Manual 12

Quality Assurance and Quality Control

The National Heart, Lung, and Blood Institute
of the National Institutes of Health

ARIC Protocol

Manual 12

Quality Assurance and Quality Control

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FOREWORD

This manual entitled, Quality Assurance and Quality Control, 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 set 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 reading centers and central laboratories, make up Manuals 4 through 11. Manual 12 on Quality Assurance and Quality Control contains a general description of the cohort study's approach to quality assurance as well as specific protocols for each of the study procedures.

The version status of each manual is printed on the title sheet. The first edition of each manual is Version 1.0. Subsequent modifications of Version 1 (paged updated, pages added, or pages deleted) are indicated as Versions 1.1., 1.2, and so on, and are described in detail in the Revision Log located immediately after the title page. When revisions are substantial enough to require a new printing of the manual, the version number will be updated (e.g., Version 2.0) on the title page.

ARIC Study Protocols and Manuals of Operation

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Manual 12. Quality Assurance and Quality Control

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1. INTRODUCTION

1.1 Brief Description of Quality Assurance and Control Procedures

The distinction between quality assurance and quality control is both arbitrary and philosophical. The former is considered here as relating to activities to assure quality of data which take place prior to collection of data, while the latter relates more to efforts during the study to monitor the quality of data at identified points in the collection and processing of data. It is quality control on which Manual 12 focuses, whereas quality assurance is the essence of the entire Manual of Operations, and includes the following activities:

1) Detailed protocol development. A clear description of the study design, training, certification, and the various data collection activities provides the blueprint for the study. Each protocol is a written reference for staff and researchers. Procedures for handling the routine, as well as the exceptional, are given. Those protocols constitute the ARIC Manuals of Operation.

2) Training and updating training. Training is the transfer of the study plans in the protocol to the research staff. The process has resulted in clarification and revision of the protocol. Special materials for this purpose have been developed for ARIC and are the basis for continuing education during the study. Continued investment in quality data during the study is made by periodic refresher training sessions which review the protocol and update personnel on any changes which have occurred.

3) Certification. Criteria to examine the adequacy of an individual's training have been established. Individuals meeting these criteria are qualified to execute a protocol or a segment of it. Certification and periodic re-certification indicate that an acceptable performance standard has been mastered or an adequate knowledge of material has been achieved. The Coordinating Center monitors the study to ensure that staff perform only those functions for which they are certified and that re-certification activities are implemented as planned and as scheduled.

For quality control purposes, ARIC data collection and transfer is monitored by observation (directly and by tape recording) and by quantitative assessment using both specific quality control procedures (e.g., repeat measurements) and statistical analysis of study data for quality control (QC) purposes. Monitoring is performed both by personnel within the field centers and by monitoring visits from the Coordinating Center and various central agencies. A summary of selected aspects of ARIC Cohort Study quality control follows.

1) Observation monitoring. Over-the-shoulder observations of staff by supervisors or those who wrote the protocols identify techniques that need improvement and points where the protocol is not understood. Also, periodic monitoring visits are made to each field center by Coordinating Center staff to observe actual clinic activities.

Detailed checklists are used to assess strict adherence to protocol. Immediate feedback is given, and general recommendations for improvements are sent to the Steering Committee for action.

Another form of observation in the ARIC study takes place with the interview portion of the protocol. A supervisor reviews the tapes on a random basis, reviewing at least one of each type per month. The supervisor checks for adherence to protocol and for accuracy of recorded responses.

2) Quantitative monitoring. Random repeat measurement by the same and by different technicians are used as quality control tools. There are two important benefits from random repeat measurements. First, randomly re-doing a fraction of an individual's work is likely to stimulate a better overall quality of data. Second, the duplicate determinations provide measurements of data quality. At the time of reporting the results of the study, it is important to establish that the "error" in the data is not so large as to threaten the validity of conclusions.

   Actual study data are useful to monitor quality of performance. Mean and standard deviations of study variables, by technician, are monitored for differences among technicians or trends over time. Digit preference in anthropometry or blood pressure measurement is monitored with study data.

3) Reporting results. Two aspects of the reporting of quality control monitoring should be emphasized. First, the results must be timely. When remedial action is required, reporting must be prompt so that a return to an acceptable level of performance is not unnecessarily delayed. Second, the reporting format must be easily understood. Tabular presentations are accompanied by clear graphical displays.

4) Action on results. With conscientious and trained staff, quality control reports provide an opportunity to praise a job well done. On the other hand, a poor performance is the basis for some remedial action. Depending upon past performance, the amount of error, and, taking due account of personal circumstances, the appropriate action may be a simple discussion to encourage a better performance. Re-training may also be appropriate at times.

1.2 Monitoring of Data Quality and Implementing Corrective Action

The subsequent sections of Manual 12 describe the procedures and reports used to monitor quality control of the ARIC Study. These reports are designed to be clearly understandable, to be distributed to individuals responsible for reading them carefully, and to lead to corrective actions. A Quality Control Committee is designated by the ARIC Steering Committee to coordinate and direct the quality control activities.

The Quality Control Committee (QCC) is charged with establishing the content of the quality control reports and with the responsibility to review all reports with specific attention given to deviation from protocol, recurrent problems and trends or shifts in data over time. Working with the specialty

subcommittees and the Coordinating Center, the QCC determines the content, areas of emphasis, and statistical treatment for each of the routine quality control reports. The QCC specifies quality control reports in response to priorities for quality assurance developed by the Steering Committee. The QCC prepares recommendations to the Steering Committee in matters of quality assurance, and contacts field centers, reading centers, or laboratories as needed, to advise them of a problem and to discuss the mechanism for correction. Central logs of data and management quality problems are reviewed by the QCC. The QCC has representation from the Coordinating Center, Field Centers, Laboratories and Program Office.

The role of the Coordinating Center (CC) in quality assurance and control is described in general in ARIC Manual 1. More specifically, as the repository for ARIC Study data, the Coordinating Center is responsible for preparation and dissemination of QC reports. These reports consist of tabulated data and summary statistics, and identify specific QC problems. The Coordinating Center maintains contact with centers to confirm that a center has been notified of a problem and that corrective action has been implemented. The Coordinating Center maintains central logs of data quality problems and solutions. The Coordinating Center conducts periodic field center monitoring during which Coordinating Center staff participate in and observe a routine ARIC clinic visit. In response to requests from the QCC, the Coordinating Center replicates pertinent sections of quality control reports prepared by reading center/laboratories. Some external quality control programs for the reading center/laboratories are administered by the Coordinating Center, and reported to the QCC.

The distribution of the QC reports and the designation of persons or groups responsible for responding to the reports and implementing corrective action are described below. Each field center and/or reading center is given the responsibility of reading, implementing corrective action, and responding to the reports in their respective area. Monitoring reports for protocol deviations, recurrent problems, or temporal trends is the responsibility of the QCC. Immediate QC problems identified by reading centers, laboratories or the Coordinating Center (e.g., data entry problems, broken vials, unacceptable pulmonary function tests) are sent to the field centers directly for correction with a record kept by the reading center/laboratory/CC. Problems identified by periodic monitoring are sent to the field centers/reading centers/laboratories with concurrent monitoring by the QCC.

The distribution of periodic reports described in Chapter 4 is as follows:

1) QC reports on technician-specific performance are sent quickly to the respective field center principal investigators, study coordinators and the QCC.

2) QC reports on laboratories/reading centers' performance are sent quickly to the respective principal investigators, and to the QCC.

3) Summary QC reports without technician-specific data are sent to the Steering Committee through the QCC.

The following centers and committees have responsibility for responding to the reports as follows:

1) Field center PIs, study coordinators, local certifiers/trainers. Review each QC and monitoring report with technican-specific quality for their field center; identify a solution to each problem; implement corrective action; report corrective action to Coordinating Center monitor.

2) Laboratory and reading center directors. Review each QC and monitoring report for their laboratory/center; identify a solution to each problem; implement corrective action; report corrective action to QCC.

3) Quality Control Committee. Review each QC and monitoring report with attention to deviation from protocol, recurrent technician or field center problems, and temporal trends; direct field center/reading center/laboratory attention to problems and recommend additional corrective action if they persist; monitor the implementation of corrective action; contact and coordinate study agencies and investigators to review data quality problems and solutions; prepare summary reports and recommendations for the Steering Committee.

4) Speciality subcommittees. Review summary reports with attention to deviations from and deficiencies in the protocol; address recommendations to QCC.

5) Steering Committee. Review QC summary reports; monitor data quality trends; direct the QCC in areas needing special attention; responsible for changes in protocol.

1.3 Organization of the Quality Control Manual

For the cohort component of the ARIC Study, procedures are described (Sections 6-12) by source of data within the field center, i.e., by work station, e.g., anthropometry or electrocardiogram (ECG). For each area there appears a brief description of the data collected and a summary of the important quality control measures. There follows a detailed list of quality assurance or quality control measures addressing each data transfer point or possible source of error. The ARIC study's system of making (blinded) repeated measurements for quality control purposes is used in so many areas of the cohort study that a separate section, Section 2, is devoted to description of this topic. Section 3 discusses the analysis of study data for quality control purposes. Section 4 briefly discusses the types and schedules of quality control reports. Section 5 ddescribes two types of quality control analyses that appear in many areas: replicate data anlaysis and monitoring for digit preference. Subsequent sections describe the quality control procedures for the various cohort study work stations, certification, and community surveillance.

2. DESCRIPTION OF THE QUALITY CONTROL SYSTEM FOR REPEATED MEASUREMENTS

In several areas, repeated measurements during a clinic examination are taken for quality control purposes and are recorded on study forms separate from the participant's original forms. These forms are designated as belonging to phantom participants. Approximately 7% of assigned study IDs are for phantom participants. The Study Coordinator in each field center (field center) generally creates phantom participant folders when needed, and initializes a phantom participant diskette. As a safeguard against gathering unnecessary data on the phantom participant forms, only a subset of the usual study forms are included for QC repeat studies. Currently, this is only anthropometry and venipuncture. (Repeat scanning with ultrasound is handled differently and is described in Manual 6.) Repeat measurements are then entered, by the technician making the measurements, on the phantom forms/diskettes just as regular study data, as explained below, and the folders are processed as regular study data. There is one extra form in the QC phantom participant's folder, the ARIC QC Phantom Participant and Non-Participant ID Form (Appendix 1), which is used to match the phantom ID to the IDs of the ARIC participants contributing repeat measurements. This form is also used to record IDs used for data collected on persons who are not ARIC study participants (e.g., monitors from the Coordinating Center). This form is sent to the Coordinating Center with a copy kept in the phantom participant's folder. As a further backup, the QC phantom ID is entered on a form in the associated ARIC participant's folder, as explained below.

The procedures for using the QC phantom participant folders are:

1) The study coordinator creates phantom folders, putting the QC phantom participant labels on the Phantom Participant Form, the anthropometry form, and the venipuncture form, and places these in the folders. When QC phantom participant IDs are assigned, the person making the assignment does the following on the Quality Control Phantom Participant and Non-Participant ID Form:

   a) Places the label for the ID assigned to the QC phantom in the space provided at the top of the form;
   b) Circles "P" for "A QC Phantom Participant" on the form;
   c) Fills in their own ID and the data the QC phantom ID was assigned in the spaces provided.

2) As ARIC participants contribute replicate data, the matching ARIC participant labels are affixed to the QC Phantom Participant Log for the data that are contributed. Eight replicate QC blood drawing tubes are assigned to a phantom participant. For anthropometry there are two or three sets of measures to complete, each set from a different ARIC participant. (The procedures for anthropometry repeats are discussed more thoroughly below in Section 5, Anthropometry. For venipuncture repeats, see Manual 7 and Section 10 of the QC Manual.)

3) After all needed repeat measures are recorded on the phantom's venipuncture or anthropometry forms (or diskette), or when two weeks have passed since the first QC data were entered on the form, the data coordinator inserts the folder in the regular stream of participant folders as if the Exit Interview had just finished. It is processed as usual, except the QC Phantom Participant Log is copied by the Study Coordinator and placed in the folder, with the original sent to the Coordinating Center.

   It is desirable to utilize each phantom participant ID for gathering both blood and anthropometry QC entries in order to use fewer ARIC IDs. However, there are times when this should not be maintained. For example, the study coordinator keeps a reserve of 2-3 phantom participant folders, so that if none is ready to leave the venipuncture station for anthropometry use, or vice versa, new folders from the study coordinator are used. Since different measurement groups in anthropometry may be sampled at different rates, the number of IDs needed to record all anthropometry repeat data groups will not be balanced.

