a motor adjusts the focus knob until the auto-focus "locks" and a clear image is identified. This "lock" is confirmed in two ways. Two vertically stacked equal signs appear in the lower left-hand corner of the screen. Also, two rectangular boxes appear, stacked one on top of the other, in the center of the monitor.

If the operator notices that the auto-focus mechanism can't "lock" (obvious when the motor keeps running for several seconds and then shuts off) no vertically stacked equal signs appear and the auto-focus mechanism turns off. At this point you can manually focus the camera by turning the focus knob until the two rectangular boxes in the middle of the monitor appear stacked.

The photographer will instruct the subject to blink once or twice just before the picture is taken. This blinking will insure a moist (and subsequently clearer) cornea and will safeguard against unwanted blinks at the moment of exposure. Once alignment is satisfactory, the shutter release, located in the tip of the joystick, is depressed and the exposure is made. Only one eye on each subject is photographed.

3.3.10 Retake Policy

Should the photographer suspect that an inadequate photograph was taken (due to a possible blink, shadow, excessive movement or mis-alignment) or should the subject comment that they blinked or did not see the flash, the size of the pupil should be checked (a larger pupil indicates that no light reached the eye) and a second picture should be taken. In this situtation, the best picture is sent to the Retinal Reading Center.

6.0 LOGS AND RECORDS

6.1 Photography Log Form

A daily Photography Log Form (see Example 1) will be maintained for each roll of film to provide an accurate listing of each subject photographed. The complete log for each film roll will contain the film roll number, date, photographer ID number, subject name, subject ID number, eye photographed, and a comments section. The photographer is encouraged to comment on anything unusual such as strange artifacts, small pupil size, pathology or other problems. This information will be helpful in identifying specific photographs, and in understanding any artifacts that may appear on the processed slides. Since comments from the log accompany the photographs to the Retinal Reading Center, staff there can take this information into account when providing feedback.

5.0 FILM HANDLING

5.1 Film processing

The film will be removed from the camera after automatically rewinding as each roll is fully exposed. Film will be processed at least weekly. Partially exposed rolls of film may be removed after rewinding the film automatically by depressing the Manual Rewind Button (see page 30 of the Operation Manual). The photographer will attach a numbered film roll label to each exposed roll of film before sending it for processing. The film roll label appears as follows:

The film roll number must correspond with the sequential number appearing on the corresponding Photography Film Log page.

The undeveloped rolls of film will be sent to a reputable Ektachrome processing laboratory[2], preferably three times per week. A record of film sent will be kept and films will be logged out and in so any lost films can be easily recognized and traced. A Film Processing Log (example 2) will be completed whenever film is sent out or received back from processing. Special attention must be paid to the slide cutting and mounting (framing into either cardboard or plastic mounts) to be certain that the date and ID information is located on the left side of the retinal image on the slide with the registration "notch" on the right-hand side.

Film is processed locally so that photographers can review their results as soon as possible for possible camera malfunction. Also, the opportunity for photographers to critique their work is critical to the maintenance of satisfactory photographic quality.

5.1.2 Film sorting and labeling

The processed films will be sorted and labeled using the Photography Log Form as a guide. Extreme care is necessary no avoid incorrect identification and labeling. The pictures will be labeled with pre-printed slide identification labels. To make them easy to locate, labels will be printed in batches by the field center computer in date and subject ID order. The labels appear as follows:

```
ID:  F999999
CY: 07    ARIC
```

[2]A professional film processing laboratory (i.e., not supermarket or drugstore service) offering consistent and timely E-6 processing for Ektachrome film must be selected. Professional photographers in your area can advise you about the identity of such a laboratory, or the Retinal Reading Center will help you find one.

