Manual 12
Quality Assurance and Quality Control

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Study website - http://www.cscc.unc.edu/hchs/

Quality Assurance and Quality Control
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1. INTRODUCTION

1.1. 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 during data collection and processing. It is quality control on which this manual 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 HCHS/SOL Manuals of Operation.

2) 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 HCHS/SOL and are the basis for continuing education during the study.

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 indicates that an acceptable performance standard has been mastered or an adequate knowledge of material has been achieved. The Coordinating Center (CC) monitors the study to ensure that the research staff performs only those functions for which they are certified.

Quality control procedures involve monitoring data collection by observation (directly and by tape recording) and quantitative assessment (using repeated measurements and statistical analysis of study data). Monitoring is performed both by personnel within the field centers and by monitoring visits from the CC. A summary of selected aspects of HCHS/SOL Study quality control follows.

1) Observation monitoring. Over-the-shoulder observations of staff by supervisors are made to identify techniques that need improvement and points where the protocol is not being followed. Also, periodic monitoring visits by CC staff are made to observe clinic activities. Immediate feedback is given on issues related to protocol adherence, and recommendations for improvements are given to the field center Principal Investigator for action.

2) Quantitative monitoring. Repeat measurements taken by the same and different technicians are used as quality control tools. Randomly re-doing a fraction of an individual's work may not only stimulate better overall quality of data, but also allows estimation of measurement reliability. 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.

Mean and standard deviations of study variables, by technician, are monitored for differences among technicians or trends over time. Digit preference in anthropometry 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 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 this Manual describe the reports used to monitor quality control. These reports are designed to be clearly understandable and to lead to corrective actions. A Quality Control Committee (QCC) is designated by the HCHS/SOL Steering Committee to coordinate and direct the quality control activities. This committee will have regular monthly conference calls to discuss issues that arise and review QC reports.

The QCC is charged with establishing the content of the quality control reports and reviewing them with specific attention given to deviation from protocol, and trends or shifts in data over time. 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. The QCC has representation from the CC, field centers, reading centers, the Central Laboratory, and NHLBI.

As the repository for HCHS/SOL Study data, the CC is responsible for preparation and dissemination of QC reports. These reports consist of tabulated data and summary statistics, and identify protocol deviations, recurrent problems, or temporal trends. Each field center and reading center is asked to respond to the reports and to implement corrective action. The distribution of periodic QC reports is as follows:

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

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

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

The following individuals should respond to the reports as follows:

1) Field center PIs, study coordinators: Review each QC report including technician-specific performance measures for their field center; identify a solution to each problem; implement corrective action; report corrective action to Coordinating Center QC Committee representative.

2) Central laboratory and reading center directors: Review each QC 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 report with attention to deviation from protocol, recurrent technician or field center problems, and temporal trends; contact field center, reading center, or laboratory investigators to review data quality problems and ensure solutions are proposed; monitor the implementation of corrective action.

4) Steering Committee: Review QC summary reports; monitor data quality trends; direct the QCC in areas needing special attention; propose changes to protocol when necessary.

1.3. Organization of the Quality Control Manual

What follows is a detailed list of quality assurance or quality control measures addressing each data transfer point or possible source of error. Section 2 describes certification procedures for field center staff. Section 3 describes the procedures for the Repeatability Study in which 60 participants (or individuals screened but not enrolled) repeat the entire clinic examination. The HCHS/SOL study's system of making (blinded) repeated measurements for quality control purposes is used in so many areas of the study that a separate section is devoted to description of this topic (Section 4). Section 5 discusses the types and schedules of quality control reports and describes the analysis of study data for quality control purposes. Subsequent sections describe the quality control procedures for the various components of the data collection protocol.

2. CERTIFICATION PROCEDURES

Certification of study personnel is an essential aspect of effective quality assurance as well as quality control in clinical research. In order to maintain proper collection of data despite potential for personnel changes over the study period, the CC is responsible for establishing and providing the requisite minimum criteria and training and ensuring continued adherence to standards.

Although all HCHS/SOL staff members are expected to be familiar with the entire study protocol, the complexity of the design requires that study coordinators and staff designated to participate in certain areas of data collection for the study each be instructed and certified on specific data collection instruments and tasks.

Study coordinators are responsible for providing continuity from participant recruitment through exiting the study. Coordinators should be routinely involved in all aspects of the study with regard to participant and staff involvement as well as data collection. This includes recruitment and scheduling of participant visits as well as the performance (or supervision) of many segments of the clinic examination. Coordinators also serve as the liaison between their clinical site, the Central Laboratory, reading centers, and the CC. They communicate with participants'

physicians when necessary with regard to study procedures and examination results. The study coordinator is responsible for accurate collection of data and oversight of the shipment of blood and urine samples to the Central Laboratory, and pertinent materials to the reading centers.

The responsibilities of study technicians can vary between field centers and with staff qualifications. The study coordinator is responsible for periodically monitoring the accuracy of the work done by auxiliary personnel. However, it should be noted that the Principal Investigator is ultimately responsible for the clinical behavior and ethical standards of all staff at his/her study center.

All study coordinators must attend a Central Training Session. This training consists of a 9- day session involving all aspects of the study presented by personnel from the CC as well as clinical specialists from other academic institutions including HCHS/SOL field center staff. Attendance at the centralized training is strongly encouraged for all study personnel.

In addition, staff must be certified on any of the following areas of the study in order to collect such data. Specific criteria and requirements for training in these areas are described in detail in the following sections of Manual 2, the field center manual (unless otherwise specified):

A. Informed Consent – Manual 2
B. Anthropometry – Manual 2
C. Seated Blood Pressure – Manual 2
D. Ankle, Brachial Blood Pressure – Manual 2
E. ECG – Manual 5
F. Biospecimen Collection & Processing – Manual 7
G. Physical Activity Monitoring – Manual 2
H. Spirometry examination – Manual 4
I. Sleep Monitoring – Manual 6
J. Data Management –Manual 13
K. Interviewing techniques – Manual 2
L. Cognitive Function – Manual 9
M. Diet and Supplements – Manual 11

Additional specialized trainings and certifications are held for technicians/examiners responsible for sampling and recruitment (Manual 1), the audiometry (Manual 8), and oral health (Manual 10) examinations, and endpoints ascertainment (Manual 15).

Study technicians may train and be certified in any of the areas they have been assigned to by their Principal Investigator (PI) or Study Coordinator. Certified Study Coordinators or lead personnel may train and certify new personnel on site after initiation of the study by following the guidelines specified in Manual 2 and certification procedures described below. It should be noted that the Study Coordinator remains responsible for all data collection, data entry, and other procedures that may be delegated to staff. Study Coordinators should frequently monitor staff members to ensure the high quality performance of all procedures.

Study Coordinators will submit a **Certification Request Form** (Appendix 11) to the CC to document that a staff member has completed the necessary requirement for certification. The **Certification Request Form** documents how, when and which procedures/interviews were certified. The CC will assign a code number upon receipt of this form to staff who gains a certification in areas requested. Should staff learn more procedures and interviews for certification since the initial certification request, a re-submission of the form is needed to update those new areas of certification.

The CC will continually update records of all certifications at each study site, and staff code numbers will be compared against the data collection forms to ensure that only certified staff performs data collection on the specific procedures/interviews to which they have been assigned. Additional training and supervision will be carried out as individually needed at the field centers. Continued supervision will be the responsibility of the Study Coordinator. If at any time a center is found to be lacking in certification requirements, or the quality of data collection is found to be less than optimal by the Quality Control Committee, the center will be notified. If the center does not institute corrective action in the time allotted, further follow-up will take place by staff charged with study administration in an attempt to resolve the issues.

3. REPEATABILITY STUDY

3.1. Participant Selection

The entire clinic visit will be repeated on 60 volunteers to determine reliability of measurement procedures. All interviews will be re-administered and new samples of blood, urine, and saliva collected. Field center staff will process these biospecimen samples according to protocol. Each site will recruit 15 volunteers at a uniform rate over the study period to participate in the Repeatability Study. Given that the measurement period will last 36 months, and the repeatability study will start 6 months after study clinic start-up, one volunteer per center per every two months is needed. Selection of participants need not be determined in a random fashion. However, representation from all subgroups (e.g., gender, age) is advised and will be monitored by the CC**.**

3.2. Data Collection Procedures

Field centers will use phantom ID numbers for data collected as part of the Repeatability Study. The phantom ID numbers are indistinguishable from other ID numbers, and forms belonging to Repeatability Study participants are entered just as regular study data. The Repeat Visit ID Form is used to match the phantom ID to the original HCHS/SOL ID of those participating in the Repeatability Study. This process is described in more detail as follows:

1) The day before the participant is schedule to have their repeat visit, one of the measurement staff completes the required fields on the **Repeat Visit ID Form** (affix the HCHS/SOL participant ID label, the phantom ID (e.g., repeat visit ID), staff ID, and the date of the repeat visit).

2) Data collected on the repeat visit is entered into the DMS using the phantom ID.

3) The repeat clinic visit should be done no sooner than 4 weeks, and no later than 8 weeks after the original clinic visit.

4) The same or different technician may be used to collect the data, but he/she should refrain from accessing data from the participant's original visit (i.e., the technician should be blinded to the original measurement values).

Data from the original and repeat visit will be analyses to estimate the reliability of all data collection procedures. Methods for computing reliability coefficients, within-person standard deviations, coefficients of variation, and systematic differences are similar to those outlined in section 5.2 of this manual.

4. QUALITY CONTROL SYSTEM FOR REPEATED MEASUREMENTS

To estimate the reliability of laboratory and body composition measures, some participants will provide an additional sample of blood or urine, or will have anthropometric measurements repeated by a second technician on the same visit. The repeated anthropometric measurements are recorded on the "Anthropometry QC" (AQC) form. The additional QC laboratory specimens are labeled with a *phantom* participant ID that is indistinguishable from other ID numbers, so that the laboratory is blinded to the QC process. Forms belonging to the phantom participant are entered into the DMS just as regular study data. The **Phantom Form** (PHT) is used to match the phantom ID to the HCHS/SOL participant IDs contributing repeat measurements. The QC phantom participant folders are created as follows:

1) Affix a phantom ID label to the **Phantom Form**; place these in a folder.
2) Every time a participant contributes replicate data, his/her HCHS/SOL participant ID is affixed to the **Phantom Form** next to the type of data that was contributed. Multiple individuals will contribute the QC specimens under a single phantom ID.

3) After completing the **Phantom Form** for the phantom, the folder is processed along with the regular stream of participant folders as if the Exit Interview had just finished.