When monitors, volunteers or other persons who are not participants in the ARIC cohort go through at least some of the ARIC examination procedure, they are assigned an ARIC cohort ID, which are recorded on the Quality Control Phantom Participant and Non-Participant ID Form. The following procedure should be used:

1) The study coordinator assigns an ARIC cohort ID at the start of their visit.

2) As soon as the ID is assigned, a label for that ID is placed in the box marked "Phantom Participant ID Number" on the QC Phantom Participant and Non-Participant ID Form, and "N", for "An ID Used for a Non-Participant" is circled.

3) Also as soon as the ID is assigned, the person making the assignment records the date and their own ID number in the spaces provided.

4) The same week the non-participant is seen, the QC Phantom and Non-Participant ID Form will be photocopied. The copy is retained at the field center, and the original is sent to the ARIC Coordinating Center.

Deadlines for sending Phantom Participant and Non-Participant ID forms to the Coordinating Center:

1) Forms filled out to record the IDs used for non-participants in the ARIC cohort study should be sent to the Coordinating Center at the end of the same week in which they are collected.

2) For quality control phantoms, the folder for the phantom should go to the study coordinator for routine processing of any Venipuncture or Anthropometry forms filled out on the phantom, and for mailing of the paper Phantom Participant and Non-Participant ID form, no later than two weeks after the first QC entries are made on the form.

3. ANALYSIS OF STUDY DATA FOR QUALITY CONTROL PURPOSES

The methods to monitor the quality of the ARIC data collection process include analyses of the study data itself. This section provides a summary and discussion of the analysis of the study data for quality control purposes.

To monitor the data entry process, most variables in the ARIC data base are analyzed periodically, by field center, in terms of:

1) status of the variables for each participant record (no problem, skipped due to skip rule, problem with the entry).

2) frequencies for categorical variables, or means, standard deviations and selected percentiles for continuous variables.

The first item, especially, allows a view of the prevalence of data entry problems.

Summary statistics by field center, by technician, or by period of observation (month or quarter) are generally not sufficient for quality control purposes, due to the large amount of explained variation in a small amount of data. For example, the means of weight measurements made by two technicians may differ simply because of age or sex differences between the two groups examined. Differences among field centers may reflect differences among the underlying populations each is sampling. In order to adjust for such known sources of variation, the Coordinating Center periodically examines selected items of study data in terms of age- and sex-adjusted means by technicians.

In addition to looking at differences among technicians within a field center in a given reporting period, the Coordinating Center also looks at trends in adjusted means and in variability after adjustment, over time. Relatively sudden shifts in the mean for a given technician or field center or increases in measurement variability after adjustment may indicate that changes in measurement technique have occurred which should be examined. Similar analyses of trends in the study data's summary statistics monitor laboratory data for signs of measurement drift or reduced measurement precision.

Certain measurements which involve a degree of subjective judgment by technicians, such as blood pressure or anthropometry data, are commonly subject to digit preference. The Coordinating Center periodically analyzes such data for digit preference, by technician.

Some data sent to central reading centers (e.g. ECG, pulmonary function tests, ultrasound) are assigned a quality grade by the respective reading centers. The Coordinating Center prepares periodic summaries of recorded quality grade, broken down by technicians or field center to monitor performance.

Certain items of data (e.g. fasting time before blood drawing) give information on protocol adherence and the validity of data obtained from each participant. The Coordinating Center periodically analyzes these data items by field center.

The Coordinating Center monitors on a monthly basis the frequency with which each technician performs specific procedures in participant exams, comparing this frequency with the minimum number of exams required to maintain proficiency.

4. QUALITY CONTROL REPORTS FOR THE COHORT COMPONENT

A large number of reports are generated by quality control work. In order to spread out the workload and the distribution of the reports, a schedule for the Cohort Component reports has been developed (although it will undoubtedly be frequently modified).

Frequency of reports vary from bimonthly to semi-annually, although there are summary reports which are more of a historical nature, covering longer periods. For a report to be of use in correcting problems in data gathering, it must appear more frequently and be prepared as soon as possible after the end of the period covered. The frequency of reports is determined by balancing the study's need for prompt and frequent monitoring with the available resources to generate such reports and the need to accumulate enough data to have an adequate sample size. For example, analysis of adjusted means by technician and of repeat measures in anthropometry is not feasible on a monthly basis, but can usefully be done each quarter. Digit preference analyses, however, are feasible on a bimonthly basis for blood pressure.

The standard QC reports generated for the categories within the Cohort Component are outlined below. QC reports for Community Surveillance are described in Chapter 15 of the manual. (Frequency for analyses appearing less often than bimonthly appear in parentheses.)

1) Certification

   a. Number of technicians certified, by area and field center
   b. Number of studies performed in past month, by area, field center, and technician
   c. As in (b.), for the past two months. This report documents which technicians are not performing enough studies to maintain certification.

   Note: In addition to the bimonthly reports, semi-annual reports are also produced to account for revisions generated by the bimonthly reports.

2) Anthropometry

   a. Digit preference (semi-annually)
   b. Repeated measures (semi-annually)
   c. Adjusted means by technician (semi-annually)

3) Sitting Blood Pressure

   a. Digit preference
   b. Adjusted means by technician (every four months)
   c. Analysis of serial measures (three repeat measurements within a sitting) (every four months)
   d. Cuff size checks (every four months)

4) Laboratory (lipids, hemostasis, clinical chemistries, hematology)

   a. Repeated measures
   b. Condition of sample on arrival (quarterly)
   c. Analysis of QC samples from frozen storage (semi-annually)
   d. Internal QC results (quarterly)
   e. External QC results (frequency varies)

5) Pulmonary Function

   a. Acceptability and reproducibility by field center and by technician
   b. Adjusted means by technician (semi-annually)
   c. Results of test pool submissions (semi-annually)
   d. Comparison of remeasured spirograms by Pulmonary Function Reading Center (monthly)

6) ECG

   a. Mean quality grade, by field center and by technician
   b. Results on test pool submitted to Halifax ECG center (quarterly)
   c. Results on test pool of 12-lead ECGs submitted to Minneapolis ECG Reading Center (quarterly)
   d. Results on test pool of 2-minute rhythm strips submitted to Minneapolis ECG Reading Center (quarterly)
   e. Summary of adjudication of Minneapolis/Halifax disagreements (semi-annually)

7) Ultrasound and Postural Change

   a. Frequency of nonvisualized boundaries, by technician and site/angle
   b. Sonographer repeat studies (quarterly)
   c. Reader repeat studies (quarterly)
   d. Adjusted means by sonographer (semi-annually)

8) Participant Protocol Compliance (semi-annually)

   a. Twelve-hour fast
   b. Abstinence from smoking/caffeine
   c. Abstinence from heavy exercise

9) Quarterly Observation with Checklists (semi-annually)

10) Venipuncture

   a. Distribution of number of stick attempts, means and distribution of filling and processing time (quarterly)

5. Special Statistical Analyses in Quality Control Reports

5.1 Replicate Data Analysis:

The collection of replicate data for anthropometry and blood chemistries is described above in Section 2 and in Manual 6a for Ultrasound. In this section, the statistical techniques used to analyze such data are described. Refer to Table 1 below for an example of a summary table of results from replicate data analysis. The following general model of variation in the study data underlies these techniques: suppose that the total variance of the study data, σ_T^2, is divided into two components, the measurement error component, σ_e^2, and the true variation between and within individuals in the study population, σ_b^2, so that $\sigma_T^2 = \sigma_b^2 + \sigma_e^2$. One quantity of interest in considering data quality is the reliability coefficient $R = \sigma_b^2/(\sigma_b^2 + \sigma_e^2)$, which is one minus the proportion of total variance due to lab variation. It can be shown that R is the correlation coefficient between two laboratory measurements made on the same (split) sample, in the blood chemistry case. In the anthropometry and ultrasound cases it is the correlation between two measures made a short time apart on a person. Let X_{i1} and X_{i2} be two repeated measures on the i-th subject in the QC replicate data, and $\overline{X}_i$ be the mean of these two measures. Then σ_e^2 is estimated from that pair by

$$s_i^2 = \sum_{j=1}^{2} (X_{ij} - \overline{X}_i)^2 = \frac{1}{2} D_i^2$$

where $D_i = (X_{i2} - X_{i1})$. Estimates of σ_e^2 from all n pairs of replicates are combined by taking the average of the pair estimates (s_i^2). That is,

$$\hat{\sigma}_e^2 = \frac{1}{n} \sum_{i=1}^{n} s_i^2 = \frac{1}{2n} \sum_{i=1}^{n} D_i^2 .$$

R may be estimated in two ways: (1) from the replicate data alone, using the technique of one-factor random effects ANOVA to divide the total variance in the replicate data into estimates of σ_b^2 and σ_e^2 (the estimator of σ_e^2 is the same as the $\hat{\sigma}_e^2$ described above); (2) by combining the information from the replicates with information from the total ARIC study data set. This second method is the one which has been used in ARIC. From the sample variance of the study data, S_T^2, we may obtain a good estimate of σ_T^2. Then, σ_b^2 is estimated by $S_T^2 - \hat{\sigma}_e^2$, so that the estimate of R is given by

$$\hat{R} = 1 - \frac{\hat{\sigma}_e^2}{S_T^2} .$$

$\hat{R}$ is useful for overall assessment of the reliability of the measurement method. For routine monitoring of the data collection process, the standard deviation $\hat{\sigma}_e$ (the square root of $\hat{\sigma}_e^2$) is most closely watched. In monitoring laboratory data, $\hat{\sigma}_e$ for each assay is compared with the target standard deviation (S.D.) which the laboratory has set based on analyses of internal quality control pools. Blind replicate estimates of the laboratory S.D. which are more than twice the target S.D. are considered cause for concern.

Several additional statistics are calculated for each assay. For each QC replicate pair, the i-th pair coefficient of variation, $C.V._i$, may be calculated by

$$C.V._i = \frac{s_i}{\overline{X}_i},$$

where s_i is the i-th pair standard deviation estimate. The mean sample pair C.V. is then calculated as the average of the n sample pair C.V.'s. A mean sample pair C.V. greater than 10% is considered very large on most assays.

In order to monitor for systematic differences between original and replicate measurements, the proportion of non-zero differences which are positive is monitored. With no systematic trend, this proportion should be one-half. A sign test is done to test for significant differences, and significant differences which persist over several months are pointed out to the laboratory. (This test is done, but is less useful, for anthropometry and ultrasound data.) Means and percentiles of these differences are also presented. It should be noted that if the mean difference is non-zero, alternative estimates of σ_e and of the reliability coefficient, R, should be considered.

Frequencies of absolute percentage differences for the replicate pairs are also given, as are percentiles of the absolute differences. For ultrasound B-mode data, instead of frequencies of absolute percentage differences, frequencies of absolute differences are given.

Before any analysis is done on the QC replicate pairs, the data are screened for possible mismatches or "strange" observations. For each <u>laboratory</u> assay, the mean and standard deviation of the difference between repeat and original pairs from prior analysis are used to determine acceptable intervals. If the difference between the repeat and original is outside the interval (determined from previous data)

Mean Assay Difference ± (2 S.D. of Assay Difference)

on <u>four</u> or more assays, the pair is excluded from analysis. Likewise, if the difference between the repeat and original is outside the interval

Mean Assay Difference ± (1.5 S.D. of Assay Difference)

on <u>five</u> or more assays, the pair is excluded.

ARIC Central Clinical Chemistry Laboratory
Repeatability Studies
ARIC Cohort Study, Sep. 1987 – Feb. 1988
Preliminary Data: Not for Publication
Summary Table

	Num. of Pairs	Mean on Q.C. Pairs	Estimated Lab S.D.	Reliab. Coeff. (1)	Prop. of Nonzero Diffs. >0 (2)	Mean Sample Pair C.V (3)	Frequencies of % Absolute Difference				Percentiles of Absolute Diff.		Target Internal Q.C. S.D. (4)
							0–10	10–25	25–50	50+	50%	75%	
ALBUMIN	128	3.95	0.12	0.79	0.29*	2.2	125	3	0	0	0.1	0.2	0.07
CALCIUM	128	9.66	0.23	0.68	0.37*	1.9	128	0	0	0	0.3	0.4	0.23
CREATININE	128	1.06	0.06	0.90	0.23*	3.9	95	33	0	0	0.1	0.1	0.08
GLUCOSE	128	116.09	3.55	0.99	0.46	2.4	123	5	0	0	3.9	6.0	3.16
INSULIN	128	11.74	2.20	0.99	0.54	18.8	42	34	31	21	2.4	3.0	2.60
MAGNESIUM	128	1.61	0.07	0.78	0.41	3.3	115	13	0	0	0.1	0.1	0.13
PHOSPHORUS	128	3.42	0.09	0.97	0.57	2.0	128	0	0	0	0.1	0.2	0.10
POTASSIUM	128	4.28	0.39	0.35	0.13*	6.4	92	26	10	0	0.4	0.5	0.05
PROTEIN	128	7.22	0.16	0.88	0.33*	1.7	128	0	0	0	0.2	0.3	0.08
SODIUM	128	141.66	1.04	0.81	0.44	0.6	128	0	0	0	1.1	2.0	1.00
UREA_NITROGEN	128	14.52	0.66	0.97	0.46	3.4	110	17	1	0	0.6	1.0	0.66
URIC_ACID	128	5.58	0.39	0.93	0.43	3.9	113	8	7	0	0.3	0.4	0.23

* Indicates proportion of nonzero differences is significantly different from 50% at $p < .05$.