5.1.3 Slide mounting

The sorted and labeled slides are loaded into Bardes plastic slide pages so that each row contains two photographs, thus only columns 1 and 3 are used. The mounting pattern is diagrammed in Example 3. Slides are mounted in the order taken and developed. The proper order is confirmed by comparing the slides with the corresponding Photography Log Form for each roll of developed slides. A roll of film of 36 exposures would result in 4 sheets of photos, spscified as sheets 1,2,3 and 4 with only 6 slides in the final sheet.

5.1.4 Photo Shipping

Packages of processed, mounted slides and the relevant Photography Log Forms are sent weekly to Rose Brothers at the ARIC Retinal Reading Center, under cover of the shipping list (Example 4).

The Reading Center recommends the use of plastic lined air bubble mailers similar to the Avery "Post-Lite" or the Jiffy "Jiffylite". These are available in a variety of sizes and do not contain the recycled fiber padding prone to shed dust and dirt on the slides. Please be sure to put the plastic slide pages in a manila folder to prevent the sharp edges from cutting through the mailing envelope. The standard Federal Express or UPS envelopes, reinforced with a manila folder around the photos, are also acceptable.

5.1.5 Shipping Couriers

When using couriers such as Federal Express or UPS, please use the Retinal Reading Center's complete street address. When sending slides by US Mail, please use the same Retinal Reading Center address. (The Retinal Reading Center no longer has a post office box.) Address information can be found under section 8. on page 14 of this protocol.

6.0 QUALITY CONTROL

Photographic quality will be continuously monitored throughout the study. Initially all photographs will be reviewed by the Photography Consultant and feedback will be provided to the photographers in cases that warrant critique. A telephone call or letter will be used detailing problems and suggesting improvements. Once the study is well underway and the photographers sufficiently trained, data on quality will be generated from the photograph readers' evaluations of all photographs. A small percentage of the photographs will be reviewed by the Photography Consultant, and feedback will be provided to the photographers in cases that warrant critique.

7.0 PHOTOGRAPHER CERTIFICATION

Each examiner taking fundus photographs will need to become certified before taking photographs for the study. The initial group of photographers received didactic and hands-on training during the January 23-25, 1993, training session in Charleston, South Carolina. Following this training they returned to their respective centers and assembled their cameras. A photographer is fully certified after submitting satisfactory quality photographs of 10 eyes. These photographs must show proper field definition, exposure, alignment and focus. The photographs must be completely labeled and mounted according to protocol.

As additional personnel need training to become certified, a certified photographer at that center will provide complete instruction and copies of the protocol and Operation Manual. The trainee photographer will practice on volunteers and, when ready, prepare and submit photographs of 10 eyes for consideration for full certification.

8.0 COMMUNICATION CHANNELS

It is vital that proper and frequently used channels of communication be established for the effective exchange of questions and information between all staff members. Following is a listing of names, addresses, and telephone numbers:

ARIC Retinal Reading Center

610 North Walnut Street
Madison, WI 53705

Rosemary Brothers (608) 263-6976
Senior Grader

Michael Neider (608) 263-9858
Photography Consultant

Matthew Davis, M.D. (608) 263-6071
Consulting Ophthalmologist

Larry Hubbard (608) 263-2245
Associate Director

Canon USA, Inc.

Thomas Penkala (708) 250-6200
Canon USA, Inc.
100 Park Boulevard
Itasca, IL 60143

Ron Kaiser (516) 328-4645
Canon USA
1 Canon Plaza
Lake Success, NY 11042-1113

ARIC Study Photography Log Form Film Roll Number _____

	Date	Ph/ID	Subject ID #	Eye	Comments
1					
2					
3					
4					
5					
6					
7					
8					
9					
1					
1					
1					
1					
1					
1					
1					
1					
1					
1					

Example 1

ARIC Study Photography Log Form Film Roll Number _____

	Date	Ph/ID	Subject ID #	Eye	Comments
1					
2					
3					
4					
5					
6					
7					
8					
9					
1					
1					
1					
1					
1					
1					
1					
1					
1					