5. ANALYSIS OF STUDY DATA FOR QUALITY CONTROL PURPOSES

The methods to monitor the quality of the HCHS/SOL data collection process include analyses of the study data itself, overall, by center, and by technician. There will be periodic reporting by field center on:

1) status of variables in the database (no problem, skipped due to skip rule, problem with the entry), to assess the prevalence of data entry problems,
2) distribution of categorical (frequencies) and continuous variables (means, standard deviations, percentiles),
3) digit preference analysis for variables with high degree of subjective judgment by technicians, such as ankle/brachial blood pressures, or anthropometry data,
4) distribution of variables that give information on protocol adherence and the validity of data (e.g., fasting time before blood drawing).

5.1. Quality Control Reports

For a report to be of use in correcting problems, it must appear frequently and reflect as much of the collected data as possible. 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 is not feasible on a monthly basis, but can usefully be done each quarter. The standard monthly QC reports will contain the following information:

1) Digit Preference
    a. Anthropometry
    b. Ankle-brachial blood pressures
2) Repeated measures
    a. Anthropometry
    b. Biospecimens
3) Protocol Compliance
    a. Twelve-hour fast
4) Descriptive statistics
5) Timeliness and completeness of data entry

5.2. Replicate Data Analysis

The following modeling process will be used to analyze replicate QC data. The total variance of the study data (σ_T^2) can be partitioned 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 for assessing data quality is the reliability coefficient, $R = \sigma_b^2 / \left(\sigma_b^2 + \sigma_e^2 \right)$, which is one minus the proportion of total variance due to error variation. The components of variance will be estimated from the replicate data using maximum likelihood (ML) or restricted maximum likelihood (REML) methods.

The estimates of reliability and error variance will be closely watched. In monitoring biospecimen data, $\hat{\sigma}_e$ for each assay is compared with the target standard deviation (SD) which the laboratory has set based on analyses of internal quality control pools. Blind replicate estimates which are more than twice the target SD are considered cause for concern. In addition, if the coefficient of variation (CV) is greater than 10% corrective action should be requested from the laboratory.

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. Means and percentiles of these differences are also presented.

Before any analysis is done on the QC replicate pairs, the data are screened for possible mismatches or "strange" observations. For each biospecimen, the mean and standard deviation of the difference between repeat and original pairs are used to determine acceptable intervals.

5.3. Monitoring for Digit Preference

Monitoring for digit preference is done by the Coordinating Center for ankle-brachial blood pressures, standing height, and waist circumference. Summary reports are sent to the QCC, 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.

Final digits 0,1,2,... 9 are possible. To discuss the analysis of both, let k be the number of possible final digits, so k = 5 (when only even digits are possible) 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

$$\chi^2 = \frac{\sum_{i=1}^{k}\left(O_i - \frac{N}{k}\right)^2}{N/k}, \quad \text{where } N = \sum_{i=1}^{k} O_i.$$

O_i is the observed frequency of the i^{th} possible digit. For large N, this statistic is distributed approximately as a chi-square distribution with k-1 degrees of freedom. Note that Chi-square = 0 when the observed number for each possible digit is N/k. For each calculated value of Chi-square, 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:

$DPS = 100\sqrt{\chi^2 / Nk}$. 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, a cutpoint used in the ARIC study for marked digit preferences was $DPS \geq 20$. A technician is judged to show "strong evidence of digit preference" if all of the following are true: (1) N ≥ minimum N required (25 for blood pressure, 50 for anthropometry); (2) $p < .05$; and (3) the $DPS \geq 20$. If digit preference is indicated, the technician will be required to undergo re-training.

6. ANTHROPOMETRY

6.1. Anthropometry Procedures

Anthropometry is performed with the participants wearing underwear under a scrub suit or examination gown. The measurements include standing height, body weight, and abdominal girth. Weight and height are measured without shoes. Important quality assurance/control measures include clear and detailed protocols for each measure, training and certification, instrument checks, replicate measurements, observation of technicians by a supervisor, and a periodic quality review of study data by the QCC.

6.2. Training and Certification

All data collectors taking anthropometric measurements must be certified by successfully completing training requirements. Training and practice sessions will be conducted prior to certification. An examiner who attends the central training and passes certification criteria can

be train and certify other examiners at the field center. Certification testing requires a minimum of 5 practice subjects be measured by both the expert trainer and the trainee. Agreement between the expert and the trainer must be within 0.5 cm for height, 0.5 kg for weight, and 2 cm for the waist measurement among 4 of the 5 subjects.

6.3. Observation of Anthropometry Measurement

Technicians are observed by the clinic coordinator twice monthly for the first month and then quarterly to ensure standardization. The Checklist for Observation of Anthropometry Measurements (Appendix 3) is used to document these observations and deviations from the protocol are reviewed with the technicians. The observations are also summarized quarterly on the Summary of Observation and Equipment Checklists (Appendix 1). A minimum of 6 procedures every month is required in order to maintain certification. Local re-training sessions are scheduled when a lack of standardization (e.g., technicians who fail to meet the certification criteria described above) is observed among the technicians.

6.4. Maintenance of Equipment

Anthropometry equipment is calibrated frequently and results are recorded on an Anthropometry Equipment Calibration Log (Appendix 8). Scales are zero balanced daily and calibrated weekly, or when moved. Place the 10 kg calibrated weights on the scale and read the result when the digital display has stabilized. The values should be within 1.5 kg of the expected weight. If it weighs outside this range, notify the clinic coordinator to have the scale recalibrated by the manufacturer or by the appropriate institution personnel. Measuring tapes are checked monthly for wear or stretching by comparing them with the height stadiometer. If the measure falls outside the 119.5 - 120.5 cm the tape should be replaced. Each day the headboard of the stadiometer should be checked to ensure it moves up and down the track smoothly. These equipment checks may be done by any certified anthropometry technician. Quarterly, the equipment logs are summarized onto the Summary of Observation and Equipment Checklist (Appendix 1), which is then sent to the Coordinating Center. Copies of the equipment logs may be requested by the Coordinating Center.

6.5. Random Replicate Measurements

Five percent of participants will be randomly selected to have anthropometry measurements repeated by a different technician. The steps in the random selection and repeat measurement process are:

1) Once the last item on the Anthropometry form (ANT) has been keyed into the DMS, the technician will be notified with a pop-up message if the participant has been selected for repeat measurements.
2) The repeat measurements should be done as soon as they can be fit in to the participant's and technician's schedules. When more than one trained technician is available, the repeat measurements should be assignment randomly to one of the certified technicians, say, by coin toss.
3) The technician who repeats the measurements completes the Anthromopetry Quality Control (AQC) form, identical to the Anthropometry form, without looking at the measurement determined by the first technician.

Inter-technician agreement is analyzed by the QCC and serves as a criterion for recertification. Retraining sessions are scheduled at the request of the Quality Control Committee when a lack of standardization is observed among the technicians.

7. SITTING BLOOD PRESSURE

The OMRON HEM-907XL sphygmomanometer is used to measure seated blood pressure. The technician explains the procedure to the participant, measures arm circumference, wraps the arm with the correct cuff, the participant sits quietly for 5 minutes, and then records the average of the three readings. Important elements in quality assurance are training and certification programs, observation of data collection by the study coordinator, quarterly simultaneous blood pressure measurements by the technician and the study coordinator, and standard equipment maintenance procedures performed and summarized quarterly onto the **Summary of Observation and Equipment Checklist** (Appendix 1) and sent to the Coordinating Center. We will also monitor the distribution of readings from the OMRON to look for any irregularities.

7.1. Training and Certification

Blood pressure technicians are trained and certified at a central training session or at local field centers by a certified technician prior to participant recruitment. Certification results from training of new staff at the field centers are submitted using a **Certification Request Form** to the CC to document certification status.

Certification for sitting blood pressure requires the trainer to observe the trainee performing blood pressure measurements on 3 volunteers (not HCHS/SOL participants) to look for adherence to protocol procedures. Results are summarized onto the **Checklist for Observation of Blood Pressure and ABI Measurement** (Appendix 4).

7.2. Observation of Blood Pressure Measurement

Quarterly, the blood pressure supervisor observes each technician responsible for taking blood pressure and ABI measurements using the checklist given in Appendix 4.

7.3. Maintenance of Equipment

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

2) OMRON sphygmomanometer: Each OMRON unit is checked every 3 months as described in Manual 2. The results of the calibration checks are recorded on the OMRON calibration log (together with the unit number, the date and the technician ID) and sent to the HCHS Coordinating Center for inclusion in the quality control reports. A sample copy of the maintenance and calibration log is found in Appendix 15.

8. ANKLE-BRACHIAL INDEX (ABI)

A hand-held Doppler probe is used to measure ABI. The participant is asked to lie supine, with arms and legs (to mid-calf) bared, on a comfortable horizontal examination table. The appropriate cuff size is selected for collection of the arm and ankle pressures. These may be different sizes. The participant lies supine for 5 minutes, and then the technician takes a signal

measurement of systolic arterial pressure at each of the following sites in the order given: right arm, right leg, left leg, and left arm.

Important elements in quality assurance are training and certification programs, observation of data collection by the study coordinator, monitoring for digit preference, quarterly simultaneous blood pressure measurements by the technician and the study coordinator, and standard equipment maintenance procedures performed and summarized quarterly onto the **Summary of Observation and Equipment Checklist** (Appendix 1) and sent to the Coordinating Center.

8.1. Training and Certification

Technicians responsible for ankle-brachial index measurements are trained and certified at a central training session or at local field centers by a certified technician prior to participant recruitment. Certification results from training of new staff at the field centers are submitted using a **Certification Request Form** to the CC to document certification status.

Certification for ABI requires agreement of within 10 mm Hg for systolic arterial pressure between the trainee and the trainer on 5 volunteers' measurements for at each of the 6 sites. In addition, certification requires the trainer to observe the trainee performing ABI measurements on 2 volunteers to look for adherence to protocol procedures. Results are summarized onto the **Checklist for Observation of Blood Pressure and ABI Measurement** (Appendix 4).

8.2. Observation of Ankle-Brachial Index Measurements

Quarterly, the ABI supervisor observes each technician responsible for taking ABI measurements using the checklist given in Appendix 4. In addition, measurements on 2 volunteers are taken by both the supervisor and the technician. Each records the blood pressure values on separate Ankle Arm Blood Pressure (ABP) Form. Supine systolic pressures between the supervisor and technician should agree within 8 mmHg at each site. At the end of the observation the measurements should be documented on the checklist given in Appendix 5.

8.3. Maintenance of Equipment

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

2) Welch-Allyn DS66 sphygmomanometer: Manufacturers recommendations will be followed.