(1) The reliability coefficient is one minus the proportion of the total variance which is attributable to lab variance. It is also interpretable as the correlation between measures on the replicate samples.
(2) Tests for systematic trends in phantom – original differences by testing hypothesis that true proportion of differences positive is 50%.
(3) This is the mean of the coefficients of variation (C.V.) over all pairs, with the C.V. on each pair being estimated by 100 times the standard deviation for the pair divided by the mean on the pair. The mean on these C.V.'s is also the mean of the absolute percentage differences on the pairs divivided by the square root of two.
(4) Target S.D is set by experience on laboratory internal Q.C. pools.

5.2 Monitoring for Digit Preference

Monitoring for digit preference is done by the Coordinating Center for blood pressure and for anthropometry, at frequencies determined by study needs. (See Section 4.) Summary reports are sent to the Quality Control Committee, and reports on individual technicians are sent to the Field Center. The actual technician-specific frequencies of final digits recorded are not revealed to the Field Center, to prevent technicians from overcompensating to avoid digits that they had preferred in previous reports.

For blood pressure only final digits 0,2,4,6,8 are possible, while for anthropometry 0,1,2,... 9 are all possible. To discuss the analysis of both, let k be the number of possible final digits, so k = 5 or 10. For a technician with no digit preference, in a large number N of studies the expected frequency of each final digit is N/k. A Pearson chi-square goodness-of-fit test is done to test the null hypothesis that all possible final digits are observed with frequency N/k. The statistic is calculated as

$$X^2 = \frac{\sum_{i=1}^{k} (O_i - \frac{N}{k})^2}{\frac{N}{k}}$$

, where O_i is the observed frequency of the i^{th} possible digit and $N = \sum_{i=1}^{k} O_i$. For large N, this statistic is distributed approximately as a chi-square distribution with k-1 degrees of freedom. Note that $X^2 = 0$ when the observed number for each possible digit is N/k. For each calculated value of X^2, the p-value is calculated as the probability upon repeated sampling (N fixed) of getting a value as extreme as that actually observed. For the validity of this test, $N \geq 25$ for blood pressure and $N \geq 50$ for anthropometry are required. A cut point of $p < .05$ is used to determine if the divergence from a uniform distribution of digits is statistically significant. However, with large enough N, even small deviations from uniformity are declared statistically significant. Thus a "digit preference score" was developed:

$$DPS = 100\sqrt{\frac{X^2}{(k-1)N}} \quad .$$

This score can be shown to have values between 0 and 100. (It is 0 when all observed digit frequencies are N/k and is 100 when all observed counts are in one cell.) Arbitrarily, after consideration of the first few months of ARIC data, a cutpoint for marked digit preferences was selected: $DPS \geq 20$. A technician is judged to show "strong evidence of digit preference" if all of the following are true: (1) $N \geq$ minimum N required (25 for blood pressure, 50 for anthropometry); (2) the p-value for the X^2 statistic is <.05; and (3) the digit preference score is greater than or equal to 20 ($DPS \geq 20$). Technician specific data are reported in a table like the one below.

TABLE 2

Clinic Visit - Blood Pressure
Digit Preference on Three BP Readings
Data received at Coordinating Center for July 1987

Field Center: Technician ID:

Measurement	N	Total Frequencies of Even Final Digits: Most Freq.	2nd	3rd	4th	Least Freq.	Probability*	Digit Preference Score
Systolic BP	57	19	13	10	8	7	0.065	19
Diastolic BP	57	21	13	11	7	5	0.009	24
Random Zero	57	15	13	12	10	7	0.515	12

* Probability of at least this much variation if no digit preference.

As noted above, a sample size $N \geq 25$ for blood pressure and $N \geq 50$ for anthropometry are needed for the validity of the chi-square test for digit preference. For this reason, the smallest period examined for digit preference is one month for blood pressure and two months for anthropometry. All reports are broken down into these periods for the two types of measures, although they may summarize the data over a longer time interval.

Although all occurrences of a month with marked digit preferences are recorded, only repeated occurrences are especially noted and the Field Center asked to initiate re-training and increased observation. If digit preferences persist over a number of months, it is requested that the technician be moved to another station. Digit preference monitoring is also used in determination of re-certification.

6. SITTING BLOOD PRESSURE

6.1 Brief Description of Sitting Blood Pressure Procedures and Related Quality Assurance and Quality Control Measures

The following equipment is used for measuring sitting blood pressure: a standard Littman stethoscope with bell; standardized Hawksley random-zero instrument; standard Baum manometer for determining peak inflation level; four standardized cuffs (from Baum). After the technician explains the procedure to the participants, measures the arm and wraps the arm with the correct cuff, the participant sits quietly for 5 minutes, and then the technician makes 3 readings, with at least 30 seconds between reading one measure and beginning the next. The average of the second and third readings is reported to the participant.

From the detailed protocol for sitting blood pressure in ARIC Manual 11, the various data transfer points and other possible sources of error have been considered, and needed quality assurance and control measures have been derived. Important elements in quality assurance are training and certification programs, observation of data collection by supervisors, quarterly simultaneous blood pressure measurements using Y-tubes by two technicians, and standard equipment maintenance procedures performed and entered into logs.

6.2 Maintenance of Equipment

1) Availability of all sizes of cuffs: The field center blood pressure supervisor makes certain that the field center always has the full range of blood pressure cuffs available at each blood pressure station. field center staff report immediately to the blood pressure supervisor if they cannot find all cuff sizes at the station.

2) Sphygmomanometers: Regular inspections of random-zero and standard sphygmomanometers are described in ARIC Manual 11, Section 1.12.1 and Appendices I, II, and V. A log sheet is kept by the field center blood pressure supervisor, who records the performance of these checks and comments on any problems found (see copy of log sheet in Manual 11, Appendix IV). Each month this log sheet is mailed to the Coordinating Center.

3) Measuring tape: Each week the blood pressure supervisor checks the condition of the measuring tape used to measure arm circumference at the blood pressure station(s), and replaces any that have become worn. The results of this check are recorded on the anthropometry weekly log. (See the anthropometry section for details.)

4) Traveling manometer: Once each year, a single standard manometer is carried between Field Centers and used to calibrate the standard and Random-Zero instruments. The Coordinating Center prepares a report on the results of this calibration check.

6.3 Field Center Monitoring of Technician Performance

1) Double stethoscoping: To help assess the accuracy and precision of blood pressure measurements, once each January, April, July, and October each blood pressure technician takes part in measuring blood pressure simultaneously with another technician, using a Y-tube. This procedure should be carried out using volunteers or other field center staff members, not ARIC study participants. The two technicians also perform independent measurements of arm circumference, which they record on the forms. If the two technician measurements lead to a disagreement on which blood pressure cuff to use, then both re-measure the arm together and use the cuff size determined by that measurement. Each records this disagreement on the Sitting Blood Pressure form. Each technician separately records all blood pressure measurements on paper on a standard Sitting Blood Pressure form. The two paper forms are given to the field center blood pressure supervisor, who compares the results.

   The field center blood pressure supervisor reviews the results of these duplicate examinations, calculating the disagreement between technicians on the blood pressure measurements and recording it on the form. The two technicians should agree on each of the three measurements of diastolic and systolic blood pressure within 4 mmHg, and their average should agree within 3 mmHg, as is required by the standards for certification. If they do not, further duplicate readings are taken to determine if either or both technicians require recertification. These further measurements should again be recorded as described in the previous paragraph.

   The IDs of each set of technicians paired for simultaneous measurement of blood pressure are recorded in the Quarterly Observation Log, which is mailed to the Coordinating Center.

2) Quarterly observation: Once every January, April, July and October, the field center blood pressure supervisor observes each blood pressure technician performing the entire measurement procedure with a study participant. The field center supervisor notes any problems with technique and discusses them with the technician after the examination has been completed. Also, another technician observes the field center blood pressure supervisor perform the entire measurement process. After the examination, the two of them discuss any questions that come up in the course of this observation. In performing these observations, the supervisor and technicians use the checklist given in Appendix III of ARIC Manual 11. For each technician, the date that the technician was observed and the observer's ID number are recorded in the Checklist for Monthly Observation of blood pressure technicians by the blood pressure supervisor.

6.4 Recording of Participant ID Data

In filling out the Sitting Blood Pressure screen, the technician verifies that the name and ID number on the diskette which accompanies the participant match the participant's to avoid ID errors. If the PC is down

and a paper form is used, the technician verifies the name on the folder accompanying the participant before using the ID labels in the folder on the forms.

6.5 Measurement of Arm Circumference and Choice of Blood Pressure Cuff

As described above, once every three months duplicate measurements of blood pressure are performed on a volunteer or field center staff member (not an ARIC participant). During the course of this procedure, both technicians measure arm circumference and record their results. The field center blood pressure supervisor compares these results, and if they differ by more than 1 cm, the measurement technique is reviewed with both technicians.

Both the arm measurement and the cuff size chosen are recorded on the SBP form. The Coordinating Center analyzes the study data recorded by each technician to check for cases in which the cuff size recorded does not fit the recorded arm circumference. The Coordinating Center notifies the field center staff when any cases of improperly chosen blood pressure cuffs are detected.

6.6 Participant Posture and Rest Before Blood Pressure Measurement

The field center blood pressure supervisor monitors that the station(s) used for blood pressure measurement continue to meet the conditions specified in the protocol, e.g., that blood pressure measurements are done in a quiet room away from other field center activities. Coordinating Center staff on monitoring visits also take note whether this condition is being maintained.

The field center blood pressure supervisor is responsible for seeing that the protocol is followed by timing blood pressure measurements early in the visit, before blood drawing, pulmonary function tests, or other stressful activities. Each month the field center supervisor reviews a sample of participant Itinerary forms for the previous month to confirm that this is done.

To assist in judging that a full five-minute rest is allowed before taking the first blood pressure measurement, the blood pressure technician uses a hand held timer or other means of accurately timing the rest period. Each quarter, the field center blood pressure supervisor observes each technician performing the full blood pressure procedure and notes whether the correct rest period is being allowed.

6.7 Coordinating Center Quality Control Analyses

The Coordinating Center analyzes data from each technician for digit preference in reading systolic or diastolic blood pressure. This check is performed bimonthly, unless problems detected call for more or less intensive monitoring. The Coordinating Center reports these results to the field center, and the field center blood pressure supervisor reviews these results with each technician.

The Coordinating Center checks that correct data entry procedures are used for recording missing data. The Coordinating Center communicates with the field centers when problems are identified.

The Coordinating Center performs periodic calculations of statistics on all ARIC participants measured for each technician on mean blood pressure (adjusted for age, sex, and possibly for other relevant variables) and analyze trends in these statistics over time for each technician.

The Coordinating Center analyzes the serial blood pressure measurements made on each ARIC participant in terms of difference between first and second or second and third measurements.

7. BLOOD COLLECTION AND PROCESSING

7.1 Brief Description of Blood Collection and Processing and Related Quality Assurance and Quality Control Measures

At the time of the home interview, participants are requested to fast for 12 hours before field center visit, unless they are diabetics taking insulin or have other medical reasons that make fasting inadvisable. A detailed protocol, set out in ARIC Manual 7 (Blood Drawing and Processing) has been developed, which describes the preparation of blood tubes, the anticoagulants to be used for samples for each laboratory, and the specific steps to be taken in blood drawing and processing. After the blood is drawn, the sample tubes go through further processing at the field center. Blood samples used for lipid, hemostasis, and clinical chemistry analyses are frozen at -70°C for weekly shipment to the ARIC central laboratories. Samples for hematology analyses are sent to local laboratories. All shipments to Central Laboratories are by local courier (Minneapolis to the Clinical Chemistry Laboratory) or overnight delivery services. All of these steps are performed by technicians trained in the ARIC protocol and certified to have adequately mastered its details.