Example 1

ARIC Study Photography Log Form Film Roll Number

	Date	Ph/ID	Subject ID #	Eye	Comments
1					
2					
2					
2					
2					
2					
2					
2					
2					
2					
2					
3					
3					
3					
3					
3					
3					
3					

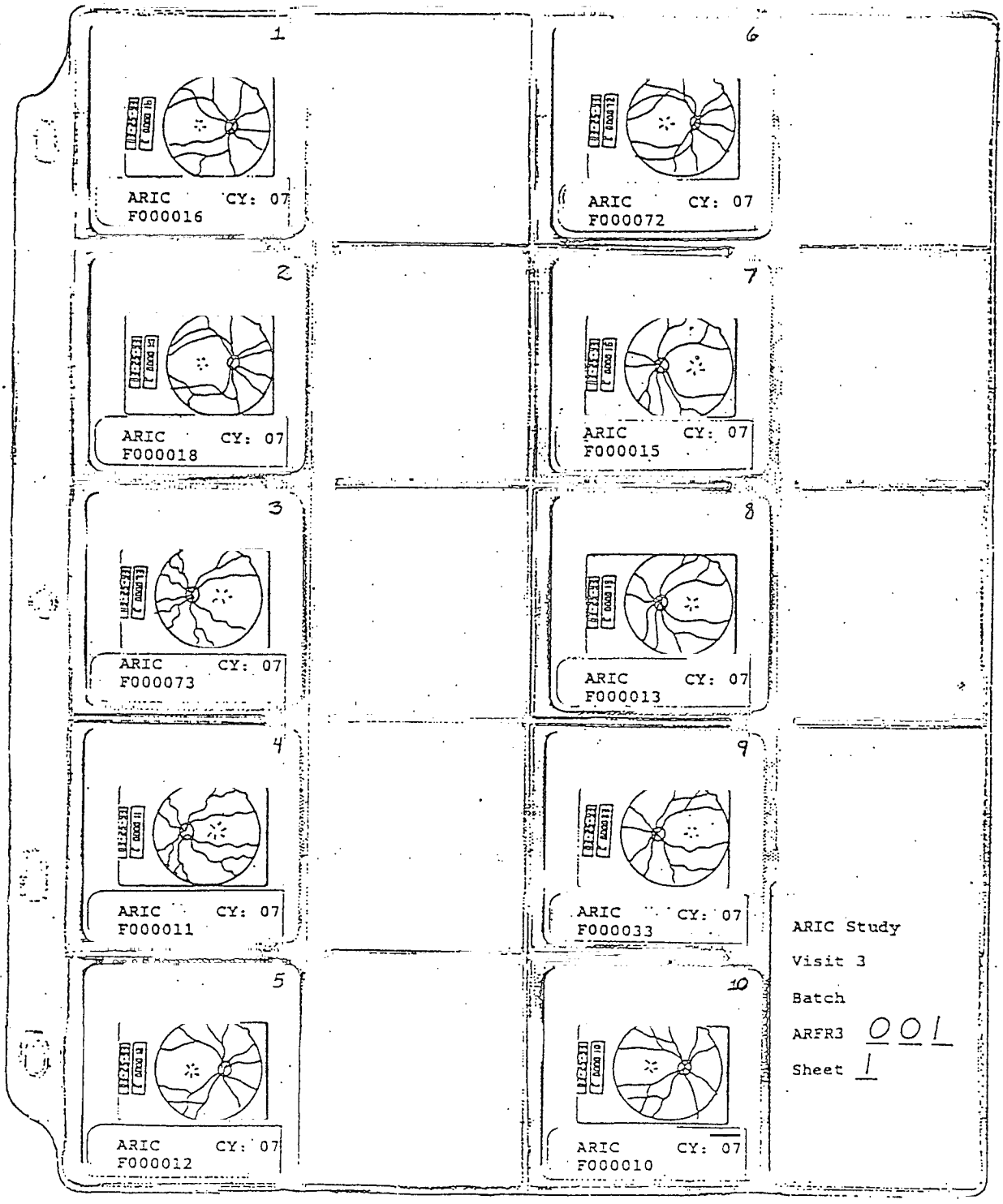
Example 1

ARIC Study Film Processing Log

Roll #	Date Out	Date In		Roll #	Date Out	Date In

Example 2

ARIC Study
Mounting of Retinal Photographs



Example 3

ARIC PROTOCOL 14a. Retinal Photography - Visit 3. VERSION 1.0 08/01/95

ARIC Study
Retinal Photography Shipping List

Clinical Center: Forsyth

Shipping Batch: ARFR3 ___ ___ ___

Number of Mounting Sheets ____ Number of Retinal Photographs _____

Date Shipped ___ ___ / ___ ___ / ___ ___ Person Shipping _____

Retinal Reading Center use only.

Date Received ___ ___ / ___ ___ / ___ ___ Person Receiving _____

Comments _____

Example 4

ARIC
Atherosclerosis Risk in Communities

Appendix 8b

RETINAL EXAMINATION FORM

O.M.B. 0925-0281
exp. 09/30/98

A-411

ID NUMBER: | | | | | | | | CONTACT YEAR: | 1 | 0 | FORM CODE: | R | E | X | VERSION: B 01/30/96

LAST NAME: | | | | | | | | | | | | | INITIALS: | | |

INSTRUCTIONS: This form should be completed on paper during the participant's visit. ID Number, Contact Year, and Name must be entered above. Whenever numerical responses are required, enter the number so that the last digit appears in the rightmost box. Enter leading zeroes where necessary to fill all boxes. If a number is entered incorrectly, mark through the incorrect entry with an "X". Code the correct entry clearly above the incorrect entry. For "multiple choice" and "yes/no" type questions, circle the letter corresponding to the most appropriate response. If a letter is circled incorrectly, mark through it with an "X" and circle the correct response.