9. ECG DETERMINATION

9.1. Training and Certification

All ECG technicians must go through the certification process before they are allowed to acquire study ECGs. Each technician must acquire 3 good quality grade ECGs and successfully transmit them to the ECG Reading Center. The 3 ECGs should be performed on 3 different volunteers or on one volunteer provided that there is at least 30 minutes between each ECG**.** Recertification process (required annually) is the same as the certification process. Once quality has been checked at the ECG Reading Center a certificate will be issued to successful technicians.

9.2. Monitoring Quality Grades

The ECG Reading Centre will evaluate and rank the ECG quality through an automated system with visual confirmation of the results if needed. There are 5 grades from 1 to 5. The best grade is 1 and the worst is 5. Generally, grades 1 and 2 are difficult to separate visually and they are considered good. Grades 3 and 4 are given to ECGs that have correctable problems (i.e., the ECG problems could be adjusted for on reading them). Grade 5 ECGs are given for ECGs that have major problems which make it impossible to read them. Monthly, the ECG Reading Center will compile a QC report for the QC Committee summarizing the distribution of quality grades, by technician. The report will be identify technicians by ID and not be technician name.

10. BIOSPECIMEN COLLECTION AND PROCESSING

10.1. Blood Collection and Processing

At the time of the telephone contact, 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. The specific steps to be taken in blood drawing and processing are described in Manual 2 (sections 9, 13). Blood samples are either shipped refrigerated on the same day as collection or frozen at -70^{o}C for weekly shipment to the Central Laboratory. All shipments to the Central Laboratory are made by courier or overnight delivery services. These steps are performed by technicians trained in the HCHS/SOL protocol and certified to have adequately mastered its details.

The first step in quality assurance for blood drawing consists in the training and certification process. Other steps include maintaining logs of equipment checks, observation of technicians (by other technicians and by CC staff on monitoring 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.

Quarterly, the field center supervisor observes each technician responsible for collection, processing, and shipping of the bio-specimens using the checklist given in Appendix 6. These observations are summarized quarterly on the Summary of Observation and Equipment Checklists (Appendix 1).

10.2. Training and Certification

To be certified, technicians complete a central training taught by certified laboratory staff which includes bio-specimen (blood, urine) collection, processing, packaging and shipping as well as quality control measures such as phantom specimens and blind replicate matching. Each technician must complete the training and pass both written and practical exams before becoming certified for the HCHS/SOL study. Certification requirements for personnel who do not attend the centralized training are:

- Collection, processing, and shipping bio-specimens for 3 volunteers under the supervision of the certified lead bio-specimen technician at the field center, and
- Completion and submission to the CC of the written exam (Appendix 10)

Those learning phlebotomy must also conform to their own institution's requirements for certification in this area. Once certified, each technician should draw and process at least once per week to maintain their certification status.

10.3. Maintenance of Equipment

Each field center performs daily temperature checks on the refrigerators, freezers and the refrigerated centrifuge as well as the rooms in which these are located. The actual speed of the centrifuge is checked and recorded annually with a tachometer. The results of these checks are recorded on the **Daily Centrifuge, Freezer, Refrigerator and Room Temperature Log** (Appendix 9) kept at the blood processing station, and are summarized onto the **Summary of Observation and Equipment Checklist** (Appendix 1) quarterly and sent to the Coordinating Center.

In addition, each technician is responsible for maintaining his/her pipettes for blood processing. Certificates should be purchased with each pipette and filed. Pipettes should be calibrated and cleaned professionally on an annual basis. Monthly calibrations can also be done professionally.

10.4. Monitoring by the Central Laboratory

The Central Laboratory reviews the drawing and processing time, as recorded on the **Laboratory Collection Form** (LAB). If there are extreme values that raise questions about the validity of laboratory results, the field center is alerted to the problems.

10.5. Packing Samples for Shipment to the Central Laboratory

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 laboratories are labeled with the laboratory ID. 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. One tube is shipped to the Central Laboratory the same day as it is collected. All frozen plasma, sera, packed cells, urine, and Paxgene tubes collected and stored within the last work week are shipped to the Central Laboratory on Monday with the exception of Quality Control aliquots, as discussed in the Quality Control section below. Samples can be shipped on Tuesday if the Field Center is closed on Monday, but the contact person at the Central Laboratory must be notified that the shipment will arrive one day later than usual.

A shipping list is enclosed with each shipment to the Central Laboratory giving the IDs for all sets of samples that are enclosed (see **Biospecimen Shipping** Form in HCHS/SOL Laboratory & Biospecimens Manual 7). The person unpacking these samples at the Central Laboratory 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.

For samples that are shipped weekly to the Central Laboratory, the staff receiving the shipment will monitor that the shipment was delivered overnight. If delays are found, the Laboratory notifies the field center to alert them. If the problem persists, and fault lies with the delivery

service, the field center will change to an alternate delivery service. If delays are due to protocol violations at the field center, the Coordinating Center is contacted in addition to the field center.

Blood vials shipped to the Central Laboratory must be packed securely to avoid both breakage and warming. Full instructions for packing samples are specified in the **Biospecimen Collection and Processing** manual. The laboratories monitor the arrival condition of the samples sent from each field center on the **Biospecimen Shipping Form**. 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 QCC should be alerted to ensure appropriate action is taken.

10.6. Urine Collection and Processing

After a participant is greeted at the clinic, he/she is asked to provide a urine specimen at the participant's convenience. When the participant is ready to void, a specimen cup (labeled with the laboratory ID) is provided, and the participant is instructed to fill the cup if possible. If the sample is insufficient for processing, the participant is requested to void again in a clean container prior to leaving the field center. Prior to processing, the technician records on the **Laboratory Collection Form** whether a urine sample was obtained, the collection time of the initial (if more than one) urine sample, and adequacy of volume.

10.7. Replicate Blood and Urine Specimens

A replicate sample is obtained by either drawing 1 to 3 additional tube(s) of blood, or by dividing a urine sample into separate containers. The replicate samples are then processed using the same method as for the original samples. The Central Laboratory staff processing the samples should be unable to distinguish original samples from replicate samples. Over the entire study, replicate samples will be obtained on 5% of all specimens (n = 800). Six participants will be needed to provide a complete set of 10 QC replicate specimens (9 tubes of blood and 1 urine specimen) for a phantom ID. Thus, one-third of participants (n = 4800 = 6 × 800) will contribute to the pool of replicate specimens. During the first 4 months of the study all participants will contribute one or more QC replicate samples. Assuming 1600 participants are seen in the first 4 months of the study, this will result in 320 QC replicates for each specimen (2%). After this initial period, the replicate sample(s) will be collected from the first participant seen in the clinic each day, resulting in an additional 480 QC replicates over the remainder of the study (3%). The extra specimen(s) will be labeled with a laboratory ID corresponding to a phantom participant ID. Eventually, a single phantom ID will have a complete collection of blood, and urine, contributed by several participants. Each month, the Coordinating Center reviews the number of QC phantom forms completed to ensure the procedures for obtaining replicate samples is being followed.

A replicate urine sample requires that the participant provide at least 15 mL of urine. A total of 12 mL are divided among eight 2.0 mL vials for determination of creatinine and albumin levels by the Central Laboratory, and storage of 6 aliquots are reserved for future testing. See the **Biospecimen Collection and Processing Manual** for details. To reduce the chance of error in linking the real participant ID with the phantom ID, as soon as replicate sample is obtained the real participant ID label is affixed to the appropriate space on the **Phantom Form**.

11. BIOSPECIMEN PROCESSING AT THE CENTRAL LABORATORY

11.1. Procedures for Central Laboratory Analyte Determinations

Blood samples are collected and processed at the field centers for shipment to a single central laboratory for analysis of several analytical tests. In the present section, the emphasis is on quality assurance in the central laboratories, beginning with the receipt of samples. This section differs 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 the central laboratory manual, which covers 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; and transcription and reporting of measurement results. This section of the manual supplements the laboratory manual by its discussion of reporting on the effectiveness of laboratory quality assurance procedures and of the utilization for quality control of (1) analyses of study data and (2) blind replicate samples from participants sent to the laboratory.

11.2. Receiving Samples at Laboratory

At the Central Laboratory, a record in the local data base is created using the laboratory ID number for each specimen when it arrives. It is important in handling HCHS/SOL frozen blood samples to avoid any unnecessary exposure to room temperature. Clear procedures for unpacking specimens upon arrival are set out in the Central Laboratory's protocol to minimize such exposure. While awaiting analysis, specimens are to be kept in storage at -70^0C. The 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.

The probable stability of different analytes in frozen storage has been assessed and standards set for how soon analyses will be performed after the arrival of specimens at the laboratory.

11.3. Maintenance Procedures at the Central Laboratory

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.

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 protocol fully specifies 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 protocol also fully specifies 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. To maintain the comparability of measurements using new and old calibration standards and controls, an overlap period is carried out, during which concentration values for the new standard are determined using the standard which is being replaced.

11.4. Internal Quality Control Pools

The Central Laboratory maintains an internal quality control program involving the analysis of multiple samples from quality control pools in each analysis run in which HCHS/SOL 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. Quarterly, the Central Laboratory provides a summary of the internal quality control results to the Coordinating Center, 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.

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

11.5. External Quality Control

For many of the assays performed in the HCHS/SOL study, the Central Laboratory participates in various standardization or certification programs run by outside agencies, such as the College of American Pathologists or the CDC Lipid Standardization Program. The Central Laboratory 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.

12. PHYSICAL ACTIVITY

The physical activity assessment includes an administration of a questionnaire by a trained interviewer and data collected from having the participant wear an activity monitor over a 1-week period.

12.1. Training and Certification

Training topics include proper coding of various physical activities and knowledge of when and how to probe. Training for the activity monitor will involve instruction on the proper method of wearing the monitor. Certification is achieved either at the successful completion of central training or at the field center (local certification). These are trained by the lead certified

interviewer at the corresponding field site and must demonstrate 5 successfully administered interviews observed by the lead interviewer in addition to be certified on Interviewing Techniques.

12.2. Practice Initialization, Download, and Transfer

Following central training, staff persons trained on procedures for initializing accelerometers and downloading data will transfer two new data files per week to the Coordinating Center until the start of data collection. The monitor should be initialized and worn by a staff volunteer for at least 24 hours before the data is downloaded and transferred. This regular use of the software will maintain familiarity with the software during the time between training and study start.

12.3. Adherence Report

The goal of this study is to obtain valid physical activity data on at least 80% of participants in the study. By "valid" data we mean that a participant has worn the monitor for a reasonable fraction of the expected wearing time. In many studies, that is defined as 4 days of at least 10 hours of data. In order to monitor compliance with wearing the monitor, an "Adherence Monitoring" report will be produced periodically by the Coordinating Center to indicate whether the transferred accelerometer files meet the minimum criteria for defining adherence. If a participant was found to be non-adherent, he/she could be asked to wear the monitor for another week in order to obtain more complete data.

