Atherosclerosis Risk in Communities Study Protocol

Manual 2

Cohort Component Procedures

Visit 3

Version 5.0

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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 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

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

1.1 Introduction

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

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

1.2 Eligibility Requirements for Annual Follow-up Interviews

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

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

1.3 Annual Follow-Up

1.3.1 Time Window for Annual Contacts Between Field Center Examinations

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

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

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

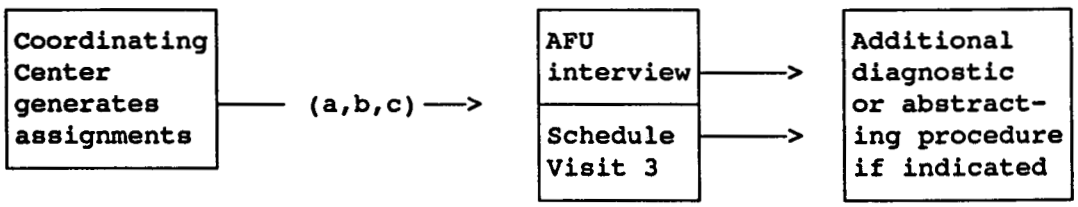
1.3.2 Follow-up Procedures

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

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

The ARIC Coordinating Center begins the AFU procedures by generating and distributing to field centers several times a year AFU materials for use in scheduling and conducting the AFU interview. These materials include a (1) list of participants with anniversary dates for a minimum of three months; (2)

(2) the participant tracing information sheet (Appendix 1.1); and (3) the verification of tracing information (UPD) form (Appendices 1.2 and 1.3). The list of participants includes the participant name, participant ID, date of Visit 1, and date of Visit 2 (optional), sorted in the order requested by the field center. The Participant Tracing Information Sheet includes the participant's name, address, telephone number(s); sex, race, date of birth, state of birth, social security number, driver's license state and number; employer's name and address; date of Visit 1, date of Visit 2; and the names, addresses and telephone numbers of two contact persons and the personal physician. The Verification of Tracing Information (UPD) form is available in long and abbreviated versions (depending on whether it is administered with the routine AFU interview or the AFU/Visit 3 scheduling interview) and lists the current data on file for the names and addresses of the participant and his/her two contact persons.



(a) Send Pre-AFU Interview (Visit 3) reminder letter (Optional).
(b) Schedule Annual Follow-up telephone interview.
(c) Send Annual Contact Letter/Pre-Visit 3 Letter for cohort members who cannot be contacted by telephone.

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

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

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

This letter contains:

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

2. A description of the purpose of the contact.

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

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

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

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

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

1.3.3 Annual Cohort Interview

Question by question (QxQ) instructions and prototype scripts have been prepared for administering the AFU interview (See Appendix 1.7). It can usually be administered by telephone in less than 10 minutes. The interview updates address and tracing information of cohort participants (See Appendix

1.2 or 1.3, UPDATE form); ascertains their vital status (AFU, section A), death information (AFU, section B); perceptions of general health (AFU, section C); chest pain on effort (AFU, section D); possible infarction (AFU, section E); intermittent claudication (AFU, section F); TIA/stroke (AFU, section G); hospitalizations (AFU, sections H and K); and functional status (AFU, section I) (See Appendix 1.6, Annual Follow-up form). At some point after the AFU interview, every participant-reported hospitalization is verified and the discharge diagnoses recorded. Potential cardiovascular events are reviewed further by the abstraction of participants' hospital records to document the presence/absence of ARIC Study endpoint criteria. Refer to Chapter 3.

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

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

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

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

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

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

1.3.3.1 Administration of London School of Hygiene Questionnaire

The purpose of the London School of Hygiene Questionnaire (the 'Rose Questionnaire') is to standardize the identification of 'angina on effort' as defined by Dr. Geoffrey Rose. It is <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.

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

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

1.5 Window for Visit 3

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

contacts are listed as Contact Year 07 and Contact Year 08, but the Visit 3 contact year is listed as Contact Year 07.

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

1.6 Scheduling of Visit 3 Field Center Examination

1.6.1 Outline of Scheduling Procedures for Visit 3

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

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

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

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

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

5. A reminder telephone call also precedes the visit.

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

1.6.2 Contacting Participants

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

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

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

1.6.3 Making the Clinic Appointment

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

1. Preferred time and date of examination;

2. Any medical conditions (e.g., diabetes, dietary restrictions) which might affect the physical examination and/or type of snack provided;

3. Need for assistance getting to or moving about the clinic.

If possible, the interviewer schedules appointments for the examination during the 30 days following the telephone call. The interviewer notifies the clinic scheduler to set an appointment day and time. The appointment is recorded on a reminder sheet which is mailed to (or left with) the participant. When possible, cohort members are scheduled for appointments at their convenience, this includes scheduling all eligible members of a single household for examinations on the same day whenever possible.

1.6.4 Instructions for the Clinic Examinations

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

1. Appointment date and time.

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

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

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

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

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

1.6.5 Scheduling Appointments

Interviewers scheduling examinations report appointment information to their field center. Sufficient appointments are scheduled each day for Monday through Friday to meet the requirement of approximately 25 appointments per week.

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

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

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

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

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

1.6.5.1 Guidelines for ARIC participants who relocate near another center

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

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

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

3. The original center sends the ARIC Coordinating Center and the alternate center written notification of the participant ID, as soon as the participant agrees to complete the exam at the new field center.

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

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

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

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

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

1.7 Retention of ARIC Participants

1.7.1 Introduction

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

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

1.7.2 Certification of Annual Follow-up Interview Staff

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

1.7.3 Pre-appointment Contacts

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

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

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

1.7.4 Contacts for No Shows

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

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

1.7.5 Reimbursement

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

1.7.6 Publicity

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

1.7.7 Supervision

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

2.0 THE THIRD COHORT EXAMINATION

2.1 Introduction

During the annual follow-up interview, cohort members in their seventh contact year (Contact Year 07) are invited to return for a third field center exam (Visit 3). As envisaged during the initial design of the ARIC study, a core component of the cohort examination has remained constant in Visit 3 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 have been included with the intention of collecting data on a one-time-basis, and some at six year intervals. Annual dietary intake and physical activity, introduced during Visit 1, are repeated in Visit 3. A test of cognitive function, administered to all participants in Visit 2, is readministered only to those participants in Forsyth County, NC and Jackson, MS having cerebral magnetic resonance imaging (MRI). Psychosocial status (anger, depression/fatigue, and social support) were assessed during Visit 2. Cerebral MRI (NC and MS), echocardiography (MS), and retinal photography (all) are new components at Visit 3.

Chapter 2 of this manual provides an overview of the third 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. Whereas the work stations are presented in the order in which they occur, descriptions of the individual interviews and procedures are provided in alphabetical order, starting with the interviews and concluding with the procedures. Table 2.1 lists the main components of Visit 3, identifying the activities at each work station and cross-referencing each procedure with its respective manual of operation.

The description of each interview/exam component in the text includes the rationale for its use (.1), operational procedures (.2), training requirements (.3), overview of certification criteria (.4), routine quality assurance measures (.5), and data collection procedures (.6). The rationale for each interview/procedure (.1) that was performed in a previous examination (Visit 1 or 2) briefly states the major premise(s) for its inclusion in the ARIC study and its continued use in Visit 3. A more detailed rationale is provided for the new Visit 3 studies. The operational procedures (.2) summarize procedures for administering the interviews, the operational procedures for conducting examinations or a reference to the appropriate manual of operations for the procedures with their own separate protocols. Training requirements (.3) and

certification criteria (.4) are listed separately from their traditional rubric of quality assurance to provide easier reference for study personnel. To reduce the use of repetitive statements for each procedure in the latter two sections, it is understood that the minimum training and certification requirements/criteria for all Visit 3 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 proper interviewer techniques are found in appendices 2.30 and 2.31, respectively. Table 2.2 lists the personnel responsible for the central and local training of each interview/procedure at the outset of Visit 3. The Quality Assurance section (.5) further 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. The final section on Data Collection (.6) 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 provide support material for Chapters 1, 2 and 3 of this manual, including 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.

2.2 Participant Flow

The participant flow, as outlined in Table 2.3, is based on that used successfully in the implementation of Visit 1, and modified to reflect study requirements and the operational needs of the individual field centers. Visit 3 begins and ends with fixed examination sequences.

2.2.1 Rationale

Participant flow at each field center is structured to contain both fixed and flexible components. The fixed components reflect the requirement to initiate the examination with the informed consent and to group the procedures which require fasting, and the logistical necessity of conducting medical data reviews and exit interviews 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 minimizes participant burden (the maximum allowable exam time is 4 hours) and reduces variability in study measurements.

2.2.2 Fixed Sequences

The fixed portion of participant flow must meet the following criteria: informed consent must be signed before any examination; twelve hours of fasting and one hour of abstinence from smoking and overt physical exercise are required for venipuncture, anthropometry measurements and sitting blood pressure (procedures for noncompliance are described below); all other interviews and exams are to be completed before the data inventory and medical data review.

2.2.3 Flexible Sequences

The sequence of the remainder of the examination is flexible and is designed and monitored by the study coordinator at each field center. These procedures include the snack, interviews, cerebral MRI (NC and MS), 12-lead ECG, echocardiogram (MS), retinal photograph and ultrasound scans.

The participant's record of data acquisition is documented on the ARIC Cohort Inventory (CXI, Appendix 2.1) form within the Data Entry System and the Participant Itinerary Sheet (Appendix 1.10). 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 Participant Itinerary Sheet 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

Reception is the first procedure. At the reception work station, the participant is greeted and welcomed, informed consent is obtained, participant questions are answered, demographic and tracking information are updated, fasting status is determined and the medication survey begun (and, in some instances, completed).

Optionally, a schedule for reporting the participant's study results is reviewed with the participant after the Update form is completed. It indicates that the results of some of the procedures done during the visit will be reviewed later with the ARIC clinician while the participant is still at the field center, and a written summary report, including some additional tests will be mailed to the participant and his/her physician (or alternate) 10 - 12 weeks after the clinic visit date, as described in Section 2.30. Samples of the report and prototypes of accompanying letters are included in Appendix 2.25-2.29.

The participant is shown where to change into an examination gown/robe, requested to remove all jewelry, and to place clothing and valuables in a secured locker. The participant is requested to empty the bladder, if possible, prior to beginning the examination.

Staff are trained for the reception work station 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 Medications Transcription/Interview (optional). 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.

Table 2.1 Components of the ARIC Cohort Visit 3 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.	2
Echocardiogram	Measure cardiac dimensions; Jackson, MS	15
ECG	Obtain resting 12 lead ECG	5
Exit Interview	Return medication; answer questions; thank participants	2
Informed Consent	Visit 3 informed consent and authorization for release of hospitalization records	2
Interviews	Collect sociodemographic data; cognitive function; health care, and medical, personal and reproductive (women only) history; medication/vitamin use; food frequency intake; physical activity.	2
MRI	Cerebral magnetic resonance imaging; Forsyth Co., NC and Jackson, MS.	14
Medical Data Review	Ascertain the completeness of the exam and verify abnormal results. Review results of the medical history and exam with the participant. Refer participant for diagnosis or treatment elsewhere if needed.	2 2
Reception	Greet the participant; determine fasting status; verify identifying information; obtain tracing data; collect medications.	2
Retinal Photo.	Obtain photograph of ocular fundus.	13
Sitting Blood	Sitting blood pressure Pressure	11
Snack	Provide snack with no stimulants.	2
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 2.2 Training for the ARIC Visit 3 Cohort Exam

	CENTRAL		LOCAL	
	Trainee	Trainer	Trainee	Trainer
AFU (Contact Yr 7)				
Annual F/U	Chief Interviewer	CSCC	Interviewers	Study Coord
V-3 Scheduling	Chief Interviewer	Minneapolis	Interviewers	Study Coord
ANTHROPOMETRY				Central
Procedure	Anthro. Techs.	Minneapolis	Anthr. Techs	Trainer
ARDES Version _.0				
Workstations	Data Coordinator	CSCC	Staff	Data Coord
Data Management	Data Coordinator	CSCC	Back-up	Data Coord
BLOOD PRESSURE				
Procedure	Technicians	Minneapolis	Staff	Chief Tech.
COGNITIVE FUNCTION				
Interview	Interviewers		Interviewers	Chief Tech.
DIETARY INTAKE				Central
Interview	N/A	N/A	Interviewers	Trainer
ECHOCARDIOGRAM	Technicians	Jackson	N/A	N/A
ECG				Central
12 lead ECG	Technicians	Minneapolis	ECG Techs	Trainer
FASTING/TRACKING				
Interview	Interviewers	CSCC	Interviewers	Study Coord
HEALTH HISTORY				
Interview	Interviewers	For/Wash Co.	Interviewers	Study Coord
LETTERS/REPORTS				
Ppt. Results Rpt.	Interviewers	CSCC	Staff	Study Coord
MED DATA REVIEW				Central
Med. Revue	PA/Nurse	Forsyth Co.	PA/Nurse P.	Trainer
MEDICATION SURVEY				
Interview	Interviewers	Forsyth Co.	Interviewers	Chief Inter.
Transcription	Interviewers	Forsyth Co.	Interviewers/ Clinic staff	Med Code Specialist
Coding	Interviewers	CSCC	Interviewers	Same
MRI				
Informed consent Screening	Technician		Technicians	Chief Tech.

Table 2.2 Training for the ARIC Visit 3 Cohort Exam, continued

	CENTRAL		LOCAL	
	Trainee	Trainer	Trainee	Trainer
PERSONAL HISTORY				
Interview	Interviewers	Hagerstown	Interviewers	Chief Inter.
PHYSICAL ACTIVITY				
Interview	Interviewers	Minneapolis	Interviewers	Chief Inter.
Coding				
RECEPTION				
Informed Consent	N/A		Staff	Study Coord
REPRODUCTIVE Hx.				
Interview	Interviewers	Hagerstown	Interviewers	Chief Inter.
Transcription				
Coding				
RETINAL PHOTO.				
Interview	Technicians	Fundus R.C.	N/A	N/A
Procedure	Technicians	Fundus R. C.	Technicians	Chief Tech
TIA/STROKE				
Interview	Interviewers	For/Wash Co.	Interviewers	Chief Inter.
Med Review	PA/Nurse	Forsyth Co.	PA/Nurse P.	
ULTRASOUND				
Scans	Sonographers	URC	Sonographers	Chief Sono.
Postural Change	Sonographers	URC	Sonographers	Chief Sono.
UPDATE				
Interview	Interviewers	CSCC	Interviewers	Study Coord
VENIPUNCTURE				
Blood drawing	Chief Technician	Hemostasis	Other Techs	Chief Tech
Blood processing	Chief Technician	Hemostasis	Other Techs	Chief Tech

Table 2.3 Participant Flow in Visit 3

PROCEDURES/WORKSTATIONS		Approximate Time
FIXED	RECEPTION	12 min
	Informed consent	
	Update	
	Fasting/Tracking	
	Medication Survey	
	CHANGE CLOTHES	
	ANTHROPOMETRY	6 min
	SITTING BLOOD PRESSURE	14 min
	VENIPUNCTURE	6 min
	SNACK	8 min
	INTERVIEWS	62 min
	Cognitive Function (NC,MS)	Personal History
	Dietary Intake	Physical Activity
	Fasting	Reproductive History
	Health History	Stroke/TIA
	Medication Survey	Vitamin Survey
	MRI Screening (NC,MS)	
	CEREBRAL MRI (Forsyth Co., Jackson)	<35 min>
	12 LEAD ECG	8 min
	ECHOCARDIOGRAM (Jackson, only)	<35 min>
	RETINAL PHOTOGRAPHY	10 min
	ULTRASOUND	45 min
	Carotid arteries	
	Postural changes in blood pressure	
FIXED	DATA INVENTORY	
	CHANGE CLOTHES	
	MEDICAL DATA REVIEW	14 min
	Medical Data Review	
	TIA/Stroke Summary (not study data)	
	EXIT	5 min

TOTAL: 3 hours 10 min.

2.4 Cognitive Function

In Visit 3, the Cognitive Function test (Appendix 2.2) is administered only to participants at the Forsyth County, NC and Jackson, MS field centers who have cerebral MRI scans.

2.4.1 Rationale

The main objective of cognitive function testing in Visit 2 was to establish a baseline for future comparison. In Visit 3, its measurement accompanies the cerebral magnetic resonance scans. Cognitive function is only administered to participants in the North Carolina and Mississippi field centers undergoing MRI.

Although the ARIC study population continues to be too young in Visit 3 to focus on frank dementia, the repeated measurement of cognitive function provides the opportunity to validate the measurements previously performed on the cohort and 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 widely used 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. This test has been used widely, is standardized, and is easy to administer.

2.4.2 Administration

At the MRI facility in North Carolina and Jackson and prior to the scan, a trained ARIC interviewer administers all three cognitive function tests 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 step by step instructions printed on the Cognitive Function paper forms (Appendix 2.2.b). 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 data entry screen by the interviewer.

2.4.3 Training

Interviewers are trained centrally prior to Visit 3, and the supervisors are responsible for training and certification of new field center interviewers.

2.4.4 Certification

Certification by the supervisor or study coordinator is required, and monitored by the Coordinating Center.

2.4.5 Quality Assurance

A non-systematic sample of Cognitive Function tests are reviewed 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.

2.4.6 Data Collection

Cognitive function data are collected on a three part paper form for delayed data entry. Scores are tallied by the interviewer or a certified staff member and recorded at the end of each test after the participant has left the interview room.

2.5 Dietary Assessment

During Visit 1, dietary data were collected in ARIC using a food frequency questionnaire developed by Walter Willett. This questionnaire was administered to all participants at the first examination and to a small sample of cohort members during Visit 2. It is administered again to all participants during the flexible component of Visit 3 (Appendix 2.3).

2.5.1 Rationale

Habitual dietary intake has documented effects on the risk of atherosclerotic diseases. ARIC collects dietary data to characterize the nutrient intake of cohort members and to determine its relationship to atherosclerosis and cardiovascular risk factors. Secondarily, ARIC explores dietary differences among the four cohorts and over time.

Dietary data are collected in ARIC using a short version of the food frequency questionnaire developed by Dr. Walter Willett. This questionnaire was chosen for ARIC because (1) it has been demonstrated to have reproducibility and validity compared with more extensive dietary methods (Willett et al., Am J Epid 1985;122:51-65), (2) it is brief, and (3) compared to other brief dietary assessments, it was believed to be better able to characterize individual dietary patterns. It is recognized that use of a brief food frequency questionnaire may sacrifice some precision in estimating nutrient intake.

2.5.2 Administration

The interview takes place in a quiet and private setting to put the participant at ease. The standard food unit models, help screens, and participant response cards are readily accessible.

The ARIC receptionist alerts the interviewer in advance if a participant is illiterate or has any problem in reading. In those instances, response cards are read by the interviewer.

The interviewers are provided with "help screens" in the data entry system for portion size/frequency adjustments, and for specification of foods to be included in or excluded from each category. The food items listed on these screens are expected to occur with sufficient frequency to need clarification. Question by question instructions are provided in Appendix 2.3.b.

The participants are told that the purpose of the interview is to obtain information about usual dietary intake, that there are questions regarding specific foods and portion sizes, and that the interviewer needs to find out how often, on average, the specified amount was consumed during the past year. Interviewers also inform participants that any difference from the stated portion size must be reported only if it is at least twice as much or half as much. The frequency of consumption is assessed as the number of times either per day, week or month. Any foods not mentioned which the participant eats frequently may be added at the end. The participant is assured that he/she may feel free to have instructions repeated or to ask questions.

Periodically the interviewer reiterates the introduction, "on average, the number of times in the past year", or reminds the participant of the stated portion size.

Standard portion size models are used at each interview station to enhance the reliability of the dietary information and ensure consistency across centers:

1. 12 oz. beverage tumbler marked with gradations for 8 oz., 12 oz.

2. 6 oz. beverage tumbler marked with 4 oz. and 6 oz. levels.

3. Set of standard measuring cups: 1 cup, 1/2 cup, 1/3 cup, 1/4 cup.

4. Set of 2 standard measuring spoons, 1 teaspoon, 1 tablespoon

5. Soup bowl for cereals, stews, hot dishes with levels marked for 1 cup and 1/2 cup.

Problem items are recorded in the note log. Resolution of these items is handled by a nutritionist at the Coordinating Center.

2.5.3 Training

Interviewers are centrally trained to use a standardized procedure for administering the dietary questionnaire. Training includes instructions in research interviewing techniques and in completing the form, including: (1) a thorough review of the form, instructions and protocol to promote adherence to the protocol; (2) practice in the use of non-judgmental attitude; (3) practice with the degree and nature of prompting permitted; (4) dealing with problem interviewing situations; (5) use of portion size-frequency conversion screen and seasonal intake; (6) use of response cards describing frequency of consumption and portion size; (7) practice handling participants' comments and

recording relevant information on the note logs; and (8) review of the post-interview responsibility for the data.

2.5.4 Certification

Interviewers are certified by the central trainer at the successful completion of training. New staff are trained and certified by the chief interviewer at each field center.

2.5.5 Quality Assurance

To promote consistency and accuracy in data collection and to minimize inter- and intra-interviewing differences, clinic supervisors monitor 5% of the interviews done by each interviewer. In addition, a brief written worksheet/quiz on portion size/frequency or interviewing problems is completed by each interviewer every six months. The quiz is distributed by the ARIC Coordinating Center and reviewed by the ARIC Cohort Operations Committee.

2.5.6 Data Collection

Data for the Dietary Intake form are usually collected by direct data entry. A paper version of the form is available for back-up and delayed data entry.

2.6 Fasting/Tracking

The Fasting/Tracking form (Appendix 2.4.a) is unchanged since Visit 2 and documents the participant's fasting status and establishes the participant's official visit date for Visit 3. It is administered at the reception workstation.

2.6.1 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.

2.6.2 Administration

Question by question instructions for administering the Fasting/Tracking form are provided in Appendix 2.4.b. The participant's fasting status is verified. Strict fasting is defined as nothing taken in by mouth, except water, for the preceding 12 hours. Participants are considered fasting if they have met the strict definition or if they have ingested no more than one cup of coffee/tea within the past 12 hours. 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. Ingestion of more substantive liquids or solids constitutes breaking the fast. If the participant has not fasted for 12 hours, the participant is offered the opportunity to repeat blood drawing in the fasting state at a later date. If in agreement, blood is not drawn and the participant is rescheduled for fasting venipuncture within the shortest feasible time period. 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. If a non-fasting participant does not wish to return, the participant's blood is drawn and the Fasting/Tracking form completed accordingly.

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 3; 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.

2.6.3 Training

Staff are centrally trained before Visit 3 and the study coordinator is responsible for providing training for new staff.

2.6.4 Certification

Certification is required, provided by the study coordinator.

2.6.5 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.

2.6.6 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.

2.7 Informed Consent

Informed consent (Appendix 2.5) is the first data collection form administered during the course of Visit 3. Its core content complies with guidelines from the National Heart, Lung, and Blood Institute, the Office of Management and Budget and the ARIC Steering Committee. The wording of the consent form 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.

2.7.1 Rationale

The primary objective of readministering Informed Consent is to inform the participant of the procedures of the ARIC cohort Visit 3, protect the rights of the ARIC Study participants, meet local Institutional Review Board requirements, and to update the participant's permission to abstract medical records in the event of hospitalization or death.

2.7.2 Administration

The goals of the ARIC study and the Visit 3 procedures are reviewed with the participant. The form explains that the goals of the study have not changed and the primary purpose for obtaining a repeat signature is to keep current his/her permission to review medical records in the event of hospitalization or death. Time is allowed for the person to read and sign the informed consent document. If he/she 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 participant is asked to sign the document. The original Informed Consent document is filed in the participant's ARIC study folder. A copy of the informed consent is given to the participant if requested by the participant or required by the local Institutional Review Board.

2.7.3 Training

Study coordinators are responsible for providing local staff training.

2.7.4 Certification

Certification by the Study Coordinator is required, as listed above.

2.7.5 Quality Assurance

Routine quality assurance is provided at each field center by means of observation by the local study coordinator.

2.7.6 Data Collection

The Informed Consent is a paper form. When the participant receives a copy of the informed consent, the field center has the option of providing a copy of the entire form, or of just the descriptive text. In all cases, the original signature page must be kept at the field center and stored in the participant's ARIC study folder.

2.8 Health History

2.8.1 Rationale

The Health History form (Appendix 2.6.a) is administered during the flexible component of the exam. In Visit 3, it has been modified to serve 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) and documents the occurrence of procedures to diagnose or treat cardiovascular disease. The occurrence of the participant-reported chest pain is confirmed as positive angina and/or myocardial infarction by London School of Hygiene criteria, its location documented, and its frequency ascertained.

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 Section B (invasive/non-invasive diagnostic and therapeutic cardiovascular procedures) is the time period between the 2nd and 3rd ARIC examinations. Detailed procedures for administering the form are provided in the question by question instructions immediately following the form in Appendix 2.6.b.

2.8.3 Training

Nurse practitioners/licensed nurses are centrally trained before Visit 3; 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 by the supervisor or study coordinator is required, and monitored by the Coordinating Center. Observation of interviews by the supervisor during the first month leads to certification. Recertification is not required.

2.8.5 Quality Assurance

Technique and adherence to protocol are monitored at least semi-annually by the 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.

2.9 Magnetic Resonance Imaging Screening

Selected participants at two of the ARIC field centers (Forsyth County and Jackson) receive cerebral magnetic resonance imaging (MRI) examinations. These include cohort members from these two communities who are 56 years or older at the time of their Visit 3 exam. They are screened to rule out prior surgery on an aneurysm in the brain; metal fragments in the eye(s), brain or spinal cord; valvular prosthesis, a cardiac pacemaker, cochlear implant, spinal cord stimulator or other internal electrical device; and pregnancy.

2.9.1 Rationale

The goal of implementing cerebral MRI into the ARIC study is to evaluate cerebral changes detected by MRI in a representative, biracial population, aged 56 to 70, and to evaluate the relationship of these changes to clinical stroke, coronary heart disease, cardiovascular risk factors, retinal microvascular changes, extracranial carotid atherosclerosis and changes in cognitive function. The MRI data are expected to supplement the clinical descriptors of cerebrovascular disease (stroke, TIA and dementia) ascertained by interview, retinal photography and the abstraction of medical records for cerebrovascular disease related hospitalizations by increasing the sensitivity of detecting subclinical disease and by distinguishing small-vessel from large vessel disease.

2.9.2 Administration

The procedures for selecting and screening age-eligible participants and performing and reading the cerebral MRI examination are fully described in a separate protocol, Manual 14. In brief, Forsyth County, NC and Jackson, MS field center staff recruit cohort members at least 56 years of age during their Visit 3 exam (or sometimes during scheduling) to have an MRI scan of their head. The procedure, its benefits and risks are explained in lay terminology. If interest is expressed, the participant is screened to rule out any exclusion criteria (MRI Screening form, Appendix 2.7). When there are no contraindications to performing a scan, a separate ARIC MRI consent form is administered prior to scheduling the scan.

2.9.3 Training

Interviewer supervisors are trained centrally in interviewing techniques prior to Visit 3, and are responsible for training and certification of the field center interviewers. New interviewers are trained locally by the supervisor or study coordinator.

2.9.4 Certification

Certification by the supervisor or study coordinator is required, and monitored by the Coordinating Center.

2.9.5 Quality Assurance

A non-systematic sample of MRI Screening interviews are reviewed by the supervisor. Interviewing technique and knowledge of subject matter are also monitored at least semi-annually by Coordinating Center monitors; data quality (completeness and accuracy) is monitored by the Quality Control Committee by the comparison of eligibility criteria documented in the field center and the MRI suite.

2.9.6 Data Collection

The MRI Screening Form is collected on paper for delayed data entry.

2.10 Medication Survey

The Medication Survey (Appendix 2.8.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 3. The survey has been updated to ascertain the epidemiology of aspirin use for the prophylactic treatment of cardiovascular disease in the ARIC population. Question by question instructions are located in Appendix 2.8.b.

2.10.1 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 examination date. Information on use of medications 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.

2.10.2 Administration

The Medication Survey questionnaire is divided into three major sections and is completed in several stages, at one or more workstations. During reception, it is determined 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 2.10) 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 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.

If the interview portion of the Medication Survey is not to be administered at the Reception workstation, after the medication names and concentrations are transcribed, the medications are placed in the carrying bag and taken to the work station designated for the completion of the medication survey.

At the appropriate workstation, a trained interviewer or the ARIC nurse/clinician shows the container of each medication transcribed in column A of Section B (MEDICATION RECORDS) to the participant and documents the classification of the drug - shared, prescribed, or over-the-counter and its use within the last 24 hours.

If the participant has not brought in all (any) medications, the interview can be completed for the missing medications at this time.

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.

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.

In the process of asking these questions about each medication, the interviewer verifies the transcription of medication names and makes corrections on the paper (or DES) form as required. Unknown and incomplete names are checked against the American Drug Index and Physician's Desk Reference.

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.

2.10.3 Training

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

2.10.4 Certification

Certification by the study coordinator is required for medication transcription and interview. No recertification is required.

Separate certification is required for medication coding, based on a certification test provided by the Coordinating Center and administered 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 recoding 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.

2.10.5 Quality Assurance

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.

2.10.6 Data Collection

The Medication Survey can either be collected on screens by direct data entry or on paper for delayed data entry.

2.11 Personal History

The Personal History form (Appendix 2.11.a) collects 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, alcohol consumption and occupation since the second examination.

2.11.1 Rationale

New questions on the use of/access to medical care to treat hypertension and hypercholesterolemia, symptoms consistent with a history of migraine headaches, lifetime exposure to passive smoking, and lifetime consumption

patterns of alcoholic beverages have been added since Visit 2. These items have been added to assess new areas, such as (1) barriers which may affect preventive treatment for high blood pressure and cholesterol; (2) the putative effects of passive exposure to cigarette smoke and increased risks of cardiovascular disease; or (3) the relation of alcohol consumption with coronary heart disease and to high density lipoprotein cholesterol.

2.11.2 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 question by question instructions (Appendix 2.11.b). Questions on alcohol consumption, occupation and annual household income may be considered sensitive by participants and care must be exercised to administer each section in a non-judgmental format.

2.11.3 Training

Interviewers are centrally trained before Visit 3. Study coordinators and interviewer supervisors are responsible for providing training to new staff in interviewing techniques and the question by question instructions for the Personal History form.

2.11.4 Certification

Certification by the supervisor or study coordinator is required, and monitored by the Coordinating Center. Satisfactory performance on five reviewed taped interviews by the field center supervisor, or successful completion of the centralized training workshop, result in certification.

2.11.5 Quality Assurance

With participant approval, all interviews are taped for quality control. A non-systematic sample of interviews is reviewed by the supervisor. Technique and adherence to protocol are also monitored at least semi-annually by the Coordinating Center monitors; data quality is monitored by the Quality Control Committee.

2.11.6 Data Collection

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

2.12 Physical Activity

The collection of data on work and leisure-time related physical activity was introduced during Visit 1, administered to a small sample of cohort members participating in case/control studies during Visit 2, and is reinstated for all cohort members in Visit 3. The Physical Activity form (Appendix 2.12.a) is administered during the flexible component of the exam.

2.12.1 Rationale

The ARIC requirements for physical activity assessment were that the instrument be (1) a questionnaire measuring usual physical activity, (2) of known validity and reliability, and (3) as brief as possible (less than 10 minutes). The ARIC Physical Activity Questionnaire is based on a self-administered questionnaire developed for a Dutch population by Baecke et al. (Am J Clin Nutr 1982;36:932-42). The questionnaire was adapted for ARIC (see Appendix IX) and the same modifications and clarifications in the version translated from Dutch that were made in Visit 1 still apply in Visit 3.

2.12.2 Administration

The ARIC Physical Activity Questionnaire is interviewer administered. Response cards are used to help the subject respond. The interviewer introduces the questionnaire by reading the introduction given on the form. The interviewer then reads each question slowly, pointing to the corresponding response card for each question, designated as [rc]. If completed on a paper form, the interviewer edits the form immediately for completeness while the participant is still present. Question by question instructions and a physical activity coding dictionary are provided in Appendix 2.12.b, and 2.12.c, respectively.

2.12.3 Coding and Scoring of Physical Activity

The coding of the physical activities reported by each participant is based on a physical activity dictionary which is appended to the question by question instructions in Appendix 2.12.d. Subsequent scoring of physical activity by the Coordinating Center is based on the algorithm developed by Dr. Baecke, the originator of the Physical Activity form.

2.12.4 Training

Interviewers are centrally trained prior to Visit 3. Topics include proper coding of various physical activities, usage of response cards, scoring and knowledge of when and how to probe.

2.12.5 Certification

Certification is required and is achieved either at the successful completion of central training or after observation of 5 interviews by the chief interviewer.

2.12.6 Quality Control

A sample of physical activity tests are reviewed by the supervisor at each field center. Bi-annually, physical activity interviewing and coding exercises are distributed to interviewers and reviewed by the ARIC Cohort Operations Committee for interviewing technique and accuracy of coding the participant-reported physical activities.

2.12.7 Data Collection

If the study data generated from the Physical Activity Questionnaire are collected on paper form, it is edited for delayed data entry. Scores are tallied by the interviewer and recorded at the end of each test after the participant has left.

2.13 Reproductive History

The Reproductive History form (Appendix 2.13.a) 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 2. The question by question instructions are located in Appendix 2.13.b.

2.13.1 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.

2.13.2 Administration

The interviewer-administered questionnaire is divided into 3 sections:

1. Recent menstrual history and onset of menopause
2. History of exogenous hormone use
3. History of gynecological surgery

Most of the questions are closed-ended or precoded 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.

2.13.3 Training

Because of the skip patterns interviewers will be trained to become familiar with the flow of the survey to insure smooth administration with a conversational tone.

2.13.4 Certification

Interviewers are certified in general clinic interviewing.

2.13.5 Quality Assurance

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

2.13.6 Data Collection

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

2.14 TIA/Stroke

The TIA/Stroke form (Appendix 2.14.a) 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 3 to assess the prevalence and incidence of stroke and transient ischemic attack. The interview is administered during the flexible component of the ARIC exam. Question by question instruction are located in Appendix 2.14.b.

2.14.1 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 2 and Visit 3.

2.14.2 Administration

The TIA/Stroke Form is administered by certified interviewers. Positive symptoms are recorded during the standardized interview along with their speed of onset, duration, and co-morbid manifestations.

2.14.3 Training

Interviewers are centrally trained before Visit 3 and study coordinators and chief interviewers are responsible for training new staff, based on a common interview training manual, question by question instructions for the TIA/Stroke Form, practice scripts, and role playing.

2.14.4 Certification

Local as well as central certification criteria have to be met for this form. Satisfactory performance on five taped interviews reviewed by the supervisor during the first month leads to certification by the study coordinator/local supervisor. Interviewers also code three TIA/Stroke forms based on three sets of scripts distributed by the Coordinating Center. Certification is conferred after review by the Coordinating Center. Yearly recertification scripts are distributed, reviewed and scored by the Coordinating Center.

2.14.5 Quality Assurance

With participant approval, all interviews are taped for quality control. A non-systematic sample of interviews is reviewed 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.

2.14.6 Data Collection

Data from the TIA/Stroke form are collected by direct data entry on a data entry screen unless the work station computer is inoperable. A paper version of the form is available for back-up and delayed data entry.

2.15 Update

The Update form (Appendix 2.15.a) is the primary source of tracking information for each participant and is administered yearly to all cohort members. During Visit 3, it is administered at the Reception Workstation. Question by question instructions are located in Appendix 2.15.b.

2.15.1 Rationale

Demographic and tracking information, initially recorded in Visit 1 and updated on the Annual Follow-Up Tracking Form, is summarized and updated 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.

2.15.2 Administration

After greeting the participant and obtaining his/her informed consent, the information on the Update (UPD) Form screen is verified by reviewing with the participant the information which was filled out on the form sent to his/her home in the Visit 3 information packet (see Appendix 1.10.d) 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 is given to or read to the participant <u>prior to</u> requesting the number. This form also includes mailing information for the health care provider designated to receive the participant's study results.

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.

2.15.3 Training

Staff are centrally trained before Visit 3 and study coordinators are responsible for providing local training for new staff.

2.15.4 Certification

Certification is required, provided by the study coordinator.

2.15.5 Quality Assurance

Routine quality assurance is provided locally by the study coordinator, by observing staff performance. Protocol adherence and interviewing technique are reviewed biannually by Coordinating Center field 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.

2.15.6 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 the interview data in this form are modified using Change Mode of the DES.

2.16 Vitamin Survey

The Vitamin Survey (Appendix 2.16.a) is introduced in Visit 3 as an extension of the Medication Survey. Although it can in theory be administered at any point during the flexible component of the exam, it is most appropriately administered immediately after the Medication Survey. Question by question instructions and a multiple vitamin coding dictionary are located in Appendix 2.16.b and 2.16.c, respectively.

2.16.1 Rationale

The purpose of the Vitamin Survey is to assess the usage and dose of vitamins, minerals and dietary supplements more completely than does the Medication Survey. Specific questions on vitamin supplements were added because of their hypothesized importance in the prevention of cholesterol oxidation (vitamins A and E), in blood pressure regulation (calcium), and hemostatic control (fish oil supplements).

2.16.2 Administration

The Vitamin Survey assesses the regular use of multiple vitamins and the regular use of other single preparation vitamins and mineral supplements. It is administered after the Medication Survey, and may in some cases, be repetitive. The reference period (time frame) for the two surveys is the same, i.e., the two weeks preceding the interview.

The form is completed based on participant-reported use of these preparations and the label on the vitamin/mineral supplement container, when available.

The use of multiple vitamins is defined as the ingestion of a preparation containing at least two different vitamins, at least once a week. The number of pills taken per week, its manufacturer, and brand name are recorded. Multivitamins are coded, based on brand name and manufacturer, from the Vitamin dictionary. The list of single preparation vitamins and mineral supplements includes vitamins A, C, B_6, D, E, B-complex, selenium, iron, zinc, calcium, beta carotene, fish oil, folic acid, iodine, copper, brewer's yeast and magnesium. The information collected on these includes its seasonal use, length of time used (in years), number of pills taken in a week, dose and unit per pill(teaspoon).

When the participant has not brought in all vitamin and supplement containers, the interviewer relies on both participant information and container labels to document the use, name, manufacturer (for multiple vitamins), and dose (for single preparation products) of each item on the form. When the preparations are not available, data collection is based on participant memory.

Question by question instructions for administering each item on the form and for coding the multiple vitamins are provided in Appendix 2.16.

2.16.3 Training

Staff are centrally trained. Study coordinators and medication coding specialists are responsible for training new staff in administering the form and coding the multiple vitamins.

2.16.4 Certification

Certification is conferred after successful completion of central training, or by the chief interviewer. For certification to be maintained, each interviewer responsible for this survey data collection takes part in the completion of the semi-annual standardization coding exercises. Annually, the Quality Control Committee reviews the proportion of incomplete coding by interviewers. Annual recertification requires successful performance on the coding exercises and the review of incomplete coding.

2.16.5 Quality Assurance

Twice a year, exercises consisting of lists of locally reported vitamins and blanks for coding are distributed to interviewers at each field center by the Quality Control Committee for (1) review of interviewer completeness and accuracy in coding, and (2) review of the completeness and accuracy of the Vitamin Coding Dictionary.

2.16.6 Data Collection

The Vitamin Survey can either be collected on screens by direct data entry or on paper for delayed data entry.

2.17 Anthropometry

Height, weight and body size are measured during Visit 3. The measures of weight and body fat distribution (waist and hip girth) are core study anthropometric indices have been measured at each examination. During Visit 3, standing height (obtained at Visit 1) is remeasured on all participants. All measurements are recorded on the Anthropometry form (Appendix 2.17.a). Procedures for measuring the height, weight, waist and hips are provided below. Instructions for completing the data collection form are provided in Appendix 2.17.b. 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.

2.17.1 Rationale

An abbreviated set of anthropometric measurements is obtained on the ARIC participants in Visit 3 to assess height, weight and body fat distribution. Standing height was measured as part of Visit 1 and is repeated at this examination. Waist and hip are core measurements which have been repeated each time the participant is seen at the field center.

2.17.2 Procedures

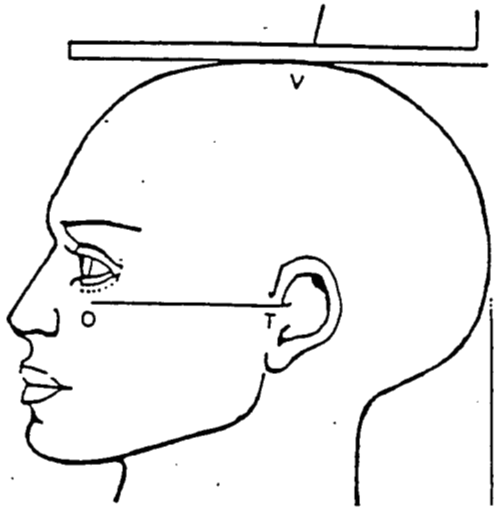
Anthropometry is performed before the clinic snack and after the participant has changed into a scrub suit or examination gown and given the opportunity to empty his/her bladder. All measurements are made with the participant wearing light-weight, nonconstricting underwear. Participants wearing nylon 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. A general checklist for performing anthropometric measurements (Appendix 2.17.c) is completed for every participant.

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, he/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. Anatomical landmarks for the anthropometric measurements are identified in Figures 2.17.2 and 2.17.3.

2.17.2.1 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 2.17.1). 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 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 Table 2.17.1).



ORBITALE: Lower margin of eye socket

TRAGION: Notch above traqui of ear or at upper margin of zygomatic bone at that point

FRANKFORT PLANE: Orbitale-tragion line horizontal

Figure 2.17.1 Frankfort Plane for Measuring Body Height

2.17.2.2 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 2.17.d). The certified technician follows a checklist for weight measurement (Appendix 2.17.e) which outlines the procedures for checking the equipment and measuring the participant's weight and enters study data on the Anthropometry form.

2.17.2.3 Waist (abdominal) girth

The participant is instructed to stand erect and relaxed with weight equally distributed on both feet. The participant is asked to lift the scrub suit top just high enough to make the area visible. 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. (See Figure 2.17.2). The full length mirror or recorder verify that the participant is standing erect and that the tape is kept horizontal. The measurement is recorded to the nearest centimeter, rounding down at the point of relaxed end exhalation. The technician follows a checklist for maximal waist measurement (Appendix 2.17.f).

2.17.2.4 Hip girth

The participant stands erect, yet relaxed, with weight distributed equally over both feet. The hip girth is measured at the level of the maximal protrusion of the gluteal muscles (hips). (See Figure 2.17.2). 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 anthropometric 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 2.17.g) 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.

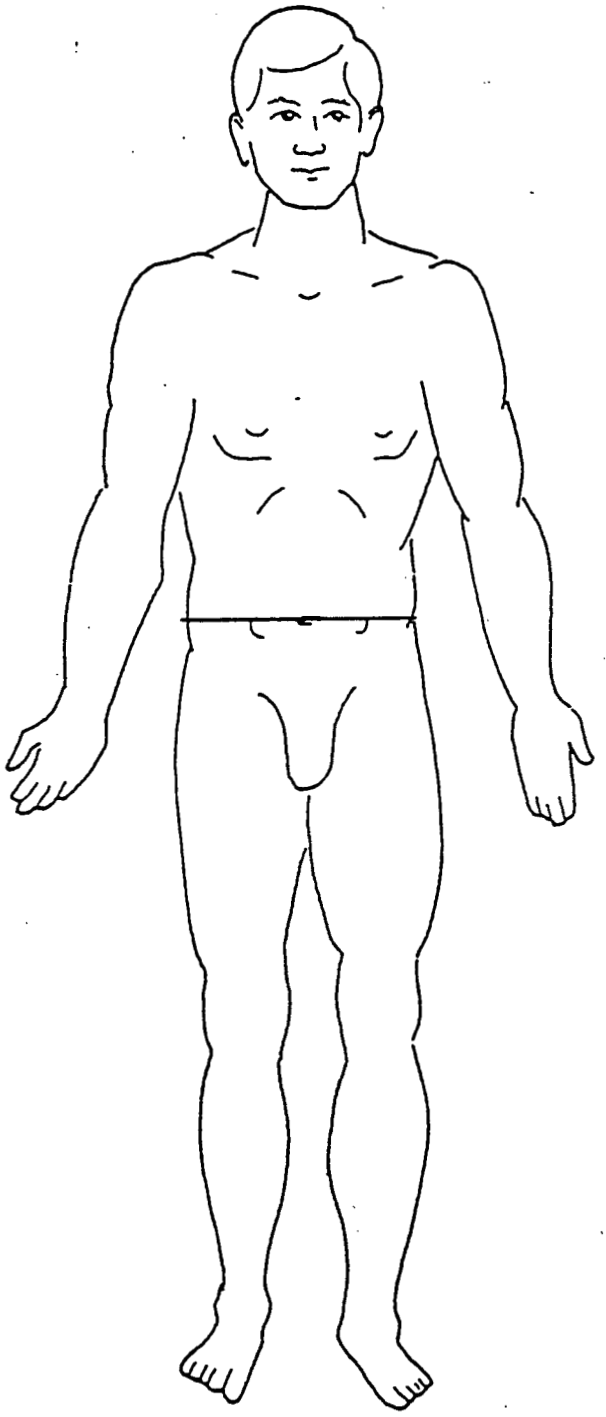
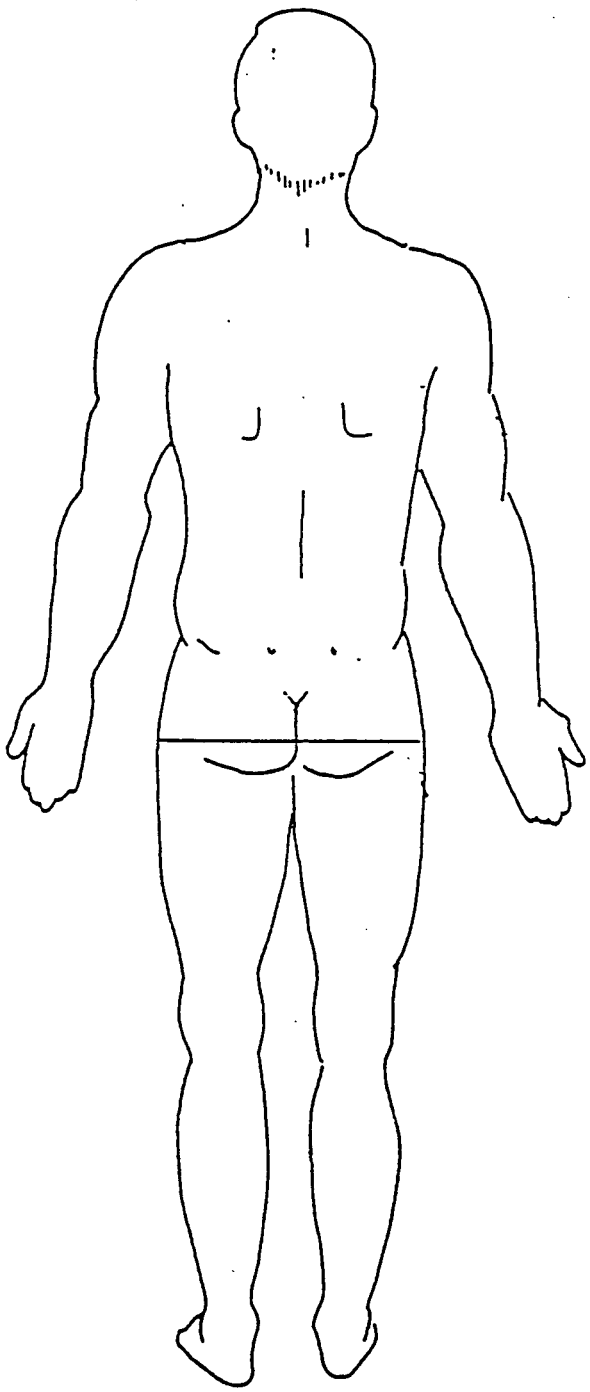


Figure 2.17.2 Location of Waist Girth Measurement



HIP GIRTH AT MAXIMUM PROTRUSION
OF GLUTEAL MUSCLES

Figure 2.17.3 Location of Hip Girth Measurement

2.17.3 Training

Technicians are trained centrally and are responsible for the local training of newly hired anthropometry technicians (observers) and recorders. Training includes an (1) introduction to the rationale for body size measurements, 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.

2.17.4 Certification

Common criteria are used for initial certification and recertification for anthropometry. Field center anthropometry supervisors and technicians are (re)certified annually by the study's central anthropometry expert. Each technician measures at least two certification volunteers, meeting the following criteria:

1. The waist and hip circumference measurements must agree within + 1.5 cm on each certification volunteer; average difference within + 0.75 cm for both volunteers.

2. Weight must agree within + 0.5 lb.

Recertification is required annually, for which the following additional criteria 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.

2.17.5 Quality Assurance

In addition to annual recertification, protocol adherence in the performance of each procedure is reviewed at least biannually 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. 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 2.17.h). These are sent to the ARIC Coordinating Center for review.

Anthropometry equipment is calibrated frequently and results are recorded on an Anthropometry Equipment Calibration Log (Appendix 2.17.d). Scales are zero balanced daily and calibrated weekly. Measuring tapes are checked quarterly and replaced as needed. The above measurements are recorded on the 'Report on Use of Observation and Equipment Checklist' and sent to the Coordinating Center biannually, at the end of January and July.

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.

2.17.6 Data Collection

The Anthropometry Form is collected by direct data entry on a data entry screen or on a paper form, by either the technician (observer) or recorder.

2.18 Blood Pressure, Sitting

Sitting blood pressure is measured on all participants at each field center. As was done in the two previous examinations, it is measured in a resting state, using three measurements with a random zero sphygmomanometer. Data are recorded on the Sitting Blood Pressure form (Appendix 2.18.a).

2.18.1 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 identical to those used in previous examinations, as detailed in Manual 11 of the ARIC Protocol.

2.18.2 Procedures

Sitting blood pressure is a fixed component of the participant flow and is measured before venipuncture. 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 2.18.b. Guidelines have been established for referring participants with abnormal blood pressures for clinical care or follow-up in sections 2.27, Medical Data Review and 2.28, Referrals and Review Guidelines of this manual.

2.18.3 Training

Blood pressure technicians are trained centrally at the beginning of each examination. New technicians, hired after Visit 3 central training are trained locally by the designated local expert. Refer to Manual 11 for further details.

2.18.4 Certification

Certification is required; criteria are listed in Manual 11. Recertification is performed biannually. 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.

2.18.5 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 (Appendix 2.17.h) is completed biannually for each certified technician. Monitoring of certification status is conducted by the Coordinating Center.

2.18.6 Data Collection

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

2.19 Echocardiography

Echocardiography is performed solely at the Jackson Field Center. The overall objectives are to (1) characterize the cardiac structure and function in a large, population-based sample of predominantly healthy, African-Americans ages 45 to 64 years and (2) to determine whether the measurements are related to traditional risk factors for cardiovascular disease, prevalent CVD and changes in CVD risk. The specific goals are to

1. Define the population distribution of various echocardiographic measurements of left ventricular size, mass and function (systolic and diastolic);

2. Describe the association between sitting blood pressure and echocardiographic parameters of left ventricular mass and function;

3. Assess whether early abnormalities in left ventricular size, mass or function precede the development of hypertension;

4. Evaluate the association between electrocardiographically detected arrhythmias and echocardiographic left ventricular mass and function.

5. Assess the possible correlates of increased left ventricular mass and dysfunction, such as age, physical activity, alcohol intake and obesity.

All Jackson ARIC participants examined between August 1993 and the completion of Visit 3 are scheduled for an echocardiogram during the Visit 3 exam.

2.19.1 Rationale

The utility of echocardiographic measures of cardiac anatomy and function has been demonstrated in clinical and population studies, but has not been studied sufficiently in African-Americans. Cardiac abnormalities assessed by this technique (e.g., left ventricular hypertrophy) have been associated with an increased incidence of cardiovascular morbidity and mortality. Given the greater sensitivity and specificity of echocardiographic measures in comparison to other indirect measures of cardiac abnormalities, the echocardiogram may serve as a surrogate measure of preclinical manifestations of cardiovascular disease and as a prognostic indicator for future clinical events (i.e., hypertension, myocardial infarction, and/or stroke).

2.19.2 Procedures

Standardized scanning and reading protocols are available for detailed information on performing echocardiographs in the ARIC study; Manual 15A for scanning and Manual 15B for reading. Essential elements of the scanning protocol include (1) M-mode measurements of the left ventricle, left atrium, and aortic root; (2) two dimensional (2D) views of aortic, mitral, and four chamber structure and function; (3) pulsed-wave doppler of the LV inflow and outflow. Essential elements of the reading protocol include (1) off-line computerized readings by Freeland Systems Computer for M-mode and 2D analyses; (2) pulsed-wave doppler readings to be performed at a later date.

Data are collected electronically during the echocardiography scanning procedure using the Acuson Imaging System without stand-alone data collection forms. Video-tapes are labelled with the ARIC participant ID and sent weekly to the University of Mississippi Heart Station for reading.

During scanning, echocardiographic images are directly digitized and stored on optical disks. Backup videos are created simultaneously. At the Heart Station, the digitized images are uploaded to the workstation computer. Readings of both the M-mode and 2D scans are performed using the Freeland Systems computer. Data from the M-mode and 2D readings are then downloaded into an ASCII format and are transferred weekly to the Coordinating Center following the standard ARIC procedures for data transfer.

2.19.3 Training

The initial training of two echocardiographers was performed at the University of Mississippi Heart Station (Division of Cardiovascular Diseases, Department of Medicine). This consisted of a three months in which each ARIC technician spent 6 hours per week observing and performing echocardiography scans under the supervision of Dr. Thomas Skelton at the Heart Station. Each technician performed 6 scans per week. At the end of the three month training and observation period, the technicians attended an additional one week

echocardiogram training course at the Framingham Heart Study. Subsequent training of new technicians is done locally by the University of Mississippi Heart Station and ARIC certified staff.

2.19.4 Certification

ARIC echocardiographic technicians are certified in scanning procedures by Dr. Thomas Skelton of the University of Mississippi Heart Station. Certification in scanning is achieved by demonstrating comparability in two - four examinations with those performed by the director on the same individuals. When the data quality of the certification scans obtained by the technician is substantially lower than the scans performed by Dr. Skelton, or are technically unacceptable for other reasons, the technician completes additional training before attempting certification.

Echocardiographic scans for the ARIC Study are read by Dr. Skelton. Should additional readers be necessary, they will be trained by Dr. Skelton to use the Freeland System 2D and read M-mode scans. Certification will be obtained after demonstrating 10 readings of comparable quality to those of Dr. Skelton.

2.19.5 Quality Assurance

The use of echocardiograms in the Jackson component of the ARIC study is the first large scale population study of middle-age African-Americans. Therefore, quality control is of particular importance. Previous population studies on young, middle-age and elderly white Americans (CARDIA, Framingham Heart Study, and CHS) have indicated that considerable training and experience are required to assure optimal echocardiographic data acquisition. The goals of this echocardiography quality control program are to (1) provide quantitative documentation of the reproducibility of the scanning and reading procedures, and (2) to assess the comparability of the ARIC scanning and reading estimates of variability with other population studies of echocardiography. The essential features include:

(1) The monitoring of the technicians performing the echocardiograms for adherence to the ARIC protocol by Dr. Skelton at the Heart Station.

(2) Weekly meetings of the technicians with Heart Station personnel to review three studies with technicians and to evaluate potential deficiencies, such as improper imaging views, poor quality recordings, or failure to follow imaging protocol.

(3) Clinic monitoring of echo scans and readings by outside consultants from the ARIC, Framingham Heart and Treatment of Mild Hypertension studies (Drs. Arnett, Benjamin, and Liebson, respectively) to identify potential protocol deviations or difficulties.

(4) Assessment of inter and intra-technician/reader variability throughout the study.

2.19.6 Data Collection

Raw echocardiographic data are directly digitized during data collection by an on-line system and stored on optical disks and super VHS videotapes. Individual echocardiograms are labelled and catalogued for subsequent reading, following standard ARIC data collection and identification protocols. Scans are read at the University of Mississippi Heart Station, data are stored on the image analysis system hard drive, and primary echocardiographic measurements are downloaded to ASCII files for transmission to the ARIC Coordinating Center.

2.20 Electrocardiogram

A resting 12-lead ECG is performed on each participant in Visit 3 using procedures and equipment identical to those employed in previous cohort examinations. Processing and coding at the Minnesota and Edmonton central electrocardiographic reading centers follows the same procedures used in the baseline visit. Full details are provided in Manual 5 of the ARIC Protocol.

2.20.1 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.

2.20.2 Procedures

Standard (12-lead) ECG operational procedures are provided in Manual 5, Electrocardiography.

2.20.3 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, consisting of (1) electrode placement, (2) skin preparation, (3) MAC PC menus and data entry, and (4) self-evaluation techniques for technical performance.

2.20.4 Certification

Certification is required for ECG technicians performing 12-lead ECGs. Requirements and procedures are listed in Manual 5. The Minnesota ECG Reading Center serves as the certifier. Recertification is performed annually.

2.20.5 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 Edmonton ECG Reading Center to each technician on an ongoing basis; a monitoring/retraining visit by the local ECG trainer takes place annually; an ECG quality control checklists is administered quarterly (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).

2.20.6 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. Tracings are transmitted daily to the ECG Computer Center at Edmonton, Alberta via modem. Paper tracings are stored in the participant's folder.

2.21 Cerebral Magnetic Resonance Imaging

Age-eligible cohort participants at the Forsyth County and Jackson field centers who pass exclusion criteria are scheduled for brain MRI scans, either immediately following their ARIC exam, or for another more convenient time. These participants also repeat the Cognitive Function test they took during Visit 2.

2.21.1 Rationale

The goal of implementing the cerebral MRI into the ARIC study is to evaluate cerebral changes detected by MRI in a representative, biracial population, aged 56 to 70, and to evaluate the relationship of these changes to clinical stroke, coronary heart disease, cardiovascular risk factors, retinal microvascular changes, extracranial carotid atherosclerosis and changes in cognitive function. The MRI data are expected to supplement the clinical descriptors of cerebrovascular disease related hospitalizations by increasing the sensitivity of detecting subclinical disease and by distinguishing small-vessel from large vessel disease.

2.21.2 Procedures

Prior to the procedure at the MRI suite, the MRI technician confirms the absence of the exclusion criteria reported on the MRI Screening form, repeats an explanation of the procedure, its potential risks and benefits and administers a second hospital-required MRI consent form (Appendix 2.19.a). Prior to receiving the MRI scan, an ARIC staff member administers the ARIC Cognitive Function exam (see Appendix 2.2 for the form and instructions).

The participant is scanned according to the ARIC MRI scanning protocol and the technician completes the MRI Procedure Form. The form and their question by question instructions are located in Appendix 2.19.b and 2.19.c, respectively.

Although ARIC does not assume responsibility for the diagnosis and treatment of medical conditions, it assumes an obligation to identify abnormalities which may require further medical attention. The MRI technologist reviews each study for the presence of any condition identified by the ARIC protocol as an emergent alert. These include tumor without significant mass effect, AVM, aneurysm, obstructive hydrocephalus, cavernous angioma, venous angioma (urgent referral) and acute subdural or epidural hematoma, subarachnoid hemorrhage, acute intraparenchymal hematoma, acute infarct, subacute infarct, obstructive hydrocephalus, cerebral venous thrombosis, abscess and suspected tumor with significant mass effect (immediate referral). The ARIC neuroradiologist is contacted and established ARIC alert procedures are initiated (see section 2.28 in this manual and the MRI Manual of Operations, No.13).

2.21.3 Training

MRI technologists must have appropriate knowledge of cross-sectional anatomy, physiology, and pathologic processes with emphasis on neurologic imaging. The preferred level of education is completion of a two year AMA-approved program for diagnostic imaging and a minimum of 3 to 6 months MRI experience. The technologist must have a basic knowledge of MRI and knowledge of computer software applications, multi-format cameras, processors and video recording devices. The MRI technologist is trained by the study's neuroradiologist to identify the anatomical location of the AC/PC Line, to implement the ARIC MRI pulse sequences, and to recognize conditions identified by the ARIC protocol as notification alerts.

2.21.4 Certification

MRI technologists are trained and certified by the local MRI\Neuroradiology Center. Certification of the readers is the responsibility of the MRI Reading Center.

2.21.5 Quality Assurance

Quality control procedures are described in detail in Manual 14. In summary, prior to the ARIC participant leaving the MRI suite, the MRI technologist reviews the scan for adherence to the ARIC MRI protocol and for technical quality. Using MRI calibration phantoms, MRI equipment is evaluated for field homogeneity, noise characteristics, spatial and contrast resolution. Masked, phantom quality control scans are sent to the MRI Reading Center for reading.

The acceptability of the MRI examination to the participants is monitored during the first three months of the study. Each week the Study Coordinator identifies two participants at random, who are contacted by an ARIC interviewer who administers the Post-MRI Acceptability Questionnaire. Results are reviewed by the Study Coordinator and Field Center PI. After 24 surveys are completed, copies are sent to the Chair of the ARIC Cohort Operations Committee for assessment.

2.21.6 Data Collection

Scans are recorded on magnetic tapes or optical disks, at the discretion of the ARIC MRI facility. Procedures for preparing, shipping and storing tapes and disks are fully described in Manual 13. Labelled tapes and disks are shipped via overnight carrier to the ARIC MRI Reading Center on a predetermined schedule, i.e., once a week (tapes) or once every two weeks (optical disks). Shipping containers include scans, log sheet, MRI Completion Forms and participant forms (refer to Manual 13).

Field centers are notified of study results, following the results reporting protocol. Summary results are transmitted electronically to the ARIC Coordinating Center for inclusion in the central data base.

2.22 Retinal Photography

One 45 degree photograph is taken under non-mydriatic conditions (i.e., not requiring pharmacologic dilation of the pupil) of one eye of each participant during Visit 3. The photographs are sent to a central reading center for assessment of retinal status.

2.22.1 Rationale

Fundus photographs are 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 are evaluated. Signs of 'malignant' hypertension (hemorrhages and microaneurysms, 'cotton wool spots', and swelling of the optic nervehead), and other significant retinal conditions, (such as diabetic retinopathy or vascular occlusions) are assessed.

2.22.2 Procedure

Prior to photographing an eye, the Retinal Examination form (Appendix 2.20.a) is administered to each participant to document the general ophthalmic history, to record the method of selecting the eye photographed, or the reason photography cannot be performed. Question by question instructions for the form are located in Appendix 2.20.b. A Canon non-mydriatic, auto-focus fundus camera with 35 mm camera back is used to take a 45 degree retinal photograph (not requiring pharmacologic dilation of the pupil) of one eye of each participant in Visit 3. Photographs are sent to the Fundus Photograph Reading Center for assessment of retinal status. Procedural and operational detail is provided in Manual 14.

2.22.3 Training

Technicians are trained by personnel of the Fundus Photograph Reading Center during central training. Chief technicians are responsible for training newly hired staff.

