Youth

Hispanic Community Children's Health Study of Latino Youth (SOL Youth) Manual 4

Quality Assurance and Quality Control

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

Quality Assurance and Quality Control
TABLE OF CONTENTS

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 SOL Youth 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 SOL Youth 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 SOL Youth 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 SOL Youth Investigator Committee (PIs can choose representatives to participate) 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 SOL Youth Investigator 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 SOL Youth 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 SOL Youth Investigator 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) Investigator 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 120 participants (or individuals screened but not enrolled) repeat a portion of the clinic examination. The SOL Youth 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. Sections 6 to 15 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 SOL Youth 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 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 3- day session involving all aspects of the study presented by personnel from the CC as well as clinical specialists from other academic institutions including SOL Youth field center staff.

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 1, the field center manual (unless otherwise specified):

A. Informed Consent – Manual 1
B. Anthropometry – Manual 1
C. Seated Blood Pressure – Manual 1
D. Biospecimen Collection & Processing – Manual 2
E. Physical Activity Monitoring – Manual 1
F. Data Management –Manual 5
G. Interviewing techniques – Manual 1
H. Diet and Supplements – Manual 3

Additional specialized trainings and certifications are held for technicians/examiners responsible for sampling and recruitment (Manual 1).

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 1 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

A portion of the clinic visit will be repeated on 120 volunteers to determine reliability of measurement procedures. The following interviews will be re-administered:

- Acculturative Stress (ASE) – administer to child only
- ARSMA (BAE) – administer to child only
- Ethnic Affirmation and Belonging (EAE) – administer to child only
- Familism (FAE) - – administer to parent
- Social Support (SSE) – administer to child
- Family Relationships –closeness/monitoring (RCE) – administer to child
- AHISMA (UNE) – administer to child

Each site will recruit 30 volunteers at a uniform rate over the study period to participate in the Repeatability Study. Given that the measurement period will last 21 months, and the repeatability study will start approximately 6-8 months after study clinic start-up, two volunteers per center per week 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 repeat visit ID numbers for data collected as part of the Repeatability Study. The repeat visit 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 repeat visit ID to the original SOL Youth 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 SOL Youth child participant ID label, the 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 repeat visit ID.

3) The repeat clinic visit should be done no sooner than 1 week, and no later than 3 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 analyzed 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 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 SOL Youth child's 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 child participant contributes replicate data, his/her SOL Youth 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 SOL Youth 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 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
2) Repeated measures
    a. Anthropometry
    b. Biospecimens
3) Protocol Compliance
    a. Fasting time
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 standing height, hip and waist circumferences. 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. Let k be the number of possible final digits, so k = 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 cut point used in the HCHS/SOL 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) $N \geq$ 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 light clothing but no shoes (thin socks or pillow slippers are OK). The participants are asked to empty their pockets and remove their belt, jacket, heavy sweater, watches and jewelry or accessories (e.g. hair piece) that could affect weight measurement. The measurements include standing height, body weight, and abdominal and hip 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 3 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 2 of the 3 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 3 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 child 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 Anthropometry 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 SOL Youth 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. FITNESS STEP TEST

The Steck Autobody 20350 Pro Step Heavy Duty Adjustable Work Platform is used to estimating aerobic fitness or maximal oxygen uptake (VO2max). The technician explains the procedure to the participant, checks for medication or safety checklist issues, measures standing height (or obtains the measurement from the anthropometry form (ANT)), adjusts the height of the bench, measures the resting heart rate, has the participant conduct the 3 minute step test, and then records the port-exercise and discharge heart rates. Important elements in quality assurance are training and certification programs, observation of data collection by the study coordinator, quarterly simultaneous step test 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 heart rates from the procedure to look for any irregularities.

8.1. Training and Certification

Step test 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 fitness step test requires the trainer to observe the trainee performing the procedure on 3 volunteers to look for adherence to protocol procedures. Results are summarized onto the **Checklist for Observation of Fitness Step Test** (Appendix 5).

8.2. Observation of Measurement

Quarterly, the study coordinator observes each technician responsible for conducting the fitness step test using the checklist given in Appendix 5.