The technician responsible for physical activity monitor processing should check the Adherence Monitoring report on the HCHS/SOL periodically to determine which participants could be invited for re-measuring.

13. SPIROMETRY

13.1. Training and Certification

Certification following the central training for pulmonary function testing includes a written examination (50 multiple choice questions), calculation of spirometry results from a spirogram (25 points), and a practical demonstration of skills including leak and calibration checks, cleaning, and testing of a volunteer (25 points). A passing score of at least 75 points is necessary for certification.

Certification of new technicians after the initial central training sessions may be performed by a technician who was centrally trained. The written exam will be administered locally, and the first 20 pulmonary function tests performed will be observed by a certified pulmonary function technician and found to be satisfactory before the new technician is certified.

13.2. Practice Examinations

Following central training, technicians should test at least one person (another technician or staff member) per week between the training session and the start of recruitment. To retain certification, technicians must test at least ten participants each month during the recruitment period.

13.3. Maintenance of Equipment

Each field center check the spirometer for leak and perform calibration checks on a daily basis. The results of these checks are recorded on the **Daily Spirometer Leak and Volume Check Log** (Appendix 12) kept at the pulmonary function station, and are summarized onto the **Summary of Observation and Equipment Checklist** (Appendix 1) quarterly and sent to the Coordinating Center.

13.4. QC Reports from Reading Center

Monthly, the Reading Center will compile a QC report for the QC Committee summarizing the following:

- average number of acceptable maneuvers, by technician
- percentage of subjects with non-repeatable tests results, by technician
- percentage of subjects with less than 3 acceptable maneuvers, by technician
- percentage of subject with less than 2-acceptable maneuvers, by technician
- average FVC quality score, by technician
- average FEV1 quality score, by technician.

The report will be identify technicians by ID and not be technician name.

14. SLEEP

14.1. Training and Certification

Staff certified at central training for performing HCHS/SOL sleep studies will be required to pass a written examination and demonstrate proficiency in using the sleep monitor for collection and transmitting data by submitting one (1) acceptable night time recording on a volunteer. This serves both as part of the technician certification and as practical experience in using the equipment in the study environment. Certification studies also allow for verification that sensors and equipment are functioning properly before being used on a study participant. Centrally certified sleep technicians will be permitted to train others at the local level. Additional staff trained locally must complete the certification process before performing these duties at the collection site. A checklist for training on site is provided to ensure technicians that have not attended central training will have basic understanding of collecting sleep data. This checklist must be signed off by the trainee and the certified technician and submitted to the Case Sleeep Reading Center (CSRC) as part of the certification process. (See Appendix D - Certification Packet.)

To be considered acceptable for certification the sleep recording must: 1) Have good quality signal on each channel (i.e.: all sensors must work and be relatively free from artifact); 2) Proper naming of study recording (Site ID followed by consecutive numbers starting with 101, e.g. B101, B102, M101, M102); and 3) Electronic file must be accompanied with proper paperwork matching study IDs and clearly identifying the technician. The performance of the download must result in successful data transmission to the CSRC.

After initial certification, Sleep certification can be maintained by performing successful data collection and transmission of a minimum of two (2) sleep studies per month. If field collection work does not permit the technician to perform these duties at such a rate certification may be

maintained by submitting enough practice studies to equal two (2) submissions a month. A practice study is defined as successful data collection (at least 4 hours in length) and transmission on a non-participant volunteer.

When the Download data from Unicorder button is selected, verify the participant information downloaded matches the label and paperwork. During the download the software performs a preliminary quality review of the study. Quality problems identified at this stage will be noted in the dialog box labeled "**History of Actions**" (See Figure 8.6 - Download Screen). This will indicate whether or not the study should be flagged for troubleshooting before reuse. If quality codes indicate a need for review, the CSRC should be notified by email. Quality messages that display will include problems with key collection signals such as: Rule One violated, Review is necessary. (Study was less than 4 hours long.); Rule Three or Four violated, Review is necessary. (Oximetry quality is questionable.); or Rule Two violated, Review is necessary. (Cannula signal is questionable.)

To protect others coming in contact with the recorder gloves must be worn when it is unpackaged and the Unicorder must be cleaned and disinfected before downloading the study. After cleaning and disinfecting the recorder the study should be downloaded promptly and battery plugged in for recharging using the Ziplinc Wall Battery Charger. The Unicorder and its paperwork is then carried to the downloading computer and connected for downloading.

It is verified that the participant information downloaded matches the label and paperwork. During the download the software performs a preliminary quality review of the study. Quality problems identified at this stage will be noted and will indicate whether or not the study should be flagged for troubleshooting before reuse. If no quality issues are identified, the monitor can be prepared for re-use and the battery recharged.

After download the next screen will ask for data entry of the information on the **Sleep Study Log** (Manual 6). An additional field will be available to include notes to the CSRC regarding any quality issues noted at download that need to be communicated. Data are uploaded to the CSRC FTP server over a secure SSL FTP server. Confirmation that all that has been received will be available for viewing at the CSRC website.

14.2. QC Reports from Reading Center

The performance of each technician, monitor and site will be reported on a monthly basis. Each study receives an overall study quality grade and each signal receives a signal specific quality grade. Studies are graded according to the overall duration and percentage of sleep time with artifact free data, with more weight ascribed to the oximtery and nasal pressure channels (considered key for scoring apneas and hypopneas).

The sleep monitors will undergo routine maintenance every 50 nights of use as well as maintenance checks every six (6) months. A log record book of all maintenance checks as well as problems with individual units and problem resolution will be maintained at each local field site.

Each sleep scorer at the Sleep Reading Center will be trained by the Chief Polysomnologist and demonstrate ability to recognize artifact and events on each channel. The scorer must

demonstrate the independent ability to score apneas and hypopneas that agree to within 5% of the number of events scored by a reference standard. Maintenance of certification requires demonstration of levels of agreement of >95% relative to prior scoring and scores of other certified scorers.

A minimum of 1.5 hrs per week is dedicated for the scorers to participate in QA exercises, which include reviews of scoring rules and problem studies, and performance of scoring reliability exercises of records that are randomly chosen or selected to represent specific challenges. Disagreements between scorers in event designation are discussed until a "consensus" designation is achieved. Levels of agreement among scorers and the consensus designation are tracked over time. Any scorer who systematically differs from the others over 3 consecutive weeks is further assessed for potential re-training. The results of the deliberations are documented, including copies of ambiguous records and summaries of arbitration. To track scoring reliability, monthly data from the actual scored research records (for any given study) are summarized and reported to the Coordinating Center, Steering Committee and relevant subcommittees (e.g., QC Subcommittee). Reports include summary statistics of key sleep parameters, calculated for each scorer over discrete time periods (monthly to quarterly). Intra- and inter-reader differences are also reviewed by the CSRC staff. If differences between scorers can not be explained or resolved, scorers noted to score differently will score together, concentrating on the areas where differences were noted. Subsequent scoring is monitored until conformity is demonstrated, with determination of any need for re-training. Studies are also assigned to the same reader at defined time periods to define intra-reader reliability. As appropriate, the Coordinating Center monitors intra- and inter-reader reliability to determine further thresholds for requiring remediation, including retraining or removing a scorer, or implementation of a formal reliability study of within and between scorer reliability. Site visits to the CSRC, coordinated by the CC, occur as directed by the Steering Committee.

Each signal will be reviewed for quality and a quality grade will be assigned for each channel that gauges the duration of artifact free data relative to the percentage of sleep period for the recording which includes oximetry, airflow (cannula), heart rate, snore channel and position (Appendix A). Any questionable or absent signal will be noted in the quality report. An overall study quality grade is also assigned that reflect the absolute duration of artifact free signals for the two primary signals: nasal pressure and oxygen saturation.

The quality of each signal and overall study quality will be assessed at the time of scoring of the record. The Scorer will code each channel of information according to the duration of i) scorable signals; ii) duration of artifact free signals during sleep, and iii) an overall QA grade to each study. The total duration of the study (from Time to Bed to the lights on) and the total duration of sleep will also be indicated. Scoring notes regarding event identification and specific physiological signal issues are also recorded on the **QS form** (Manual 6). After full scoring, the scorer will generate a **Quality Report** containing all quality grades and scoring notes will be generated for each study. The Quality Reports are posted generally within 2 weeks of receipt of the sleep study at the CSRC.

15. ORAL HEALTH

All HCHS/SOL staff who will be performing periodontal examinations for the study, as well as all staff members who will function as recorders entering data into the Dental Data Entry System (DDES) need to complete the training and certification requirements prior to examining study participants. The purpose of Dental Examiner training and certification is to standardize the reliability of measuring dental caries and periodontal parameters.

15.1. Training and Certification of Dental Examiners

Only dental professionals with extensive experience in oral examinations, such as licensed dental hygienists or general dentists/periodontists, will be trained to conduct the oral health examination and any follow-up dental or periodontal evaluations.

Prior to beginning the central training, Examiners will review the Oral Health Examination Manual of Operations (MOP). The training session will include a review of the MOP, use of the specific indices, instrumentation, case scenario slides, and demonstration models. The Reference Dental Examiner will review the criteria for certification for each component of the examination and will answer questions.

All examiners must pass the certification requirements for HCHS/SOL before performing study examinations. The Dental Examiners will be required to agree on measurements taken from six practice subjects with the Reference Dental Examiner within a specific tolerance. In addition, comparisons will be made on at least three other examiners to estimate inter-examiner agreement for future comparison with similar replicate measurements obtained during the course of the study. Practice subjects recruited for the central training will be selected to represent a range of periodontal health (AAP types I-III) and caries status. The sequence of examination, i.e., whether the examiner precedes or follows the Reference Examiner, could influence agreement between measurements. Thus, the order of measurements will be determined in a quasi-random fashion (e.g., Examiner 1 may be the first examiner to measure Subject 1, the 4th to measure Subject 2, the 8th to measure Subject 3, etc.). In this way any potential bias will be consistent for all examiners. Only Examiners who have reached the stipulated level of agreement with the Reference Examiner will be allowed to undertake HCHS/SOL dental examinations.

The criteria needed for certification of the Dental Examiner are as follows.

Agreement on a tooth basis: Measurements that are taken on a tooth basis will be performed on the same set of six volunteer subjects for all Examiners and the Reference Examiner. The trainee measurements of tooth count codes (1=primary tooth, 2=permanent tooth, 3=implant, E=missing due to caries or periodontal disease, M=missing due to trauma or other reason, U=un-erupted or congenitally missing, 5=Permanent root tip is present) and tooth surface codes (0=sound surface, 1=caries, 2=restoration) are expected to agree with those of the Reference Examiner for 90% of teeth evaluated. For example, if each volunteer has 32 teeth, we would expect agreement on tooth count code for 172 of the 192 teeth evaluated.