2.22.4 Certification

Photographer certification is conferred after training, either at the central training session the beginning of Visit 3 or by a field center certified photographer. Practice on local volunteers, and the submission of satisfactory photographs of ten eyes to the Fundus Photography Reading Center are required. Satisfactory quality includes proper field definition, exposure, alignment and focus. Photographs must be completely labeled and mounted according to protocols and accompanied by Photography Log Form(s) and completed shipping manifest.

2.22.5 Quality Assurance

The quality of photographs is monitored throughout the study. For new technicians all photographs are reviewed by the reading center and feedback provided to the photographers in cases that warrant critique. Data on quality of the photographs are routinely generated by the readers on all photographs and reported to field centers, via the ARIC Coordinating Center. A small percentage of the photographs is reviewed by the Reading Center and feedback provided to individual field center photographers when appropriate. One to two participants per week at each field center are asked to volunteer for a repeat photograph (same eye), which is sent to the reading center under a (blinded) quality control ID number.

2.22.6 Data Collection

Data for the Retinal Examination Form (Appendix 2.20.a) are routinely collected on paper for delayed data entry. Question by question instructions for completing the form are located in Appendix 2.20.b. A daily Photography Log Form (Appendix 2.20.c) is maintained at the field center for use by the reading center for each roll of film which includes the film roll number, date, photographer code, participant ID, eye (right or left) and the photographer's comments. A film processing log (Appendix 2.20.d) is maintained at the field center to track the local development of film prior to film mounting and mailing to the reading center. A shipping manifest is prepared by the field center for inclusion in each film shipment to the reading center.

2.23 Ultrasound

Ultrasound B-mode imaging of the carotid arteries is a core study measurement performed at each examination on all, or a sample of participants, to detect early changes in arterial walls. It represents 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.

2.23.1 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 continue to be collected to test their ability to predict incident cardiovascular events in the ARIC cohort. During Visit 3, 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.

2.23.2 Procedures

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

2.23.3 Training

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

2.23.4 Certification

Certification of experienced sonographers is based on the ability to visualize arterial walls, consistent with the process average of all sonographers certified in Visits 1 and 2 and adherence to the scanning protocol. The process average for visualization is monitored using statistical process control techniques at the Ultrasound Reading Center. Certification remains in effect as long as visualization is consistent with the overall sonographer process average.

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.

Loss of certification occurs when a sonographer's average monthly visualization falls significantly below the process average for one site, by a small amount for a number of sites, or the visualization reports reveal any trend toward a loss of visualization, or if the scans deviate from the ARIC protocol, or if the sonographer does not meet the minimum number of scans per month.

2.23.5 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, 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.

2.23.6 Data Collection

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; a back-up ½ inch tape remains at the field center. Data on blood pressures, beat-to-beat heart rate, and their timing are sent to the URC on diskette.

2.24 Venipuncture

Venipuncture, which strictly follows a standardized protocol at each field center, permits the measurement of associations of atherosclerotic manifestations and new coronary heart disease with clinical chemistries (glucose), plasma lipid, lipoprotein cholesterol, and plasma apolipoprotein levels and hemostatic factors which are known or suspected to be risk factors for coronary heart disease.

2.24.1 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.

2.24.2 Procedures

Venipuncture is performed in a fixed sequence in the participant flow, after anthropometry and sitting blood pressure measurements on all cohort members who have met fasting requirements (or who are medically unable or indicate an unwillingness to adhere to fasting). The venipuncture protocol is a separate document, Manual 7: Blood Collection and Processing. The Venipuncture form (Appendix 2.21.a) documents blood drawing and blood processing procedures. Question by question instructions for completing the form are located in

Appendix 2.21.b. A Venipuncture Incident Record (Appendix 2.21.c) is completed if one or more blood samples are not drawn, the tourniquet is reapplied, there is inappropriate fist clenching by the participant or there is needle movement during the procedure. Shipping problems, such as broken tubes, clotting, hemolysis, lipemia, etc., are also recorded on this form.

2.24.3 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.

2.24.4 Certification

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

2.24.5 Quality Assurance

Data quality monitoring includes periodic review by the Quality Control Committee of (1) tube filling time, (2) number of venipuncture attempts, (3) condition of specimens on arrival at the central laboratories, and (4) selected markers of lack of adherence to protocol during phlebotomy and/or processing of specimens at the field center laboratory.

2.24.6 Data Collection

Venipuncture data are collected on a hard copy of the Venipuncture Form (see Appendix 2.3.g). Notes reflecting blood drawing or processing problems are recorded on the accompanying Venipuncture Incident Log which is forwarded as hard copy to the central laboratories and Coordinating Center.

2.25 Snack

A light snack is scheduled as soon as possible after venipuncture. Caffeine-free refreshments are provided, including decaffeinated coffee and tea. Menus are locally determined.

2.26 Data Inventory

The data inventory step initiates the second fixed component of the field center examination sequence, 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 3 and require summarization and placement in the participant's folder for nurse/clinician review.

2.26.1 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 emergent or immediate referral for medical care are put together into one document, the Medical Data Review Printout (Appendix 2.22), and reviewed with the participant prior to the completion of the examination. Data inventory is the data management process by which the Medical Data Review Printout is produced.

2.26.2 Procedures

A staff person reviews the participant's itinerary sheet and folder for completeness. 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. Medical data review may be conducted in street clothes.

2.26.3 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.

2.26.4 Certification

Certification for data inventory is the responsibility of the field center Data Coordinator.

2.26.5 Quality Assurance

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

2.26.6 Data Collection

Please refer to the Manual of Operations for Data Coordinators.

2.27 Medical Data Review

2.27.1 Rationale

Although it is made clear to all cohort participants and their providers of medical care that the interviews and clinical exams which they 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 nurse/clinician to provide the participant with a preliminary summary of study results: weight, blood pressure and preliminary ECG reports. (Please refer to the results reporting sheet, Appendix 2.23.a).

From the perspective of the investigators, the primary objective of the medical data review, is to safeguard participant safety. Clinical interview data are reviewed with the participants to confirm selected positive symptoms reported during the interviews/exams and to determine if these appear to warrant immediate or additional medical follow-up. When all laboratory data

reported by the central agencies (laboratories and reading centers) have been received, all 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, participant Visit 3 data are reviewed at three levels. The first is designated the Medical Data Review (see below, section 2.27.2), which is conducted by the nurse/clinician after all interviews and physical exams have been completed and all data have been assembled as part of the Data Inventory step (section 2.26). The second and third levels of medical data review are described in sections 2.29 (Physician Review) and 2.30 (Results Reporting), respectively.

2.27.2 Procedures

The nurse/clinician conducts the medical data review to (1) summarize the results of selected measurements obtained during the exams/interviews and to answer participant questions, (2) determine whether a reported stroke/TIA symptom(s) constitutes a possible cerebrovascular event(s), and (3) identify potential medical problems. Prior to meeting with the participant, the Annual Follow-up Form (to document reported positive Rose Angina symptoms), the interview note logs, ECG, blood pressure, TIA/Stroke form, weight, demographics, major medical problems on the Medical Data Review printout (Appendix 2.11) are examined.

During the Medical Data Review, the participant's data are reviewed for positive findings during Visit 2 (i.e., alert values and referral letters), positive findings during any of the three Annual Follow-up interviews between Visit 2 and Visit 3 (such as positive Rose Angina, cardiac procedures or hospitalizations), or comments on the participant's current itinerary form made by interviewers or technicians. A networked program within the ARIC data entry system is concurrently run on the participant's data to generate a printout of selected items pertinent for the Medical Data Review, including:

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 reported by participant;
   b. Physician diagnosis of high cholesterol reported by participant;
   c. Physician diagnosis of cancer reported by participant;

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. Possible congestive heart failure on Personal History form;
   d. Stroke/TIA reported on TIA/Stroke form;
   e. 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 revascularization 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
   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 I, O, or D of item 4 (uterine bleeding) of the Female Reproductive History form are followed-up as part of the Medical Data Review. The participant's response to item 4 is printed on the Medical Data printout; the back-up procedure in case of computer failure or incomplete data collection is to identify this item on the paper form for review during the Medical Data Review. When a referral takes place for this condition, it is identified on the Alert/Referral form under Other Conditions, Specify.

If the response to Item 4 is either I, O, or D, ask whether the participant 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. If there is another condition that merits an urgent referral (to the same physician) at the time of the clinic visit, the bleeding should also be mentioned.

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

The data coordinator, or staff member designated by the study coordinator to prepare participant folders, should be the only person accessing Visit 1 or 2 information prior to the follow-up visit. 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 Visit 1 or 2 information to be brought to the attention of the entire staff. It is to be noted on the Visit 3 Participant Itinerary Sheet or the PIN Sheet. The person performing the medical data review has access to all previous ARIC findings relevant to the medical review, immediately prior to discussing the participant's clinic visit report (Appendix 2.23.a).

If during the course of the Visit 3 examination the participant asks about changes in laboratory values/clinical procedures since Visit 2, 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 exam, 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.

Below are guidelines for Visit 3 recommendations.

1. Changes in anthropometrics should be focused on weight gained or lost. These are summarized in the participant results reports.

2. The blood pressure readings, based on the average of the second and third measurements, are discussed at the Medical Data Review according to the categories listed in Table 2.27.1.a and in the Clinic Visit Report. The referral guidelines published from the fifth report of the Joint National Committee (Table 2.27.1.b) are made for adults aged 18 and older. A caveat to this algorithm is provided by the Committee with the statement that "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

Table 2.27.1.a 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 2.27.1.b Joint National Committee on Detection, Evaluation and Treatment of High Blood Pressure (JNC V): Recommendations for Follow-Up

Systolic Pressure (mm Hg)	Diastolic Pressure (mm Hg)	Explanations to Participants and Follow-up Recommendations[1]
< 130	< 85	Your blood pressure is normal[2]; recheck in 2 years (no ARIC referral)
130-139	85-89	Your blood pressure is high normal; recheck in 1 year (no ARIC referral)
140-159	90-99	Your blood pressure is elevated; confirm or refer to source of care within 2 months
160-179	100-109	Your blood pressure is elevated; evaluate or refer to source of care within 1 month
180-209	110-119	Your blood pressure is high; evaluate or refer to source of care within 1 week
≥ 210	≥ 120	Your blood pressure is very high; evaluate or refer to source of care immediately

[1] If the systolic and diastolic categories are different, follow recommendations for the shorter-time follow-up (eg, 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.

Figure 2.27.1 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)

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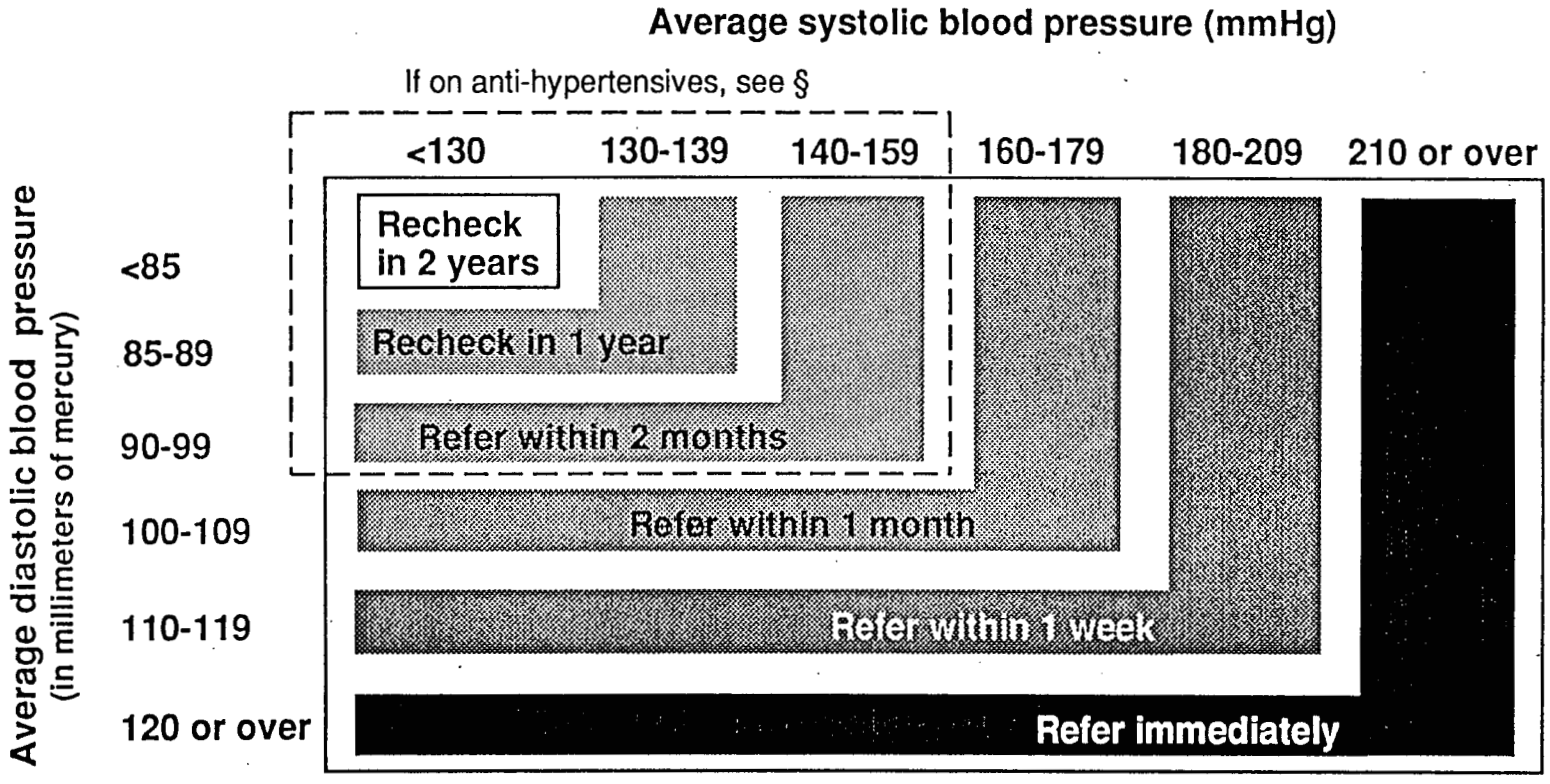
Name: _____ Your blood pressure is: _____/_____ mmHg

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)

of individuals with a previous history of high blood pressure, other CVD risk factors, or target-organ disease, the ARIC referral guidelines (Figure 2.27.1), adapted from the fifth Joint National Committee recommendations, are followed for all participants, unless the study physician recommends 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 3 in an asymptomatic participant does not warrant repeat referral.

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.

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. The participant's responses to selected items of the various questionnaires administered during the field center examination are printed on the Medical Data printout for ease of review by the clinician performing the Medical Data Review. This printout is a compilation of participant responses with potential medical care impact or participant safety implications. The back-up procedure in case of computer failure or incomplete data collection is to identify such items on the paper form for review during the Medical Data Review. Referral guidelines and alert values are listed in Section 2.28.

The TIA/Stroke Worksheet is completed when participants have reported positive symptoms on the TIA/Stroke form to document (1) the presence of noncerebrovascular causes for an event(s), (2) the impression of a TIA or stroke, and (3) the most recent date of a putative event. Should this event(s) be attributable to cerebrovascular symptoms within the last six months, the field center medical director is consulted for recommendations on referral for medical care.

In summary, factual information (the First Participant Report, Appendix 2.24.c) is given to participants about their results during the Medical Data Review, identifying any abnormalities and recommending referral as needed, but avoiding medical advice about prognosis, prevention or therapy. Physician back-up is available at all times.

2.27.3 Training

Nurse/clinicians are trained by the ARIC medical director and/or field center principal investigator. The medical director of one of the field centers serves as the central trainer.

2.27.4 Certification

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

review. This certification is obtained after review of procedures with the central trainer; it is acceptable to do this over the telephone.

2.27.5 Quality Assurance

It is the responsibility of the medical director of each ARIC field center to ensure that the medical data review, referrals and reporting of results are done according to the procedures in the ARIC protocol.

2.27.6 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 and Referral Form.

2.28 Referrals and Review Guidelines

2.28.1 Rationale

Participants are referred based on the guidelines for referral listed below. For participant safety, the nurse/clinician is alerted prior to the Medical Data Review that the participant has provided affirmative responses to key items indicative of hypertension, diabetes, ischemic heart disease, hypercholesterolemia, cancer, uterine bleeding, chest pain on effort, congestive heart failure, TIA/stroke, and intermittent claudication. Guidelines for the staff 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. 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 2.23.a and 2.23.b, respectively.

2.28.2 Procedures

Referrals made during the Medical Data Review 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 sent a letter of explanation (Appendix 2.25, REFMD.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. The ARIC physician calls the participant's provider of care, and sends a referral letter. (Appendix 2.25, REFMD.a)

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's physician. Referral letters are sent to participants and their providers of medical care (Appendices 2.26-2.29).

5. No Referral. The study results are summarized for the participant and held for a routine results letter. Letters indicating no abnormal findings are sent to participants and their physicians (Appendices 2.26-2.28)

Procedure/symptom specific guidelines are summarized in Table 2.28.1. Certain interview items or measurements (identified with an asterisk) require confirmation. Referral guidelines for blood pressure differ based on a prior history of an elevated blood pressure during the second examination. 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 2.30.2; examples of the texts of these letters are provided in Appendices 2.25-2.28.

Table 2.28.1 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.

* Interview items or measurements require confirmation during Medical Data Review

Table 2.28.1 Medical Care Referral Guidelines, continued

Referral Classification	Examination Findings	Recommendation to Participant	Explanation to Participant
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.
	*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.

* Interview items or measurements require confirmation during Medical Data Review

Table 2.28.1 Medical Care Referral Guidelines, continued

Referral Classification	Examination Findings	Recommendation to Participant	Explanation to Participant
ECG Findings Requiring Review by M.D. Before Participant leaves Field Center.	Acute pattern abnormalities MI, ischemia...)*	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.
Retinal photos	Acute abnormalities.#		All photographs are read off-site. If there is a pro-blem, we will notify you and your MD if you agree.
	Abnormalities requiring routine referral.+		
	Normal results.		
Cerebral MRI	Acute pattern abnormalities. @	Would like to review with MD.	
	Minor chronic findings.%		All scans are read off-site; If there is a problem, we will notify you and your MD if you agree.

* 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.

\# Immediate/urgent referrals: Vascular occlusions; malignant hypertension; papillary swelling; high risk diabetic retinopathy; central macular edema; retinal detachment; advanced maculopathy; active chorioretinitis; possible melanoma/tumor.

\+ Routine evaluations: Mild to moderate diabetic retinopathy; questionable diabetic retinopathy; glaucoma.

@ Urgent referral: Tumor without significant mass effect; AVM, aneurysm, obstructive hydrocephalus; cavernous angioma, venous angioma. Immediate referral: Acute subdural, epidural, intraparenchymal hematoma; subarachnoid hemorrhage; acute or subacute infarct; hydrocephalus.

% Old infarct greater than 5mm or old hematoma.

2.29 Physician Reviews

2.29.1 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 by the nurse/clinician at 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 reported 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.

2.29.2 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.

2.30 Results Reporting

2.30.1 Rationale

This activity concludes a process which extends over 4 to 12 weeks after the participant completes Visit 3. 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 2.30.6, and mailed to participants and physicians.

As alert values (see Section 2.27.2) are returned from the central laboratories and reading centers, the medical staff reviews them and assumes responsibility for referrals (see Table 2.30.1). 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.

Table 2.30.1 Laboratory Alert, and Normal Reference Values

Test	Alert Value *	Reference Range ARIC Laboratory**	
TOTAL CHOLESTEROL (mg/dL).....	--	< 200	Desirable
		200-239	Mildly elevated
		≥ 240	Markedly elevated
LDL CHOLESTEROL (mg/dL).....	--	< 130	
HDL CHOLESTEROL (mg/dL).....	--	> 35	
TRIGLYCERIDES (mg/dL).....	> 1,000	< 220	
GLUCOSE (mg/dL).....	<60, >200	70 - 130	

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

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

Reporting of Visit 3 values is made in the context of Visit 2 results. Specifically, all alert values, such as those in Table 2.27.1, are reported. However, if an abnormal result is noted to be similar or identical to one that resulted in a referral at Visit 2 (an electrocardiogram for example), a repeat referral in Visit 3 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.

With participant approval, results of all the standard medical tests (normal and abnormal) are reported to the participant's physician. Standard 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 each field center.

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. 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.

2.30.2 Overview of Results Reporting

Figures 2.30.1 and 2.30.2 (Summaries of Review of Results, Reporting, and Referral) provide an overview of this process and illustrate the interface between the review of medical data, the referral process, and the notification of study results. The figures also illustrate 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 2.30.2 and Appendices 2.25-.29) 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.

1. At reception, the participant is given the document Schedule of ARIC Results Reporting (Appendix 2.24.c), describing 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 2.27. A preprinted Summary of Visit 3 Report (Appendix 2.24.a) is given to the participant to summarize exam results.

3. At the Medical Data Review, a referral may be necessary. Three levels of referral are designated: Immediate, Urgent, Routine, and the corresponding referral letters are sent to the participant's physician (Appendix 2.25.a). In some cases, a phone call may be indicated.

4. Once a week, a physician review occurs during which the ARIC physician reviews participant data and interprets ECG tracings, as described in section 2.29.2. If an abnormality is detected at this time, a report or referral letter is sent to the participant and his/her physician (Appendix 2.26-2.28).

5. Subsequent to the exam, results are received from the central laboratories and reading centers as described below. If there are "alert values", the participant is notified using a Alert Value Referral Letter (Appendix 2.26.e and f) and the medical care provider is notified (Appendix 2.26.b and c). If there are no "alert values", the results are entered in the database for final Results Letters.

6. A record is kept of all alert values and referrals on the Alert/Referral Log (Appendix 2.23.b) and a copy of all referral letters is filed in each participant's folder.

7. 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 2.30.2.

8. 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.

ARIC Referral/Notification Procedures

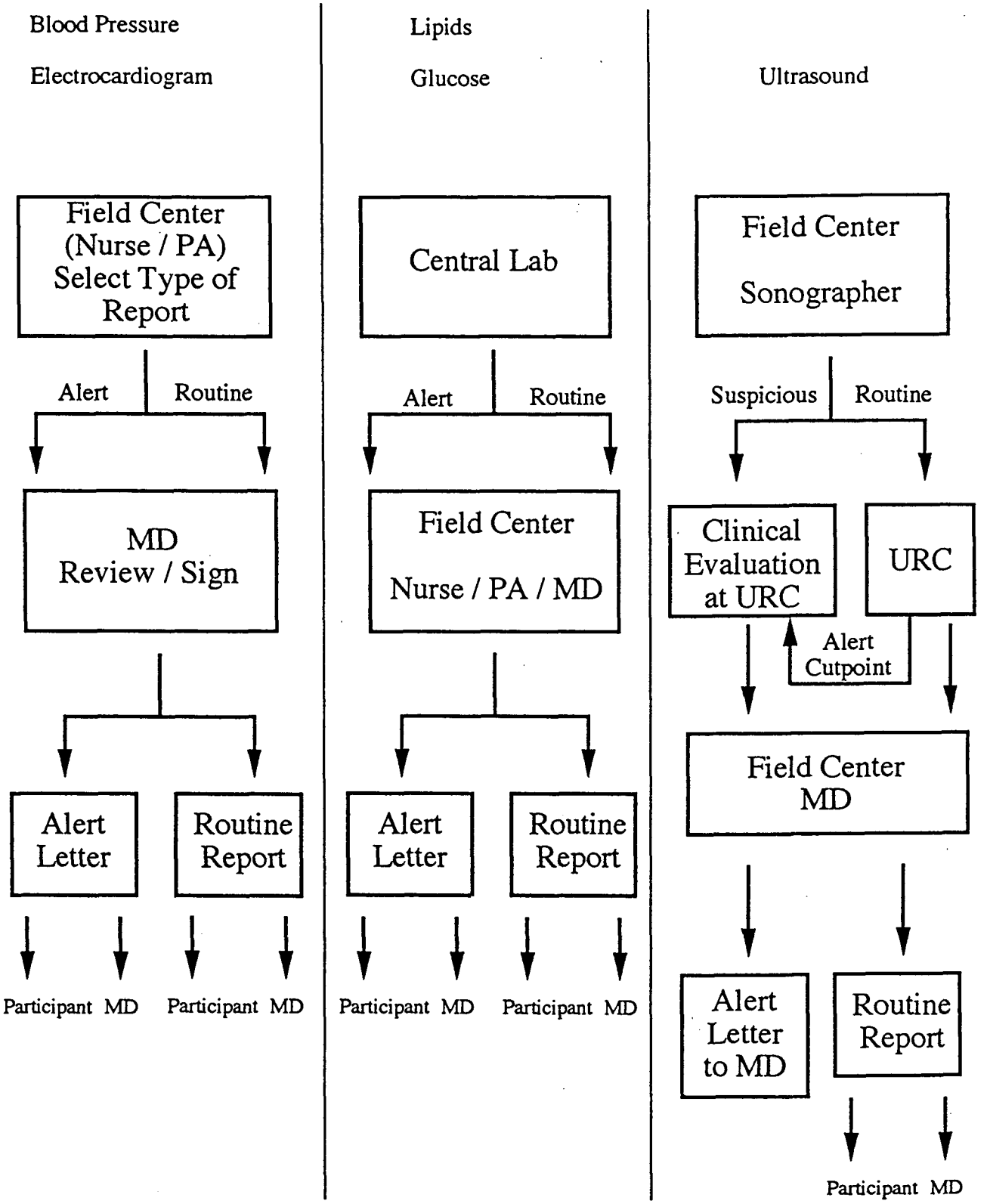


Figure 2.30.1 ARIC Referral/Notification Procedures

ARIC Referral/Notification Procedures

(Continued)

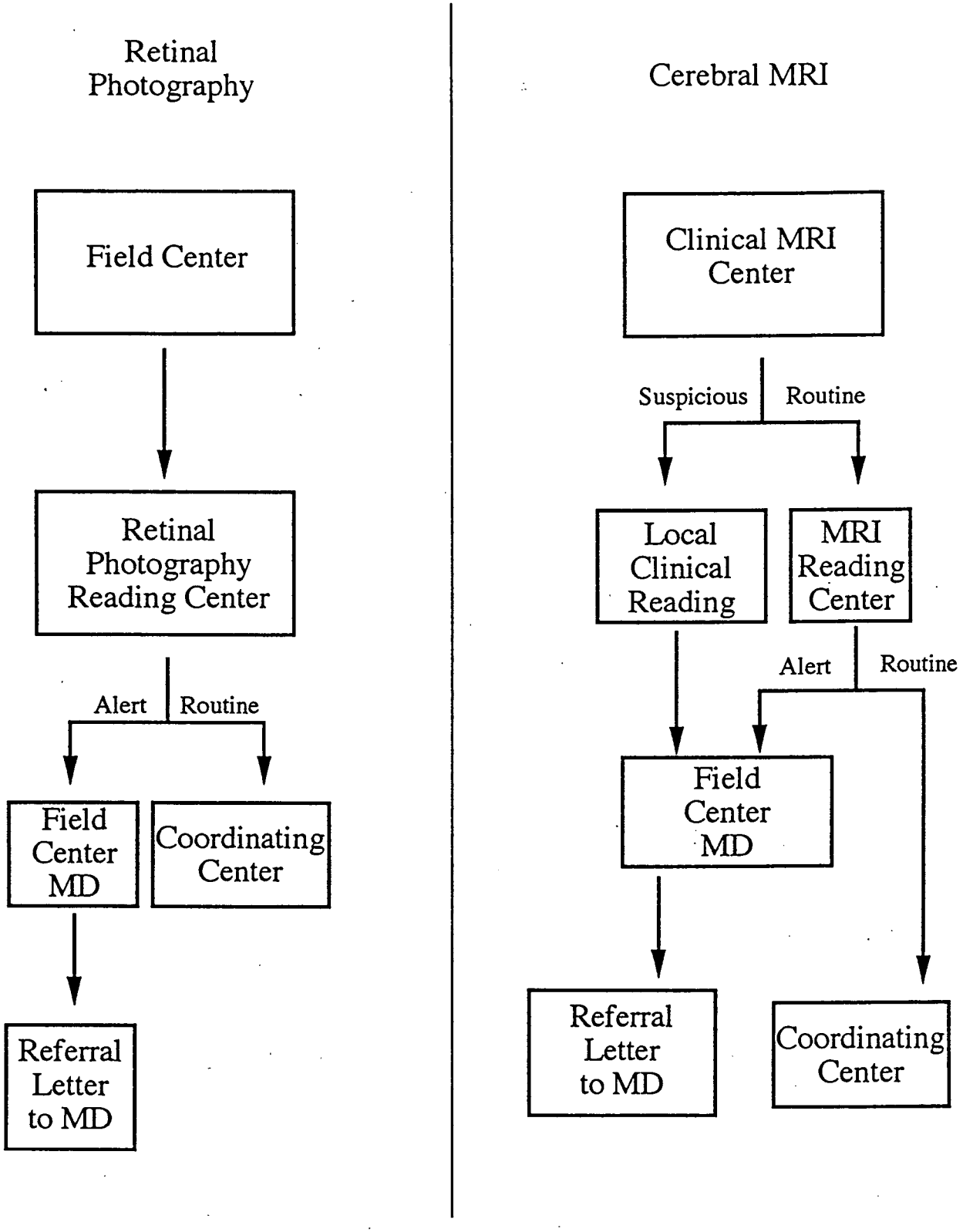


Figure 2.30.2 ARIC Referral/Notification Procedures

Table 2.30.2 Cover Letters for the Reports to Participants and Physicians

RECIPIENT	TYPE OF RESULTS LETTERS	
	REFERRAL LETTERS FOR ALERT VALUES	
Physician	REFMD.a)	referral at clinic visit
	b)	referral post clinic visit
Participant	REFPPT.a)	referral at clinic visit (N/A)
	b)	referral post clinic visit (with MD)
	c)	referral post clinic visit (no MD)
	COVER LETTERS FOR SUMMARY VISIT 3 RESULTS REPORT	
Physician	V3MD.a)	Normal results
	b)	Abnormal results, no previous referral made
	c)	Abnormal results, previous referral made
Participant	V3PPT.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
	COVER LETTERS REPORTING RESULTS FOR MRI	
Physician	MRIMD.a)	Normal results
	b)	Minor abnormal findings, no referral indicated
	c)	Abnormal results
	d)	Abnormal results, participant not informed
Participant	MRIPPT.a)	Normal results
	b)	Minor abnormal findings, no referral indicated
	c)	Abnormal results, referral recommended
	d)	Normal or abnormal results, no MD designated
	COVER LETTERS REPORTING RESULTS FOR RETINAL PHOTOGRAPHY	
Physician	RETINMD.a)	Abnormal results
Participant	RETINPPT.a)	Abnormal results, referral recommended
	b)	Abnormal results, no MD designated
	COVER LETTERS REPORTING RESULTS FOR ULTRASOUND	
Physician	USMD.a)	Abnormal results
Participant	USPPT.a)	Abnormal results, referral recommended
	b)	Abnormal results, no MD designated

2.30.3 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 (changes in arterial distensibility, for example, or 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. Field centers then contact the study participant and their provider of medical care by phone and by a letter signed by the medical director (Appendix 2.29.a-c). If in the course of routine readings a minimal residual carotid artery lumen of 2 mm or less or an arterial wall thickness of 2 mm or greater is detected, this is also reported to the field center. 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.

2.30.4 Report of Retinal Photography Measurements

The Retinal Reading Center sends notification of retinal abnormalities to each field center for participants with conditions where referral to an ophthalmologist or other pertinent provider of medical care may be advisable. A letter is prepared both for conditions where prompt referral to a clinician is suggested and for conditions where routine evaluation by an ophthalmologist may be advisable (Appendix 2.28.a-c). The immediate referral alerts are sent to the field center via FAX with a follow-up phone call to ensure that the alert was received. The notifications for routine evaluation are also sent via FAX, but the follow-up phone call is not required. In both cases, the original report is mailed to the field center secondary to the FAX.

20.30.4.1 Retinal alert notifications

Retinal alert notifications for referral to an ophthalmologist or other provider of medical care are sent for the conditions listed below.

1. Recent, fresh vascular occlusions, including both arteriolar and venous.

2. Signs suggestive of malignant hypertension, such as extensive flame-shaped retinal hemorrhages, with soft and/or hard exudates. The alert for this findings includes a disclaimer that the lesions could reflect hypertensive retinopathy, diabetic retinopathy, or some other disease process.

3. Severe papillary swelling accompanied by retinal hemorrhage and/or exudates.

4. Presumed diabetic retinopathy with an overall retinopathy level characterized as:

   a. High risk characteristics (retinal levels 71,75,81 or 85);
   b. Proliferative retinopathy (levels 61 and 65); or
   c. Severe non-proliferative retinopathy (level 53).

5. Macular edema threatening or involving the center, as inferred from hard exudates, hard exudate rings or changes in retinal transparency.

6. Retinal detachment.

7. Advanced maculopathy characterized by evidence of subretinal neovascularization.

8. Active chorioretinitis.

9. Possible melanoma or choroidal tumor.

Possible alert conditions observed by the grader are confirmed by an ophthalmologist (the Reading Center director) prior to initiating alert notification procedures. The grader also initiates alert procedures if a condition not listed above is of medical concern and the consulting ophthalmologist concurs. The Reading Center director suggests an appropriate time to referral, either immediate or urgent within a stated time frame, for inclusion in the alert notification. Retinal alerts are completed at the time the photos are read or, if time is needed for consultation, within two working days.

20.30.4.2 Retinal abnormality notifications

Retinal abnormality notifications advising routine evaluation by a clinician are sent for the following conditions:

1. Presumed diabetic retinopathy characterized as early, mild to moderate, background retinopathy (retinal levels 20,31,43 and 47). The letter includes a disclaimer that the lesions could be due to diabetes, hypertension, or some other disease process.

2. Questionable diabetic retinopathy, characterized by diabetic lesions without microaneurysms (retinal levels 14 and 15). The letter includes a disclaimer that the lesions could be due to diabetes, hypertension, or some other disease process.

3. Signs suggestive of glaucoma, such as hemorrhage on the disc or crossing the disc margin, or a cup to disc ratio greater than or equal to .7, accompanied by disc pallor, notching of the rim or undercutting of retinal vessels at the edge of the cup.

These notifications recommending routine evaluations are either sent at the time the photo is read or deferred for up to seven working days until a larger group of photos are read.

20.30.4.3 Retinal notification status: batch reports to the field centers

The Retinal Reading Center provides each field center with a cover letter and a batch report on the retinal notification status of all participants concurrent with its routine transmission of data to the ARIC Coordinating Center (See Manual 13). The batch report contains the following retinal notification status codes and the date of the FAX notification letter (if applicable), which were entered in the grading database at the Retinal Reading Center from the grading form.

0 = no retinal notification

2 = retinal notification sent, and

8 = cannot grade for retinal notification conditions.

The report first lists all participants who had no abnormalities prompting either an alert for referral or routine evaluation, followed by participants who previously received a retinal notification letter, and ending with those whose photographs could not be read due to technical problems. The cover letter provides explanations on the photographic problem(s) or other items of special interest in the report.

2.30.5 Report of Cerebral MRI Measurements

Study participants with certain MRI scan abnormalities may require further medical attention. ARIC does not assume responsibility for diagnosis and management of its participants, but has assumed an obligation to refer such individuals to their local source of medical care. Alert conditions requiring urgent or immediate referral (see Section 2.30.5.1) can be identified either at the imaging center or the MRI reading center.

The MRI technologist at the local MRI Center reviews each study for the presence of any condition identified as an emergent alert. When found, the

ARIC neuroradiologist is notified, and the occurrence recorded on the MRI Procedure Form. After review of the potential urgent or immediate alert by the MRI Center neuroradiologist, a brief report is prepared within 24 hours, the field center is notified, and the notification process is recorded on the MRI Procedure Form. The field center is responsible for contacting the participant.

When a condition identified as an emergent alert (i.e., requiring immediate or urgent referral) is noted at the MRI Reading Center, the alert status is recorded on the participant's result file. If the alert has previously been identified at the local MRI Center, no further action is taken by the MRI Reading Center. If the MRI Procedure Form does not identify an alert, or refers to an alert condition different from that detected at the MRI Reading Center, the Reading Center physician prepares a brief report which is included with the participant's file, the Reading Center sends the MRI results data file to the field center by electronic mail or FAX, and a hard copy of the MRI scan film to the field center by overnight delivery.

2.30.5.1 MRI scan alert notifications

MRI scan abnormalities which require urgent referral for possible further medical attention are defined as

1. tumor without significant mass effect, AVM, aneurysm, obstructive hydrocephalus;

2. cavernous angioma, venous angioma.

Those requiring immediate referral are:

1. acute subdural or epidural hematoma, subarachnoid hemorrhage, acute intraparenchymal hematoma, acute infarct, subacute infarct, obstructive hydrocephalus (less severe than those requiring urgent referral), cerebral venous thrombosis, abscess and suspected tumor with significant mass effect.

Conditions not listed which require referral in the opinion of an MRI technologist are triaged and reported accordingly, per the judgement of the field center or MRI center neuroradiologist. Doubtful cases are triaged to the more severe category.

2.30.5.2 MRI scan routine notifications

MRI scan abnormalities classified as old infarcts, old hematomas, and exceptionally, other chronic abnormalities result in letters to participants indicating that there were minor chronic findings 'which are often seen on MRI' for which referral to a physician is optional. Corresponding letters to physicians indicate that an old infarct greater than 5 mm or an old hematoma was visualized, but the clinical significance of these findings is not known. When there are no clinically significant findings, this is indicated in a letter to the participant.

2.30.6 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 2.26-2.29 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 (see Appendix 2.24.c).

2.30.6.1 Results routinely reported to the participant

Results reported to the participant during the clinic visit (ARIC CLINIC VISIT 3 REPORT, Appendix 2.24.a) include current weight and weight at the previous examinations, current height and height at Visit 1, current blood pressure and blood pressure measurements from the previous two 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 two months after Visit 3, the following report (SUMMARY OF ARIC VISIT 3 RESULTS FOR PARTICIPANTS AND THEIR PHYSICIANS, Appendix 2.24.b) is mailed to the participant. This report includes the following confirmed study results from Visit 3: weight and height; blood pressure; summary report of electrocardiogram; summary report of echocardiogram (Jackson participants); summary report of the retinal photograph of one eye; summary report on the cerebral MRI (Forsyth County and Jackson participants);and blood tests (total cholesterol, LDL cholesterol, total HDL cholesterol, triglycerides, and glucose).

2.30.6.2 Results routinely reported to the physician

Participants' physicians receive a copy of the reports sent to their patients, as indicated in Section 2.30.2. In addition, physicians are notified of any important symptoms reported by the participant and they are provided with the participant's electrocardiogram.

2.30.7 Results Reported Only by Request

All other study measurements, i.e., those not routinely reported to the 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 of release must accompany the request from the participant and 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 2.26.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.

2.30.8 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 2.27. 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, the MRI 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 2.30.1.

2.31 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 participant 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 2.3.1).

2.31.1 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 3. 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 minor and major emergencies are described in section 2.31.2.

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 11. 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 patient 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 postural effects. When the postural changes are measured, the sonographer is positioned closely behind the patient as a protective measure should he or she become faint. A sturdy chair is 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 in section Manual 11 are followed.

2.31.2 Methods for Handling Emergencies

While all life threatening emergencies (eg. 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.

2.31.2.1 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. At every clinic session a staff person with certification in basic life support is on duty and physically present. 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 is available on a standard ARIC form. The home and work telephone numbers of the next of kin are also listed. 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.

All personnel are trained to carry out their specific responsibility during an emergency. Retraining is conducted at least yearly.

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.

2.31.2.2 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., before 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 2.31.2.1 are followed.

2.31.3 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.

2.31.4 Notification of Study Results

Before the informed consent is administered, the ARIC participant is told about each component of the examination. It is emphasized that the ARIC examination is not a substitute for clinical examination. The participant is told, however, that one of the benefits of participation is possible early detection of warning signs of certain diseases.

As described in section 2.30, the ARIC notification mechanism is designed to provide a clear statement to the participant to seek medical care, when confirmation or further investigation of study results indicates this course of action. An additional criterion built into the notification mechanism is to avoid anxiety in the study participants when presented with medical information, and any unnecessary consultation to practitioners.

All letters of notification conform to common procedures stipulated in the ARIC protocol. Appendix 2.25 of this Manual includes prototype letters of notification. The wording of these letters can be modified by the principal investigators of the ARIC Field Centers, to conform to the referral practices of each ARIC study community.

Section 2.30 of this Manual identifies the minimum set of significant findings and the alert values of laboratory results to be reported to participants and/or their physicians. It also specifies the schedule followed by the ARIC central agencies and field centers in notifying study participants, according to an expedited and a routine notification procedure. Section 2.27 describes the medical data review mechanisms that generate a referral, and the report to the participant and his/her the physician.

APPENDICES

(Used appendices from Version 4.0 since no updates in Version 5.0)

NAME: _____ ID: _____ Contact Year: __

ARIC ANNUAL FOLOW-UP
PARTICIPANT TRACING INFORMATION SHEET

Address: _____
_____

Home Phone: (___) ___-____
Other Phone: (___) ___-____
Nickname: _____
Maiden Name: _____

Sex: _ Race: _
Date of Birth: __ / __ / __
State of Birth: __
Social Security No: ___-__-____
Driver's License No: _____
Driver's License State: __

Date of Baseline Visit: __/__/__
Date of Visit 2: __ / __ / __

Final Status: _____
Date Determined: __ / __ / __

Contact Person 1:

Name: _____
Address: _____
_____
Phone: (___) ___-____
Relation: _____

Contact Person 2:

_____
_____
_____
(___) ___-____
_____

Physician: Dr. _____
Address: _____
_____

Employed for pay
Employer: _____
Address: _____
_____

NAME: _____ ID: _____ Contact Year: __

ARIC ANNUAL FOLOW-UP
VERIFICAITON OF TRACING INFORMATION (UPD updated by: _____)
SHORT FORM

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: _____

Appendix 1.4 Participant Letter: Notification of Forthcoming Annual Follow-up Interview

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

ATHEROSCLEROSIS RISK IN COMMUNITIES STUDY

FORSYTH CO.	JACKSON	SUBURBAN MINNEAPOLIS	WASHINGTON CO.
N CAROLINA	MISSISSIPPI	MINNESOTA	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: D 03/03/93

NAME: _____

CONTACT YEAR ( ) DATE RANGE

Earliest: ___/___/___ Target: ___/___/___ Latest: ___/___/___

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			

*RESULT CODES (CIRCLE THE FINAL SCREENING RESULT CODE)

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 Contact

ARIC COHORT ANNUAL FOLLOW-UP

ID: _____ CONTACT YEAR: 07 FORM CODE: TRC VERSION: D 03/03/93

NAME: _____

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

CY 07 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				
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				

*RESULT CODES (CIRCLE THE FINAL SCREENING RESULT CODE)

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 Contact

** APPOINTMENT CODES (AFUD item 45)

00 Appointment scheduled (record date, time, and special needs).
01 Appointment deferred (by clinic staff).
02 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.
05 Appointment refused, but willing to do annual follow-up.
06 Refused clinic visit and does not want any further contact
07 Unable to locate.
08 Deceased.

ARIC
Atherosclerosis Risk in Communities

ANNUAL FOLLOW-UP QUESTIONNAIRE FORM

ID NUMBER: | | | | | | | | CONTACT YEAR: | | | FORM CODE: A F U VERSION: D 03-03-93

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

Public reporting burden for this collection of information is estimated to average 8 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 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 (AFUD screen 1 of 13)

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 (AFUD screen 2 of 13)

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 (AFUD screen 3 of 13)

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 (AFUD screen 4 of 13)

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 (AFUD screen 5 of 13)

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 (AFUD screen 6 of 13)

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

No N

→ Go to Item 29, Screen 7

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 (AFUD screen 7 of 13)

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 (AFUD screen 8 of 13)

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 participants, 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 to the second floor 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 (AFUD screen 9 of 13)

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 (AFUD screen 10 of 13)

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 (AFUD screen 11 of 13)

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: [ ][ ][ ]

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

ANNUAL FOLLOW-UP QUESTIONNAIRE (AFUD screen 12 of 13)

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. Hospitalization 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. Hospitalization 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. Hospitalization 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 (AFUD screen 13 of 13)

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)

INSTRUCTIONS FOR THE ANNUAL FOLLOW-UP TRACING FORM AND QUESTIONNAIRE, AFU, VERSION D, 3/3/93
PREPARED 9/23/93

I. GENERAL INSTRUCTIONS

Annual follow-up of the ARIC Study cohort is used to (1) maintain contact and correct address information of cohort participants and (2) ascertain interim medical events between the three-year comprehensive examinations. Annual follow-up contacts are scheduled approximately every 12 months after the participant's clinic examination. Each follow-up is completed by telephone (preferred) or in person (if necessary). The follow-up call in contact year 07 is preceded by a letter sent by mail about two weeks in advance of the call.

Two data collection forms are used in completing the annual follow-up. The ARIC Annual Follow-Up Tracing Form is a computer-generated paper form which contains a "Participant Tracing Information Sheet" 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 the participant's cardiovascular health since their clinic visit, functional status and major life events, and a "Hospitalizations" section to record information on any hospitalizations. The questionnaire should always be completed on paper and then batch-entered into the local database.
Contact Year 07 AFU will also include the scheduling of the third clinic visit. If the participant refuses or does not show for a visit in Contact Year 07, scheduling should also be attempted in Contact Years 08 or 09.

II. ANNUAL FOLLOW-UP PROCEDURES

A. Contacting Procedures and Rules

Either the Coordinating Center or the field center staff will periodically generate 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

The initial call for annual contact should be no more than three weeks or so before the target date except in contact year 07, in which the contact can be made up to 4 months earlier to aid clinic scheduling. Ideally, the contact should take place as closely as possible to the "Target" date. If for some reason contact is not made until after the "Latest" date, this contact must be assigned to the following Contact Year. This 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.

As mentioned previously, the first step in the contacting procedures in contact year 07 is a letter sent to the participant about two weeks prior to the first attempted phone call. Before placing the phone call, the interviewer assembles the participant's computer-generated tracing form, the Annual Follow-up (AFU) form, the accompanying question-by-question instructions, and an appointment calendar for scheduling Visit 3.

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 is used to keep track of attempts to contact a participant and appointment scheduling. One line should be 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 (contact year 07, 08 or 09) 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 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.

For Contact Year 07, appointment codes (with possible final codes indicated by *) are:

*00: Appointment scheduled

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

02: 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).

*05: Appointment refused, but willing to do annual follow-up. Record reason for refusal for entry into a DES note log.

*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.

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

a. Refusals (attempt conversion).

b. Difficult contacts or other non-completes. In particular, the supervisor decides when it is no longer practical to continue to investigate a person. All possible alternatives must be exhausted for this decision to be made.

c. Undocumented deaths. If a death is reported for which no death certificate can be located, the supervisor reviews the case and attempts to resolve it. If no death certificate is ultimately located, including an NDI search, the vital status may be changed to "Unknown".

2. Questionnaire

Once 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 (CY08, CY09), 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 (CY07), 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:

		/			/		

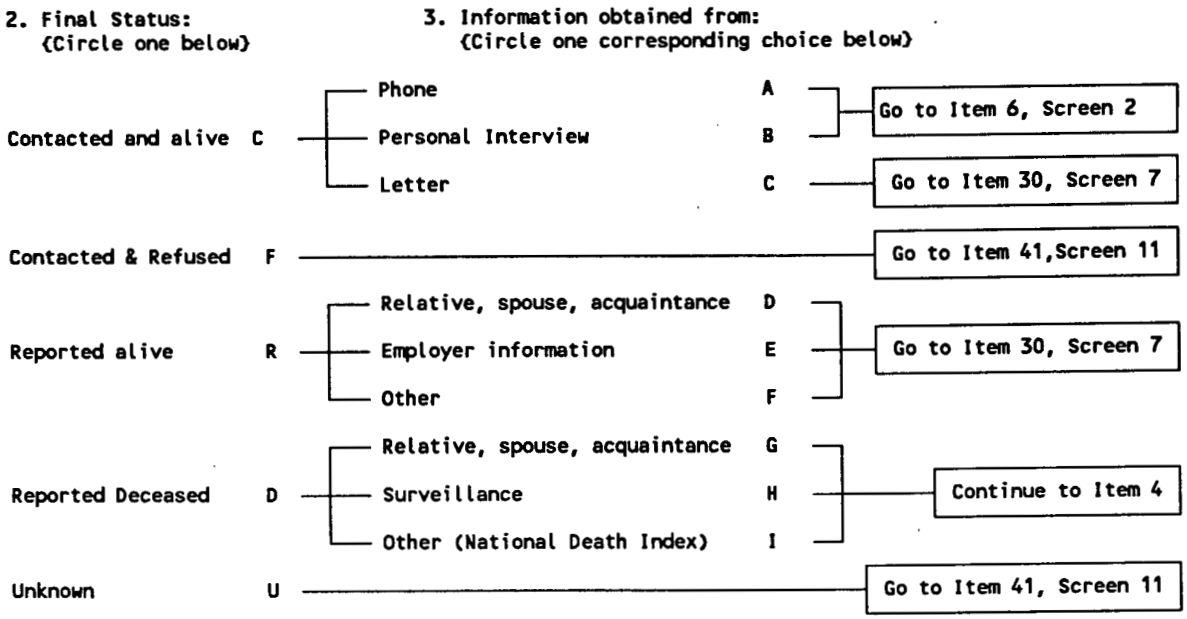
Month Day Year

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

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

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

Unknown (U): Neither the participant nor another source of information has been contacted in a manner sufficient to provide reliable vital status data. In this case, the "date of status determination" is 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. It 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 font 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. However, if direct contact is not made, but a reliable source of information has provided a status of "Reported alive" or "Reported deceased" in item 2, then 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, not the 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.

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 <u>not</u> a riding lawn mower), or "painting walls or wallpapering."

33. The focus of the question is on the participant's <u>ability</u> 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 <u>able</u> to walk up and down stairs. If the respondent is uncertain, code as NO.

34. Again, the emphasis is on the <u>ability</u> 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 35b). Regardless of the response, skip Item 36 and go to Item 37a.

If YES, go to Item 36a.

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 37a.

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 36a is absence from work anytime within the four weeks prior to the interview for at least half a day because of illness. If this occurred (YES for Item 36a), determine how many days the participant was absent from work (Item 36b). The maximum number of days not worked is 28.

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 37b 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 38a 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. If this occurred (YES for Item 38a), determine on how many days the participant had to reduce his or her activity level (Item 38b). The maximum number of days of reduced activity is 28.

39. The time frame for Item 39a 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 39b) 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 39a), 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 39a is NO, go to Item 40a.

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 39b and determine if the unknown weight loss was intentional (Item 39c).

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 40a and then all the response categories. If the response is MARRIED or NEVER MARRIED, record the appropriate letter, skip Item 40b and go to Item 40c. If the response is WIDOWED, DIVORCED, or SEPARATED, record the appropriate letter and determine how long ago the event took place (Item 40b). Do not read the response categories, but probe if the participant's response is sufficiently unclear for you to select a category.

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

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 40d. 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 40e). 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 3 Scheduling Not Needed

For AFU contacts for which a clinic visit not being scheduled (contact years other than 07, 08, 09), 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 3 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 third 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 4 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. For vitamins and supplements, we are interested in a longer time period. Please bring in the bottles or containers of the vitamins or supplements you have taken in the FOUR 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. RESOLVE ANY QUESTIONS OR CONCERNS.

"Do you have any questions?"

f. UPDATE MAILING ADDRESS (VERIFY TRACING INFORMATION).

"Finally, this is a good time to verify your mailing address to make sure that all the material you need for the clinic appointment reaches you. This will 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. Tracing form: Verification of Tracing Information

Verify the items on the Verification of Tracing Information sheet for contact next year by saying: "You have previously provided us with information on how to contact you. To help us contact you next year, please tell me if the information I have is still correct." These include the participant's name, address, and phone number(s), as well as (except in CY07) 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 3 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 Participant Letter: Notification of Forthcoming Scheduling of Visit 3

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

ATHEROSCLEROSIS RISK IN COMMUNITIES STUDY

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

1~
2~
3~

Dear 4~

It has been almost three years since you were contacted for Clinic Visit 2 in 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 third examination is similar to the other two. It includes health interviews, electrocardiogram (ECG), blood pressure measurements, blood tests, ultrasound picture of the arteries in your neck, and the addition of retinal photography.

In the next few days an ARIC Study interviewer will telephone you to set up an appointment time for the examination. **Please have your calendar available with possible dates identified, to help our interviewer schedule a convenient date and time for your visit.** The interviewer will also ask a few questions about your health as has been done in our previous telephone contacts. It would be helpful if you could have ready any information about hospitalizations and illnesses you may have had in the past year. The telephone interview should take less than 10 minutes.

If you think it will be difficult for us to reach you in the next one to two weeks, **PLEASE CALL** the ARIC Study office at **777-3067** to schedule a telephone interview, or to schedule an appointment for your third visit.

We thank you again for your participation in this most important research project!

Sincerely,

Jean M. Marlow
ARIC Field Supervisor

Frederic J. Romm, M.D.
Medical Director

5~
6~

VISIT 3 SCHEDULING SCRIPT

There are several points we would like to cover to make your clinic visits easier.

For your visit we ask that you fast, taking nothing by mouth but water and essential medication for 12 hours before your appointment. You will be given a snack 15-20 minutes into your visit, after we have drawn your blood sample.

72. Some medicines, such as insulin for diabetes, cannot be taken while fasting. Do you take insulin for diabetes?

Yes.....Y — Continue to take insulin the way you normally do. You should not fast before you come to the clinic. GO TO QUESTION 79.
No.....N

73. Do you have any medical reason why you must not fast for 12 hours?

Yes (SPECIFY).....Y _____
No.....N GO TO QUESTION 75.

74. Is it possible for you to arrange with you doctor a way to fast before you come to the clinic?

Yes.....Y — Good. Please do so.
No.....N — Then it will be o.k. for you to eat before the visit as you normally do.

75. Some medications can be taken fasting or delayed until the snack at the clinic. Do you have a medicine you must take for which you must not fast for 12 hours?

Yes.....Y _____
No.....N GO TO QUESTION 77.

76. Is it possible for you to arrange with your doctor a way to take this medicine without fasting or fasting for a shourter time before you come to the clinic?

Yes.....Y — Good. Please do so.
No.....N — Then it will be o.k. for you to take it before the visit as you normally do.

77. Do you have any special diet we should consider for the clinic snack?

Yes (SPECIFY).....Y _____
No.....N

78. Will you need any assistance climbing steps or getting around the clinic?

Yes (SPECIFY).....Y _____
No.....N

79. Do you have any other special needs for the clinic visit that we should know about?

Yes (SPECIFY).....Y _____
No.....N

80. TIME INTERVIEW ENDED [ ][ ] : [ ][ ] a p
HOUR MINUTES

Blood Pressure Measurement

WHERE IS ARIC HAPPENING?

- Forsyth County, North Carolina
- Jackson, Mississippi
- Minneapolis suburbs, Minnesota
- Washington County, Maryland

Sponsored by the National Heart, Lung, and Blood Institute of the U.S. National Institute of Health in conjunction with:

- The University of North Carolina
- The University of Mississippi
- The University of Minnesota
- The Johns Hopkins University

WHERE CAN YOU REACH US?

ARIC
Forsyth County 2060 Beach Street
(Cloverdale Ave. Extension)
Winston-Salem, N.C. 27103
Telephone: (919) 777-3067
(919) 777-3040

ARIC Community Advisory Board

Mr. Dewey Chapple, Jr.
Mr. Bill East
Mr. John W. Halverson
The Rev. Stimson Hawkins
Mr. Norman W. Hearn
Mr. Manly Lancaster
Mrs. Martha Martinat
Mrs. Marge Sosnick
Mr. Roger P. Swisher
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Earl Watts, M.D.
Peter Robie, M.D.
Robert Cooper, M.D.

The information collected in this study is authorized by the U.S. Public Health Service Act, Section 421 (42-USC-285b-3).

ARIC
ATHEROSCLEROSIS RISK IN COMMUNITIES STUDY

What is the ARIC Project?

ARIC
ATHEROSCLEROSIS RISK IN COMMUNITIES STUDY

WHAT IS THE ARIC PROJECT?

Atherosclerosis Risk In Communities Study

WHAT IS THAT?
ARIC is an important and exciting new medical study that involves a large number of people from four different communities in the U.S. It is sponsored by the National Institutes of Health, and The University of North Carolina in collaboration with Wake Forest University.

The purpose of ARIC is to investigate atherosclerosis, also known as "hardening of the arteries." This condition occurs when deposits are formed on the artery walls, thus slowing down or stopping blood circulation.

This leads to heart disease and stroke as well as other diseases of the blood vessels. Researchers will use the data gathered in ARIC to learn more about heart disease and stroke and the factors which cause them.

The ARIC clinic is an independent facility available to ARIC participants only.

ARIC is an historic nationwide project. People involved in it will make a unique contribution.

WHO CAN PARTICIPATE?
At least 4000 residents of Forsyth County who are at least 45-64 years of age will be randomly selected and invited to participate.

WHAT WILL HAPPEN?
First we'll conduct a brief interview in your home. Then you'll be invited to a nearby clinic for an examination at no cost to you. The exam takes 3 to 3 1/2 hours and includes the following:

. blood pressure measurement;

. electrocardiogram (EKG) which records heart function;

. lung function test;

. blood test to determine levels of cholesterol, fats and other substances in the blood; and

. ultrasound examination (a "picture" taken by sound waves) of the arteries in your neck and thigh;

After the initial examination we will contact you yearly by phone or mail and ask about your health. After three years, we will repeat the examination process.

HOW WILL YOU BENEFIT?
You and your physician can receive valuable information about your heart, blood, lungs, and arteries.

Your examination will be safe and painless.

You will make an important contribution toward learning how to prevent heart disease and stroke.

Your participation will not interfere with your present medical care or employee health plan.

You will not be charged a fee for this examination.

IF YOU ARE CHOSEN, PLEASE SAY YES!

IS THE INFORMATION CONFIDENTIAL?
Yes, all the information given by participants is held in strict confidence and will be used for statistical research purposes only. The information will never be associated with your name. The results are protected by Federal regulation and only you can authorize their release.

Ultrasound Examination.

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

ATHEROSCLERORIS RISK IN COMMUNITIES STUDY

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

Thank you for agreeing to come to Visit 3 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 you 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.

* 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 an schedule, it is most important that you be on time for your appointment. Here is a list of activities for your visit.

Reception
Blood Pressure Measurement
Blood Drawing
Anthropometry (Body Measurements)
Ultrasound
Interview
Retinal Photography
Electrocardiogram (ECG)
Snack
Medical Review

Total Exam Time: 3 1/2 - 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.

WHY IT IS IMPORTANT TO KEEP YOUR APPOINTMENT

Unlike a regular doctor~s office or clinic, at ARIC we . . .
Schedule only 6 or 7 participants a day. Have a clinic staff of 11 to work exclusively with ARIC participants.

If you cancel your appointment without 3 days notice . . . .
It would be doing a disservice to another Forsyth County participant who could have been scheduled during your time period; considerable costs would occur because staff time and equipment set aside for you would be wasted, resulting in a misuse of tax dollars; we may not be able to reschedule you for a time as convenient for you.

PlEASE DON'T BE A NO SHOW!

WE LOOK FORWARD TO SEEING YOU AGAIN.

READ THE FOLLOWING MEDICATION INSTRUCTIONS:

"During your visit to the Clinic we would like to record any medicines you are taking, because they tell us about a person's health and may have effects on the tests which we will perform.

We are interested in ALL medicines that you take for ANY reason in the TWO WEEKS before your visit to the ARIC clinic, not just in heart medicines.

The best way to get this information is for you to bring in this carrying bag (HAND MEDICATIONS BAG TO PARTICIPANT) the containers of any medicines used in the two weeks before you visit, including:

* Prescription drugs from your physician or dentist;

* Prescription drugs you may have received from other people, such as friends or relatives;

* Over-the-counter medicines you may have bought at the drug store or a supermarket, such as medicines for colds, constipation, allergies, vitamins, minerals, and the like.

We ask that you bring the containers so that we can copy the information from the label. If you don't have the container, please bring the prescription or any other information that has the name of the drugs. Even if you only have loose pills or capsules, please bring them to the clinic so that we can identify them.

At the clinic we will handle all your medicines and containers very carefully and will return them in this same bag before you leave. Like all other information we collect, your use of medicines will be kept in strict confidence."

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 _____

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

To Whom It May Concern:

Your employee has been selected to participate in an important medical research project called the Atherosclerosis Risk in Communities (ARIC) Study. 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 to collect the medical information. We hope you will allow your employee time off to complete this examination. Their participation is important to the study. If you have any further questions. you may call me at 919-777-3067.

Thank you.