The first step in quality assurance for blood drawing consists in this training and certification process. Other steps include maintaining logs of equipment checks, observation of technicians (by other technicians and by monitors on visits) as they go through the sequence of steps in blood drawing and processing; review of the condition of samples received at central laboratories for problems in shipment; and periodic analysis of the study data for participant compliance with fasting and for signs of problems in drawing or processing, such as hemolysis or delays in completing processing.

7.2 Maintenance of Equipment

Each field center performs daily temperature checks on refrigerators, freezers, the refrigerated centrifuge, and the heating block (see ARIC Manual 7, Section 1.8.1). The actual speed of the centrifuge is checked and recorded monthly with a tachometer. The results of these checks are recorded on a log sheet kept at the blood processing station, and a copy of this log is sent to the Coordinating Center monthly.

7.3 Participant Compliance with Protocol

To obtain valid and comparable measurements of blood chemistries, the ARIC participants must have fasted for 12 hours before blood is drawn. Failure to fast can affect the values of various measurements (e.g. lipids, glucose) and compromise their value to the study. ARIC participants should also abstain from smoking and vigorous physical effort before the visit to the field center, since smoking may affect electrocardiograms or blood pressure and vigorous activity may activate fibrinolysis and alter blood levels of

tPA and FPBβ. Home interviewers are trained to explain the importance of compliance with these restrictions when recruiting ARIC participants and to obtain their agreement to comply. When Field Centers contact participants before their appointment to remind them about the scheduled visit, they repeat these instructions.

The Coordinating Center analyzes study data for information on length of time fasting and time since smoking and hard exercise, broken down by field center, to obtain the number and percent of participants at each field center each month who do not comply with these restrictions.

7.3 Maintaining Proficiency

To maintain their proficiency, technicians are urged to perform blood drawing and processing at least once each week (or 8 times each 2 months). The Coordinating Center analyzes the study data to assure that all technicians collecting and processing blood in the Field Centers are performing these procedures frequently enough to maintain their proficiency.

7.4 Periodic Observation

Periodically (each month in the beginning) each field center technician performing blood drawing and processing is observed performing the entire procedure by either another trained technician or a supervisor, using a detailed checklist to verify that the technician is continuing to follow all parts of the ARIC protocol. Carrying out this observation also provides a review of the protocol for the person doing the observation. (See ARIC Manual 7, Appendix VII, for a copy of the checklist, "ARIC Blood Drawing Processing Certification or Recertification".) This checklist is also used for observations by visitors from the Coordinating Center performing monitoring. The IDs of observer and observed are recorded in the Checklist for Blood Drawing/Processing Certification or Recertification, which is mailed to the Coordinating Center.

7.6 The Venipuncture Form

To avoid ID errors in which information regarding a given participant's samples is written down on the wrong form, the technician should begin filling out each Venipuncture form as the blood is drawn, verifying the ID from the folder which accompanies the participant.

7.7 Monitoring by Central Hemostasis Lab

The Central Hemostasis Laboratory reviews the times required for various steps in blood processing, as recorded on the Venipuncture form, when extreme values raise questions about the validity of results observed in the laboratory. The laboratory contacts the field center if problems with processing are noted.

7.8 Quality Control Replicate Data

The system of drawing extra tubes of blood for QC replicate analysis is fully explained in ARIC Manual 7. In this system specified extra tubes of blood are drawn from a number of participants and matched to two "phantom participants" per week. See also Chapter 2 of Manual 12 for an explanation of the QC phantom system.

The field center blood drawing station maintains a schedule of which tubes should be drawn for phantoms each day (See ARIC Manual 7, Section 6.2.1) to help fit the QC phantom sets into the work flow and make it easy to keep track of what is required.

The Coordinating Center reviews each month, broken down by field center, the number of QC phantom forms for which blood drawing is indicated. If Field Centers fail to provide sufficient sets of QC phantom blood, the Coordinating Center contacts the Field Centers to discuss the problem.

To reduce the risk of labeling a QC phantom blood tube with the wrong ID or of recording the wrong match between phantom and participant IDs on the QC Phantom Participant Forms, QC blood is drawn from no more than one member of each pair of participants whose blood is processed together.

To help make certain that the correct match is recorded between real participant ID and QC phantom ID, as soon as blood-drawing has been completed an ID label for the real participant ID is added to the appropriate space on the QC Phantom Participant Form in the QC phantom folder.

7.9 Analysis of Venipuncture and Processing Data for Quality Control

The Coordinating Center analyzes the study data to determine the frequencies of filling time, number of stick attempts and reported presence of hemolysis, and to identify delays in processing, broken down by the ID of the technician performing the blood drawing or processing. (Standards for time needed for various processing steps are given in ARIC Manual 7, Figure 3.)

7.10 Packing Samples for Shipment to Laboratories

All vials of blood samples as well as the plastic bags in which the samples for a given participant are packed for shipment to the several laboratories are labeled with the participant's ID. A shipping list is enclosed with each shipment to the Central Laboratories giving the IDs for all sets of samples that are enclosed. The person unpacking these samples at the Central Laboratories verifies that the IDs on the vials match the ID on the plastic bag and checks both against the shipping list. If any discrepancies are detected, the Central Laboratory contacts the field center to resolve the problem.

Blood vials shipped to the Central Laboratories must be packed securely to avoid both breakage and warming. Full instructions for packing samples are specified in ARIC Manual 7, Sections 5.1-5.3. The laboratories monitor the arrival condition of the samples sent from each field center. If problems

are encountered, the laboratories notify the Field Centers involved. If a pattern of sample damage becomes apparent that suggests a need to modify the materials used to ship samples (e.g. excessive leakage of a certain type of vial) or how samples are packed, the Laboratory Subcommittee takes appropriate action. Each laboratory sends to the ARIC Coordinating Center a monthly summary of the condition of samples on arrival, detailing by field center the number of samples received, the number arriving intact, the number broken, the number thawed, and other special problems encountered. The Coordinating Center prepares quarterly summaries of these reports and reviews the data for frequent or major problems.

ARIC blood samples are mailed promptly to the Central Laboratories at the start of the week after they are drawn. The laboratories monitor the dates of blood drawing on samples which they receive and notify the field center and the Coordinating Center if they receive samples that were shipped at a later date than that called for under this schedule. (Note: quality control phantom blood tubes are held over one week before shipping, but the date of drawing on these samples that is reported to the laboratory is altered to conceal their identity as QC.) The field centers should phone the central laboratories to notify them if they are shipping on a day other than Monday.

To avoid delays in transit to the laboratories which might cause samples to be warmed or thawed in shipping, all samples are shipped by an overnight delivery service except for blood samples in Minneapolis going to the Clinical Chemistry Laboratory. To avoid delays over weekends or holidays in delivering samples or in moving them to the Central Laboratory freezer once they are delivered to the receiving area, all samples are shipped out at the beginning of the working week, on Monday or Tuesday. The laboratories notify the Coordinating Center and the field center if a shipment is received that was shipped out on a later day in the week, and the field center reports to the Coordinating Center on the reasons for this deviation from protocol. The laboratories notify the Field Centers if sets of samples are received late. If a pattern of delays is encountered with the delivery service a field center is using, the field center will change to an alternate delivery service.

8. PULMONARY FUNCTION TESTING

8.1 Brief Description of Pulmonary Function Testing and Related Quality Assurance and Quality Control Measures

The pulmonary function measurements in the ARIC study are made on a volume displacement spirometer which is connected to an IBM Personal Computer (PC) through an analog-to-digital interface. The calibration and analytic programs needed have been installed on the PC. The computer assists the operator in calibration, spirometric testing, and analysis. A printer is connected to the computer for report generation. Participants' data are sent to the Pulmonary Function Reading Center (PFRC) each week for quality analysis and adjustment due to between-field center and within-field center variation in volume calibration. Adjusted data are then sent to the Coordinating Center.

From the detailed protocol for pulmonary function testing in ARIC Manual 4, the various data transfer points and other possible sources of error are considered, along with needed quality assurance measures. Important elements in the Quality Assurance and Control for the field centers are training and certification programs, daily calibration of instruments, annual volume standardization of the four centers by PFRC, review by the PFRC of quality of results, and the PFRC hand measurement of a 10% sample of field center tracings for comparison to field center computer-generated results. Important quality control measures for the PFRC are (1) the use of a test library of previously coded records to exercise all features of the PFRC computer program and (2) hand measuring of original tracings from the standard library.

8.2 Daily Calibration Checks

For a description of computer programs to guide daily checks, see ARIC Manual 4, Chapter 6.

For a description of the required log of results of daily checks, see ARIC Manual 4, Chapter 6. A copy of this log is sent to the PFRC.

8.3 Annual Calibration Check

The field center spirometer is calibrated by the standard PFRC syringe for annual recertification. The PFRC syringe is used to carry out the annual volume calibration check (Manual 4, Section 11.4.3.d.). At the annual calibration, the procedure is done n times, alternating with a similar procedure with the field center syringe (n=6 for the October 1986 PFRC volume calibration check of the field center spirometers; for annual recertification the number will be jointly agreed upon by the PFRC and the Coordinating Center). With each calibration check the computed values corresponding to the volume displacement are measured. (See ARIC Manual 4, Section 6.8.) The mean for the n measurements for each syringe is computed. If the difference between the two means (field center syringe vs. PFRC syringe is

more than 1% of the mean for the PFRC syringe, the field center syringe and/or spirometer must be serviced, after which the calibration must be repeated.

The calibration check also determines a correction factor (PFRC mean ÷ field center mean) to be applied to correct volumes measured at the field center to the PFRC calibration. The field center volumes are multiplied by this factor after being corrected for temperature and for the daily calibration factor.

8.4 Field Center Data Check

The technician doing the pulmonary test confirms that the ID number on the participant's folder matches that put on the spirogram, and that both match the ID on the computer record that is printed out with the test results. This check is made at the time these pieces of paper are added to the folder. Date, time, technician code, participant name, age, sex, height, ethnic group and spirometer temperature are also checked at the time of filing the tracing in the participant's folder.

8.5 Coordinating Center Data Check

Data editing at the Coordinating Center includes cross-checks on age, sex, height and ethnicity between the pulmonary function record and other records (such as anthropometry) on which this information is recorded. In the event of a discrepancy, the field center is asked to resolve the error. If this results in a change on the pulmonary function record, the Coordinating Center notifies the PFRC that predicted values (for FVC, etc.) for that individual were calculated based on incorrect participant information, and the PFRC reprocesses this record using the corrected information. The Coordinating Center updates its files using the PFRC corrections.

8.6 Review of Pulmonary Function Reading Center Calibration and Checking Procedures

The PFRC evaluates the Daily Spirometer Log sheets sent by field centers to ensure that all checks were recorded as performed, that the values reported for the linearity check and volume check appear reasonable, and that the sheets match the data sent. (For a full description of the PFRC's review of the log for adequacy of daily calibration and checking procedures, see ARIC Manual 4, Section 11.4.) The PFRC compares the volume calibration constant recorded on each diskette with the standard calibration constant generated for each field center in the annual calibration check for each field center, with differences within 2.5% of the field center standard constant being accepted. Note that this daily calibration constant also determines a daily correction factor (calibration constant for that day divided by field center standard constant), which is multiplied by the temperature-corrected volumes in order to correct volume measurements. (See ARIC Manual 4, Section 11.4.3.)

8.7 Pulmonary Function Reading Center Review of Quality of Tracings

The PFRC reviews the quality of recordings and the field center technician's judgment of quality. (See ARIC Manual 4, Section 11.4.7.) Each week after processing of the field center data, the PFRC prepares a report to be sent to the field center with a copy to the Coordinating Center. This report covers: (1) number of pulmonary function tests from each technician received at the PFRC covered in the current report, (2) average quality (assessed by technician) for each technician (3) average quality (assessed by PFRC) for each technician; and 4) cross-tabulation of PFRC and technician assessment of quality for each technician. (Details of the five-point scale used to grade quality are in Section 8.6.4 of ARIC Manual 4.) An appropriate summary statistic may be used to grade agreement between PFRC and technician on quality of recordings.

An acceptable level of quality (assessed by the PFRC) is set for each technician and technicians falling below that quality in a given month are notified. Technicians whose recordings are moderately below the acceptable quality for several months in a row or severely below acceptable quality in any one month are required to be recertified to demonstrate ability to achieve acceptable quality of recording.

Follow-up by PFRC on problems encountered with technician judgment of quality (compared to PFRC) or with poor overall quality obtained is written, with a copy to the ARIC Quality Control Committee, and, if appropriate, telephone feedback is given. Decertification of technicians unable to meet an acceptable level of quality is handled on an ad hoc basis.