Agreement on a site basis: Measurements that are taken at multiple sites of each tooth can only be performed a limited number of times on each volunteer as the measurement procedure results in changes in the measurement value and can cause discomfort to the subject. Therefore, each

volunteer will have site measurements taken on only half of the mouth (excluding the 3rd molars) by at most two Examiners and the Reference Examiner. The trainee measurements of probing depth and cemental-enamel junction (CEJ) are expected to agree within ±1 mm of those of the Reference Examiner for 90% of sites evaluated. For example, if 14 teeth are evaluated for each volunteer, we would expect agreement within ±1 mm on probing depth for 226 of the 252 sites (14 teeth × 6 sites × 3 volunteers) evaluated.

Practice sessions after training: The final stage of certification requires each Examiner at a field center to perform examinations on five subjects with data recorded into the DDES. The data will be examined at the CC for errors, missing data, and agreement between Examiners. Certification requires that no obvious errors in the data are detected, and that the inter-examiner agreement is similar to that observed at the central training.

Retraining and certification sessions will be held at UNC annually for examiners whose measurements are found to drift over time (identified through data analysis reports comparing examiners over time), and who fail to demonstrate an acceptable performance standard or an adequate knowledge of the protocol (identified at the time of the Reference Dental Examiner site visit).

15.2. Training and Certification of Recorders

The Dental Data Entry System (DDES) has been developed to record measurement from the HCHS/SOL Oral Health Examination. The DDES is expected to improve the quality of the dental data by performing data validation checks (e.g., valid range checks, missing data warnings) as the examination is taking place. Though many examiners in HCHS/SOL will be experienced with other periodontal examination data entry systems, the data field ordering, naming conventions, and nomenclature in the DDES are not always standard. Data entry of a periodontal exam requires synchronization and communication between the examiner and the recorder in order to provide quality assurance of data, and to reduce examination time considerably.

Prior to central training, each field center will be provided the HCHS/SOL DDES User's Guide (also posted on the study website). This manual should be reviewed prior to the central training. At the training, recorders will practice entering data into the DDES.

It is understood that some field centers will only send the dental examiner to the central training. However, the dental examiner will not be the recorder who enters the dental measurements into the DDES. Thus, either dental examiners or recorders may be trained and certified on the use of the DDES. If the dental examiner is trained, they may train their recorders when they return to the field center. All recorders, whether centrally trained or locally trained, must pass the certification requirements before recording data for participant examinations.

Training will involve practice sessions to familiarize users with the DDES, while also serving to pilot test the HCHS/SOL forms and procedures prior to the study start. These practice sessions are required to certify as a dental recorder for HCHS/SOL. In particular, recorders are required to enter dental examination data from five practice subjects, and successfully transfer this data to the coordinating center to satisfy certification requirements.

15.3. Observation of Dental Examination

The Reference Dental Examiner will visit the field centers once each year to monitor for to deviations from the Oral Health Examination protocol. The first monitoring visit will take place within the first 3 months after examinations start as deviations from the protocol are more likely to occur then. Subsequent monitoring visits will take place in years 2 and 3. A checklist will be completed noting whether correct procedures were followed for each item on the list. The name of the Reference Dental Examiner and the technician ID will be recorded on the checklists and sent to the CC. Major deviations from the protocol will be brought to the attention of the QC Committee.

As part of the monitoring visit, replicate measurements will be taken for a randomly selected quadrant of a participant's mouth. If licensing permits, the Reference Examiner (if will conduct the replicate examination. If the State licensing laws do not allow the Reference Examiner to take measurements, and there are two Examiners at the site, the second Examiner will take the replicate measurements. Re-training should be considered if the Examiner-Reference agreement fails to meet the certification criteria set out at the central training (section 15.2) or if inter-examiner agreement is below that observed at the central training.

16. PARTICIPANT INTERVIEW

Establishing quality control for interviews is critical in ascertaining whether interviews are conducted according to protocol. If all interviews are not conducted according to protocol, then the information that one interviewer obtains from a participant may be different from the information another interviewer might have obtained from the same participant. Audio recording and observation are used to monitor the quality of the data that interviewers collected as described below.

16.1. Certification on Interviewing Technique

Requirements for certification or re-certification on interviewing techniques include:

- Attending central training, or reviewing a presentation on Interviewing Techniques (request from the CC), for initial certification.
- Successfully completing a short written exam on material, for initial certification.
- Round-robin (explained below) or Reading Center review of taped interviews, covering all questionnaires.
- Adequate frequency of interviews with each instrument, with acceptable level of missing data.
- There are additional requirements for certification for Medications Transcription, handled by the Coordinating Center
- Certification and audiotape review is handled separately for the neurocognitive instruments and for dietary recall, by the respective reading centers.

Completed written exams are sent to the CC for evaluation.

16.2. Observation of Interviewing Technique

Quarterly, the field center supervisor will observe each interviewer twice while the interview is in progress. Interviewers will not know in advance which interviews will be monitored for quality control purposes. The study coordinator will rate the interviewer's performance using standard criteria from a checklist (Appendix 2) and give the interviewer immediate feedback. These interviews should be summarized quarterly on the Summary of Observation and Equipment Checklists (Appendix 1).

16.3. Audiotaping of Interview

Every interview will be audio recorded and the cassettes tracked on an inventory list. Recording of every interview allows for *any* interview to be selected randomly for quality control review. This is important because interviewers will not know in advance which interviews will be assessed, and are less likely to conduct the interview differently because they know it is being monitored. Prior to taping, participants have read and signed the consent form authorizing taping of the interview for quality control purposes.

> Prior to starting an interview staff can use a reminder such as:
> "*For quality control all interviews are tape-recorded for review by a supervisor if you agree. As with all of the examination procedures, the information on the audiotape will be kept confidential.*"

Each tape or digital file of recordings will contain all interviews for one interviewer for one day. Each would be labeled by interviewer code and date and the set of questionnaires included . Audio recording of the 24 hr dietary recall interview and of the neurocognitive session would be handled separately.

One audio recorded interview conducted by each interviewer will be randomly selected and reviewed by the interview supervisor each month, checking for adherence to protocol, using the observation checklist. These reviews should be summarized on the Checklist for Review of Audio Recorded Interviews (Appendix 13).

Round-robin review: Bimonthly, the interview supervisor will select at random two audiotapes per interviewer from a list selected by the Coordinating Center and mail to the supervisor at another field center for review using the observation checklist. These reviews will be documented on the Bimonthly Checklist for Interviews (Appendix 14). Notes about any inconsistencies in implementing the interview protocol will be documented and sent to the CC. The CC will distribute a summary of the comments, protocol violations and discrepancies in interview methods and the summary will be discussed on a QC conference call with interview coordinators. Local retraining of interviewers takes place when needed. Interviewers are recertified after a round-robin review of their taped interviews or after the CC receives notification from the field center interview supervisor that adequate local post-round-robin review retraining has been implemented.

16.4. Analysis of Study Data

Study data will be analyzed periodically to assess frequency of interviews for each interviewer, for each questionnaire. Minimum levels will be set to allow for continued certification. Levels of missing data will also be assessed by interviewer, and maximum acceptable levels set.

17. COGNITIVE FUNCTION

The following battery of neurocognitive tests will be administered: the Mini-Mental Status Examination (6-item), the Spanish English Verbal Learning Test, the Word Fluency Test of the Multilingual Aphasia Examination (letters F and A), and the Digit Symbol Substitution Test of the Wechsler Adult Intelligence Scale-Revised (WAIS-R). These measures tap five cognitive domains: global mental status, verbal learning and memory, word fluency, and psychomotor speed, respectively.

17.1. Training and Certification

Staff completing the Cognitive Function form are trained and certified at a centralized training or locally by certified study coordinators and/or certified lead interviewer in this area. New staff receives training in interviewing techniques and the form's question by question instructions by the lead interviewer, in addition to be certified on Interviewing Techniques and following any additional requests from the centralized training instructor. Local certification requires:

- The instructions for each test are presented clearly, at an appropriate rate, and in accordance with the instructions on the template,
- The administrator handles the testing materials and timing appropriately (e.g., is discrete with timing, etc.) and
- The scoring for each test is accurate.
- Performing 5 practice interviews on colleagues at the field center's reception workstation under close supervision with the final session signed off by a lead certified colleague (preferably one certified at the centralized training by T. Mosley).
- Being certified on Interviewing Techniques.

17.2. Audiotaping of Neurocognitive Component of Interview

During the first 6 months of the study, 2 audiotaped sessions and associated documentation for each interviewer will be reviewed by the neurocognitive trainer (Mosley) to ensure appropriate pacing, adherence to protocol, and accuracy of recorded responses. Notes about any inconsistencies will be relayed to the study coordinator. After the initial 6 month period, Dr. Mosley will review one neurocognitive session per interviewer, noting deviations from the standardized protocol. General feedback that pertains to all examiners will be provided by Dr. Mosley on QC conference call involving field center study coordinators. These calls will also provide an opportunity to discuss and problem-solve various exam issues that may arise.

18. DIET AND SUPPLEMENTS

18.1. Training and Certification

Following central training on the use of the Nutrition Data System for Research (NDSR) software package, dietary interviewers will conduct one practice recall per day they work for the Diet and Supplement section and submit results to the Nutrition Reading Center coordinator until the start of data collection. The HCHS/SOL coordinator will review and provide feedback as

needed. This regular use of the software will maintain familiarity with the software during the time between training and study start.

The dietary interviewer will review and edit the diet and supplement recall as soon as possible after its administration, using the 24-hour Recall Checklist (Appendix X). Obvious errors should be corrected on the spot. When the dietary interviewers have questions, they may discuss these with the lead interviewer to reach a consensus. Lead interviewers may consult with the Nutrition Reading Center coordinator for more information. Once per week, the lead interviewer will review all dietary and supplement recalls collected at the field center. The lead interviewer may make or recommend changes to the diet and supplement recall only after discussing the proposed change(s) with the dietary interviewer.

18.2. Observation of Diet and Supplement Component of Interview

In addition to regular monitoring visits by the Coordinating Center, during the first year of data collection, NRC personnel visit each field center to evaluate adherence to the HCHS/SOL Field Center Manual of Procedures, observe dietary and supplement interviews, evaluate local quality control procedures, understand field center challenges, check for confidentiality of dietary and supplement data and respond to questions about overall NDSR data management and collection issues. Following the visit to the field center, the NRC staff will submit a detailed report to the CSCC about the progress and issues noted during the site visit. The HCHS/SOL Field Center Checklist (Appendix 7) is used to document dietary and supplement data collection procedures.