8.3. Maintenance of Equipment

The step bench construction will need to be checked daily to ensure no components of the bench have been damaged. The metronome will need to be checked for calibration issues monthly as follows:

Equipment needed: Metronome and stopwatch.

1) Set the metronome at 88 counts per minute
2) Turn on metronome.
3) Start the stop watch on one “click”.
4) Count the number of “clicks” for 30 seconds. There should be 44 clicks.
5) If the count is accurate (±1 click) then the metronome is calibrated.
6) If the count beyond acceptable limits:

    A. If lower than 43, set the metronome to the next greater count and redo the 30 second test. Repeat if necessary until the correct count is obtained.
    B. If greater than 45, set the metronome to the next lower count and redo the 30 second test. Repeat if necessary until the correct count is obtained.

When the correct count is obtained then that should be the correct setting. Note on metronome for future use.

9. TANNER STAGING

Children go through many biological changes during puberty. Some of these changes include maturation of their bodies. We would like to determine the stage of maturation of SOL Youth participants. In order to accurately assess the stage of maturation, 80 participants will briefly be visually examined. This examination will be similar to how a doctor periodically assesses a child, except this assessment will only be visual and there will be no touching involved. For girls, we will view their breasts and genitalia and for boys we will only view their genitalia. This visual inspection will take less than 1-2 minutes. Parents may stay in the room with the child during this part of the visual examination.

Because the onset and progression of puberty are so variable, Tanner has proposed a scale, which is now uniformly accepted, to describe the onset and progression of pubertal changes (see Manual 1, Section 15: Appendix 3 for females, 4 for males). Boys and girls are rated on a 5 point scale. Boys are rated for genital development and pubic hair growth, and girls are rated for breast development and pubic hair growth.

9.1. Training and Certification

Technicians are trained and certified at local field centers by a certified technician prior to participation in the Tanner staging assessment. 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.

Each examiner will assess five standardized photographs for breast and pubic hair development using a practice sheet. The practice sheet includes their name, date, site, email and marked for certification.

Instructions for the examiners:

1. Open the envelope and list the breast photographs in numerical order in the left column, and the pubic hair photographs on the right-hand column.

2. Make your assessment of each photo using B for breast stage and PH for pubic hair. Stage 2 of breast development would be marked B2. Stage 4 of pubic hair development would be marked PH4. The sheet that lists and describes the maturity stages for breast and pubic hair development may be used as a reference for this certification.

3. Fax the certification sheets to Virginia Bishop at 773-269-2663 to be graded.

4. To be certified, examiners must agree with the exact stages assigned by Dr. Bishop for at least four out of five for each set and be no more than 1 stage off for the fifth.

5. Examiners, Principal Investigators and the coordinating Center will be notified of who is certified for the sexual maturity ratings.

6. Examiners who have not been initially certified can participate in a follow-up and review call (date to be determined).

7. After every examiner at each site is certified, the correct stages for all certification photographs will be available for reference and practice.

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 3 and 4). 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 SOL Youth 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 SOL Youth 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, and packed cells 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 SOL Youth Laboratory & Biospecimens Manual 2). 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. Replicate Blood Specimens

As part of the overall quality control program for laboratory determinations from blood samples, duplicate specimens are sent to the laboratory, with one half of each specimen pair sent under the participant's regular HCHS-SOL-Youth laboratory ID number, and the other half under a Quality Control Phantom Participant (QC) laboratory ID number. The QC laboratory ID numbers are not distinguishable from other laboratory ID numbers so that this forms a blinded external quality control program monitoring measurement variability.

To reduce the burden on any single participant, extra blood is drawn from three participants and sent out under the same QC ID number. For data analysis, results on each laboratory measurement are matched to the appropriate participant results at the Coordinating Center from the QC Phantom ID Form (Appendix 6) that is completed by Field Center technicians.

If extra QC blood is drawn for a tube that is processed for weekly shipment (Tubes #1, 2, 3, 4, and 5), the aliquots are stored at the Field Center for extra week/weeks until the entire QC set is complete and then the complete QC set is sent to the Central Laboratory with a regular shipment. **Two complete QC sample sets per month** should be sent to the Central Lab for the **first six months** of the study and then for the remaining months of the study only **one complete QC sample set per month** should be sent to the Central Lab.