8.8 Pulmonary Function Reading Center Review of a Sample of Paper Tracings

A sample of 10% of each week's tracings is randomly selected and sent to the PFRC, with the sample selected to include at least one tracing from each field center technician working that week (See ARIC Manual 4, Section 9.4.6). The PFRC matches each ID to the date the spirogram was performed and to the log of calibration results recorded on that date (See ARIC Manual 4, Section 11.4). A report on results from this sample is prepared by the PFRC and sent to the field center and the Coordinating Center. At the PFRC these tracings are read and the resulting pulmonary function measurements compared with those from the recording on the diskette, with the results reported to the field center and to the Coordinating Center. The report includes summary statistics for each field center (and by technician within field center) on the differences between diskette and paper tracing on each of the pulmonary function measurements examined, as well as a listing by ARIC ID of the comparison for each test. The PFRC sets standards, working with the Coordinating Center and the Program Office, for the maximum allowable disagreement on these measurements. A summary of follow-up activity taken in response to problems seen in earlier reports is included in each report until the problems are resolved.

8.9 Automatic Entry of Data Onto Diskette if Computer is Up or Use of Paper Tracings as Backup when Computer is Down

A paper tracing is recorded concurrently with the computer record and is used as a back-up in the event of computer failure during the exam. (See ARIC Manual 4, Section 5.3.) Participant descriptive information (age, height, sex and ethnicity) is written on the paper tracing when it is used as a back-up. The Coordinating Center cross-checks these data against the record of the same variables on other forms, such as Anthropometry. The PFRC reviews tracings received from the field center when the computer is down and independently assesses the three best trials. Discrepancies between the choices by field center technicians and the PFRC are recorded and a summary added to the PFRC's assessment of field center technician judgment of recording quality. The PFRC evaluates errors in performing FEV1 and FVC measurements on tracing. A 3% difference in measurement results is allowable under the American Thoracic Society standard.

8.10 Comparison of Information on Hard Disk with Archive Diskette kept for Ten Weeks at Field Center

Before mailing diskettes to the Pulmonary Function Reading Center, listings of participants whose data are on each diskette are printed. A listing of the contents of the archiving disk is also printed. The two listings are compared to verify that the lists are identical. (See ARIC Manual 4, Chapter 9.)

8.11 Copying of Information onto Diskette to be Sent to Reading Center

When the hard disk is copied, a program is run automatically to verify that the copied files are identical to those on the hard disk. (See ARIC Manual 4, Section 9.4.)

8.12 Mailing Week's Data from the Field Center to the Reading Center

As noted above, verification that all data have been sent is accomplished by comparing a listing of the directory of the diskette with the week's results to be sent to the PFRC against the directory of the hard disk. (See Manual 4, Section 9.4.)

The spirometer log sheet accompanying the diskette must match the volume number on the diskette.

The PFRC acknowledges receipt of data by return post card. Back-up copies of diskette files are retained on the archive disk for 10 weeks. (Archive copies should not be deleted until the PFRC has verified that files can be read by the PFRC.) Photocopies of tracings sent to the PFRC for QC purposes are retained at least until the PFRC has verified their arrival.

8.13 Filing of Original Tracings at Field Center

The original tracings form a backup for the material on the hard disk and the archive diskette in the event both might be lost. These tracings are kept at least until the PFRC notifies the field center that the data have been received and that data on diskettes have been read successfully. This is done within a week of the PFRC's receipt of the data. The PFRC returns the paper tracings sent there after it has finished with them.

8.14 Receipt of Data at Pulmonary Function Reading Center

Each week the PFRC notifies the field center by post card that the data have arrived. Within a week of the arrival of the data, the PFRC also sends a report to the field center on the reading of the data. This report also serves as verification that the diskette received was actually readable. The field center should not erase the archive diskette until this verification has been received. (See ARIC Manual 4, Chapter 11.)

8.15 Archival Storage of Original Data from Field Center Diskettes or Original Tracings at Pulmonary Function Reading Center

As part of the routine computer processing of incoming data, the data are copied for archival storage on a Bernoulli disk. Back-up copies of stored data are kept off site to avoid destruction in a catastrophe.

8.16 Return of Original Tracings Sent to Pulmonary Function Reading Center for Quality Control Sample to Field Center

The PFRC monitors any accumulation of a backlog of tracings awaiting return to the Field Centers. The field center sends a postcard to the PFRC acknowledging return of original tracings sent to the PFRC.

8.17 Shipment of Diskettes from the Pulmonary Function Reading Center to the Coordinating Center

As a check that shipments sent by the PFRC have actually arrived intact, the Coordinating Center acknowledges the receipt of data diskettes from the PFRC with a post card giving the shipment number, the date it was received, the number of records in the shipment, and a confirmation that the diskette was readable.

8.18 Repeated Pulmonary Function Reading Center Measurement of Electronic Tracings in a Test Library

A test library of original tracings was set up by the Coordinating Center using the data from the first year of the study, in consultation with the PFRC on the selection of tracings for the library. The library is replenished throughout the study, so that it contains both relatively current tracings and tracings dating to the start of the study. This library is

selected to exercise all features of the processing program. The tracings in the library are reprocessed at least once every year (or more often if any software or hardware changes are made at the PFRC), and a report prepared on the comparability of the original and reprocessed results.

8.19 Analysis of Study Data by the Coordinating Center

The Coordinating Center analyzes study data for trends in between-center differences that might be due to calibration drift. The Coordinating Center compares on a quarterly basis age-, sex-, and height-adjusted means for each technician within each field center on pulmonary function measurements. The proportion of acceptable and reproducible tests, by technician, is also monitored, as well as reason for non-acceptability. These data are scrutinized for trends that might indicate changes in calibration as well as for evidence of other problems.

9. ELECTROCARDIOGRAPHY

9.1 Brief Description of Electrocardiography and Related Quality Assurance Measures

The electrocardiography for the ARIC cohort is done with the MAC PC Personal Cardiograph. During the baseline examination a standard supine 12-lead resting ECG and 2-minute rhythm strip are recorded after a 12-hour fast followed by a light snack and at least one hour after smoking tobacco or ingestion of caffeine.

For each participant a 12-lead ECG, consisting of 10 seconds of each of the leads simultaneously, is stored in the MAC PC, and the accumulated records are transmitted daily by telephone to the Halifax ECG Reading Center, where the ECGs are computer-coded. Additionally, a two-minute rhythm strip ECG is printed (but the record not stored) for each participant. These rhythm strips are mailed to the Minneapolis ECG Reading Center for coding.

All abnormal and a random sample of normal 12-lead ECGs are transmitted from Halifax and visually coded at the Minneapolis center. Results from Halifax and Minneapolis are independently reported to the Coordinating Center. Differences in coding found by the Coordinating Center are then adjudicated in Minneapolis.

Important elements in the Quality Assurance and Control for the field centers are training and certification programs, quarterly observation checklists, quality requirements built into the ECG recorder for accepting data, and evaluation by the Halifax Center of quality of ECGs received. There are transmissions every other week of test sets of data from Minneapolis to Halifax to check phone transmission and reproducibility of coding in Halifax. Repeat visual coding of 12-lead tracings from a test library provides a quality check for the Minneapolis ECG Reading Center, and also repeats visual coding of abnormals in the set sent from Minneapolis to Halifax. Repeat coding of rhythm strips from a test library provides quality control of this aspect of coding in the Minneapolis Center.

9.2 Recording of the ECG at the Field Centers

The participant ID is verified when the field center copy of the 2-minute rhythm strip is filed.

The Halifax ECG Reading Center evaluates the technical quality of ECGs received from each field center. See ARIC Manual 5 (Section 1.9), for criteria for assigning quality grades for noise, overall drift, and beat-to-beat drift. The Halifax Computer ECG Center computes the quality grade of each ECG. Periodic summaries of ECG quality grade are prepared by the Coordinating Center.

Each January, April, July and October the field center ECG supervisor observes other ECG technicians, using the ECG Technician Procedure Review Checklist (Manual 5, Appendix Q). Also, the supervisor is observed by another technician. The Coordinating Center is notified that these observations have been done. ECG technicians are also observed by visiting monitors from the Coordinating Center on periodic visits.

9.3 Transmission of the ECGs to Halifax

IDs on the ECG PC directory are verified before transmission of the data to Halifax.

Before transmission of the ECGs to Halifax, the field center technician verifies that the best quality recording for each participant is sent.

To avoid loss of data, the field center awaits verification from Halifax of which records were received before deleting any records from the hard disk. The field center does not keep backups of the files on the hard disk, which normally only keep data 1-2 days before Halifax confirms arrival by electronic mail. In the event of loss of one of these records, the field center paper ECG strip is the backup.

9.4 Coding of ECGs at Halifax

The repeatability of the Halifax coding is tested with the test sets sent from Minneapolis. Periodically the Coordinating Center sends to the Minneapolis ECG Reading Center a list of IDs from the test library, together with the match between the QC ID and the original ID of the test recording. Every two weeks five ECGs from one field center are sent to Halifax, with the QC IDs and dates replacing the original IDs and dates, so that Halifax is blinded to the test status of the ECGs. The Minneapolis ECG Reading Center notifies the respective field center of the transmission.

Paper copies of the abnormal ECGs in the test set sent bi-weekly and retransmitted to Minneapolis are compared regularly with the original paper ECG strips for this set to monitor any changes in the quality of reproduction of paper ECGs at Minneapolis. A log is kept of this comparison, and Halifax and the Coordinating Center are notified immediately if any problems are detected.

The accuracy of coding by the Halifax computer algorithm is confirmed by visual coding (in Minneapolis) of all ECGs with abnormal Minnesota codes and a 10% random sample of the normals. Paper tracings for these ECGs are regenerated at Minneapolis from ECGs electronically transmitted from Halifax.

9.5 Transmission by Halifax of Abnormal and a Random Sample of Normals to Minneapolis for Visual Coding

In each transmission of ECGs by the Halifax Computer ECG Center to the Minneapolis ECG Reading Center, a transmission list is included. The Minneapolis ECG Center notifies Halifax when each transmission is received and verifies that the transmission list matches the records received.

Some of the records transmitted to Minneapolis come from the test set sent electronically from Minneapolis to Halifax. Comparisons between old and new copies of this set are made to check accuracy of transmission.

The Coordinating Center reviews the process by which Halifax chooses a sample of normals for visual coding by Minneapolis to guarantee that an appropriate randomization procedure is followed. The proportion sampled is adjusted, if problems are detected, to allow more intensive monitoring.

9.6 Visual Coding at Minneapolis of ECGs Transmitted by Halifax

Abnormal tests in the weekly test sets of ECGs transmitted from Minneapolis to Halifax are regularly returned to Minneapolis for visual coding. If results on these repeat codings do not agree with the original coding, it may be due to problems in the visual coding process at Minneapolis. By itself, repeated visual coding of these few tracings is not a sufficient check on the accuracy of visual coding at Minneapolis, since it is highly likely that the coders soon become familiar with this small group of abnormal tracings, and that results on this set are not reflective of how reproducible the visual coding is overall.

Repeat visual coding of actual ARIC ECGs is done in a blinded fashion to test the reproducibility of visual coding. To carry this out, in the first year of the study the Coordinating Center selected a sample of ECGs that had already been visually coded at Minneapolis. Periodically the Coordinating Center sends Halifax a list of IDs selected from this test set together with matched QC IDs. Halifax replaces the original IDs on the test set with QC IDs. Halifax then transmits groups of these QC ECGs along with the regular transmission of ECGs to Minneapolis. These QC ECGs are transmitted to Minneapolis at the rate of 5 QC ECGs per 50 study ECGs. The 5 test ECGs should not be at the beginning or end of the transmission so as to not reveal their QC nature. Dates and other identifying information on the tracing are altered to conceal the repetition. Halifax notifies the Coordinating Center after each transmission which tracings have been sent, giving both the original ID and the QC ID number used.

In the first few cycles through the test set, tracings on which disagreements occur between original and repeat coding are adjudicated to correct erroneous original codings. Such a corrected library then serves as a test set of knowns for looking at the accuracy of the visual coding over time.

Analysis of Halifax-Minneapolis disagreements which go through the adjudication process also provides a check on the accuracy of visual coding at Minneapolis. The analysis looks for trends in the proportion of disagreements on particular codes, trends in proportion of disagreements on which the adjudication sustained the visual or computer coding, and patterns in the codes on which computer and visual coding disagree. Such an analysis is prepared periodically by the Coordinating Center, and is supplemented by review of actual tracings by an experienced specialist in electrocardiography to help detect causes for underlying patterns in the visual-computer disagreements.

