Jackson Heart Study Protocol

Manual 5

Quality Control

Visit 2

Version 2

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FOREWORD

This manual is one of a series of protocols and manuals of operation for the Jackson Heart Study (JHS). The complexity of the JHS requires that a sizeable number of procedures be described, thus this rather extensive list of materials has been organized into the set of manuals listed below. Manual 1 provides the background, organization, and general objectives of the JHS Study. Manuals 2, 3, and 4 describe the operation of the Cohort Procedures, Blood Pressure and Events Ascertainment Components of the study. Manual 5 comprises the JHS activities to ensure quality assurance and quality control. Quality control includes activities that are designed to assure quality of data, which take place prior to the collection of data. Quality control relates to efforts during this study to monitor the quality of data. Detailed Manuals of operation for specific procedures, including those for Blood Pressure and Quality Control, make up Manual 4 and 5. The Data Management System is described in Manual 6.

JHS Study Protocols and Manuals of Operation

MANUAL	TITLE
1	General Description and Study Management
2	Cohort Component Procedures
3	Blood Pressure
4	Morbidity and Mortality
5	Quality Control
6	Data Management

Manual 5. Quality Control

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1.0 Introduction

The distinction between quality assurance and quality control is both arbitrary and philosophical. Quality assurance includes activities that are designed to assure quality of data, which take place prior to collection of data. Quality control, on the other hand, relates more to efforts during the study to monitor the quality of data at identified points in the collection and processing of data. This manual focuses primarily on quality control, 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 JHS Manuals of Operation.

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

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

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

1) Observation monitoring. Over-the-shoulder observations of staff by supervisors or those who wrote the protocols identify techniques that need improvement and points where the protocol is not understood. Also, periodic monitoring visits are made to the EC by CC staff to observe actual clinic activities. Detailed checklists are used to assess strict adherence to protocol as articulated in the Manuals of Operation (MOO). Immediate feedback is given, and general recommendations for improvements are sent to the Statistics and Quality Assurance Subcommittee (SQA) for review and corrective action. The recommended corrective action by the SQA will be sent to the Steering Committee for action or for information purposes. Another form of observation in the JHS study takes place with the interview portion of the protocol. The CC/EC Clinic Liaison (Clinic Liaison) reviews the tapes on a random basis, reviewing at least one of each type per month. The Director of Retention/Annual Follow Up reviews individual interviewer performance regularly using a remote listening device that allows her/him to randomly select an interviewer. At least one interview is monitored each quarter. The Coordinating Center conducts regular quality assurance of data from AFU interviews by interviewer code, providing output to the interviewer. In conjunction with the Data Manager, any data discrepancies are addressed. Discrepancies in excess of 5% require review of protocol elements and reanalysis within 6 weeks to assure correction of identified issues.

2) Quantitative monitoring. Random repeated measurement by the same and by different technicians are used as quality control tools. There are two important benefits from random repeat measurements. First, randomly re-doing a fraction of an individual's work is likely to

stimulate a better overall quality of data. Second, the duplicate determinations provide measurements of data quality. At the time of reporting the results of the study, it is important to establish that the "error" in the data is not so large as to threaten the validity of conclusions. Actual study data are useful to monitor quality of performance. Mean and standard deviations of study variables, by technician, are monitored for differences among technicians or trends over time, such as digit preference in body composition or blood pressure measurement is monitored with study data.

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

4) Action on results. With conscientious and trained staff, quality control reports provide an opportunity to praise a job well done. On the other hand, a poor performance is the basis for some remedial action. Depending upon past performance, the amount of error, and, taking due account of personal circumstances, the appropriate action may be a simple discussion to encourage a better performance. However, for continued poor quality data collection, staff will be removed from further data collection until re-certification is achieved.

1.1 Monitoring of Data Quality and Implementing Corrective Action

The subsequent sections of this manual describe the procedures and reports used to monitor quality control of the JHS. These reports are designed to be clearly understandable, to be distributed to individuals responsible for reading them carefully, and to lead to corrective actions. The JHS Statistics and Quality Assurance subcommittee (SQA) is the designated committee to coordinate and direct the quality control activities. The SQA is charged with the responsibility to review all reports with specific attention given to deviation from the protocols as articulated in the Manuals of Operation, recurrent problems and trends or shifts in data over time. The Quality Control (QC) Workgroup of the SQA may be charged to study and provide recommendations for specific QC needs of the study. The SQA prepares recommendations to the Steering Committee in matters of quality assurance, and contacts the Examination Center (EC) or laboratory as needed, to advise them of a problem and to discuss the mechanism for correction. Central logs of data and management quality problems are reviewed by the SQA as well.