Sincerely,

Jean M. Marlow
ARIC Field Supervisor

```
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.	SMP	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 ...

Form as of 09/09/93 14:10:55

ID:T000000 FORM: SMP VERSION: B CONTACT YEAR:07

SAMPLES INVENTORY FORM (SMPB screen 1 of 1)

	SAMPLE TYPE	a. COLLECTED (Yes, No or Pending)	b. DATE OF COLLECTION (mm/dd/yy)	c. COMMENT
1.	Lipids (LIP)	a.Q *D*	b._____ *E*	c._____ *E*
2.	Hemostasis(HEM)	a._ *E*	b._____ *E*	c._____ *E*
3.	ECG (ECG)	a._ *E*	b._____ *E*	c._____ *E*
4.	Ultrasound (ULT)	a._ *E*	b._____ *E*	c._____ *E*
5.	Retinal Photography (RET)	a._ *E*	b._____ *E*	c._____ *E*
6.	MRI (MRI)	a._ *E*	b._____ *E*	c._____ *E*
7.	ECHO (ECHO)	a._ *E*	b._____ *E*	c._____ *E*

8. Code number of person completing this form: ___ *E*

O.M.B. 0925-0821
exp. 10/31/95

ARIC
Atherosclerosis Risk in Communities

COGNITIVE FUNCTION FORM

ID NUMBER: | | | | | | | | CONTACT YEAR: | 0 | 7 | FORM CODE: | C | N | F | VERSION: B 09/15/92

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	_____

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 (CNFB, 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 (CNFB, 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 (CNFB, 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 (CNFB, Part C): | | |

PART D: ADMINISTRATIVE INFORMATION

5. DATE OF DATA COLLECTION: | | | / | | | / | | |
   month day year

6. INTERVIEWER CODE NUMBER: | | | |

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.			

ID NUMBER: | | | | | | | | CONTACT YEAR: | 0 | 7 | FORM CODE: | C | N | F | VERSION: B 09/15/92

LAST 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

2	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

INSTRUCTIONS FOR THE COGNITIVE FUNCTION WORKSHEET
CNF, Version B, 09/15/92
PREPARED 04/22/93

I. GENERAL INSTRUCTIONS

1. The Digit Symbol Substitution Task (DSS) sheet remains unattached from the CNF form until completed by the participant. Complete the header information on both the CNF form and the DSS prior to the clinic visit.

2. Minimize extraneous noise in the testing environment as this may be distracting and affect test results.

3. The interviewer must sit quietly and minimize any movements to avoid distracting the participant.

4. 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.

5. Tape recorders cannot be used during the administration of the cognitive function forms.

6. 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.

7. 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

8. 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."

9. 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".

10. 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."

11. 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."

12. 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.

13. When this process is completed, GO TO PART B: THE DIGIT SYMBOL TEST.

PART B: DIGIT SYMBOL SUBSTITUTION (DSS) TASK INSTRUCTIONS

14. DISCREETLY PICK UP THE STOPWATCH.

15. 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."

16. 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."

17. 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.

18. AFTER MARKING THE FIRST THREE SAMPLES ITEMS, SAY:

"Now you fill in the squares up to this heavy line."

19. 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."

20. 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.

21. WHEN THE SAMPLE EXERCISE HAS BEEN COMPLETED SUCCESSFULLY SAY,

"When I tell you to start, you do the rest of them."

22. 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."

23. 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.

24. 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 1s) SAY,

"Do them in order. Don't skip any."

25. POINT TO THE FIRST ITEM OMITTED AND SAY,
"Do this one next."

26. IF THE PARTICIPANT GETS TO THE END OF A LINE AND STOPS, SAY

"Please go on to the next line."

27. GIVE NO FURTHER ASSISTANCE EXCEPT (IF NECESSARY) TO REMIND THE PARTICIPANT TO CONTINUE UNTIL INSTRUCTED TO STOP.

28. 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."

29. 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."

30. ONCE THESE INSTRUCTIONS HAVE BEEN GIVEN, START THE STOPWATCH. Use the stopwatch discreetly to avoid creating anxiety or a sense of time pressure.

31. USING PAGE 1, COLUMN 3 OF THE WORKSHEET, CHECK OFF ALL THE WORDS RECALLED WITHIN 60 SECONDS.

32. 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

33. 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."

34. START STOPWATCH. RECORD VERBATIM. DO NOT CORRECT ERRORS.

35. 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 begins with the letter __?"

Do not stop the test until the entire 60 seconds is over.

36. 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.

37. 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.

38. 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."

39. 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.

40. 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 (CNFA, 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 (CNFA, 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 (CNFA, 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 (CNFA, 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, "senorita" 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 (CNFA, Q.4)

9. ENTER THE DATE OF DATA COLLECTION ON PAGE 4 OF THE CNF WORKSHEET, ITEM 5 (CNFA, Q.5).

10. ENTER THE CODE NUMBER OF THE INTERVIEWER WHO ADMINISTERED THIS FORM ON PAGE 4 OF THE CNF WORKSHEET, ITEM 6 (CNFA, Q.6).

O.M.B. 0925-0821
exp. 10/31/95

ARIC
Atherosclerosis Risk in Communities

DIETARY INTAKE FORM

ID NUMBER: | | | | | | | | CONTACT YEAR: | 0 | 7 | FORM CODE: | D | T | I | VERSION: C 09/09/92

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

Instructions: This form is completed during the interview portion of the participant's visit. ID Number, 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 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 or write in 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.

"In this part of the clinic visit we want to obtain information on your usual eating habits. We will go over specific foods by groups. I'll name a food and a portion size and you tell me how often, on average, you ate that during the past year.

If your portion was much different from the amount I say, please tell me if it was at least twice as much, or half as much. We have a few sizes of cups and glasses here for reference. Here are the choices for "how often" (show RC 1). The choices are number of times a day or week or month. Please respond with the appropriate letter. For example, "once a day" would be "D". If you ate or drank something less than twelve times a year, that would be the same as "less than once a month," which is "I".

It is important that your answer be short in order to save time, but we want you to be as accurate as possible. If we miss food items that you usually eat, we will list those at the end. Feel free to ask questions or have me repeat instructions if I am not being clear."

Dietary Intake Form (DTIC screen 1 of 15)

Response Categories:	> 6 per day (A) 4-6 per day (B) 2-3 per day (C)	1 per day (D) 5-6 per week (E) 2-4 per week (F)	1 per week (G) 1-3 per month (H) Almost never (I)

A. DAIRY FOODS [RC 1]

"In the past year, how often on average did you consume..."

1. Skim or low fat milk; 8 oz. glass .....
2. Whole milk; 8 oz. glass .....
3. Yogurt; 1 c. .....
4. Ice cream; 1/2 c. .....
5. Cottage cheese or ricotta cheese; 1/2 c. .....
6. Other cheeses, plain or as part of a dish; 1 slice or serving .....
7. Margarine or a margarine/butter blend; pats added to food or bread .....
8. Butter; pats added to food or bread .....

Dietary Intake Form (DTIC screen 2 of 15)

Response Categories:	> 6 per day (A) 4-6 per day (B) 2-3 per day (C)	1 per day (D) 5-6 per week (E) 2-4 per week (F)	1 per week (G) 1-3 per month (H) Almost never (I)

B. FRUITS [RC 1]

"In the past year, how often on average did you consume..."

9. Fresh apples or pears; 1 .....
10. Oranges; 1 .....
11. Orange or grapefruit juice; small glass .....
12. Peaches, apricots or plums; 1 fresh or 1/2 c. canned or dried .....
13. Bananas; 1 .....
14. Other fruits; 1 fresh or 1/2 c. canned, including fruit cocktail .....

C. VEGETABLES [RC 1] -- Portion is 1/2 c.

"In the past year, how often on average did you consume..."

15. String beans or green beans; 1/2 c. .....
16. Broccoli; 1/2 c. .....

Dietary Intake Form (DTIC screen 3 of 15)

Response Categories:	> 6 per day (A) 4-6 per day (B) 2-3 per day (C)	1 per day (D) 5-6 per week (E) 2-4 per week (F)	1 per week (G) 1-3 per month (H) Almost never (I)
17. Cabbage, cauliflower, brussels sprouts; 1/2 c.	☐		
18. Carrots; 1 whole or 1/2 c. cooked	☐		
19. Corn; 1 ear or 1/2 c.	☐		
20. Spinach, collards or other greens, but do not include lettuce; 1/2 c.	☐		
21. Peas or lima beans; 1/2 c. fresh, frozen or canned	☐		
22. Dark yellow, winter squash such as acorn, butternut; 1/2 c.			☐
23. Sweet potatoes; 1/2 c.			☐
24. Beans or lentils, dried cooked, or canned, such as pinto, blackeye, baked beans; 1/2 c.			☐
25. Tomatoes; 1, or tomato juice; 4 oz.			☐

Dietary Intake Form (DTIC screen 4 of 15)

Response Categories:	> 6 per day (A) 4-6 per day (B) 2-3 per day (C)	1 per day (D) 5-6 per week (E) 2-4 per week (F)	1 per week (G) 1-3 per month (H) Almost never (I)
D. MEATS [RC 1] "In the past year, how often on average did you consume..."			
26. Chicken or turkey, without skin	☐		
27. Chicken or turkey, with skin	☐		
28. Hamburgers; 1	☐		
29. Hot dogs; 1	☐		
30. Processed meats: sausage, salami, bologna, etc.; piece or slice			☐
31. Bacon; 2 slices			☐
32. Beef, pork or lamb as a sandwich or mixed dish, stew, casserole, lasagne, or in spaghetti sauce, etc.			☐
33. Beef, pork or lamb as a main dish, steak, roast, ham, etc.			☐
34. Canned tuna fish; 3-4 oz.			☐

Dietary Intake Form (DTIC screen 5 of 15)

Response Categories:	> 6 per day (A) 4-6 per day (B) 2-3 per day (C)	1 per day (D) 5-6 per week (E) 2-4 per week (F)	1 per week (G) 1-3 per month (H) Almost never (I)

35. Dark meat fish, such as salmon, mackerel, swordfish, sardines, bluefish; 3-5 oz. ..... ☐

36. Other fish, such as cod, perch, catfish, etc.; 3-5 oz ..... ☐

37. Shrimp, lobster, scallops as a main dish ..... ☐

38. Eggs; 1 ..... ☐

E. SWEETS, BAKED GOODS, CEREALS [RC 1]

"In the past year, how often on average did you consume..."

39. Chocolate bars or pieces, such as Hershey's, Plain M & M's, Snickers, Reeses; 1 oz. ..... ☐

40. Candy without chocolate; 1 oz ..... ☐

41. Pie, homemade from scratch; 1 slice ..... ☐

Dietary Intake Form (DTIC screen 6 of 15)

Response Categories:	> 6 per day (A) 4-6 per day (B) 2-3 per day (C)	1 per day (D) 5-6 per week (E) 2-4 per week (F)	1 per week (G) 1-3 per month (H) Almost never (I)

42. Pie, ready-made or from a mix; 1 slice ..... ☐

43. Donut; 1 ..... ☐

44. Biscuits or cornbread; 1 ..... ☐

45. Danish pastry, sweet roll, coffee cake, croissant; 1 ..... ☐

46. Cake or brownie; 1 piece ..... ☐

47. Cookies; 1 ..... ☐

48. Cold breakfast cereal; 1/2 c. ..... ☐

49. Cooked cereals such as oatmeal, grits, cream of wheat; 1/2 c. ..... ☐

50. White bread; 1 slice ..... ☐

51. Dark or whole grain bread; 1 slice ..... ☐

F. MISCELLANEOUS [RC 1]

"In the past year, how often on average did you consume..."

52. Peanut butter; 1 tbsp ..... ☐

Dietary Intake Form (DTIC screen 7 of 15)

Response Categories:	> 6 per day (A) 4-6 per day (B) 2-3 per day (C)	1 per day (D) 5-6 per week (E) 2-4 per week (F)	1 per week (G) 1-3 per month (H) Almost never (I)

53. Potato chips or corn chips; small bag or 1 oz. ..... ☐

54. French fried potatoes; 1 serving, 4 oz. ..... ☐

55. Nuts; 1 oz. ..... ☐

56. Potatoes, mashed; 1 c. or baked; 1 ..... ☐

57. Rice; 1/2 c. ..... ☐

58. Spaghetti, noodles or other pasta; 1/2 c. ..... ☐

59. Home-fried food, such as any meats, poultry, fish, shrimp, eggs, vegetables, etc.; 1 serving ..... ☐

60. Food fried away from home, such as any fish, chicken, chicken nuggets, etc. ..... ☐

Dietary Intake Form (DTIC screen 8 of 15)

Response Categories:	> 6 per day (A) 4-6 per day (B) 2-3 per day (C)	1 per day (D) 5-6 per week (E) 2-4 per week (F)	1 per week (G) 1-3 per month (H) Almost never (I)

G. BEVERAGES [RC 1]

"In the past year, how often on average did you consume..."

61. Coffee, not decaffeinated; 1 c. ..... ☐

62. Tea, iced or hot, not including decaf or herbal tea; 1 cup ..... ☐

63. Low calorie soft drinks, such as any diet Coke, diet Pepsi, diet 7-Up; 1 glass ..... ☐

64. Regular soft drinks, such as Coke, Pepsi, 7-Up, ginger ale; 1 glass ..... ☐

65. Fruit-flavored punch or non-carbonated beverages, such as lemonade, Kool-Aid or Hawaiian Punch; not diet; 1 glass ..... ☐

H. OTHER DIETARY ITEMS

66. How often do you eat liver; 3-4 oz. serving? ..... [rc 2]

1/week	A
2-3/month	B
1/month or less	C
Never	D

Dietary Intake Form (DTIC screen 9 of 15)

67. Are there any other foods that you usually eat at least twice per week such as tortillas, prunes, or avocado? Do not include dry spices nor something that has been listed previously. ..... Yes Y

No N

Go to Item 74, Screen 10

68. Food #1 eaten at least twice per week (enter code and specify food and usual portion size below): ..... [ ][ ][ ]

a. _____

69. Frequency for food #1: ..... > 6/day A [rc 3]

4-6/day B

2-3/day C

1/day D

5-6/wk E

2-4/wk F

70. Food #2 eaten at least twice per week (enter code and specify food and usual portion size below): ..... [ ][ ][ ]

a. _____

71. Frequency for food #2: ..... > 6/day A [rc 3]

4-6/day B

2-3/day C

1/day D

5-6/wk E

2-4/wk F

Dietary Intake Form (DTIC screen 10 of 15)

72. Food #3 eaten at least twice per week (enter code and specify food and usual portion size below): ..... [ ][ ][ ]

a. _____

73. Frequency for food #3: ..... > 6/day A [rc 3]

4-6/day B

2-3/day C

1/day D

5-6/wk E

2-4/wk F

74. What do you do with the visible fat on your meat? [rc 4]

Eat most of the fat A

Eat some of the fat B

Eat as little as possible C

Don't eat meat D

75. What kind of fat do you usually use for frying and sauteing foods at home, excluding "Pam"-type spray? [rc 5]

Real Butter A

Margarine B

Vegetable Oil C

Vegetable Shortening D

Lard E

Bacon Grease F

Not Applicable G

Unknown H

Go to Item 77, Screen 11

76. Enter code and specify brand and form below: ..... [ ][ ][ ]

a. _____

Dietary Intake Form (DTIC screen 11 of 15)

77. What kind of fat do you usually use for baking? [rc 5]

- Real Butter — A
- Margarine — B
- Vegetable Oil — C
- Vegetable Shortening — D
- Lard — E
- Bacon Grease — F
- Not Applicable — G
- Unknown — H

→ Go to Item 79

78. Enter code and specify brand and form below: ..... [ ][ ][ ]

a. _____

79. What brand and form of margarine do you usually use at the table? [rc 6]

a. Form: .....
- None — A → Go to Item 80, Screen 12
- Stick — B
- Tub — C
- Diet (low calorie) — D
- Other — E

b. Code number: ..... [ ][ ][ ]

c. Brand: _____

Dietary Intake Form (DTIC screen 12 of 15)

80. What kind of cold breakfast cereal do you most often use? (Enter code and specify brand name below): ..... [ ][ ][ ]

a. Brand: _____

81. Are you currently on a special diet? ..... Yes — Y

No — N → Go to Item 84, Screen 13

82. How many years have you been on it? .... [ ][ ]

83. People are often on more than one diet at a time. We are interested in learning what diet or diets you are currently on. Are you on any of these?

	Yes	No	Unknown
a. Weight Loss	Y	N	U
b. Low Salt	Y	N	U
c. Low Cholesterol	Y	N	U
d. Weight Gain	Y	N	U
e. Diabetic	Y	N	U
f. Other	Y	N	U

Dietary Intake Form (DTIC screen 13 of 15)

84. How many teaspoons of sugar do you add to your food daily? Include sugar added to coffee, tea, cereal, etc. ..... ☐☐

85. In cooking vegetables, how often do you add fat such as salt pork, butter, or margarine? ..... [rc 7]

2-3 times per day	A
1 time per day	B
5-6 times per week	C
2-4 times per week	D
1 time per week	E
1-3 times per month	F
Never	G
Unknown	H

86. How often is salt or salt-containing seasoning such as garlic salt, onion salt, soy sauce, or Accent added to your food in cooking? [rc 7]

2-3 times per day	A
1 time per day	B
5-6 times per week	C
2-4 times per week	D
1 time per week	E
1-3 times per month	F
Never	G
Unknown	H

87. How many shakes of salt do you add to your food at the table every day? ..... ☐☐

Dietary Intake Form (DTIC screen 14 of 15)

88. How often do you add catsup, hot sauce, soy or steak sauces to your food? ..... [rc 7]

2-3 times per day	A
1 time per day	B
5-6 times per week	C
2-4 times per week	D
1 time per week	E
1-3 times per month	F
Never	G
Unknown	H

89. How often do you eat special low salt foods such as low salt chips, nuts, cheese, or salad dressing? ..... [rc 7]

2-3 times per day	A
1 time per day	B
5-6 times per week	C
2-4 times per week	D
1 time per week	E
1-3 times per month	F
Never	G
Unknown	H

Dietary Intake Form (DTIC screen 15 of 15)

I. ADMINISTRATIVE INFORMATION

90. Interviewer's opinion of information:

Reliable	A
Questionable	B
Participant uncooperative	C
Participant unable to estimate frequencies	D

91. Date of data collection: ☐☐/☐☐/☐☐
Month Day Year

92. Method of data collection ..... Computer C
Paper form P

93. Code number of person completing this form: ..... ☐☐☐

INSTRUCTIONS FOR THE DIETARY INTAKE FORM
DTI, VERSION C, 09/09/92
PREPARED 02/28/95

I. GENERAL INSTRUCTIONS

The Dietary Intake Form is completed during the interview portion of the participant's clinic visit. The interviewer must be certified and 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 are completed as described in that document.

The physical setting should be quiet and private to put the participant at ease. The standard food unit models, help screens, instructions, and participant response cards (RC) must be readily accessible. The participant's form is checked for completeness of I.D.

Note: The clinic staff receptionist should alert the interviewer in advance if participant is illiterate or has any problem in reading. In those instances, response cards must be read each time by the interviewer.

Greet the participant cordially. Explain that the purpose of the interview is to obtain information about what they usually eat and drink, that there will be questions on specific foods and portion sizes, and that you need to find out how often, on average, the specified amount was eaten or drunk during the past year. Explain that any difference from the stated portion size must be reported only if it is at least twice as much or half as much. Frequency of eating will be based on number of times either per day, week or month. State that any foods not mentioned which he/she eats frequently may be added at the end. Assure the participant that he/she should feel free to have instructions repeated or to ask questions.

The interviewer must show an interest in the interview, using a pleasant non-judgmental tone and posture. In introducing the questionnaire the interviewer may use his/her own words but must cover the relevant points. The suggested statement follows:

> "Hello (participant's name). My name is _____. In this part of the clinic visit we want to obtain information on your usual eating habits. We will go over specific foods by groups. I'll name a food and a portion size and you tell me how often, on average, you ate that during the past year."
>
> "If your portion was much different from the amount I say, please tell me if it was at least twice as much, or half the portion size or less. We have a few sizes of cups and glasses here for reference.

> Here are the choices for "how often" (show RC 1). The choices are number of times a day or week or month. Please answer with the appropriate letter. For example, "once a day" would be "D". If you ate or drank something less than twelve times a year, that would be the same as "less than once a month," which is "I".
>
> It is important that your answer be brief in order to save time, but we want you to be as accurate as possible. If we miss food items that you usually eat, we will list those at the end. Feel free to ask questions or have me repeat instructions if I am not being clear. First, the dairy group: In the past year, how often on average did you eat...?"

Make sure that the appropriate response card, as indicated on the form, is given to the participant. Remove response cards for questions that do not call for them.

When reading the instructions to the participant regarding portion size and frequency, read the item SLOWLY AND CAREFULLY, pause after each sentence, point to the appropriate place on the response card (RC 1) when you are giving your instructions and example.

All interviewers must be consistent in reading the Food and Amounts list to the participant. Read the questions clearly, using the exact wording on the form. It is imperative that there be no exclusions or inclusions in reading the food list. Do not add any interpretations.

For Sections A through G, these instructions list items that may be included for each category. Refer to them only if the participant asks if he/she should include certain food items. For example, the participant may ask if skim or low fat milk includes cocoa mix. By referring to these instructions, the interviewer can see that it does.

Periodically the interviewer may have to reiterate the comment "on average, the number of times in the past year", or may remind the participant of the stated portion size.

Problem items should be recorded in the note log. Resolution of these items will be handled by a nutritionist.

Enter frequency of intake in the appropriate column utilizing the help screen for portion/frequency conversions (this table appears at the end of these instructions). For example, the portion size for ice cream is 1/2 cup. If the participant reports a portion of 1 cup, 2-4 times per week, the interviewer calls up the portion/frequency help screen and finds the 2X Row in the Multiple of the Amount column. The interviewer reads across to the 2-4 Week column to obtain the adjusted frequency. The

adjusted frequency is entered as 5-6 per week, or "E". If the amount is 3X or more, calculate the adjusted frequency or record the information in a note log and calculate later.

If the participant reports a seasonal intake of a food item which would total to more than 12 times per year, the average frequency must be calculated for the year (or the help screen for seasonal intake can be used). For example, if peaches are eaten only in season, but two peaches are eaten every week for three months, the frequency would be calculated as follows: 2 peaches x 4 weeks x 3 months = 24 divided by 12 (months in year) = 2 per month. The seasonal intake help screen is reprinted at the end of these instructions.

II. DETAILED INSTRUCTIONS FOR EACH ITEM

A. DAIRY FOODS [RC 1]

1. {Skim or low fat milk} This includes 1/2%, 1%, and 2% milk; reconstituted non-fat dry milk; cocoa from mix or vending; buttermilk -- lowfat or unknown; low fat chocolate milks.

2. {Whole milk} This includes whole; "homogenized"; jersey milk; whole milk cocoa; whole buttermilk; unknown milk.

3. {Yogurt} This includes whole milk yogurts, regular or frozen, 2% or low fat yogurts, regular or frozen.

4. {Ice cream} This includes all brands, not ice milk (list at end if ice milk is eaten more than twice per week).

5. {Cottage cheese or ricotta cheese} This includes any cottage or ricotta cheese including any in recipes; farmer's cheese. Includes lowfat cottage and ricotta cheese.

6. {Other cheeses, plain or as part of a dish} This includes processed, cheddar and all hard natural cheeses. This does not include cheese sauce.

7. Margarine added at any time, such as at the table.

8. Butter added at any time, such as at the table.

B. FRUITS [RC 1]

10. {Oranges} This includes tangerines.

11. {Orange or grapefruit juice} Small glass is equivalent to a 4 to 6 ounce glass.

12. {Peaches, apricots or plums} This includes nectarines.

14. {Other fruits} This includes cantaloupe; grapefruit; strawberries; papaya; raspberries; raisins; grapes; pineapple; kiwi.

C. VEGETABLES [RC 1]

Do not include small amounts in mixed dishes.

15. {String beans or green beans} Frozen or fresh; this includes wax beans; fava beans.

16. {Broccoli} Raw or cooked.

17. {Cabbage, cauliflower, brussels sprouts} Raw or cooked; coleslaw; sauerkraut.

18. {Carrots} Raw or cooked.

19. {Corn} Fresh, frozen or canned; niblets, cream style, cob.

20. {Spinach, collards or other greens} Raw or cooked; includes beet greens, chard, kale, mustard greens, turnip greens, and romaine. Do <u>not</u> include iceberg lettuce.

21. {Peas or lima beans} This includes mixed vegetables (peas, carrots, corn and limas), frozen or canned butter beans; not dried limas.

22. {Dark yellow, winter squash} This includes hubbard, danish, buttercup, delicious, and crookneck squash. Zucchini not included.

23. {Sweet potatoes} This includes pumpkin, yams, fresh or canned.

24. {Beans or lentils} This includes red, brown, navy, northern, kidney, blackeye, garbanzo, split peas, refried beans, and dried limas. Include baked beans.

25. {Tomatoes} This includes fresh or canned tomatoes; V-8 juice. Include tomato in salad if portion size is at least as large as one half tomato.

D. MEATS [RC 1]

26. {Chicken or turkey, without skin} This includes cornish hen; pheasant.

27. {Chicken or turkey, with skin} This includes cornish hen; turkey roll; pheasant.

28. {Hamburgers} This includes any ground beef in patty form.

29. {Hot dogs} This does not include chicken-type hot dogs.

30. {Processed meats} This includes cold cuts; luncheon meats, packaged or canned; tongue; (liver spread goes with liver).

31. {Bacon} This does not include Canadian style; Canadian bacon is coded in next category.

32. {Beef, pork, or lamb as a sandwich} This includes hot dish; meat pies; pizza; meatloaf; meatball; barbeque; chitterlings; Canadian bacon; souse meat; pigs feet.

33. {Beef, pork, or lamb as a main dish} This includes chops, corned beef.

34. {Canned tuna fish} This includes all kinds, about 1/2-2/3 can.

35. {Dark meat fish} This includes canned salmon; lake trout; shad; herring; fresh tuna; capelin; dogfish; eel; halibut; sablefish; Atlantic sturgeon; Arctic char; lake whitefish.

36. {Other fish} This includes orange roughy; grouper; walleye; crappie; whiting; unknown.

37. {Shrimp, lobster, scallops} This includes clams; oysters; crab.

38. {Eggs} This includes boiled; poached; fried; scrambled; omelettes; egg salad; and quiche. This does not include egg whites only nor egg substitutes such as Egg Beaters.

E. SWEETS, BAKED GOODS, CEREALS [RC 1]

39. {Chocolate bars or pieces} Average bar = about 1 oz. Chocolate cream = 1/2 oz. This includes chocolate fudge, chocolate chips and Reeses. This does not include peanut M&M's (recorded with nuts in section F).

40. {Candy without chocolate} About 3-4 pieces = 1 oz. This includes hard candies; gum drops; and 1 pkg. life savers. This does not include "dietetic" candies.

41. {Pie, homemade from scratch} This includes any kind of pie or tarts, crust from scratch.

42. {Pie, ready-made or from a mix} This includes any kind of pie or tarts, bakery, mix or frozen dough or restaurant; cheese cake; cream puff; pound cake.

43. {Donut} This includes all kinds.

44. {Biscuit or cornbread} This includes muffins.

46. {Cake or brownie} This includes cupcake; all cakes and bars.

48. {Cold breakfast cereal} This includes all ready-to-eat; wheat germ.

49. {Cooked cereals} This includes all cooked cereals and hot instant cereals.

50. {White bread} This includes French; Italian; raisin; challah-bread; 1/2 bagel; 1/2 white English muffin; average dinner roll; 1/2 frankfurter roll; 1/2 hamburger bun; pita bread; and matzoh 4" x 6". Include low-calorie bread. Do not include bread sticks or muffins.

51. {Dark or whole grain bread} This includes whole wheat; mixed grain such as oats and wheat; rye or pumpernickel; 2 graham cracker squares (2 1/2"); 3 rye wafers (2" x 3"). Include low-calorie dark bread. This does not include banana bread, nut bread, and muffins.

F. MISCELLANEOUS [RC 1]

52. {Peanut butter} This does not include peanut butter containing candies.

53. {Potato chips or corn chips} This includes nachos; 1 oz. = about 1 c.

54. {French fried potatoes} 4 oz. = 1 c.

55. {Nuts} This includes all nuts, peanuts; mixed nuts; M&M peanut candy; 1 oz. = about 3 tbsp.

56. {Potatoes} This includes boiled.

57. {Rice} This includes white rice; brown rice; wild rice; Rice-a-Roni.

58. {Spaghetti, noodles or other pasta} This includes macaroni; fettucini; noodles in lasagne.

59. {Home-fried food} This includes any food fried at home except french fries; include sauteed foods.

60. {Food fried away from home} This includes any deep fried foods; fish sticks; fish patties; and McNuggets. This does not include french fries.

G. BEVERAGES [RC 1]

61. {Coffee, not decaffeinated} This includes brewed or instant.

63. {Low calorie soft drinks} This includes all low calorie or diet carbonated beverages or sodas.

64. {Regular soft drinks} This includes all non-diet carbonated beverages or sodas.

65. {Fruit-flavored punch} This includes Tang, Hi-C.

H. OTHER DIETARY ITEMS

66. {Liver} Remove Response Card (RC) 1; show participant RC 2. After this item, remove RC 2.

68. {Other foods} Look up food in "FOODS" list. Record 3-digit code number, if given. If it is not given, draw two horizontal lines through the boxes.

68a. Enter food name. If the food does not appear in the "FOODS" list, also record usual portion size.

69. For the above food, enter frequency using Response Card 3. If the food appears in the list, base frequency on the portion size given in parentheses in that list. If the food does not appear in the "FOODS" list, base frequency on the portion size entered in (a).

70-71. Repeat above procedure for food #2. If none, skip to item 74. (Use "Next Field" key on computer).

72-73. Repeat above procedure for food #3. If none, skip to item 74. (Use "Next Field" key on computer).

74. The question refers to visible fat on steaks, roasts, etc. Use Response Card 4, and remove it after this question.

75. {Fat used for frying at home} Ask for the most often used, showing Response Card 5. If A, E, F, G, or H, skip to item 77.

76. If "Margarine" was answered above, record the 3-digit code found in the "MARGARINE" listing. If "Vegetable

Oil" or "Vegetable Shortening," record the code found in the "COOKING OILS" listing. If no code is given, draw two horizontal lines through the boxes.

Margarine: Do not assume a brand or type. If the brand name or type given by the respondent is incomplete, then ask for full brand name or type. If the brand name is not on the list or the brand is unknown, then use the GENERIC at the front of the list. GENERIC would mean a generic brand, an unknown brand, or use of any brand available. If insufficient information is available to code using the GENERIC list then code it with 2 horizontal lines.

Oil: Do not assume a brand or type. If the brand name or type given by the respondent is incomplete, then ask for the full brand name or type. If the type of oil is known (say safflower), but the brand is not or multiple brands are used, use the "ANY" codes at the beginning of the oil list. If the respondent uses oil, but neither the brand nor type is known, use code 020, GENERIC.

76a. Record the brand name of the oil, shortening, or margarine. If margarine, also record the <u>form</u> (tub,stick, diet, squeeze, etc.).

77-78. Complete as for items 75 and 76 above.

79. Note that the question refers to margarine used at the table. Obtain <u>both brand name and form</u>. Use Response Card 6, removing it after this item.

79b. Record 3-digit code number found in "MARGARINE" list. If none is given, draw two horizontal lines through the boxes.

79c. Record the brand name of the margarine.

80. Look up the brand name in the "CEREALS" list, and enter the 3-digit code found there. If none is given, draw two horizontal lines through the boxes.

80a. Record the brand name of the cereal.

81. Record "Yes" if participant is currently on one or more special diets.

82. The question refers to the current diet(s) only. If the person is currently on more than one diet, the question refers to the diet of longest duration.

83. Read each type of diet, marking "Yes," "No," or "Unknown" as the participant responds.

84. {Teaspoons of sugar added} Note 1 tablespoon = 3 teaspoons.

85. {Fat added to cooking vegetables} Show the participant Response Card (RC) 7 for items 85, 86, 88, and 89.

86. {Salt or salt-containing seasoning} Show the participant RC 7. Include hot sauces. Remove RC 7.

87. If the respondent does not know how many shakes of salt are added to food at the table every day, suggest that most people establish a 'salting' pattern over time. Ask the participant to demonstrate how he or she would salt the food on a plate, and then count the number of shakes in that motion. Based on that pattern, reask the participant how many times the pattern is repeated when salting food to estimate the number of shakes used.

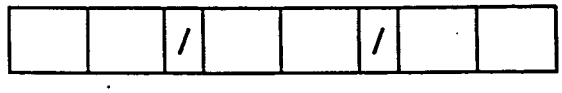
88. {Catsup, hot sauce, soy or steak sauces} Show the participant RC 7. Added at any time, such as at the table.

90. Evaluate the quality of the interview, emphasizing the dietary portion.

Question 90 requests that the interviewer give her/his opinion of the quality of the interview. The interviewer should take this question seriously, since it is used for analysis of the DTI data, and report the general overall quality of the dietary portion of the interview. This should reflect the general quality and not the quality of one specific item on the dietary interview.

III. ADMINISTRATIVE INFORMATION

91. Enter the date on which the interview was administered. Code in numbers using leading zeroes where necessary to fill all boxes. For example, May 3, 1993, would be entered as:



month day year

92. 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."

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

CONVERSION OF NONSTANDARD PORTION SIZES TO FREQUENCIES

	FREQUENCY								
MULTIPLE OF AMOUNT	A > 6 per day	B 4-6 per day	C 2-3 per day	D 1 per day	E 5-6 per wk	F 2-4 per wk	G 1 per wk	H 1-3 per mo	I Almost never
2X	A	A	B	C	D	E	F	H	I
0.5X	B	C	D	F	F	G	H	I	I

FREQUENCY CONVERSION FOR SEASONAL INTAKE

	FREQUENCY				
SEASON LENGTH	1 time /week	2 times /week	3 times /week	4-5 times /week	1 time /day
2 mo.	I	H	H	H	G
3 mo.	H	H	H	G	G
4 mo.	H	H	G	G	F

2/14/95 Cereal Code List

095	***Any Sugared Cereal
036	***Any Unsugared Cereal
===	***None
===	***Rarely
===	***Seldom
036	***Store Brand
999	***Variety of Brands
999	***Variety of Brands***
246	100% Amaranth Crunch with Raisins, Health Valley
007	100% Bran Cereal (Nabisco)
127	100% Golden Corn Lites (Health Valley Brand)***
247	100% Natural Bran, Health Valley
245	100% Natural Cereal with Amaranth, Raisins and Nuts
279	100% Rice Lites (HV)
128	100% Wheat Lites (Health Valley Brand)
009	40% Bran Flakes (Kelloggs)***
120	40% Bran Flakes (Post)
099	40% Bran Flakes (Ralston Purina)
259	40+ Bran Flakes, Kelloggs
125	7 Grain
001	All Bran
171	All Bran with Extra Fiber (Kelloggs)
163	Almond Delight (Ralston Purina)
002	Alpen
003	Alpha Bits
246	Amaranth Crunch with Raisins, 100%, Health Valley
244	Amaranth Flakes, Health Valley
132	Amaranth with Banana (Health Valley Brand)
202	Apple Cinnamon Squares (Kelloggs)
201	Apple Fruit Wheats (Nabisco)***
004	Apple Jacks
142	Apple Raisin Crisp (Kelloggs)
292	Basic 4 (GM)
275	Benefit (GM)
276	Benefit with Raisins (GM)
284	Big Mixx (Kelloggs)
215	Blueberry Squares (Nabisco)
151	Body Buddies
153	Booberry
006	Bran
005	Bran Buds
006	Bran Cereal
008	Bran Chex
009	Bran Flakes
225	Bran Mueslix Kelloggs
229	Bran News Ralston Purina
134	Bran with Apples and Cinnamon (Health Valley Brand)
135	Bran with Raisins (Health Valley Brand)
247	Bran, 100% Natural, Health Valley

126 Familia
097 Featherweight Corn Flakes, Low Sodium
159 Fiber One (General Mills)
131 Fini Bircher Muesli Mixed Cereal with Fruit and Nuts
260 Frankenberry
030 Froot Loops
031 Frosted Flakes
172 Frosted Miniwheats, Apple Flavored (Kelloggs)
032 Frosted Miniwheats, Sugar Frosted
101 Frosted Rice Krispies
122 Fruit & Bran
034 Fruit & Fiber***
117 Fruit & Fiber, Apple and Cinnamon
118 Fruit & Fiber, Dates, Raisins, and Walnuts
209 Fruit & Fiber, Peaches, Raisins, Almonds (Post)
208 Fruit & Fiber, Pineapple, Banana, Coconut (Post)
183 Fruit & Fiber, Tropical Fruit (Post)
095 Fruit Brute
128 Fruit Lites
230 Fruit Muesli Ralston Purina with Raisins, Dates and Almonds
268 Fruit Muesli-Raisins, Dates+Cranberries, Ralston Purina
253 Fruit Oat Bran Crunch, Kolln
251 Fruit Sweet Granloa Raspberry with Cream
250 Fruit Sweet Granola Blueberry with Cream
201 Fruit Wheats
242 Fruit and Nut Brano's, Health Valley
267 Fruit and Nut Supreme, Uncle Roy's
236 Fruit-e-o's, New Morning
122 Fruitful Bran (Kelloggs)
205 Fruity Marshmallow Krispies (Kelloggs)
035 Fruity Pebbles

036 General Flake
292 General Mills Basic 4
275 General Mills Benefit
276 General Mills Benefit with Raisins
130 General Mills Cinnamon Toast Crunch
212 General Mills Clusters
159 General Mills Fiber One
169 General Mills Honey Buckwheat
213 General Mills Oatmeal Raisin Crisp
161 General Mills Raisin Nut Bran
291 General Mills Triples
218 General Mills Yummy Mummy
165 Ghostbusters (Ralston Purina)
037 Golden Grahams
197 Grainfield's Corn Flakes
139 Grainfield's Raisin Bran
138 Grainfield's Whole Grain Crispy Brown Rice
140 Grainfield's Whole Wheat Flakes
051 Granola
039 Grape Nuts
040 Grape Nuts Flakes

072	Grape Nuts Flakes with Raisins
246	Health Valley 100% Amaranth Crunch with Raisins
244	Health Valley Amaranth Flakes
127	Health Valley Brand 100% Golden Corn Lites
128	Health Valley Brand 100% Wheat Lites
132	Health Valley Brand Amaranth with Banana
134	Health Valley Brand Bran with Apples and Cinnamon
135	Health Valley Brand Bran with Raisins
133	Health Valley Brand Orangeola with Almonds and Dates
129	Health Valley Brand Orangeola with Banana and Coconut
125	Health Valley Brand Sprout 7
136	Health Valley Brand Stoned Wheat Raisin Brand
128	Health Valley Fruit Lites
242	Health Valley Fruit and Nut Brano's
241	Health Valley Oat Bran Flakes
243	Health Valley Oat Bran Flakes with Raisins
248	Health Valley Wheat Germ + Fiber with Almonds and Dates
249	Health Valley Wheat Germ + Fiber with Banana + Tropical Fruit
247	Health Valley, 100% Natural Bran
103	Heartland Natural Cereal, Coconut
102	Heartland Natural Cereal, Plain
104	Heartland Natural Cereal, Raisin
270	Heartwise Crunch Flake, Kelloggs
269	Heartwise High Fiber Fruit Nugget, Kelloggs
009	High Fiber
041	Homemade Granola
240	Honey Almond Oatios, New Morning
043	Honey Bran
271	Honey Bran Oatbake, Kelloggs
169	Honey Buckwheat (General Mills)
264	Honey Bunches of Oats Honey Roasted
263	Honey Bunches of Oats with Almonds
198	Honey Graham Chex (Ralston)
137	Honey Grahams
116	Honey Nut Crunch Raisin Bran
173	Honey Smacks(Kelloggs)
014	Honey and Nut Cheerios
044	Honeycomb
187	Horizon (Post)
174	Just Right, All Grain (Kelloggs)
175	Just Right, with Fruit (Kelloggs)
045	Kaboom
255	Kashi, Puffed (7 whole grains + sesame)
036	Kelloggs
009	Kelloggs 40% Bran Flakes
259	Kelloggs 40+ Bran Flakes
171	Kelloggs All Bran with Extra Fiber
202	Kelloggs Apple Cinnamon Squares
142	Kelloggs Apple Raisin Crisp
284	Kelloggs Big Mixx

225	Kelloggs Bran Mueslix
223	Kelloggs Common Sense Oat Bran
224	Kelloggs Common Sense Oat Bran + Raisins
020	Kelloggs Corn Flakes
121	Kelloggs Cracklin' Oat Bran
123	Kelloggs Crispix
293	Kelloggs Double Dip Crunch
172	Kelloggs Frosted Miniwheats, Apple Flavored
122	Kelloggs Fruitful Bran
205	Kelloggs Fruity Marshmellow Krispies
270	Kelloggs Heartwise Crunch Flake
269	Kelloggs Heartwise High Fiber Fruit Nugget
173	Kelloggs Honey Smacks
174	Kelloggs Just Right, All Grain
175	Kelloggs Just Right, With Fruit
281	Kelloggs Kenmei Rice Bran
176	Kelloggs Marshmallow Crispies
226	Kelloggs Mueslix 5 Grain
204	Kelloggs Nut and Honey Crunch
162	Kelloggs Nutrigrain Almond and Raisin
206	Kelloggs Nutrigrain Nuggets
273	Kelloggs Nutrigrain Raisin Bran
271	Kelloggs Oatbake Honey Bran
272	Kelloggs Oatbake Raisin Nut
203	Kelloggs Pro-Grain
060	Kelloggs Product 19
064	Kelloggs Puffed Rice
065	Kelloggs Puffed Wheat
069	Kelloggs Raisin Bran
156	Kelloggs Raisin Squares
076	Kelloggs Rice Krispies
077	Kelloggs Shredded Wheat
214	Kelloggs Strawberry Squares
081	Kelloggs Sugar Frosted Flakes, Corn
281	Kenmei Rice Bran (Kelloggs)
046	King Vitamin
047	Kix
254	Kolln Crispy Oats
253	Kolln Fruit Oat Bran Crunch
252	Kolln Oat Bran Crunch
092	Kretschmer Wheat Germ
048	Life
127	Lites
188	Loma Linda Ruskets
095	Lucky Charms
239	Maple Nut Meusli, New Morning
176	Marshmallow Crispies (Kelloggs)
230	Meusli, Fruit, with Raisins, Dates and Almonds, Ralston Purina
032	Mini Wheats
032	Miniwheat
280	Morning Funnies (Ralston Purina)

131 Muesli
277 Muesli-Raisins, Peaches and Pecans, Ralston Purina
226 Mueslix 5 Grain Kelloggs
225 Mueslix, Bran, Kelloggs
290 Multi Bran Chex (Ralson Purina)

077 Nabisco
201 Nabisco Apple Fruit Wheats***
215 Nabisco Blueberry Squares
200 Nabisco Raisin Fruit Wheats
077 Nabisco Shredded Wheat
160 Nabisco Shredded Wheat and Bran
289 Nabisco Shredded Wheat with Oat Bran
199 Nabisco Strawberry Fruit Wheats
266 Nabisco, Raspberry Fruit Wheats
050 Natural Cereal
245 Natural Cereal, 100% with Amaranth, Raisins and Nuts
051 Nature Valley Granola, Cinnamon Raisin
145 Nature Valley Granola, Coconut Honey
053 Nature Valley Granola, Fruit and Nut
052 Nature Valley Granola, Toasted Oat******
234 New Morning Corn Flakes
235 New Morning Crispy Rice
236 New Morning Fruit-e-o's
240 New Morning Honey Almond Oatios
265 New Morning Honey Frosted Flakes
239 New Morning Maple Nut Meusli
233 New Morning Oatios
237 New Morning Super Bran
238 New Morning Super Raisin Bran
262 Nintendo Ralston Purina
204 Nut and Honey Crunch (Kelloggs)
216 Nutrific
055 Nutrigrain
206 Nutrigrain Nuggets (Kelloggs)
273 Nutrigrain Raisin Bran, Kelloggs
162 Nutrigrain, Almond and Raisin (Kelloggs)
056 Nutrigrain, Corn
055 Nutrigrain, Wheat
144 Nutrigrain, Wheat and Raisin
196 Nutty Rice (Bread & Circus)

252 Oat Bran Crunch, Kolln
243 Oat Bran Flakes with Raisins, Health Valley
241 Oat Bran Flakes, Health Valley
261 Oat Bran Options
283 Oat Bran Squares (Quaker)
124 Oat Chex
222 Oat Flakes Post
058 Oat Flakes, Fortified
217 Oat Squares, Quaker
282 Oat Total - Oat Flakes
126 Oat, Wheat, Millet Flakes
271 Oatbake Honey Bran, Kelloggs

272 Oatbake Raisin Nut, Kelloggs
121 Oatbran
240 Oatios, Honey Almond, New Morning
233 Oatios, New Morning
213 Oatmeal Raisin Crisp (General Mills)
182 Oh's (Quaker)
278 Oh's, Cinnamon Apple
210 Oh's, Honey Graham (Quaker)
258 Old Fashioned Corn Flakes, Stow Mills
133 Orangeola with Almonds and Dates (Health Valley Brand)
129 Orangeola with Banana and Coconut (Health Valley Brand)

120 Post 40% Bran Flakes
207 Post Crispy Critters
209 Post Fruit & Fiber, Peaches, Raisins, Almonds
208 Post Fruit & Fiber, Pineapple, Banana, Coconut
183 Post Fruit & Fiber, Tropical Fruit
187 Post Horizon
222 Post Oat Flakes
070 Post Raisin Bran
221 Post Smurf Magic Berries
059 Post Toasties
181 Post Trail Mix
039 Post Wheat and Barley
203 Pro-Grain (Kelloggs)
060 Product 19
080 Puffed Corn, Sweetened
061 Puffed Corn, Unsweetened
255 Puffed Kashi (7 whole grains + sesame)
193 Puffed Millet
062 Puffed Oats
063 Puffed Oats, Sugar-coated
195 Puffed Rice (Bread & Circus)
064 Puffed Rice (Kelloggs)***
064 Puffed Rice (Quaker)
065 Puffed Wheat (Kelloggs)***
066 Puffed Wheat (Quaker)

067 Quaker
067 Quaker 100% Natural
105 Quaker 100% Natural, Apples and Cinnamon
106 Quaker 100% Natural, Raisins and Dates
283 Quaker Oat Bran Squares
217 Quaker Oat Squares
182 Quaker Oh's
210 Quaker Oh's Honey Graham
064 Quaker Puffed Rice
066 Quaker Puffed Wheat
178 Quaker Raisin Life
287 Quaker Rice Bran
068 Quisp

139	Raisin Bran (Grainfield's)
069	Raisin Bran (Kelloggs)
071	Raisin Bran (Other)***
070	Raisin Bran (Post)
071	Raisin Bran (Ralston Purina)
071	Raisin Bran (Skinner)
200	Raisin Fruit Wheats (Nabisco)
072	Raisin Grape Nuts
178	Raisin Life (Quaker)
161	Raisin Nut Bran (General Mills)
272	Raisin Nut Oatbake, Kelloggs
156	Raisin Squares (Kelloggs)
268	Ralson Purina Fruit Muesli-Raisins, Dates+Cranberries
198	Ralston Honey Graham Chex
099	Ralston Purina 40% Bran
163	Ralston Purina Almond Delight
229	Ralston Purina Bran News
021	Ralston Purina Corn Flakes
228	Ralston Purina Dinosaurs
230	Ralston Purina Fruit Meusli with Raisins, Dates and Almonds
165	Ralston Purina Ghostbusters
280	Ralston Purina Morning Funnies
277	Ralston Purina Muesli-Raisins, Peaches and Pecans
290	Ralston Purina Multi Bran Chex
262	Ralston Purina Nintendo
071	Ralston Purina Raisin Bran
288	Ralston Purina Rice Bran Options
082	Ralston Purina Sugar Frosted Flakes
158	Ralston Purina Sunflakes
266	Raspberry Fruit Wheats, Nabisco
287	Rice Bran (Quaker)
288	Rice Bran Options (Ralston Purina)
286	Rice Bran and Raisins and Almonds (Kelloggs)
281	Rice Bran, Kenmei (Kelloggs)
074	Rice Cereal
075	Rice Chex
076	Rice Krispies (Kelloggs)
076	Rice Krispies (other)***
279	Rice Lites, 100%
188	Ruskets (Loma Linda)
125	Seven Grain
160	Shredded Wheat & Bran (Nabisco)
077	Shredded Wheat (Kelloggs)
077	Shredded Wheat (Nabisco)***
078	Shredded Wheat (Spoonsize)
077	Shredded Wheat (Sunshine)
078	Shredded Wheat Miniature
289	Shredded Wheat with Oat Bran (Nabisco)
071	Skinner Raisin Bran
221	Smurf Magic Berries Post
079	Special K
078	Spoonsize Shredded Wheat

125 Sprout 7 (Health Valley Brand)
136 Stoned Wheat Raisin Bran (Health Valley Brand)
257 Stow Mills Crispy Brown Rice
258 Stow Mills Old Fashioned Corn Flakes
096 Strawberry Crazy Cow
199 Strawberry Fruit Wheats (Nabisco)
080 Sugar Corn Pops
082 Sugar Frosted Flakes (Ralston Purina)
081 Sugar Frosted Flakes, Corn (Kelloggs)
083 Sugar Smacks
158 Sunflakes (Ralston Purina)
077 Sunshine Shredded Wheat
237 Super Bran, New Morning
238 Super Raisin Bran, New Morning
085 Super Sugar Crisp
084 Superfortified

108 Tasteeos
086 Team Flakes
109 Toasties
087 Total
219 Total Raisin Bran
282 Total, Oat -Oat Flakes
181 Trail Mix (Post)
291 Triples (GM)
088 Trix

267 Uncle Roy's Fruit and Nut Supreme
256 Uncle Roys Breakfast Cashew Raisin Deluxe
137 Uncle Sam Cereal (Laxative)

089 Weetabix
036 Wheat
039 Wheat & Barley (Post)
091 Wheat & Raisin Chex
144 Wheat & Raisin Nutrigrain
194 Wheat Biscuits (Nutrisystems)
090 Wheat Chex
092 Wheat Germ (Kretschmer)
248 Wheat Germ+Fiber with Almonds and Dates, Health Valley
249 Wheat Germ+Fiber with Banana+Tropical Fruit, Health Valley
048 Wheat Life
055 Wheat Nutrigrain
093 Wheaties
138 Whole Grain Crispy Brown Rice (Grainfield's)
094 Whole Wheat Flakes
140 Whole Wheat Flakes (Grainfield's)
285 Whole Wheat and Berries

218 Yummy Mummy, General Mills

9/9/92 Margarine Code List

L: Light
R: Regular
XL: Extra Light

098	Tub	R	***GENERIC corn oil
272	Stick	R	***GENERIC corn oil
344	Stick	XL	***GENERIC extra lite spread
050	Tub	XL	***GENERIC extra lite spread
119	Tub	L	***GENERIC "lite"
183	Stick	L	***GENERIC "lite"
281	Stick	R	***GENERIC safflower
282	Tub	R	***GENERIC safflower
346	Stick	R	***GENERIC safflower oil Salt-free
123	Sqz	R	***GENERIC Squeeze
271	Stick	R	***GENERIC vegetable oil
097	Tub	R	***GENERIC vegetable oil
095	Tub	R	A&P
215	Stick	R	A&P Corn Oil
091	Tub	R	A&P Liquid Oil
215	Stick	R	A&P Premium, Ann Page
154	Stick	R	Accolade Baker's
181	Stick	R	Acme (Ideal)
040	Tub	R	Acme (Ideal)
129	Tub	R	Albertson's
257	Stick	R	Albertson's
045	Tub	R	Alpha Beta
227	Stick	R	Alpha Beta
121	Tub	L	Ann Page "Plu" Spread
215	Stick	R	Ann Page, A&P Premium
217	Stick	L	Autumn Spread
092	Tub	L	Autumn Spread
154	Stick	R	Baker's Accolade
045	Tub	R	Beta, Alpha
227	Stick	R	Beta, Alpha
245	Stick	R	Block, Delta
265	Stick	R	Blue Bonnet
331	Whip'd	R	Blue Bonnet
090	Tub	R	Blue Bonnet
337	Stick	R	Blue Bonnet Butter Blend
338	Tub	R	Blue Bonnet Butter Blend
115	Tub	L	Blue Bonnet Spread
349	Tub	XL	Blue Bonnet Spread (48%)
192	Stick	R	Blue Ribbon
182	Stick	R	Blue Seal
239	Stick	R	Blue Seal Lard
231	Tub	R	Bluebrook
225	Stick	R	Bonnie Hubbard
303	Tub	R	Bonnie Hubbard

266	Stick	R	Bonnie Hubbard Corn Oil
088	Tub	R	Boy, Tom
223	Stick	R	Boy, Tom
338	Tub	R	Butter Blend,Blue Bonnet
337	Stick	R	Butter Blend,Blue Bonnet
000			Butter Buds
348	Stick	R	Butter Match
347	Stick	R	Butter-up
080	Tub	R	Chiffon
333	Whip'd	R	Chiffon
218	Stick	L	Chiffon Lite Spread
176	Stick	R	Chiffon Tub
130	Tub	R	Chiffon Unsalted
256	Stick	R	Chiffon Unsalted
083	Tub	R	Churn Gold
352	Stick	L	Country Morning Blend Light Spread, Land O'Lake
351	Tub	L	Country Morning Blend Light Spread, Land O'Lake
072	Tub	R	Country Morning Blend/Spread, Land O'Lakes
284	Stick	R	Country Morning Blend/Spread,Land O'Lakes
179	Stick	R	Dean's
251	Stick	R	Dellbrook
245	Stick	R	Delta Block
195	Stick	R	Eagle (Lady Lee Corn Oil)
202	Stick	R	Eagle (Lady Lee)
066	Tub	R	Eagle (Lady Lee)
043	Tub	R	Eatmore
220	Stick	R	Elgin Lard
156	Stick	R	Elgin Vegetable
207	Stick	R	Fame
062	Tub	R	Farm Charm
152	Stick	R	Farm Charm Soybean Quarters
332	Whip'd	R	Farm Gold
173	Stick	R	Farm Gold
249	Stick	R	Farmdale
047	Tub	R	Fed Mart
041	Tub	R	Flavorite
221	Stick	R	Flavorite
122	Tub	L	Flavorite 60% Spread
155	Stick	R	Flavorite Corn Oil
203	Stick	R	Fleischmann's
094	Tub	R	Fleischmann's
334	Whip'd	R	Fleischmann's
358	Tub	XL	Fleishmann's Extra Light Spread
363	Stick	XL	Fleischmann's Extra Light Spread
342	Tub	L	Fleischmann's Light Corn Oil Spread(60% fat)
343	Stick	L	Fleischmann's Light Corn Oil Spread(60%fat)

068	Tub	R	Fleischmann's Tub Golden
275	Sqze	L	Fleischmann's Squeeze (70% oil)
089	Tub	R	Fleischmann's Sweet Unsalted
267	Stick	R	Fleischmann's Unsalted
073	Tub	R	Food Club
159	Stick	R	Food Club
350	Tub	L	Food Club Spread (52%)
171	Stick	R	Foodland
077	Tub	R	Foodtown
172	Stick	R	Foodtown Corn Oil
196	Stick	R	Four Winds
252	Stick	R	Fred Meyer
188	Stick	R	Gaylord
240	Stick	R	Genuardi
233	Stick	R	Gerlands Vegetable Quarters
301	Tub	R	Giant Corn Oil
085	Tub	R	Gold'n Korn
216	Stick	R	Gold'n Korn
102	Tub	L	Gold'n soft spread (52%)
168	Stick	R	Golden Mist
201	Stick	R	Golden Mist Corn Oil
194	Stick	R	Good Value
067	Tub	R	Good Value
232	Stick	R	Grand Union
048	Tub	R	Grand Union
158	Stick	R	Grand Union Corn Oil Quarters
294	Stick	R	Gregg's Gold'n Tub
293	Tub	R	Gregg's Gold'n Tub
210	Stick	R	Harvest
361	Tub	XL	Heartbeat Spread
255	Stick	R	Heritage House
061	Tub	R	Heritage House
281	Stick	R	Hollywood Safflower
346	Stick	R	Hollywood Safflower Salt-free
044	Tub	R	Holsum
271	Stick	R	Holsum
161	Stick	R	Homestead
209	Stick	R	Hormel
170	Stick	R	Hotel Bar
204	Stick	R	Hy Top
185	Stick	R	Hy Vee
059	Tub	R	Hy Vee
241	Stick	R	Hy Vee Corn Oil
283	Stick	R	I Can't Believe It's Not Butter
291	Tub	R	I Can't Believe It's Not Butter
040	Tub	R	Ideal (Acme)
181	Stick	R	Ideal (Acme)
128	Tub	R	Imperial

268	Stick	R	Imperial
336	Whip'd	R	Imperial
100	Tub	L	Imperial Tub-spread Light
101	Tub	L	Janet Lee 60% Vegetable Oil Spread
107	Tub	L	Janet Lee Spread
206	Stick	R	Jewel Maid Corn Oil
097	Tub	R	Kellers
174	Stick	R	Kellers
186	Stick	R	King, Thrift (soy+cottonseed)***
243	Stick	R	King, Thrift (soy+palm)
302	Tub	R	Kingston
187	Stick	R	Kingston (Unity)
242	Stick	R	Kingston (formerly Unity)
096	Tub	R	Kraft
270	Stick	R	Kraft Corn Oil
345	Whip'd	R	Kraft Miracle Brand Margarine
285	Tub	L	Kraft Touch of Butter Lite Spread
160	Stick	R	Kroger Corn Oil
360	Stick	R	Krona
202	Stick	R	Lady Lee (Eagle)
066	Tub	R	Lady Lee (Eagle)
195	Stick	R	Lady Lee Corn Oil (Eagle)
060	Tub	R	Land O'Lakes
151	Stick	R	Land O'Lakes Corn Oil Premium
284	Stick	R	Land O'Lakes Country Morning Blend/Spread
072	Tub	R	Land O'Lakes Country Morning Blend/Spread
352	Stick	L	Land O'Lake Country Morning Blend Light Spread(52%)
351	Tub	L	Land O'Lake Country Morning Blend Light Spread(52%)
353	Tub	L	Land O'Lake Spread with Sweet Cream (60%)
356	Stick	L	Land O'Lake Spread with Sweet Cream (60%)
213	Stick	R	Land O'Lakes Soy***
359	Tub	XL	Latta Spread
362	Stick	XL	Latta Spread
091	Tub	R	Liquid Oil, A&P
049	Tub	R	Log Cabin
165	Stick	R	Log Cabin (soy+cottonseed)
269	Stick	R	Log Cabin (soy+palm)
244	Stick	R	Log Cabin***
097	Tub	R	Low Salt (Generic)
271	Stick	R	Low Salt (Generic)
278	Stick	R	Lucerne
279	Tub	R	Lucerne
211	Stick	R	Lucky 7

127	Tub	R	Mazola
178	Stick	R	Mazola
357	Tub	L	Mazola Light Spread
280	Tub	R	Mazola Unsalted
164	Stick	R	Mazola Unsalted
078	Tub	R	Meadolake
076	Tub	R	Meadow Gold
264	Stick	R	Meadow Gold
105	Tub	L	Meadow Gold 52% Corn Oil Spread
191	Stick	R	Monarch
352	Stick	L	Morning Blend Light Spread, Country, Land O'Lake
351	Tub	L	Morning Blend Light Spread, Country, Land O'Lake
284	Stick	R	Morning Blend, Country, Land O'Lakes
072	Tub	R	Morning Blend, Spread, Country, Land O'Lakes
296	Tub	R	Mother's
288	Stick	R	Mother's
287	Tub	R	Mother's Sweet Unsalted
340	Stick	R	Mother's Sweet Unsalted
341	Tub	L	Mothers Sweet Unsalted Corn Oil Spread
300	Tub	R	Mrs. Filbert's
289	Tub	R	Mrs. Filbert's 100% Corn Oil
065	Tub	L	Mrs. Filbert's 75% Vegetable Oil Spread
118	Tub	L	Mrs. Filbert's Family spread
237	Stick	R	Mrs. Filbert's Golden Quarters***
354	Tub	L	Mrs. Filbert's Spread 25
120	Tub	L	Mrs. Filbert's spread
290	Stick	R	Mrs. Filberts 100% Corn Oil
055	Tub	R	My-te-Fine
166	Stick	R	My-te-Fine Quarters
230	Stick	R	National Corn Oil
052	Tub	R	National***
298	Stick	R	NuMade
093	Tub	R	Nucoa
219	Stick	R	Nucoa
299	Tub	R	Numade
183	Stick	L	Number 1 (Shedd) Solid
103	Tub	L	Nuspred Spread
112	Stick	L	Nuspred Spread
247	Stick	R	Olsen's (Sun Valley)
197	Stick	R	Orchard Park (Value Plus)
234	Stick	R	Parade
229	Stick	R	Parkay
335	Whip'd	R	Parkay
096	Tub	R	Parkay
270	Stick	R	Parkay Corn Oil
053	Tub	R	Parkay Corn Oil
108	Tub	L	Parkay Light Corn Oil Spread
109	Tub	L	Parkay Light spread
364	Stick	L	Parkay Light

123	Sqz	R	Parkay Liquid
051	Tub	R	Pathmark
246	Stick	R	Pathmark
119	Tub	L	Pathmark 60% spread
259	Stick	R	Pathmark Corn Oil
198	Stick	R	Piggly Wiggly Golden Quarters
193	Stick	R	Pleasemore
304	Tub	L	Promise (68%)
153	Stick	L	Promise (68%)
344	Stick	XL	Promise Extra Light Spread (40%)
050	Tub	XL	Promise Extra Light Spread (40%)
046	Tub	L	Promise Light Spread (53%)
113	Stick	L	Promise Light Spread (53%)
263	Stick	R	Rainbow (lard)
199	Stick	R	Rainbow (soy)
069	Tub	R	Red Owl
184	Stick	R	Red Owl Corn Oil
238	Stick	R	Red Owl Vegetable
157	Stick	R	Red and White
087	Tub	R	Red and White
208	Stick	R	Rice
177	Stick	R	Richfood 100% Corn Oil
346	Stick	R	Safflower Salt-free
273	Stick	R	Saffola
126	Tub	R	Saffola
297	Stick	R	Saffola Salt-free
254	Stick	R	Schnuck's
262	Stick	R	Sentry
306	Tub	R	Sentry
330	Whip'd	L	Shedd's
183	Stick	L	Shedd's #1 Solid Vegetable
124	Tub	L	Shedd's 52% Corn Oil
054	Tub	L	Shedd's Bowl
111	Stick	L	Shedd's Corn Oil Spread
125	Tub	L	Shedd's Country Crock Spread (52% soy)
355	Sqz	L	Shedd's Spread (64%)
163	Stick	L	Shedd's Spread Quarter (64% soy)
162	Stick	R	Shurfine
162	Stick	R	Shurfresh
071	Tub	R	Shurfresh (Shurfine)
180	Stick	R	Shurfresh Corn Oil
068	Tub	R	Tub Golden, Fleischmann's
252	Stick	R	Sonny Boy
165	Stick	R	Soy+Cottonseed (Log Cabin)
354	Tub	L	Spread 25, Mrs. Filbert's
353	Stick	L	Spread with Sweet Cream (60%), Land O'Lakes
356	Stick	L	Spread with Sweet Cream (60%), Land O'Lakes
084	Tub	R	Springfield
212	Stick	R	Springfield (soy)
205	Stick	R	Staff

079	Tub	R	Staff
214	Stick	R	Star
058	Tub	R	Star
150	Stick	R	Star Corn Oil
056	Tub	R	Stop'n Shop
250	Stick	R	Stop'n Shop
247	Stick	R	Sun Valley (Olsen's)
226	Stick	R	Sunglory
261	Stick	R	Sure Good
075	Tub	R	Sweet'n Fresh
169	Stick	R	T.V. Brand Corn Oil
305	Tub	R	Thorofare
175	Stick	R	Thrift King (lard)
186	Stick	R	Thrift King (soy+cottonseed)***
243	Stick	R	Thrift King (soy+palm)
223	Stick	R	Tom Boy
088	Tub	R	Tom Boy
285	Tub	L	Touch o' Butter Lite Spread, Kraft
260	Stick	R	Two Guys
232	Stick	R	Union, Grand
187	Stick	R	Unity (Kingston)
302	Tub	R	Unity (Kingston)
242	Stick	R	Unity (now Kingston)
197	Stick	R	Valu Plus (Orchard Park)
114	Tub	L	Value Time 52% Spread
233	Stick	R	Vegetable Quarter, Gerlands
104	Tub	L	Velvet 52% Spread
274	Diet	XL	Weight Watcher's
190	Stick	XL	Weight Watcher's
308	Diet	XL	Weight Watcher's Unsalted
248	Stick	R	Weingarten
276	Stick	R	Western Family
277	Tub	R	Western Family
236	Stick	R	Willow Run
082	Tub	R	Winn Dixie