The Minnesota codes for ECG abnormalities set up rules for suppressing certain codes when other codes are present (e.g. T-wave abnormality codes

5-1 to 5-3 are not assigned in the presence of the code 7-1-1 for complete left bundle branch block). See Appendix E of ARIC Manual 5 for details of these coding and consistency rules. The Coordinating Center analyzes all visual coding results received and flags any records on which incompatible Minnesota codes are reported. The Minneapolis ECG Reading Center reviews and reports the corrected codes for these records.

Coders should carefully guard against errors in recording the participant ID listed on the paper strip on the coding form. Instructions for coders include a step in which, at the completion of coding, they double-check the ID written on the coding form against the original paper strip to verify its accuracy. At later stages of the process of analyzing the data, ID errors may be detected when records are sent to adjudication due to disagreements with Halifax, or when a record fails to appear for one ID, or appears for an ID that has not been assigned to any participant. At those stages, discovering the correct ID and tracing to match to an erroneous record may be extremely difficult. When ID errors are detected, the visual coders responsible are made aware of them so that they will be encouraged to take more care in the future.

9.7 Shipment of Results to Coordinating Center

To avoid loss of data in shipment to the Coordinating Center, shipping lists accompany each shipment indicating which records have been sent. The Coordinating Center sends the respective ECG Reading Center a postcard confirming that each shipment has arrived.

9.8 Coordinating Center Identification of Tracings on Which Halifax and Minneapolis Disagree and Notification of Minneapolis

Any disagreements between the Minneapolis ECG Reading Center and the Halifax Computer ECG Center on Q-wave codes are identified by the Coordinating Center and referred back to Minneapolis for adjudication. Certain records may be identified as disagreements in the Minnesota codes assigned by the computer in Halifax and the visual coders at Minneapolis due to errors in recording the ID during the coding process. A check by the Minneapolis Coding Center to see whether such an error may have occurred is part of the adjudication process.

The Coordinating Center carefully monitors its computer algorithm to identify disagreements between Minneapolis and Halifax to guarantee that all disagreements which should go to adjudication are flagged.

The Coordinating Center analyzes all ECG data received for disagreements between Halifax and Minneapolis that require adjudication. Once records have been received from both reading centers, the Coordinating Center sets and monitors the frequency for comparing the Halifax and Minneapolis ECG codings so as to prevent the time lag from becoming excessive.

9.9 Use of Adjudication for Feedback on the Accuracy of Coding at Minneapolis

ECG coders are notified when adjudication identifies records for which inaccurate visual codes were assigned.

9.10 Reporting Results from Adjudication to Coordinating Center

The Coordinating Center checks that the IDs on adjudication results received match those on records identified for adjudication.

The Coordinating Center monitors the time lag between referral of records to Minneapolis for adjudication and receipt of the result at the Coordinating Center.

9.11 Storage of ECG Computer Records at Minneapolis

To prevent loss of original ECG data in computer files, back-up files are kept, including some stored off site to avoid catastrophic destruction of all back-ups.

9.12 Recording of the Rhythm Strip at Field Center

The ECG technician verifies that the ID and name on the rhythm strip match the name on the participant's folder when the strip is filed.

As described in ARIC Manual 5, the MAC PC system for recording ECGs has certain fault detection procedures which provide some safeguards for data quality.

Problems in recording the quality of 12-lead ECGs (which may also affect the recording of the rhythm strips using the same set of electrodes) are detected by the Halifax Computer ECG Center, which assigns a quality grade to each ECG. The presence of technical problems on the 2-minute rhythm strips is also noted on the coding form filled out on each strip at the Minneapolis Reading ECG Center. (See ARIC Manual 5, Appendix N.) The Coordinating Center prepares periodic analyses of the numbers of rhythm strips with technical problems for each field center and/or technician.

9.13 Mailing of Paper Rhythm Strip to Minneapolis ECG Reading Center

On Friday of each week, the accumulated rhythm strips are sent to the Minneapolis ECG Reading Center, along with a shipping list. The list of strips sent is checked against the list of participants seen during that week and any discrepancies checked, in order to verify that all rhythm strips recorded are being sent.

The rhythm strips, along with a shipping list, are sent to the Minneapolis ECG Reading Center by certified mail, with a return receipt to verify the arrival of the shipment.

The Minneapolis ECG Reading Center takes note if the weekly shipments from the field centers are not received at the usual time and inquires if shipping was delayed or a shipment lost. The Coordinating Center monitors the time lag between the date of a visit and the date that the rhythm strip is coded at Minneapolis. In cases where this interval is excessive, the Coordinating Center investigates delays and initiates corrective action at the field center (delay in shipping).

9.14 Coding of 2-Minute Strips at Minneapolis

The Minneapolis ECG Reading Center regularly circulates internally test sets of rhythm strips (six sets, consisting of 20 strips each) to its coders. Summaries of the results of these comparisons are sent quarterly to the Coordinating Center.

9.15 Coordinating Center Analysis of Study Data

The Coordinating Center conducts analyses of the study data to detect changes in the frequencies of certain codes within short periods that are unlikely to be the result of trends in the population. These include analysis of the frequency of rhythm strip results, by coder.

The Coordinating Center analyzes study data for the mutual consistency of the different codes assigned for each record under the rules of the Minnesota ECG codes. Records on which inconsistent codes are detected are reported to the ECG Reading Center for correction.

The Coordinating Center checks the data reported by the Minneapolis ECG Reading Center for ID errors by monitoring the data for IDs for which no rhythm strip results are reported, or for rhythm strip results for an ID for which no field center visit is reported. Possible ID errors are referred back to the ECG Center for verification.

The Coordinating Center conducts periodic analyses of study data to identify the time lag between field center visits and arrival at the Coordinating Center of rhythm strip results from the Minneapolis ECG Reading Center. These analyses look at the average time lag and identify test results with unusually long delays in reporting. The Coordinating Center communicates with the ECG Center to resolve any problems with excessive delays on particular test results or with excessive average delay in coding.

9.16 Test Library of Rhythm Strips

The Coordinating Center and the Minneapolis ECG Reading Center together develop a test library of rhythm strips. The Coordinating Center periodically sends to Minneapolis a list of participant IDs from the test set, together with matched QC IDs. The Minneapolis ECG Reading Center inserts the rhythm strips into the regular stream of rhythm strips for coding. After coding of the test ECGs, the Minneapolis ECG Reading Center data coordinator changes

the IDs of the test ECGs to the matched QC IDs and transmits the coding results to the Coordinating Center. The Coordinating Center compares the coding of the QC ECGs with the original coding.

9.17 Shipment of Data to the Coordinating Center

A shipping list is sent with each batch of data sent from the Minneapolis ECG Center to the Coordinating Center. The Coordinating Center notifies the ECG Center when shipments are received and verifies that the records listed on the shipping list match those received.

9.18 Storage of Coded Strips at Minneapolis

The Minneapolis ECG center maintains a system for filing ECG rhythm strips that allows easy location of particular strips. The effectiveness of these filing procedures should be tested periodically by checking to see whether a random sample of rhythm strips that have been received can actually be located in the files.

The Minneapolis ECG center has established clear procedures for receiving strips from the field centers and tracking their status as they are transmitted to the coders and put into permanent storage. Standards are set for how long rhythm strips may accumulate before being filed, and the ECG Center supervisors monitor that excessive backlogs do not accumulate at any step.

10. HEMOSTASIS, LIPIDS AND LIPOPROTEINS, AND CLINICAL CHEMISTRIES

10.1 Brief Description of Procedures for Hemostasis, Lipids, and Clinical Chemistry Analyses and Quality Assurance and Quality Control Measures

In the ARIC study blood samples are collected and processed at the field centers for shipment to three central laboratories for analysis of hemostatic factors, lipids and lipoproteins, and clinical chemistries, respectively. At these laboratories, certain assays are performed on all blood samples soon after they are received. Other assays are only performed on samples in case-control studies. Aliquots of blood for each participant are kept in frozen storage at -70°C at each laboratory for the latter purpose. (In addition to these analyses performed at the central laboratories, each field center sends blood samples from each participant to a laboratory in its area for hematology measurements. Quality assurance for ARIC hematology is discussed in Section 12).

In Section 7 quality assurance has been discussed for blood collection and processing in the field centers. In the present section, the emphasis is on quality assurance in the central laboratories, beginning with the receipt of samples. This section differs somewhat from other chapters of this manual in being more of a general overview and summary of quality assurance measures. These matters receive careful and detailed discussion in each of the central laboratory manuals, which cover procedures for: receiving samples and storing them at a proper temperature until analysis; schedules of equipment maintenance; storage and handling of reagents, calibration standards, and quality control materials; internal and external quality control programs; long-term storage of case-control samples; and transcription and reporting of measurement results. This section of the manual supplements the laboratory manuals by its discussion of reporting on the effectiveness of laboratory quality assurance procedures and of the utilization for quality control of (1) analyses of ARIC study data and (2) blind replicate samples from ARIC participants sent to the laboratories.

10.2 Shipment of Samples to Laboratories

To reduce the possibility of damage to samples due to excessive delays at the Field Centers while awaiting shipping, the ARIC protocol calls for shipping samples to the central laboratories once each week, regardless of the size of the shipment. These shipments are done using a local courier or an overnight delivery service. To avoid the possibility that samples might arrive at a central laboratory on a weekend and wait several days to be unpacked and moved to the freezer, the protocol prescribes that shipments should only be sent on Mondays or Tuesdays. (See ARIC Manual 7, Section 5.3.) If a field center does not send specimens on Monday, it should notify the respective central laboratories. In the event that a laboratory receives a shipment that is sent out other than on Monday or Tuesday, the laboratory notifies the ARIC Coordinating Center and contacts the field center involved to remind them of protocol. If a shipment is received that has been delayed in transit, the laboratory notifies the field center.

If a pattern of delays becomes apparent, the field center should look for a more reliable means of overnight shipping.

The Coordinating Center analyzes the study data to identify the time lag between date of visit to the field center and when a report of the laboratory results is received by the Coordinating Center. If prolonged reporting delays are noted, the Coordinating Center works with the lab to determine if these result from delays in shipping samples at the field center, delays in analyzing samples at the lab, or delays in reporting results.

A shipping list accompanies all shipments to the central laboratories. Upon receipt of the samples, the laboratory verifies the contents of the shipment and notifies the field center of the arrival of the samples. The verification includes comparison of the IDs on each vial against the ID numbers on the plastic bags holding them, and on the shipping list. In the event of any discrepancies, the laboratory contacts the field center and works to resolve any ID errors or other problems that caused the discrepancy. (See ARIC Manual 8, Section 2.1.2; ARIC Manual 9, Section 1.4; ARIC Manual 10, Sections 1.1-1.2.4.)

The laboratories note the status of the samples on arrival on their local data bases (e.g., frozen, vial unbroken; frozen, vial broken; thawed, vial intact; thawed, vial broken). The laboratories contact the Field Centers if problems are encountered with sample condition. The laboratories send monthly summaries to the Coordinating Center on the condition of samples on arrival. The Coordinating Center prepares quarterly summaries of this information. If patterns of frequent problems with sample condition appear, the laboratories will work with the field center to decide what appropriate steps (changing packing materials, changing source of vials, changing shipping service, etc.) will correct these problems.

10.3 Receiving Samples at Laboratory

Procedures for creating and identifying a record for each specimen upon arrival differ among the central laboratories. At the Central Lipid Laboratory, a record in the local data base is created for each specimen when it arrives. This record includes a local specimen identification number, as well as the ARIC ID number. The local specimen ID number is the linking variable used to update the record for each specimen (either by direct data transfer from the analytic instrument or by entry of results from worksheets) after the specimen is analyzed. It is therefore crucial that care be taken when labeling specimens with local IDs that the local ID recorded for each ARIC specimen on the data base matches that by which the specimen is actually identified as it is processed in the lab. Laboratory supervisors periodically review how this process is carried out and instruct laboratory technicians in techniques to use to avoid ID errors. The Central Clinical Chemistries and Central Hemostasis Laboratories use only the ARIC ID rather than adding a local ID number.

It is important in handling ARIC frozen blood samples to avoid any unnecessary exposure to room temperature. Clear procedures for unpacking specimens upon arrival are set out in each central laboratory's protocol

to minimize such exposure. (See ARIC Manual 8, Section 2.1.2; ARIC Manual 9, Section 1.5; ARIC Manual 10, Section 1.2.2). While awaiting analysis, specimens are to be kept in storage at -70°C. Each laboratory has provisions for (1) prompt detection of power failure or of failure of freezer to maintain the proper temperature, including both local alarms and alarm signals to a central security office that will notify appropriate laboratory personnel if a problem develops after hours; (2) back-up power supplies in the event of power failure; (3) plans for the use of dry ice to maintain the sample temperature until any problems with the freezer can be repaired. In addition, the Central Hemostasis Laboratory has one back-up freezer available. (See ARIC Manual 9, Section 1.5.)