RETINAL EXAMINATION FORM (REXB screen 1 of 8)

1. When was the last time you saw a doctor, optometrist, or eye specialist concerning your vision?

Less than 1 year	A
At least 1 year but less than 2 years	B
At least 2 years but less than 3 years	C
3-10 years	D
Greater than 10 years	E
Never	F

2.a. Has a doctor ever told you that you had sugar diabetes? ..... Yes Y

No N

Go to Item 3a, Screen 2

2.b. Has a doctor ever told you that you have eye problems as a result of diabetes? ..... Yes Y

No N

Unknown U

Go to Item 3a, Screen 2

c. Which eye or eyes were affected? ..... Right R

Left L

Both B

Unknown U

d. Have you ever had laser treatments on your eyes for diabetes? ..... Yes Y

No N

Unknown U

Go to Item 3a, Screen 2

RETINAL EXAMINATION FORM (REXB screen 2 of 8)

2.e. On which eye or eyes? ..... Right R
Left L
Both B
Unknown U

3.a. Has a doctor ever told you that you have eye problems as a result of glaucoma, or increased pressure inside one or both of your eyes? ..... Yes Y
No N
Unknown U

Go to Item 4a, Screen 3

b. Which eye or eyes were affected? ..... Right R
Left L
Both B
Unknown U

RETINAL EXAMINATION FORM (REXB screen 3 of 8)

4.a. Has a doctor ever told you that you have eye problems as a result of age-related macular degeneration? ..... Yes Y
No N
Unknown U

Go to Item 5a, Screen 4

b. Which eye or eyes were affected? ..... Right R
Left L
Both B
Unknown U

4.c. Have you ever had laser treatments on your eyes for macular degeneration? ..... Yes Y
No N
Unknown U

Go to Item 5a, Screen 4

d. On which eye or eyes? ..... Right R
Left L
Both B
Unknown U

RETINAL EXAMINATION FORM (REXB screen 4 of 8)