167	Stick	R	Winn Dixie

9/9/92 Oil Code List

000	***	Don't Use
060	***	Any Canola Oil
002	***	Any Corn Oil
010	***	Any Olive Oil
018	***	Any Peanut Oil
019	***	Any Safflower Oil
024	***	Any Sesame Oil
020	***	Any Soy Oil
020	***	Any Soybean Oil
021	***	Any Sunflower Oil
020	***	Any Vegetable Oil
098	***	Butter
020	***	Generic
098	***	Margarine
098	***	Shortening
020	***	Store Brand
002		A&P Corn Oil
062		Almond
071		Apricot Oil
036		Arrowhead Mills Olive Oil
035		Arrowhead Mills Peanut Oil***
098		Bacon Fat
010		Bertolli Olive Oil
098		Butter
060		Canola Oil
037		Carother's Olive Oil
052		Caruso
044		Casa Mia Soybean
044		Casa Mia Vegetable
073		Clover Oil
070		Coconut Oil
020		Cold Processed Blend
020		Contadina
057		Cottonseed
098		Crisco Shortening
003		Crisco Lite
003		Crisco Vegetable
060		D'Vine Rapeseed Oil
068		Della Blended Oil
020		Demoules Soybean
020		Demoules Vegetable
020		Dukes
033		Eden Corn***
031		Eden Olive Oil
032		Eden Safflower
034		Eden Sesame

046 Filippo Berio Pure Olive Oil
027 Fleischman's Corn Oil
098 Fleischman's Light
020 Food Club
020 Franco

020 Gem
067 Grapeseed

028 Hain Cold Processed Blend
041 Hain Corn***
040 Hain Safflower
042 Hain Sesame
061 Hain Sunflower
060 Heartbeat
060 Heartbeat Canola Oil
060 Hollywood Canola
030 Hollywood Peanut Oil
045 Hollywood Safflower
020 Hyvee

020 Kraft
020 Kroger

098 Lard
047 Laspagnola
039 Laspagnola Corn Oil
065 Linseed

098 Margarine
006 Mazola
056 Mct
098 Mrs. Filbert's Corn Oil
098 Mrs. Filbert's Lite

020 Numade

076 Oat Oil
038 Old Monk Olive Oil
074 Olive Oil Pam Spray

072 Palm Oil
007 Pam
074 Pam Olive Oil Spray
098 Parkay
020 Pathmark
069 Passarelli Cottonseed and Olive (10%)
048 Pastine Pure Olive Oil
008 Planters Peanut Oil
020 Polyunsaturated Oil
051 Pope Blended Oil (Olive)
009 Progresso Oil (Olive)
098 Promise
010 Pure Olive Oil
011 Puritan

060 Rapeseed Oil
020 Red & White
043 Rita's Blended Oil

019 Saffola
019 Saffron
024 Sesame
013 Shedds Peanut
020 Shop Rite
098 Shortening
047 Spagnola
020 Spartan
098 Spry
020 Star Soybean
020 Star Vegetable Oil
002 Stop'n Shop Corn Oil
020 Stop'n Shop Soybean
020 Stop'n Shop Vegetable
014 Sunlite Sunflower
060 Sunola Oil
049 Supreme Pure Olive Oil
002 Sweet Life Corn Oil

050 Virginia Soybean
050 Virginia Vegetable

054 Walnut
020 Weis
020 Weis Quality
015 Wesson
063 Wesson Corn
015 Wesson Lite
015 Wesson Soybean
059 Wesson Sunflower
059 Wesson Sunlite
015 Wesson Vegetable
020 Western Family

075 50% Canola 50% Olive
025 50% Olive, 50% Other
029 50% Soybean, 50% Corn
064 75% Corn 25% Olive

7 Up (code as Regular Soft Drink)

128 Alba 66 cocoa (1 packet)
128 Alba 77 Fit 'n Frosty (1 packet)
128 Alba hot chocolate (1 packet)
Alfalfa Sprouts, no code (1/2 cup)
Almonds (code as Nuts)
Aloe Vera juice, no code
American Cheese (code as Other Cheese)
Anchovy (code as Dark fish)
343 Antelope (4 oz)
Apple (SEE Q)
040 Apple Butter (1 Tbs)
227 Apple Cider (1 glass)
227 Apple Juice (1 glass)
125 Apple-dried (1/4 cup)
002 Applesauce (1/2 cup)
186 Apricot Juice (1 cup)
001 Apricot-dried (5 med halves)
Apricots (code as Peaches-canned)
003 Artichoke (1 medium bud)
Artificial Sweetener, no code
004 Asparagus, fresh (1/2 cup)
004 Asparagus, frozen (1/2 cup)
006 Avocado (1/2 fruit)

Bacon (SEE Q)
Bagel (code as White Bread)
Baked Beans (code as Beans)
007 Bamboo Shoots (1/2 cup)
Banana (SEE Q)
137 Banana-dried (1/4 cup)
185 Barbecue Sauce (1 Tbs)
170 Barley Soup (1 cup)
307 Bean & Meat Burrito (1)
307 Bean Burrito (1)
151 Bean Sprouts,mung (1/2 cup)
Beans (SEE Q)
Beans-baked and dried (code as Beans)
167 Beans-fava (1/2 cup)
Beans-string (code as String Beans)
Beans-yellow waxed (code as String Beans)
Beef (SEE Q)
321 Beef Jerky (1)
Beef Liver (code as Liver)
213 Beef Vegetable Soup (1cup)
Beef broth (code as Broth)
Beef-sandwich (code as Sandwich Beef)
Beer, no code

	Beer-lite (code as Beer)
008	Beets-not greens (1/2 cup)
201	Beta Carotene (10,000 IU)
	Biscuit/cornbread (SEE Q)
039	Black Olives (3 medium)
009	Blackberries-canned (1/2 cup)
010	Blackberries-fresh (1/2 cup)
010	Blackberries-frozen (1/2 cup)
	Blueberries-fresh,frozen,canned (code as Other Fruits)
	Bluefish (code as Dark fish)
037	Bok choy (1 cup)
	Bologna (code as Processed Meats)
	Bouillon, no code
	Bourbon (code as Liquor)
030	Brains (3 oz)
	Bran, no code
	Bran Muffin (code as Biscuit/cornbread)
292	Bran-oat (1/3 cup)
	Bran-wheat (code as Bran)
	Bread (code as White Bread)
	Bread-Diet (code as White Bread)
	Bread-Gluten Free (code as White Bread)
098	Bread-corn (1 piece)
	Bread-dark (code as Dark Bread)
	Bread-low protein (code as White Bread)
	Bread-pita (code as White Bread)
	Bread-pocket (code as White Bread)
	Bread-protein (code as White Bread)
	Bread-rice (code as White Bread)
	Bread-syrian (code as White Bread)
	Bread-wheat (code as Dark Bread)
	Bread-white (code as White Bread)
133	Breadsticks (1 stick)
156	Breakfast Bars (1 bar)
	Breakfast Cereal-cooked (code as Oatmeal and other cereal)
124	Breakfast Drink (1 packet)
	Breakfast cereal-cold (code as Cold cereal)
080	Brewer's Yeast Powder (tbs)
	Broccoli (SEE Q)
	Broth, no code
148	Brown Rice Crackers (5 cracker)
148	Brown Rice Snaps (5 cracker)
	Brown rice (code as White Rice)
	Brownie (code as Cake-commercial)
	Brussel Sprouts (code as Cabbage-cooked)
342	Buffalo (4 oz)
122	Burdock Root (1/4 cup)
	Burger King French Fries (code as French fried potatoes)
307	Burrito (1)
307	Burrito-bean (1)

307	Burrito-bean & meat (1)
	Butter (SEE Q)
059	Buttermilk (1 cup)
	Cabbage-cooked (SEE Q)
	Cabbage-uncooked (code as Cabbage-cooked)
110	Cafix (1 tsp)
	Cake-commercial (SEE Q)
	Cake-home baked (code as Cake-commercial)
344	Cake-no fat (1 slice)
	Cake-snack type (code as Cake-commercial)
	Calf Liver (code as Liver)
118	Cambridge diet (1 packet or 1 cup)
	Candy (SEE Q)
	Candy & nuts (code as Chocolate bar)
	Candy with nuts (code as Chocolate bar)
	Candy without chocolate (code as Candy)
330	Candy-tofu (1 bar)
009	Canned Blackberries (1/2 cup)
	Canned Peaches (code as Peaches-canned)
312	Canned Pears (1/2 cup)
	Cantaloupe (code as Other Fruits)
	Capers, no code
	Carbonated Beverage with sugar (code as Regular Soft Drink)
	Carbonated Soda (code as Regular Soft Drink)
	Carbonated Beverage with sugar - non cola (code as Regular Soft Drink)
	Carduini (code as Kale)
124	Carnation Instant Breakfast (1 packet)
005	Carob bar (3 oz)
012	Carrot Juice (8 oz)
	Carrots-cooked (SEE Q)
287	Carrots-raw (1/2 or 2-4 sticks)
	Casserole-Beef,pork or lamb (code as Sandwich Beef)
	Catsup, no code
	Cauliflower (code as Cabbage-cooked)
219	Caviar (1/2 oz)
195	Celery (4" stick or 1/2 stalk)
190	Celery juice (1 cup)
	Cereal (code as Cold cereal)
145	Cereal-cream of rice (1 cup)
147	Cereal-cream of wheat (1 cup)
144	Cereal-farina (1 cup)
	Chard Greens (code as Kale)
	Cheddar Cheese (code as Other Cheese)
013	Cheeries-canned (1/2 cup)
014	Cheeries-fresh (1/2 cup)
014	Cheeries-raw (1/2 cup)
131	Cheese curls (1 cup)
310	Cheese nachos (6-8)

134 Cheese sauce (1/2 cup)
346 Cheese substitute (1 oz)
Cheese-American,Cheddar, other (code as Other Cheese)
Cheese-cottage (code as Cottage Cheese)
Cheese-ricotta (code as Cottage Cheese)
Chewing gum (code as Gum)
319 Chex Party Mix (1 cup)
212 Chicharrones (1 oz)
Chicken Liver (code as Liver)
Chicken broth (code as Broth)
161 Chicken dog (1)
300 Chicken noodle soup (1 cup)
Chicken nuggets (code as Chicken with skin)
Chicken with no skin (SEE Q)
Chicken with skin (SEE Q)
Chicken-fried (code as Chicken with skin)
Chickpeas (code as Beans)
054 Chicory (1 cup)
188 Chili (1 cup)
Chili Sauce, no code
139 Chili peppers (oz)
136 Chinese food,meat&veg combo (serving)
169 Chinese food,mixed veg only (serving)
191 Chives,fresh (1 Tbs)
Chlorophyll, no code
Chocolate bar (SEE Q)
Chocolate bar with nuts (code as Chocolate bar)
Chocolate chip cookie (code as Cookie)
Chocolate chip cookie-homemade (code as Cookie)
135 Chocolate syrup (2 Tbs)
Chowder, no code
227 Cider (1 glass)
189 Clamato juice (1 cup)
060 Clams (1 dozen)
096 Clams-fried (1 dozen)
Club soda, no code
097 Cocoa (4 tsp)
222 Coconut milk (1 cup)
155 Coconut,dry (1 Tbs)
061 Coconut,fresh (1/8 cup)
Cod (code as Cod and catfish)
Cod and catfish (SEE Q)
113 Cod liver oil (1 Tbs)
Coffee (SEE Q)
Coffee cake-home made (code as Sweet Roll-commercial)
Coffee cake-ready made (code as Sweet Roll-commercial)
Coffee whitener, no code
Coffee-decafeinated (code as Decaffeinated Coffee)
Coke (code as Regular Soft Drink)
Coke no caffeine (code as Regular Soft Drink)
Cold Cuts (code as Processed Meats)

	Cold cereal (SEE Q)
	Coleslaw (code as Cabbage-cooked)
210	Condensed milk (1 Tbs)
	Condiments(e.g. dill), no code
118	Continental diet (1 packet or 1 cup)
	Cooked Carrots (code as Carrots-cooked)
	Cooked Cereal (code as Oatmeal and other cereal)
145	Cooked Cereal-cream of rice (1 cup)
147	Cooked Cereal-cream of wheat (1 cup)
292	Cooked oat bran (1/3 cup)
	Cooked oatmeal (code as Oatmeal and other cereal)
	Cookie (SEE Q)
	Cookie-commercial (code as Cookie)
	Cookie-homemade (code as Cookie)
345	Cookie-nofat (1 each)
152	Cookies-fig (1)
071	Cool Whip (1 Tbs)
	Corn (SEE Q)
	Corn Chips (code as Potato Chips)
015	Corn Tortilla (1)
163	Corn grits (1 cup)
098	Cornbread (1 piece)
	Cottage Cheese (SEE Q)
085	Crabmeat (4 oz)
	Cracked wheat bread (code as Dark Bread)
	Crackers (code as Dark Bread)
337	Crackers-graham (2)
332	Cranberries (1/2 cup)
099	Cranberry Sauce (1/8 cup)
145	Cream of Rice (1 cup)
147	Cream of Wheat (1 cup)
017	Cream sauce (1/4 cup)
	Cream soup (code as Chowder)
	Creamy Salad Dressings (code as Mayonaise)
034	Crenshaw melon (1/6 melon)
176	Croutons (1/4 cup)
	Cucumber, no code
019	Currants-dried (1/2 cup)
020	Currants-fresh (1/2 cup)
062	Custard (1/2 cup)
	D'Zerta, no code
121	Daikon root radishes (1/4 cup)
	Dandelion greens (code as Kale)
	Dark Bread (SEE Q)
	Dark Orange Squash (code as Yellow Squash)
	Dark fish (SEE Q)
021	Dates (5)
	Decaffeinated Coffee, no code
	Decaffeinated tea, no code
	Diet 7Up (code as Low calorie Soft Drinks)

	Diet Bread (code as White Bread)
	Diet Coke or Diet Pepsi or Diet Cola (code as Low calorie Soft Drinks)
	Diet Gingerale (code as Low calorie Soft Drinks)
174	Diet Mayonaise (1 Tbs)
118	Diet Supplement Drink (1 packet or 1 cup)
	Diet gelatin, no code
	Diet jello, no code
	Diet jelly, no code
073	Dill pickles (one)
	Donut (SEE Q)
	Doughnut (code as Donut)
	Dressing-olive oil and vinegar (code as Oil & Vinegar Dressing)
125	Dried Apple (1/4 cup)
001	Dried Apricot (5 med halves)
137	Dried Banana (1/4 cup)
036	Dried Bean Soup (1 cup)
019	Dried Currants (1/2 cup)
107	Dried Figs (1)
114	Dried Fruit (1/4 cup)
114	Dried Mixed Fruit (1/4 cup)
323	Dried Mixed Fruit -diet (1 pkg)
117	Dried Mixed Fruit and nuts (1/4 cup)
184	Dried Nectarines (1)
092	Dried Papayas (1)
091	Dried Peaches (2)
123	Dried Pineapple (1 ring)
220	Duck (3 oz)
090	Egg beaters or substitute (1/4 cup)
209	Eggnog (1 cup)
	Eggplant (code as Zucchini)
	Eggs (SEE Q)
309	Enchilada-cheese and beef (1)
105	Endive (1cup)
	English Muffin (code as White Bread)
205	Ensure nutri supplement (1 can or 1 cup)
	Equal, no code
106	Escarole (1 cup)
	Extra Lean Hamburger (code as Hamburger)
063	Falafel (1 serving)
144	Farina (1 cup)
167	Fava beans (1/2 cup)
152	Fig Bars (1)
152	Fig Newtons (1)
152	Fig cookies (1)
023	Figs (1 small)
107	Figs-dried (1)
187	Figurines Diet Bar (1 bar)

288	Fish oil Concentrate (1000 mg)
	Fish-dark (code as Dark fish)
	Fish-fried (code as Cod and catfish)
	Flounder (code as Cod and catfish)
	Fluff (code as Jam)
200	Fortified Cereal (1 cup)
221	Fozen gelatin pop (1)
	Frankfurter (code as Hotdog)
164	Frappe (12 oz)
	French fried potatoes (SEE Q)
	French fries (code as French fried potatoes)
	Fresca (code as Low calorie SoftDrinks)
010	Fresh Blackberries (1/2 cup)
020	Fresh Currants (1/2 cup)
096	Fried Clams (1 dozen)
	Fried chicken (code as Chicken with skin)
	Fried fish (code as Cod and catfish)
010	Frozen Blackberries (1/2 cup)
	Frozen Yogurt (code as Sherbet)
	Fruit Cocktail (code as Other Fruits)
	Fruit Drink (code as Punch)
104	Fruit rollups (1)
166	Fudge sauce (2 Tbs)
104	Fun fruits (1)
	Garbanzo Beans (code as Beans)
291	Garlic (clove or shake)
064	Gatorade (1 cup)
116	Gelatin (1/2 cup)
118	Generic Diet Drink (1 packet or 1 cup)
	Gin (code as Liquor)
	Gingerale (code as Regular Soft Drink)
	Gluten Free Bread (code as White Bread)
	Gluten Free Cookie (code as Cookie)
218	Goat meat (3 oz)
217	Goat milk (1 cup)
179	Goldfish crackers (1/2 cup)
337	Graham Crackers (2)
149	Granola (1/4 cup)
026	Granola bar (1 bar)
	Grapefruit (code as Other Fruits)
	Grapefruit Juice (code as Orange Juice)
132	Grapenut Pudding (1/2 cup)
	Grapes (code as Other Fruits)
065	Gravy (2 Tbs)
045	Green Peppers (1/2 pepper)
	Greens-kale dandelion mustard chard or turnip (code as Kale)
	Griddle Cakes (code as Pancakes)
163	Grits (1 cup)
027	Guava (1)

028 Guava paste (Tbs)
Gum, no code
211 Gunios (2 oz)

Haddock (code as Cod and catfish)
Halibut (code as Cod and catfish)
Ham (code as Beef)
Hamburger (SEE Q)
Hamburger-extra lean (code as Hamburger)
Hamburger-lean (code as Hamburger)
Hash-beef, pork, or lamb (code as Sandwich Beef)
Hawaiian Punch (code as Punch)
Head lettuce (code as Iceberg lettuce)
207 Hearts (1/2 cup or 2.5 oz)
Herbal Tea, no code
118 Herbal life Powder (1 packet or 1 cup)
Hershey's (code as Chocolate bar)
198 High Fiber Cereal (1 cup)
088 High Protein diet supplement (1 cup or 1 packet)
088 High Protein hot chocolate (1 cup or 1 packet)
200 High Vitamin Fortified Cereal (1 cup)
154 Hollandaise Sauce (1/2 cup)
Homemade chocolate chip cookie (code as Cookie)
Honey (code as Jam)
029 Honeydew (1/4 melon)
066 Horseradish (Tbs)
Hot Cakes (code as Pancakes)
160 Hot Dog-turkey (1)
166 Hot Fudge Sauce (2 Tbs)
139 Hot Peppers (oz)
144 Hot cereal-farina (1 cup)
130 Hot chocolate (cup)
Hotdog (SEE Q)
067 Humus (1/2 cup)

Ice Cream (SEE Q)
335 Ice Cream - no fat (1/2 cup)
208 Ice Cream - tofu (1/2 cup)
Ice Milk (code as Sherbet)
Iceberg lettuce, no code
Iced Tea (code as Tea -not herbal)
181 Iced Tea - sweetened (3 tsp)
124 Instant Breakfast (1 packet)
088 Instant protein (1 cup or 1 packet)
Italian Salad Dressing (code as Oil & Vinegar Dressing)

Jam, no code
068 Jello (1/2 cup)
221 Jello Frozen pop (1)
Jelly (code as Jam)
321 Jerky (1)

192	Jerusalem Artichoke (1/2)
285	Jicama (1/2 cup)
	Juice-V8 (code as Tomato)
227	Juice-apple (1 glass)
190	Juice-celery (1 cup)
	Juice-grapefruit (code as Orange Juice)
100	Juice-lemon,concentrate (Tbs)
101	Juice-lemon,prepared (cup)
	Juice-orange (code as Orange Juice)
	Juice-other fruit, no code
159	Juice-pineapple (1 cup)
126	Juice-prune (4 oz)
	Juice-tomato (code as Tomato)
203	K+ (1000 mg)
118	KLB6 Diet Mix (1 packet or 1 cup)
	Kale (code as Spinach-Cooked)
	Kefir (code as Yogurt)
	Ketchup (code as Catsup)
171	Kholrabi (1/2 cup)
030	Kidneys (3 oz)
182	Kiwi fruit (1)
	Komplete meal formula, no code (1serv = 2scoops)
057	Kool Aid (cup)
313	L'trim Diet Plan (1 serv or 2 scoop)
322	Lactaid (cup)
	Lamb (code as Beef)
286	Lard (tsp)
	Lasagna (code as Sandwich Beef)
	Leaf lettuce (code as Romaine Lettuce)
	Lean Hamburger (code as Hamburger)
031	Leeks (1/2 c)
032	Lemon (1/4 lemon)
100	Lemon juice concentrate (Tbs)
101	Lemon juice prepared (cup)
	Lemonade (code as Punch)
141	Lentil Soup (1 cup)
	Lentils (code as Beans)
	Less Bread (code as Dark Bread)
	Light Beer (code as Beer)
	Lima beans (code as Peas)
018	Lime (1/8)
	Liquor, no code
	Lite Beer (code as Beer)
	Liver (SEE Q)
204	Liver Tablets (6 tablets)
	Liver-Beef,Pork, Calf (code as Liver)
	Liver-chicken,turkey (code as Liver)
111	Liverwurst (1 oz or slice)
	Lobster (code as Shrimp)

	Low Calorie Caffeinated Soda (code as Low calorie Soft Drinks)
	Low Calorie Non Caffeinated Soda (code as Low calorie Soft Drinks)
	Low Calorie Non Cola Soda (code as Low calorie Soft Drinks)
112	Low Calorie Salad Dressing (1 Tbs)
118	Low Calorie diet supplement (1 packet or 1 cup)
346	Low Cholesterol Cheese (1 oz)
109	Low Fat Cheese (1 oz or slice)
108	Low Fat Cottage Cheese (1/2 cup)
	Low Fat Milk (code as Skim Milk)
	Low Protein Bread (code as White Bread)
	Low calorie SoftDrinks (SEE Q)
	Low calorie candy, no code
127	Lox (2 oz)
	M&M's (code as Chocolate bar)
	Mackeral (code as Dark fish)
033	Mango (1/2 fruit or 1/2 cup)
153	Mango Juice (1 cup)
	Margarine-stick,tub, diet (SEE Q)
318	Marmite (tsp)
	Mashed Potatoes (SEE Q)
338	Matzoh (1 large)
	Mayonaise, no code
174	Mayonaise-diet (1 Tbs)
	McDonald's French Fries (code as French fried potatoes)
115	Meat Analog (3 oz)
307	Meat Burrito (1)
115	Meat Substitute (3 oz)
339	Meat-wild game (4 oz)
093	Melba Toast (1)
034	Melon,crenshaw (1/6 melon)
348	Metamucil (1 tsp-rounded)
308	Mexican Food (small)
	Milk (SEE Q)
	Milk 1% (code as Skim Milk)
	Milk 2% (code as Skim Milk)
210	Milk-condensed (1 Tbs)
	Milk-low fat (code as Skim Milk)
322	Milk-low lactose (cup)
	Milk-skim (code as Skim Milk)
164	Milkshake (12 oz)
	Milky Way (code as Chocolate bar)
177	Millet (1 oz)
069	Miso (Tbs)
120	Miso Soup (cup)
158	Miso Tofu Soup (cup)
114	Mixed Dried Fruit (1/4 cup)
	Mixed Vegetables (code as Peas)

216 Mocha Mix (1 cup)
035 Molasses (1 Tbs)
341 Moose (4 oz)
Muffin (code as Biscuit/cornbread)
129 Mung Beans (1/2 cup)
Mushrooms (code as Mushrooms-raw)
Mushrooms-raw, no code (1)
Mustard, no code
Mustard - dry or prepared (code as Mustard)
Mustard Greens (code as Kale)

310 Nachos with cheese (6-8)
070 Nectarine (one)
184 Nectarines-dried (1)
311 Niacin (1000 mg)
Non Caffeine Diet Soda (code as Low calorie Soft Drinks)
Non Carbonated Fruit Drink (code as Punch)
Non Cola Soda (code as Regular Soft Drink)
Non Dairy Coffee Whitener (code as Coffee whitener)
071 Non Dairy Whipped Topping (1 Tbs)
344 Non Fat Cake (1 slice)
335 Non Fat Ice cream (1/2 cup)
334 Non Fat Salad Dressing (1 Tbs)
345 Non Fat cookie (1 each)
333 Non Fat yogurt (1 cup)
Noodles (code as Pasta)
Nutrasweet, no code
118 Nutrisystems Foods (1 packet or 1 cup)
Nutritional Speaking International
(code as Komplete meal formula)
Nuts (SEE Q)

292 Oat Bran-cooked (1/3 cup)
292 Oat bran (1/3 cup)
Oatmeal (code as Oatmeal and other cereal)
Oatmeal and bran (code as Oatmeal)
Oatmeal and other cereal (SEE Q)
Oil & Vinegar Dressing, no code
038 Okra (1/2 cup)
206 Olive Oil (2 Tbs or 1 oz)
Olive oil and vinegar dressing
(code as Oil & Vinegar Dressing)
Olive oil salad dressing (code as Oil & Vinegar Dressing)
039 Olives-any type (3 medium)
288 Omega 3-fatty acids (1000 mg)
284 Onion Rings (8-9)
303 Onions (1 Tbs)
Orange (SEE Q)
Orange Juice (SEE Q)
030 Organs (3 oz)
150 Oriental Vegetables (1/2 cup)

	Other Cheese (SEE Q)
	Other Fish (code as Cod and catfish)
227	Other Fruit Juice (1 glass)
	Other Fruits (SEE Q)
	Other Nuts (code as Nuts)
081	Ovaltine- plain or cocoa flavored (2 Tbs)
072	Oysters (3 oz or 6 medium)
	Pancakes, no code
143	Papaya Juice (1 cup)
041	Papayas (1/2 fruit or1/2 cup)
092	Papayas-dried (1)
168	Parsley-fresh (1 Tbs)
042	Parsnip (1/2 cup)
	Pasta (SEE Q)
	Pastry-home made (code as Sweet Roll-commercial)
	Pastry-ready made (code as Sweet Roll-commercial)
043	Pate (1 slice or 2 Tbs)
140	Pea Soup (1 cup)
	Peaches (code as Peaches-canned)
	Peaches-canned (SEE Q)
091	Peaches-dried (2)
	Peaches-fresh (code as Peaches-canned)
	Peanut Butter (SEE Q)
	Peanuts (code as Nuts)
044	Peapods (peas in pod) (1/2 cup)
	Pears (code as Apple)
312	Pears-Canned (1/2 cup)
	Peas (SEE Q)
	Pecans (code as Nuts)
	Pepper - shake, no code
	Pepperoni (code as Processed Meats)
045	Peppers-green (1/2 pepper)
045	Peppers-red (1/2 pepper)
045	Peppers-stuffed (1/2 pepper)
	Pepsi (code as Regular Soft Drink)
197	Persimmons (1 fruit)
157	Picante Sauce (1/4 cup)
074	Pickle - sweet (1)
073	Pickles-dill (one)
	Pie-commercial (SEE Q)
	Pie-homemade (SEE Q)
	Pineapple (code as Other Fruits)
159	Pineapple Juice (1 cup)
047	Pineapple-canned in own juice (1/2 cup)
046	Pineapple-canned in syrup (1/2 cup)
123	Pineapple-dried (1 ring)
047	Pineapple-fresh (1/2 cup)
	Pita Bread (code as White Bread)
	Pizza, no code
022	Plaintain (1)

	Plums (code as Peaches-canned)
	Pocket Bread (code as White Bread)
048	Pomegranate (1 fruit)
	Popcorn, no code
	Popsicle (code as Sugar)
178	Poptart (1)
	Pork (code as Beef)
	Pork Liver (code as Liver)
110	Postum (1 tsp)
203	Potassium (1000 mg)
	Potato Chips (SEE Q)
	Potato-baked or boiled (code as Mashed Potatoes)
	Potato-sweet (code as Sweet Potato)
	Potatoes (code as Mashed Potatoes)
	Potatoes-french fried (code as French fried potatoes)
	Potatoes-mashed (code as Mashed Potatoes)
	Preserves (code as Jam)
324	Pretzels (1 oz)
	Processed Meats (SEE Q)
	Protein Bread (code as White Bread)
088	Protein powder (1 cup or 1 packet)
126	Prune Juice (4 oz)
	Prunes, no code
075	Pudding (1/2 cup)
082	Pudding Pops (1 or 1.75 fl oz)
132	Pudding-Grapenut (1/2 cup)
325	Pumpkin Seeds (1/4 cup)
	Punch (SEE Q)
016	Quince (1/2 cup)
011	Rabbit (4 oz)
049	Radish (2)
	Raisins (code as Other Fruits)
051	Raspberries (1/2 cup)
050	Raspberries - canned (1/2 cup)
051	Raspberries-frozen (1/2 cup)
051	Raspberrries-fresh (1/2 cup)
287	Raw Carrot (1/2 or 2-4 sticks)
	Red Beans (code as Beans)
045	Red Peppers (1/2 pepper)
	Red Wine, no code
	Reeses (code as Chocolate bar)
	Regular Soft Drink (SEE Q)
053	Rhubarb (1/2 cup)
053	Rhubarb-fresh (1/2 cup)
053	Rhubarb-frozen (1/2 cup)
	Rice Bread (code as White Bread)
138	Rice Cake (1 cake=1/2 oz)
172	Rice Pudding (1/2 cup)
	Rice-brown (code as White Rice)

Rice-white (code as White Rice)
Ricotta cheese (code as Cottage Cheese)
Roast (code as Beef)
Romaine Lettuce (code as Spinach-Cooked)
Rum (code as Liquor)
103 Rutabage (1/2 cup mashed)

Salad Dressing-Italian (code as Oil & Vinegar Dressing)
Salad Dressing-creamy types (code as Mayonaise)
334 Salad Dressing-nofat (1Tbs)
Salad Dressing-oil & vinegar
(code as Oil & Vinegar Dressing)
Salad, unspecified contents, no code
Salami (code as Processed Meats)
Salmon (code as Dark fish)
Salt, no code
Sandwich Beef (SEE Q)
Sandwich-lamb (code as Sandwich Beef)
Sandwich-pork (code as Sandwich Beef)
Sardines (code as Dark fish)
185 Sauce-barbecue (1 Tbs)
134 Sauce-cheese (1/2 cup)
099 Sauce-cranberry (1/8 cup)
154 Sauce-hollandaise (1/2 cup)
Sauce-spaghetti (code as Tomato Sauce)
Sauce-tomato (code as Tomato Sauce)
094 Sauerkraut (1/2 cup)
Sausage (code as Processed Meats)
055 Scallions (5)
Scallops (code as Shrimp)
090 Scramblers (1/4 cup)
Scrod (code as Cod and catfish)
119 Sea Vegetables (1/2 cup)
095 Sealegs (4 oz)
056 Seeds (1/4 cup)
325 Seeds-pumpkin (1/4 cup)
056 Seeds-sunflower (1/4 cup)
214 Seigo ¬ Lite (1 can)
202 Seitan (1/2 cup)
Seltzer Water, no code
076 Sesame Butter (Tbs)
180 Sesame Seeds (1/4 cup)
Seven Grain Bread (code as Dark Bread)
088 Shaklee Instant Protein (1 cup or 1 packet)
118 Shaklee slim plan drink (1 packet or 1 cup)
Sherbet, no code
Shoyu, no code
Shrimp (SEE Q)
Skim Milk (SEE Q)
118 Slender Me (1 packet or 1 cup)
187 Slim Bar (1 bar)

336	Slim Fast- Ultra (1 serving)
118	Slimfast diet Drink (1 packet or 1 cup)
	Snickers (code as Chocolate bar)
	Soda- low calorie (code as Low calorie SoftDrinks)
	Soda-caffeine free (code as Coke no caffeine)
	Soda-low calorie caffeinated (code as Low calorie SoftDrinks)
	Soda-non cola (code as Regular Soft Drink)
170	Soup-barley (1 cup)
213	Soup-beef vegetable (1 cup)
	Soup-cream (code as Chowder)
036	Soup-dried bean (1 cup)
141	Soup-lentil (1 cup)
140	Soup-pea (1 cup)
142	Soup-tomato (1 cup)
213	Soup-vegetable beef (1 cup)
304	Sour Cream (1 Tbs)
	Soy Sauce, no code
	Soybeans (code as Tofu)
194	Soymilk (1 cup)
	Spaghetti (code as Pasta)
	Spaghetti Sauce (code as Tomato Sauce)
	Spinach (code as Spinach-Cooked)
	Spinach-Cooked (SEE Q)
	Spinach-Raw (code as Spinach-Cooked)
193	Sprouts-wheat (1/2 cup)
	Squash (code as Yellow Squash)
	Squash - dark orange (code as Yellow Squash)
084	Squid (1 cup)
340	Squirrel (4 oz)
	Steak (code as Beef)
	Stew-beef, pork, or lamb (code as Sandwich Beef)
	Strawberry-fresh,frozen,canned (code as Other Fruits)
	String Beans (SEE Q)
045	Stuffed Peppers (1/2 pepper)
077	Stuffing (1/2 cup)
	Sugar (SEE Q)
181	Sugared Iced Tea (3 tsp)
	Summer Squash (code as Zucchini)
056	Sunflower Seeds (1/4 cup)
173	Sunflower Sprouts (1/2 cup)
088	Supplemental Protein (1 cup or 1 packet)
095	Surimi (4 oz)
074	Sweet Pickle (1)
	Sweet Potato (SEE Q)
	Sweet Roll-commercial (SEE Q)
	Sweet Roll-home made (code as Sweet Roll-commercial)
215	Sweet Whey (1 cup)
	Sweet and Low, no code
030	Sweetbreads (3 oz)
	Swordfish (code as Dark fish)

	Syrian Bread (code as White Bread)
	Syrup (code as Jam)
	T V dinners, no code
	Tab (code as Low calorie SoftDrinks)
308	Taco (small)
078	Tahini (Tbs)
320	Tamarind (1)
165	Tang (1 cup)
079	Tangerine (1 medium)
102	Tapioca (1/2 cup)
	Tea (code as Tea -not herbal)
	Tea -not herbal (SEE Q)
181	Tea-Iced and sweetened (3 tsp)
	Tea-iced (code as Tea -not herbal)
052	Tempeh (3 oz)
	Tofu, no code
330	Tofu Candy (1 bar)
208	Tofu Ice Cream (1/2 cup)
208	Tofutti (1/2 cup)
	Tomato (SEE Q)
	Tomato Juice (code as Tomato)
	Tomato Sauce, no code
142	Tomato Soup (1 cup)
015	Tortilla (1)
088	Total Image k-28 (1 cup or 1 packet)
117	Trail Mix (1/4 cup)
	Trout (code as Cod and catfish)
	Tuna (SEE Q)
	Tuna packed in oil (code as Tuna)
	Tuna packed in water (code as Tuna)
160	Turkey Frankfurter (1)
160	Turkey Hot dog (1)
	Turkey Liver (code as Liver)
	Turkey with no skin (code as Chicken with no skin)
	Turkey with skin (code as Chicken with skin)
058	Turnip (1/2 cup)
	Turnip Greens (code as Kale)
336	Ultra Slim Fast (1 serving)
199	Unknown food item

	V-8 juice (code as Tomato)
	Veal (code as Beef)
213	Vegetable Beef Soup (1 cup)
	Vegetable broth. (code as Broth)
169	Vegetables-chineses (serving)
086	Venison (4 oz)
	Vinegar, no code
200	Vitamin Fortified Cereal (1 cup)
	Vodka (code as Liquor)
	Waffles (code as Pancakes)
	Water, no code
087	Water Chestnuts (1/8 cup)
183	Watercress (1/2 cup)
	Watermelon, no code
	Weight Watcher's Orange Treat, no code
323	Weight Watcher's dried fruit (1 pkg)
	Wheat Germ, no code
193	Wheat Sprouts (1/2 cup)
	Wheat bran (code as Bran)
	Wheat bread (code as Dark Bread)
146	Wheatena (1 cup)
215	Whey Drink (1 cup)
	Whipped Potatoes (code as Mashed Potatoes)
071	Whipped Topping (1 Tbs)
	Whiskey (code as Liquor)
	White Bread (SEE Q)
	White Rice (SEE Q)
	White Rice Bread (code as White Bread)
	White Wine, no code
	Whole Milk (code as Milk)
339	Wild Game Meat (4 oz)
	Wine (code as White Wine)
	Winter Squash (code as Yellow Squash)
	Yams (code as Sweet Potato)
080	Yeast (Tbs)
	Yellow Mustard (code as Mustard)
	Yellow Squash (SEE Q)
	Yellow Waxed Beans (code as String Beans)
	Yogurt (SEE Q)
	Yogurt Covered Almonds (code as Nuts)
	Yogurt- frozen (code as Sherbet)
333	Yogurt-Nonfat (1 cup)
	Yuca, no code
	Zucchini, no code

O.M.B. 0925-0821
exp. 10/31/95

ARIC
Atherosclerosis Risk in Communities

FASTING/TRACKING FORM

ID NUMBER: _____ CONTACT YEAR: 0 7 FORM CODE: F T R VERSION: C09/10/92

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 nunber 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 uith 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:m m

b. AR ..... 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 consuned: __:__
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
Paper P

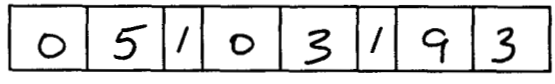
8. Code number of person completing this form: ..... _____

INSTRUCTIONS FOR THE FASTING/TRACKING FORM
FTR, VERSION C, 09/10/92
PREPARED 06/25/93

The Fasting/Tracking Form is completely filled out at the beginning of the participant's visit. This form may be updated (in the CHANGE mode of the data entry system) if the participant had broken the fast before Visit 3 and agreed to return 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 3. Enter the date on which the participant signs the Visit 3 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 3 date, code in the numbers using leading zeroes where necessary to fill all spaces. For example, May 3, 1993 would be entered as:



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 of Visit											
		AM					PM						
Time Last Consumed		7-7:59	8-8:59	9-9:59	10-10:59	11-11:59	12-12:59	1-1:59	2-2:59	3-3:59	4-4:59	5-5:59	6-6:59
Yesterday...													
PM	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
	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...													
AM	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
	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
PM	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
	3-3:59									0	1	2	3
	4-4:59										0	1	2
	5-5:59											0	1

ARIC
Atherosclerosis Risk in Communities

Consent Form Information

As you know, ARIC is a medical research project sponsored by the National Institutes of Health, conducted in four communities in the United States. The purpose of the study is to learn more about the factors associated with heart diseases and hardening of the arteries. 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 third 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, exercise, 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. We will take 2.5 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.

5. A photograph of one or both of your eyes, to measure the blood vessels inside your eye (the retina). No drops will be put in your eyes nor will the camera touch your eye. Although you will see a flash of light when the picture is taken, this flash is not harmful to the eye.

As in the past ARIC clinic visits, these examinations will take about 3.5 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.

In the unlikely event that during the examination procedures you should require medical care, first aid will be available. If the examinations uncover any medical problems that require medical diagnosis or treatment, you will be so advised and that information will be provided to the physician or clinic that you choose. In that case payment must be provided by you and your third party payer, if any (for example, health insurance or Medicare). If an injury or illness occurs as a direct result of my participation in this study, Bowman Bray School of Medicine will pay for medical treatment reasonably necessary to treat that injury or illness. No other compensation is available.

The ARIC Study does not provide medical treatment, and the examination you receive here does not substitute for a medical examination your doctor might give you. Similarly, the ultrasound examination you receive here is different from a medical ultrasound examination and does not provide the same information to a physician. We will report to you and/or your physician those results from the examination that are of known medical value.

Following the examination we will contact you once a year by phone or mail to ask about your health during the past year. The examination will be repeated after three years. Following this fourth examination we will contact you again once a year by phone or mail to ask about your health.

If you are hospitalized for any reason, we would like to check your hospital records to obtain medical information that may apply to this study. If you have a heart attack or stroke during the study period, or if you were to die, we would like to ask your relatives and physician for details about your illness that apply to this study.

The information obtained during your examination will be kept confidential to the extent provided by law. It will be used only for scientific purposes without revealing your name. If you give permission, the results of your tests will be provided to your physician. Your personal information will be released only with your explicit approval.

We anticipate that your participation in this study will help provide new and valuable information that will reduce the risk of heart disease in the U.S. and in other countries.

If you have any additional questions about the ARIC Study, feel free to ask our personnel, or contact any of the following persons:

Ms. Jeannette Bensen, Study Coordinator at 777-3040

Catherine Messick, Medical Director at 777-3040

Dr. Gerardo Heiss, Principal Investigator at 966-7421

CONSENT FORM
ARIC
Atherosclerosis Risk in Communities

I have read the above and understand that I am invited to participate in the third 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 ____ 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 also understand that in three years I will be invited to the ARIC field center for a repeat examination.

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

ARIC HEALTH HISTORY FORM

Atherosclerosis Risk in Communities

ID NUMBER: | | | | | | | | CONTACT YEAR: | 0 | 7 | FORM CODE: | H | H | X | VERSION: C 03-11-93

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.

HEALTH HISTORY FORM (HHXC screen 1 of 5)

A. AFU CHEST PAIN CONFIRMATION

1. Did the participant report positive Rose angina in the Annual Follow-up call preceding this visit?..... Yes Y

   Go to Item 4, Screen 2. ← 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

   Go to Item 4, Screen 2. ← No-pain not recalled P

   Go to Item 3 ← No-location not recalled L

[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 (HHXC screen 2 of 5)

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. [PROBE FOR TYPE OF INVASIVE PROCEDURE]

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. Other: ..... Yes Y
No N

HEALTH HISTORY FORM (HHXC screen 3 of 5)

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. [PROBE FOR TYPE OF PROCEDURE]

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, Screen 4. ← No N

Specify: _____

_____

HEALTH HISTORY FORM (HHXC screen 4 of 5)

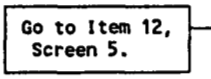
C. DIAGNOSTIC PROCEDURES

9. Since your last visit to the ARIC clinic, have you had any of the following procedures performed?

	Yes	No
a. Echocardiogram:	Y	N
b. Electrocardiogram:	Y	N
c. Treadmill or cardiac stress test:	Y	N
d. Carotid ultrasound studies:	Y	N
e. MRI exam of the brain:	Y	N
f. CAT scan of the brain:	Y	N

D. WALKING/STANDING

10. Does the participant use a wheelchair, crutches or walker? ..... Yes Y / No N



11. Does the participant walk with a cane? ..... Yes Y / No N

HEALTH HISTORY FORM (HHXC screen 5 of 5)

E. ADMINISTRATIVE INFORMATION

12. Date of data collection: ..... [ ][ ]/[ ][ ]/[ ][ ]
month day year

13. Method of data collection: ..... Computer C / Paper form P

14. Code number of person completing this form: ..... [ ][ ][ ]

INSTRUCTIONS FOR THE HEALTH HISTORY FORM
HHX, VERSION C, 3/11/93
PREPARED 06/25/93

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 sixth AFU contact (CY07), the most recent contact in which the third ARIC examination (Visit 3) was scheduled. In every case, it refers to the most recent participant contact prior to the third 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-3.

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 notelog 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 any positive response to a reported change in the frequency, duration or onset at rest of the chest pain which has occurred in the last two months prior to this interview compared to any previous episodes of chest pain.

B. Invasive Procedures

4. The frame of reference for this question is the time period between the second and third ARIC examinations. If the second examination was missed, then the frame of reference is the time period between the first and third ARIC examinations. "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. Also, abdominal aortic aneurysm repair is not included here. Code NO and skip to Item 6 if the participant denies this type of surgery since the last ARIC visit. Code YES if there is any doubt, because you will be probing as part of Item 5 anyway.

5. When probing, remember that a person who has had coronary bypass surgery may have had another "open heart" procedure concomitantly (or vice versa), in which case YES is coded for both Items 5a and 5b. Specify type of "other heart procedure(s)" in the notelog following Item 5b.

   Examples of "other heart procedures" include: valve replacement, ventricular aneurysm resection, ASD repair, VSD repair, patent ductus closure, etc. Note that coarctation of the aorta would not be included here as an isolated surgical procedure.

   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 denies this procedure, continue with Item 5e. If the response is YES, identify the site(s) of the procedure in Item 5d. Identify <u>all</u> 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 notelog.

If another type of procedure is reported, code YES for Item 5f. However, a notelog is not necessary.

6. "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.

7. 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. If there is a positive response to "other arterial catheterization", code YES and specify the procedure in the following notelog.

C. Diagnostic Procedures

9. Ask the question as written. The frame of reference is the interval between the last and current ARIC examinations, not the last AFU interview.

   a. Echocardiogram; if required, describe the procedure to the participant.

   b. Electrocardiogram; an ECG at rest, do not include the treadmill or stress test.

   c. Treadmill or cardiac stress test; also called exercise test; include Thallium or other nuclear tests.

   d. Carotid ultrasound studies; do not count the previous procedure in the ARIC examination.

   e. Cerebral MRI; magnetic resonance imaging of the brain. This may have been done as part of a more comprehensive MRI scan.

   f. Cerebral CT scan; a scan by computerized tomography of the brain. This may have been done as part of a more comprehensive CT scan.

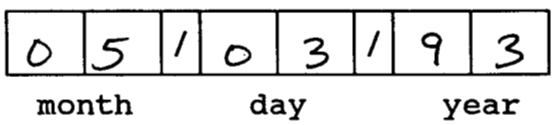
D. Walking/Standing

10. The response is coded by the interviewer without asking the participant. A positive response skips the interviewer to Item 12.

11. The response is coded by the interviewer without asking the participant.

E. ADMINISTRATIVE INFORMATION

12. 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, 1993, would be entered as:



13. 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."

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

O.M.B. 0925-0821
exp. 10/31/95

ARIC
Atherosclerosis Risk in Communities

MRI SCREENING FORM

ID NUMBER: | | | | | | | | CONTACT YEAR: | | | FORM CODE: M S C VERSION: A 04-21-93

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

Public reporting burden for this collection of information is estimated to average 2 minutes per response, including 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 the burden estimate or any other aspect of this collection of information including suggestions for reducing this burden to Reports Clearance Officer, PHS, 721-H Hubert H. Humphrey Bldg., 200 independence Ave. SW, Washington, D.C. 20201, Attn. PRA; and to the Office of Management and Budget, Paperwork Reduction Project (OMB 0925-0281), Washington, D.C. 20503.

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.

MRI SCREENING FORM (MSCA screen 1 of 4)

A. EXCLUSION

1. Have you ever had an MRI scan? ..... Yes Y / No N

2. Have you ever had surgery on an aneurysm in your brain? ..... Yes Y → Exclude, Go to Item 7. / No N / Unknown U

3. Do you have metal fragments in your eyes, brain, or spinal cord? ..... Yes Y → Exclude, Go to Item 7. / No N

4. Do you have a cardiac pacemaker or a heart valve prosthesis? Yes Y → Exclude, Go to Item 7. / No N

5. Do you have any internal electrical devices, such as a cochlear implant or spinal cord stimulator? ..... Yes Y → Exclude, Go to Item 7. / No N

6. [For females only] Could you be pregnant? ..... Yes Y → Exclude. / No N / Don't Know D

7. Does participant pass all MRI exclusion criteria? ..... Yes Y / No N → Go to Item 16, Screen 4.

MRI SCREENING FORM (MSCA screen 2 of 4)

B. INTERVIEW

8.a. Have you ever had an injury that resulted in loss of consciousness (knocked out)? Yes Y / No N / Don't Know D

Go to Item 9a.

b. How many times? .....

9.a. Have you ever been in a coma? ... Yes Y / No N / Don't Know D

Go to Item 10.

b. What was the cause?

10. Have you ever been told you have cerebral palsy? ..... Yes Y / No N / Don't Know D

11. Have you ever been told you have a brain tumor? ..... Yes Y / No N / Don't Know D

12.a. Have you ever had an operation on your brain? ..... Yes Y / No N / Don't Know D

Go to Item 13, Screen 3.

b. What for?

MRI SCREENING FORM (MSCA screen 3 of 4)

13.a. Have you ever had a seizure or convulsion? ..... Yes Y / No N / Don't Know D

Go to Item 14.

b. Was this only as a child? Yes Y / No N / Don't Know D

Go to Item 14.

c. Did this occur within the last 5 years? ..... Yes Y / No N / Don't Know D

14. Do you have loss of memory other than for people's names? Yes Y / No N / Don't Know D

C. MRI APPOINTMENT INFORMATION

Read description of MRI procedure and invite participation.

15.a. Does participant agree to MRI? Yes Y / No N

Go to Item 16, Screen 4.

MRI SCREENING FORM (MSCA screen 4 of 4)

15.b. Would you please tell me why you don't want the MRI examination?

Go to Item 16.

- No time/interest N
- Claustrophia C
- Previous MRI P
- Illness I
- Other O

c. If other, specify:

D. ADMINISTRATIVE INFORMATION

16. Date of data collection: ..... | | | / | | | / | | | (month / day / year)

17. Method of data collection: ..... Computer C; Paper form P

18. Code number of person completing this form: .....

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O.M.B. 0925-0821
exp. 10/31/95

ARIC
Atherosclerosis Risk in Communities

MEDICATION SURVEY FORM

ID NUMBER: [ ][ ][ ][ ][ ][ ][ ] CONTACT YEAR: [0][7] FORM CODE: [M][S][R] VERSION: C 02/25/93

LAST NAME: [ ][ ][ ][ ][ ][ ][ ][ ][ ][ ][ ][ ] INITIALS: [ ][ ]

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 SURVERY FORM (MSRC screen 1 of 8)

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 (MSRC screen 2 of 8)

"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 SURVERY FORM (MSRC screen 3 of 8)

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. CODE NO.	c. "Was this medication prescribed for you, over-the-counter or shared?" RX (R)/OTC (O)/ SHARED (S)/ UNKNOWN (U)	d. "Did you take this medication in the past 24 hours?" YES (Y)/ NO (N) UNKNOWN (U)
4.	_____ _____	[ ][ ][ ][ ][ ][ ]	R O S U	Y N U
5.	_____ _____	[ ][ ][ ][ ][ ][ ]	R O S U	Y N U
6.	_____ _____	[ ][ ][ ][ ][ ][ ]	R O S U	Y N U
7.	_____ _____	[ ][ ][ ][ ][ ][ ]	R O S U	Y N U

MEDICATION SURVERY FORM (MSRC screen 4 of 8)

RECORD NUMBER	a. MEDICATION NAME & CONCENTRATION	b. CODE NO.	c. RX (R)/OTC (O)/ SHARED (S)/ UNKNOWN (U)	d. YES (Y)/ NO (N) UNKNOWN (U)
8.			R O S U	Y N U
9.			R O S U	Y N U
10.			R O S U	Y N U
11.			R O S U	Y N U
12.			R O S U	Y N U
13.			R O S U	Y N U
14.			R O S U	Y N U
15.			R O S U	Y N U
16.			R O S U	Y N U
17.			R O S U	Y N U
18.			R O S U	Y N U
19.			R O S U	Y N U
20.			R O S U	Y N U

MEDICATION SURVERY FORM (MSRC screen 5 of 8)

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 SURVERY FORM (MSRC screen 6 of 8)

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

MEDICATION SURVERY FORM (MSRC screen 7 of 8)

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 SURVERY FORM (MSRC screen 8 of 8)

D. ADMINISTRATIVE INFORMATION

29. Date of data collection: ..... ☐☐/☐☐/☐☐
Month Day Year

30. Method of data collection: ..... Computer C

Paper form P

31. Code number of person completing this form: ..... ☐☐☐

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INSTRUCTIONS FOR MEDICATION SURVEY FORM
MSR, VERSION C, 02/25/93
PREPARED 04/22/93

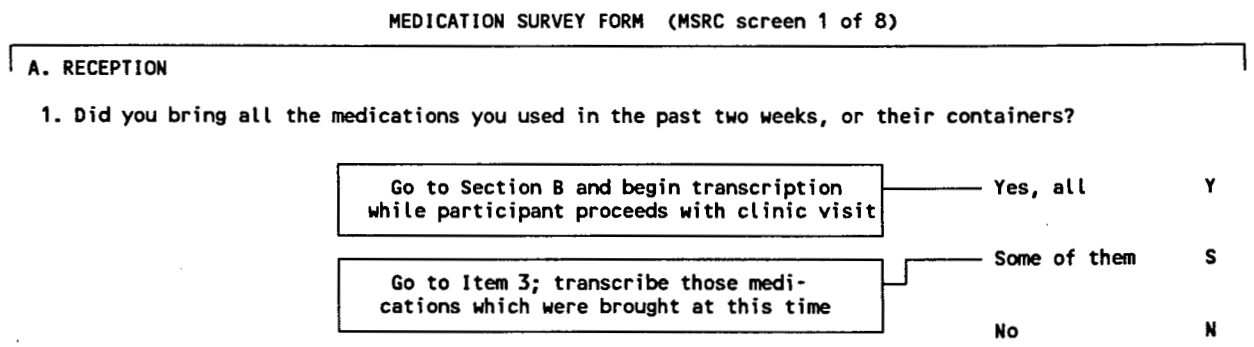
I. GENERAL INSTRUCTIONS

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 3.

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



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, medica- tions 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 medica-tion. 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 (field or screen forward). Section C (INTERVIEW, Items 24-26) is administered by a certified interviewer, 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 two components to document information about each medication used by the participant: (I) Transcription and (II) Interview. Transcription has two parts: the name and concentration (strength) of each medication is listed in column (a); a code number is entered in column (b). The interview also has two parts: the source of the medication (prescription, over-the-counter, or shared) is recorded in column (c). And the use of the medication within the last 24 hours is documented in column (d). The transcription of the medication name and concentration (column a) can be done by a trained transcriptionist or in conjunction with the administration of the questions in columns (c) and (d) by a trained interviewer. The coding of the medications is always done later by a trained coder after the interview is completed.

Column (a). MEDICATION NAME & 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, 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: Drug Name (1 space) weight (1 space) unit. For example:

AMPICILLIN 250 mg	ASCORBIC ACID 250 mg
CHLOR-TRIMETHON 12 mg	NOSTRIL 1/2%
TELORIN 8 mg	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 Caffeine = APC
Ammononium = AMMON	

B
Balanced Salt Solution = BSS
Buffered = BUF

C
Caffeine = CAFF
Calcium = CA
Capsules = CAP
Carbonate = CARBON
Chewable = CHEW
Chlordiazepoxide = CHLORDIAZ
Chloride = CL
Chlorpheniramine = CHLORPHEN
Codeine = COD
Compound = CPD or CMP or CMPD
Concentrate = CON

D
Decongestant = DECONG
Dextromethorphan = DM
Dioctylsodium Sulfosuccinate = DSS
Diproprionate = DIPROP
Docusate Sodium = DSS

E
Expectorant = EXP
Extra = EX

F
Ferrous = FE
Fluoride = F
Formula = FORM

G
Gluconate = GLUCON
Glyceryl Guacolate = GG
Guaifenesin = GG

H
Hydrochloride = HCL
Hydrochlorthiazide = HCTZ
Hydrocortisone = HC
Hydroxide = HYDROX

I
Inhalation = INHAL
Injection = INJ

J
Junior = JR

L
Laxative = LAX
Liquid = LIQ
Long Acting = LA
Lotion = LOT

M
Magnesium = MG
Maximum = MAX
Minerals = M
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
ml - milliliter
/ml - per milliliter
mEq - milliequivalents
hr - hour
/hr - per hour and
% - percent

gm = gram(s)
gr = grain(s)
mg = milligram

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 and asking the participant whether each medication is a prescription, over-the-counter, or shared medication and whether it was taken (used) within the last 24 hours.

Prioritization 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. The definitions of prescription, over-the-counter and shared medications and the instructions for the administration of the interview questions are below in the instructions for administering columns (c) and (d).

Example:

MEDICATION SURVEY FORM (MSRB screen 3 of 8)

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. CODE NO.	c. "Was this medication prescribed for you, over-the-counter or shared?" RX (R)/OTC (O)/ SHARED (S)/ UNKNOWN (U)	d. "Did you take this medication in the past 24 hours?" YES (Y)/ NO (N) UNKNOWN (U)
4.	_____	[ ][ ][ ][ ][ ][ ]	R O S U	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 (MSRB screen 5 of 8)

21. Total number of medications in bag: ..... [ ][ ]

22. Number of medications unable to transcribe: ..... [ ][ ]

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 (b). CODE NUMBER.

The six-digit medication code numbers are found in 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 drug entry which contains more than one word, look for a match of the entire name in the dictionary. If the name matches then code it. If the dictionary only contains a single entry containing the first word in the compound name and no other entry containing this word, then use that word and corresponding code for the entry.

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 (c). SOURCE OF MEDICATION

If done separately from the transcription of medication names/concentration, begin the interview portion of Section B by retrieving the participant's medication bag and form (if data are collected by paper form) and verifying the participant's name. Otherwise, begin this portion of Section B by placing all medications from the bag on the desk or counter so that the participant can see each one.

Take each medication, one at a time, and verify its name and the concentration as transcribed on the form (or enter it in column (a)). If the medication names have already been transcribed, verify the accuracy of the transcription and correct any discrepancies. Confirm that each medication was used during the last two weeks. If not, cross out its name and concentration in the transcription list (column a). If its use is confirmed, show the medication to the participant and ask the question in column (c) and then the question in column (d).

c. "Was this medication prescribed for you, over-the-counter, or shared?"

There are four response categories for this question: RX (R), prescription; OTC (O), over-the-counter; SHARED (S); and UNKNOWN (U). For the purposes of this study, a PRESCRIPTION medicine is one for which the participant has received from his or her physician a prescription that is filled by a pharmacist. An OVER-THE-COUNTER medication is one that may be purchased without a prescription from a physician. Physicians sometimes write prescriptions for over-the-counter medications. For example, the participant may take one aspirin a day. If the physician wrote a prescription for the aspirin, then it counts as a prescription medication. If the physician recommended the use of an over-the-counter medicine, such as aspirin, but did not write a prescription for it, then the aspirin is not coded as a prescription medication. Be sure to ask the participant if a product was prescribed. Even if it is normally an OTC product, or not labelled as a prescription, it may have been prescribed. A SHARED medication is a prescription medication written for another individual (e.g., other than the participant). An UNKNOWN medicine is a medication for which the dispensing source cannot be determined.

Column (d). USE IN PAST 24 HOURS

This is the second part of the interview. For each medication, past use should be determined immediately after the source, while the

medication being queried is clearly and visibly indicated to the participant. The following question is asked for each medication:

d. "Did you take this medication in the last 24 hours?"

The question in column (d) is self-explanatory. To assist the participant in remembering, one may ask the question 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. "Was this medication prescribed for you, over-the-counter or shared?" RX (R)/OTC (O)/ SHARED (S)/ UNKNOWN (U)	d. "Did you take this medication in the past 24 hours?" YES (Y)/ NO (N) UNKNOWN (U)
4.	_____	[ ][ ][ ][ ][ ][ ]	R O S U	Y N U
	_____			

Repeat this process for all medications, e.g., transcribe or verify the transcription of the medication/concentration and ask the questions in columns (c) and (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 the questions in columns (c) and (d). 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 an interview the participant may recall other medications or vitamins taken during the past two weeks. These should be transcribed and their source and last ingestion (use) documented 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 the 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. Items 25 - 26 are administered to all participants, even if use of any medication during the last two weeks was denied or no medication was brought to the field center. It may help to preface Items 25-26 with an explanation. "I know you said you took no medications, but we use these questions as a memory jogger" or "In addition to recording the names of the medication(s) you used in the last two weeks, we want to know why you are taking this (these) medication(s)."

For Item 24, ask if medications were taken in the past two weeks for the nine listed reasons. If answered affirmatively, be sure that the medication is recorded in Section B. It is not, however, necessary to indicate which medication corresponds to which symptom/condition. 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, <u>not</u> 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 (MSRC screen 6 of 8)

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

Item 25 is 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. Comparable explanations about "memory jogging" or "medical conditions" given for Item 24 may be offered at the beginning of this question. Although the primarily 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 3. 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.

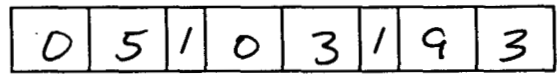
Ask Item 27 as written. Do not read the choices. If the participant mentions avoiding heart attack or stroke as part of his/her response, record "H." Individuals could be following the advice of their provider of medical care in doing this, or they could be acting on their own, based on information obtained 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 "0," 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.

D. ADMINISTRATIVE INFORMATION

29. 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:



30. 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."

31. 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.

III. MEDICATION CODING

Each medication name is coded by trained field center personnel, as specified in the instructions for column b. This may be done after the participant has left. A translation dictionary is used at the field center. If no match is found in the dictionary, set the status field to Q (questionable). The drug will be coded by the pharmacist at the Coordinating Center. The appropriate code will then be relayed to the field center for local data entry. Only exact matches and specific spelling variants listed in the dictionary are coded, by entering the corresponding numeric code in the boxes in column (b) of Section B.

CONFIDENTIAL

PARTICIPANT INFORMATION SHEET (PIN)

VERSION A

August 30, 1993

ID: _____ Ultrasound: ___

Name: _____ Visit 1 Age: __

VISIT 1 INFORAMTION
Visit 1 Date: _____
Visit 1 Weight: ____
Wisit 1 Height: _____ cm
(_ feet __ inches)
Visit 1 SBP: ___
Visit 1 DBP: ___
Visit 1 Race: _

VISIT 2 INFORAMTION
PPL Visit Date: _____
Visit 2 Date: _____
Visit 2 Weight: ____
Visit 2 SBP: ___
Visit 2 DBP: ___

Date of Birth
Visit 1: _____ Visit 2: _____

REPRODUCTIVE HISTORY
Menstrual Periods Within 2 Years Prior to Visit 2: ___
Partial or Total Hysterectomy at Visit 2: ___

Comment: _____

_____

_____

ARIC Visit 3: MSRC

ARIC PARTICIPANT ITINERARY FORM
VISIT 3 / PILOT

ID NUMBER:_____ DATE __/__/__ CONTACT YEAR: 07

NAME:_____ RACE/SEX ___/___

DATE OF BIRTH:___/___/___ AGE:___ TIME OF CHECK-IN __:___

VISIT 2 NOTES _____

ANY MAJOR MEDICAL PROBLEMS WE SHOULD KNOW ABOUT?

DIABETES_____ SURGERY IN PAST SIX WEEKS_____

SEIZURE DISORDERS____ HEART TROUBLE_____

RECENT BLACKOUTS_____ HX ANEURYSMS_____

OTHER_____

ANCILLARY STUDY PARTICIPANT? YES____ NO____

CLINIC PROCEDURES	TIME STARTED	TIME COMPLETED	STAFF CODE#
___ RECEPTION (UPD,FTR,MSR).....	__:__	__:__	_____
___SBP.....CUFF SIZE_____..	__:__	__:__	_____
___ANTHROPOMETRY.....	__:__	__:__	_____
___VENIPUNCTURE...FAST TIME____.....	__:__	__:__	_____
___SNACK			
___RETINAL PHOTOGRAPHY.....	__:__	__:__	_____
___ECG (HHX QUESTIONS).....	__:__	__:__	_____
___ULTRASOUND.....	__:__	__:__	_____
___INTERVIEWS.....	__:__	__:__	_____
1. COGNITIVE FUNCTION.....			_____
2. PERSONAL HISTORY.....			_____
3. REPRODUCTIVE HX (FEMALE ONLY)			_____
4. DIETARY INTAKE			_____
5. PHYSICAL ACTIVITY.....			_____
6. STROKE/TIA.....			_____
___MEDICAL DATA REVIEW.....	__:__	__:__	_____

***PROCEDURE RESCHEDULED.....____DATE/TIME_____

O.M.B. 0925-0821
exp. 10/31/95

ARIC
Atherosclerosis Risk in Communities

PERSONAL HISTORY FORM

ID NUMBER: [| | | | | | |] CONTACT YEAR: [0 | 7] FORM CODE: [P | H | X] VERSION: A 03-11-93

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 (PHXA screen 1 of 19)

A. MEDICAL CARE

"The following questions ask about your routine medical care and health."

1. How long has it been since you last saw a doctor for any reason?

a. [|] years b. [|] months

[IF 1 YEAR OR LESS, GO TO ITEM 3]

2. Have you seen a physician's assistant or a nurse practitioner for any reason in the last 12 months? ..... Yes Y
No N

3. How often do you have a routine physical examination, that is, not for a particular illness, but for a general check up?

[READ CHOICES SLOWLY]

At least once a year ..... Y
At least once every five years ..... F
Less than once every five years L
Do not have routine physical examinations ..... N
Unknown ..... U

PERSONAL HISTORY FORM (PHXA screen 2 of 19)

4. Do you have health insurance, Medicaid, Medicare, or a medical plan, such as an HMO, which pays part of a hospital, doctor's, or surgeon's bill? ..... Yes Y

No N

Unknown U

Go to Item 6.

5. Do you have:

	Yes	No	Unknown
a. Prepaid insurance or health plan, such as BC/BS or HMO	Y	N	U
b. Medicare	Y	N	U
c. Medicaid	Y	N	U
d. Other	Y	N	U

6. When you want help with a health problem, where do you usually go? By a "health problem" I mean an illness, a question or concern, or a need for a test or treatment. [DO NOT READ CHOICES]

Private physician ..... P

Walk-in clinic ..... W

HMO ..... H

Regular clinic C

Hospital emergency room ..... E

Other ..... O

a. If "Other," Specify:

PERSONAL HISTORY FORM (PHXA screen 3 of 19)

7. Have you ever seen a heart specialist? ..... Yes Y

No N

Unknown U

8.a. Has a doctor ever said you had high blood pressure or hypertension (high blood) ..... Yes Y

No N

Unknown U

Go to Item 8e., Screen 4

b. Has there ever been a time when you didn't get treatment for your high blood pressure when you needed it?

Yes Y

No N

Treatment not needed T

Go to Item 8d., Screen 4.

8.c. What was the main reason you were unable to get blood pressure treatment? [USE RESPONSE CARD 1]

Could not pay for it and didn't have enough insurance ..... A

Didn't have a doctor or clinic to get medical care ..... B

Wasn't able to get to the doctor or drug store C

Didn't have time or had more important things to take care of ..... D

Other ..... E

PERSONAL HISTORY FORM (PHXA screen 4 of 19)

8.d. When did you last see a doctor about your high blood pressure?

[ ][ ]/[ ][ ]
month year

e. Has a doctor ever said you had high blood cholesterol? ..... Yes Y

No N

Go to Item 8f., Screen 5. — Unknown U

f. Has there ever been a time when you didn't get treatment for your high blood cholesterol when you needed it?

Yes Y

Go to Item 8h., Screen 5. — No N

Treatment not needed T

8.g. What was the main reason you were unable to get treatment for your high blood cholesterol when you needed it?
[USE RESPONSE CARD 1]

Could not pay for it and didn't have enough insurance ..... A

Didn't have a doctor or clinic to get medical care ..... B

Wasn't able to get to the doctor or drug store C

Didn't have time or had more important things to take care of ..... D

Other ..... E

PERSONAL HISTORY FORM (PHXA screen 5 of 19)

8.h. When did you last see a doctor about your high blood cholesterol?

[ ][ ]/[ ][ ]
month year

"Has a doctor ever said you had any of the following?"

i. Heart attack? ..... Yes Y

No N

Unknown U

j. Heart failure or congestive heart failure? ..... Yes Y

No N

Unknown U

k. Diabetes (sugar in the blood)? ..... Yes Y

No N

Unknown U

l. Chronic lung disease, such as bronchitis, or emphysema? ..... Yes Y

No N

Unknown U

8.m. Asthma? ..... Yes Y

Go to Item 8.o. — No N

Unknown U

n. Do you still have it? ..... Yes Y

No N

o. Cancer? ..... Yes Y

Go to Item 9, Screen 6. — No N

Unknown U

p. Can you tell me in what part of the body the cancer was located?

_____

q. And the date it was diagnosed?

[ ][ ]/[ ][ ]
month year

PERSONAL HISTORY FORM (PHXA screen 6 of 19)

8.r. Have you had another cancer? ..... Yes Y

No N

Go to Item 9.

Unknown U

s. Can you tell me in what part of the body the cancer was located?

_____

t. And the date it was diagnosed?

[ ][ ]/[ ][ ]

month year

B. CONGESTIVE HEART FAILURE

9. Since your last ARIC visit, have you had to sleep on 2 or more pillows to help you breathe? ..... Yes Y

No N

10. Since your last ARIC visit, have you been awakened at night by trouble breathing? ..... Yes Y

No N

11. Since your last ARIC visit, have you had swelling of your feet or ankles (excluding during pregnancy)? [INCLUDE PARENTHETICAL COMMENT FOR FEMALES ONLY.] ..... Yes Y

Go to Item 13, Screen 7.

No N

12. Did it tend to come on during the day and go down overnight? ..... Yes Y

No N

PERSONAL HISTORY FORM (PHXA screen 7 of 19)

C. MIGRAINE HEADACHES

"The next questions ask you about headaches."

13. Have you had headaches lasting more than 4 hours? ..... Yes Y

No N

Go to Item 23, Screen 8.

Unknown U

14. Was the pain mostly on one side of your head? ..... Yes Y

No N

15. Did your headache throb, pulsate or pound? ..... Yes Y

No N

16. Was your headache accompanied by nausea and/or vomiting? ..... Yes Y

No N

17. During your headache, did lights bother you or make the headache worse? ..... Yes Y

No N

18. During your headache, did sounds bother you or make the headache worse? ..... Yes Y

No N

19. When you got your headache, did you feel like going into a dark room and lying down? ..... Yes Y

No N

20. How many years have you had headaches like this? [ ][ ] Years

PERSONAL HISTORY FORM (PHXA screen 8 of 19)

21. How many headaches like this have you had in the past year?

22. Did you ever notice spots, jagged lines or "heat waves" in one or both eyes *before you got the headache?* ..... Yes Y

No N

23. Have you ever been told by a physician that you have "migraine" headaches? ..... Yes Y

No N

24. Did either of your parents suffer from "migraine" headaches? ..... Yes Y

No N

PERSONAL HISTORY FORM (PHXA screen 9 of 19)

D. Smoking

"The next series of questions ask about smoking."

25. Have you ever smoked cigarettes? [Code "NO" if less than 400 cigarettes in a lifetime.] ..... Yes Y

No N → Go to Item 32, Screen 11.

26. Did a doctor or other health professional ever advise you to stop smoking? ..... Yes Y

No N

27. Do you now smoke cigarettes? Yes Y

No N → Go to Item 30, Screen 10.

28. When did you smoke your last cigarette?

Less than 2 months ago A

At least 2 months, but less than 12 months B

At least 12 months, but less than 24 months C

At least 24 months, but less than 36 months D

36 or more months ago E → Go to Item 32, Screen 11.

PERSONAL HISTORY FORM (PHXA screen 10 of 19)

29. 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 31.

30. How many cigarettes do you smoke per day now?
[CODE "00" IF LESS THAN ONE PER DAY.]

☐☐ cigarettes

31. Do(Did) you inhale the cigarette smoke?
[Read response categories]

Not at all	N
Slightly	S
Moderately	M
Deeply	D

PERSONAL HISTORY FORM (PHXA screen 11 of 19)

32. Please tell me if you are currently using or have ever used a pipe, cigars, cigarillos, chewing tobacco, snuff, or nicotine gum or patch prescribed by a doctor; for example, Nicorette, Nicoderm, Habitrol?

a. Pipe/cigars/cigarillos	Currently	C
	Never	N
	Past Use	P
b. Chewing tobacco	Currently	C
	Never	N
	Past Use	P
c. Snuff	Currently	C
	Never	N
	Past Use	P
d. Nicotine gum or patch	Currently	C
	Never	N
	Past Use	P

E. PASSIVE SMOKING

33. 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

34. Does anyone living with you now smoke cigarettes? ..... Yes Y

No N

Unknown U

PERSONAL HISTORY FORM (PHXA screen 12 of 19)

35. Have you ever lived for at least one year with someone (including a parent or spouse) who smoked cigarettes regularly in your home? ..... Yes Y

Go to Item 37. — No N; Unknown U

36. For how many years in total have you lived with someone who smoked cigarettes regularly in your home?

☐☐ years

37. Does anyone working with you now smoke cigarettes regularly in your work area? ..... Yes Y

No N

Does not work W

Unknown U

38. Have you ever worked for at least one year with someone who smoked cigarettes regularly in your work area? ..... Yes Y

Go to Item 40, Screen 13. — No N; Unknown U

39. For how many years in total have you worked with someone who smoked cigarettes regularly in your work area?

☐☐ years

PERSONAL HISTORY FORM (PHXA screen 13 of 19)

F. ALCOHOL

"Next I am going to ask you about wine, beer and drinks made with hard liquor because these are the three major types of alcoholic beverages."

40. Do you presently drink alcoholic beverages? ..... Yes Y

No N

Go to Item 44a.

41. Have you ever consumed alcoholic beverages? ..... Yes Y

Go to Item 53, Screen 16. — No N

42. Approximately how many years ago did you stop drinking?

☐☐ years

43. For how many years did you consume alcoholic beverages?

☐☐ years

Go to Item 49, Screen 14.

44.a. How many glasses of wine do you usually have per week? (4 oz. glasses; round down)

[IF NONE, GO TO ITEM 45a, SCREEN 14]

☐☐ per week

b. How many days in a week do you usually drink wine?

☐ days

PERSONAL HISTORY FORM (PHXA screen 14 of 19)

45.a. How many glasses, bottles, or cans of beer do you usually have per week? (12 oz. glasses, bottles, or cans, round down)

[IF NONE, GO TO ITEM 46a]

☐☐ per week

b. How many days in a week do you usually drink beer?

☐ days

46.a. How many drinks of hard liquor do you usually have per week? (1.5 oz. shots; round down)

[IF NONE, GO TO ITEM 47]

☐☐ per week

b. How many days in a week do you usually drink hard liquor?

☐ days

47. During the past 24 hours, how many drinks have you had?

☐☐ drinks

48. For how many years have you consumed alcoholic beverages?

☐☐ years

"The next 4 questions look at the amount of alcohol you have consumed in your lifetime."

49. Thinking about the entire time you consumed alcoholic beverages, how many glasses of wine did you usually have per week? (4 oz. glasses; round down)

☐☐ per week

PERSONAL HISTORY FORM (PHXA screen 15 of 19)

50. Thinking about the entire time you consumed alcoholic beverages, how many glasses, cans, or bottles of beer did you usually have per week? (12 oz. glasses, bottles or cans; round down)

☐☐ per week

51. Thinking about the entire time you consumed alcoholic beverages, how many drinks of hard liquor did you usually have per week? (1.5 oz. shot, round down)

☐☐ per week

52. Was there ever a time in your life when you consumed 5 or more drinks of any kind of alcoholic beverage almost every day? ..... Yes Y

No N

Unknown U

PERSONAL HISTORY FORM (PHXA screen 16 of 19)

G. OCCUPATION

53. Since your last ARIC visit, have you changed your occupation, stopped working, or retired? ..... Yes Y

No N

→ Go to Item 60, Screen 18.

54. I would like you to look at this card while I read it to you. Please tell me the letter of the one which best describes your CURRENT occupation. [HAND CARD 2 TO RESPONDENT AND READ EACH RESPONSE CATEGORY.]

Homemaking, not working outside the home ..... A → Go to Item 60, Screen 18.

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 → Go to Item 56, Screen 17.

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

PERSONAL HISTORY FORM (PHXA screen 17 of 19)

55. Did you retire because of health reasons? ..... Yes Y

No N

56.

ASK ITEM 1 FROM OCCUPATION WORKSHEET

Are(were) you self employed for this occupation? ..... Yes Y

No N

ASK ITEM 2 FROM OCCUPATION WORKSHEET

57. Since your last ARIC visit, have(did) you change(d) the company for which you work(ed)? ..... Yes Y

No N

→ Go to Item 60, Screen 17.

58. Please give me the name and address of your company. It will help us categorize your (former) occupation.

a. COMPANY NAME

_____

b. STREET ADDRESS

_____

_____

_____

c. _____ CITY

d. _____ STATE e. _____ ZIPCODE

ASK ITEM 3 FROM OCCUPATION WORKSHEET

PERSONAL HISTORY FORM (PHXA screen 18 of 19)

59. Occupation code from worksheet: ☐☐☐

(Code 000 for never worked)

60. Please look at this card. Which of these income groups represents your <u>total combined family income for the past 12 months</u>? Include income from all sources such as wages, salaries, social security or retirement benefits, help from relatives, rent from property, and so forth. (HAND CARD 3 TO RESPONDENT.) Please tell me the letter only.

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

PERSONAL HISTORY FORM (PHXA screen 19 of 19)

61. On average, how many people lived in your house for the last 12 months? ..... ☐☐

62. Are you currently caring for a sick or disabled relative? ..... Yes Y

No N

H. ADMINISTRATIVE INFORMATION

63. Date of data collection: ..... ☐☐/☐☐/☐☐

month day year

64. Method of data collection: ..... Computer C

Paper form P

65. Code number of person completing this form: ..... ☐☐☐

ID Number : | | | | | | | | Contact Year: | | |

OCCUPATIONAL WORKSHEET

1. What is(was) your current(most recent) occupation?
   IF MORE THAN ONE JOB, RECORD OCCUPATION FOR JOB
   FOR MOST HOURS WORKED PER WEEK.

_____

_____

| | | | (3 digit Occupation code)

2. What are(were) your most important activities or duties?
   For example, selling cars, keeping account books,
   or sweeping floors?

a. _____

b. _____

c. _____

3. What type of business is this?
   [READ RESPONSE CATEGORIES] ... Manufacturing M
   Retail R
   Wholesale W
   Service S
   Other O

Specify _____

INSTRUCTIONS FOR THE PERSONAL HISTORY FORM
PHX, VERSION A, 03/11/93
REVISED 09/14/93

The Personal History Form collects 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, alcohol consumption and occupation since Visit 2. 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. Because there are many skip patterns in this form, the interviewer should be very familiar with the flow of the questions to insure smooth administration with a conversational tone. Some of the questions on alcohol consumption and occupation 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.

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.

A. Medical Care

Section A contains questions on the use of medical care services. Items on the frequency and type of medical care use refer to the participant's lifetime, whereas, the two questions on health insurance (items 4 and 5) refer to current coverage. Begin with the introductory statement provided at the beginning of the form.

1. Item 1 refers to any type of medical interaction with a <u>doctor</u> (physician) for a general check-up or a specific problem. Family doctors, specialists, hospitals, and clinics all apply. Dentists do <u>not</u> apply. If asked for clarification, tell the participant that nurses, physician assistants, chiropractors, herbalists and other allied health care professionals also do <u>not</u> apply. Zero fill the "years" boxes if the participant has seen a doctor within the last 12 months and record the number of months. Zero fill both the "years" boxes and the "months" boxes if a physician was seen less than 4 weeks prior to the interview. When the time periods falls between months, round

down (e.g., 10 weeks ago would be coded as '00' years and '02' months. If the time period is less than or equal to 12 months, skip Item 2.

2. This question is answered only by participants who have not seen a doctor within the last year, therefore, the time frame for this item is restricted to the last 12 months.

3. Emphasize that this refers to general check-ups, including a routine gynecologic exam, and not a visit to resolve a specific medical problem. READ THE RESPONSE CATEGORIES and ask the participants to select the one that best describes the frequency of their routine physical exams.

4. "Health insurance" 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. This can include but cannot be limited to coverage for dental care. Follow the skip pattern to Item 6 for a response of NO or UNSURE.

5. Ask and enter a response for each of the four categories. Types of coverage are not necessarily mutually exclusive. 'Prepaid insurance or health plan' (response 5a) includes private in contrast to public health care insurance policies. Medicare (response 5b) and medicaid (response 5c) are public supported health care insurance polices. 'Other' includes other government insurance (i.e., not medicare or medicaid), such as veterans benefits, CHAMPUS, or workman's compensation.

6. Do not read the responses. "Regular clinic" is defined as a medical facility which pre-schedules patients for appointments (i.e., not a "walk-in" appointment) with available physicians (i.e., the patient does not have a "private" physician). The question refers to the usual source of health care. If more than one usual source is given, ask the participant to choose the type which describes the one used most often. If the participant's response does not correspond to one of the listed categories, select OTHER and specify the type.

7. Heart specialist refers to a cardiologist or a physician specializing in the diagnosis and/or treatment of heart disease.

8. Enter YES, NO or UNSURE for each item that identifies a specific condition (8a,e,i,j,k,l,m,o,r). A response is positive only if the condition was diagnosed by a physician. A diagnosis of "borderline" is coded as YES if the participant's condition was diagnosed by a physician as borderline. 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 in a note log. Follow the skip patterns closely for responses of NO or UNKNOWN.

a. This item begins a series of four questions (8a-d) on the diagnosis and treatment of hypertension during the participant's lifetime. The emphasis is physician diagnosis. Skip to item 8e if the participant has never been diagnosed as having high blood pressure or is unsure of that diagnosis.

b. Treatment refers to (1) medical care by a health professional for the high blood pressure after it was diagnosed or (2) prescription medication to lower blood pressure. If the response is NO (i.e., treatment has always been obtained), code NO and skip to item 8e. If participant was told that treatment was not needed, code T and skip to item 8d.

c. This item is a follow-up to the previous question in which the participant indicated that there was at least one time when he or she did not get treatment for high blood pressure. Read the question emphasizing that we are looking for the <u>main reason</u> that treatment was not obtained. Show the response card. Because the reasons for nontreatment are not mutually exclusive, ask the participant to select the situation with best describes his/her reason for not obtaining the treatment reported in the previous question. If treatment could not be obtained on multiple occasions, ask the participant to select the type of situation which was(is) most typical. If none of the reasons is applicable, select "Other".

d. This question is comparable to Item 1, except that the reason for the visit should be restricted to the treatment of or control for hypertension. "Doctor" refers to a physician in private or clinic/hospital practice, a hospital or clinic in contrast to a nurse or physician's assistant. The intent of the question is to document the most recent interaction with a physician for the hypertension. If the participant has not seen a doctor since the initial diagnosis, the date of the initial diagnosis should be used. Otherwise, the date of most recent contact. Fill in the month and year. Zero fill the years boxes if the participant has seen a doctor within the last 12 months. If the month is unknown, ask for the participant's "best estimate". If the participant does not remember the exact year when a doctor was seen for treating the hypertension, ask for and record a best estimate of the year.

e-h. These questions and instructions are identical to those for Items 8a-d, except that they refer to the diagnosis and treatment of high blood cholesterol. Show Response Card 1 for item 8g.

i-l. A positive response to each of these conditions (heart attack, congestive heart failure, diabetes, and chronic lung disease) requires diagnosis by a physician. The time frame is any time prior to this examination.

m. Asthma is also a physician diagnosed condition. If the response is NO or UNSURE, skip to Item 8.o.

n. If the response to Item 8.m is YES, determine if the asthma is still present, i.e., the participant still experiences episodes of wheezing leaving him/her short of breath.

o-t. If the response to Item 8.o is NO or UNSURE, go to Item 9. If the response is YES, ask what part of the body was affected and record the site (Item 8.p) and date of diagnosis (Item 8.q). Ask if the participant has had multiple diagnoses of cancer (Item 8.r). If NO or UNSURE, go to Item 9. If YES, record the site (Item 8.s) and date of diagnosis (Item 8.t). 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 <u>earliest</u> diagnoses. Do not probe to determine whether these diagnoses represent two separate malignancies or a malignancy and its recurrence.

B. Congestive Heart Failure

The purpose of this section of the interview on symptoms of congestive heart failure is a standardized update of the questions originally asked at the first and second examinations. Do not alter the conduct of the interview to compensate for possible misclassifications during earlier visits. Interviewer's comments may be recorded in the notelogs, but should not appear in the spaces provided for recording answers.

9. The time frame for questions 9-12 is the interim between the most recent and current <u>examination</u> (ARIC clinic visit), not the last AFU contact.

10. Do not define "trouble breathing".

11. Include the parenthetical comment only for women. If the response is NO, go to Item 13.

12. The question refers to the swelling of the feet or ankles established in the previous item.

C. Migraine Headaches

This section collects information on headaches that are not part of a hangover, viral illness, such as the flu, sinus conditions or the common cold. Headaches due to any of these causes are not eligible for this section; i.e., are not applicable. Do not describe the symptoms to the participant.

13. Headaches cannot be present in conjunction with a hangover, viral or other illness and must last at least 4 hours or be treated with medications prescribed by a physician for migraine headache for the response to be YES. If the participant responds YES to ever having had a headache lasting at least 4 hours and qualifies the response with one of the above explanations, probe for headaches lasting more than 4 hours for any other reasons. If no eligible headaches occurred (or if the headaches never occurred), code NO and skip to Item 23. If the participant is unsure of the duration of the headache(s) meeting the eligible qualifications, code UNKNOWN and continue.

14. A positive response to pain on "one side of your head" can be described as the 'front', 'back', 'left side' or 'right side' of the head in contrast to descriptions of diffuse pain, such as 'all over' or 'like a band around my head'.

15. Any description of a pulsating quality, such as a 'drum beating in my head' or 'throbs like a heart beating', is coded as YES.

16. Any description of nausea, vomiting or a loss of appetite (that is not part of a hangover) prior to, during or after the headache is coded as YES.

17. Any description of photophobia (sensitivity to light), such as 'dimming the lights during the headache', 'avoiding sunlight', 'wearing sun glasses to decrease the sunlight', 'seeking a dark room', etc., is coded as YES.

18. Any description of phonophobia (sensitivity to sound), such as 'turning down the TV or radio', 'asking people to talk more quietly', or 'closing the door in a room for quiet', etc., is coded as YES.

19. This question is deliberately redundant. The participant may answer YES because of photophobia, phonophobia, or seeking 'rest' so the headache will go away.

20. This question attempts to assess lifetime duration of this type of headache, even if the condition is no longer present. If the response is 'since my teens', use age 16 as the year of onset and calculate forward. Characteristically, onset of migraine headaches in women is closely tied to onset of menses, but onset prior to age 10 is not uncommon.

21. This is to establish whether the participant has an "aura" accompanying the headache. People who have experienced these know what you are asking. Any description such as 'blind spots', 'colorful wavy lines', especially in the periphery of vision, or general distortions of vision that signal the onset of or accompanies the headache(s) is coded as YES.

22. The time frame is the last 12 months. You are looking for an exact count (e.g., 15 headaches per year (enter '015') or 3 headaches per month, which would be coded as '036'). If the respondent cannot/is not willing to give you an exact number, ask for a best guess. Right justify the number and zero fill when necessary.

23. The focus of this question is whether the migraine headache(s) was diagnosed by a physician.

24. The focus of this question is whether one or both of the participant's parents had similar type headaches, regardless of whether the participant defines them as 'migraine'. If the participant is unsure or doesn't know, code NO.

D. Smoking

The questions in this section on smoking habits are adapted from the NHLBI Epidemiology Standardization Project. The purpose of its use at Visit 3 is to update the information on smoking patterns obtained during the previous examinations and to quantify lifetime passive exposure to smoke from cigarettes. Begin administering this section of the form with the introductory statement.

25. The focus of this question is to measure the participant's lifetime cigarette smoking habits, i.e., *'Have you <u>ever</u>...?'* 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 32.

26. This is a new question; the emphasis is on the admonition to stop smoking by a health care practitioner.

27. "Now" refers to within the last month, i.e., the last 4 weeks prior to the interview. If YES, go to Item 30.

28. Do not read the responses. If the last cigarette was smoked more than 36 months (Item 4e), go to item 32. (If the participant quit smoking more than 36 months ago, consumption patterns will have been documented at Visit 2 and the data do not need to be collected again.)

29. 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 30, and continue with Item 31.

30. As in Item 27, the question refers to the daily number of cigarettes smoked on an average day during the last month.

31. Choose the verb tense based on the participant's response to Item 27. Read the question and the RESPONSE CATEGORIES. If the respondent varied inhalation, code what was done for the longest period of time.

32. This question covers current and lifetime smoking habits. *Read the introduction and then determine the frequency of use for each of the four types of smoking(tobacco) product.* "Currently" is defined as within the last month; "Past Use" refers to any time prior to a month before this interview. Note that the use of nicotine gum or a patch must have been prescribed by a doctor.

E. Passive Smoking

Questions on passive smoking are administered to all participants, not just non-smokers as was done in Visit 2.

33. To obtain information on passive exposure to only cigarette smoke (i.e., not cigars, pipes and cigarillos) in any type of close quarters (car, home, public transportation, work, etc.), 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.

34. *Now* refers to the same time period used to define current smoking in Item 27, i.e., within the past four weeks prior to the interview.

35. Exposure is limited to (1) cigarette smoke from one or more regular smoker(s), (2) for a minimum of one year, (3) in the home, any time during the participant's life. If NO, skip item 37.

36. Calculate the cumulative exposure by summing the total number of years of exposure to cigarette smoke since birth, subtracting those years in which the participant did not live with an individual(s) who smoked regularly in the home.

37. The reference period is the same time period used to define current smoking in Item 34, i.e., within the past four weeks

prior to the interview; the environment is restricted to the work place; and the coworker(s) must smoke on a regular (habitual) basis, e.g., all day long, during breaks, at lunch, etc. If the participant is retired, unemployed or does not work outside the home, enter 'W'.

38. Exposure is limited to (1) cigarette smoke from one or more regular smoker(s), (2) for a minimum of one year, (3) in the workplace, any time during the participant's life. If NO, skip item 40.

39. Calculate the cumulative exposure by summing the total number of years of exposure to cigarette smoke since starting work, subtracting those years in which the participant did not work with an individual(s) who smoked regularly in the workplace.

F. Alcohol Consumption

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".

40. If the participant asks, or if the answer is not explicit, "presently" is defined as within the last 6 months. If YES, go to Item 44a.

41. If the response is "NO", skip to item 53. If the response is "YES", continue with Question 42 to determine past alcohol consumption.

42. Record the response in years, rounding down. For example, "1½ years ago" would be recorded as "01" years. "About a half a year ago" would be recorded as "00". If the participant stopped more than once, record the number of years since he or she most recently stopped drinking. For example, if the participant says: "The last time I quit was two years ago. The first time I quit was twenty years ago," the response would be recorded as "02".

    If using a paper form, record a response of 'don't know' by drawing two horizontal lines through the boxes.

43. For those who have stopped drinking more than one time, record the total number of drinking years combined. Include in the total years those years that were "light" drinking years. If the total number of years is not known, draw two horizontal lines through the boxes on the paper form. After recording the response, skip to Item 49.

The next three questions (Items 44-46) 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. *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 44a, skip Items 44b and continue with the questions about beer (Item 45a). If the number of drinks is more than 99 record as "99". In determining the number of days in a week the participant usually drinks each of the three types of alcoholic beverage, record the average number of days in the week. The maximum number of days per week is 7. For example, a person could have a glass of wine with dinner every night of the week (record 7 in Item 44b), drink beer only on weekends (record 2 in Item 45b) and never drink hard liquor (record 0 in Item 46b). An alcohol consumption by the drink conversion table is included at the end of this section. If recording the data on a paper form and the participant cannot give a response, draw two horizontal lines through the box(es).

44.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, cordials, and "sweet wines". The period of reference is a seven day week, which includes weekends. If wine is not consumed, go to Item 45a.

44.b The focus of this question is the participant's habitual drinking pattern.

45.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 46a.

45.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.

46.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 'liqueurs'. The period of reference is a seven day week, which includes weekends. If hard liquor is not consumed, go to Item 47.

46.b The focus of this question is the participant's habitual (usual) drinking pattern.

47. 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 44-46, i.e., 4 ounces for wine, 12 ounces for beer and 1½ ounces for hard liquor.

48. Calculate the cumulative years of alcohol consumption by summing the total number of years alcoholic beverages have been consumed, subtracting those years in which the participant did not drink wine, beer or hard liquor.

The following four questions assess lifetime consumption of alcoholic beverages in all participants who reported drinking alcoholic beverages at some time during their life. The questions on the number of drinks per week are similar to those just asked of current drinkers, except that the frame of reference is the entire time that the person has been drinking which may reflect a different habitual lifetime consumption pattern than that reported in Items 44-46. Read the transition statement.

49. Observe the change in verb tense and emphasize the change in the frame of reference. 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, cordials, and "sweet wines". The period of reference is the average seven day week (which includes weekends) over the entire period of time in which the participant has consumed alcoholic beverages.

50. Observe the change in verb tense and emphasize the change in the frame of reference. 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) over the entire period of time in which the participant has consumed alcoholic beverages.

51. Observe the change in verb tense and emphasize the change in the frame of reference. Hard liquor is measured in 1½ ounce shots, rounding down; adjust the number reported as necessary to accommodate different sized drinking containers. Refer to the Alcohol Consumption by the Drink Conversion Table if necessary. Hard liquor also includes 'liqueurs'. The period of reference is a seven day week (which includes weekends) over the entire period of time in which the participant has consumed alcoholic beverages.

52. *Alcoholic beverages* refer to wine, beer or hard liquor. *Almost every day* refers to having 5 or more drinks of an alcoholic beverage on the majority of days in a week sometime during the person's life time. This is in contrast to a person who has 5 or more drinks for a limited time period, such as every weekend.

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

G. Occupation

This section updates occupational information on participants who have changed their occupation since Visit 2. An OCCUPATION WORKSHEET has been added to collect sufficient information on those who have changed their occupation to code it in Item 59. Only use this worksheet if the person has changed occupations (YES to Item 53). Place the participant's ID label on the Occupational Worksheet, enter the contact year, determine the current or most recent occupation (#1), record the most important activities or duties associated with that job (#2), and the type of business (#3).

The categories for annual family income have been expanded and this information is collected on everyone.

53. This item identifies the participants who have changed their occupation since Visit 2. Go to Item 60 for persons who have <u>not</u> changed their occupation. Complete Items 54-59 on those who have changed their job.

54. GIVE THE RESPONSE CARD to the participant and READ <u>ALL</u> THE RESPONSES. If the participant selects category A (*homemaking*), go to item 60. 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 Item 55 if response is B-E. RETRIEVE THE RESPONSE CARD.

55. "Health reasons" refer to the participant's personal health and not the health of someone the participant needs to take care of.

Go to the OCCUPATION WORKSHEET and ask Item 1. Select the verb tense based on whether the participant is currently working or not (see Item 54). 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. Probe to obtain a job title which reflects as accurately as possible the type of work performed. Be as specific as possible. "Restaurant worker" is not sufficient. Probe to see if he or she was a waiter/waitress, cook, manager, maintenance person, cashier, or something else. The following are examples of adequate and inadequate entries.

Inadequate	Adequate
Adjuster	Claims, brake, machine, complaints, or insurance adjuster.
Agent	Freight, insurance, sales, advertising, or purchasing agent.
Caretaker or Custodian	Servant, janitor, guard, building superintendent, gardener, groundskeeper, sexton, property clerk, locker attendant.
Clerk	Stock, shipping, or sales clerk,i.e., a person who sells goods in a store is a salesman or sales clerk.
Data Processor	Computer programmer, keypunch operator, computer operator, coding clerk.
Doctor	Physician, dentist, veterinarian, osteopath, chiropractor.
Engineer	Civil, locomotive, mechanical or aeronautical engineer.
Entertainer	Singer, dancer, acrobat, musician.
Equipment Operator	Road grade, bulldozer, or trench operator.
Factory Worker	Electric motor assembler, forge heater, turret lathe operator, weaver, loom fixer, knitter, stitcher, punch press operator, spray painter, riveter.
Firefighter	Locomotive, city, or stationary fire fighter.

Foreperson/foreman	Specify the craft or activity involved, as foreman carpenter, foreman truck driver.
Helper	Baker's, carpenter's, or janitor's helper.
Laborer	Sweeper, charwoman, porter, janitor, stevedore, window washer, car cleaner, section hand, hand trucker.
Layout Person	Pattern maker, sheet metal worker, compositor, commercial artist, structural steel worker, boiler maker, draftsman, cooper smith.
Mechanic	Auto, dental, radio, airplane, or office machine mechanic.
Nun	Specify the type of work done, such as grammar school teacher, housekeeper, art teacher, organist, cook, laundress, registered nurse.
Trainee vs Skilled Worker	Professional, technical, and skilled occupations usually require periods of training or education which a young person normally has not had. Upon further inquiry you may find that the young person is really only a trainee, apprentice, or helper (for example, accountant trainee, electrician trainee, apprentice plumber, electrician's helper).
Secretary vs Official Secretary	The title 'secretary' should be used for secretarial work in an office. A secretary who is elected or appointed an officer of a business, lodge, or other organization should be reported as an 'official secretary'.
Names of Departments or Places of Work	Occupation entries which give only the name of the department or a place of work are unsatisfactory. Examples of such are 'works in warehouse', 'works in shipping department', 'works in cost control'. The occupation must tell what the worker does, not what the department of the company does.

RETURN TO ITEM 56 ON THE PHX FORM.

56. Select the appropriate verb tense.

Record the response and return to Item 2 on the OCCUPATION WORKSHEET. Determine what are (were) the most important activities/duties associated with the job. Be as specific as possible. Return to Item 57 on the PHX form.

57. The focus of this item is to identify those participants who have changed jobs since Visit 2, but have not changed employers. No additional information on the employer needs to be collected if it is the same one as in the previous examination. Select the appropriate verb tense. If the person is working for the same company as in Visit 2, record NO and skip Items 58-59. If the person has changed companies, or doesn't remember if he or she has changed companies since the last examination, record YES and fill in the name and address of the company in Item 58.

58. Read the question, including the parenthetical phrase if the person is no longer working. If the participant asks, explain that the company's name and address will be used to assist in coding the occupation and for tracing purposes if he or she is lost to follow-up. If the person is self-employed, record SELF under Item 58a and leave items 58b-e blank.

    Go to Item 3 on the Worksheet and read the question and the response categories. If the respondent is unsure of the proper response category, record as much information as possible on the worksheet as an aid for later coding, and enter a brief description under the category 'specify'.

59. Based on the information on the OCCUPATION WORKSHEET, code the person's occupation. Code '000' for an individual who never worked.

60. 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.

61. 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.

62. "Currently" is defined as within the last month. The sick or disabled relative does <u>not</u> have to be living within the participant's home.

H. Administrative Information

63. 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	

64. 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."

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

O.M.B. 0925-0281
exp. 10/31/95

ARIC
Atherosclerosis Risk in Communities

PHYSICAL ACTIVITY FORM

ID NUMBER: | | | | | | | | CONTACT YEAR: | 0 | 7 | FORM CODE: | R | P | A | VERSION: C 09/30/92

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

Public reporting burden for this collection of information is estimated to average 2 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 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.

PHYSICAL ACTIVITY FORM (RPAC screen 1 of 10)

A. WORK ACTIVITY

"Now I'm going to ask you some questions about your physical activity. We are interested in your physical activity during the past year. I'll begin by asking about your activity level at work."

1. At work do you sit: ..... Never N
[rc 1]
SeLdom L
SoMetimes M
Often O
Always A
Does not work D
Go to item 8, Screen 3

2. At work do you stand: ..... Never N
[rc 1]
SeLdom L
SoMetimes M
Often O
Always A

3. At work do you walk: ..... Never N
[rc 1]
SeLdom L
SoMetimes M
Often O
Always A

PHYSICAL ACTIVITY FORM (RPAC screen 2 of 10)

4. At work do you lift heavy loads: ..... [rc 2]

Never	N
SeLdom	L
SoMetimes	M
Often	O
Very often	V

5. After working are you physically tired: ..... [rc 2]

Never	N
SeLdom	L
SoMetimes	M
Often	O
Very often	V

6. At work do you sweat: ..... [rc 2]

Never	N
SeLdom	L
SoMetimes	M
Often	O
Very often	V

7. In comparison with others of your own age do you think your work is physically: ..... [rc 3]

Much lighter	A
Lighter	B
As heavy	C
Heavier	D
Much heavier	E

PHYSICAL ACTIVITY FORM (RPAC screen 3 of 10)

B. SPORTS

8. Do you exercise or play sports? ..... Yes Y

Go to Item 26, Screen 7 ——— No N

9. Which sport or exercise do you do most frequently? ..... [Do not show list]

If the activity is coded, enter code and go to Item 10; if not coded, enter 499 and specify the activity below.

a.

10. How many hours a week do you do this activity? [rc 4]

Less than 1	A
At least 1 but not quite 2	B
At least 2 but not quite 3	C
At least 3 but not quite 4	D
4 or more	E

11. How many months a year do you do this activity? [rc 5]

Less than 1	A
At least 1 but not quite 4	B
At least 4 but not quite 7	C
At least 7 but not quite 10	D
10 or more	E

PHYSICAL ACTIVITY FORM (RPAC screen 4 of 10)

12. Do you do other exercises or play other sports? ..... Yes Y

Go to Item 25, Screen 7 — No N

13. What is your second most frequent sport or exercise? ..... [Do not show list]

If the activity is coded, enter code and go to Item 14; if not coded, enter 499 and specify the activity below.

a.

14. How many hours a week do you do this activity? [rc 4]

Less than 1	A
At least 1 but not quite 2	B
At least 2 but not quite 3	C
At least 3 but not quite 4	D
4 or more	E

15. How many months a year do you do this activity? [rc 5]

Less than 1	A
At least 1 but not quite 4	B
At least 4 but not quite 7	C
At least 7 but not quite 10	D
10 or more	E

PHYSICAL ACTIVITY FORM (RPAC screen 5 of 10)

16. Do you do other exercises or play other sports? ..... Yes Y

Go to Item 25, Screen 7 — No N

17. What is your third most frequent sport or exercise? ..... [Do not show list]

If the activity is coded, enter code and go to Item 18; if not coded, enter 499 and specify the activity below.

a.

18. How many hours a week do you do this activity? [rc 4]

Less than 1	A
At least 1 but not quite 2	B
At least 2 but not quite 3	C
At least 3 but not quite 4	D
4 or more	E

19. How many months a year do you do this activity? [rc 5]

Less than 1	A
At least 1 but not quite 4	B
At least 4 but not quite 7	C
At least 7 but not quite 10	D
10 or more	E

PHYSICAL ACTIVITY FORM (RPAC screen 6 of 10)

20. Do you do other exercises or play other sports? ..... Yes Y

Go to Item 25, Screen 7 — No N

21. What is your fourth most frequent sport or exercise? .....
[Do not show list]

If the activity is coded, enter code and go to Item 22; if not coded, enter 499 and specify the activity below.

a.

22. How many hours a week do you do this activity? [rc 4]

Less than 1	A
At least 1 but not quite 2	B
At least 2 but not quite 3	C
At least 3 but not quite 4	D
4 or more	E

23. How many months a year do you do this activity? [rc 5]

Less than 1	A
At least 1 but not quite 4	B
At least 4 but not quite 7	C
At least 7 but not quite 10	D
10 or more	E

PHYSICAL ACTIVITY FORM (RPAC screen 7 of 10)

24. Do you do other exercises or play other sports? ..... Yes Y

No N

C. LEISURE TIME

25. During leisure time would you say you play sports or exercise: ..... [rc 2]

Never	N
SeLdom	L
SoMetimes	M
Often	O
Very often	V

26. In comparison with others of your own age do you think your physical activity during leisure time is: ..... [rc 6]

Much less	A
Less	B
The same	C
More	D
Much more	E

PHYSICAL ACTIVITY FORM (RPAC screen 8 of 10)

27. During leisure time do you sweat: ..... [rc 2]

Never	N
SeLdom	L
SoMetimes	M
Often	O
Very often	V

28. During leisure time do you watch television: ..... [rc 2]

Never	N
SeLdom	L
SoMetimes	M
Often	O
Very often	V

29. During leisure time do you walk: ..... [rc 2]

Never	N
SeLdom	L
SoMetimes	M
Often	O
Very often	V

30. During leisure time do you bicycle: ..... [rc 2]

Never	N
SeLdom	L
SoMetimes	M
Often	O
Very often	V

PHYSICAL ACTIVITY FORM (RPAC screen 9 of 10)

D. OTHER ACTIVITIES

31. How many minutes do you walk and/or bicycle per day to and from work or shopping? [rc 7]

(If seasonal, give average over the past year)

Less than 5	A
At least 5 but not quite 15	B
At least 15 but not quite 30	C
At least 30 but not quite 45	D
45 or more	E

32. How many flights of stairs do you climb up each day? [One flight equals 10 steps]

☐☐ flights per day

33. Have you done any heavy physical work in the last 12 hours? ..... Yes Y

No N → Go to Item 34

How long ago did you complete it?

a. ☐☐ hours, b. ☐☐ minutes

PHYSICAL ACTIVITY FORM (RPAC screen 10 of 10)

34. Did you do any vigorous exercise or play any vigorous sports in the last 12 hours? ..... Yes Y

Go to Item 35 ——— No N

How long ago did you complete it?

a. [ ][ ] hours, b. [ ][ ] minutes

E. ADMINISTRATIVE INFORMATION

35. Date of data collection: [ ][ ]/[ ][ ]/[ ][ ]
Month Day Year

36. Method of data collection .....Computer C
Paper form P

37. Code number of person completing this form: ..... [ ][ ][ ]

INSTRUCTIONS FOR PHYSICAL ACTIVITY FORM
RPA, VERSION C, 09/30/92
PREPARED 04/22/93

I. GENERAL INSTRUCTIONS

The Physical Activity Form is completed during the interview portion of the participant clinic visit. The interviewer must be certified and should 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. Items on the form enclosed in brackets are instructions to the interviewer, and are not stated verbally during the interview. Items in double quotes are read aloud. Skip rules are enclosed in boxes. When after a brief explanation doubt remains as to whether the participant's answer should be coded as "Yes" or "No", the answer should be recorded as "No".

II. DETAILED INSTRUCTIONS FOR PHYSICAL ACTIVITY QUESTIONS

A. WORK ACTIVITY

These questions pertain to work activity. Record one answer per question.

1. Show response card number 1 to the respondent. Read the response categories out loud to the participant the first time each response card is shown; it is not necessary to reread a response card that has been shown before unless the participant asks for (or needs) assistance. If the participant responds that he/she does not work, skip to question 8.

2. Show response card number 1 to the respondent.

3. Show response card number 1 to the respondent.

4. Show response card number 2 to the respondent.

5. Show response card number 2 to the respondent.

6. Show response card number 2 to the respondent. This question asks about sweating as a result of <u>activity</u>, not background sweating due to climate or temperature. If the participants say they sweat a lot because it is hot outside, try to get them to focus on sweat due to activity and beyond ambient conditions.

7. Show response card number 3 to the respondent.

B. SPORTS

Note the sequencing logic of these question. If participants report not playing sports or exercising, the follow-up questions are not asked. If the response is positive, then participants are asked to report the major activities (up to four, in order of frequency) and to indicate the hours per week and months per year they do this activity.

A code list is provided for the interviewer, giving most physical activities and a corresponding three digit code. This list is not to be shown to the participant, because we do not want to prompt recall of activities. The three digit codes of the reported activities are entered in the three boxes for questions 9, 13, 17 and 21, as needed. If an activity cannot fit into one of the categories on the list, code the box 499 and specify the activity in the space provided. Interviewers should be thoroughly familiar with the code list so that the 499 code is used sparingly. Some codes, such as swimming, require additional probing to determine speed. Do <u>not</u> create new codes for activities not on this list. These will be assigned codes during closure activities.

In general, the hours per week reported by the participant should exclude rest time. If the reported hours seem excessive, repeat the number of hours to the participant to be certain. If the activity is seasonal, it should be averaged over the months the activity is engaged in.

The follow-up question "How many months a year do you do this activity?" will be confusing if the participant just began performing the activity. In that case, the interviewer should project for a one year period the participant's pattern of activity for the months since taking it up. For example, if the person took up an activity four months ago and has done it for three months out of four, that would project to a nine month per year pattern (assuming the activity could be done year round). Do your best to place it into a year time frame, based on <u>current</u> habit.

8. If the respondent answers "No" go to question 26.

9. Do <u>not</u> show response card or the physical activity code list.

10. Show response card number 4 to the respondent.

11. Show response card number 5 to the respondent.

12. If the respondent answers "No" go to question 25.

13. Do <u>not</u> show response card or the physical activity code list.

14. Show response card number 4 to the respondent.

15. Show response card number 5 to the respondent.

16. If the respondent answers "No" go to question 25.

17. Do not show response card or the physical activity code list.

18. Show response card number 4 to the respondent.

19. Show response card number 5 to the respondent.

20. If the respondent answers "No" go to question 25.

21. Do not show response card or the physical activity code list.

22. Show response card number 4 to the respondent.

23. Show response card number 5 to the respondent.

24. Indicate if the participant does more than four sports or exercises.

C. LEISURE TIME

These questions pertain to leisure time activity. Leisure time is defined as time away from work. If the respondent is confused by "leisure time," you can provide this definition. Record one answer per question.

25. Show response card number 2 to the respondent.

26. Show response card number 6 to the respondent.

27. Show response card number 2 to the respondent. This question asks about sweating at leisure as a result of activity, not climate or temperature. If the participants say they sweat a lot because it is hot outside, try to get them to focus on sweat due to activity and beyond ambient conditions.

28. Show response card number 2 to the respondent.

29. Show response card number 2 to the respondent.

30. Show response card number 2 to the respondent.

D. OTHER ACTIVITIES

31. Show response card number 7 to the respondent. This question is limited to the total (round trip) time spent walking or bicycling from one's residence to work or shopping. It should be completed even if walking or bicycling was listed in questions 9, 13, 17 or 21. Include time walking to and from car, but, for example, don't include time at work or shopping, or time spent walking for exercise in a mall.

32. Includes stair climbing at home, at work, or during leisure time. (This does not include climbing ladders.) If the flights of stairs the participant climbs have fewer or more than 10 steps, translate the response into 10 step flights, rounding down to the nearest whole number.

33. If the respondent answers "No," skip to question 34.

34. If the respondent answers "No," skip to question 35.

E. ADMINISTRATIVE INFORMATION

35. Record the date on which the interview took place using standard date format. Code in numbers using leading zeros where necessary to fill in all boxes. For example, May 3, 1993 would be entered as:

0	5	/	0	3	/	9	3

Month Day Year

36. 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."

37. The clinic interviewer who administered this form must enter his/her ARIC staff code number.

SPORTS LIST

(for use with ARIC RPAC Form)

CODE	ACTIVITY
001	Archery
002	Aqua (water) aerobics, swimnastics
003	Aerobic exercise (excluding aerobic dance, codes 82, 85)
004	Backpacking
007	Badminton
010	Baseball
013	Basketball, Game
016	Basketball, Non-Game
019	Biathlon
022	Bicycle Racing
025	Bicycling < 10 mph (Exercyclecode 350)
028	Bicycling ≥ 10 mph
031	Billiards
037	Bobsledding
040	Body Building
043	Bowling
046	Boxing
049	Broomball
052	Calisthenics (eg. pushups, situps) - moderate or high intensity
055	Canoeing < 2.6 mph
058	Canoeing in Competition
060	Carpentry/Woodworking (excludes paid job)
061	Car Racing
067	Crew
070	Cricket
073	Croquet
076	Crossbowing
079	Curling
082	Dancing, Aerobic (low to moderate); include Jazzercise
085	Dancing, Aerobic (high intensity)
088	Dancing, Ballet
091	Dancing - Jazz, Modern
094	Dancing - Ballroom and/or Square
097	Darts
100	Diving
109	Equestrian Events
112	Fencing
115	Field Hockey
118	Figure Skating
121	Fishing from Bank or Boat
124	Fishing in Stream with Wading Boots

125 Floor Exercise (bending, stretching, etc., low intensity)
127 Football, Game
130 Football, Non-Game
133 Frisbee - Competition/Games
136 Frisbee - Recreational
139 Gardening/Yard Work
142 Golf - using cart
145 Golf - walking and carrying clubs
146 Gutbuster/stomach exercises
148 Gymnastics (beam, high bar, horse, parallel and uneven bars, rings)
151 Gymnastics (floor exercise, vault)
154 Hackey Sack
157 Handball
160 Hang Gliding
163 Hiking
166 Hiking in the Mountains
169 Hiking on Flat Trail
172 Hockey
175 Horseback Riding
178 Horseshoes/Quoits
181 Hunting
184 Hurling
187 Ice Sailing
190 Ice Skating
193 Jacket Wresting
196 Jai-Alai
199 Jogging < 6 mph
202 Jogging ≥ 6 mph
205 Judo
208 Juggling
211 Jujitsu
214 Jumping Rope
217 Karate
220 Kayaking
223 Kick Boxing
226 Lacrosse
229 Lawn Bowling
232 Luge
235 Mini-trampoline
238 Motorcross

241 Mountain Climbing
244 Mowing lawn with riding mower or walking behind power mower
247 Mowing lawn pushing hand mower
249 Nautilus machine (exercise with weight machine, exercise machine)
250 Orienteering
253 Paddleball
259 Polo

262 Power Lifting
265 Racewalking
268 Racquetball
271 Roller Skating
274 Rowing (includes rowing machine)
277 Rugby
280 Running ≥ 6 mph
283 Running, Cross-Country
286 Sailing, calm waters
289 Sailing, rough waters
292 Scuba Diving
295 Sculling < 95 meters/min.
298 Sculling ≥ 95 meters/min.
301 Shoveling
304 Shuffleboard
310 Skateboarding
313 Ski Jumping
316 Skiing, Cross-Country (includes machine)
319 Skiing, Downhill
322 Sky Diving
325 Sledding or Tobogganing
328 Snorkeling
331 Snow Blowing/Shoveling
333 Snowmobiling/All terrain vehicle
334 Snow Shoeing
337 Soccer
340 Softball
343 Speed Skating
346 Squash
349 Stair Climbing (includes Stairmaster equipment)
350 Stationary bike/exercise bike
352 Surfing
355 Swim Recreational
358 Swimming, Backstroke ≤ 35 yds/min
361 Swimming, Backstroke > 35 yds/min
364 Swimming, Breaststroke ≤ 40 yds/min
367 Swimming, Breaststroke > 40 yds/min
370 Swimming, Butterfly
373 Swimming, Crawl
376 Swimming, Elementary Backstroke
379 Swimming, Sidestroke ≥ 40 yds/min
382 Synchronized Swimming
385 Table Tennis
388 Tae Kwon Do