The probable stability of different analytes in frozen storage has been assessed and standards set for how soon analyses (other than for case-control studies) will be performed after the arrival of specimens at the laboratory. In the Hemostasis Laboratory, Factor VIII:C, VWF:Ag, Fibrinogen, and Factor VII are unstable even at -70°C and should be assayed within one week of the arrival of samples at the laboratory. AT-III and Protein C should be assayed within one month after blood drawing. (See ARIC Manual 9, Sections 1.4 and 1.5.) The stability of materials analyzed in routine studies at the other central laboratories does not create as severe a need for prompt analysis as is the case for the Hemostasis laboratory.

Every three months Central Hemostasis Laboratory provides a summary for each assay of the time between arrival of samples at the laboratory and the analysis of the samples. This report notes the number of samples analyzed later than the time periods called for above and comment on any special circumstances which caused this delay. This report may be included with the regular quarterly internal quality control report which the laboratory sends to the Coordinating Center.

10.4 Maintenance Procedures at the Central Laboratories

Maintenance procedures for laboratory equipment are fully specified in the laboratory protocols or in manufacturers' manuals referenced in the protocols. Technicians are fully instructed in these procedures. (See ARIC Manual 8, Section 2.2.2; ARIC Manual 9, Section 5.0 and Appendix C; ARIC Manual 10, Section 2.8 and pp. 3.2 through 3.21 of the DACOS manual; other instrument manuals.)

A regular schedule is set up for routine maintenance procedures, with logbooks kept on their performance. The laboratory supervisors review these logs on a regular basis to verify that proper maintenance procedures are being carried out according to the schedule set and that any special maintenance procedures needed are carried out.

The laboratory protocols fully specify the reagents used, the sources from which they are procured, and the procedures used to prepare and store reagents to guarantee the stability of the reagent and the accuracy of

the assay. The laboratory protocols also fully specify the sources of calibration standards and quality control materials, the procedures used to prepare and store calibration standards and quality control materials, to guarantee the stability of the material and the accuracy of the assay. (See ARIC Manual 8, descriptions of each assay and Appendix A and B; ARIC Manual 9, Section 4.0; and ARIC Manual 10, Sections 2.3 and 2.4.)

To guarantee accuracy of measurements which are calibrated with standard pools which may decay with time, it is necessary to replace these pools when their "shelf-life" is over. (Replacement of standards may also be necessary for other reasons, such as exhaustion of the stock on hand, or a decision to switch to a new supplier of a commercially prepared standard.) To maintain the comparability of measurements using the new and old standards, an overlap period is carried out, during which concentration values for the new standard are determined using the standard which is being replaced. At the Central Hemostasis Laboratory, an overlap of 20 runs is provided when a new standard is brought into use. At the Central Clinical Chemistries Laboratory, a 14-day overlap period is provided for new standards used on the DACOS analyzer. Similar considerations occur when new internal quality control pools are brought into use to replace old pools. If results on QC pools are to be used to estimate measurement trends (see below, Section 11.5, 11.8), it is necessary to establish an overlap between measurements on different pools. (For discussions of overlap of quality control pools, see ARIC Manual 8, Chapter 4; ARIC Manual 9, Section 4.1.4; ARIC Manual 10, Section 15.2, 15.7.)

10.5 Internal Quality Control Pools

Each laboratory in the ARIC study maintains an internal quality control program involving the analysis of multiple samples from quality control pools in each analysis run in which ARIC study samples are analyzed. Results on these samples are used to decide whether the measurement process is in control and whether the results on the study samples will be accepted or whether the measurements should be repeated after taking corrective action. Every three months the Central Laboratories prepare for the Coordinating Center a quarterly summary of the internal quality control results, including the following information for each assay: (1) monthly summary statistics (n, mean, and standard deviation) on all quality control pools, including new pools being overlapped to replace established QC pools; (2) summaries of any unusual problems or conditions noted. The Coordinating Center reviews these reports for evidence of trends with time in results on these pools. A summary of internal quality control at each laboratory is shown in Tables 1 A-C. (For details of internal quality programs at each laboratory see ARIC Manual 8, Chapter 4; ARIC Manual 9, Chapter 4; ARIC Manual 10, Chapter 15.)

Results on analyses of quality control pools are analyzed by the Coordinating Center for trends over time that may represent either (1) shifts

Table 1A. Summary of Internal Quality Control Measures in the ARIC Central Hemostasis Laboratory

Factor Assayed	Assay Procedure	Internal Quality Control		Replicate Analysis of Individual Samples*	Max # of Unknowns Per Run or Row	Ratio of QC to Max. Unknowns
		Control Pools	# Pool Specimens Used			
I. Assays Performed on All Participant Samples						
aPPT	Coag-a-Mate	UCRP	2 sets of duplicates	Yes	22 (in dup)	.09
Fibrinogen	"	UCRP	2 sets of duplicates	Yes	15 (in dup)	.13
Factor VII	"	UCRP	2 sets of duplicates	Yes	15 (in dup)	.13
Factor VIII:C	"	UCRP	2 sets of duplicates	Yes	15 (in dup)	.13
VWF:Ag	ELISA	UCRP	1 control at end of each row	Yes	35 (in dup)	.14
AT-III	Chromogenic	UCRP	1 control at end of each row	Yes	35 (in dup)	.14
Protein C	ELISA	UCRP	1 control at end of each row (one row has 8)	Yes	35 (in dup)	.14
II. Assays Performed for Case-Control Studies						
PF-4	RIA	CACP	2 sets of duplicates	Yes	20	.20
β TG	RIA	CACP	2 sets of duplicates	Yes	20	.20
FPA	RIA	A&B	2 sets of duplicates	Yes	20	.20
		CACP	1 set of duplicates			
TXB2	RIA	NSP	2 sets of duplicates	Yes	20	.20
tPA:Ag	ELISA	NPP	1 control at end of each row	Yes	7	.14
FPBβ	ELISA	NBβC	?	Yes	7	.14

*Individual samples are analyzed in duplicate; the replicates must match within 10% or the sample must be repeated.

CACP: Normal Combined-Anticoagulant Reference Plasma
NSP: Normal Serum Pool
UCRP: Universal Coagulation Reference Plasma
NBβC: Normal Bβ Peptides Control
NPP: Normal Plasma Pool
A&B: Stago kit for normal (A) and high (B)

Table 1B. Summary of Internal Quality Control Measures in the ARIC Central Lipid Laboratory

Factor Assayed	Assay Procedure	Internal Quality Control: Control Pools	Internal Quality Control: # Pool Specimens Used	Replicate Analysis of Individual Samples*	Max # of Unknowns Per Run or Row	Ratio of QC to Max. Unknowns
I. Assays Performed on All Participant Samples						
Total Cholesterol	BMD enzymic	CDC Q's	2 each from 2 pools	No	19	.21
Triglyceride	" "	CDC Q's	2 each from 2 pools	No	19	.21
HDL-Cholesterol	BMD,dextran Mg2+	CDC AQ,MQ	2 each per batch or run	No	19	.10
HDL(3)-Cholesterol	" " "	CDC AQ,MQ	2 each per batch	No	19	.10
ApoA-I	RIA	CLL PP	6 each from 3 pools	Yes**	100 (in tripl)	.06
		CDC	depends on availability			
ApoB	RIA	CLL PP	6 each from 3 pools	Yes**	100 (in tripl)	.06
		CDC	depends on availability			
Lp(a)	ELISA	CLL IP	3 QCs, each in triplicate	Yes**	22	.12
II. Assays Performed for Case-Control Studies						
Glycerol	BMD enzymic		CDC MQ? one per run?	No	ND	ND
LDL-Cholesterol	ultracentrifuge &		NA NA	No	ND	ND
LDL-apoB	precipitate LDL		NA NA			
epitopes of apoB	monoclonal antibodies		NA NA	No	ND	ND
phenotypes of apoE	?		NA NA	No	ND	ND
RFLP of apo genes	electrophoresis of gene fragments		NA NA	No	ND	ND

* Number of pool specimens used counts the total number of measurements obtained on a pool, whether from replicate measurements of one aliquot or measurements from several aliquots.

** Samples are re-analyzed when CV of sample analyzed in triplicate exceeds 18%.

***Individual samples re-analyzed when CV of replicates exceeds 15%.

CLL PP: Central Lipid Lab Plasma Pool

CLL IP: Samples from individuals (not pooled) prepared

CDC: Pool prepared by Centers for Disease Control

NA: Not applicable

Table 1C. Summary of Internal Quality Control Measures in the ARIC Central Clinical Chemistries Laboratory

Factor Assayed	Assay Procedure	Internal Quality Control		Replicate Analysis of Individual Samples	Max # of Unknowns Per Run or Row	Ratio of QC to Max. Unknowns
		Control Pools	# Pools Specimens Used			
I. Assays Performed on All Participant Samples						
Glucose	DART glucose A+B reagent	LBS	2 levels, analyzed in duplicate,per run	No	50	.08
Creatinine	DART creatine A+B reagent	LBS	2 levels, " " " " "	No	50	.08
Urea Nitrogen	DART urea nitrogen reagent	LBS	2 levels, " " " " "	No	50	.08
Calcium	DART calcium reagent	LBS	2 levels, " " " " "	No	50	.08
Magnesium	Lancer Magnesium reagent	LBS	2 levels, analyzed in duplicate,per run	No	50	.08
Phosphorus	DART phosphorus A+B reagent	LBS	2 levels, " " " " "	No	50	.08
Total Protein	DART protein reagent	LBS	2 levels, " " " " "	No	50	.08
Albumin	DART albumin reagent	LBS	2 levels, " " " " "	No	50	.08
Uric Acid	Dri-STAT U.A.-UV Endpt. Reag.	LBS	2 levels, " " " " "	No	50	.08
Sodium	DART Na/K A+B Standards	LBS	2 levels, analyzed in duplicate,per run	No	50	.08
Potassium	DART Na/K A+B Standards	LBS	2 levels, " " " " "	No	50	.08
Insulin	RIA	LHS	3 levels, analyzed in duplicate,per run	No	35	.08

LBS: Liquid Bovine Serum

LHS: Lyophilized Human Serum

in measurement or (2) changes over time in the concentration of the analyte in a given pool. To determine which of these is the case, trends in a given pool can be compared with (1) trends in other pools (if any) used to control analyses of a given analyte; (2) trends in differences on measurements of samples from quality control phantom participant duplicates which are repeated several months apart (see Section 11.9, below); (3) trends in the study data. If there is evidence of changes in the concentration of a control pool over time, it should be replaced.

10.6 External Quality Control

For many of the assays performed in the ARIC study, the Central Laboratories participate in various standardization or certification programs run by outside agencies, such as the Centers for Disease Control, the College of American Pathologists, or the Minnesota State Board of Health. The ARIC laboratories should continue to maintain acceptable results in these programs and promptly provide the Coordinating Center with copies of any reports on their performance generated by these programs. Should any of the results achieved in these programs appear problematic, they are reviewed by the Coordinating Center and the Laboratory Committee together with other quality control information on the assay in question to determine what action is appropriate. See Tables 2 A-C for a summary of external standardization programs in which the ARIC central laboratories participate.

10.7 Quality Control Replicate Blood Sample Program

Each week, each ARIC field center draws duplicate blood tubes from ARIC participants sufficient to make up 1-2 full sets of the blood tubes sent to the Central Laboratories, with each ARIC participant contributing no more than two extra tubes. The vials prepared from these duplicate tubes are sent to the Central Laboratories under the QC Phantom IDs and are sent one week later than the matching participant tubes. The field center records the match between original donor ID and QC phantom ID for each tube on a QC Phantom Participant Form and sends this information to the Coordinating Center. (For a more complete description of this procedure, see ARIC Manual 7, Section 6.2.) After the laboratory has reported to the Coordinating Center results on both the tube sent in under the original donor ID and the tube sent in under the QC phantom ID, the Coordinating Center matches these two results and compares them to estimate measurement precision. The Coordinating Center prepares a summary report on these QC repeated measures every three months. Copies of the reports are sent to the Quality Control Committee, Central Laboratories, and the Steering Committee.