The QC blood samples are collected in sequential order (cycling back to Tube #1 after QC Tube #5 has been collected). Over the entire study, each Field Center will collect QC samples from approximately 7% of all specimens (n=28). Three participants will be needed to provide three QC replicate specimens to form one phantom ID. Thus, one-fifth of participants (n=84=3x28) per field center will contribute to the pool of replicate specimens. Two QC sample sets should be sent to the Central Lab monthly for the first 6 months of the study. One QC sample set should be sent to the Central Lab monthly for the remaining months of the study. Choose older children with a larger body weight as QC sample candidates.

See the **Biospecimen Collection and Processing Manual** (Manual 2) 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 SOL Youth 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 SOL Youth 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 SOL Youth 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 3 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 SOL Youth periodically to determine which participants could be invited for re-measuring.

13. 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.

13.1. 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.

13.2. 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).

13.3. Recording of Interview

For a one week period every month, interview-administered questionnaire components will be audio recorded with a handheld digital recorder and recordings tracked on an inventory list. Prior to recording, participants should be reminded that interviews are used for quality control purposes and the information on the audiotape would be kept confidential and destroyed after review. *(Interview components <u>not to be recorded</u> are: the 24-h dietary recall.)*

Each digital recording for a single participant visit should contain recordings for interview components**.** Recordings will be labeled and organized by staff-ID, participant-ID, date and content. If the same staff member is administering multiple questionnaires consecutively to the same participant, he/she does not need to make a separate recording for each questionnaire, but can make one continuous recording.
The label/name of the recorded file(s) should look like:

111_ X1234567_ 8-20-10 _general interview
Staff ID *Part-ID* *Date* *component*

One recorded participant interview file 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: Quarterly, the CC will randomly select three participant interview recordings from each field center for review using the observation checklist. These reviews will be documented on the Quarterly 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 to the QC Committee 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.

The CC will run periodic reports to see if there are staff who have not been part of the monthly recording and quarterly reviews. In this case, the CC and the Field Center will work together in order to insure that all staff are recorded during the next quarterly review.

Table 13.3.1 -Schedule for exchange of audio tapes between field centers:

Exchange	Originating Field Center	Reviewing Field Center
#1	Chicago	Bronx
	Bronx	Chicago
	Miami	San Diego
	San Diego	Miami
#2	Chicago	Miami
	Bronx	San Diego
	Miami	Chicago
	San Diego	Bronx
#3	Chicago	San Diego
	Bronx	Miami
	Miami	Bronx
	San Diego	Chicago
#4	Chicago	San Diego
	Bronx	Chicago
	Miami	Bronx
	San Diego	Miami

13.4. 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.

13.5. Analysis of CDART Data Entry from Forms Administered on Paper

Study data collected on paper first and subsequently entered into the CDART data management system will be analyzed periodically to access proper keying of collected data. There are two main instances where this quality control check must occur:

a. Examinations at the start of the study where ALL exam forms (questionnaires, procedures, administrative, recruitment) were collected on paper and later entered into the CDART system.
b. Exam forms that are continually collected on paper throughout the SOL Youth Study even after the CDART system is fully operational:

    - Self-administered questionnaires to children (CDE, MAE, PDE, TUE, AUE, LSE, TSF/TSM)
    - Other SOL Youth forms collected on paper based on field center-specific clinic operations (ex. Clinic Exam Checklist forms (CKC and CKP), procedure forms, etc.)

The step-by-step procedure for the CDART data entry QC will be as follows:

1. CC to select a random sample of 10% of IDs for the QC of data entry based on a cutoff date of clinic visits.
2. FCs will compare the paper forms to the online data for those selected IDs.
3. Focus will not be on 100% of the forms for those IDs, but on key variables from selected key forms which will be outlined in the selection process and communicated to the FCs as the study progresses to allow for adjustments based on QCC findings.
4. Tolerance of 0.5 % or less, by data entry operator (staff ID); if above, must re-train and re-enter all forms of that data entry operator.

14. DIET AND SUPPLEMENTS

14.1. 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 SOL Youth 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 7). 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.

14.2. 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 SOL Youth 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 SOL Youth Field Center Checklist (Appendix 7) is used to document dietary and supplement data collection procedures.