5.a. Has a doctor ever told you that you have eye problems as a result of cataracts, or cloudiness of the lens, in one or both of your eyes? ..... Yes Y

No N

Go to Item 6a, Screen 5 — Unknown U

b. Which eye or eyes were affected? ..... Right R

Left L

Both B

Unknown U

5.c. Have you ever had eye surgery because of cataracts? ..... Yes Y

No N

Go to Item 6a, Screen 5 — Unknown U

d. On which eye or eyes? ..... Right R

Left L

Both B

Unknown U

RETINAL EXAMINATION FORM (REXB screen 5 of 8)

6.a. Has a doctor ever told you that you have eye problems as a result of blockage of an artery or vein in one or both of your eyes? ..... Yes Y

No N

Go to Item 7a, Screen 6 — Unknown U

b. Which eye or eyes were affected? ..... Right R

Left L

Both B

Unknown U

6.c. Have you ever had laser treatments on your eyes for this blockage? ..... Yes Y

No N

Go to Item 7a, Screen 6 — Unknown U

d. On which eye or eyes? ..... Right R

Left L

Both B

Unknown U

RETINAL EXAMINATION FORM (REXB screen 6 of 8)

7.a. Have you ever had eye surgery for another condition? ..... Yes Y

No N

Unknown U

Go to Item 8a.

b. What was the condition?

c. On which eye or eyes? ..... Right R

Left L

Both B

Unknown U

8.a. Have you ever had laser treatments on your eyes for another condition? ..... Yes Y

No N

Unknown U

Go to Item 9a, Screen 7

b. What was the condition?

c. On which eye or eyes? ..... Right R

Left L

Both B

Unknown U

RETINAL EXAMINATION FORM (REXB screen 7 of 8)

9.a. Are you completely blind in one or both eyes? ..... Yes Y

No N

Unknown U

Go to Item 10a.

b. In which eye? ..... Right R

Left L

Both B

10.a. Have you ever had an eye removed? ..... Yes Y

No N

Unknown U

Go to Item 11, Screen 8

b. Which eye was removed? ..... Right R

Left L

Both B

RETINAL EXAMINATION FORM (REXB screen 8 of 8)

11. Type of eye selection? ..... Assigned A
Selected S

If selected, explain:

_____

12. Which eye was photographed? .. Right R
Left L
Both B
None N

Go to Item 14.

13. Reason for not photographing?
Equipment failure A
Participant refusal B
Biologically not feasible C
Other D

14. Interviewer ID: [ ][ ][ ]

15. Photographer ID: [ ][ ][ ]

16. Date of data collection: [ ][ ]/[ ][ ]/[ ][ ]

Appendix 8c

INSTRUCTIONS FOR THE RETINAL EXAMINATION FORM
REX, VERSION A: 03-09-93
PREPARED 08/30/93

The Retinal Examination (REX) Form is administered to all cohort participants in Visit 3. Its primary purposes are to obtain information about the participant's general ophthalmic history. The technician taking the retinal photograph also uses the form to record the method of selecting the eye photographed, or if photography cannot be performed, the reason.

The questionnaire is completed immediately prior to taking the retinal photograph. If clinic flow permits, it is administered after the subject is seated at the camera in the darkened room, while the technician is waiting for the pupil to dilate through dark adaptation.

The interviewer must be certified in general clinic interviewing and familiar with the "General Instructions for Completing Paper Forms" prior to administering this form. Items in BRACKETS and/or CAPITAL LETTERS are instructions to the interviewer and are not read to the participant.

READ INTRODUCTORY SCRIPT

> "These questions ask about the status of your eyes and any medical history we should know about when we evaluate the photographs of the blood vessels in the back of your eyes. Some of the questions need a direct answer from you and some require you to choose an answer form a series of responses. I will let you know which type of response is necessary for each question."