10.8 Long-Term Consistency of Methods

The laboratory protocols fully describe the measurement methods and procedures to be used in the ARIC study. To maintain the long-term comparability of measurement results throughout the ARIC study, the same measurement methods will be maintained throughout the study. If measurement methods are to be changed, comparison studies must demonstrate to the satisfaction of the ARIC Steering Committee that the method to be used has been shown in the ARIC Central Laboratory to give results fully comparable

Table 2A. Participation in External Standardization or Certification Programs by the ARIC Central Hemostasis Laboratory

Factor Assayed	Agency Running Program	Frequency with Which Samples Sent For Analysis	Frequency of Reports on Lab Performance
I. Assays Performed on All Participant Samples			
aPPT	CAP	Quarterly	Quarterly
	T.S.	**	**
Fibrinogen	CAP	Quarterly	Quarterly
	T.S.	**	**
Factor VII	T.S.	**	**
Factor VIII:C	CAP	Quarterly	Quarterly
	T.S.	**	**
VWF:Ag	CAP	Quarterly	Quarterly
	T.S.	**	**
AT-III	CAP	Quarterly	Quarterly
	T.S.	Quarterly	Quarterly
Protein C	T.S.	Quarterly	Quarterly
II. Assays Performed for Case-Control Studies			
PF-4	none	N.A.	N.A.
β TG	none	N.A.	N.A.
FPA	none	N.A.	N.A.
TXB2	none	N.A.	N.A.
tPA:Ag	none	N.A.	N.A.
FPBβ	none	N.A.	N.A.

CAP: College of American Pathologists.
T.S.: Thromboscreen (Pacific Hemostasis Curtin-Matheson Scientific Program).
N.A.: Not Applicable.

** T.S. pools are used daily. Currently there are not enough labs using comparable methods to ARIC to offer useful comparative information.

Table 2B. Participation in External Standardization or Certification Programs by the ARIC Central Lipid Laboratory

Factor Assayed	Agency Running Program	Frequency with Which Samples Sent For Analysis	Frequency of Reports on Lab Performance
I. Assays Performed on All Participant Samples			
Total Cholesterol	CDC	Quarterly	Quarterly
Triglyceride	CDC	Quarterly	Quarterly
HDL-Cholesterol	CDC	Quarterly	Quarterly
HDL(3)-Cholesterol	none	N.A.	N.A.
ApoA-I	CDC	As available	As available
ApoB	CDC	As available	As available
Lp(a)	none	N.A.	N.A.
II. Assays Performed for Case-Control Studies			
Glycerol	none	N.A.	N.A.
LDL-Cholesterol	none	N.A.	N.A.
LDL-apoB	none	N.A.	N.A.
epitopes of apoB	none	N.A.	N.A.
phenotypes of apoE	none	N.A.	N.A.
RFLP of apo genes	none	N.A.	N.A.

CDC: Centers for Disease Control
N.A.: Not Applicable

Table 2C. Participation in External Standardization or Certification Programs by the ARIC Central Clinical Chemistries Laboratory

Factor Assayed	Agency Running Program	Frequency with Which Samples Sent For Analysis	Frequency of Reports on Lab Performance
I. Assays Performed on All Participant Samples			
Glucose	CAP	Quarterly	Quarterly
Creatinine	CAP	Quarterly	Quarterly
Urea Nitrogen	CAP	Quarterly	Quarterly
Calcium	CAP	Quarterly	Quarterly
Magnesium	CAP	Quarterly	Quarterly
Phosphorus	CAP	Quarterly	Quarterly
Total Protein	CAP	Quarterly	Quarterly
Albumin	CAP	Quarterly	Quarterly
Uric Acid	CAP	Quarterly	Quarterly
Sodium	CAP	Quarterly	Quarterly
Potassium	CAP	Quarterly	Quarterly
Insulin	CAP	Quarterly	Quarterly

CAP: College of American Pathologists

to the method initially used. It is important to demonstrate that comparable results can successfully be achieved in the implementation of the method in the ARIC laboratory, rather than to rely merely on descriptions of comparisons in the literature, as there are often significant differences in the results achieved by the same analytic method at different laboratories. Use of a back-up method in the event of the temporary failure of the usual ARIC method to achieve in-control results should only be done with the permission of the ARIC Steering Committee after the back-up has already been implemented in the laboratory and shown to maintain comparable results. In both cases, the experiments to demonstrate method comparability will be designed jointly by the laboratory in question and the Coordinating Center.

10.9 Use of Quality Control Replicates to Monitor Measurement Drift

Use of duplicate sets of samples which are sent in under phantom IDs means that some of these duplicate tubes are sent to frozen storage for future case-control studies. These duplicate tubes can be used for another purpose without giving up the ability of the study to use the blood tubes sent in under the real participant ID for future case-control studies are used to monitor measurement drift in the analyses that are routinely performed.

While not all blood tubes set aside for case-control analyses are suitable for repeating the analyses routinely performed, in each laboratory there will be stored blood from QC phantoms which can be used for this purpose. Periodically, the Coordinating Center designates to the laboratories IDs of tubes from QC phantoms to be taken from long-term storage and thawed. These tubes are analyzed for the routine tests in the same batches as the samples currently being analyzed at the laboratories. The results on these samples are processed and reported to the Coordinating Center in the same fashion as are the results from current samples.

The Coordinating Center compares these results with those obtained when the QC phantoms were originally analyzed. The result of this program is a series of overlapping sets of difference scores (original analysis--delayed repeat) which may be used to estimate measurement trends. The analyses are repeated frequently enough that the analytes in question are believed to be stable in storage at -70°C for that length of time. These results may be compared with trends observed on the internal QC pools and standards and may give evidence to judge whether a pool is decaying and should be replaced. Note that this program will not use all of the case-control phantom samples set aside, in order to preserve some from each period of the ARIC study for QC of case-control analyses.

The phantom tube stored for case-control and then thawed to repeat the usual assays has the same ID as the phantom tube on which we performed the assays when the blood was first sent to the lab. Because having repeat measurements coming in under the same ID is not possible under the data management systems in use in some of the ARIC Central Laboratories, these results must be reported separately. Care must be taken that these later results for the same ID are not entered into the local database, since

this would result in "updating" the original data value for the phantom ID and the possible loss of the original measurement result.

10.10 Analysis of Study Data

The Coordinating Center analyzes the study data periodically for trends in age- and sex-adjusted means for each field center which may indicate measurement shifts or problems with blood collection at the Field Centers. The Coordinating Center also monitors the variability of the study data, to see if there are changes in overall variability, or increases in the number of outlying values which may indicate problems in the measurement process.

10.11 Storage of Materials for Case-Control Studies

Each central laboratory has a clear protocol for how materials for case-control studies are to be handled on arrival at the laboratory and their separation for long-term storage. (See ARIC Manual 8, Section 2.1.3; ARIC Manual 9, Section 1.5; ARIC Manual 10, Section 1.3, 1.9). Separate freezers are used for blood vials stored for case-control studies and those blood vials used for routine analyses.

Over the projected six-year course of the ARIC study, some 32,000 sets of samples for case-control studies will accumulate in each laboratory. This makes it essential that each laboratory develop an inventory control system for recording the arrival of samples that fully and accurately describes the physical location of each sample in the freezer. Current back-ups for these inventory records exist both on the local computer data base and in a hard copy form. It is not unknown for studies to accumulate serum banks which they later have great difficulty in using because the specific samples needed can no longer be located years after they were first placed in the freezer. (See ARIC Manual 8, Section 2.1.3; ARIC Manual 9, Section 1.5; ARIC Manual 10, Section 1.2.2.)

The periodic removal of QC phantom samples from long-term storage for repeat analyses (see Section 11.9, above) tests the frozen storage inventory system maintained at the laboratories. The Coordinating Center follows up on failures by the laboratories to locate QC samples requested for this purpose to determine if there are problems with the storage and record-keeping systems in use at the Central Laboratories.

As noted above, precautions must be taken to prevent loss of samples due to freezer failure. This need is even more crucial for the case-control samples than for the samples awaiting routine analyses, since there is a much greater volume of case-control samples which are vulnerable at any one time in the event of failure, and the impact of freezer failure upon the study data would be correspondingly greater. Each laboratory has provisions for prompt detection of power failure or failure of the freezer to maintain the proper temperature. (See ARIC Manual 9, Section 1.5.)

Back-up power for freezers and provisions to use dry ice to cool samples temporarily until a broken freezer can be repaired are ready at all Central Laboratories. In addition, the Central Hemostasis Laboratory has one back-up freezer in the event of failure and a liquid nitrogen system which could be used for up to 72 hours to maintain temperatures.

The long-term stability in frozen storage at -70°C of some of the materials proposed for analysis in ARIC case-control studies has not been established. For this reason, the Central Hemostasis Laboratory has prepared quality control pools for these analytes, which are stored in the same freezers as the samples set aside for case-control studies. Each three months, aliquots of these samples are thawed and analyzed to estimate the decay rate of these analytes. (ARIC Manual 9, Section 4.3 and Table 4.)

10.12 "Running-in Time" for Case-Control Analyses

The assays performed on case-control samples will not necessarily be in routine use in the laboratories. A certain amount of "learning time" is needed to set up a new assay in any laboratory and be certain that analyses are "in control" before reliable results can be obtained. This process must be implemented and quality control procedures put into operation for any assay used in an ARIC case-control study before any samples are thawed. The laboratory in question will have established quality control pools to be used for each assay used for case control studies and will have repeated that assay enough times to have established QC limits and demonstrated that the assay is in control. Normal QC procedures will be used during the analysis of samples from case-control studies.

10.13 Transcription of Measurement Results onto the Local Data Base

The Central Laboratories differ in the extent to which the linkage between analytic instruments and the local computer data base is automated. In cases where hand entry of data is required, a variety of steps are taken to reduce data entry errors. These include (1) minimizing the number of transcription steps that take place between printing out the instrument result and entering the data; (2) use of double-entry techniques in which the data must be initially entered and then verified by repeating entry before they are added to the data base; (3) range checks in the data entry programs which flag improbable values for confirmation. (Such checks should also be used to flag alert values which require notification to the Field Centers.) Range checks should also be used with automated data entry systems so that the laboratory may confirm that some error has not been made (e.g. failure to enter a dilution factor correctly) that invalidates the measurement result. For details of data entry at each laboratory, see ARIC Manual 8, Section 3; ARIC Manual 9, Section 3; and ARIC Manual 10, Section 1.6-1.8.)

10.14 Reporting Results to the Coordinating Center and to the Field Centers

The Coordinating Center monitors the delay between visit to field center and receipt of laboratory measurements at the Coordinating Center and follows up on instances where individual records are delayed or where the average lag in reporting has become prolonged.

APPENDIX I

ARIC Quality Control Phantom Participant and Non-Participant ID Form

ARIC QUALITY CONTROL PHANTOM PARTICIPANT AND NON-PARTICIPANT ID FORM

Form Code: PNPA Record Type: 028

Note: This form should be sent to the Coordinating Center: (1) the same week it is filled out for a non-participant's ID, or (2) within two weeks of the first entry for a QC phantom.

Phantom Participant
ID Number _____ Contact Year: _____

This ID is for (circle one): P A QC Phantom Participant
N An ID used for a Non-Participant

Date ID Assigned: ___/___/___ ID of Person Assigning ID: _____

Venipuncture Phantom QC Log

Tube	Matching Participant ID	Date Drawn (Mo/Day/Yr)	Technician ID
1	_____	___/___/___	_____
2 & 3	_____	___/___/___	_____
4 & 5	_____	___/___/___	_____
6 & 7	_____	___/___/___	_____
8	_____	___/___/___	_____

Anthropometry Phantom QC Log

Procedure	Matching Real Participant ID	Date of Meas. (Mo/Day/Yr)	Technician ID
Measurement Group D (triceps skinfold, subscapular skinfold, wrist breadth)	_____	___/___/___	_____
Measurement Group G (waist girth, hip girth, unadjusted sitting height, stool height)	_____	___/___/___	_____

APPENDIX II

Anthropometry Participant Repeatability Studies Forms

SAMPLE PARTICIPANT REPEATABILITY STUDIES FORMS

ARIC
PARTICIPANT REPEATABILITY STUDIES
FORSYTH COUNTY Sequence #2287

The following measures should be repeated by a DIFFERENT technician:

ANTA	Q#	DESCRIPTION
5.		Triceps Skinfold
6.		Subscapular Skinfold
8.		Wrist Breadth

Affix the ID label of the matching quality control phantom below:

_____

Affix Participant's ID Label Below:

_____

___ ___ ___
List the code number of the technician who made the first measures:

ARIC
PARTICIPANT REPEATABILITY STUDIES
FORSYTH COUNTY Sequence #2288

This ARIC participant does not need to repeat anthropometric measures.

Affix Participant's ID Label Below:

_____

___ ___ ___
List the code number of the technician who made the first measures: