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

<table>
<thead>
<tr>
<th>Work station</th>
<th>Description</th>
<th>Manual</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anthropometry</td>
<td>Measure weight, height, waist and hips.</td>
<td>2</td>
</tr>
<tr>
<td>Echocardiogram</td>
<td>Measure cardiac dimensions; Jackson, MS</td>
<td>15</td>
</tr>
<tr>
<td>ECG</td>
<td>Obtain resting 12 lead ECG</td>
<td>5</td>
</tr>
<tr>
<td>Exit Interview</td>
<td>Return medication; answer questions; thank participants</td>
<td>2</td>
</tr>
<tr>
<td>Informed Consent</td>
<td>Visit 3 informed consent and authorization for release of hospitalization records</td>
<td>2</td>
</tr>
<tr>
<td>Interviews</td>
<td>Collect sociodemographic data; cognitive function; health care, and medical, personal and reproductive (women only) history; medication/vitamin use; food frequency intake; physical activity.</td>
<td>2</td>
</tr>
<tr>
<td>MRI</td>
<td>Cerebral magnetic resonance imaging; Forsyth Co., NC and Jackson, MS.</td>
<td>14</td>
</tr>
<tr>
<td>Medical Data</td>
<td>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.</td>
<td>2</td>
</tr>
<tr>
<td>Reception</td>
<td>Greet the participant; determine fasting status; verify identifying information; obtain tracing data; collect medications.</td>
<td>2</td>
</tr>
<tr>
<td>Retinal Photo.</td>
<td>Obtain photograph of ocular fundus.</td>
<td>13</td>
</tr>
<tr>
<td>Sitting Blood</td>
<td>Sitting blood pressure</td>
<td>11</td>
</tr>
<tr>
<td>Snack</td>
<td>Provide snack with no stimulants.</td>
<td>2</td>
</tr>
<tr>
<td>Ultrasound</td>
<td>Obtain B-mode scan of extracranial carotid arteries. Record heart rate and blood pressure changes as participant arises from supine position.</td>
<td>6,11</td>
</tr>
<tr>
<td>Venipuncture</td>
<td>Obtain blood samples for laboratory tests and storage of specimens.</td>
<td>7</td>
</tr>
</tbody>
</table>
Table 2.2  Training for the ARIC Visit 3 Cohort Exam

<table>
<thead>
<tr>
<th>Procedure</th>
<th>CENTRAL</th>
<th>LOCAL</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Trainee</td>
<td>Trainer</td>
</tr>
<tr>
<td>AFU (Contact Yr 7)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Annual F/U V-3 Scheduling</td>
<td>Chief Interviewer</td>
<td>CSCC</td>
</tr>
<tr>
<td>Anthropometry</td>
<td>Interviewers</td>
<td>Minneapolis</td>
</tr>
<tr>
<td>ARDES Version _-0 Workstations</td>
<td>Data Coordinator</td>
<td>CSCC</td>
</tr>
<tr>
<td>Data Management</td>
<td>Data Coordinator</td>
<td>CSCC</td>
</tr>
<tr>
<td>Blood Pressure</td>
<td>Technicians</td>
<td>Minneapolis</td>
</tr>
<tr>
<td>Cognitive Function</td>
<td>Interviewers</td>
<td></td>
</tr>
<tr>
<td>Dietary Intake</td>
<td>Interviewers</td>
<td>N/A</td>
</tr>
<tr>
<td>Echocardiogram</td>
<td>Technicians</td>
<td>Jackson</td>
</tr>
<tr>
<td>ECG 12 lead ECG</td>
<td>Technicians</td>
<td>Minneapolis</td>
</tr>
<tr>
<td>Fasting/Tracking</td>
<td>Interviewers</td>
<td>CSCC</td>
</tr>
<tr>
<td>Health History</td>
<td>Interviewers</td>
<td>For/Wash Co.</td>
</tr>
<tr>
<td>Letters/Reports</td>
<td>Interviewers</td>
<td>CSCC</td>
</tr>
<tr>
<td>Med Data Review</td>
<td>PA/Nurse</td>
<td>Forsyth Co.</td>
</tr>
<tr>
<td>Medication Survey</td>
<td>Interviewers</td>
<td>Forsyth Co.</td>
</tr>
<tr>
<td></td>
<td>Interviewers</td>
<td>Forsyth Co.</td>
</tr>
<tr>
<td></td>
<td>Coding</td>
<td>CSCC</td>
</tr>
<tr>
<td></td>
<td>Interviewers</td>
<td></td>
</tr>
<tr>
<td>MRI</td>
<td>Informed consent Technician</td>
<td>Technicians</td>
</tr>
</tbody>
</table>
Table 2.2  Training for the ARIC Visit 3 Cohort Exam, continued

<table>
<thead>
<tr>
<th>CENTRAL</th>
<th>LOCAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trainee</td>
<td>Trainer</td>
</tr>
</tbody>
</table>

| 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

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

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
dокументs 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

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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 workstation 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 hypercholesteroleemia, 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 prior to 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, B₆, 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).

![Diagram of Frankfort Plane](image)

**Figure 2.17.1** Frankfort Plane for Measuring Body Height

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

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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
Figure 2.17.3 Location of Hip Girth Measurement

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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.