18.3. Replicate Measurements of Diet and Supplement Component of Interview

To quantitatively evaluate reliability of the dietary and supplement interviews, each dietary interviewer conducts an interview with staff from the NRC six times per year after the start of regular data collection. The NRC staff person follows an exact script for this telephone interview. The script is changed three times each year of the data collection. This approach provides replicate measurements for analysis and helps identify possible problem issues in data collection.

18.3. Replicate Measurements of Diet and Supplement Component of Interview

One method of assessing quality control for interviews is to ask a subset of participants to provide duplicate dietary recalls to different interviewers and then to compare the nutrient profiles of each individual subject's two recalls. Rather than burden participants with having to provide two dietary recalls in a row, repeated dietary recalls will be conducted on someone from the Nutrition Reading Center.

Bimonthly, each dietary interviewer will interview the same person from the Nutrition Reading Center and these interviews will be summarized on the Bimonthly Checklist for Interviews (Appendix 14). This volunteer will report on the same 24 hour period for each interviewer, and results compared. Even with only two dietary interviewers per center, over 3 years this would provide around 150 pairs of repeat measurements for comparison. In order to acquire an early look at repeatability the frequency of these repeat measurements will be increased to monthly for the first 3 months.

19. MEDICATION TRANSCRIPTION

19.1. Training and Certification

The **Medication Use Questionnaire** (MUE) records all prescription and over-the-counter medications, including cold and allergy medications, vitamins, herbals or supplements used by participants in the four weeks preceding their interviews. The survey ascertains usage of up to 25 medications. Ascertainment includes scanning of twelve-digit Universal Product Code (UPC) bar code symbols when available. Medical Therapeutic Classification (coding) is automated where possible. Otherwise, manual coding is centralized (performed only in the Coordinating Center).

Interviewers are centrally trained and when certified, assume responsibility for providing local staff training in medication scanning / transcription.

Interviewers are certified to administer the MUE by attending the central training, completing the scanning / transcription exercise designed by the central trainer, and passing with a score of ≥ 80%. New staff unable to attend central training are eligible for remote certification when:

- The candidate is trained by the lead certified interviewer at the corresponding Field Center.
- The Coordinating Center has sent to the Study Coordinator a mock medication bag with detailed instructions for the candidate's certification.
- The candidate independently completes an MUE and enters it into the Data Entry System.
- The Study Coordinator returns the medication bag with all of its contents, the instructions, and printouts of the MUE screens to the Coordinating Center for evaluation.
- The candidate passes with a score of ≥ 80%.

Appendix 1. Summary of Observation and Equipment Checklists

Instructions: *This form should be completed quarterly and sent to the Coordinating Center.*

Field Center: _____ Date: ___ / ___ / _____
(mm dd yyyy)

Quarterly Reporting period:

Jan - Mar 20____ Apr - Jun 20____ July - Sep 20____ Oct - Dec 20____

A. Observation Checklist

	Technician ID	Supervisor ID	Date (mm/dd/yy)
General interview techniques	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
Anthropometry observation	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
Blood pressure observation	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
Ankle-brachial Index observation	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
Simultaneous ABI readings	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
Biospecimen collection	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____

B. Equipment Checklist

	Frequency	No. times assessed	No. times within calibration
Anthropometry			
(1) Scale read zero	Daily	_____	_____
(2) Headboard of stadiometer	Daily	_____	_____
(3) Weight scales	Weekly	_____	_____
(4) Measuring tape	Monthly	_____	_____
Blood Pressure/ABI equipment			
(1) Sphygmomanometer inspection	Quarterly	_____	_____
(2) Calibration checks of sphygmomanometer	Quarterly	_____	_____
Biospecimen collection			
(1) Refrigerators, freezers, room temp	Daily	_____	_____
(2) Speed of centrifuge	Annually	_____	_____
(3) Pipettes	Annually	_____	_____
Spirometer			
(1) Checked for leaks	Daily	_____	_____
(2) Volume checked	Daily	_____	_____

Comments: _____

_____

_____

_____

Appendix 2. Checklist for Observation of General Interviewing Techniques

Field Center: _____ Tech ID: _____Supervisor ID:_____ Date: ___/___/___

Interviews Observed (Check all that apply)

Alcohol (ALE/ALS)	☐	Personal Information (PIE/PIS)	☐
Dietary behavior (DBE/DBS)	☐	Physical Activity (PAE/PAS)	☐
Economic (ECE/ECS)	☐	Respiratory (RSE/RSS)	☐
Health care use (HCE/HCS)	☐	SF-12 Health Survey (SFE/SFS)	☐
Hearing Exam (HEE/HES)	☐	Sleep (SLE/SLS)	☐
Hearing Hx (HHE/HHS)	☐	Social Network Index (SNE/SNS)	☐
Medical Hx (MHE/MHS)	☐	Sociocultural (SCE/SCS)	☐
Medication Use (MUE/MUS)	☐	Tobacco Use (TBE/TBS)	☐
Occupation (OCE/OCS)	☐	Weight Hx (WHE/WHS)	☐
Oral Health (OHE/OHS)	☐	Well Being (WBE/WBS)	☐
Personal Identifiers (IDE/IDS)	☐		

Item	Yes	No	Comments
1. Introduces her/himself at beginning of the interview; thanks participant at the end.	_____	_____	_____
2. Verifies participant's name.	_____	_____	_____
3. Explains purpose of interview when appropriate, e.g., reads introductions or transition statements when included on form.	_____	_____	_____
4. Reads questions exactly as written, stressing time frame and key elements.	_____	_____	_____
5. Demonstrates familiarity with content, flow, definitions, and skip patterns.	_____	_____	_____
6. Uses standardized tone of voice with supportive, non -judgmental statements.	_____	_____	_____
7. Paces interview in response to participant's level of comprehension/comfort.	_____	_____	_____
8. Trains participant in response patterns when appropriate.	_____	_____	_____
9. Refrains from probing except to clarify ambiguous, unclear, untrue, or inconsistent, responses.	_____	_____	_____
10. Uses standardized definitions when asked for clarification.	_____	_____	_____
11. Repeats questions stressing portions of question which were misunderstood.	_____	_____	_____
12. Selects appropriate type of probe.	_____	_____	_____
13. Accurately records participants' responses.	_____	_____	_____

Comments: _____

_____

Appendix 3. Checklist for Observation of Anthropometry Measurement

Instructions: *This checklist documents observation of anthropometry technicians by supervisors. Quarterly, checklists and logs are summarized onto the* ***Summary of Observation and Equipment Checklists*** *(Appendix 1). Copies of this log may be requested by the CC.*

Field Center: _____ Tech ID: _____Supervisor ID:_____ Date: ___/___/___

	Yes	No	Comments
1. Anthropometry is done BEFORE the snack.	_____	_____	_____
2. If the participant is wearing any nylon hose other than knee highs, the participant is instructed to remove hose.	_____	_____	_____
3. Participant is wearing light-weight, non-constricting underwear.	_____	_____	_____
4. Participant is wearing a light clothes or scrub suit.	_____	_____	_____
5. Participant has removed shoes.	_____	_____	_____
6. Participant has emptied bladder.	_____	_____	_____

Standing Height Measurement

1. Procedure is explained to participant.	_____	_____	_____
2. Participant's spine and heels are placed against the wall.	_____	_____	_____
3. Participant's eye to ear plane is horizontal [i.e., Frankfort plane].	_____	_____	_____
4. Measurement is taken with triangle or measuring block.	_____	_____	_____
5. Data recorded accurately in cm	_____	_____	_____

Technician's measurement of participant height: _____ cm
Supervisor's measurement of participant height:: _____ cm

Weight Measurement	**Yes**	**No**	**Comments**
A. Equipment			
1. Scale firm on floor.	_____	_____	_____
2. 10 kg standard weight available.	_____	_____	_____
3. Anthropometry Equipment Calibration log up-to-date.	_____	_____	_____
B. Procedure			
1. Participant prepared and procedure explained.	_____	_____	_____
2. Participant is bare-foot.	_____	_____	_____
3. Position of participant on center of scale.	_____	_____	_____
4. Balance achieved.	_____	_____	_____
5. Recordings completed.	_____	_____	_____
6. Data recorded accurately in kg	_____	_____	_____

Technician's measurement of participant weight: _____ kg
Supervisor's measurement of participant weight: _____ kg

Waist Measurement	**Yes**	**No**	**Comments**
1. Procedure is explained to participant.	_____	_____	_____
2. Subject stands erect, yet relaxed, with weight equally distributed on both feet, and feet together.	_____	_____	_____
3. Measuring tape is placed around subject's waist using lateral border of ilium as bony landmark.	_____	_____	_____
4. Subject takes a normal breath and gently exhales, holding breath in a relaxed manner at the end of exhalation.	_____	_____	_____
5. Tape is horizontal and snug, but not tight enough to compress tissue. [Invert tape, if needed, to insure reading edge of tape is snug to skin for measurement.]	_____	_____	_____
6. Reading is recorded to the nearest centimeter, rounding down.	_____	_____	_____

Technician's measurement of participant waist: _____ cm

Supervisor's measurement of participant waist: _____ cm

Comments: _____

_____

_____

_____

Appendix 4. Checklist for Observation of Blood Pressure and ABI Measurement

Instructions: *This checklist documents observation of blood pressure and ankle brachial index (ABI) technicians by supervisors. Quarterly, checklists and logs are summarized onto the* ***Summary of Observation and Equipment Checklists*** *(Appendix 1). Copies of this log may be requested by the CC.*

Field Center: _____ Tech ID: _____Supervisor ID:_____ Date: ___/___/___

Blood Pressure Measurement	**Yes**	**No**	**Comments**
1. Checks function settings on OMRON unit (ENTER, 3 inflations, 30)	_____	_____	_____
2. Checks Mode and P-setting on OMRON unit	_____	_____	_____
3. Makes sure AC adapter for OMRON unit is securely connected (tends disconnect from unit)	_____	_____	_____
4. Checks AC adapter cord and tubing for cracks	_____	_____	_____
5. Cleans all the equipment	_____	_____	_____
6. Allows subject to rest for five full minutes	_____	_____	_____
7. Performs arm measurement and cuff selection properly	_____	_____	_____
8. Identified brachial pulse location properly	_____	_____	_____
9. Proper cuff placement	_____	_____	_____
10. Attaches cuff to monitor	_____	_____	_____
11. Uses proper settings on OMRON unit	_____	_____	_____
12. Turns monitor on with ON/OFF button	_____	_____	_____
13. Sets MODE selector to AVG	_____	_____	_____
14. Sets P-SET knob to AUTO	_____	_____	_____
15. Pushes START button	_____	_____	_____
16. Records 1st, 2nd, 3rd systolic and diastolic BP readings and average heart rate	_____	_____	_____
17. Instructions to participant are clear	_____	_____	_____
18. Holds arm vertically for 5 seconds between readings	_____	_____	_____
19. Informs participant of average readings	_____	_____	_____