14.3. 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.

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.

15. MEDICATION TRANSCRIPTION

15.1. 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 10 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	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
Biospecimen collection	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
Tanner Staging	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____

	Technician ID	Supervisor ID	Date (mm/dd/yy)
Fitness Step Test	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____

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			
(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	_____	_____
Fitness Step Test			
(1) Step bench construction	Daily	_____	_____
(2) Metronome calibration	Monthly	_____	_____

Comments: _____

_____

_____

_____

Appendix 2. Checklist for Observation of General Interviewing Techniques

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

Interviews Observed (Check all that apply)

To Children Only			**To Parent Only**		
After School Environment - Child	AEE	☐	Barriers to Activity in Neighborhood - Parent	BNE	☐
Away from Home Foods - Child	AFE	☐	Demographics - Parent	DPE	☐
Alcohol Susceptibility - Child	AUE	☐	Demographics - Partner/Spouse - Parent	DSE	☐
Body Image - Child	BIE	☐	Equipment Checklist in Home - Parent	ECE	☐
Child Depression Inventory - Child	CDE	☐	Familism - Parent	FAE	☐
Demographics - Child	DCE	☐	Foods in the Home - Parent	FHE	☐
Eating Disorders - Child	EDE	☐	Family Meals - Parent	FME	☐
Dietary/PA Family Support - Child	FSE	☐	Food and Neighborhood Environment - Parent	FNE	☐
How I Feel (Lie) Scale - Child	LSE	☐	Food Security - Parent	FOE	☐
MASC-10 - Child	MAE	☐	Health Insurance - Parent	HPE	☐
Physical Activity - Child	PAE	☐	Neighborhood SES - Parent	NSE	☐
Parenting for Eating and PA - Child	PCE	☐	Parenting for Eating and PA - Parent	PPE	☐
Family Relationship - Child	RCE	☐	SES - Parent	SPE	☐
Social Attitudes Towards Weight - Child	SAE	☐	**To Parent About Each Child**		☐
School Food Environment - Child	SFE	☐	Authoritative Parenting Index - Parent (each child)	APE	☐
Sleep Duration - Child	SLE	☐	Health Insurance - Parent (each child)	HCE	☐
Social Support - Child	SSE	☐	Medical History - Parent (each child)	MHE	☐
Tobacco Susceptibility - Child	TUE	☐	Medication Use - Parent (each child)	MUE	☐
Food Practices with TV/Video viewing - Child	TVE	☐	Pre-Migration of Child- Parent (each child)	PME	☐
AHISMA Scale - Child	UNE	☐	Family Relationship - Parent (each child)	RPE	☐
Workout Equipment in Home - Child	WEE	☐	School Type - Parent (each child)	STE	☐
To Both Parent and Child			**Procedures/Exams**	**Code**	
Acculturative Stress - Both	ASE	☐	Safety Check for Fitness Step Test	SST	☐
ARSMA Scale - Both	BAE	☐	Tanner Staging - Female - Child	TSF	☐
Ethnic Affirmation and Belonging - Both	EAE	☐	Tanner Staging - Male - Child	TSM	☐
Family Function - Both	FFE	☐	Pubertal Assessment - Child	PDE	☐

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 light clothes or scrub suit.	_____	_____	_____
5. Participant has removed shoes.	_____	_____	_____
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. Subject takes a normal breath, holding breath in a relaxed manner, and then gently exhales,	_____	_____	_____
5. Measurement is taken with triangle or measuring block.	_____	_____	_____
6. Data recorded accurately in cm	_____	_____	_____
Technician's measurement of participant height:	_____ cm	_____ cm	_____ cm
Supervisor's measurement of participant height:	_____ cm	_____ cm	_____ cm
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	_____ cm	_____ cm
Supervisor's measurement of participant waist:	_____ cm	_____ cm	_____ cm

Hip 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 hip using maximal posterior protrusion of the gluteal muscles (buttocks) as landmark.	_____	_____	_____
4. 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.]	_____	_____	_____
5. Reading is recorded to the nearest centimeter, rounding down.	_____	_____	_____
Technician's measurement of participant hip:	_____ cm	_____ cm	_____ cm
Supervisor's measurement of participant hip:	_____ cm	_____ cm	_____ 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

Comments: _____

_____

_____

_____

Appendix 4. Checklist for Observation of Blood Pressure 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. Position arm at heart level, legs uncrossed with both feet flat on the floor/step stool	_____	_____	_____
16. Pushes START button	_____	_____	_____
17. Records average, 1st, 2nd, 3rd systolic and diastolic BP readings and average heart rate	_____	_____	_____
18. Instructions to participant are clear	_____	_____	_____
19. Holds arm vertically for 5 seconds between readings	_____	_____	_____

Comments: _____

_____

_____

Appendix 5. Checklist for Observation of Fitness Step Test Measurement

Instructions: *This checklist documents observation of fitness step test measurement 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: ___/___/___

Fitness Measurement	Yes	No	Comments
1. Checks to be sure step-bench construction is sturdy	___	___	_____
2. Checks to be sure wood platform is immediately available	___	___	_____
3. Checks to be sure chair, metronome & stopwatch is immediately available	___	___	_____
4. Checks to be sure data form is available	___	___	_____
5. Asks the child's pre-testing screening questions	___	___	_____
6. Explains step-test procedures to child	___	___	_____
7. Measures the child's height (if needed) and sets correct bench height	___	___	_____
8. Identifies the child's pulse (radial or carotid)	___	___	_____
9. Set the proper metronome cadence (88 bts/min)	___	___	_____
10. Allows the child time to practice	___	___	_____
11. Allows child to recover before administering step-test Heart rate ≤ 100 bts/min	___	___	_____
12. Verbally assist the child in keeping proper cadence during test	___	___	_____
13. Provide verbal encouragement and monitoring during test	___	___	_____
14. At the end of the test, quickly seats child and finds pulse	___	___	_____
15. Counts pulse for 15 seconds and records on data form	___	___	_____
16. Monitors child until heart rate below 100 bts/minute	___	___	_____

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. Vials sealed	___	_____
8. V-Form completed	___	_____
19. Freezer organization	___	_____
10. Time constraints	___	_____
11. Disposal of contaminated supplies	___	_____
12. 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 Sa Su

Headboard of the stadiometer moves up and down the track smoothly

___ ___ ___ ___ ___ ___ ___
M T W Th F Sa Su

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

Month of:_____ Tech ID:_____

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: ____/____/____

Quarterly Checks

Quarter (circle one):Q1/Q2/Q3/Q4 Year: ____ Tech ID:_____

A. Submit Summary of Observation and Equipment Checklists to CSCC Yes Y No N

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 Certification

PRACTICAL EXAM FOR SOL YOUTH BLOOD DRAWING TECHNICIAN

1. Place the following blood collection tubes in the correct set-up order and location for the venipuncture: 2-5 mL red top, 1-4.5 mL blue top, and 2-5 mL lavendar top tubes.

2. Specify which tube(s) remain at room temperature after collection, and which are put into a cup with ice slush.

3. Remove the appropriate tubes from the tray and place them in the centrifuge in balanced positions. How long do they spin? At what speed?

4. Set up a sponge tray with the appropriate number and order of specimen storage tubes. Indicate the colors of screw caps and the types of specimen put into 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.

WRITTEN EXAM FOR SOL YOUTH BIOSPECIMEN COLLECTION AND PROCESSING TECHNICIAN

Name: (please print) _____ Field Center: _____

DATE: _____

1. When handling biological specimens, which of the following protective apparel must **ALWAYS** be worn?
   a) gloves
   b) sterile shoe covers
   c) sterile head covers
   d) lab coat and gloves

2. For the first six months of the study, how many HCHS-Youth participants at each field center will be asked to donate additional blood specimens collected to be used as part of the phantom duplicate?
   a) Six per month
   b) Six per week
   c) Everyone
   d) Eight per week

3. From which tubes are the packed cells used?
   a) #1 and #2
   b) #4 and #5
   c) #3
   d) none of the above

4. How long should tubes #1and #2 sit at room temperature before centrifugation?
   a) 5 minutes
   b) 30 minutes
   c) 2 hours
   d) No waiting time required

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

6. For what type of tests will the 4.5-mL blue-stoppered tubes be used?
   a) Chemistry
   b) Lipid
   c) Coagulation
   d) DNA testing

7. Which of the following labels must be affixed to the outside of a frozen shipping box?
   a) biohazardous specimens
   b) dry ice
   c) Category B UN3373
   d) dry ice and Category B UN3373

8. What is the minimum amount of dry ice that must be used for frozen shipments?
   a) 2 lbs
   b) 5 lbs
   c) 10 lbs
   d) 12 lbs

9. When transferring plasma to the microvials, how much plasma is left above the cells in the tubes?
   a) ¼ - ½ inch
   b) ½ - ¾ inch
   c) ¾ - 1 inch
   d) none, all the plasma is removed

10. In what manner is the buffy coat from tubes #4 and #5 initially pipetted?
   a) Using slow aspiration avoiding plasma and red cells.
   b) Using slow aspiration and include the remaining plasma and some red cells.
   c) Using quick aspiration avoiding plasma and red cells.
   d) Using quick aspiration and include the remaining plasma and some red cells.

11. What paperwork is completed and sent with each weekly frozen shipment?
   a) Copy of the Biospecimen Collection form
   b) Original of the Biospecimen Collection form
   c) Shipping Form Contents Sheet(s)
   d) Original Shipping Form Face Sheet, Original Contents Sheet(s), and Original of all Biospecimen Collection forms

12. The LMX4 anesthetic cream needs to be applied 30-45 minutes prior to the blood collection to adequately numb the skin?
   a) True
   b) False

13. The inner Styrofoam shipper needs to be taped shut?
   a) True
   b) False

14. During the phlebotomy procedure it is important to always maintain a soft, quiet voice with the child?
   a) True
   b) False

15. What choice below includes positive reinforcement techniques for a “happy child” following the phlebotomy procedure?
   a) Use general positives such as “good girl” or “good boy”
   b) Positive reinforcement is not needed after the phlebotomy procedure
   c) Say specific positive things that the child did; holding still, being brave
   d) None of the above

Appendix 11. SOL Youth 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 Franklyn Gonzalez II at the Coordinating Center (CC) to receive a code number once a staff member is certified. A new form is submitted to the CC for additional procedures/interviews a staff member is trained and certified on after the original submission.*

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

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

3. Assigned staff code number by Coordinating Center ☐☐☐ (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)*
A. Anthropometry		
B. Sitting BP		
C. Fitness Step Test		
D. Data Management		
E. Biospecimen collection, processing		
F. Physical Activity		
G. General Interviewing Techniques		
H. Medication and Supplements		
I. Recruitment		

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

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

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)
_______	_______	_______
_______	_______	_______
_______	_______	_______
_______	_______	_______
_______	_______	_______
_______	_______	_______
_______	_______	_______
_______	_______	_______
_______	_______	_______
_______	_______	_______
_______	_______	_______
_______	_______	_______
_______	_______	_______
_______	_______	_______
_______	_______	_______
_______	_______	_______
_______	_______	_______
_______	_______	_______
_______	_______	_______
_______	_______	_______
_______	_______	_______
_______	_______	_______
_______	_______	_______
_______	_______	_______
_______	_______	_______
_______	_______	_______
_______	_______	_______
_______	_______	_______
_______	_______	_______

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** Construction of step bench checked (Appendix 5) –**7.3** Temperature check in refrigerators, freezers, etc. (Appendix 9) **– 10.3**
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) **– 14.3** Calibration of metronome (Appendix 5) –**7.3**
Bimonthly	Each dietary interviewer will interview the same person from Nutrition Reading Center (Appendix 14) **– 14.3** Coordinator selects two audiotapes per interviewer to be mailed to another center (Appendix 14) **– 13.3**
Quarterly	Anthropometry technicians observed (Appendix 3), recorded (Appendix 1) **– 6.3** Anthropometry equipment checks summarized, info sent to CC (Appendix 1) **– 6.4** 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** Supervisor observes interviewer twice (Appendix 2), recorded (Appendix 1) **– 13.2** Supervisor observes dietary interview (Appendix 7), recorded (Appendix 1) **– 14.2**
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 **– 14.3**