391 Tai Chi
394 Team Handball
397 Tennis
400 Trampoline
403 Trapshooting
404 Treadmill walking
406 Unicycling
409 Volleyball
412 Walking briskly

415 Walking during work break
418 Walking for pleasure
421 Walking to and from work
424 Water Polo
427 Water Skiing
430 Weight Lifting
433 Whitewater Rafting
436 Windsurfing
437 Woodcutting (splitting or chopping wood)
439 Wrestling
442 Wrist Wrestling
448 Yachting
Yard Work (See Gardening)
451 Yoga
498 Health club class or exercise, not otherwise specified
499 Unspecified

O.M.B. 0925-0821
exp. 10/31/95

ARIC
Atherosclerosis Risk in Communities

REPRODUCTIVE HISTORY FORM

ID NUMBER: [ ][ ][ ][ ][ ][ ][ ] CONTACT YEAR: [0][7] FORM CODE: [R][H][X] VERSION: B 03-11-93

LAST NAME: [ ][ ][ ][ ][ ][ ][ ][ ][ ][ ][ ][ ] INITIALS: [ ][ ]

INSTRUCTIONS: This form is administered to females only and 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.

REPRODUCTIVE HISTORY FORM (RHXB screen 1 of 8)

A. REPRODUCTIVE HISTORY

1. Did the participant have menstrual periods within 2 years prior to her last visit? [See PIN sheet] ..... Yes Y

   No N

   Unknown U

   → Go to Item 10, Screen 2

2. Have you had any menstrual periods or bleeding during the last 2 years? ..... Yes Y

   No N

   → Go to Item 6

3. In what month and year was your last menstrual period or bleeding?

   [ ][ ]/[ ][ ]

   month year

4. Was this a natural period, or was it due to the use of hormones, or to some other cause? [HAND RESPONSE CARD TO PARTICIPANT AND READ EACH RESPONSE CATEGORY.]

   Natural periods N

   Hormones Only H

   Illness I

   Other O

   Don't Know D

5. In the past 2 years, how many periods did you miss? [If "00" go to item 9]

   [ ][ ]

6. Have you reached menopause? ..... Yes Y

   No N

   Unknown U

   → Go to Item 10, Screen 2

REPRODUCTIVE HISTORY FORM (RHXB screen 2 of 8)

7. At approximately what age did menopause begin? ..... ☐☐

8. Was your menopause natural or the result of surgery or radiation? ..... Natural N
Surgery S
Radiation R
Unknown U

9. Are you having hot flashes? ..... Yes Y
No N

10. Since your last ARIC visit on (date) have you taken or used any female hormone pills, skin patches, shots, or implants? ..... Yes Y
No N
Unknown U

Go to Item 35, Screen 7

"Please give me the names of all female hormones you have used since that exam, starting with any you may be taking currently or with the most recent one. Please exclude hormone creams."

11. Name 1:

a. _____

_____

Concentration (mg or mcg units):

b. ☐☐☐☐☐
first hormone

12. Code 1: ☐☐☐☐☐☐

REPRODUCTIVE HISTORY FORM (RHXB screen 3 of 8)

13. At what age did you start taking this hormone for the first time? ..... ☐☐

14. Are you currently taking this hormone? ..... Yes Y
No N

Go to Item 16

15. At what age did you stop taking this hormone? ..... ☐☐

16. For how long altogether since your last ARIC exam have you used this hormone?

a. ☐☐ years b. ☐☐ months

17.a. Do(Did) you take this hormone by mouth? ..... Yes Y
No N

Go to Item 18, Screen 4

b. How many days do(did) you take this hormone in a 4 week period?

☐☐ days

REPRODUCTIVE HISTORY FORM (RHXB screen 4 of 8)

17.c. On a typical day when you take(took) this hormone, how many pills do(did) you take?

☐ per day

Go to Item 23, Screen 5

18. How did/do you use this hormone? [READ EACH RESPONSE]

Patch P

Shot S → Go to Item 20

Implant I → Go to Item 21

19. On a typical day when you have(had) a patch on, how many do(did) you use?

☐ → Go to Item 23, Screen 5

20. How often do(did) you receive your shot?

a. ☐☐ per

Week W

b. Month M

Other O

Go to Item 23, Screen 5

21. Where is(was) your implant placed? [READ EACH RESPONSE]

Upper Arm A

Uterus [womb] W

Other O

REPRODUCTIVE HISTORY FORM (RHXB screen 5 of 8)

22. On a typical day when you have(had) your implant in place, how many do(did) you have in place? ..... ☐

23. Have you taken a second female hormone since your last ARIC visit? ..... Yes Y

No N → Go to Item 35, Screen 7

a. _____

_____

Concentration (mg or mcg units):

b. ☐☐☐☐☐

first hormone

24. Code 2: ☐☐☐☐☐☐

25. At what age did you start taking this hormone for the first time? ..... ☐☐

26. Are you currently taking this hormone? ..... Yes Y

No N → Go to Item 28,

27. At what age did you stop taking this hormone? ..... ☐☐

28. For how long altogether since your last ARIC exam have you used this hormone?

a. ☐☐ years

b. ☐☐ months

REPRODUCTIVE HISTORY FORM (RHXB screen 6 of 8)

29.a. Do(did) you take this hormone by mouth?

Yes Y

Go to Item 30 — No N

b. How many days do(did) you take this hormone in a 4 week period?

[ ][ ] days

c. On a typical day when you take(took) this hormone, how many pills do(did) you take?

[ ] per day

Go to Item 35, Screen 7

30. How did/do you use this hormone? [READ EACH RESPONSE]

Patch P

Go to Item 32 — Shot S

Implant I

Go to Item 33, Screen 7

31. On a typical day when you have(had) a patch on, how many do(did) you use?

[ ] — Go to Item 35, Screen 7

32. How often do(did) you receive your shot?

a. [ ][ ] per

Week W

b. Month M

Other O

Go to Item 35, Screen 7

REPRODUCTIVE HISTORY FORM (RHXB screen 7 of 8)

33. Where is(was) your implant placed? [READ EACH RESPONSE]

Upper Arm A

Uterus [womb] W

Other O

34. On a typical day when you have(had) your implant in place, how many do(did) you have in place? ..... [ ]

35. Did participant have a partial or total hysterectomy or oophorectomy at the time of her last visit? ..... Yes Y [See PIN sheet]

Go to Item 37 — No N

Unknown U

36. At your last visit on (date), you reported prior surgery to have your uterus or ovaries removed. Have you had additional surgery on your uterus or ovaries?

Go to Item 38 — Yes Y

No N

Go to Item 42, Screen 8

37. Have you had surgery to have your uterus or ovaries removed? (That is, a partial or total hysterectomy or oophorectomy.) ..... Yes Y

Go to Item 42, Screen 8 — No N

Unknown U

REPRODUCTIVE HISTORY FORM (RHXB screen 8 of 8)

38. Has your uterus (womb) been removed? ..... Yes Y

No N

Unknown U

Go to Item 40

39. How old were you when this operation was performed? ..... ☐☐

40. Have you had either one or both ovaries removed? ..... Yes, one O

Yes, both B

No N

Unknown U

Go to Item 42

41. How old were you when this operation was performed? ..... ☐☐

B. ADMINISTRATIVE INFORMATION

42. Date of data collection: ..... ☐☐/☐☐/☐☐

month day year

43. Method of data collection: ..... Computer C

Paper form P

44. Code number of person completing this form: ..... ☐☐☐

INSTRUCTIONS FOR THE REPRODUCTIVE HISTORY FORM
RHX, VERSION B, 03/11/93
PREPARED 09/23/93

This form updates some aspects of the reproductive history of female participants since Visit 2. 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. Because there are many skip patterns, the interviewer should be very familiar with the flow of the survey to insure smooth administration with a conversational tone. 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.

READ INTRODUCTORY SCRIPT

> "These questions update information you provided us about your reproductive history since your last ARIC visit. Some of the questions need a direct answer from you and some require you to choose an answer from a series of responses. I will let you know which type of response is necessary for each question."

Some participants may view this material as very sensitive. The interviewer should be aware of the sensitive nature of the information and make the participant feel comfortable. If required, the interviewer should explain that these are characteristics that sometimes can explain the development of heart disease. Beyond this, however, no specific information should be mentioned to the participant.

A. Reproductive History

1. DO NOT READ THE QUESTION, CHECK THE ARIC PARTICIPANT INFORMATION (PIN) SHEET to determine whether the participant had menstrual periods within 2 years prior to Visit 2. If YES or UNKNOWN, go to Item 2. If NO, go to Item 10.

2. Even if the participant has had only one menstrual period in the past 2 years, or reports any bleeding in the past 2 years, enter "Yes". Consider regular bleeding induced by hormone medication as a menstrual period. If the participant reports that she has not had any menstrual

periods during the past 2 years, skip to Item 6 to determine whether the participant has reached menopause.

3. If the participant cannot remember when she had her last menstrual period, draw 2 horizontal lines through the boxes.

4. Read the question and the response categories after handing the response card to the participant. The overall intent of this question is to identify the reason for the above reported menstrual periods or bleeding during the last 2 years; a narrower objective is to identify the cause of periods/bleeding in women who are postmenopausal. "Natural periods" refer to cyclic bleeding women experience when pre- or peri-menopausal. "Hormone use" refers to the use of hormone replacement treatment during menopause or peri-menopause (not hormones for the purpose of contraception) and can result in cyclic and non-cyclic uterine bleeding. Some "illnesses" (cancer, infections, miscarriage, etc.) can cause non-cyclic uterine bleeding. "Other" conditions can cause bleeding, and should be coded as '0'. If more than one response category was applicable, ask the participant to select the one which explains the cause of the majority of her periods or bleeding during the last two years.

   A response of ILLNESS, OTHER or DON'T KNOW will be discussed with the participant during the medical data review.

5. This question determines the number of periods missed over the last 2 years. If the participant has not missed any periods over the last 2 years, enter '00' and skip to item 9. If not known, draw 2 horizontal lines through the boxes.

6. If the term "menopause" is not immediately understood, ask: "Have your periods stopped for at least 6 months?" If the participant hesitates or is unsure, record "unknown" as her response and skip to question 10. If she reports with certainty that she has not reached menopause, enter "NO" and skip to question 10.

7. If the term "menopause" is not immediately understood, the age at which menopause began should be defined as the age at which "periods had stopped for at least 6 months". If not known, draw two horizontal lines through the boxes. A logical inconsistency among the previous responses is acceptable here; for instance, if a participant has indicated that she has reached menopause (YES to Item 6) but she has also reported menstrual periods or bleeding within the last 6 months (Items 2, 3 or 5). There could be reasons for these "inconsistencies" which are not explored

in the interview, such as irregular menses or symptoms associated with the peri-menopausal stage.

8. If the participant reports that she had already reached menopause before she had gynecological surgery, record the response as "natural".

9. If the participant is unsure of having hot flashes, suggest that a hot flash is "an intense sensation of warmth or feeling flushed all over, lasting anywhere from a few seconds to a few minutes".

10. Hormonal creams do not apply. Birth control pills prescribed for therapeutic indications other than family planning should be included in this section (e.g., for control of symptoms of a painful pelvic condition called "endometriosis;" for control of too frequent or too irregular menstrual periods). If the participant only reports having taken at least one complete cycle (21 or 28 day) since Visit 2, record "YES." (Consider a complete "mini-pill" regimen the same as a cycle.) If the participant hasn't completed even one (21 or 28 day) cycle, record "NO." If the response is NO or UNSURE, go to Item 35.

NOTE: Items 11-24 record information on a maximum of two different hormone preparations, starting with the most recent one. Information on the first hormone is recorded in Items 11-22; information on the second in Items 23-34. If more than two hormones were used in the interim between the second and third examination, only record the two which were most recent. This should not be confused with a single hormone preparation that consists of two hormones.

11 & 23. Transcribe the name of the hormone. Print clearly. If the name is not known, draw two horizontal lines here and through the boxes for medication code, but attempt to complete the remaining questions.

When a hormone(s) is reported in Item 11.a (Item 23.a), look it up in the List of Gonadal Hormones at the end of these instructions. This list provides the location of the picture of the drug in the Physicians Desk Reference (PDR), its MEDISPAN drug code, its trade and generic names and the possible concentrations. If the participant has the hormone with her, use the label on the bottle in conjunction with the list to determine and record the correct concentration (Items 11.b and 23.b). If the label is not informative or if the participant has no bottle or pills, use the PDR picture to help determine the name and concentration. Enter leading zeros if necessary so the response is right justified. All valid concentrations are provided on the list. Most hormones have multiple

concentrations listed; pick the correct one. In Visit 3 (in contrast to Visit 2), only the concentration of the first hormone in the preparation is recorded on the form. If the hormone is not on the list or cannot be found in the PDR, set the status field to Q (questionable).

12 & 24. Record the 6-digit medication code number of the hormone just recorded. If using a paper form, this item may be temporarily skipped and completed later. In selecting the MEDISPAN code for a preparation with multiple hormones, identify the code based on the FULL NAME OF THE PRODUCT, not just the first hormone.

13 & 25. If the participant started taking the specified hormone more than once, enter the age of the first time. If not known, draw two horizontal lines through the boxes.

14 & 26. "Current" means either in a cycle at the time of the interview or between cycles, or currently in a program of female hormone shots or implants. If the response is YES, go to Item 16 (28).

15 & 27. Enter the age at which she last stopped taking the specified hormone. If not known, draw two horizontal lines through the boxes.

16 & 28. Add together all the years and months since the last ARIC visit during which the specified hormone was used. If the participant's response sums to a total greater than the total number of years and months since the Visit 2 exam, remind the participant that "we are looking for the length of time that you have used the hormone since your exam at Visit 2." If the participant has used the hormone more than once, enter the total number of months or years used, not counting the intervening periods of non-use. This requires summing all the time intervals of usage.

17-22 & 29-34. These items have been added to Visit 3 to document more fully use of exogenous hormone(s) between the two ARIC exams. There are four separate sets of questions to describe the four ways the female hormone could be taken: pills, patches, shots (injections) and implants. Only one set can be filled out for each drug. The questions are worded either in the present or past tense.

Choose the proper tense, based on the information from Item 14 (26), and use it consistently through the set of questions.

17 & 29. Items 17a-c cover female hormones taken by mouth (i.e, pills). If the hormone was not taken by mouth, record NO go to Item 18. If YES, determine how many days in a 4 week period the pills were prescribed to be taken (Item 17b) and

how many pills were taken on a typical day (Item 17c). If the response to Item 17b is greater than 28, tell your participant that we are defining a '4 week period' as 28 days, and then reask the question. If the response to Item 17c is '½ a pill' (e.g., a 10 mg pill split in half), enter '0' per day. The number of pills taken each day can be calculated from the name and concentration listed in items 11a and 11b during analysis. Repeat the sequence for the second hormone (if more than one was taken), beginning with Item 29.

18 & 30. Determine how the hormone was administered. Follow the skip patterns.

19 & 31. Select the appropriate tense, based on Item 14(26). Multiple patches can be worn simultaneously. If a different number of patches were worn at different times, determine and record the number of patches currently (or most recently) in place. Then go to Item 23.

20 & 32. Record the number of injections (Item 20a) in a specific time period (Item 20b). For example, 2 shots per month:

20.a. ☐☐ per

b. Time — Week W; Month M; Other O

Then go to Item 23 or 35, respectively.

21 & 33. Select the appropriate tense, based on Item 14(26). Determine where the implant was placed and follow the skip rules. If the participant had more than one implant in place since Visit 2, determine the location of the current (or most recent) implant.

22 & 34. Record the number of implants in place at the above location.

23-34. These items are repeats of Items 11-22 for a second female hormone. If more than two hormones were used in the interim between the second and third examination, only record the two which were most recent. This should not be confused with a single hormone preparation that consists of two hormones. If the participant only took one hormone, leave Item 23 blank and go to Item 35.

35. DO NOT READ THIS QUESTION TO THE PARTICIPANT. CHECK THE VISIT 2 INFORMATION SHEET (PIN) to determine whether the participant reported having had a partial or total hysterectomy or an oophorectomy at Visit 2. If YES, enter Y and continue to the

next question. If NO or UNSURE, go to Item 37. If a Visit 2 PIN sheet is not available, enter UNSURE and go to Item 37.

36. A positive response to Item 35 does not rule out the possibility of additional gynecologic surgery since the last ARIC visit. This question documents additional surgery which may have been done on the uterus or ovaries. If no additional surgery was performed, go to Item 42; otherwise, skip to Item 38.

37. If the participant is unsure, probe by suggesting that the uterus is also called the womb, and that in some places this is called a "female operation." It may be necessary in some cases to clarify that surgery to "tack-up the bladder" is a different operation that does not involve the uterus or ovaries. If NO or UNSURE, go to Item 42.

38. If necessary, suggest that the uterus is also called the womb.

39. Enter the age at which the uterus was removed, If not known, draw two horizontal lines through the boxes.

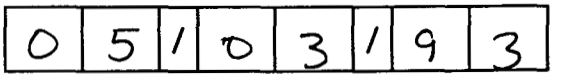
40. The interviewer should probe to determine whether only one or both ovaries were removed. Also note that with a vaginal hysterectomy (when the uterus is removed through the vagina and no abdominal incision is made), the ovaries are <u>not</u> removed.

    <u>Note</u>: "Half" an ovary should be recorded as <u>no</u> ovary removed. If the response is NO or UNSURE, go to Item 42.

41. If more than one operation was performed, record the age of the most recent one. If not known, draw two horizontal lines through the boxes.

B. Administration

42. 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:



43. 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."

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

O.M.B. 0925-0821
exp. 10/31/95

ARIC
Atherosclerosis Risk in Communities

TIA/STROKE FORM

ID NUMBER: | | | | | | | | CONTACT YEAR: | 0 | 7 | FORM CODE: | T | I | A | VERSION: D 03/11/93

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

Public reporting burden for this collection of information is estimated to average 7-10 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 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 (TIAD screen 1 of 30)

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

No N → Go to Item 3, Screen 1

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

Don't know D → Go to Item 10, Screen 6

TIA/STROKE FORM (TIAD screen 2 of 30)

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 (TIAD screen 3 of 30)

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 (TIAD screen 4 of 30)

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 (TIAD screen 5 of 30)

9.c. Paralysis or weakness ..... Yes Y

No N

Go to Item 9.e, Screen 5

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 (TIAD screen 6 of 30)

9.i. Visual Disturbances ..... Yes Y

No N

Go to Item 10, Screen 6

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

Go to Item 17, Screen 10

No N

Don't Know D

TIA/STROKE FORM (TIAD screen 7 of 30)

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 (TIAD screen 8 of 30)

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 (TIAD screen 9 of 30)

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, Screen 9

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 (TIAD screen 10 of 30)

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 (TIAD screen 11 of 30)

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 (TIAD screen 12 of 30)

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 (TIAD screen 13 of 30)

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 (TIAD screen 14 of 30)

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 (TIBD screen 15 of 30)

E. 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

Go to Item 32, Screen 20 — No N

Don't Know

24. Did the feeling of numbness or tingling occur only when you kept your arms or legs in a certain position?

Go to Item 32, Screen 20 — Yes Y

No N

Don't Know D

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 (TIBD screen 16 of 30)

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 (TIBD screen 17 Of 30)

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 (TIBD screen 18 of 30)

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 (TIBD screen 19 of 30)

31.b. Paralysis or weakness ..... Yes Y

No N

Go to Item 31.d, Screen 19

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 (TIBD screen 20 of 30)

31.i. Visual Disturbances ..... Yes Y

No N

Go to Item 32, Screen 20

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:

_____

F. 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 25

TIA/STROKE FORM (TIBD screen 21 of 30)

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 (TIBD screen 22 of 30)

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 (TIBD screen 23 of 30)

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 (TIBD screen 24 of 30)

39.b. Numbness or tingling	Yes	Y
	No	N

Go to Item 39.d Screen 24

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 (TIBD screen 25 of 30)

39.i. Visual Disturbances ..... Yes Y

No N

Go to Item 40, Screen 25

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 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 30

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 30

TIA/STROKE FORM (TIBD screen 26 of 30)

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 27

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 (TIBD screen 27 of 30)

42.d. Numbness or tingling ..... Yes Y

No N

Go to Item 42.f, Screen 27

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 (TIBD screen 28 of 30)

42.i. Visual Disturbances ..... Yes Y

No N

Go to Item 43, Screen 28

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 (TIBD screen 29 of 30)

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 (TIBD screen 30 of 30)

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

H. 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: ..... [ ][ ][ ]

INSTRUCTIONS FOR THE TIA/STROKE FORM
TIA/STROKE, VERSION D, 03/11/93
PREPARED 04/23/93

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 and complexity of the TIA/Stroke Version D (TIAD) paper form, it was necessary to split the single paper form into two data entry forms (TIAD and TIBD). Questions 1-22i of the paper form comprise the DES form TIA and questions 23-49 of the paper form comprise DES form TIB. The TIA DES form additionally has questions 22j-22l (date of data collection, method of data collection, and technician code) that are to be taken from questions 47-49 on the paper form.

II. GENERAL DEFINITIONS

This set of questions is designed to help determine whether the participant has had a physician-diagnosed or undiagnosed stroke or transient ischemic attack (TIA) since the second exam (Visit 2). The reference period for an event during the baseline visit was anytime in the past, e.g., "have you ever had ...?". During subsequent exams, beginning with Visit 2, the reference period is the interim between the previous and current exam, generally about 3 years. The lead-in question to each section is now 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. A series of questions is asked for each symptom to determine whether an event took place, its duration, and its location, e.g., right carotid, left carotid or vertebrobasilar (VBI).

TIA is considered to be a slight (light) stroke where the same patterns occur as in a stroke; the major difference being 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 <u>at the same time</u> 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."

221. 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 "<u>Since the last ARIC Visit</u>" and <u>sudden</u> 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 <u>at the same time</u> 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 <u>"Since the last ARIC Visit"</u> and <u>sudden</u> 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 <u>at the</u>

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.

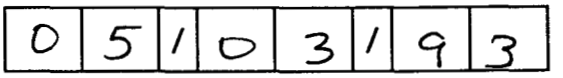
45. Use parenthetical phrase if multiple events were reported. DO NOT READ RESPONSES, but probe to select appropriate category.

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:



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.

(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

{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 12/03/92

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 3, 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 3 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 3 the participant was asked to fill out an information sheet with the names and addresses of two contact persons, the primary care physician, and their 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 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 name 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.

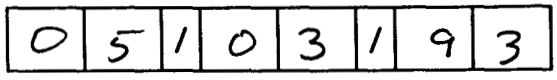
16.(b-f) Read the mailing address to the participant, and verify its accuracy. If the participant changed physicians, enter the new address.

E. ADMINISTRATIVE INFORMATION

Show and explain to the participant a blank copy of the Results Reporting Sheet that they will receive after Visit 3 and then read Item 17. Do not read the responses.

17. This question should be asked regardless of whether or not a response is already present from Visit 2 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 should be updated. Code in numbers using leading zeroes where necessary to fill all boxes. For example, May 3, 1993, would be entered as:



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.

O.M.B. 0925-0821
exp. 10/31/95

ARIC
Atherosclerosis Risk in Communities

VITAMIN SURVEY FORM

ID NUMBER: | | | | | | | | CONTACT YEAR: | 0 | 7 | FORM CODE: | V | I | T | VERSION: A 02/25/93

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

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.

VITAMIN SURVEY FORM (VITA screen 1 of 12)

Ask questions as written. Use vitamin containers for dosage.

1.a. Do you regularly take multiple vitamins? ..... Yes Y

Go to Item 2, Screen 2 ——— No N

b. How many pills do you take per week? ..... | |

Ask, "Did you bring the container with you?" If the answer is "Yes," copy the manufacturer's name first and brand name second from the label of the container. If the answer is "No," ask, "Do you know what brand you usually take and who the manufacturer is," and enter the manufacturer's name first and brand name second. Enter the brand name exactly as it appears on the container.

c. Manufacturer: _____

d. Brand Name: _____

e. Enter 4 digit code number from the multiple vitamin code list:..... | | | | |

VITAMIN SURVEY FORM (VITA screen 2 of 12)

2. Not counting multiple vitamins, do you take any of the following preparations? (Please answer either "Yes" or "No" for each preparation.)

a. Vitamin A, not including Beta-carotene: ..... Yes Y

No N

Go to Item 3a, Screen 3

b. Do you take it seasonally or most months? ..... Seasonally S

Most months M

c. How many years have you taken it? ..... ☐☐

d. How many pills do you take per week? ..... ☐☐

e. Dose per pill: ..... ☐☐☐☐☐

f. Units: ..... mg. M

mcg. C

IU I

Other O

If other, specify _____

VITAMIN SURVEY FORM (VITA screen 3 of 12)

3.a. Vitamin C? ..... Yes Y

No N

Go to Item 4a, Screen 4

b. Do you take it seasonally or most months? ..... Seasonally S

Most months M

c. How many years have you taken it? ..... ☐☐

d. How many pills do you take per week? ..... ☐☐

e. Dose per pill: ..... ☐☐☐☐☐

f. Units: ..... mg. M

mcg. C

IU I

Other O

If other, specify _____

VITAMIN SURVEY FORM (VITA screen 4 of 12)

4.a. Vitamin B_6? ..... Yes Y

No N

Go to Item 5a, Screen 5

b. How many years have you taken it? .....

c. How many pills do you take per week? .....

d. Dose per pill: .....

e. Units: ..... mg. M

mcg. C

IU I

Other O

If other, specify _____

VITAMIN SURVEY FORM (VITA screen 5 of 12)

5.a. Vitamin E? ..... Yes Y

No N

Go to Item 6a, Screen 6

b. How many years have you taken it? .....

c. How many pills do you take per week? .....

d. Dose per pill: .....

e. Units: ..... mg. M

mcg. C

IU I

Other O

If other, specify _____

VITAMIN SURVEY FORM (VITA screen 6 of 12)

6.a. Selenium? ..... Yes Y

No N

Go to Item 7a, Screen 7

b. How many years have you taken it? ..... ☐☐

c. How many pills do you take per week? ..... ☐☐

d. Dose per pill: ..... ☐☐☐☐☐

e. Units: ..... mg. M

mcg. C

IU I

Other O

If other, specify _____

VITAMIN SURVEY FORM (VITA screen 7 of 12)

7.a. Iron? ..... Yes Y

No N

Go to Item 8a, Screen 8

b. How many years have you taken it? ..... ☐☐

c. How many pills do you take per week? ..... ☐☐

d. Dose per pill: ..... ☐☐☐☐☐

e. Units: ..... mg. M

mcg. C

IU I

Other O

If other, specify _____

VITAMIN SURVEY FORM (VITA screen 8 of 12)

8.a. Zinc? ..... Yes Y

No N

Go to Item 9a, Screen 9

b. How many years have you taken it? ..... ☐☐

c. How many pills do you take per week? ..... ☐☐

d. Dose per pill: ..... ☐☐☐☐☐

e. Units: ..... mg. M

mcg. C

IU I

Other O

If other, specify _____

VITAMIN SURVEY FORM (VITA screen 9 of 12)

9.a. Calcium? (Include calcium in Dolomite) ..... Yes Y

No N

Go to Item 10a, Screen 10

b. How many years have you taken it? ..... ☐☐

c. How many pills do you take per week? ..... ☐☐

d. Dose per pill: ..... ☐☐☐☐☐

e. Units: ..... mg. M

mcg. C

IU I

Other O

If other, specify _____

VITAMIN SURVEY FORM (VITA screen 10 of 12)

10.a. Beta-carotene? ..... Yes Y

No N

Go to Item 11a, Screen 11

b. How many years have you taken it? .....

c. How many pills do you take per week? .....

d. Dose per pill: .....

e. Units: ..... mg. M

mcg. C

IU I

Other O

If other, specify _____

VITAMIN SURVEY FORM (VITA screen 11 of 12)

11.a. Fish oil? (Including omega-3 fatty acids, EPA, cod liver oil) ..... Yes Y

No N

Go to Item 12a, Screen 12

b. How many years have you taken it? .....

c. Do you take it as pills or teaspoons? ..... pill P

teaspoon T

d. How many pills or teaspoons do you take per week? .....

VITAMIN SURVEY FORM (VITA screen 12 of 12)

12. Are there other supplements that you take on a regular basis? (Please answer either "Yes" or "No" for each of the following questions.)

a. Folic acid	Yes	Y
	No	N
b. Vitamin D	Yes	Y
	No	N
c. B-complex vitamins	Yes	Y
	No	N
d. Iodine	Yes	Y
	No	N
e. Copper	Yes	Y
	No	N
f. Brewer's Yeast	Yes	Y
	No	N
g. Magnesium	Yes	Y
	No	N

ADMINISTRATIVE INFORMATION

13. Date of data collection..... | | | / | | | / | | | (Month / Day / Year)

14. Method of data collection ..... Computer C
Paper form P

15. Code number of person completing this form: ..... | | | |

INSTRUCTIONS FOR THE VITAMIN FORM AND QUESTIONNAIRE
VIT, VERSION A, 02/25/93
PREPARED 06/25/93

I. GENERAL INSTRUCTIONS

The purpose of the VITAMIN SURVEY is to assess the usage of vitamins, minerals, and supplements (and their dose) more completely than the MEDICATION SURVEY does. After all medications (including vitamins) have been recorded and verified on the MEDICATION SURVEY, the same interviewer completes the VITAMIN SURVEY.

VITAMINS, MINERALS, AND SUPPLEMENTS are recorded on the VITAMIN SURVEY FORM even though they were recorded on the MEDICATION SURVEY FORM. The VITAMIN SURVEY FORM is completed regardless of whether the participant brought all medications, but any medication brought in should be available during the interview for reference. The reference period (time frame) for the two surveys is different. The Medication Survey refers to the two weeks preceding the interview; the Vitamin Survey covers the four weeks prior to the interview.

The form should be completed based upon the participant's response and the label on the vitamin container, when available. Any contradiction between the participant's response and the label on the vitamin container is resolved in favor of the container. If the participant forgot to bring the container, obtain the information from him/her to the extent that he/she recalls. If he/she agrees to a follow-up contact (Question #3 on the MEDICATION SURVEY FORM), be sure to get what you need to complete the VITAMIN SURVEY FORM during the follow-up interview.

II. SPECIFIC INSTRUCTIONS

All questions address CURRENT usage. If asked by the participant, define current as applying to the four weeks preceding the interview.

1.a If the participant asks the meaning of "regularly," the response is "At least once a week."

If the participant asks the meaning of "multiple vitamins," the response is: "A preparation containing at least two different vitamins."

1.b Pills are used as synonyms with tablets and capsules. The number of pills refers to current usage (see above). If the number has varied over the past 4 weeks, ask for the estimate of the typical average week. A week includes all seven days, including the weekend. If a participant is taking more than one multiple vitamin preparation, record the one most frequently used. If all are equally used, record the one containing the largest number of vitamins. In the unlikely event that a preparation is taken in a liquid form, enter '00' and record as

much information as possible in items 1c and 1d. Use a notelog if necessary to record information on the weekly dose. After determining the average number of multiple vitamins taken during a week, ask the participant "Did you bring the container(s) with you?" If the answer is YES, copy the manufacturer's name first and brand name second from the label on the container.

1.c The manufacturer's name refers to the name of the drug company (e.g. "Squibb," "Nature Made," "CVS").

1.d The brand name refers to the vitamin description on the label (e.g. "Centrum," "Mega-2000," "B-Complex + C," "Supplement with Calcium, Iron and Zinc.").

Example:

1.c Manufacturer: Schiff
1.d Brand Name: Mega high II

1.e The goal of Question 1e is to assign a four-digit code for the specific multiple vitamin prepration recorded in Question 1c using the ARIC multiple vitamin code list.

The multiple vitamin code list is sorted alphabetically. Each preparation usually appears twice in the code list: (1) by manufacturer's name first and brand name second (e.g. Nature Made B-complex + C); (2) by brand name first and manufacturer's name in parenthesis second (e.g. B-complex + C (Nature Made)). Therefore, an appropriate code can be found by searching for the manufacturer's name or the brand name.

Assign an appropriate code to Question 1e based upon the following rules:

1. If you can find a code that matches the particular manufacturer's name and brand name, enter the four digit code including leading zeros. For example, "3585" is the appropriate code for "Nature Made B-complex + C."
2. If a manufacturer's name is available but a brand name is not, use the manufacturer's generic multiple vitamin code (e.g. 0083 for Nature Made). If you cannot find the manufacturer's generic code, enter a code "0199."
3. If a manufacturer's name is missing but a brand name is available, choose the code that matches the brand name. If there is more than one code for the brand name, choose one of them.
4. If the manufacturer's name and the brand name are complete but you cannot find the matching code, enter code "0199."
5. If a non-skipped response to Question 1c is missing or incomprehensible, enter two horizontal lines, "====."

Examples:

Manufacturer	Brand Name	Code	Rule #
Squibb	Theragram M	0138	(1)
Thompson	Unknown	0142	(2)
Unknown	B-50	3159	(3)
Super Health	Multiformula	0199	(4)
Missing	Missing	====	(5)

Please note that the following codes are legal: "====" (for missing or incomprehensible response); code numbers between 0001 and 3686 and 9999. Please do not enter illegal codes such as "120," "0000," "000A," "0," and "O."

Questions 2-12 are for preparations containing only a single vitamin. Preparations containing two or more vitamins should be recorded as multiple vitamins. A preparation containing a single vitamin plus some other non-vitamin non-mineral component (e.g., flavoring) should be recorded as a single vitamin.

When a participant is repeatedly asked whether a vtaimin, mineral or suplement (items 2 through 12) is being taken, the participant may volunteer that he/she does not take any such preparations. If this occurs, indicate - politely - that you have to ask all of these questions without changing the order, and that it will take very littly time to complete the rest of the questionnaire. If a participant asks for clarification of a name, or is unsure that he/she is taking the supplement on a regular basis, record NO.

"Vitamin Name" (2a - 11a)

Some vitamin A-labeled preparations contain beta-carotene as the active ingredient. If the term beta-carotene is mentioned anywhere on the label, record "NO" for vitamin A, and fill out questions 10a-e (beta-carotene) instead. If the preparation contains vitamin A plus another vitamin (e.g., vitamin A+D), it should be recorded as a multiple vitamin preparation; not as a single vitamin.

"Do you take it seasonally or most months?" (2b, 3b)

If the participant asks the meaning of "seasonally" the response is "No more than 3 months per year.: To take a preparation seasonally does not require that the vitamin preparation be taken continuously during 3 months.

"How many years have you taken it" (2c, 3c, 4b - 11b)

These questions apply to the total number of years that a participant has taken a specified preparation. "Years" are counted as calendar years, not by adding the number of months a preparation has been taken during a calendar year. If a

preparation has been taken seasonally, count a full calendar year regardless of the length of time the preparation was taken during the year. Round down to full years and zero fill when necessary (e.g., 01 year, 07 years, 12 years).

"How many pills do you take per week?" (2d, 3d, 4c - 10c)

Ask the participant 'How many pills do you take per week?' In questions 2 through 11, pills are used as synonyms for tablets and capsules. If the number per week varies, ask for an estimate of the typical average per week. If the preparation is taken seasonnally, this average should reflect the dose per week during the time the preparation is taken. In the unlikely event that the number of pills per week exceeds 100, record '99'. If the preparation is taken less than once epr week, e.g., every other week, record '00'.

"Dose per pill" you take it as pills, teaspoons, or other liquid measures ?" (2e, 3e, 4d - 10d)

If a container is available, transcribe the concentration from the label by recording the number of mg/mcg/IU, or other units contained in one pill (or tablet, capsule). Example: the label indicates that each capsule contains 100 IU of Vitamin E. In this case, '00100' is recorded under dose per pill (Item 5.d).

9. In addition to Calcium tablets, Dolomite products and some antacids (e.g. "TUMS," "Rolaids," "Chooz," "Alka-Seltzer") contain calcium. Check ingredient list of Dolomite and antacids and if you find calcium as an ingredient, report daily calcium dose including those from Dolomite and antacids.

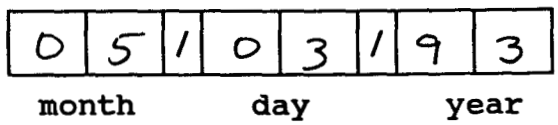
11. There are many fish oil preparations. If any of the following preparations is mentioned as an ingredient, record the preparation as fish oil: omega-3; EPA; MaxEPA; MEGA-EPA; CARDIOEPA; eicosapentaenoic acid; marine oil; marine lipid; cod liver oil; fish oil. If more than one fish oil preparation is taken, record the information on the one used most frequently. If all are equally used, record the one with the highest concentration of fish oils.

After being asked repeatedly whether s/he takes a vitamin, mineral, or supplement (items 2 through 12), the participant may volunteer that s/he is not taking <u>any</u> such preparations. If this occurs, indicate - politely - that you have to ask all of these questions without changing the order, and that it will take very little time to complete the rest of the questionnaire.

12. Participants who do not take a supplement may not be familiar with the name. If the participant asks for clarification of a name, or is unsure that s/he is taking the supplement on a regular basis, record "No". Respond to such inquiries in a

polite manner but do not attempt to clarify composition, brand names, or equivalent supplements in this item.

13. Enter the date on which the participant completed the Vitamin Survey Form. Code in numbers using leading zeroes where necessary to fill all boxes. For example, May 3, 1993, would be entered as:



14. 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."

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

9/9/92 Vitamin Code List

0199 *** ANY MULTIPLE VITAMINS

3471 100% US RDA PAK
3470 24 HR DIET PLAN PAK
3251 50 & PAK (YOUR LIFE)
3185 A & D PERLES (OWEN'S)
0209 A & P
1039 A & P IRON PLUS
3245 A - Z (GOLDENSUN)
0343 A H ROBBINS
0434 A TO Z
3143 A TO ZINC (ALACER)
3220 A-Z MULTIVITAMINS & MINERALS (HALL)
0550 A-ZINC
3173 A.C.N.E. W/ ZINC AND B6 (FOOD PLUS)
0206 AARP
3021 AARP ACTIVITAMINS
3283 AARP ALPHABET VITAMINS
3282 AARP CHEWABLE
3302 AARP DAILY VITAMIN WITH IRON & CALCIUM
3093 AARP ENERGY FORMULA
3028 AARP FORMULA 101
3639 AARP FORMULA 103
3640 AARP FORMULA 104
0999 AARP FORMULA 105
3632 AARP FORMULA 106
3298 AARP FORMULA 107
3040 AARP FORMULA 109
3301 AARP FORMULA 113
3036 AARP FORMULA 115
3285 AARP FORMULA 116
3302 AARP FORMULA 118
3645 AARP FORMULA 120
3644 AARP FORMULA 122
3021 AARP FORMULA 126
3093 AARP FORMULA 127
3270 AARP FORMULA 129
3019 AARP FORMULA 131
3020 AARP FORMULA 133
3635 AARP FORMULA 139
3308 AARP FORMULA 141
3562 AARP FORMULA 142
3293 AARP FORMULA 145
3269 AARP FORMULA 150
3271 AARP FORMULA 152
3564 AARP FORMULA 156 B COMPLEX 50 WITH C
3637 AARP FORMULA 160
3297 AARP FORMULA 171
3646 AARP FORMULA 175
3268 AARP FORMULA 195
3056 AARP FORMULA 196

0074 AARP FORMULA 198
3027 AARP FORMULA 199
3026 AARP FORMULA 2-2-2
3634 AARP FORMULA 210
3647 AARP FORMULA 310
3649 AARP FORMULA 322
3283 AARP FORMULA 358
3641 AARP FORMULA 360
3642 AARP FORMULA 362
3032 AARP FORMULA 364
3643 AARP FORMULA 366TR
3636 AARP FORMULA 368
3648 AARP FORMULA 375
3303 AARP FORMULA 384
3311 AARP FORMULA 385
3057 AARP FORMULA 390
3307 AARP FORMULA 404
3022 AARP FORMULA 407
3287 AARP FORMULA 460TR
3295 AARP FORMULA 502
3278 AARP FORMULA 644
3633 AARP FROMULA 112
3287 AARP HIGH B COMPLEX
3022 AARP HIGH POTENCY
3278 AARP HIPOTENTCY VITAMINS AND MINERALS
0999 AARP MATURITY FORMULA
3027 AARP MEGAVITAMINS
3019 AARP MULTIVIT + MIN
3036 AARP ONE A DAY
3057 AARP PLENTIFUL VITAMINS
3268 AARP RDA + FE
3290 AARP SPECIAL RDA WITH IRON
3030 AARP STRESS FORMULA
3032 AARP STRESS FORMULA WITH ZINC
3040 AARP THERAPEUTIC
3056 AARP U.S.A. R.D.A
3026 AARP VITAMIN INSURANCE
3299 AARP WITHOUT IRON
0921 AATES
0001 ABBOTT (DAYALETS)
0133 ABBOTT SURBEX
0135 ABBOTT SURBEX 750 + IRON
0134 ABBOTT SURBEX T
0002 ABDEC
0259 ABDOL-M
0218 ABUNDOVITA - SUPER 40
2022 ACE + ZINC(LEGORE)
0326 ACME
3474 ACTION 75 (COUNTRY LIFE)
0790 ACTION DAILY MULTIPLE VITAMIN
1018 ACTION GERI-VITES
3222 ACTIVE FORMULA (HALL)
0481 ADABEC

0873 ADAVITE M (HUDSON)
0003 ADAVITE(HUDSON)
3519 ADULT CHEWABE MVM (RICHLIFE)
3652 ADULT MVM (NATURE'S PLUS)
0983 ADULT-PLEX, THOMPSON
3037 ADVANCED PROTECTION III
3447 ADVANCED SOLOTRON (GNC)
3536 ADVANCED STRESS TABS 600
3520 AEROBIC PAK (RICHLIFE)
0219 AID
0768 AIR-VI-MINS
3521 AL PAK (RICHLIFE)
2023 AL-VITE (DRUG IND)
0004 ALACER
3143 ALACER A TO ZINC
3140 ALACER ESSENTIALLY ALL
3141 ALACER SUPER GRAM II
3142 ALACER SUPER GRAM III
3600 ALBA-LYBE
0578 ALBERTSON'S
0005 ALBUCON
0006 ALEXANDERS
3175 ALL AROUND VITAMIN AND MINERAL (FOOD PLUS)
3480 ALL DAY ALL NIGHT FORMULA (COUNTRY LIFE)
3736 ALL-SPORTS (ESSENTIAL ORGANICS)
0848 ALLBEE
0008 ALLBEE C-800 (ROBBINS)
0007 ALLBEE + C CAPLETS (ROBBINS)
0929 ALLBEE + C800 + IRON
0840 ALLBEE + IRON
0851 ALLBEE T
0416 ALLIN ONE
3738 ALPHA (MEGA FOOD)
3254 ALPHAMINS
0294 ALTHENA
0575 AMCAPS
3006 AMCAPS M
0802 AMERICAN DRUG CO.
0244 AMERICAN VIT. CO.
0793 AMWAY
0182 AMWAY NUTRILITE
0867 AMWAY NUTRILITE 100
3016 ANABOLIC ANAPLEX
0273 ANABOLIC FOODS
3367 ANABOLIC PAK
3080 ANABOLIC TRI-B PLEX
3357 ANTIOXIDANT, BRONSON (#74)
3448 APATATE
2024 AQUASOL A (ARMOUR)
3522 AR PAK (RICHLIFE)
0592 ARBOR DAILY PLUS IRON
3074 ARCO MEGA B WITH C
2028 ARCO MEGADOSE

0195 ARCO MULTI. VIT.
0579 ARISTA
0910 ARMED FORCES EXCHANGE SERVICE
2024 ARMOUR AQUASOL A
0389 ARNOLDS
0930 ATHLETE NUTRITIONAL SUPPLEMENTS
3523 ATHLETIC PAK (RICHLIFE)
3233 AVAIL
0316 AVCOM
0667 AVON
0558 AYERST
0304 AYTINAL
3502 B 125 (COUNTRY LIFE)
3305 B COMPLEX & C & CALCIUM
3217 B COMPLEX (MEDIMART)
3205 B COMPLEX (SCHIFF)
3639 B COMPLEX + C (AARP 103)
3004 B COMPLEX + C (MEDIMART)
3585 B COMPLEX + C (NATURE MADE)
3419 B COMPLEX + C + E (BRONSON #4)
3408 B COMPLEX + C + E TIME RELEASED (BRONSON)
3450 B COMPLEX + C STRESS FORMULA (SOLGAR)
3412 B COMPLEX STRESS, NATURAL, SOLGAR
3206 B GUARD (SCHIFF)
0012 B PLUS 50
3106 B W/ B12 (OSCO)
3156 B W/ C (THOMPSON)
3105 B W/ C800 (OSCO)
3104 B W/C (OSCO)
3160 B-100 (CVS)
3215 B-100 (MEDIMART)
3199 B-100 (YOUR LIFE)
3161 B-150 (CVS)
3200 B-150 (YOUR LIFE)
3159 B-50 (CVS)
3216 B-50 (MEDIMART)
3154 B-50 (THOMPSON)
3198 B-50 (YOUR LIFE)
3409 B-50 SOLGAR
3410 B-60 SOLGAR
3155 B-75 (THOMPSON)
3411 B-CID
3728 B-COMPLEX+EXTRA B12 (NEW CHAPTER)
3184 B-PLEX A (OWENS)
3742 BABY & ME (MEGA FOOD)
3618 BABY VITAPLEX (THOMPSON)
3656 BABY-PLEX (NATURE'S PLUS)
0009 BARTHS
0010 BASIC DRUG INC.
3449 BASIC ONE (RICHLIFE)
3376 BASIC PREVENTION MVM
3310 BASIC PREVENTIVE
0672 BECKER DRUG BRAND

0306 BECOTIN
0937 BECOTIN + C
0905 BECOTIN T
0580 BEDFORD
0461 BEE POLLEN
3084 BEECHAM GERITOL COMPLETE MULTIVIT & MINERAL WITH HIGH POTENCY IRON
0800 BEEVIM + C
0581 BELFER
0582 BELLOCAPS
0235 BEMINAL
0872 BEMINAL 500
3091 BEMINAL STRESS PLUS WITH IRON
3092 BEMINAL STRESS PLUS WITH ZINC
0210 BEROCCA
0942 BEROCCO PLUS
3679 BERPLEX PLUS
0781 BERTS
0567 BESCO
3451 BETTER HALF PAK
0828 BEX-SCOR SPIRIT
0506 BI MART
0534 BIG 4
0866 BIMINAL FORTE + C
0775 BIOBEE + C
0201 BIOGANIC
0583 BIOLINE
0013 BLALOW
0584 BNC SUPERCAP
0412 BOAMAN
3628 BOB LEE EVERYTHING FORMULA
3580 BOB LEE MINIVITES 33
3629 BOB LEE PEAK 75
3630 BOB LEE THERADAY
3067 BOCK PRENATE 90
3752 BONE DENSITY FACTORS (COUNTRY LIFE)
3260 BONE MEAL WITH VITAMINS A & D (WALT DELAND)
3124 BONE PAK (RICH LIFE)
3569 BONE-ALL (SCHIFF)
0296 BOSCON
0339 BRADLEES
3693 BROEMMEL'S THERAPEUTIC MULTIVIT + MINERALS
0585 BROFLAVINAIDS
0014 BRONSON
3393 BRONSON #93
3419 BRONSON B COMPLEX + C + E (#4)
3761 BRONSON CHEWABLE PRENATAL (#173)
3606 BRONSON CHEWABLE VITAMINS (#21)
3763 BRONSON CHILDREN'S VITAMIN WITH IRON AND ZINC (#22)
3605 BRONSON DAILY NUTRITIONAL PACKETS (#130)
3044 BRONSON FEMALE FORMULA (#9)
3422 BRONSON FORTIFIED MULTIVIT AND MIN INSURANCE (#92)
3054 BRONSON GERIATRIC FORMULA (#7)

3611 BRONSON GTC #2 FORMULA (#123)
3612 BRONSON GTC #3 FORMULA (#124)
3610 BRONSON GTC FORMULA (#122)
3421 BRONSON HEMATINIC (#10)
3764 BRONSON LIVER YEAST AND VITAMINS (#8)
3054 BRONSON MATURITY FORMULA (#7)
3603 BRONSON MINERAL COMPLEX (#129)
3418 BRONSON MINERAL INSURANCE (#12)
3357 BRONSON MULTI ANTIOXIDANT (#74)
3617 BRONSON MULTIVITAMIN DROPS FOR INFANTS (#20)
3420 BRONSON MUTIVIT AND MINERAL CHEWABLE (#70)
3602 BRONSON NUTRITIONAL PACKETS FOR ACTIVE MEN (#144)
3608 BRONSON NUTRITIONAL PACKETS FOR ACTIVE WOMEN (#143)
3766 BRONSON NUTRIVISION (#156)
3760 BRONSON PEAK PERFORMANCE FORMULA (#170)
3762 BRONSON PRENATAL 2 (#155)
3275 BRONSON PRENATAL(#19)
0014 BRONSON RDA MULTIPLE VITAMINS (#117)
3765 BRONSON SUPER ANTIOXIDANT (#154)
3423 BRONSON SUPER B (#6)
3393 BRONSON SUPER MULTIVIT + TRACE MINERALS (#93)
3272 BRONSON THERAPEUTIC (#2)
3408 BRONSON TIME RELEASED B COMPLEX + C + E
3604 BRONSON TRACE ELEMENTS (#114)
3273 BRONSON VITAMIN & MINERAL FORMULA (#3)
3058 BRONSON VITAMIN & MINERAL INSURANCE FORMULA (#1)
3759 BRONSON VITAMIN AND MINERAL POWDER SUPPLEMENT (#151)
3053 BRONSON VITAMIN INSURANCE FORMULA (#82)
3767 BRONSON VITAMINS A, C, E WITH BETA CAROTENE (#23)
3607 BRONSON WOMEN'S FORMULA #2 (#131)
3044 BRONSON WOMEN'S FORMULA (#9)
3274 BRONSON Z PLEX (#72)
0846 BUFFIM'S
0586 BUGS BUNNY
3452 BUGS BUNNY + EXTRA C
3405 BUGS BUNNY + IRON
3429 BUGS BUNNY VITAMIN AND MINERALS
0587 BUSY BODY
3177 BUSY BODY (FOOD PLUS)
0015 BYRITE
3158 C COMPLEX & ZINC (CVS)
0904 C-CON
0017 CAL STRESS 600 (CALDOR)
0018 CAL-BEX-T(CALDOR)
0451 CALCET
3060 CALCET PLUS (MISSION)
3189 CALCIUM & D (YOUR LIFE)
3133 CALCIUM MALTIES (C,D,PH,MG) (RICHLIFE)
3336 CALCIUM PLUS (NATURAL BRAND, IRON, MAGNESIUM, A,D,C)
3277 CALCIUM PLUS (NATURE MADE)
3213 CALCIUM W/ VITAMIN D (MEDIMART)
0016 CALDOR
0018 CALDOR CAL-CEX-T

0998 CALDOR MULTI VIT + MINERALS
0017 CALDOR STRESS(CAL STRESS 600)
0141 CALDOR THERA-M-VITS
0897 CALDOR W/ IRON
1002 CALLSON SUPER DAILY
3094 CALPADON
3234 CALTRATE
3095 CALTRATE 600 & D (LEDERLE)
3257 CALTRATE 600 (LEDERLE)
3263 CALTRATE 600 WITH IRON & D (OPTISORB)
3413 CALTRATE JUNIOR
3258 CALTRATE WITH IRON AND D (LEDERLE)
0237 CAMPUS LIFE
0560 CANADIAN
3476 CAP TEN (COUNTRY LIFE)
3744 CARDIO FACTORS (COUNTRY LIFE)
0286 CARE FREE
3414 CARITAB
0806 CARL MULTI VIT W/ IRON
0019 CARLS
0841 CARLS STRESS FORMULA 600
0020 CARLSON
0984 CARYL DRUG
3178 CEB PLUS T (FOOD PLUS)
0342 CEBEFORTIS
3625 CEBEKAPS (HUDSON)
3626 CEBEKAPS THERAPEUTIC (HUDSON)
0022 CEEBEVIM (HUDSON)
0021 CEFOL
3753 CELL PROTECTA (COUNTRY LIFE)
0842 CENTABS
3209 CENTABS (MEDIMART)
0955 CENTR-A-MINS
3069 CENTRAL PHARMACY NIFEREX FORTE, PRENATAL
3186 CENTRAVITE (YOUR LIFE)
0839 CENTRAX
0529 CENTROVITE
0023 CENTRUM (LEDERLE)
3039 CENTRUM JUNIOR
3424 CENTRUM JUNIOR + IRON + CALCIUM
3183 CENTRUM JUNIOR with EXTRA C
3348 CENTRUM JUNIOR with IRON
3673 CENTRUM SILVER
0505 CENTURY 21
3472 CENTURY VITE (NATURE MADE)
0577 CETA-B
3415 CEVIBID
3416 CEVIFER
0408 CHAMBRE TOTAL
0258 CHASE CHEMICAL
0811 CHASE MULTIVITAMIN & MINERALS
0240 CHASE-PRENATAL
0820 CHATEAU

0553 CHE VIM 75
3333 CHELA - VITAMIN E - PLUS MEGA VITAMIN MINERAL LIPOTROPIC
3660 CHELATED MULTIPLE MINERALS (PURITAN PRIDE)
0371 CHESTNUT RIDGE
3453 CHEWS EZE
3694 CHILDREN'S CHEWABLE VITAMIN (PURITAN PRIDE)
3048 CHILDREN'S COMPLETE MULTIVIT
3048 CHILDREN'S MULTIVIT COMPLEX
3046 CHILDREN'S MULTIVIT PLUS IRON
3047 CHILDREN'S MULTIVIT PLUS VITAMIN C
3651 CHILDREN'S MVM (NATURE'S PLUS)
3137 CHILDREN'S VITAMIN AND MINERALS (RICH LIFE)
3763 CHILDREN'S VITAMIN WITH IRON AND ZINC (#22) (BRONSON)
3677 CHILDRENS (SHAKLEE)
3417 CHILDRENS CHEWABLE (CVS)
0249 CHIVOSIL
3366 CHOLESTEROL PAK, YOUR LIFE
0665 CHOX CHILDREN'S
0499 CHRIS NATURAL
3454 CHROMAGEN
3059 CHROMAGEN-OB (SAVAGE)
3473 CIPLEX (SOLGAR)
3437 CITRACAL
3439 CITRACAL, SUPER
0024 CLARIVITES(HUDSON)
0328 CLOVER
0444 CLUSIVOL
9999 CO Q10
3149 COACHES FORMULA (THOMPSON)
3769 COLGAN INSTITUTE MEN'S 50+ AM FORMULA
3768 COLGAN INSTITUTE MEN'S 50+ AM/PM FORMULA
3770 COLGAN INSTITUTE MEN'S 50+ PM FORMULA
0559 COLONEY
0588 COLONIAL
0960 COLUMBIA THERA 9M
0399 COMPENSATE 750
3061 COMPETE (MISSION)
3190 COMPETITION PAK (YOUR LIFE)
0088 COMPLETE FORMULA #1 (NUTRITION HEADQUARTERS)
0589 COMPREHENSIVE FORM. #28
0025 COMPREVITES-EC(HUDSON)
0974 CONSUMER VALUE
0438 COOP
0624 COOPERS MANNA-MIN
0590 CORE
0982 CORE-C 500
3474 COUNTRY LIFE ACTION 75
3480 COUNTRY LIFE ALL DAY ALL NIGHT FORMULA
3752 COUNTRY LIFE BONE DENSITY FACTORS
3476 COUNTRY LIFE CAP TEN
3744 COUNTRY LIFE CARDIO FACTORS
3753 COUNTRY LIFE CELL PROTECTA
3692 COUNTRY LIFE DAILY TARGET-ALL

3478 COUNTRY LIFE DAILY TOTAL ONE
3479 COUNTRY LIFE DAILY VEGETARIAN
3747 COUNTRY LIFE FLIXI-FACTORS
3745 COUNTRY LIFE GLYCEMIC FACTORS
3502 COUNTRY LIFE HI B 125
3481 COUNTRY LIFE HIGH POTENCY ACTION 75
3482 COUNTRY LIFE HIGH POTENCY MULTI 75
3597 COUNTRY LIFE HIPOTENCY MAXI B CAPS
3746 COUNTRY LIFE LIGA-TEND
3750 COUNTRY LIFE MALE FACTORS
3483 COUNTRY LIFE MAX FOR MEN
3485 COUNTRY LIFE MAXI HAIR
3484 COUNTRY LIFE MAXI MENERALS
3488 COUNTRY LIFE MAXI PRENATAL PAK
3755 COUNTRY LIFE MAXIMUS PERFORMANCE PAK
3486 COUNTRY LIFE MAXINE
3487 COUNTRY LIFE MAXINE CAPS
3756 COUNTRY LIFE MULIT-MINERALS
3757 COUNTRY LIFE MULTIVITAMIN
3749 COUNTRY LIFE PRE-MENSES
3754 COUNTRY LIFE PROSTA-MAX
3518 COUNTRY LIFE QUICK PICK UP
3475 COUNTRY LIFE SENIORITY
3489 COUNTRY LIFE STRESS M
3491 COUNTRY LIFE SUPER POTENCY MULTI 100
3477 COUNTRY LIFE TALL TREE (CHILD MV)
3751 COUNTRY LIFE THYRO-MAX SUPPORT
3490 COUNTRY LIFE TOTAL 2 CAPS
3758 COUNTRY LIFE TOTAL MINS COMPLEX
3748 COUNTRY LIFE TRAVELERS SUPPORT
0551 COURTESY
0874 COURTESY PLUS IRON & E
0488 CROWN VALLEY
0517 CUNNINGHAMS DRUG
0823 CVA
0026 CVS
3012 CVS B + C + ZINC
3160 CVS B-100
3161 CVS B-150
3159 CVS B-50
3158 CVS C COMPLEX & ZINC
3384 CVS CALCIUM MAGNESIUM ZINC
3017 CVS CEN-TAB
3426 CVS CHILDREN CHEWABLE + EXTRA C
3417 CVS CHILDRENS CHEWABLE
3425 CVS CHILREN CHEWABLE + IRON
3579 CVS DAILY STRESS COMPLEX
0936 CVS FORMULA Z & C
3373 CVS G FORMULA
0993 CVS HI-POTENCY FORMULA W/B+C
0824 CVS HIGH POTENCY B
0785 CVS HIGH POTENCY FORMULA 36
3011 CVS HIGH POTENCY STRESS + ZINC

3010 CVS HIGH POTENCY VIT + MINERAL
3163 CVS MAXIMUM CHOICE
3259 CVS MEGA MILTIVITAMIN
3009 CVS MULTI-VIT + MINERAL
0794 CVS MULTI-VITES
0784 CVS MULTIPLE W/ IRON
3583 CVS MULTIVITAMIN AND MINERAL TIME-RELEASED
3164 CVS MYAVITE
3492 CVS NATURAL MVM
3262 CVS OYSTER SHELL CALCUIM WITH D
3493 CVS PRENATAL
3162 CVS SENIOR'S CHOICE
3166 CVS SPECTRAVITE
3582 CVS STRESS + ZINC
0787 CVS STRESS FORMULA
0863 CVS STRESS FORMULA W/ IRON
3264 CVS STRESS PAK
0027 CVS THERA
0944 CVS THERA M
3165 CVS THERAPLUS
0028 CVS UNIVITE M
3372 CVS ZN + CALCIUM
0591 CVV (CWV) FORMULA 75
3109 DAILY VITAMIN PAK FOR ATHLETES (OSCO)
3363 DAILY COMBO, NUTRIPLUS
0417 DAILY DOSE
3118 DAILY GOLD PACK (SOLGAR)
3250 DAILY PAK FOR MEN (YOUR LIFE)
3249 DAILY PAK FOR WOMEN (YOUR LIFE)
0592 DAILY PLUS IRON (ARBOR)
0751 DAILY QUOTA
3692 DAILY TARGET-ALL (COUNTRY LIFE)
3478 DAILY TOTAL ONE (COUNTRY LIFE)
3479 DAILY VEGETARIAN (COUNTRY LIFE)
3108 DAILY VITAMIN PAK FOR MEN (OSCO)
3107 DAILY VITAMIN PAK FOR WOMEN (OSCO)
3494 DAILY VITAPAK (GNC)
0593 DAILY-VITE
3734 DAILY-VITES (ESSENTIAL ORGANICS)
0833 DALES THERAPEUTIC VIT & MIN
3045 DAPLEX - THOMPSON
0397 DARBY
0169 DARLITE
0029 DART DRUG
0469 DARTELL
3657 DAY & NIGHT (NATURE'S PLUS)
0177 DAY MOORE
0594 DAY-LEE
0030 DAYALETS
0001 DAYALETS (ABBOTT)
3427 DAYALETS + IRON
3023 DAYTIME VITAMIN, WOMEN'S
3772 DAYTIME/NIGHTTIME FORMULA, WOMEN'S

3577 DAYVITE
0243 DECAVITS
0418 DECELIRON
0896 DEE CEE LABS INC
0423 DEPREE
0673 DEPT. OF DEFENSE MIL STD
0447 DERITON
3524 DERMA PAK (RICHLIFE)
0031 DFS-DIETARY FOOD SUPPLEMENT(PLUS)
0574 DICTIC
0543 DIET AID
0450 DIET CENTER
0949 DIET REVOLUTION CENTER
3033 DIET VITAMIN (NO SPECIFIC BRAND)
0031 DIETARY FOOD SUPPLELMENT(PLUS)
3525 DIETERS PAK (RICHLIFE)
0032 DIFFERS
3556 DINOSAUR
0033 DISTA (MICEBRIN)
0876 DIXON
0349 DOLOMITE (SCHIFF)
0116 DOUBLE DAY (SCHIFF)
3204 DOUBLE DAY JUNIOR (SCHIFF)