Comments: _____

_____

_____

ABI Measurement	Yes	No	Comments
1. Checks Examination Table for No Tilt			
2. Checks Examination Table for proper length			
3. Inspects arms and ankles for open lesions			
4. Measures arm and legs for correct cuff size			
5. Palpates right and left brachial arteries			
6. Marks right and left brachial arteries			
7. Palpates right PT and DP arteries			
8. Marks right PT and DP arteries			
9. Palpates left PT and DP arteries			
10. Marks left PT and DP arteries			
11. Inspects BP cuffs for cleanliness			
12. Wraps cuff around right and left arms			
13. Wraps cuff around right and left ankles			
14. Applies ultrasound gel to Doppler probe head			
15. Turns on the Doppler probe power			
16. Applies Doppler probe to right brachial artery			
17. Listens for arterial pulsation			
18. Angles the Doppler probe to obtain best signal			
19. Inflates the blood pressure cuff			
20. Stops inflation of cuff at 20mmHg above sound disappearance			
21. Ensures probe has not moved during inflation			
22. Decreases cuff pressure slowly			
23. Notes reappearance of arterial pulsation sound			
24. Continues slow pressure deflation			
25. Records systolic blood pressure on data form			
26. Repeats tasks 13 – 22 for each arterial site			
27. Unwraps all 4 BP cuffs			
28. Removes excess gel form Doppler head and cleans head with chemical cleaner before use on next participant.			

Comments: _____

Appendix 5. Simultaneous Ankle-Brachial Index Measurements

Instructions: *Quarterly, ABI measurements are taken by technicians and supervisors on the same two volunteers (not an HCHS/SOL participants). Each technician records his/her measurements on an ABI form. The supervisor transfers the results onto this form and calculates the differences between the two sets of measurements. If the systolic blood pressure measurements differ by more than 8 mmHg at any of the 6 sites, the supervisor should indicate the corrective action taken on this form.*

Field Center: _____ Tech ID: _____Supervisor ID:_____ Date: ___/___/___

Ankle-Brachial Index Measurement Observations

Technician's measurement of systolic BP readings (mm Hg):

Right brachial ☐☐☐ Right posterior tibial ☐☐☐ Right dorsalis pedis ☐☐☐

Left dorsalis pedis ☐☐☐ Left posterior tibial ☐☐☐ Left brachial ☐☐☐

Supervisor's measurement of systolic BP readings (mm Hg):

Right brachial ☐☐☐ Right posterior tibial ☐☐☐ Right dorsalis pedis ☐☐☐

Left dorsalis pedis ☐☐☐ Left posterior tibial ☐☐☐ Left brachial ☐☐☐

Comments: _____

_____

_____

_____

_____

Appendix 6. Checklist for Observation of Biospecimen Collection and Processing

Instructions: *This checklist documents observation of technicians responsible for biospecimen collection, processing, and shipping by supervisors. Quarterly, checklists and logs are summarized onto the* ***Summary of Observation and Equipment Checklists*** *(Appendix 1). Copies of this log may be requested by the CC.*

Field Center: _____ Tech ID: _____Supervisor ID:_____ Date: ___/___/___

Biospecimen Collection	**Satisfactory/ Unsatisfactory**	**Comments**
1. Labels checked	___	_____
2. Participant prepared and procedure explained	___	_____
3. Tourniquet application and release	___	_____
4. Venipuncture technique	___	_____
5. Tube collection sequence	___	_____
6. Inversion technique	___	_____
7. Tube incubation location	___	_____
8. Stasis obtained	___	_____
9. Needle disposal	___	_____
10. Laboratory Collection form completion	___	_____
Biospecimen Processing		
1. Knowledge of centrifuge operation	___	_____
2. Aliquotting supply set-up	___	_____
3. Stage 1 tube spin	___	_____
4. Stage 2 aliquotting	___	_____
5. Stage 3 tube spin and processing	___	_____
6. Stage 4 tube spin and processing	___	_____
7. Urine processing	___	_____
8. Vials sealed	___	_____
9. V-Form completed	___	_____
10. Freezer organization	___	_____
11. Time constraints	___	_____
12. Disposal of contaminated supplies	___	_____
13. Paxgene tube freezing	___	_____
Biospecimen packing and shipping		
1. Specimens bagged	___	_____
2. Adequate dry ice used in shipping	___	_____
3. Shipping paperwork	___	_____
Miscellaneous		
1. Incident Form	___	_____
2. QC Procedure	___	_____
3. Containers correctly labeled for shipping	___	_____

Comments: _____

_____

_____

Appendix 7. Checklist for Observation of Dietary Interview

Instructions: *This checklist documents observation of technicians responsible for administration of the dietary interview. Items are circled below to indicate strengths and weaknesses in the administration of the Dietary Intake Form. A"=Acceptable "NA"=Not Acceptable. Quarterly, checklists and logs are summarized onto the* ***Summary of Observation and Equipment Checklists*** *(Appendix 1). Copies of this log may be requested by the CC.*

Field Center: _____ Tech ID: _____Supervisor ID:_____ Date: ___/___/___

1. Establishes Rapport

A NA Establishes and maintain a friendly and trusting atmosphere

A NA Presents questions appropriately

A NA Remains objective during interview; accepts information in a non-judgmental manner

A NA Encourages active participation

2. Provides Simple and Clear Instructions

A NA Basic instructions included as text on the interview form were presented conversationally and participant's understanding ensured; instructions were provided, opportunity for questions was provided

A NA Participant was oriented to cups/glasses, response cards; response card was read at least once when first given to participant

A NA Interviewer does not get bogged down with details

A NA Interviewer does not become preoccupied with serving sizes

3. Uses Good General Interview Skills

A NA Reads in a natural and conversational rhythm, as if speaking; reads items conversationally (e.g. "2% milk", not "milk, 2%")

A NA Uses transitions as necessary

A NA Is prepared and knows the material. Reads at a good pace...not too fast...not too slow....

A NA Responds to participant's comments (confused, bored, fatigued, frustrated, amused)

A NA Repeats or rephrases question if answered inappropriately

A NA Asks every question on the FFQ...does not assume that he/she knows the answer to the question

A NA Remains patient

4. Uses Probing Techniques Appropriately

A	NA	Uses silence to get a response
A	NA	Does not accept a “Don’t know” answer
A	NA	Watches for irrelevant answers: realizes importance of acknowledging responses and makes it clear that participant’s responses were heard, but probes for the appropriate information
A	NA	Watches for vague, incomplete answers
A	NA	Repeats the question or answers categories or uses paraphrasing: Acknowledges what the participant said, then goes on to solicit the necessary information
A	NA	Lets the participant know that 100% accuracy is not required
A	NA	Uses neutral probes that do not suggest answers or imply judgments
A	NA	Stays on track and keeps participant focused on interview
A	NA	Avoids "Depends” or other qualified answers by the participant

5. Cultural Sensitivity

A	NA	Presents all lines of the FFQ, no matter what
A	NA	If the participant is unfamiliar with a particular food, it is unlikely to be an important source of nutrients. Time is minimized on these items.
A	NA	Is aware and familiar with the variety of foods on the FFQ
A	NA	If participant gives an unfamiliar food (as an open-ended response), the participant is asked to describe it. Writes this information down.

Appendix 8. Anthropometry Equipment Calibration Log

Instructions: *This checklist documents the daily, weekly, and monthly calibration of anthropometry measurement equipment. Quarterly, checklists and logs are summarized onto the* ***Summary of Observation and Equipment Checklists*** *(Appendix 1). Copies of this log may be requested by the CC. There should be one such log done each week, though the monthly portion will be filled out only in the weeks that it is needed. If there is more than one piece of equipment used for a particular function, indicate the checks for each piece on the same log.*

Week of:_____ Field Center:_____ Tech ID:____
[Monday's Date]

Daily Checks:

Scales read zero

___ ___ ___ ___ ___
M T W Th F

Headboard of the stadiometer moves up and down the track smoothly

___ ___ ___ ___ ___
M T W Th F

Weekly Checks

A. Reading of scale with 10 kg weight

Date: ___/___/___ Time: _____ Reading: _____

*If reading outside of 8.5 to 11.5 range, the scale should be serviced.

Date service REQUESTED, Date: ____/____/____ Time: _____

Date RECALIBRATED by service technician. Date: ____/____/____ Time: _____

B. Repeat calibration because of moving scales

Date: ____/____/____ Time: _____ Reading: _____

Date: ____/____/____ Time: _____ Reading: _____

C. Height Rule (rounding down)

a. Touches hard-surfaced platform which measures are done _____
b. Perpendicular to the floor _____

Monthly Checks

Week of:_____ Tech ID:_____
[Monday's Date]

A. Measuring tape

Excess wear or damage found? Yes Y No N

With the 0 mark of the tape is aligned with the 150 cm mark of the height rule,
1. Height (to nearest cm) on height rule of the 30 cm mark of the tape _____cm
* If reading is outside the 119.5 – 120.5 cm range, the tape should be replaced.

2. Height (to nearest cm) on height rule of the 100 cm mark of the tape_____cm
* If this measure is outside the 49.5 – 50.5 cm range, the tape should be replaced.

Date tape replaced: ____/____/____

Appendix 9. Daily Centrifuge, Freezer, Refrigerator and Room Temperature Log

Tech ID	Date	Centrifuge	Freezer	Refrigerator	Room
______	___/___/___				
______	___/___/___				
______	___/___/___				
______	___/___/___				
______	___/___/___				
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______	___/___/___				
______	___/___/___				
______	___/___/___				

Appendix 10. Sample Written Exams for Blood Drawing Certification

Sample Exam #1

1. Place the following 8 blood collection tubes in the correct set-up order and location for the venipuncture: one 10 ml red and gray top; one 4.5 ml blue anticoagulant; one BCT, lavender top; one ACD yellow-top; 2 lavender 10-ml tubes; one 5 ml lavender tube.
2. Specify which tube(s) go into the ice bath after collection.
3. Remove the appropriate tubes from the tray, balance them and place them in the centrifuge. How long should they spin? At what speed?
4. Set up a sponge tray with the correct number and order of specimen storage tubes. Indicate the number and colors of screw caps to be used on these tubes.
5. Place the collection tubes in front of their respective sample tubes. Describe what further processing is required of each collection tube before it is aliquotted into its respective sample tube.
6. Organize the color-capped sample tubes and prepare them for shipment.
7. Describe the quality control for each piece of equipment.