1. This question is intended to apply to visits to a physician ("doctor") or ophthalmologist ("eye specialist") or optometrist (non-medical doctor who prescribes eye glasses).

2a. A positive answer for diabetes requires an explicit statement by the physician using that term, or 'high blood sugar', for which treatment was prescribed. Gestational diabetes is not included in this question.

2b. This question only asks whether the doctor (physician) said the participant had an eye problem as a result of diabetes.

2c. This question refers to a previous diagnosis of an eye problem due to diabetes, such as diabetic retinopathy (Item 2b=yes), any time during the participant's life, and may include one or both eyes. Select UNKNOWN if the participant is unsure which eye(s) was affected.

2d. Laser treatment to the eye for diabetes is often called laser photocoagulation, and refers to the use of a focused beam of light to seal off areas of bleeding or leakage in the retina, the light sensitive layer at the back of the eye. Other or unknown types of treatment are coded as NO or UNKNOWN, respectively.

2e. Read the question as written; do <u>not</u> read the response categories.

3a. This question is looking for physician-diagnosed glaucoma. Read the question as worded, which includes a non-medical description of glaucoma. Do not define 'glaucoma' beyond what is used in the question. If the response is NO or UNKNOWN, skip item 3b.

4a. If asked, define age-related macular degeneration as a loss of vision that could not be corrected with glasses due to changes in your retina caused by aging. This condition used to be called "senile" macular degeneration (or SMD), and is now often abbreviated as ARMD or AMD.

6a. Blockage of an artery or vein in the eye is called an occlusion. Symptoms of occlusion include areas of reduced or lost vision (blind spots) which may be temporary or permanent.

6c. Laser photocoagulation is sometimes applied to the retina to inhibit further deterioration when a vein has been occluded.

7a. Participants might respond to this question with a wide range of eye surgeries. Of particular interest is any surgery which affects the retina: retinal detachment surgery (including insertion of gas or silicon oil bubbles-tamponades to push the retina back down, buckles-bands that push the retina and the layer underlying it back together, and cryotherapy-cold cauterization to tack the retina to the layer underlying it), or vitrectomy (a microsurgical technique in which instruments are introduced into the eye to cut away scar tissue and to remove cloudy vitreous humor). Note that 'laser treatments' are not considered 'eye surgery':These procedures are documented in Items 8a-c.

8b. If more than one condition, specify the most recent eye problem.

8c. Restrict the selection of the eye to the condition described above in Item 8b.

9a. Complete blindness means that the participant has no light perception in the eye (cannot see light and shadow).

10a. If an eye(s) was removed by surgery or as the result of an accident, record YES.

11. The right eye is assigned if there are no contraindications to photographing that eye and the participant ID ends in an even number (0,2,4,6,8). The left eye is assigned if the ID ends in an odd number (1,3,5,7,9) and there is no contraindication to photograph it. In either of these instances, enter ASSIGNED. The choice is marked as SELECTED if the technician determines that the assigned eye cannot be satisfactorily photographed and chooses to photograph the other eye instead. The criterion for switching is that a reasonably clear view of the retina cannot be obtained in the assigned eye, typically due to inability to dilate, or opacities of the ocular media (e.g., cataract of the lens).

12. Indicate which eye(s) was photographed. If the photograph could not be taken, enter NONE.

13. Do not ask the participant this question. Select the best answer. Photography is not biologically feasible if a view of the retina cannot be obtained in either eye, or if the subject is physically or otherwise incapable of cooperating sufficiently to allow a view of the retina. Select OTHER if none of the first three categories accurately describe the reason the photograph could not be taken.

Film Roll Number _____

ARIC
Atherosclerosis Risk in Communities

PHOTOGRAPHY LOG FORM

A-419

#	Date	Photographer Code	Participant ID	Eye	Comments
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					

ARIC
Atherosclerosis Risk in Communities

Appendix 8e

FILM PROCESSING LOG

Roll #	Date Out	Date In	Comments