3402 DOUBLE X
1009 DR.ATKINS VIT-MIN NUTR FORMULA
0287 DRUCO
0034 DRUG FAIR
0595 DRUG GUILD
2023 DRUG IND AL-VITE
0670 DRUG MART
0596 DRUGSTORE
0365 DUANE READE
0035 DUO KAPS(HUDSON)
0674 DUPREE
0393 DURA-DAY
0761 DURADAY W/ IRON
0597 DURAVALS
3495 E PLUS
3708 EARTH SOURCE (SOLGAR)
1016 EAST MULTIVITS
0441 EASTMAN KODAK
0836 EATON MULTI VIT
2025 ECEE PLUS (EDWARDS)
0036 ECHARDS
3404 ECKARD'S CHEWABLE + IRON
0281 ECKERT DRUG
0370 ECOLOGY
2032 EDNOR
0927 EDOM FORMULA 75 LABS
2025 EDWARDS ECEE PLUS
0598 EKCO
3062 ELDERCAPS (MAYRAND)
3082 ELDERTONIC (MAYRAND)

0436 ELLIOTS
3685 ENCOMPEX
0037 ENECBRIN(LILLY)
3093 ENERGY FORMULA (AARP)
0952 ENGRAN HP
0923 ENHANCE SUPREME
0442 ENORGITE
0599 ENTERRA
3063 ENVIRO STRESS, ZINC & SELENIUM (VITALINE)
0382 ENVIRON
3688 ESSENTIAL BALANCE (NATURE MADE)
0600 ESSENTIAL ORGANICS
3736 ESSENTIAL ORGANICS ALL-SPORTS
3734 ESSENTIAL ORGANICS DAILY-VITES
3735 ESSENTIAL ORGANICS FEM-PLEX
3737 ESSENTIAL ORGANICS H/N/S-PLEX
3732 ESSENTIAL ORGANICS MEGA-VITES
3729 ESSENTIAL ORGANICS OMEGA
3730 ESSENTIAL ORGANICS OMNI-PLEX TR
3733 ESSENTIAL ORGANICS SUPER-VITES
3731 ESSENTIAL ORGANICS V-PLEX
3140 ESSENTIALLY ALL (ALACER)
3710 ESTER-C PLUS (SOLGAR) [CALCIUM, MG, K ZINC]
3712 ESTER-C PLUS MULTIMINERAL (SOLGAR) [CALCIUM,MG, K, ZINC]
2026 EVERETT LIBIDINAL
3723 EVERY MAN (NEW CHAPTER)
3722 EVERY WOMAN (NEW CHAPTER)
3628 EVERYTHING FORMULA (BOB LEE)
3621 EX-PO 36 (THOMPSON)
0880 EXCEL W/ IRON
3034 EXERCISE VITAMIN (NO SPECIFIC BRAND)
0533 EXIL
3711 EXTRA-POTENCY ESTER-C PLUS (SOLGAR) [CALCIUM, MG, K ZINC]
0562 F & M
0675 FA FLOWER LIGHT CO (POWERCAPS)
0335 FALPLEX
0917 FAMILY CHOICE
0524 FAMILY PRIDE
3219 FAMILY VITAMINS (HALL)
0174 FAMILY VITS (PARKER DAVIS)
0601 FAMPREN FORTE
0473 FARADAY
0920 FAY'S
0801 FAY'S DAILY MULTI VIT W/ IRON
0815 FAY'S HIGH POTENCY VITAMIN
1037 FAY'S STRESS FORMULA
0038 FAY'S STRESS WITH IRON
0039 FAYS TRI R MULTI VIT
0424 FED-MART
0040 FEDCO
3627 FEDCO T FORMULA M
0602 FEDERAL PRESCRIPTION SERVICE
0041 FEDMART

0532 FEDULITS
0205 FEM IRON
3735 FEM-PLEX (ESSENTIAL ORGANICS)
3740 FEM-TABS (MEGA FOOD)
3044 FEMALE FORMULA (BRONSON #9)
0603 FEMININE FORMULA
0176 FEMININS
0280 FEOSOL SPANSULE
3496 FERANCEE
3497 FERANCEE HP
0676 FERANCEE MP
0319 FERASCORB
0538 FERGON PLUS
3428 FERGON IRON + CALCIUM
0518 FEROFOLIC 500
0511 FEROGRADS 500
3438 FERRALET
0422 FERRO-SEQUELS
3065 FIELDING GERIMED
3068 FIELDING NESTABS FA, PRENATAL
0224 FIELDS OF NATURE
0932 FIELDS OF NATURE W/ IRON
0510 FIGURETTES
0604 FILAXIS
0526 FILENES
1030 FILIBON FA
3064 FILIBON FORTE (LEDERLE)
0187 FILIBON VIT (PRENATAL)
0445 FIT
3382 FITNESS FOR MEN, MDR
3383 FITNESS FOR WOMEN, MDR
3747 FLEXI-FACTORS (COUNTRY LIFE)
3361 FLINESTONES + IRON
3429 FLINESTONES COMPLETE
0042 FLINTSTONES(MILES)
0465 FLOYDS
0409 FOLBY
0043 FOOD PLUS
3173 FOOD PLUS A.C.N.E. W/ ZINC AND B6
3175 FOOD PLUS ALL AROUND VITAMIN AND MINERAL
3177 FOOD PLUS BUSY BODY
3178 FOOD PLUS CEB PLUS T
1027 FOOD PLUS FORMULA 644
3172 FOOD PLUS GERITABS
3174 FOOD PLUS MULTI - 75
3176 FOOD PLUS SPECTROVITE
3261 FOOD PLUS THERIN
3179 FOOD PLUS THERIN PLUS
0289 FOOD TOWN
0985 FOOD TOWN HI-POTENCY
3135 FOR ATHLETES ONLY (RICH LIFE)
3498 FOR MEN ONLY (GNC)
3241 FOR MEN ONLY (GOLDENSUN)

0631 FORDS NATURAL BEAUTIFUL
3691 FORMU3-INTERNATIONAL
3303 FORMUAL 384 (AARP)
0994 FORMULA
3639 FORMULA 103 (AARP)
3640 FORMULA 104 (AARP)
3632 FORMULA 106 (AARP)
3298 FORMULA 107 (AARP)
3633 FORMULA 112 (AARP)
3301 FORMULA 113 (AARP)
3285 FORMULA 116 (AARP)
3302 FORMULA 118 (AARP)
3645 FORMULA 120 (AARP)
3644 FORMULA 122 (AARP)
3093 FORMULA 127 (AARP)
3270 FORMULA 129 (AARP)
3635 FORMULA 139 (AARP)
3308 FORMULA 141 (AARP)
3562 FORMULA 142 (AARP)
3293 FORMULA 145 (AARP)
3269 FORMULA 150 (AARP)
3271 FORMULA 152 (AARP)
3564 FORMULA 156 (AARP B COMPLEX 50 WITH C)
3637 FORMULA 160 (AARP)
3297 FORMULA 171 (AARP)
3646 FORMULA 175 (AARP)
3268 FORMULA 195 (AARP)
3117 FORMULA 200, ONE UP (PLUS)
3634 FORMULA 210 (AARP)
3647 FORMULA 310 (AARP)
3649 FORMULA 322 (AARP)
3283 FORMULA 358 (AARP)
3641 FORMULA 360 (AARP)
3642 FORMULA 362 (AARP)
3643 FORMULA 366TR (AARP)
3636 FORMULA 368 (AARP)
3648 FORMULA 375 (AARP)
3311 FORMULA 385 (AARP)
3307 FORMULA 404 (AARP)
3287 FORMULA 460TR (AARP)
0763 FORMULA 47(MULTI-VITES)
3295 FORMULA 502 (AARP)
3278 FORMULA 644 (AARP)
0591 FORMULA 75 (CVV)
3650 FORMULA 75 (HUDSON)
0981 FORMULA M
0487 FORMULA S-6
0226 FORMULA T-M
3713 FORMULA VM-2000 (SOLGAR)
0329 FORTE PLUS 24
3422 FORTIFIED MULTIVIT AND MIN INSURANCE, BRONSON (#92)
0546 FORTREX
0459 FOS FREE

0263 FOXCO
0239 FREEDA VIT
0200 FRUIT OF THE LAND
3430 FULL SPECTRUM CALCIUM SOFTGELS- (HI POTENCY MULTI MIN) SOLGAR
0493 FULVITA
3373 G FORMULA, CVS
0916 G-TOL
3389 GARRY NULLS AM
3771 GARRY NULLS AM/PM FORMULA
3390 GARRY NULLS PM
0462 GEMCO
0914 GEN-KING
0268 GENADEC
0049 GENADEE (GNC)
0394 GENE
3034 GENERAL 'EXERCISE' VITAMIN
3035 GENERAL 'GERI' VITAMIN
3033 GENERAL DIET VITAMIN
0044 GENERAL NUTRITION
0270 GENOVESE
0875 GENOVESE HIGH POTENCY W/ MIN
0773 GENOVESE STRESS CAPS
1013 GENOVESE STRESS FORMULA W/ZINC
1044 GERE-E-TIME
0344 GERETREX
0516 GERI RITE
3035 GERI VITAMIN (NO SPECIFIC BRAND)
0353 GERI-GEN
3662 GERI-PRIDE (PURITAN PRIDE)
1012 GERI-VIM
0380 GERIATIC
3698 GERIATRIC (PURITAN PRIDE)
3054 GERIATRIC FORMULA (BRONSON #7)
3317 GERIATRIC GOLDENSUN
3083 GERIAVIT PHARMATON (NUTRITIONAL SPECIALITY)
0605 GERIBAN
0250 GERILITE
0318 GERIMAX
3065 GERIMED (FIELDING)
3589 GERIPLEX LIQUID
3078 GERIPLEX-FS KAPSEALS (PARKE DAVIS)
3172 GERITABS (FOOD PLUS)
0045 GERITOL
3084 GERITOL COMPLETE MULTIVIT & MINERAL WITH HIGH POTENCY IRON (BEECHAM)
3682 GERITOL EXTEND
0883 GERITOL HIPOTENCY IRON & VITAMIN
0046 GERITOL MEGAVITAMINS
3665 GERIVITES
0452 GERO-PLUS
0678 GERRETS
0406 GERSERIX
0606 GESTONEED

0762 GEVRABON LIQUID
0311 GEVRAL
3085 GEVRAL T (LEDERLE)
0047 GIANT STORE BRAND
0607 GIBSON B-50
3431 GLUTOFAC
3745 GLYCEMIC FACTORS (COUNTRY LIFE)
0048 GNC
0049 GNC - GENADEE
3447 GNC ADVANCED SOLOTRON
3494 GNC DAILY VITAPAK
3498 GNC FOR MEN ONLY
3545 GNC MEGA 100
3507 GNC MEGA ONE
0080 GNC NATURAL SALES
3514 GNC PMS
3387 GNC PREVENTION STRESS CALCIUM, B, C, AMINO ACIDS
0100 GNC PREVENTRON
3169 GNC SOLOTRON WOMEN'S FORMULA
3535 GNC STRESS FORMULA
3537 GNC STRESS VITAPAK
0976 GNC STRESS-O-VITE
0132 GNC SUPER X
1001 GNC ULTRA MEGA
0821 GNC UNIGEN W/IRON
3552 GNC WOMEN POWER PAK
0050 GOLD CIRCLE
0355 GOLD LINE
0838 GOLD LINE Z-GEN
3276 GOLD SEAL (WALGREEN)
3327 GOLD SEAL A TO Z HIGH POTENCY
3326 GOLD SEAL HIGH POTENCY MUM
3332 GOLD SEAL MULTIVITAMIN WITH IRON
3329 GOLD SEAL STRESS
3322 GOLD SEAL STRESS & C
3321 GOLD SEAL STRESS & C & IRON
3323 GOLD SEAL STRESS & C & ZINC & BIOTIN
3328 GOLD SEAL STRESS TIME RELEASE
3324 GOLD SEAL THERAGRAN
3599 GOLD SEAL THERAPEUTIC M
3325 GOLD SEAL ULTRAPOTENCY III
3330 GOLD SEAL WOMEN'S WAY
3331 GOLD SEAL ZINC WITH B, C, E
0522 GOLD SHIELD
0750 GOLDEN TABS
3245 GOLDENSUN A - Z
3318 GOLDENSUN FOR HAIR
3241 GOLDENSUN FOR MEN ONLY
3317 GOLDENSUN GERIATRIC
3242 GOLDENSUN IRON COMPLEX
3244 GOLDENSUN MEGA B 100
3246 GOLDENSUN ONE DAY W/ IRON
3247 GOLDENSUN PREMENSTRUAL VITAMIN FORMULA

3243 GOLDENSUN SUPER B COMPLEX
3239 GOLDENSUN SUPER MINERAL COMPLEX
3237 GOLDENSUN SUPER PRO-VITE MULTIVITAMINS & MINERALS
3236 GOLDENSUN THERA - M
3240 GOLDENSUN TODAY'S WOMEN EXTRA STRENGTH DAILY
0425 GOLDINE MAXI-VIT
0432 GOOD NATURE
0679 GOOD NEWS
0052 GRAND UNION
0677 GRANT FOOD
0051 GRAY'S
0477 GREAT EARTH
0935 GREAT EASTERN
0322 GREENLIFE
3334 GYNEDYN WITH MAMMARY CONCENTRATE
3737 H/N/S-PLEX (ESSENTIAL ORGANICS)
3499 HALERCOL
3220 HALL A-Z MULTIVITAMINS AND MINERALS
3222 HALL ACTIVE FORMULA
3219 HALL FAMILY VITAMINS
3319 HALL IRON COMPLEX
3221 HALL MEGA POTENCY SUPREME
3218 HALL PHASE IV, A-Z, MULTIVITAMINS & MINERALS
3223 HALL PRENATAL
3226 HALL STRESS & IRON
3227 HALL STRESS & ZINC
3225 HALL STRESS FORMULA
3224 HALL THERAPEUTIC FORMULA
1019 HALL'S DAILY VITE M W/IRON
0217 HALLS MULTI
0609 HALLS TWINCAPS
0540 HARRISON
0145 HARRISON TWO GUYS
0959 HARVEST
3500 HEALTH BEAUTY PAK
0478 HEALTH BUILDES
0507 HEALTH FAIR
0865 HEALTH GUARD
0053 HEALTH RITE
0856 HEALTH SAVERS
0951 HEALTH SHOP METAPLEX
0185 HEMATINIC
3501 HEMATINIC (SOLGAR)
3421 HEMATINIC BRONSON (#10)
0471 HENRY SOHEIN
3432 HEPFORTE
0216 HEPTUNA PLUS
0957 HERBALIFE
0375 HERITAGE
0282 HERRSCHNER
0291 HESS
3353 HEXAVITAMINS
0390 HEXAVITS

3208 HI - B COMPLEX (SCHIFF)
3502 HI B 125 (COUNTRY LIFE)
0611 HI B/C
3540 HI POTENCY STRESS 600 (THOMPSON)
0612 HI VITE DIETETIC VITS
0186 HI-MAGNOPIN
0055 HI-PO-VITES (HUDSON)
3614 HIGH PLAN-TWO, HIGH POTENCY (PLUS)
3457 HIGH POTENCY A - Z (OSCO)
3481 HIGH POTENCY ACTION 75 (COUNTRY LIFE)
3581 HIGH POTENCY LEE COMPLETE
3482 HIGH POTENCY MULTI 75 (COUNTRY LIFE)
3337 HIGH POTENCY MULTIMINERAL (RICHLIFE)
0893 HIGH POTENCY MULTIPLE
0054 HIGH-ONE (NUTR. HEDQ. INC.)
0563 HILCAN
0610 HILCOA
0467 HILLS
3252 HIPOTENCY MULTIVIT & MINERAL SUPPLEMENT (YOUR LIFE)
3126 HIPOTENCY MULTIVITAMIN AND MINERALS (RICH LIFE)
3120 HIPOTENCY SOFT MULTIPLE (KAL)
3102 HIPOTENCY THERAPEUTIC M (OSCO)
3096 HIPOTENCY VITAMIN & MINERAL (WALT DELAND)
3139 HIPOTENCY VITAMIN PAK (RICH LIFE)
0241 HOFFMAN
0995 HOFFMAN LAROCHE MULTIVITAMIN
0385 HOLMER
0225 HOUSE
0056 HUDSON
0003 HUDSON ADAVITE
0873 HUDSON ADAVITE M
3625 HUDSON CEBEKAPS
3626 HUDSON CEBEKAPS THERAPEUTIC
0022 HUDSON CEEBEVIM
0024 HUDSON CLARIVITES
0025 HUDSON COMPREVITES-EC
0035 HUDSON DUO KAPS
3650 HUDSON FORMULA 75
0055 HUDSON HI-PO-VITES
0069 HUDSON MINAQUIN
1025 HUDSON MULTI-VIT PLUS MINERALS
0919 HUDSON STRESS FORM 600
0933 HUDSON STRESS PLUS IRON
0140 HUDSON THERA-VIM
0207 HUDSON ULTRA B-50
0157 HUDSON VIODAY
0941 HUDSON VIODAY PLUS IRON
0163 HUDSON ZEL-KAPS
3503 HY BIO (SOLGAR)
3152 HYPO - 50 (THOMPSON)
0057 IBERET
3391 IBERET 500
0830 IBERET-FOLIC

0791 IDE GENERIC W/MINERALS
0795 IDE MULTILOR
0858 IDE STAR TABS
0912 IDE SUPER HI POTENCY
0788 IDE VITE W/MINERALS
0404 IDG
3690 IMAGE ESSENTIALS (NUSKIN)
3591 INCREMIN WITH IRON
0834 INTERSTATE DRUG EXCHANGE
0613 INTERVAL I-T
0466 IROMIN
3433 IROMIN G
3211 IRON & B COMPLEX (MEDIMART)
3242 IRON COMPLEX (GOLDENSUN)
0435 IRON-TIME
0614 IRWIN PARIS
0615 JA VENEX
0367 JAFRA
0167 JAMESWAY
0997 JAMESWAY HI-POTENCY
0275 JEFFING FEEL CO.
1020 JEFFREY HILL-E.K.
0503 JEURABON
0491 JEWEL
0616 JOGGERS (SOLGAR)
0350 JOHNSON
0680 JUVENEX
0058 K-MART
0835 K-MART STRESS FORMULA
0476 KAL
3120 KAL HIPOTENCY SOFT MULTIPLE
3504 KAL MEGA VITAMIN
3121 KAL MULTIMAX
3122 KAL PMS FORMULA
3505 KAL STRESS 1
3119 KAL VEGETARIAN MULTIPLE
3704 KARUNA MAXXUM 1,2,3
3705 KARUNA MAXXUM 4
3706 KARUNA MINI-MAX
0528 KAYSERS
0229 KENMORE
3255 KENMORE KIDS MULTIVITAMIN WITH IRON
3180 KENMORE OXY - E 200
3181 KENMORE SUPER C AND E
0211 KENTS
0892 KENYON
3182 KIDS MULTIVITAMIN
3255 KIDS MULTIVITAMIN WITH IRON (KENMORE)
0334 KINGS
1011 KINGS DAILY PLUS IRON
0411 KINGSTON
0862 KINNEY'S ONE A DAY
0398 KLB6

0183 KODAK JEFFREY FALL CO.
0617 KOR/VAL
0059 KORVETTE
0060 KROGER
0618 KRONOS (578)
0509 L & M
0992 LANDAU'S HI-VITALIN
0061 LANE'S
0483 LANOBEC
3434 LAROBEC
0251 LAWSON-REED
0681 LAZARUS
0619 LBC COMPLEX
0215 LEADER DRUGS
0449 LEADER PLEX
3718 LEAN BODY FACTORS (NEW CHAPTER)
3257 LEDERLE CALTRATE 600
3095 LEDERLE CALTRATE 6OO & D
3258 LEDERLE CALTRATE WITH IRON AND D
0023 LEDERLE CENTRUM
3064 LEDERLE FILIBON FORTE
3085 LEDERLE GEVRAL T
3079 LEDERLE LEDERPLEX CAPSULES
3066 LEDERLE MATERNA 1-60
3052 LEDERLE PERIHEMIN HEMATINIC CAPSULES
3031 LEDERLE SPARTUS
3088 LEDERLE SPARTUS PLUS IRON
0808 LEDERLE STRESSTABS W/ZINC
1010 LEDERLE VIT B STRESS TABS 600
3079 LEDERPLEX CAPSULES (LEDERLE)
0301 LEE
3581 LEE COMPLETE, HIGH POTENCY
0570 LEE FELTONS
0943 LEES NUTRITION
0366 LEGEND
0861 LEGEND PHARMACY DAILY W/ IRON
2022 LEGORE ACE + ZINC
0620 LEVOBUYS
0926 LEXTRON
0315 LIBERTY DRUG
2026 LIBIDINAL (EVERETT)
0492 LIFE LINE
3717 LIFE SHIELD (NEW CHAPTER)
3228 LIFESTAGE FOR CHILDREN (VICK'S)
3230 LIFESTAGE FOR MEN (VICK'S)
3229 LIFESTAGE FOR TEEN'S (VICK'S)
3038 LIFESTAGE FOR WOMEN (VICK'S)
3232 LIFESTAGE STRESS FOR MEN (VICK'S)
3231 LIFESTAGE STRESS FOR WOMEN (VICK'S)
3746 LIGA-TEND (COUNTRY LIFE)
0428 LILLY
0037 LILLY ENECBRIN
0629 LILLY MULTI -CEBRIN

0414 LIPO FLAVONOID
3573 LIPO-NICIN 100
3333 LIPOTROPIC VITAMIN MINERAL TAB
0426 LIVEK
0565 LIVER & IRON
3764 LIVER YEAST AND VITAMINS, BRONSON (#8)
0486 LIVIN N' ON
0621 LIVITAMINS
0358 LLOYD'S
0063 LONG'S
0360 LSA W/ MINERAL
0685 MACROBERTS
0622 MAGNA ONE
3750 MALE FACTORS (COUNTRY LIFE)
0190 MALL DRUG (THEREPEUTIC M)
0283 MALLEY'S
0624 MANNA-MIN (COOPERS)
0623 MARION
3041 MARION OSCAL PLUS
3086 MARLYN PMS
0261 MASON NAT.
0369 MASTER FORMULA
0247 MATERNA
3066 MATERNA 1-60 (LEDERLE)
0625 MATERNA-L-60
3483 MAX FOR MEN (COUNTRY LIFE)
0537 MAXI -VIMS
3597 MAXI B CAPS, HIPOTENCY, COUNTRY LIFE
3485 MAXI HAIR (COUNTRY LIFE)
3484 MAXI MINERALS (COUNTRY LIFE)
3488 MAXI PRENATAL PAK(COUNTRY LIFE)
3506 MAXIM VITAPAK
3620 MAXIMUM 1 & 2 (THOMPSON)
3163 MAXIMUM CHOICE (CVS)
3194 MAXIMUM CHOICE (YOUR LIFE)
3300 MAXIMUM FORMULA, ONE A DAY
3300 MAXIMUM FORMULA, ONE A DAY
3248 MAXIMUM PAK (YOUR LIFE)
3755 MAXIMUS PERFORMANCE PAK (COUNTRY LIFE)
3486 MAXINE (COUNTRY LIFE)
3487 MAXINE CAPS (COUNTRY LIFE)
3153 MAXIPLEX (THOMPSON)
3704 MAXXUM 1,2,3 (KARUNA)
3705 MAXXUM 4 (KARUNA)
3062 MAYRAND ELDERCAPS
3082 MAYRAND ELDERTONIC
3070 MAYRAND NU-IRON-V
0464 MCKAY
0213 MCKESSON
0472 MCNESS
0922 MD NATURAL VITAMINS
3675 MD PHARMACEUTICAL THERA-M
3382 MDR FITNESS FOR MEN

3383 MDR FITNESS FOR WOMEN
0293 MEAD JOHNSON
0522 MED HEALTH
0330 MEDALIST
0172 MEDI MART
1026 MEDI MART MULTI-VIT PLUS IRON
0171 MEDI MART NION RAY
2027 MEDI-PLEX (U.S. CHEM)
0474 MEDIATRIC
0064 MEDIBEE-C
0849 MEDICAL GROUP DAILY NEEDS M W/ MIN
3072 MEDICAL PRODUCTS VG CAPSULES
0065 MEDICINE SHOPPE
0626 MEDICO
0066 MEDIGUARD
3217 MEDIMART B COMPLEX
3004 MEDIMART B COMPLEX + C
3215 MEDIMART B-100
3216 MEDIMART B-50
3213 MEDIMART CALCIUM W/ VITAMIN D
3209 MEDIMART CENTABS
3211 MEDIMART IRON & B COMPLEX
3210 MEDIMART MULTIVITAMIN & MINERALS
3212 MEDIMART STRESS
3214 MEDIMART STRESS W/ ZINC
3005 MEDIMART THERAPEUTIC-M
3075 MEDIPLEX (U.S. PHARMACY)
0969 MEGA 100
3545 MEGA 100 (GNC)
3435 MEGA 2000 (NATURE MADE)
0827 MEGA 80 (THOMPSON)
0978 MEGA B
3244 MEGA B 100 (GOLDENSUN)
3074 MEGA B WITH C (ARCO)
3676 MEGA FOOD 1 DAILY
3738 MEGA FOOD ALPHA
3742 MEGA FOOD BABY & ME
3740 MEGA FOOD FEM-TABS
3741 MEGA FOOD SPORTS FORMULA
3201 MEGA HIGH II (SCHIFF)
3131 MEGA II (RICH LIFE)
0627 MEGA LORD
3259 MEGA MULTIVITAMIN (CVS)
0267 MEGA ONE
3507 MEGA ONE (GNC)
3171 MEGA ONE (NUTRITION SQUARE)
3132 MEGA ONE (RICH LIFE)
3526 MEGA PAK (RICHLIFE)
0067 MEGA PLEX 75 (NATURE'S PLUS)
3127 MEGA PLUS (RICH LIFE)
3221 MEGA POTENCY SUPREME (HALL)
3349 MEGA STRESS B+C
3703 MEGA VITA GELS (PURITAN PRIDE)

0264 MEGA VITAMIN
3654 MEGA-MINS (NATURE'S PLUS)
3008 MEGA-TIME
3664 MEGA-VITA-MIN (PURITAN PRIDE)
3732 MEGA-VITES (ESSENTIAL ORGANICS)
3368 MEGABOLIC MULTIPOWER PAK
2028 MEGADOSE (ARCO)
3716 MEGASORB B-COMPLEX 50 (SOLGAR)
0305 MEIJER
0682 MEIR MINERALS
3769 MEN'S 50+ AM FORMULA (COLGAN INSTITIUTE)
3768 MEN'S 50+ AM/PM FORMULA (COLGAN INSTITUTE)
3770 MEN'S 50+ PM FORMULA (COLGAN INSTITUTE)
0266 METAPLEX
0357 METAVITE
0576 METHISHOL
3436 MEVANIN C
0156 MEYER VI CON-C
0068 MI-CEBRIN
0777 MI-CEBRIN T
0033 MICEBRIN DISTA
0359 MIDANEED
0535 MIGHTY VIT
0260 MILES
0042 MILES FLINTSTONES
0934 MILES LAB ONE A DAY PLUS IRON
3081 MILES WITHIN FOR WOMEN
3508 MILLTRIUM
0069 MINAQUIN (HUDSON)
3145 MINERAL COMPLEX (THOMPSON)
3418 MINERAL INSURANCE (BRONSON #12)
3706 MINI-MAX (KARUNA)
3653 MINI-PLEX (NATURE'S PLUS)
3580 MINVITES 33 (BOB LEE)
0554 MISSION
3060 MISSION CALCET PLUS
3061 MISSION COMPETE
3441 MISSION PRENATAL
3442 MISSION PRENATAL F.A.
3443 MISSION PRENATAL HP
3444 MISSION PRENATAL RX (PRENATAL VITAMINS AND MINS)
3440 MISSION SURGICAL SUPPLEMENT
0508 MITC
0070 MOL-IRON
0242 MONTCO
0220 MONTGOMERY WARD FIT
0071 MOORE GRAN M
0504 MOORMAN
3394 MORE
0628 MOTHER EARTH
0686 MS POWER
3601 MULTA GEN 12 + E CAPS
3174 MULTI - 75 (FOOD PLUS)

3357 MULTI ANTIOXIDANT, BRONSON (#74)
3595 MULTI II CAPS (SOLGAR)
3699 MULTI MEGA MINERALS (PURITAN PRIDE)
3369 MULTI MEGAMIN
3146 MULTI MINERAL COMPLEX (THOMPSON)
0317 MULTI MINERALS
0072 MULTI RDA
3666 MULTI-CENTRA
0496 MULTI-DARTRATE
0383 MULTI-DAY
3721 MULTI-MINERAL (NEW CHAPTER)
3661 MULTI-MINERAL (PURITAN PRIDE)
3756 MULTI-MINERALS (COUNTRY LIFE)
0671 MULTI-REN 12+E
3667 MULTI-THERA
3668 MULTI-THERA-M
0073 MULTI-VIT
0852 MULTI-VIT PLUS IRON
0763 MULTI-VITES FORMULA 47
0629 MULTICEBRIN (LILLY)
0232 MULTIDYN
0683 MULTILEX WITH MINERALS
3121 MULTIMAX (KAL)
3445 MULTIMINERAL (SOLGAR)
0392 MULTIPLENS
0991 MULTIPLEX
3743 MULTIPLEX 1 (TYLER)
3420 MULTIVIT AND MINERAL, CHEWABLE (BRONSON #70)
3210 MULTIVITAMIN & MINERALS (MEDIMART)
3757 MULTIVITAMIN (COUNTRY LIFE)
3099 MULTIVITAMIN AND MINERAL (OSCO)
3617 MULTIVITAMIN DROPS FOR INFANTS (BRONSON) (#20)
3100 MULTIVITAMIN W/ IRON (OSCO)
3115 MULTIVITAMINS & MINERALS FOR DIETERS (OSCO)
3113 MULTIVITAMINS & MINERALS FOR PEOPLE WHO DON'T EAT RIGHT (OSCO)
3112 MULTIVITAMINS & MINERALS FOR SENIORS (OSCO)
3114 MULTIVITAMINS & MINERALS FOR SMOKERS (OSCO)
3111 MULTIVITAMINS & MINERALS FOR TEENAGERS (OSCO)
3446 MULVIDEN F
3615 MUNCHABLES (PLUS)
0684 MVC-V-ESSENTIALS
3191 MY A MULTI (YOUR LIFE)
0255 MY-A-MULTI
0075 MYADEC (PARKER-DAVIS)
3164 MYAVITE (CVS)
0688 NATA COMP FA
0076 NATABEC
3509 NATABEC FA
3510 NATABEC RX
0561 NATAFORT
0077 NATALINS
3511 NATALINS RX
0325 NATIONAL

0977 NATIONAL HEADQUARTERS
0453 NATUR-PRACTIC
0630 NATURA
0803 NATURAL
0631 NATURAL BEAUTIFUL (FORDS)
0754 NATURAL BRAND
0879 NATURAL C 1000 W/ ROSE HIPS
0970 NATURAL COMPLETE (SCHIFF)
3193 NATURAL DAILY PAK (YOUR LIFE)
0079 NATURAL ESSENTIAL ORGANICS
0166 NATURAL ORGANIC (WINDMILL)
0913 NATURAL PURE-VITE
0080 NATURAL SALES (GNC)
1045 NATURAL SUPER MULTIPLE
1023 NATURAL SUPER VIT-A-DAY
0081 NATURAL VIOZYMIC
0082 NATURAL VIT. IC.
0782 NATURAL-GNA
0557 NATURALLY SLENDER
3396 NATURE BOUNTY STRESS 605
0203 NATURE FOOD CENTER
3346 NATURE FOOD CENTER MULTIPLE VITAMIN & MINERAL FORMULA 100
3341 NATURE FOOD CENTER MULTIPLE VITAMIN & MINERAL FORMULA 35
3340 NATURE FOOD CENTER MULTIPLE VITAMIN & MINERAL FORMULA 40
3343 NATURE FOOD CENTER MULTIPLE VITAMIN & MINERAL FORMULA 60
3344 NATURE FOOD CENTER MULTIPLE VITAMIN & MINERAL FORMULA 70
3345 NATURE FOOD CENTER MULTIPLE VITAMIN & MINERAL FORMULA 80
3342 NATURE FOOD CENTER MULTIPLE VITAMIN FORMULA 90
0189 NATURE FOOD CENTER ORGANEX
0083 NATURE MADE
3585 NATURE MADE B COMPLEX + C
3277 NATURE MADE CALCIUM PLUS
3472 NATURE MADE CENTURY VITE
3688 NATURE MADE ESSENTIAL BALANCE
3435 NATURE MADE MEGA 2000
3586 NATURE MADE THERAPEUTIC
0192 NATURE MOST
0829 NATURE STORE
0882 NATURE'S BEST
0485 NATURE'S BLEND
0252 NATURE'S BOUNTY
3087 NATURE'S BOUNTY 1 TABLETS
0953 NATURE'S BOUNTY STRESS 1000
0440 NATURE'S CONCEPT
0687 NATURE'S FINEST
0443 NATURE'S GARDEN
0555 NATURE'S LIFE
0632 NATURE'S PLUS
3652 NATURE'S PLUS ADULT MVM
3656 NATURE'S PLUS BABY-PLEX
3651 NATURE'S PLUS CHILDREN MVM
3657 NATURE'S PLUS DAY & NIGHT
0067 NATURE'S PLUS MEGA PLEX 75

3654 NATURE'S PLUS MEGA-MINS
3653 NATURE'S PLUS MINI-PLEX
3658 NATURE'S PLUS PILL-PLEX
0096 NATURE'S PLUS POWER PLEX
3655 NATURE'S PLUS PRENATAL COMPLEX
0857 NATURE'S PLUS ULTRA ONE
0155 NATURE'S PLUS VEGA PLEX
0084 NATURE'S SUNSHINE
0814 NATURE'S WAY
1036 NATURE'S WONDER
1041 NATURE-S GUARDIAN
0527 NATURITE
0906 NATURVITE (SOLGAR)
3596 NATURVITE POWDER (SOLGAR)
0633 NEO LIFE
0396 NEO-LIFEEE
0372 NEO-VADREN
3674 NEOLIFE FORM 4
3266 NEOLIFE STRESS 30 PAK
3512 NEOTABS
3377 NEPHROCAPS
3068 NESTABS FA, PRENATAL (FIELDING)
3728 NEW CHAPTER B-COMPLEX+EXTRA B12
3723 NEW CHAPTER EVERY MAN
3722 NEW CHAPTER EVERY WOMAN
3718 NEW CHAPTER LEAN BODY FACTORS
3717 NEW CHAPTER LIFE SHIELD
3720 NEW CHAPTER ONLY ONE
3727 NEW CHAPTER SKIN, HAIR AND NAIL FACTORS
3719 NEW CHAPTER STRESS SUPPORT
3724 NEW CHAPTER TINY TABS UNIFIED MULTIPLE
3726 NEW CHAPTER UNIFIED CALCIUM
3721 NEW CHAPTER UNIFIED MULTI-MINERAL
3725 NEW CHAPTER UNIFIED MULTIPLE+MINERAL
0887 NEW HY-VITE
3339 NIACIN
3513 NICOBID
0381 NIFEREX
3374 NIFEREX DAILY
3378 NIFEREX FORTE
3069 NIFEREX FORTE, PRENATAL (CENTRAL PHARMACY)
3375 NIFEREX PN FORTE
3379 NIFEREX-PN
3455 NIFREX 150 FORTE
3024 NIGHTTIME VITAMIN, WOMEN'S
9999 NON-VITAMIN
0256 NONAVITS
0634 NORLAC RX
3371 NOURISH NAIL
2034 NOURISHAIR
0690 NOVA
0246 NOVRONS
0278 NRTA

3070 NU-IRON-V (MAYRAND)
0085 NUPLEX (THOMPSON)
3690 NUSKIN IMAGE ESSENTIALS
3689 NUSKIN SHAPE ESSENTIALS
0689 NUTRI 200
3116 NUTRI- CMD
0455 NUTRI-HOMO
0087 NUTRI-MEGA
0352 NUTRI-PLUS
0295 NUTRI-SYSTEM
0479 NUTRI-TECH
0498 NUTRI-TIME
1003 NUTRI-VITAMIN
0695 NUTRIENTS BEST SUPER 35
0769 NUTRIENTS BEST,INC
3584 NUTRIFORT LIQUID (SOLGAR)
3130 NUTRILIFE (RICH LIFE)
0182 NUTRILITE (AMWAY)
0909 NUTRILITE DAILY
0831 NUTRILITE DOUBLE X
3363 NUTRIPLUS DAILY COMBO
0238 NUTRITINAL DYNAMICS
0088 NUTRITION HDQ (COMPLETE FORMULA #1)
1032 NUTRITION HEADQUARTERS
0054 NUTRITION HEADQUARTERS INC.HIGH-ONE
0320 NUTRITION HEADQUARTERS VM 33
3171 NUTRITION SQUARE MEGA ONE
0173 NUTRITION SQUARE SUPER 4
0130 NUTRITION SQUARE SUPERTRON
1006 NUTRITION SQUARE SUPERTRON HI-POTENCY W?MINERALS
0321 NUTRITION SQUARE UNIGEN
3602 NUTRITIONAL PACKETS FOR ACTIVE MEN (#144)-BRONSON
3083 NUTRITIONAL SPECIALITY GERIAVIT PHARMATON
3766 NUTRIVISION, BRONSON (#156)
0127 NUTRIXX
0766 OBESCO
3687 OCCUVITE
3729 OMEGA (ESSENTIAL ORGANICS)
3730 OMNI-PLEX TR (ESSENTIAL ORGANICS)
0377 OMNINATAL
0519 OMNIPLEX
0907 OMNITABS
0089 ONE A DAY
0755 ONE A DAY CORE C
0832 ONE A DAY ESSENTIAL
3300 ONE A DAY MAXIMUM FORMULA
0798 ONE A DAY STRESSGUARD
0807 ONE A DAY VIT + MIN
0871 ONE A DAY W/ ZINC
3188 ONE DAILY (YOUR LIFE)
3554 ONE DAILY + IRON, CALCIUM, ZINC (YOUR LIFE)
3246 ONE DAY W/ IRON (GOLDENSUN)
0108 ONE TAB DAILY (REXALL)

3117 ONE UP, FORMULA 200 (PLUS)
0757 ONE-A-DAY PLUS IRON
0168 ONE-ONLY
0925 ONE-ONLY PLUS IRON
0090 ONE-UP (PLUS)
3720 ONLY ONE (NEW CHAPTER)
0091 OPTILETS
0092 OPTILETS-M-500
3263 OPTISORB CALTRATE 600 WITH IRON & D
3042 OPTIVITE FOR WOMEN
3456 OREXIN
0189 ORGANEX (NATURE FOOD CENTER)
0313 ORGANIC THERA
0759 ORIGIN SUPER POT.
0384 OS-CAL
3571 OSCAL 500
3572 OSCAL 500 + D
0623 OSCAL FORTE MV PLUS M
3041 OSCAL PLUS (MARION)
2033 OSCO
3106 OSCO B W/ B12
3104 OSCO B W/ C
3105 OSCO B W/ C800
3109 OSCO DAILY VITAMIN PAK FOR ATHLETES
3108 OSCO DAILY VITAMIN PAK FOR MEN
3107 OSCO DAILY VITAMIN PAK FOR WOMEN
3457 OSCO HIGH POTENCY A - Z
3102 OSCO HIPOTENCY THERAPEUTIC M
3099 OSCO MULTIVITAMIN AND MINERAL
3100 OSCO MULTIVITAMIN W/ IRON
3115 OSCO MULTIVITAMINS & MINERALS FOR DIETERS.
3113 OSCO MULTIVITAMINS & MINERALS FOR PEOPLE WHO DON'T EAT RIGHT.
3112 OSCO MULTIVITAMINS & MINERALS FOR SENIORS
3114 OSCO MULTIVITAMINS & MINERALS FOR SMOKERS.
3111 OSCO MULTIVITAMINS & MINERALS FOR TEENAGERS
3458 OSCO MV + CALCIUM + IRON
3459 OSCO PRENATAL
3101 OSCO STRESS
3256 OSCO VITAMIN FOR EXERCISE
3103 OSCO ZINC WITH B,E,C
0760 OVA TABS
0191 OWEN THERAVITEM
3185 OWEN'S A & D PERLES
3184 OWEN'S B-PLEX A
0547 OWENS
3180 OXY - E 200 (KENMORE)
3097 OYSTER SHELL CALCIUM WITH D (WALT DELAND)
3315 PAK VITAMINS STRESS FORMULA (RICHLIFE)
0635 PALDADEC
0636 PAN-VM
0402 PANOVAL
0515 PARAMET
3354 PARAMETTES BASIC

3355 PARAMETTES COMPLETE VITAMIN AND MINERAL
0378 PARAVIMS
3078 PARKE DAVIS GERIPLEX-FS KAPSEALS
3077 PARKE DAVIS THERA-COMBEX H-P
0075 PARKER DAVIS MYADEC
0174 PARKER-DAVIS FAMILY VITS.
3555 PARNATAL RX
0204 PATHMARK
0868 PATHMARK MULTI VIT W/ IRON
0877 PATHMARK STRESS
0963 PATHMARK SUPER DAILY
0990 PATHMARK THERA PLUS M
0946 PATTON'S HI-POTENCY
0542 PAY N' SAVE
0093 PAYLESS DRUG
3629 PEAK 75 (BOB LEE)
3760 PEAK PERFORMANCE FORMULA (#170) (BRONSON)
0482 PENTA STRESS
0094 PEOPLES DRUG STORE BRAND MULTI-VIT
3052 PERIHEMIN HEMATINIC CAPSULE (LEDERLE)
0290 PERITINIC
0637 PERREGO
0387 PERRY'S
3563 PERSONAL RADICAL SHIELD
1040 PETERSON
0400 PFIZER
0312 PHARMACITY
0901 PHARMACY SERVICE MULTIVITS W/ IRON
3218 PHASE IV, A-Z, MULTIVITAMINS & MINERALS (HALL)
0354 PIC-N-SAVE
1017 PILGRIM PRIDE VIT + MIN
3658 PILL-PLEX (NATURE'S PLUS)
0928 PLAINS PHARMACY
1034 PLUS
3050 PLUS 72A
0031 PLUS DIETARY FOOD SUPPLEMENT
0986 PLUS FORMULA
3117 PLUS FORMULA 200-ONE UP
3614 PLUS HIGH POTENCY HIGH PLAN-TWO
3615 PLUS MUNCHABLES
0090 PLUS ONE-UP
3613 PLUS SUPER POTENCY MULTIVITAMIN AND MINERAL SUPPLEMENT(#198)
3616 PLUS VITAMIN SYRUP FOR CHILDREN
0095 PLUS-FORMULA 74A
3514 PMS (GNC)
3086 PMS (MARLYN)
3515 PMS (SOLGAR)
3122 PMS FORMULA (KAL)
3460 POLY VI FLOR + IRON
3671 POLY VI SOL DROPS (INFANTS)
3672 POLY VI SOL DROPS + IRON
0860 POLY-VI-FLOR
3049 POLY-VI-SOL PLUS IRON AND ZINC

0376 POLY-VI-SOL(CHILDREN'S)
3365 POSTURE D
0361 POTENT VITS
0096 POWER PLEX (NATURE'S PLUS)
0979 POWER-VITE
3527 PR PAK RICHLIFE
0691 PRAMET FA
0097 PRAMILET FA FILMTABS (ROSS)
3749 PRE-MENSES (COUNTRY LIFE)
3619 PRE-TEEN PLEX (THOMPSON)
3247 PREMENSTRUAL VITAMIN FORMULA (GOLDENSUN)
3275 PRENATAL (BRONSON #19)
3223 PRENATAL (HALL)
3516 PRENATAL (SCHEIN)
3170 PRENATAL (SOLOTRON)
3762 PRENATAL 2, BRONSON (#155)
3655 PRENATAL COMPLEX (NATURE'S PLUS)
3128 PRENATAL FORMULA (RICH LIFE)
3144 PRENATAL FORMULA (THOMPSON)
3125 PRENATAL PAK (RICH LIFE)
3530 PRENATAL PLUS RUGBY
3531 PRENATAL RX (RUGBY)
3761 PRENATAL, BRONSON, CHEWABLE (#173)
3441 PRENATAL, MISSION
3528 PRENATALS (RICHLIFE)
3714 PRENATALS (SOLGAR)
3067 PRENATE 90 (BOCK)
3587 PRENAVITE (RUGBY)
3517 PRENAVITE USA
1007 PRESCOTT
0099 PREVENTAID
0100 PREVENTRON GNC
0888 PREVENTRON W/ MINERALS
0165 PRICE CHOPPER
0568 PRIME
0285 PRIVATE
0101 PROBEC T
0638 PROCADS
3754 PROSTA-MAX (COUNTRY LIFE)
0523 PROVITA
0512 PUBLIX
3134 PURELY VITAMINS (RICH LIFE)
0102 PURITAN
3660 PURITAN PRIDE CHELATED MULTIPLE MINERALS
3694 PURITAN PRIDE CHILDREN'S CHEWABLE VITAMIN
3662 PURITAN PRIDE GERI-PRIDE
3698 PURITAN PRIDE GERIATRIC
3663 PURITAN PRIDE HI-POTENCY VITA-MIN FORMULA
3703 PURITAN PRIDE MEGA VITA GELS
3664 PURITAN PRIDE MEGA-VITA-MIN
3699 PURITAN PRIDE MULTI MEGA MINERALS
3661 PURITAN PRIDE MULTI-MINERAL
3659 PURITAN PRIDE ONE

3696 PURITAN PRIDE PURITRON
3695 PURITAN PRIDE SOLOVITES
3700 PURITAN PRIDE SUPER CHELATED MULTI MINERAL
3697 PURITAN PRIDE THERAVIM-M
1024 PURITAN PRIDE ULTRA VIT MIN
3701 PURITAN PRIDE VITALITY 21
0103 PURITAN'S PRIDE
3696 PURITRON (PURITAN PRIDE)
0845 QUALITY
3707 QUANTUM SEE
0448 QUEST
3518 QUICK PICK UP (COUNTRY LIFE)
0314 QUINTABS
3281 QUINTREM (TREASURY)
0548 RADANT
0104 RADIANCE
0692 RAGUS
0415 RALEYS
0105 RALPH'S
0433 RAWLEIGH
0430 RDA
3268 RDA + FE (AARP)
0106 REA & DERRICK
0373 READS
0347 REAVITA
3073 REID-ROWELL ZENATE PRENATAL
0107 REVCO
3407 REVCO ANIMAL FRIENDS
0899 REXALL
0109 REXALL - SUPER PLENAMINS
0847 REXALL MULTIVITE PLUS IRON
0918 REXALL STRESS TABS
0816 REXALL-MULTIVITE
0108 REXALL-ONE TAB DAILY
0193 RIBOMINS
3124 RICH LIFE BONE PAK
3133 RICH LIFE CALCIUM MALTIES (C,D,PH,MG)
3137 RICH LIFE CHILDREN'S VITAMIN AND MINERALS
3135 RICH LIFE FOR ATHLETES ONLY
3126 RICH LIFE HIPOTENCY MULTIVITAMIN AND MINERALS
3139 RICH LIFE HIPOTENCY VITAMIN PAK
3131 RICH LIFE MEGA II
3132 RICH LIFE MEGA ONE
3127 RICH LIFE MEGA PLUS
3130 RICH LIFE NUTRILIFE
3128 RICH LIFE PRENATAL FORMULA
3125 RICH LIFE PRENATAL PAK
3134 RICH LIFE PURELY VITAMINS
3123 RICH LIFE STRESS
3136 RICH LIFE SUPER ONE
3129 RICH LIFE VEGETARIAN FORMULA
3138 RICH LIFE WOMEN POWER
0222 RICHARDS

0640 RICHEIFER VEG. FORM.
0110 RICHLIFE (SUPER ONE DAILY)
3519 RICHLIFE ADULT CHEWABLE MVM
3520 RICHLIFE AEROBIC PAK
3521 RICHLIFE AL PAK
3522 RICHLIFE AR PAK
3523 RICHLIFE ATHLETIC PAK
3449 RICHLIFE BASIC ONE
3524 RICHLIFE DERMA PAK
3525 RICHLIFE DIETERS PAK
3337 RICHLIFE HIGH POTENCY MULTIMINERAL
3526 RICHLIFE MEGA PAK
3315 RICHLIFE PAK VITAMINS STRESS FORMULA
3527 RICHLIFE PR PAK
3528 RICHLIFE PRENATALS
3529 RICHLIFE SUPER ATHLETIC PAK
3551 RICHLIFE WOMEN POWER PAK
0111 RITE AID
0894 RITE AID B & C COMPLEX
3015 RITE AID MULTIVIT + IRON
0799 RITE AID NATURAL
0007 ROBBINS ALLBEE + C CAPLETS
0008 ROBBINS ALLBEE C-800
0643 ROBRAMIN
3681 ROCHE
3680 ROCHE + FE
0470 ROGER MACDOUGALL
0642 RONSON
0097 ROSS PRAMILET FA FILMTABS
0223 ROTHCO HI POTENCY
0379 ROWELL
1021 ROWELL ALBE VIO-GERIC
0113 RUBGY-THEREMS
0112 RUGBY
3350 RUGBY HIGH VITAMINS + MINERALS
3530 RUGBY PRENATAL PLUS
3531 RUGBY PRENATAL RX
3587 RUGBY PRENAVITE
3335 RUGBY SUPER POTENCY COMPREHENSIVE FORMULA
0819 RUGBY SUPRA-TAL
3543 RUGBY ULTRA HI B COMPLEX
0881 RUGBY UNICOMPLEX
0973 RUGBY UNICOMPLEX M
3547 RUGBY VI STRESS + ZINC
3148 RUNNER FORMULA (THOMPSON)
0386 RUNNERS
0644 RVP
0886 RYBUTOL
0331 RYUTOL NAT.
0114 SAFEWAY
0276 SANASEE
3398 SANASOL
0645 SATTLER'S

3059 SAVAGE CHROMAGEN-OB
0115 SAVON
0429 SAWALLS
3516 SCHEIN PRENATAL
0859 SCHEIN TOTA VITE
0797 SCHIFF
3205 SCHIFF B COMPLEX
3206 SCHIFF B GUARD
3569 SCHIFF BONE-ALL
0349 SCHIFF DOLOMITE
0116 SCHIFF DOUBLE DAY
3204 SCHIFF DOUBLE DAY JUNIOR
3208 SCHIFF HI - B COMPLEX
3201 SCHIFF MEGA HIGH II
0970 SCHIFF NATURAL COMPLETE
3055 SCHIFF SINGLE DAY
3207 SCHIFF SUPER B COMPLEX
3316 SCHIFF SUPER MINERAL
3532 SCHIFF V COMPLETE
3202 SCHIFF VEGETARIAN MULTIPLE
3205 SCHIFF WHOLE RICE B COMPLEX
3359 SCOOBY DOO + C
3352 SCOOBY DOO + IRON
0212 SEARS
3388 SEARS SUPER G VITAMIN IMPROVEMENT PROGRAM
0902 SEARS SUPER KAPS W/ MINERALS
0401 SEBOL
3162 SENIOR'S CHOICE (CVS)
3192 SENIOR'S CHOICE (YOUR LIFE)
3475 SENIORITY, COUNTRY LIFE
0420 SENTRAGRAN
3385 SENTRAL VITE
0502 SEROYAL
0117 SHAKLEE
3677 SHAKLEE CHILDRENS
0980 SHAKLEE VIT-CAL
3631 SHAKLEE VITA CAL PLUS IRON
0764 SHAKLEE VITALEAS
3689 SHAPE ESSENTIALS (NUSKIN)
0571 SHEIN
3262 SHELL CALCIUM WITH D (CVS)
0457 SHERATON
0118 SHERMAN'S
0368 SHERRAY QUOTAB
0119 SHOP RITE
1015 SHOP RITE EXTRA HIGH POTENCY
3014 SHOP RITE MULTIVIT + MINERALS
0989 SHOP RITE PLUS IRON
0822 SHOP RITE STRESS C-600 W/ZINC
0961 SHOP RITE STRESS C600
0170 SIG TAB (PRESCRIPTION)
0810 SIMIRON PLUS
0556 SIMRON C

3055 SINGLE DAY (SCHIFF)
0421 SKAGGS
0500 SKILLERN'S
3727 SKIN, HAIR AND NAIL FACTORS (NEW CHAPTER)
0351 SKY LINE
0765 SKY LINE ONE A DAY PLUS IRON
0456 SLENDER NOW
0646 SLIM AGAIN
0303 SNYDER
3560 SOFT GEL MULTIVITAMIN (THOMPSON)
3533 SOLAMINS (SOLGAR)
1014 SOLGAR
3450 SOLGAR B COMPLEX + C STRESS FORMULA
3412 SOLGAR B COMPLEX STRESS, NATURAL
3409 SOLGAR B-50
3410 SOLGAR B-60
3473 SOLGAR CIPLEX
3118 SOLGAR DAILY GOLD PACK
3708 SOLGAR EARTH SOURCE
3712 SOLGAR ESTER-C PLUS MULTIMINERAL [CALCIUM, MG, K, ZINC]
3710 SOLGAR EXTER-C PLUS [CALCIUM, MG, K ZINC]
3711 SOLGAR EXTRA-POTENCY ESTER-C PLUS [CALCIUM, MG, K ZINC]
3713 SOLGAR FORMULA VM-2000
3430 SOLGAR FULL SPECTRUM CALCIUM SOFTGELS (HI POTENCY MULTIMIN)
3501 SOLGAR HEMATINIC
3503 SOLGAR HY BIO
0616 SOLGAR JOGGERS
3716 SOLGAR MEGASORB B-COMPLEX 50
3595 SOLGAR MULTI II CAPS
3445 SOLGAR MULTI MINERAL
1038 SOLGAR MULTIPLE 75
0906 SOLGAR NATURVITE
3596 SOLGAR NATURVITE POWDER
3584 SOLGAR NUTRIFORT LIQUID
3515 SOLGAR PMS
3714 SOLGAR PRENATALS
3533 SOLGAR SOLAMINS
0121 SOLGAR SOLOVITE
0129 SOLGAR SUPER PLEX TABS
3465 SOLGAR TRACE MINERALS
3709 SOLGAR ULTIMATE B+C COMPLEX
0152 SOLGAR UNIVITE TABLETS
3715 SOLGAR VITA-KID WAFERS
3549 SOLGAR VITAMIN ONLY
3550 SOLGAR VITAREX
0120 SOLGAR VM 75
3468 SOLGAR ZINC DAILY
0221 SOLOTRON
3370 SOLOTRON FOR WOMEN
3534 SOLOTRON JR + MINERALS
3170 SOLOTRON PRENATAL
3169 SOLOTRON WOMEN'S FORMULA (GNC)
0121 SOLOVITE (SOLGAR)

3695 SOLOVITES (PURITAN PRIDE)
0694 SOS CENTRAL
3031 SPARTUS (LEDERLE)
3088 SPARTUS PLUS IRON (LEDERLE)
3166 SPECTRAVITE (CVS)
3176 SPECTROVITE (FOOD PLUS)
1031 SPECTRUM
0668 SPEN-O-LET M
0647 SPENCER
0340 SPIRTS
3741 SPORTS FORMULA (MEGA FOOD)
3168 SQUIBB THERAGRAN - STRESS FORMULA
0138 SQUIBB THERAGRAN M
0194 STAFF
0310 STANDARD
0772 STANDARD PROCESS
0123 STAR
0809 STAR IDE
0971 STAR SUPERVITE
0889 STAR-TAB W/ IRON
0771 STOP $ SHOP STRESS
0188 STOP & SHOP
0938 STOP & SHOP W/ IRON
3226 STRESS & IRON (HALL)
3227 STRESS & ZINC (HALL)
3212 STRESS (MEDIMART)
3101 STRESS (OSCO)
3123 STRESS (RICH LIFE)
3157 STRESS (THOMPSON)
3397 STRESS + CALCIUM
3642 STRESS + FE (AARP 362)
3505 STRESS 1 (KAL)
3266 STRESS 30 PAK (NEOLIFE)
3540 STRESS 600, HI POTENCY (THOMPSON)
3396 STRESS 605, NATURE BOUNTY
0786 STRESS CAP W/IRON
0956 STRESS CAPS
3314 STRESS COMPLETE SOFT (THOMPSON)
0885 STRESS FORMULA
3641 STRESS FORMULA (AARP360)
3225 STRESS FORMULA (HALL)
0835 STRESS FORMULA (K-MART)
3195 STRESS FORMULA (YOUR LIFE)
3535 STRESS FORMULA GNC
0853 STRESS FORMULA PLUS IRON
3196 STRESS FORMULA W/ IRON (YOUR LIFE)
3197 STRESS FORMULA W/ ZINC (YOUR LIFE)
0758 STRESS GUARD
0648 STRESS LIFE
1029 STRESS LIFE PLUS IRON
3489 STRESS M (COUNTRY LIFE)
3264 STRESS PAK (CVS)
3553 STRESS PAK (YOUR LIFE)

1005 STRESS PLUS E
3091 STRESS PLUS WITH IRON (BEMINAL)
3092 STRESS PLUS WITH ZINC (BEMINAL)
3719 STRESS SUPPORT (NEW CHAPTER)
0804 STRESS TABS
3312 STRESS TABS 600 & IRON
1010 STRESS TABS 600 (LEDERLE)
3536 STRESS TABS 600 ADVANCED
0779 STRESS TABS 600 W/ZINC
0850 STRESS TABS HI-POTENCY
0898 STRESS TABS W/ IRON
0818 STRESS TABS W/MINERALS
0778 STRESS TABS W/ZINC
0808 STRESS TABS WITH ZINC (LEDERLE)
0770 STRESS VITAMINS
3537 STRESS VITAPAK (GNC)
0864 STRESS W/ C600
3214 STRESS W/ ZINC (MEDIMART)
3386 STRESS ZINC + IRON
0693 STRESS-O-VITE
0976 STRESS-O-VITE (GNC)
0126 STUART FORMULA
0780 STUART NATALS 1+1
3461 STUART PRENATAL
0284 STUARTINIC
0127 STUR DEE
0696 SUBSTANCE II
3265 SUBSTANCE II PERSONAL DAILY VITAMIN PAK
0566 SUFAH C
0391 SUN ALL DAY
0346 SUN BRAND
0214 SUNASU
0884 SUNBURST
0843 SUNDOWN MAXI-MEGA VITE '75'
3559 SUNDOWN MULTIPLE WITH IRON AND BETA CAROTENE
0128 SUNDOWN VITS.
3593 SUNKIST (CHILDREN'S)
3464 SUNKIST + EXTRA C (CHILDREN'S)
3463 SUNKIST + IRON (CHILDREN'S)
3403 SUNKIST COMPLETE WITH IRON + MINERALS
0695 SUPER 35 (NUTRIENTS BEST)
0173 SUPER 4 NUTRITION SQUARE
0218 SUPER 40 (ABUNDOVITA)
3765 SUPER ANTIOXIDANT,BRONSON (#154)
3529 SUPER ATHLETIC PAK (RICHLIFE)
3051 SUPER AYTINAL, WALGREEN'S
0324 SUPER B
3640 SUPER B + C (AARP 104)
3423 SUPER B BRONSON (#6)
3243 SUPER B COMPLEX (GOLDENSUN)
3207 SUPER B COMPLEX (SCHIFF)
0160 SUPER B COMPLEX (WALGREEN)
0202 SUPER B-100 (SUPERIOR HEALTH)

3181 SUPER C AND E (KENMORE)
3235 SUPER CALCICAPS
3700 SUPER CHELATED MULTI MINERAL (PURITAN PRIDE)
3439 SUPER CITRACAL
0262 SUPER DRUG
0564 SUPER G
3388 SUPER G VITAMIN IMPROVEMENT PROGRAM, SEARS
3141 SUPER GRAM II (ALACER)
3142 SUPER GRAM III (ALACER)
0649 SUPER HI-POT.
0902 SUPER KAPS W/MINERALS (SEARS)
0812 SUPER M STORE MULTIVIT & IRON
3150 SUPER MAXI (THOMPSON)
3147 SUPER MAXICAPS (THOMPSON)
3316 SUPER MINERAL (SCHIFF)
3239 SUPER MINERAL COMPLEX (GOLDENSUN)
0362 SUPER MOX
0299 SUPER NATIONAL
3356 SUPER ONCE A DAY
3136 SUPER ONE (RICH LIFE)
0110 SUPER ONE DAILY (RICHLIFE)
0109 SUPER PLENAMINS (REXALL)
3335 SUPER POTENCY COMPREHENSIVE FORMULA (RUGBY)
3491 SUPER POTENCY MULTI 100 (COUNTRY LIFE)
3237 SUPER PRO-VITE MULTIVITAMINS & MINERALS (GOLDENSUN)
3030 SUPER STRESS 1000
0544 SUPER T
3151 SUPER VITAPLEX (THOMPSON)
0924 SUPER VM
0132 SUPER X (GNC)
0129 SUPER-PLEX TABS. (SOLGAR)
3733 SUPER-VITES (ESSENTIAL ORGANICS)
3395 SUPEREX MVM + ZINC
0202 SUPERIOR HEALTH (SUPER B-100)
0130 SUPERTRON (NUTRITION SQUARE)
1006 SUPERTRON HI-POTENCY W/MINERALS (NUTRITION SQUARE)
0131 SUPERVITE 75 (WILLNER)
3043 SUPREME II
0133 SURBEX (ABBOTT)
0135 SURBEX 750 WITH IRON (ABBOTT)
3089 SURBEX 750 WITH ZINC
0855 SURBEX STRESS W/ ZINC
0134 SURBEX T (ABBOTT)
0891 SURBEX W/ VIT C
1000 SWEET LIFE
0572 SYNERGY PLUS
0413 T & M
3627 T FORMULA M (FEDCO)
3291 T.D. MINOVITE
0697 TAB-A-DAY WITH IRON
1046 TABARD MULTI VITS
0228 TABRON
3477 TALL TREE (COUNTRY LIFE)

0541 TARGET
3567 TEEN-PLEX (THOMPSON)
1004 TEFOL
3400 TELCO MV
3401 TELCO MV FOR CHILDREN
0248 THAYER
0911 THAYER MULTI VIT W/ IRON & E
0752 THER BEE CEE
3236 THERA - M (GOLDENSUN)
0669 THERA BASIC
0198 THERA COMBEX
0870 THERA COMP VIT & MIN
0844 THERA GUILD M
0948 THERA HI-POTENCY FORMULA
0944 THERA M (CVS)
3538 THERA MILL
3539 THERA MILL M
0650 THERA MIN
0651 THERA VIT
0947 THERA-AMCAPS M
0753 THERA-BEC
3077 THERA-COMBEX H-P (PARKE DAVIS)
0698 THERA-GARDS
0141 THERA-M-VITS (CALDOR)
0940 THERABAL M
0531 THERABID
3578 THERACEBRIN PULVULES
3630 THERADAY (BOB LEE)
0136 THERADEC
1028 THERADEX M
3592 THERAGRAM LIQUID
0137 THERAGRAN (SQUIBB)
3168 THERAGRAN -STRESS FORMULA (SQUIBB)
0826 THERAGRAN HEMATINIC
3406 THERAGRAN JR + EXTRA C
0138 THERAGRAN-M (SQUIBB)
0230 THERAGRAN-Z
0463 THERAMEAD
2029 THERAMIN MINERAL
0139 THERAPAX L0
0271 THERAPEUTIC
0652 THERAPEUTIC M
3272 THERAPEUTIC (BRONSON #2)
3586 THERAPEUTIC (NATURE MADE)
3224 THERAPEUTIC FORMULA (HALL)
3599 THERAPEUTIC M (GOLD SEAL)
3693 THERAPEUTIC MULTIVIT AND MINERALS (BROEMMEL'S)
3005 THERAPEUTIC-M (MEDIMART)
0954 THERAPHEM-M
3165 THERAPLUS (CVS)
3187 THERAPLUS (YOUR LIFE)
3576 THERAVEE
0140 THERAVIM (HUDSON)

3697 THERAVIM-M (PURITAN PRIDE)
0817 THERAVITE
0191 THERAVITEM (OWEN)
0446 THEREMS
0958 THEREMS M
0272 THEREX
3261 THERIN (FOOD PLUS)
0327 THERIN PLUS
3179 THERIN PLUS (FOOD PLUS)
0348 THEROVIT
0964 THEROVITE-M
0939 THERPAX 25 W/ MINERALS
0460 THEX FORTE
0277 THIHEMIC
0142 THOMPSON
0983 THOMPSON ADULT-PLEX
3156 THOMPSON B W/ C
3154 THOMPSON B-50
3155 THOMPSON B-75
3618 THOMPSON BABY VITAPLEX
3541 THOMPSON CALCIUM, MAGNESIUM, ZINC
3149 THOMPSON COACHES FORMULA
3045 THOMPSON DAPLEX
3621 THOMPSON EX-PO 36
3540 THOMPSON HI POTENCY STRESS 600
3152 THOMPSON HYPO - 50
3620 THOMPSON MAXIMUM 1 & 2
3153 THOMPSON MAXIPLEX
0827 THOMPSON MEGA 80
3145 THOMPSON MINERAL COMPLEX
3146 THOMPSON MULTI MINERAL COMPLEX
3623 THOMPSON MULTIVITAMIN AND MINERAL
3624 THOMPSON MULTIVITAMIN AND MINERAL SOFT CAPS
0085 THOMPSON NUPLEX
3619 THOMPSON PRE-TEEN PLEX
3144 THOMPSON PRENATAL FORMULA
3148 THOMPSON RUNNER FORMULA
3560 THOMPSON SOFT GEL MULTIVITAMIN
3157 THOMPSON STRESS
3314 THOMPSON STRESS COMPLETE SOFT
3150 THOMPSON SUPER MAXI
3147 THOMPSON SUPER MAXICAPS
3151 THOMPSON SUPER VITAPLEX
3567 THOMPSON TEEN-PLEX
3622 THOMPSON VEGETARIAN VITAPLEX
0789 THOMPSON VITAPLEX
0869 THREE-P PRODUCTS
0143 THRIFT DRUG
0475 THRIFTY
3751 THYRO-MAX SUPPORT (COUNTRY LIFE)
0890 TIME RELEASE ULTRA MEGA
3408 TIME RELEASED B COMPLEX + C + E (BRONSON)
3253 TIME RELEASED HIPOTENCY MULTIVIT & MINERAL (YOUR LIFE)

3724 TINY TABS UNIFIED MULTIPLE (NEW CHAPTER)
3240 TODAY'S WOMEN EXTRA STRENGTH DAILY (GOLDENSUN)
0265 TOP B
0184 TOPCO
3490 TOTAL 2 CAPS (COUNTRY LIFE)
3071 TOTAL FORMULA (VITALINE)
0813 TOTAL IMAGE ULTRA DIET
0431 TOTAL LIFE
3758 TOTAL MINS COMPLEX (COUNTRY LIFE)
3381 TOTOL FORMULA
0653 TOWN PRIDE
3465 TRACE MINERALS (SOLGAR)
0501 TRADER DARWIN'S
3748 TRAVELERS SUPPORT (COUNTRY LIFE)
0144 TREASURY
3399 TREASURY DRUG CHILDREN'S
3281 TREASURY QUINTREM
0490 TRI LIPOID
3080 TRI-B PLEX (ANABOLIC)
3338 TRI-VI-FLOR
3347 TRI-VI-SOL
0231 TRINSICON
0654 TRIPLE POTENCY B12
3338 TRIVIFLOR
3466 TRIVISOL LIQUID + IRON
3588 TROPHITE
1008 TRUGANIC
3557 TWIN LAB DAILY ONE CAP WITH BETA CAROTENE
3684 TWIN LAB DUAL
0145 TWO GUYS HARRISON
3743 TYLER MULTIPLEX 1
2027 U.S. CHEM MEDI-PLEX
0539 U.S. HEALTH CLUB
3075 U.S. PHARMACY MEDIPLEX
0154 U.S.A.
3709 ULTIMATE B+C COMPLEX (SOLGAR)
0569 ULTIMS
0364 ULTRA 75
2035 ULTRA B
3542 ULTRA B 100
3467 ULTRA B-100
0207 ULTRA B-50 (HUDSON)
3543 ULTRA HI B COMPLEX (RUGBY)
3292 ULTRA MAX 42
0146 ULTRA MED
1001 ULTRA MEGA (GNC)
0302 ULTRA PLEX
0968 ULTRA TWO
1024 ULTRA VIT MIN (PURITAN PRIDE)
3007 ULTRA VITA TIME
0655 ULTRAVIT
0484 UNI-MULT
0336 UNIBON

3702 UNICAP CAPSULES (UPJOHN)
3003 UNICAP CHEWABLE (CHILDREN'S)
0149 UNICAP MINERALS (UPJOHN)
2036 UNICAP SENIOR (UPJOHN)
0150 UNICAP T (OR UNICAP THERAPEUTIC)
0148 UNICAP TABLETS (UPJOHN)
0756 UNICAP W/IRON
0480 UNICOMPLEX
3544 UNICOMPLEX M
0151 UNIDAY
3726 UNIFIED CALCIUM (NEW CHAPTER)
3725 UNIFIED MULTIPLE+MINERAL (NEW CHAPTER)
0374 UNIGARD
0321 UNIGEN (NUTRITION SQUARE)
0300 UNION
0332 UNIPLEX
0152 UNIVITE TABLETS (SOLGAR)
0656 UPJOHN
0148 UPJOHN UNICAP
3702 UPJOHN UNICAP CAPSULES
0149 UPJOHN UNICAP MINERALS
2036 UPJOHN UNICAP SENIOR
0164 UPJOHN ZYMACAP
0405 V - COMPLETE
3076 V-DAYLIN MULTIVITAMIN
3731 V-PLEX (ESSENTIAL ORGANICS)
0468 VALU-RITE
0837 VALUTIME
0439 VANCE
0155 VEGA-PLEX (NATURE'S PLUS)
3129 VEGETARIAN FORMULA (RICH LIFE)
3119 VEGETARIAN MULTIPLE (KAL)
3202 VEGETARIAN MULTIPLE (SCHIFF)
3622 VEGETARIAN VITAPLEX (THOMPSON)
0234 VEGETRATE
0657 VENUS
0514 VENUS NATURVITE
0356 VERABEE W/C
3072 VG CAPSULES (MEDICAL PRODUCTS)
0530 VI
3546 VI AQUA
0254 VI CAL
0156 VI CON-C (MEYER)
0454 VI DAY-LIN
3547 VI STRESS + ZINC (RUGBY)
0658 VIBRANCY
0307 VIBRANT HEALTH
3228 VICK'S LIFESTAGE FOR CHILDREN
3230 VICK'S LIFESTAGE FOR MEN
3229 VICK'S LIFESTAGE FOR TEEN'S
3038 VICK'S LIFESTAGE FOR WOMEN
3232 VICK'S LIFESTAGE STRESS FOR MEN
3231 VICK'S LIFESTAGE STRESS FOR WOMEN

2030 VICON FORTE (GLAXO)
2031 VICON PLUS (GLAXO)
0972 VICON W/ IRON
3351 VIDAYLIN + IRON
3669 VIDAYLIN DROPS
3670 VIDAYLIN DROPS + IRON
0179 VIGRAN
0962 VIGRAN + IRON
0245 VIMAGNA
0666 VIO BEC WITH C
1021 VIO-GERIC (ROWELL ALBE)
0388 VIO-ZYMIC
0157 VIODAY (HUDSON)
0941 VIODAY + IRON (HUDSON)
0549 VIOLINE
0494 VIP
1033 VIT-MIN 75
0520 VITA 75
0497 VITA BEE
3631 VITA CAL PLUS IRON (SHAKLEE)
0178 VITA FRESH
0945 VITA FRESH STRESS
0796 VITA FRESH W/IRON
0345 VITA H
0659 VITA LIFE
0333 VITA LIME
0988 VITA PERLES
0573 VITA PRIDE
0158 VITA SLIM
0545 VITA TIME
0903 VITA-FRESH STRESS W/ IRON
3715 VITA-KID WAFERS (SOLGAR)
3548 VITABANK
0878 VITAJOY
0521 VITAL
0764 VITALEAS (SHAKLEE)
3063 VITALINE ENVIRO STRESS, ZINC & SELENIUM
3071 VITALINE TOTAL FORMULA
3701 VITALITY 21 (PURITAN PRIDE)
3273 VITAMIN & MINERAL FORMULA (#3) (BRONSON)
3098 VITAMIN A & D (WALT DELAND)
3058 VITAMIN AND MINERAL INSURANCE FORMULA (BRONSON #1)
3759 VITAMIN AND MINERAL POWDER SUPPLEMENT (BRONSON) (#151)
3256 VITAMIN FOR EXERCISE (OSCO)
3358 VITAMIN FOR WOMEN OVER 40
3558 VITAMIN IMPROVEMENT PROGRAM
3053 VITAMIN INSURANCE FORMULA (BRONSON #82)
3549 VITAMIN ONLY (SOLGAR)
0298 VITAMIN POWER
0274 VITAMIN QUOTA
0292 VITAMIN SPECIALTIES
3616 VITAMIN SYRUP FOR CHILDREN (PLUS)
0288 VITAMINERALS

3767 VITAMINS A, C, E WITH BETA CAROTENE, BRONSON (#23)
0789 VITAPLEX (THOMPSON)
3550 VITAREX MULTIVITAMIN/MINERAL (SOLGAR)
0660 VITAREY
0236 VITARINE
3395 VITAWORTH SUPEREX MVM + ZINC
0323 VITE FERROWS
0279 VITERRA
0536 VITION C
0967 VITRINS
3029 VITRON-C
0525 VIVA MAX
0699 VIZAC
0320 VM 33 (NUTRITION HEADQUARTERS)
0120 VM 75 (SOLGAR)
0661 VM NUTRI (33)
3713 VM-2000 (SOLGAR)
0495 VONS STRESS
3678 W.L.C. SERVICE MVM
0908 WALD
0931 WALDBAUM'S HIPOTENCY
0159 WALGREEN
3276 WALGREEN GOLD SEAL
0160 WALGREEN SUPER B COMPLEX
3051 WALGREEN'S SUPER AYTINAL
0161 WALLACE
3260 WALT DELAND BONE MEAL WITH VITAMINS A & D
3096 WALT DELAND HIPOTENCY MULTIVITAMIN & MINERAL
3097 WALT DELAND OYSTER SHELL CALCIUM WITH D
3098 WALT DELAND VITAMIN A & D
3320 WALT DELAND'S TR HIPOTENCY MUM
0662 WARD FORMULA 16
0458 WARDS
0825 WATKINS
0767 WEGMAN'S
0257 WEIGHT LOSS CLINIC
3013 WEIGHT LOSS CLINIC VIT + MINERAL
3033 WEIGHT LOSS VITAMIN (NO SPECIFIC BRAND)
0489 WHEATA-VIMS
0338 WHEATAVIMS
0663 WHITEAID MULTIPLE
3205 WHOLE RICE B COMPLEX (SCHIFF)
0437 WHOLESALE NUT. CLUB
0395 WIDMAN
0131 WILLNER SUPERVITE 75
0341 WILLVITE
0166 WINDMILL - NATURAL ORGANIC
0175 WINDMILL HI-POTENCY
0776 WINDMILL STRESS W/IRON
3392 WITHIN CALCIUM IRON ZINC
3081 WITHIN FOR WOMEN (MILES)
3138 WOMEN POWER (RICH LIFE)
3552 WOMEN POWER PAK (GNC)

3551 WOMEN POWER PAK (RICHLIFE)
3044 WOMEN'S FORMULA (BRONSON #9)
3169 WOMEN'S FORMULA (SOLOTRON-GNC)
3023 WOMEN'S VITAMIN DAYTIME
3772 WOMEN'S VITAMIN DAYTIME/NIGHTTIME FORMULA
3024 WOMEN'S VITAMIN NIGHTTIME
0363 WONDEROLA PLUS
0783 WORLD OF NATURE
3575 WUN-A-VIT
0975 X-NATURAL
0297 YOUR LIFE
3251 YOUR LIFE 50 & PAK
3199 YOUR LIFE B-100
3200 YOUR LIFE B-150
3198 YOUR LIFE B-50
3189 YOUR LIFE CALCIUM & D
3186 YOUR LIFE CENTRAVITE
3366 YOUR LIFE CHOLESTEROL PAK
3190 YOUR LIFE COMPETITION PAK
3250 YOUR LIFE DAILY PAK FOR MEN
3249 YOUR LIFE DAILY PAK FOR WOMEN
3252 YOUR LIFE HIPOTENCY MULTIVIT & MINERAL SUPPLEMENT
3194 YOUR LIFE MAXIMUM CHOICE
3248 YOUR LIFE MAXIMUM PAK
3191 YOUR LIFE MY A MULTI
3193 YOUR LIFE NATURAL DAILY PAK
3188 YOUR LIFE ONE DAILY
3554 YOUR LIFE ONE DAILY + IRON, CALCIUM, ZINC
3192 YOUR LIFE SENIOR'S CHOICE
3195 YOUR LIFE STRESS FORMULA
3196 YOUR LIFE STRESS FORMULA W/ IRON
3197 YOUR LIFE STRESS FORMULA W/ ZINC
3553 YOUR LIFE STRESS PAK
3187 YOUR LIFE THERAPLUS
3253 YOUR LIFE TIME RELEASED HIPOTENCY MULTIVIT & MINERAL
3274 Z PLEX (BRONSON #72)
0162 Z-BEC
0308 Z-CON-C
0838 Z-GEN (GOLD LINE)
3469 ZE-CAPS
0163 ZEL-KAPS (HUDSON)
3073 ZENATE PRENATAL (REID-ROWELL)
0269 ZENIVITES
0410 ZENTINIC
0337 ZEST TABS
0407 ZIMAN
3468 ZINC DAILY (SOLGAR)
3103 ZINC WITH B,E,C (OSCO)
3360 ZIPPY ZOO
3362 ZIPPY ZOO + EXTRA C
3361 ZIPPY ZOO + IRON
0164 ZYMACAP (UPJOHN)

ARIC

Atherosclerosis Risk in Communities

ANTHROPOMETRY FORM

ID NUMBER: [| | | | | | |] CONTACT YEAR: [0 | 7] FORM CODE: [A | N | T] VERSION: C 07/31/92

LAST NAME: [| | | | | | | | | | | |] INITIALS: [| |]

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 (ANTC screen 1 of 1)

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

C. ADMINISTRATIVE INFORMATION

4. Date of data collection: ..... [| | / | | / | |]
   month day year

5. Method of data collection: .... Computer C
   Paper form P

6. Code number of person completing this form: ..... [| |]

INSTRUCTIONS FOR THE ANTHROPOMETRY FORM
ANT, VERSION C, 07/31/92
PREPARED 04/22/93

I. GENERAL INSTRUCTIONS

The Anthropometry form should be completed during the participant's clinic visit to record the results of that procedure. The technician must be certified and should have a working knowledge of the anthropometry procedures documented in Manual 2, Cohort Component Procedures for the Third 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 and after offering the participant an opportunity to empty the bladder.

1. 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 between centimeter marks, round down to the nearest whole number.

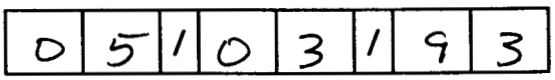
2. Weight is taken with minimal clothing. Record results to the nearest pound, rounding down.

3. Girth measurements are to be taken against the skin or over lightweight non-constricting underwear.

3a. (Waist) 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. 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:



5. 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."

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

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.	___	___

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 _____

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 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:

_____

_____

_____

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: _____

_____

_____

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			

ARIC

Atherosclerosis Risk in Communities

SITTING BLOOD PRESSURE FORM

ID NUMBER: [ ][ ][ ][ ][ ][ ][ ] CONTACT YEAR: [0][7] FORM CODE: [S][B][P] VERSION: C 03/03/93

LAST NAME: [ ][ ][ ][ ][ ][ ][ ][ ][ ][ ][ ] INITIALS: [ ][ ]

Public reporting burden for this collection of information is estimated to average 12 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 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 (SBPC screen 1 of 3)

A. TEMPERATURE

1. Room Temperature (degrees centigrade): [ ][ ]

B. TOBACCO AND CAFFEINE USE

"Smoking can change the results of the exams and laboratory tests we will do today. Because of this we would like to ask you..."

2. Have you smoked or used chewing tobacco, nicotine gum or snuff within the last 4 hours 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

"We are going to ask you not to smoke until you have completed your visit with us today. We do this so that your test results are not affected by smoking. If you must smoke, please tell us that you did before you leave."

4. Have you had any caffeinated beverages, such as coffee, tea, or colas, or chocolate within the last 4 hours? ... Yes Y
   No N

   → Go to Item 6 Screen 2

SITTING BLOOD PRESSURE FORM (SBPC screen 2 of 3)

5. How long ago did you last have any caffeinated beverage, or chocolate?

a. ☐ hours, b. ☐☐ minutes

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 (SBPC screen 3 of 3)

E. SECOND BLOOD PRESSURE MEASUREMENT

16. Systolic: ..... ☐☐☐

17. Diastolic: ..... ☐☐☐

18. Zero Reading: ..... ☐☐

F. THIRD BLOOD PRESSURE MEASUREMENT

19. Systolic: ..... ☐☐☐

20. Diastolic: ..... ☐☐☐

21. Zero Reading: ..... ☐☐

G. COMPUTED MET AVERAGE OF SECOND AND THIRD BLOOD PRESSURE MEASUREMENTS

22. Systolic: ..... ___ ___ ___

23. Diastolic: ..... ___ ___ ___

H. ADMINISTRATIVE INFORMATION

24. Date of data collection: ☐☐/☐☐/☐☐ (month / day / year)

25. Method of Data Collection: .. Computer C / Paper Form P

26. Code number of person completing this form: ..... ☐☐☐

WORKSHEET FOR COMPUTING AVERAGE OF 2ND AND 3RD READINGS (ITEMS 21 AND 22)

	SYSTOLIC	DIASTOLIC
Second Measurement	___ ___ ___ (#16)	___ ___ ___ (#17)
2nd Zero Reading	– ___ ___ (#18)	– ___ ___ (#18)
Second Corrected	___ ___ ___	___ ___ ___
Third Measurement	___ ___ ___ (#19)	___ ___ ___ (#20)
3rd Zero Reading	– ___ ___ (#21)	– ___ ___ (#21)
Third Corrected	___ ___ ___	___ ___ ___
Average Corrected	___ ___ ___ (#22)	___ ___ ___ (#23)

INSTRUCTIONS FOR THE SITTING BLOOD PRESSURE FORM
SBP, VERSION C, 03/03/93
PREPARED 06/25/93

I. GENERAL INSTRUCTIONS

The Sitting Blood Pressure Form should be 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 should be 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 three times using a random zero sphygmomanometer. The detailed instructions below should be reviewed in combination with the Blood Pressure Manual of Procedures.

II. DETAILED INSTRUCTIONS FOR VARIOUS QUESTIONS

A. TEMPERATURE

1. Record the room temperature in degrees centigrade. A thermometer need not be read each time the procedure is initiated, but should be consulted two or three times during the day to note fluctuations.

B. TOBACCO AND CAFFEINE USE

2. Ask the question as stated. Any type of smoking, chewing tobacco, snuff, nicotine gum, etc. should be noted if within the last 4 hours. Note that the question has been updated to include the use of a nicotine patch. 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. At present, the script question between items 3 and 4 is asked only to reinforce the need to abstain from smoking. No action is required if the participant reports having smoked.

4-5. Ask the questions as stated, following the same procedures given for items 2 and 3 above. Note that the question has been updated to include colas under caffeinated beverages.

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. 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. Record the time. 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 & F. SECOND AND THIRD BLOOD PRESSURE MEASUREMENTS

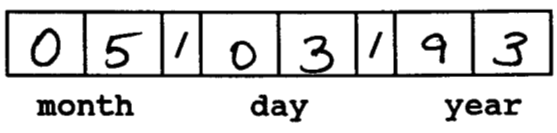
16-21. Repeat as in 13-15 above.

G. COMPUTED NET AVERAGE OF SECOND AND THIRD BLOOD PRESSURE MEASUREMENTS

22-23. Average systolic (item 22) and diastolic (item 23) 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 second and third 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 22 and 23. Items 16-21 are transcribed onto that worksheet in the specified spaces. The "corrected" readings are calculated as the measurement itself minus the corresponding zero reading. These (second and third corrected) are then averaged to obtain the average corrected systolic and average corrected diastolic pressures. An example is given below.

H. ADMINISTRATIVE INFORMATION

24. 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:



25. 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."

26. 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 2ND AND 3RD READINGS

(ITEMS 22 AND 23)

	SYSTOLIC	DIASTOLIC
Second Measurement	142 (#16)	100 (#17)
2nd Zero Reading	-18 (#18)	-18 (#18)
Second Corrected	124	082
Third Measurement	138 (#19)	100 (#20)
3rd Zero Reading	-22 (#21)	-22 (#21)
Third Corrected	116	078
Average Corrected	120 (#22)	080 (#23)

ARIC PARTICIPANT LABEL

CONSENT FOR MAGNETIC RESONANCE IMAGING

Cerebral Magnetic Resonance Imaging for Stroke Risk Factors in the Atherosclerosis Risk in Communities (ARIC) Study

I have been invited to participate in a research study on the relationship between risk factors for stroke and the results of a type of brain scan known as magnetic resonance imaging (MRI). About 2000 men and women who are participating in the Atherosclerosis Risk in Communities (ARIC) study will have this procedure.

I understand that the MRI exam involves lying on a table inside of a large scanning device that will take pictures of my head using magnetic fields. The MRI device does not use ionizing radiation (such as x-rays), and is not known to have any significant risks. No blood will be drawn and no dye will be injected into my veins for this procedure. There is no physical pain. The study will require that I remain still for about 20 minutes so that the pictures can be made. Because the MRI machine is noisy, I understand that I must wear ear plugs or earphones. These will reduce any discomfort and any risk to my hearing. Some people may experience psychological discomfort in the scanner if they are uncomfortable in tight places (claustrophobia).

I am not pregnant; have not had prior surgery for an aneurysm (bulging of a large blood vessel due to a weakness of its wall) in my body or head; do not have metal fragments in my eyes, brain or spinal cord; do not have a cardiac pacemaker or a heart valve pro thesis; and do not have any internal electrical devices, such as a cackler implant or spinal cord stimulator.

There will be no costs to me as a result of my participation in this study, and I will receive $50.00 (fifty dollars) as monetary compensation for the additional time this exam takes beyond my regular ARIC visit.

I understand that the use of the MRI scan will not replace any other diagnostic procedure which might be of benefit to my health. I am aware that I may refuse to have an MRI, and may withdraw from this study at any time. Neither failure to join or withdrawal from this study will affect the availability of my medical care at Bowman Gray School of Medicine.

The ARIC study does not provide diagnosis, medical advice or treatment to participants. During the course of this study, if an abnormality is found on the MRI scan which requires medical follow-up, my personal physician and I will be informed.

If an injury or illness occurs as a direct result of my participation in this study, Bowman Gray School of Medicine will pay for medical treatment reasonably necessary to treat that injury or illness. No other compensation is available.

This study has been approved by the Institutional Review Board of this institution.

Further information about the study or my participation in it is available from the investigator(s), Dr. Fred Romm or Jeannette Bensen at (919) 777-3040.

I understand that my medical records will be confidential, but that they may be reviewed by representatives of the National Heart, Lung and Blood Institute which has funded this study. I understand that my identity will be kept confidential in any publication or public disclosure of the information resulting from this study.

I have been given the opportunity to ask questions about this procedure and have received answers that I understand. This study has been explained to me to my satisfaction and I agree to participate.

_____

Participant's signature Date

_____

Participant's name

_____

Person informing participant Date

_____

Witness Date

INSTRUCTION FOR AN MRI SCAN

WHAT AN MRI SCAN IS:

THIS EXAMINATION, CALLED AN MRI (MAGNETIC RESONANCE IMAGING) SCAN, USES MAGNETIC AND LOW ENERGY RADIOWAVES TO PRODUCE A SERIES OF PICTURES OF YOUR HEAD. IT DOES NOT USE ANY X-RAYS, RADIOACTIVE MATERIALS OR ANY FORM OF IONIZING RADIATION. IT, TO THE BEST OF OUR KNOWLEDGE, PRODUCES NO HARMFUL SIDE EFFECTS OR UNPLEASANT SENSATIONS. IT WILL BE ADMINISTERED BY A TECHNOLOGIST TRAINED IN ITS USE.

PREPARATION:

NO PREPARATION IS NECESSARY TO PERFORM AN MRI SCAN. THE EXAM IS NOT AFFECTED BY ANYTHING YOU MAY HAVE EATEN, DRUNK OR ANY MEDICATION YOU MAY HAVE TAKEN.

PRECAUTIONS:

THE PRESENCE OF ANY METALLIC OBJECTS EITHER ON YOUR PERSON, CLOTHING OR IN YOUR BODY MAY INTERFERE WITH THE SCAN. BEFORE THE SCAN IS DONE, THE TECHNOLOGIST WILL ASK YOU TO REMOVE ALL JEWELRY, WATCHES, HAIRPINS, (GLASSES, WALLETS AND THE LIKE, AND CHANGE INTO HOSPITAL GOWNS. IMPORTANT: IF YOU HAVE UNDERGONE SURGERY ON YOUR HEAD OR BRAIN FOR WHICH INTERNAL METAL CLIPS MAY HAVE BEEN LEFT IN PLACE, PLEASE TELL THE TECHNOLOGIST ABOUT THIS BEFORE GETTING ON THE SCANNING TABLE. ALSO, PLEASE TELL THE TECHNOLOGIST IF YOU HAVE A CARDIAC PACEMAKER OR ARTIFICIAL METALLIC JOINT.

WHAT HAPPENS DURING AN MRI SCAN:

AFTER YOU HAVE CHANGED INTO HOSPITAL GOWNS AND REMOVED ALL METAL OBJECTS, THE TECHNOLOGIST WILL POSITION YOU ON A SPECIAL TABLE. YOUR HEAD WILL BE PLACED IN A PADDED PLASTIC CRADLE OR ON A PILLOW, AND THE TABLE WILL THEN SLIDE INTO THE SCANNER. IT WILL SEEM AS THOUGH YOU ARE BEING ROLLED INTO A LONG TUNNEL.