Sample Exam #2

1. Name the two most significant bloodborne diseases:

   a._____

   b._____

2. List the three steps to take following an accidental specimen exposure:

   a._____

   b._____

   c._____

3. Give four examples of broken skin other than punctures:

   a._____ c._____

   b._____ d._____

4. Give three examples of mucous membranes:

   a._____ c._____

   b._____

5. What three steps should be followed before exiting the laboratory?

   a._____ c._____

   b._____

6. From which tubes are the packed cells used?
   a) #1
   b) #2
   c) #3 and #4
   d) #5 and #6

7. How long should tube #1 sit at room temperature before centrifugation?

   a) 5 minutes
   b) 30 minutes
   c) 2 hours
   d) No waiting time required

8. Why is this step (un)necessary?_____

9. Which tube is drawn last?

   a) A 10 ml red and gray-stoppered
   b) A 10 ml lavender-stoppered
   c) A 10 ml yellow-stoppered
   d) A 5 ml lavender-stoppered

10. For what type of tests will the 10-ml lavender-stoppered tubes be used?

    a) Chemistry
    b) Lipid
    c) Coagulation
    d) Special coagulation

11. When is the tourniquet removed?

    a) after tube #1 fills
    b) after tube #2 fills
    c) after all tubes fill
    d) it does not matter

12. At what temperature are the U-TEK +30ºF refrigerant packs stored for placement with the ACD tubes that are shipped daily to the Central Hemostasis Laboratory for lymphocyte collection?

Appendix 11. HCHS/SOL Certification Request Form

Instructions: *This form documents which procedures/interviews a staff member is certified for and how they received certification. It is submitted by the* ***Trainer*** *or* ***Study Coordinator*** *(SC) to Marston Youngblood at the Coordinating Center (CC) for final evaluation for certification and to receive a code number once a staff member is certified. This form is re-submitted to the CC to document quality control methods carried out on procedures/interviews for certified staff members since their original training.*

1. Submitted by _____ at the _____ field center on _____
(name of trainer) (date)

2. Requesting a staff code number for _____
(name of the staff)

3. Staff code number (if any) (3-digit number)
(Leave this field blank if the staff does not have an existing code number)

4. Specify for which procedure/interviews the staff member has completed certification or quality control requirements and describe specific actions that were taken to achieve these steps (including supervisors or certified staff members who observed the process).

Procedure & Interview	**Date Certified**	**Certification Method** (select ALL that applies) *1 = Attended central training presentation* *2 = Certified by central trainer* *3 = Direct observation by the local certified lead staff member in specified area* *4 = Completed written exam* *5 = Completed practice. Specify how many sets of practice were performed, and the differences of the measurements compared to the local trainer's for local certification.* *6 = Other (specify)* *7 = N/A (not applicable to the staff member)*
Anthropometry		
Seated BP		
Ankle-Brachial BP		
ECG		
Data Management		
Biospecimen collection, processing		
Physical Activity		
Spirometry		
Sleep		

Procedure & Interview	**Date Certified**	**Certification Method** (select ALL that applies) *1 = Attended central training presentation* *2 = Certified by central trainer* *3 = Direct observation by the local certified lead staff member in specified area* *4 = Completed written exam* *5 = Completed practice. Specify how many sets of practice were performed, and the differences in the measurements compared to the local trainer's for certification at field center* *6 = Other (specify)* *7 = N/A (not applicable to the staff member)*
Interviewing Techniques Cognitive Function		
Medication and Supplements		
Recruitment		
Audiometry Oral Health Endpoints ascertainment		

Coordinating Center Use Only

Assigned staff code number: _____

Certified for procedures/interviews (circle ALL that apply)
A, B, C, D, E, F, G, H, I, J, K, L, M, N, O

Date Received: _____, Processed by _____ (Staff initial)____

Appendix 12. Daily Spirometer Leak and Volume Check Log

Instructions: *This checklist documents the daily spirometer checks. Quarterly, checklists and logs are summarized onto the* ***Summary of Observation and Equipment Checklists*** *(Appendix 1). Copies of this log may be requested by the CC. There should be one such log done each month. If there is more than one spirometer used, indicate the checks with a separate log for each spirometer,*

Month/Year: ___/______

Day of Month	Spirometer Checked for Leaks	Volume checked on Spirometer
_______	_______	_______
_______	_______	_______
_______	_______	_______
_______	_______	_______
_______	_______	_______
_______	_______	_______
_______	_______	_______
_______	_______	_______
_______	_______	_______
_______	_______	_______
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_______	_______	_______
_______	_______	_______
_______	_______	_______
_______	_______	_______
_______	_______	_______
_______	_______	_______
_______	_______	_______
_______	_______	_______
_______	_______	_______
_______	_______	_______
_______	_______	_______
_______	_______	_______
_______	_______	_______
_______	_______	_______
_______	_______	_______
_______	_______	_______

Appendix 13. Checklist for Review of Audio Recorded Interviews
(Excluding 24 Hour Dietary Recall and Neurocognitive Interview)

Instructions: *This checklist documents the monthly checks regarding the interviews (excluding 24 hour dietary recalls and the neurocognitive interviews). There should be one such log done each month.*

Month/Year: ___/______

Technician ID	**Supervisor ID**	**Date (mm/dd/yy)**
_______	_______	_______
_______	_______	_______
_______	_______	_______
_______	_______	_______
_______	_______	_______
_______	_______	_______
_______	_______	_______
_______	_______	_______
_______	_______	_______
_______	_______	_______
_______	_______	_______
_______	_______	_______
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_______	_______	_______
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_______	_______	_______
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_______	_______	_______
_______	_______	_______
_______	_______	_______
_______	_______	_______
_______	_______	_______

Appendix 14. Bimonthly Checklist for Interviews

Instructions: *This checklist documents the bimonthly checks of the interviews. There should be one such log done every two months.*

Month/Year ___/_____ **and** ___/_____

	Technician ID	Supervisor ID	Date (mm/dd/yy)
Two interviews randomly selected and sent to another field center (Excluding 24 Hour Dietary Recall Neurocognitive Interview)	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
Dietary interviewer interviews the same person from the Nutrition Reading Center	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____

Appendix 15. OMRON Maintenance and Calibration Log

Instructions: *This checklist documents the quarterly checks for the OMRON. There should be one such log done every quarter. If there is more than one sphygmomanometer used, indicate the checks with a separate log for each sphygmomanometer.*

Tech ID: _____ Field Center: _____ Date: _____ OMRON unit #:_____

Cracking?	Yes	Y	No	N	Action: _____
Holes?	Yes	Y	No	N	Action:_____
Worn outer cloth of Velcro?	Yes	Y	No	N	Action:_____
Leakage of cuff bladder?	Yes	Y	No	N	Action:_____

Calibration Check with Pressure-Vacuum Meter (see Manual 2, section 12.7.2)

Smooth descent of OMRON LED mm Hg from 280 to 20 mm Hg? Yes Y No N

Observed pressure values on the Pressure-Vacuum Meter and the OMRON from 250 to 20 mmHg, in approximant decrements of 20 mm Hg:

Measurement Number	Pressure-Vacuum Meter	OMRON
1	☐☐☐☐.☐ mmHg	☐☐☐☐.☐ mmHg
2	☐☐☐☐.☐ mmHg	☐☐☐☐.☐ mmHg
3	☐☐☐☐.☐ mmHg	☐☐☐☐.☐ mmHg
4	☐☐☐☐.☐ mmHg	☐☐☐☐.☐ mmHg
5	☐☐☐☐.☐ mmHg	☐☐☐☐.☐ mmHg
6	☐☐☐☐.☐ mmHg	☐☐☐☐.☐ mmHg
7	☐☐☐☐.☐ mmHg	☐☐☐☐.☐ mmHg
8	☐☐☐☐.☐ mmHg	☐☐☐☐.☐ mmHg
9	☐☐☐☐.☐ mmHg	☐☐☐☐.☐ mmHg
10	☐☐☐☐.☐ mmHg	☐☐☐☐.☐ mmHg
11	☐☐☐☐.☐ mmHg	☐☐☐☐.☐ mmHg
12	☐☐☐☐.☐ mmHg	☐☐☐☐.☐ mmHg

Appendix 16. Timeline for Supervisor Checking of Technicians

Table 1: Frequency of Regular Checks and Observations (with section number where task description can be found)	
Daily	Anthropometry scales balanced to read zero (Appendix 8) – **6.4** Headboard of the stadiometer checked (Appendix 8) –**6.4** Temperature check in refrigerators, freezers, ect. (Appendix 9) **– 10.3** Check the spirometer for leaks and perform calibration checks (Appendix 12) **– 13.3**
Weekly	Anthropometry scales calibrated or when scaled moved (Appendix 8) **– 6.4**
Monthly	Measuring tapes checked for wear or stretching (Appendix 8) **– 6.4** One audio recorded interview selected and reviewed by coordinator (Appendix 2), recorded (Appendix 13) **– 16.3**
Bimonthly	Each dietary interviewer will interview the same person from Nutrition Reading Center (Appendix 14) **– 18.3** Coordinator selects two audiotapes per interviewer to be mailed to another center (Appendix 14) **– 16.3**
Quarterly	Anthropometry technicians observed (Appendix 3), recorded (Appendix 1) **– 6.3** Anthropometry equipment checks summarized, info sent to CC (Appendix 1) **– 6.4** ABI and BP technician(s) observed (Appendix 4), recorded (Appendix 1) **– 7.2, 8.2** Test agreement of ABI measurements (Appendix 5), recorded (Appendix 1) **– 8.2** Calibration and inspection of the OMRON (Appendix 15), recorded (Appendix 1) – **7.3** Biospecimen technicians collecting, processing and shipping observed (Appendix 6), recorded (Appendix 1) **– 10.1** Biospecimen equipment checks summarized, info sent to CC (Appendix 1) **– 10.3** Spirometry equipment checks summarized, info sent to CC (Appendix 1) **– 13.3** Supervisor observes interviewer twice (Appendix 2), recorded (Appendix 1) **– 16.2** Supervisor observes dietary interview (Appendix 7), recorded (Appendix 1) **– 18.2**
Annually	Checking of the actual speed of the centrifuge (Appendix 1) **– 10.3** Calibration and professional cleaning of pipettes (Appendix 1) **– 10.3**

Table 2: Frequency of Additional Checks and Observations During the First Three Months of Study	
Twice during the first month	Anthropometry technicians observed (Appendix 3) **– 6.3**
Monthly for the first three months	Each dietary interviewer will interview the same person from Nutrition Reading Center **– 18.3**