OUTSIDE THE SCANNER TUNNEL SURROUNDING YOUR HEAD AND BODY, THERE IS A LARGE MAGNET WITH A RADIO TRANSMITTER AND RECEIVER. INFORMATION FROM THESE INSTRUMENTS IS ACCUMULATED AND FED INTO A COMPUTER. THE COMPUTER THEN PRODUCES A SERIES OF PICTURES OF YOUR HEAD.

WHILE THE MACHINE IS TAKING YOUR PICTURES, YOU WILL HEAR REPEATING, LOUD THUMPING NOISES COMING FROM THE WALLS OF THE SCANNER. THEREFORE EARPLUGS WILL BE PROVIDED. ANY MOVEMENT, ESPECIALLY OF YOUR HEAD OR BACK (EVEN MOVING YOUR JAW TO TALK) DURING THIS TIME WILL SERIOUSLY BLUR THE PICTURES. DURING THE SCANNING, YOU SHOULD BREATHE QUIETLY AND NORMALLY BUT OTHERWISE REFRAIN FROM ANY MOVEMENT, COUGHING OR WIGGLING. WHEN THE THUMPING NOISE STOPS, THE PICTURES WILL BE PROCESSING AND YOU MAY RELAX FOR A FEW MINUTES, BUT YOU MUST REFRAIN FROM CHANGING YOUR POSITION OR MOVING ABOUT. THE ENTIRE EXAM ORDINARILY TAKES APPROXIMATELY 25 MINUTES.

A - 310

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ARIC MRI PROCEDURE FORM

Atherosclerosis Risk in Communities

ID NUMBER: | | | | | | | | CONTACT YEAR: | | | FORM CODE: M P R | VERSION: A 04-06-93

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.

MRI PROCEDURE FORM (MPRA screen 1 of 2)

1. Status of MRI procedure:

Go to Item 3b.	Completed	C
Go to Item 3a.	Attempted, incomplete	I
	Not attempted	N

2. The reason MRI was not attempted:

No show	A
Rescheduled	B
Refused to sign informed consent form	C
Refused for other reasons (specify)	D
Other (specify)	E

Specify: _____

GO TO ITEM 7, SCREEN 2.

3.a. Reason for incomplete MRI:

Claustrophobia	C
Other (Specify)	O

Specify: _____

b. Date MRI attempted or completed:

		/			/		
M	M		D	D		Y	Y

4. Record the order of Scanning Pulse Sequence. (If all series were completed in order, enter 1, 2, 3)

OPTIONS:

Series 1: T1 Sagittal	1
Series 2: Spin density/ T2 Oblique Axial	2
Series 3: Oblique Axial	3
Other	4

IF 4 IS ENTERED, PLEASE EXPLAIN BELOW:

_____

MRI PROCEDURE FORM (MPRA screen 2 of 2)

5. Was oblique axial scan parallel to the AC/PC line? ..... Yes Y
No N

6.a. Were any emergent alert conditions noted? ..... Yes Y
No N

Go to Item 7.

b. Specify the alert condition:

6.c. Who was notified of this alert?

d. Date of alert notification:

M M / D D / Y Y

7. MRI Technologist initials:

8. Date of data collection:

M M / D D / Y Y

TO BE COMPLETED BY MRI READING CENTER:

Tape Number:

Date Received: M M / D D / Y Y

Date Archived: M M / D D / Y Y

Date of dBase Entry: M M / D D / Y Y

INSTRUCTIONS FOR THE MRI PROCEDURE FORM
MPR, VERSION A: 04-06-93
PREPARED 10-14-93

The MRI Procedure Form (MPR) is completed by the MRI technologist during the course of the MRI scan. The primary purposes of the form are to record whether the scan was completed, document the reasons for not attempting or completing the scan, record the scanning pulse sequence, verify that the oblique axial scan was taken parallel to the AC/PC line, document the presence of any emergent alert conditions, who was notified of this condition and the date of notification.

The questionnaire is completed by the MRI technologist at the MRI center at different stages during the procedure. A form is completed for every participant who is scheduled for an MRI by the field center, regardless of whether the MRI Center Informed Consent document is signed or the scan is initiated and prematurely terminated.

The MRI Procedure Form is collected using the paper version of the form. No questions are read to the participant. If a response needs to be changed after it has been entered, an 'X' is placed over the incorrect numeric or multiple choice response. For numeric entries, the correct response is clearly written above the incorrect entry. For 'multiple choice' and 'yes/no' responses, the correct response is circled. If there is additional information (for which there is no data entry field) that could be of use to staff at the field center or the MRI reading center, write it on the form. This information, however, will not become part of the database.

1. The completion status of the MRI scan is entered once the technologist is certain of its status. This can be done either at the beginning of the procedure and corrected as required at the end of the study or completed at the end of the procedure, at the discretion of the technologist.

   If the scan is not attempted, enter 'N' and the reason for not doing the scan in Item 2.

   If the scan is started and prematurely terminated, enter 'I'. The reason for not completing the scan is entered in Item 3.a and the date on which it was performed is entered in Item 3.b.

   If the scan is started and completed, enter 'C' and the scan date in Item 3.b, leaving the intervening items blank.

2. Item 2 is completed when the scan is not attempted. Several common reasons for not attempting the scan are available as response categories. Select only one. If more than one response category applies, or if there is another reason, select OTHER, and enter the reason in the space provided. Complete the

administrative data (Items 7 and 8) at the end of the form. Send the form to the ARIC field center.

3a. Enter the reason the scan was not completed, selecting claustrophobia (C) or other (O). If there are multiple reasons, including claustrophobia, select 'C' in preference to the other reasons. If the scan was not completed for a reason other than claustrophobia, select 'O' and enter the reason in the space provided (SPECIFY).

3b. Enter the date on which the scan is performed regardless of whether the scan is terminated prior to completion or the scan is completed, using the standard date format.

When the scan is terminated prior to the collection of any data, leave Items 4-6 blank and go to Item 7. When the scan includes some data, continue with Item 4.

4. Record in the three boxes the sequence in which the scanning pulses are performed. If all series were completed in order, enter 1, 2, 3. If one or more of the series is not completed or one or more of the standard series are repeated, enter 4 in the appropriate box and record the final pulse sequence on the line below.

5. Indicate whether the oblique axial scan was done parallel to the AC/PC line.

6. Record the presence or absence of any emergent alert conditions, as defined in the MRI protocol. If none are present (NO), go to Item 7. If YES, specify the alert condition in Item 6.b, record the name of the neuroradiologist who reviews the possible alert condition, and record the date on which the field center is notified of the alert condition.

If the MRI radiologist does not feel the condition observed on the scan warrants alert status, correct 6.a, 6.b and 6.c.

7. Enter the MRI technologist's initials.

8. Enter the date on which the form is completed.

O.M.B. 0925-0821
exp. 10/31/95

ARIC
Atherosclerosis Risk in Communities

RETINAL EXAMINATION FORM

ID NUMBER: | | | | | | | | CONTACT YEAR: | | | FORM CODE: R E X VERSION: A 03-09-93

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 (REXA 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 (REXA 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 (REXA 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 (REXA 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 (REXA 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 (REXA 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 (REXA 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 (REXA 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: [ ][ ]/[ ][ ]/[ ][ ]

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 not 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

#	Date	Photographer Code	Participant ID	Eye	Comments
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					

Film Roll Number _____

#	Date	Photographer Code	Participant ID	Eye	Comments
12					
13					
14					
15					
16					
17					
18					
19					
20					
21					
22					
23					
24					

Film Roll Number _____

#	Date	Photographer Code	Participant ID	Eye	Comments
25					
26					
27					
28					
29					
30					
31					
32					
33					
34					
35					
36					
37					

ARIC
Atherosclerosis Risk in Communities

FILM PROCESSING LOG

Roll #	Date Out	Date In	Comments

RETINAL PHOTOGRAPHY

During your ARIC exam, we will be taking a photograph (not an x-ray) of the back of one of your eyes (the retina) so we can study the blood vessels and look for any 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 will 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. We will ask you to follow the blinking green light as we move it. Just before we take the picture, we will ask you to blink your eyes and then open them real wide. There will be a bright flash from within the camera 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 S to 7 minutes and causes no damage to the eye. Please remember that we are only taking one picture of a small portion of the back of one of your eyes, and that this picture will not substitute as an eye examination. You will 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.

ARIC VENIPUNCTURE FORM

Atherosclerosis Risk in Communities

ID NUMBER: | | | | | | | | CONTACT YEAR: 0 7 FORM CODE: V E N VERSION: C 02/23/93

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

INSTRUCTIONS: This form should be completed on paper during the participant's visit.

A. BLOOD DRAWING

1. Do you have any bleeding disorders? ..... Yes Y
   No N
   Don't Know D

   If Yes, specify in Item 13.

2. Date of blood drawing: ..... | | / | | / | |
   month day year

3.a. Time of blood drawing: ..... | | : | |
   h h m m

   b. AM or PM: ..... AM A
   PM P

4. Was all blood drawn before the snack? ..... Yes Y
   No N

   If No, specify non-fasting tubes on page 3.

5. Number of venipuncture attempts: ..... |

6. Filling time of Tube 1: ..... | | seconds

7. Was the tourniquet reapplied? ..... Yes Y
No N

If Yes, specify on page 3.

8. Code number of phlebotomist: ..... [ ][ ][ ]

B. BLOOD PROCESSING

9.a. Time at which specimen Tubes 2-7 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 specimens were placed in freezer: [ ][ ]:[ ][ ]
h h m m

b. AM or PM: ..... AM A
PM P

12. Code number of technician processing the blood: [ ][ ][ ]

13. Comments on blood drawing/processing: ..... Yes Y
No N

If Yes, Specify: _____

---

14. Paper Incident Record (page 3) used? ..... Yes Y
No N

PLACE ARIC ID LABEL HERE.

VENIPUNCTURE INCIDENT RECORD

A. BLOOD DRAWING INCIDENTS: THIS LOG IS COMPLETED TO DOCUMENT PROBLEMS WITH THE VENIPUNCTURE. PLACE AN "X" IN BOXES CORRESPONDING TO THE TUBES IN WHICH BLOOD DRAWING PROBLEMS OCCURRED. IF A PROBLEM OTHER THAN THOSE LISTED OCCURRED, USE ITEM 6.

	Tubes							
	1	2	3	4	5	6	7	8
1. Sample not drawn								
2. Partial sample drawn								
3a. Tourniquet reapplied								
3b. Fist Clenching								
4. Needle movement								

5. Phlebotomist code: __ __ __

6. Other problems in blood drawing: _____

_____

B. BLOOD PROCESSING INCIDENTS: THIS LOG IS COMPLETED TO DOCUMENT PROBLEMS PROCESSING THE SPECIMENS. PLACE AN "X" IN BOXES CORRESPONDING TO THE TUBES IN WHICH PROCESSING PROBLEMS OCCURRED. IF A PROBLEM OTHER THAN THOSE LISTED OCCURRED, USE ITEM 13.

	Tubes							
	1	2	3	4	5	6	7	8
7. Broken tube								
8. Clotted								
9. Hemolyzed								
10. Lipemic								
11. Other Contamination								

12. Blood Processor Code: __ __ __

13. Other problems in blood processing: _____

_____

14. Date of procedures: __ __ / __ __ / __ __ .

ORIGINAL TO ARIC COORDINATING CENTER; COPIES TO CENTRAL LABS AND FIELD CENTER.

INSTRUCTIONS FOR VENIPUNCTURE FORM
VEN, VERSION C, 02/23/93
PREPARED 03/19/93

I. GENERAL INSTRUCTIONS

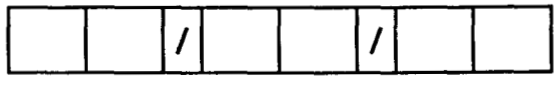
The Venipuncture Form should be completed during the participant's clinic visit to record the results of that procedure. Technicians performing venipuncture and blood processing must be certified and should have a working knowledge of the ARIC Blood Collection and Processing Manual of Operations. Technicians 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. BLOOD DRAWING

1. 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 13 of the Venipuncture Form.

2. 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:



   If the participant is rescheduled for another day, the actual date when blood is drawn should be entered.

3. 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.

4. Check the participant's Itinerary Sheet, or ask the participant if he/she has had the clinic snack. If so, specify non-fasting tubes in Section A, question 6 of the Incident Record.

5. Include all venipuncture attempts by all phlebotomists. The same technician should not attempt a venipuncture more than twice.

6. Note the time required to fill tube 1. If the flow rate in the tube is so slow that blood does not fill the first collection tube within 36 seconds, stop the blood collection and repeat on the other arm. If blood is flowing freely, the butterfly needle may be taped to the donor's arm for the duration of the draw.

7. Do not reapply the tourniquet during tubes #2 - #5. Only reapply the tourniquet <u>after</u> tube #5, and only if this is necessary to spare the participant another stick. Specify which tubes correspond to the tourniquet reapplication in Section A of the Incident Record.

8. The phlebotomist who performed the blood drawing procedure must enter his/her code number in the fields provided. If more than one phlebotomist attempts to draw the blood, enter the code of the <u>first</u> phlebotomist.

B. BLOOD PROCESSING

9. Note the time at which the centrifuge containing these tubes 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 this tube began to spin. Fill in the fields using leading zeroes where necessary and indicate AM or PM.

11. Note the time at which the samples were placed in the freezer. Fill in the fields using leading zeroes where necessary and indicate AM or PM.

12. Enter the code number of the technician who <u>began</u> processing the blood.

13. Include any clarifications or other information relevant to the assays being performed that are not included in the Incident Record, 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.

14. Answer "Y" if any problem occurred in either blood drawing or blood processing that necessitated use of the paper Incident Record attached to the venipuncture form. In such a case, attach the correct ARIC ID label on the original and make copies. Send original to the ARIC Coordinating Center and a copy to the pertinent central laboratory(ies). Place one copy in the participant's folder. Answer "N" if no such problems occurred. In this case, an Incident Record is unnecessary and therefore a copy need not be made.

Medical Data Review Printout For ARIC Visit 3

1. Name (UPDB1b,c,d):

2. Id Number:

3. Date of Birth (UPDA14): / /

4. Date of Visit (FTRC1): / /

5. Age in Years (UPDA14,FTR1):

6. Physician Name (UPDB15a,b):

7. Height (ANTC1):

8. Weight (ANTC2):

.....

9. Average sitting BP (SBPC22/SBPC23): /

10. Participant currently taking antihypertensives (MSRC24a)?

11. M.D. ever said you had High Blood Pressure (PHXA8a)?
When did you last see M.D. about HBP (PHXA8d mm/yy)?

.....

12. M.D. ever said you had Diabetes (PHXA8k)?

13. M.D. ever said you had High Cholesterol (PHXA8e)?

14. M.D. ever said you had Cancer (PHXA8o)?

15. [For females only] Uterine bleeding (RHXB4):

.....

16. History Consistent With:

a. Rose questionnaire angine:
Reported seeing an M.D. because of chest pain, during latest AFU (AFUD15):
If Yes, date of pertinent AFU call (AFUD1 mm/yy):
Recalled chest pain/discomfort from last AFU call (HHXC2):
Has chest discomfort worsened in the past 2 months (HHXC3)?

b. Possible congestive heart failure:
Since last visit, ever sleep with 2+ pillows to breathe (PHXA9)?
Awakened by trouble breathing (PHXA10)?
Swelling go down overnight (PHXA12)?

c. Recognized TIA or stroke:
Stroke/TIA reported during latest AFU (AFUD29)?
If Yes, date of pertinent AFU call (AFUD1 mm/yy): /
Since last visit, told by M.D. you had stroke or TIA (TIAD1)?
During this time, date first occurred (TIAD2 mm/yy): /

d. Intermittent claudication:
Claudication reported on latest AFU (AFUD28=L):
If Yes, date of AFU call (AFUD1 mm/yy): /

17. Invasive Cardiovascular Procedure:

a. Since last visit, had heart or arterial surgery (HHXC4)?
Coronary bypass (HHXC5a)?
Other heart procedure (HHXC5b)?
(If Yes, see note log)
Carotid endarterectomy (HHXC5c)?
Site (HHXC5d)?
Other arterial revascularization (HHXC5e)?
Balloon angioplasty (HHXC6)?
Angioplasty of coronary artery (HHXC7a)?
Angioplasty of neck artery (HHXC7b)?
Angioplasty leg artery (HHXC7c)?
Cardiac catheterization (HHXC8a)?
Carotid artery catheterization (HHXC8b)?
Other arterial revascularization (HHXC8c)?
(If Yes, see note log)

18. Diagnostic Procedures:

Since last visit, had echocardiogram (HHXC9a)?
ECG (HHXC9b)?
Treadmill or cardiac stress test (HHXC9c)?
Carotid ultrasound (HHXC9d)?
MRI of the brain (HHXC9e)?
CAT scan of the brain (HHXC9f)?

.....

19. ECG: Read tracing.

a. Significant findings in preliminary interpretation:

_____

_____

b. Differences from previous tracing(s)?

No _____ Yes _____ If yes, summarize _____

_____

_____

c. Was a physician notified? No _____ Yes _____

If yes, physician's name _____ Date ____/____/____

.....

20. Other significant findings?

No _____ Yes _____ If yes, summarize _____

_____

21. 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 _____

_____

_____

22. Was a referral made? No _____ Yes _____

If Yes, specify on Report and Referral Form

.....

23. Code of person completing Medical Data Review: ___ ___ ___

25. Code of M.D. reviewing this form. ___ ___ ___

24. Date of Med. Data Review:

_____/_____/_____
mm dd yy

26. Date of Review by M.D.

_____/_____/_____
mm dd yy

.....

ARIC REPORT AND REFERRAL FORM

Atherosclerosis Risk in Communities

ID NUMBER: | | | | | | | | CONTACT YEAR: 0 7 FORM CODE: R E F VERSION: A 11/18/92

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 (REFA screen 1 of 2)

A. VISIT 3 CLINIC EXAMINATION

1. Summary of VISIT 3 Referrals/Alerts

a. Referral/alert made at this time? ... Yes Y

No N

Go to Item 2

Was a referral made for:	Yes	No
b. Blood pressure	Y	N
c. Glucose	Y	N
d. Lipids	Y	N
e. Other Chemistries	Y	N
f. Retina	Y	N
g. MRI*	Y	N
h. Echocardiogram*	Y	N
i. Ultrasound	Y	N
j. ECG	Y	N
k. Other conditions	Y	N

* Field center specific procedure

B. PREVIOUS CLINIC EXAMINATIONS

2. Summary of VISIT 2 Referrals/Alerts

a. Referral/alert made at that time? ... Yes Y

No N

Go to Item 3

Was a referral made for:	Yes	No
b. Blood pressure	Y	N
c. Hematology	Y	N
d. Glucose	Y	N
e. Lipids	Y	N
f. Other Chemistries	Y	N
g. Ultrasound	Y	N
h. ECG	Y	N
i. Pulmonary function	Y	N
j. Other conditions	Y	N

REPORT AND REFERRAL FORM (REFA screen 2 of 2)

3. Summary of VISIT 1 Referrals/Alerts

a. Referral/alert made at that time? ... Yes Y

No N

Go to Item 4

Was a referral made for:	Yes	No
b. Blood pressure	Y	N
c. Hematology	Y	N
d. Glucose	Y	N
e. Lipids	Y	N
f. Other Chemistries	Y	N
g. Ultrasound	Y	N
h. ECG	Y	N
i. Pulmonary function	Y	N
j. Other conditions	Y	N

C. ADMINISTRATIVE INFORMATION

4. Date of data collection: ..... | | | / | | | / | | |

month day year

5. Method of data collection: .... Computer C

Paper form P

6. Code number of person completing this form: ..... | | | |

ARIC
Atherosclerosis Risk in Communities

ARIC ALERT/REFERRAL LOG

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______________________________

INSTRUCTIONS FOR THE REPORT AND REFERRAL FORM AND THE ALERT/REFERRAL LOG
REF, VERSION A, 11/18/92
ALT, VERSION A, 11/17/92
PREPARED 03/19/93

I. GENERAL INSTRUCTIONS

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".

During cohort Visits 1 and 2, ARIC field centers maintained a paper record (log) of medical alerts and referrals, as well as a separate log of ultrasound alert notifications. An additional purpose of the Report and Referral Form developed for Visit 3 is to collect the historical information from the Alert/Referral Logs in the participant files from cohort Visits 1 and 2. Thus, SECTION A of the Report and Referral Form records a summary of the referrals and alerts resulting from cohort Visit 3, whereas SECTION B does the same thing for the previous clinic examinations (Visit 2 and Visit 1, respectively).

As before, the daily management and tracking of alert values and participant reports as they are received at the field center is done on the Alert/Referral Log. This log is a slightly revised version of the one previously used by ARIC field centers during cohort Visits 1 and 2, and continues to serve the same function. Once all reports and study results have been obtained from the local laboratory, the central laboratory and the central reading agencies (ECG, ultrasound, retinal photography, and MRI) 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 all results have been received at the field center and a final report to the study participant is being prepared. At this time, all the information needed to record whether an alert and/or medical referral has been made is available, and can be recorded in SECTION A for the current cohort examination visit.

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). This also provides the opportunity to record the alert notifications and medical referrals from previous visits on the Report and Referral Form.

II. DETAILED INSTRUCTIONS FOR EACH ITEM

A. Visit 3 Clinic Examination

1. Summary of Visit 3 Referrals/Alerts

a) Referral/alert made at this time? 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 3, or are being made at this time, they will be recorded in Items 1.b through 1.k. Otherwise, record NO and skip to SECTION B (previous clinic examinations).

In recording the type of referral and/or alert in items 1.b through 1.k, answer YES or NO 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 1.b through 1.k. Item k (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 k (other conditions) are referrals due to uterine bleeding.

B. Previous Clinic Examinations

2. Summary of Visit 2 Referrals/Alerts

This panel is analogous to SECTION A, with the exception that it refers to referrals/alerts generated during cohort Visit 2. All other definitions specified for SECTION A apply here.

2.a. Referral/Alert Made at That Time?

This statement applies to the information residing in the participant's Visit 2 file, including the report of study results, letters to the participant and his/her physician, as well as possible alert values and medical referral notifications.

Items 2.b through 2.i. list the reportable study measurements from Visit 2. Item 2.j again refers to medical referrals generated at that time on account of "other conditions".

3. Summary of Visit 1 Referrals/Alerts

The next panel (Items 3a-j) refers to Visit 1 referrals and/or alerts, and is analogous to the two prior panels. Medical alerts and/or referrals to be recorded in this panel are those that can be found from hard copy records or electronic files of Visit 1 materials on this participant.

C. Administrative Information

4. 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, 1993, would be entered as:

5. 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."

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

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 and 2, 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.

ATHEROSCLEROSIS RISK IN COMMUNITIES

ARIC CENTER VISIT 3 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.
Visit 2 Weight: ____ pounds	
Visit 1 Weight: ____ pounds	Visit 1 Height _____ ft. ___ in.

Current Blood Pressure _____ / _____ mm Hg

Visit 2 Blood Pressure _____ / _____ mm Hg

Visit 1 Blood Pressure _____ / _____ mm Hg

Please read carefully the item about your blood pressure checked below.

___ Your blood pressure is in the "normal" range.

___ Your blood pressure is elevated. You should have the level checked again in the next _____ by your physician.

___ Your blood pressure is clearly and importantly elevated. You must see your physician in the next week to have it remeasured to determine whether treatment should be started or changed.

___ You have a high blood pressure that requires immediate attention. You must see your physician at the earliest opportunity to confirm this finding.

Electrocardiogram

A preliminary screening of your electrocardiogram was performed today. An ARIC physician will review your electrocardiogram and a copy will be sent to your physician with the rest of your results.

Ultrasound:

Portions of the arteries in your neck were video taped using ultrasound. A preliminary review of this scan at our center did not reveal any blockage to these arteries. 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 _____

_____

_____

_____

_____

Signature Date

_____

Full Name

Electrocardiogram

A preliminary screening of your electrocardiogram was performed today. An ARIC physician will review your electrocardiogram and a copy will be sent to your physician with the rest of your results.

Ultrasound:

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 _____

_____

_____

_____

_____

Signature Date

_____

Full Name

Atherosclerosis Risk in Communities

SUMMARY OF ARIC VISIT 3 RESULTS FOR PARTICIPANTS AND THEIR PHYSICIANS

Participant's name: pt full name~

Date of visit to the ARIC center: visit date~

Birth date: birth date~

Our Reference (ARIC ID): aric id#~

These are the results of your ARIC Visit 3 examination:

Weight: weight~ pounds

Height: height ft~ ft. height in~ in.

Blood pressure: bp sy/di~ mm Hg (Average of 2 measurements).
systolic diastolic

- If SBP<140, DBP<90:

  "Your reading was normal."

- If SBP 140-199, DBP 90-104:

  "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 200-239, DBP 105-114:

  "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 BP>240 or DBP>115:

  "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."

Our Reference (ARIC ID): aric id#~

Blood Tests	Your Value	Reference Range
Total cholesterol (mg/Dl).....	total chol~	Less than 200: Desirable 200 - 239: Mildly elevated 240 or more: Markedly elevated
LDL cholesterol (mg/dL).....	ldl chol~	less than 160
Total HDL cholesterol (mg/dL)....	total hdl~	Males greater than 35 Females greater than 40
Triglycerides (mg/dL).....	trig~	Males less than 250 Females less than 220
Glucose (mg/dL).....	glucose~	70 - 130

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.

Glucose is your blood sugar and is altered in conditions such as diabetes.

- If All chemistries are in usual range:

  "Your blood test results are all normal."

- If Some outside usual range:

  "Your results show at least one value slightly outside of the usual range, identified by asterisks (*). You may want to check with your physician about this."

- If Alert values:

  "Your results show a value outside of the usual range, identified by asterisks (*). You should check with your physician about this soon, if you have not already done so."

Our Reference (ARIC ID): aric id#~

Electrocardiogram:

"Normal or insignificant findings."

"Normal or insignificant findings. Your electrocardiogram has been sent to your physician with a copy of this report.

* **"Please check your findings with your physician if you have not already done so. Your electrocardiogram has been sent to your physician with a copy of this report.**

B-Scan Ultrasound examination of the arteries:

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."

Retinal Photography examination of the eyes:

If routine:

"The study has completed an evaluation of the retinal photograph of your left/right~ eye. This evaluation did not show any abnormalities. Please note that this does not constitute a complete eye examination."

If alert:

"We have previously sent a report suggesting that you see your doctor about a finding noted in this retinal photograph."

If other:

"Because of technical difficulties in taking this photograph, it was not possible to perform an evaluation at this time. If you wish to have this photograph repeated, please call us for an appointment."

SCHEDULE FOR REPORTING YOUR ARIC RESULTS

AT THE END OF YOUR CLINIC VISIT YOU WILL RECEIVE A SUMMARY OF:

HEIGHT AND WEIGHT
BLOOD PRESSURE
ELECTROCARDIOGRAM (preliminary report)

YOUR TESTS WILL BE SENT TO SPECIALIZED LABORATORIES FOR MEASUREMENTS AND INTERPRETATION. APPROXIMATELY 2 MONTHS 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
ELECTROCARDIOGRAM
BLOOD TESTS:
- TOTAL CHOLESTEROL, LDL CHOLESTEROL, HDL CHOLESTEROL, TRIGLYCERIDES AND FASTING GLUCOSE

REPORT OF IMPORTANT SYMPTOMS YOU MAY HAVE

IF AN IMPORTANT ABNORMALITY IS DETECTED IN ANY TEST, YOU AND YOUR PHYSICIAN WILL BE NOTIFIED IMMEDIATELY.

2.25.a. Physician: Referral at Clinic Visit

<DATE>

<NAME> <ADDRESS>

Dear Dr. <NAME>:

We saw your patient, <NAME>, in the ARIC Study clinic on <DATE>. During the course of our evaluation, the following problems were identified which we believe need attention:

<FINDING>

The ARIC Study does not provide diagnoses, medical advice, nor treatment. We have recommended to <NAME> that <HE/SHE> contact you within <TIME FRAME> to determine how to follow up on these results.

Should you have any questions, please feel free to contact us at <PHONE #>. A full report with results of our tests will be forwarded when available.

Sincerely,

_____, M.D.
Medical Director

2.25.b. Physician: Referral Post Clinic Visit

<DATE>

<NAME> <ADDRESS>

Dear Dr. <NAME>:

We saw your patient, <NAME>, in the ARIC Study clinic on <DATE>. We have since received some results on your patient from our central laboratories/reading centers. They include a finding which we believe needs attention.

<FINDING>

The ARIC Study does not provide diagnoses, medical advice, nor treatment. We have recommended to <NAME> that <HE/SHE> contact you within <TIME FRAME> to determine how to follow up on these results.

Should you have any questions, please feel free to contact us at <PHONE #>. A full report with results of our tests will be forwarded when available.

Sincerely,

_____, M.D.
Medical Director

2.25.c. Participant: Referral Post Clinic Visit with MD

<DATE>

<NAME> <ADDRESS>

Dear <NAME>:

Since your examination at the ARIC Study clinic on <DATE> we have obtained some results of your studies. Your ..... 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. <NAME>. We suggest that you contact <HIM/HER> within <TIME FRAME> to determine how to follow up on these results.

Should you have any questions, please feel free to contact us at <PHONE #>. A full report with results of our tests will be forwarded when available.

Sincerely,

_____, M.D.
Medical Director

2.25.d. Participant: Referral Post Clinic Visit no MD

<DATE>

<NAME> <ADDRESS>

Dear <NAME>:

Since your examination at the ARIC Study clinic on <DATE> we have obtained some results of your studies. Your ..... 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, to alert <HIM/HER> 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 <LOCAL MEDICAL SOCIETY, TELEPHONE #>.

Should you have any questions, please feel free to contact us at <PHONE #>. A full report with results of our tests will be forwarded when available.

Sincerely,

_____, M.D.
Medical Director

2.26.a. Physician: Normal Results

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,

_____, M.D.
Medical Director

Enclosures

2.26.b. Physician: Abnormal Results, No Previous Referral Made

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,

_____, M.D.
Medical Director

Enclosure

2.26.c. Physician: Abnormal Results, Previous Referral Made

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,

_____, M.D.
Medical Director

Enclosure

2.26.d. Participant: Normal Results

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,

_____M.D.
Medical Director

Enclosure

2.26.e. Participant: Abnormal Results, No Previous Referral Made

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,

_____, M.D.
Medical Director

Enclosure

2.26.f. Participant: Abnormal Results, Previous Referral Made

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,

_____, M.D.
Medical Director

Enclosure

2.26.g. Participant: Normal Results, No MD Designated

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 _____.

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,

_____, M.D.
Medical Director

Enclosure

2.26.h. Participant: Abnormal Results, No MD Designated

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 _____.

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,

_____, M.D.
Medical Director

Enclosure

2.26.i. Cover Letter for Transmission of Study Data to Third Party

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,

_____, MD

c: name of participant~

2.27.a. Physician: Normal Results

date~

md full name~
md address~

Dear Dr. md last name~:

pt full name~, a patient of yours, participated in a study of magnetic resonance imaging (MRI) of the brain and atherosclerotic risk factors, as part of the Atherosclerosis Risk in Communities (ARIC) Study. The scanning protocol was an abbreviated research MRI and is not equivalent to a standard clinical study. Your patient requested that we send you the results of this MRI scan. The results of this cerebral MRI performed on mri date~ are reported below.

Normal for age

We have mailed a letter to mr./mrs. last name~ to report that no abnormalities were found in this scan, and that this was reported to you. Please do not hesitate to call if you have any questions regarding the above.

Sincerely,

_____, M.D.
Medical Director

Enclosures

2.27.b. Physician: Minor Abnormal Findings, No Referral Indicated

date~

md full name~
md address~

Dear Dr. md last name~:

pt full name~, a patient of yours, participated in a study of magnetic resonance imaging (MRI) of the brain and atherosclerotic risk factors, as part of the Atherosclerosis Risk in Communities (ARIC) Study. The scanning protocol was an abbreviated research MRI and is not equivalent to a standard clinical study. The ARIC Study does not provide diagnosis, medical advice or treatment. Your patient requested that we send you the results of this MRI scan.

The results of this cerebral MRI performed on mri date~are reported below.

Type	Present	Number	Side	Location
Old Infarct >5mm				
Old Hematoma				

The clinical significance of these findings is not known, because this type of study is not usually performed in asymptomatic subjects.

We have mailed a letter to mr./mrs. last name~ to report that there were minor chronic findings which are often seen on MRI, which should not be a cause for concern and that this was reported to you. Please do not hesitate to call if you have any questions regarding the above.

Sincerely,

_____, M.D.
Medical Director

Enclosures

2.27.c. Physician: Abnormal Results

date~

md full name~
md address~

Dear Dr. md last name~:

pt full name~, a patient of yours, participated in a study of magnetic resonance imaging (MRI) of the brain and atherosclerotic risk factors, as part of the Atherosclerosis Risk in Communities (ARIC) Study. the scanning protocol was an abbreviated research MRI and not equivalent to a standard clinical study. Your patient requested that we send you the results of this MRI scan.

The results of this cerebral MRI performed on mri date~ are reported below.

finding~

A report from Dr. neuro md last name~ is attached for your information. These findings should be considered in the context of the patient's medical history.

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 _____.

Sincerely,

_____, M.D.
Medical Director

2.27.d. Physician: Abnormal Results, Participant Not Informed

date~

md full name~
md address~

Dear Dr. md last name~:

pt full name~, a patient of yours, participated in a study of magnetic resonance imaging (MRI) of the brain and atherosclerotic risk factors, as part of the Atherosclerosis Risk in Communities (ARIC) Study. the scanning protocol was an abbreviated research MRI and not equivalent to a standard clinical study. Your patient requested that we send you the results of this MRI scan.

The results of this cerebral MRI performed on mri date~ are reported below.

finding~

A report from Dr. neuro md last name~ is attached for your information. These findings should be considered in the context of the patient's medical history.

The ARIC Study does not provide diagnoses, medical advice, nor treatment.
Due to the longstanding nature of this MRI finding your patient has not been notified.

Should you have any questions, please feel free to contact us at _____.

Sincerely,

_____, M.D.
Medical Director

2.27.e. Participant: Normal Results

date~

pt full name
pt address

Dear mr./mrs. last name~:

Thank you for taking part in the study of magnetic resonance imaging (MRI) of the brain as part of the ARIC Study. We are grateful for your time and effort. The results of your MRI scan of the brain are reported below.

Your scan is in the normal range

We have communicated these results to your physician, Dr. md last name~. Please remember that this MRI examination is for research purposes and is <u>not</u> the same as the standard MRI exam which your doctor might order. If you have any questions in this regard, please feel free to contact us at _____.

Thank you again for your participation in the ARIC Study.

Sincerely,

_____, M.D.
Medical Director

2.27.f. Participant: Minor Abnormal Findings, No Referral Indicated

date~

pt full name~
pt address~

Dear mr./mrs. last name~:

Thank you for taking part in the study of magnetic resonance imaging (MRI) of the brain as part of the ARIC Study. We are grateful for your time and effort. The results of your MRI scan of the brain are reported below.

There are minor chronic findings which are often seen on MRI. These should not be a cause for concern on your part.

We have communicated these results to your physician, Dr. md last name~. Please remember that this MRI examination is for research purposes and is <u>not</u> the same as the standard MRI exam which your doctor might order. If you have any questions in this regard, please feel free to contact us at _____.

Thank you again for your participation in the ARIC Study.

Sincerely,

_____, M.D.
Medical Director

2.27.g. Participant: Abnormal Results, Referral Recommended

date~

pt full name~
pt address~

Dear Mr./Mrs. last name~:

Thank you for taking part in the study of magnetic resonance imaging (MRI) of the brain as part of the ARIC Study. We are grateful for your time and effort. The results of your MRI scan of the brain are reported below.

There is a finding which may require futher medical evaluation. We have communicated these results to your physician, Dr. md last name~. Please contact your physician to determine how to follow up on these results.

Please remember that this MRI examination is for research purposes and is <u>not</u> the same as the standard MRI exam which your doctor might order. If you have any questions in this regard, please feel free to contact us at _____.

Thank you again for your participation in the ARIC Study.

Sincerely,

_____, M.D.
Medical Director

2.27.h. Participant: Normal or Abnormal Results, No MD Designated

date~

pt full name~
pt address~

Dear mr./mrs. last name~:

Thank you for taking part in the study of magnetic resonance imaging (MRI) of the brain as part of the ARIC Study. We are grateful for your time and effort. During your ARIC visit you indicated that we should send the results of this exam to you.

Your scan is in the normal range

or

There are minor chronic findings which are often seen on MRI. These should not be a cause for concern on your part.

or

There is a finding which may require further medical evaluation. A copy of the report from a specialist is enclosed. Please contact your physician to determine how to follow up on these results. If you do not have a personal physician or do not know where to find one we suggest that you call _____.

If you find that the attached report is not clear, please call us at _____.

Thank you again for your participation in the ARIC Study.

Sincerely,

_____, M.D.
Medical Director

Enclosure

2.28.a. Physician: Abnormal Results

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~. As part of this examination, the retina of one eye was photographed, and sent for evaluation and measurements at a specialized reading center. This evaluation followed a research protocol and is not comparable to a clinical evaluation.

In the course of this evaluation of the retinal photograph, the following abnormal findings were noted:

description of finding~

We have sent a letter to mr./mrs. last name~ suggesting that he/she~ contact you to discuss these findings and their possible evaluation by an ophthalmologist.

If you have any questions, please feel free to contact us at _____.

Sincerely,

_____, M.D.
Medical Director

2.28.b. Participant: Abnormal Results, Referral Recommended

date~

pt full name~
pt address~

Dear mr./mrs. last name~:

We have completed an evaluation of the retinal photograph taken during your visit at the ARIC Center on visit date~. The report from our Reading Center included a finding which should be discussed with your physician.

We have sent a letter to Dr. md last name~ with these results, indicating that we have asked you to contact him/her~. We suggest that you contact Dr. md last name~ at your convenience.

If you have any questions please feel free to call us at _____.

Sincerely,

_____, M.D.
Medical Director

2.28.c. Participant: Abnormal Results, No MD Designated

<DATE>

<PPT FULL NAME>
<PPT ADDRESS>

Dear Mr./Mrs. <LAST NAME>,

We have completed an evaluation of the retinal photograph taken during your visit at the ARIC Center on <VISIT DATE>. The report from our Reading Center included a finding which 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 the 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 _____.

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,

_____, M.D.
Medical Director

Enclosure

2.29.a. Physician: Abnormal Results

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 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 _____. A full report with results of our tests will be forwarded when available.

Sincerely,

_____, M.D.
Medical Director

2.29.b. Participant: Abnormal Results, Referral Recommended

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 {FIELD}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 {FIELD}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 _____. A full report with results of our tests will be forwarded when available.

Sincerely,

_____, M.D.
Medical Director

2.29.c. Participant: Abnormal Results, No MD Designated

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 {FIELD}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 {FIELD}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 _____.

Should you have any questions, please feel free to contact us at _____. A report from our Ultrasound Reading Center is attached.

Sincerely,

_____, M.D.
Medical Director

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

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 : 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
Before Yesterday B

Go to Item 6

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 P

8. Code number of person completing this form: ..... [ ][ ][ ]

Figure 2

Example of ARIC Form - Page with Multiple Screens

TIA/STROKE FORM (TIAD screen 2 of 30)

1. During this time, how many episodes of loss or changes in speech have you had?

1

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

2. 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 FORM (TIAD screen 3 of 30)

3. 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

4. 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?

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).

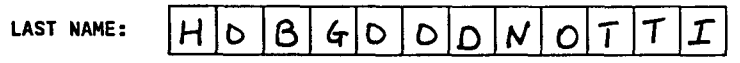
1. Fill In The Boxes: Recording Information

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:

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:

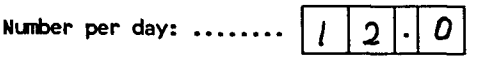


Whenever numerical responses are required, enter the number so that the last digit appears in the rightmost box. Enter leading zeroes where necessary to fill all boxes. (This does not apply to the address section or to any item which combines alphabetic and numeric information. Such items should be treated as alphabetic.)

Example: If the participant's diastolic blood pressure were 96, it should be coded as:

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:



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:

Yes (X)
No (N)

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:

Yes (X) (Y)
No (X)

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

INSTRUCTIONS FOR RECORDING RESPONSES THAT DO NOT MATCH PRECODED RESPONSE CATEGORIES

Most of the questions in the ARIC instruments have precoded responses. There are a few questions, however, that are open-ended--that is, you must write in a response to the question. Some questions have precoded responses as well as an "Other (SPECIFY)" 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 respondents' answers and to assure that 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 (SPECIFY)" categories, print the response verbatim.

* Record the response immediately after it is given.

* Use a black ball point pen provided by your Field Center.

* 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 an answer code is to be circled for each disease listed.

Atherosclerosis Risk in Communities Study

OVERVIEW OF INTERVIEWING

A. Interviewer bias - includes anything that creates a systematic difference between responses obtained by different interviewers.

1. Respondent's perception of the interviewer and his/her reaction to that.

2. Interviewer's perception of the respondent and his/her reaction to that.

B. Characteristics of a good interview.

1. There is an appropriate atmosphere
   - friendly, but businesslike

2. The respondent is at ease
   - female interviewers may be perceived as less threatening
   - ensure confidentiality of participant
   - someone much older than respondent may be viewed as more judgmental
   - space for interviewing is appropriate, quiet, friendly

3. The interviewer obtains the answer to the question that is asked
   - proper use of probes
   - repeats question, rather than interpreting it.

4. Clarification is obtained for confusing answers

5. The interviewer gives only neutral responses to the respondent's answers

6. The response is recorded accurately

C. Specific skills required for interviewers

1. Be able to ask questions at the correct pace and in a conversational tone

2. Know the questions and response categories well enough to keep the interview flowing smoothly

3. Know when there are probes that can be used, and know how to use them

4. Be able to think as an interviewer, and put aside other roles (researcher, and health care provider, etc.) for the time being

5. Be able to maintain a positive attitude about the interview so that respondent feels that the interview is important

6. Be able to keep some level of control over the interview process, e.g. by rewarding the respondent for answering questions, and not for other behavior

7. Neat, pleasant, professional dress; not too timid, not too aggressive

Atherosclerosis Risk in Communities Study

ADMINISTRATION OF INTERVIEWING

A. Administration of work

1. Supervisor
   - One supervisor for each ten interviewers
   - Importance of prompt review of work, and quick feedback
   - Face to face conference with each interviewer once a week

2. Other considerations
   - Good pay and working conditions help keep up morale

3. Tracking procedures
   - Response rate, overall and by interviewer
   - Reasons for non-response
   - Length of interview, overall and by interviewer

B. Interviewer training

1. Must cover all aspects of the interview
   - Introducing yourself
   - Handling people who are reluctant
   - Following instructions for administration of interview form
   - Obtaining consent
   - Answering consent
   - Obtaining privacy for the interview
   - Setting respondent at ease
   - Administering the interview
   - Ending the interview

2. Importance of role playing, using both standard and problematic situations
   - Discuss problems that arose

C. Quality Control of field work

1. Observation
   - Supervisor going with interviewer
   - Tape recording
   - Monitoring telephone interview

2. Editing
   - Field editing
   - Editing by supervisor - edit first few interviews, if no problems then only need edit a sample of remaining interviews

3. Validation
   - That interview was done - by re-interview, telephone call, or sending a letter

D. Ways to reduce the standard errors from interview effects by 10% for at least the one third of items most affected by interviewers (Source: Fowler F, Mangione TW)

1. Increase effective sample size by about 20 % (if simple random sample)

2. If interviewers receive less than 1 day of basic training, increase by a day or two

3. Tape all or a sample of interviews; review one a week per interviewer, provide feedback

4. Rewrite questions to reduce the need for probing and make administration and reading of questions easier

5. Reduce the number of interviews per interviewer by 20% by using 20% more interviewers

Reference

Fowler FJ, Mangione TW. Reducing Interviewer effects on health survey data - Executive Summary. Center for Survey Research - Univ of Massachusetts/Boston. Report No. NCHSR 86-8. U.S. Department of Health and Human Services

Atherosclerosis Risk in Communities Study

ARIC INTERVIEWER TECHNIQUES

A. Standardized Interviewing Techniques

The Atherosclerosis Risk in Communities (ARIC) Study is a collaborative study being conducted through four Field Centers located throughout the United States. In a collaborative study, the aim is to produce a study that represents 16,000 people throughout the country rather than four small studies of 4,000 scattered geographically. The statistical power of a collaborative study is far greater than the smaller ones.

In order to produce data that can be considered collaborative, the study designers must pay attention to the training and the methods in which the data are collected. Thus, a standardized approach to interviewing and the training of interviewers is necessary. The study is standardized through the use of scripts in training, centralized training of supervisors, setting of qualifications for supervisors, reviewing of data that is collected, listening to tapes that are produced at interviews and finally observing the interviewer in the field.

Scripts are used to teach you techniques in probing as well to determine how well you are following skip patterns in the forms and adhering to the various aspects of protocol. Scripts are specifically used in TIA/Stroke and Rose Questionnaire. All of your interviews will be taped and you will gain knowledge about how to do this by talking with experienced interviewers who are systematically reviewed by your supervisor to determine that you are asking the questions as written and are not leading the study respondent or providing answers for them. You will occasionally be observed through monitoring visits to your site.

The study is further standardized in centralizing training for supervisors and where possible for the interviewers. The study initially will train local interviewer supervisors who will be responsible for training on site as the need for new personnel is required. Supervisors will be in touch with each other and will be involved in sharing of tapes to determine adherence to protocol.

B. Interviewing the Study Respondent in Renewal

The ARIC Study respondents will include a variety of people; some of them in the elderly age range since they are aging as the study continues.

Some points that you should consider as you begin to work with an aging population include the following:

1. Difficulty in Understanding the Questions. Some of your interviews will be with persons who have difficulty comprehending your questions. You should read the questions slowly and distinctly and allow the respondent adequate time to answer. Repeat the question if necessary but you must be careful no to insult the respondent by suggesting that they are not understanding. And you must be careful no to change the meaning of the questions in rewording it. Stick to the question as written!

2. Focussing the Interview. Some of the study respondents will welcome this opportunity to talk with someone who is neutral about their health and family problems. In an effort to explain their problems fully, they may stray from the questions asked. You will be expected to know when to allow them time to express themselves and when to bring them back to the focus on the question. You should control the interview but you do not want to alienate the respondent.

3. Leading the Respondent. Some respondents will want to respond in ways that they believe you and/or the government want them to respond. Thus they may expect you to help them with answers rather then giving their opinions or knowledge. We are trying to gather objective data. Reassure the study respondents that there are no wrong and right answers. Encourage them to respond out of their experience and their knowledge.

4. Diffusing Sensitive Questions. Some respondents may feel that some of the questions are sensitive and do not want to respond with answers. Specific questions that may cause problems would be around income and alcohol consumption. Your professionalism and handling of the situation should help to alleviate their fears. However, if all else fails, you can simply offer them the option to decline a specific question. Again the more secure you feel about the confidentiality of the study, the more apt you will be to bring a sense of security to the study respondent.

C. Probing

You will be required at times to probe to obtain more complete or more specific answers from a respondent. It is important that you be knowledgeable about the objectives of the question. "Q x Q's are provided for each interview for this purpose. When you know the objective of a question, you will be able to judge whether a response is adequate or inadequate. In order to elicit complete, adequate answers, you often will need to use an appropriate neutral or nondirective probe. The important thing to remember when probing is that you must not suggest answers or lead the respondent.

General rules for probing follow.

1. Use neutral questions or statements to encourage a respondent to elaborate on an inadequate response. Examples of neutral probes are "What do you mean?", "How do you mean?", "Tell me what you have in mind.", "Tell me more about...".

2. The silent probe, which is pausing or hesitating to indicate to the respondent that you need more or better information, is a good probe to use after you have determined the respondent's response pattern.

3. Clarification probes should be used when the response is unclear, ambiguous or contradictory. Be careful no 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.

4. Repeat the question if the respondent misunderstood or misinterpreted the question. After hearing the question the second time, the respondent will likely understand what information is expected.

5. Unless you have been provided with a response code of "Unknown," the "I don't know" response almost always requires a probe since this response can mean one of several things: the respondent doesn't understand the question and says DK to avoid saying he/she doesn't understand; the respondent is thinking the question over and says DK to fill the silence and gain time to think; the respondent may be trying to evade the issue because he/she feels uninformed, is afraid to giving a wrong answer or the question seems too personal; or, the respondent may really not know.

Some of the questions 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 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 occured.