The role of the JHS CC in quality assurance and control is described later in this manual. More specifically, as the repository for JHS Study data, the CC is responsible for preparation and dissemination of QC reports. These reports consist of tabulated data and summary statistics, and identify specific QA/QC problem. The JHS CC, through its CC/EC clinic liaison, maintains contact with the EC to confirm that it has been notified of a problem and that specific corrective action has been implemented. The CC maintains central logs of data quality problem and solutions. The CC conducts periodic EC monitoring during which CC staff participate in and observe a routine JHS clinic visit.

The distribution of the QC reports and the designation of persons or groups responsible for responding to the reports and implementing corrective action are described below. The EC is given the responsibility of reading, implementing corrective action, and responding to the report related to data collection by clinic staff. Monitoring reports for protocol deviations, recurrent problems, or temporal trends is the responsibility of the SQA. Any immediate QC problem identified by the CC (e.g., data entry problems) during daily or weekly data checks should be sent to the EC directly for correction with a record kept by the CC. Problems identified by periodic monitoring (say monthly or quarterly quality control analyses) are sent to the EC by the CC with concurrent monitoring by the SQA. The distribution of periodic reports described latter in this manual is as follows:

1) QC reports on technician-specific performance are sent quarterly to the EC Director/Co-PI and the appropriate unit Director (e.g. Retention, Clinic, Surveillance), and the SQA within a week of generating the report.

2) Summary QC reports without technician-specific data are sent to the Steering Committee by the CC through the SQA. The following centers and subcommittees have responsibility for responding to the reports as follows:
    a) EC Director/Co-PI, EC Data Manager. Review each QC and monitoring report with technician-specific quality; identify a solution to each problem; implement corrective action; report corrective action to the CC. ..
    b) SQA. Review each QC and monitoring report with attention to deviation from protocol as articulated in the MOO, recurrent technician or EC data collection problem and temporal trends; direct EC attention to problem and recommend additional corrective action if they persist; monitor the implementation of corrective action; contact and coordinate study investigators to review data quality problem and solutions; prepare summary reports and recommendations for the Steering Committee.
    c) Steering Committee. Review QC summary reports; monitor data quality trends; direct the QC in areas needing special attention; responsible for changes in protocol.

Table 1: Schedule of Quality Assurance and Control Activities

Procedure	Quality Assurance or Quality Control	Monitoring Methods	Responsible	Frequency	Written Report to CC & SSQC
AFU Interviews	QA QC	Weekly Monitoring – observation (5% of interviews)	Director of Retention	Monthly	Yes
Data:					
Data	QC (Data Entry)	Completeness & integrity of data	CC	Weekly	No
	QA (Transmittal)	Completeness & integrity of data	CC	Monthly	No
Cohort Procedure:					
Interviewer-administrated forms for re-certification	QA	Content analysis of taped interviews; and by observation.	Clinic Manager & CC/EC Liaison	Yearly	No
Clinic	QA (Procedures)	Observation – Completion of data collection instrument in Appendix IV	Clinic Manager	Weekly	No
	QC (Interviews)	Monitoring - Observation	Clinic Manager	Weekly	No
Protocol adherence & interviewing techniques	QA	Monitoring of examinations	CC	Quarterly Semi-annually	Yes
Measuring Tapes	QA: Equipment Validation	Checked for damage	Clinic Staff	Weekly	No
Scales	QA: Equipment Validation	Zero balanced/calibrated	Clinic Staff	Daily/ weekly	No
Sitting Blood Pressure	QA: **Equipment Maintenance**	Recording of all checks, problems and maintenance	Clinic Staff	Daily	No
	QC	Adjusted means of BP data	CC	Quarterly	Yes
		Re-certification of technicians		Semi-annually	

Procedure	Quality Assurance or Quality Control	Monitoring Methods	Responsible	Frequency	Written Report to CC & SSQC
Sphygmomanometers Tanita 300A Cholestech	QA **Equipment Maintenance**	➢ Random zero inspection ➢ Standardization of manometer	Clinic Staff	➢ Weekly ➢ Monthly	➢ No ➢ No
Medical data review	QA	Done in accordance to JHS Protocol	Clinic Manager	Quarterly	No
Referrals & results reporting	QA	Done in accordance to JHS Protocol	Clinic Manager	Quarterly	No
Exam Center Refrigerator / Freezer	QA Equipment Maintenance	Check Freezer Temp, refrigerator	Clinic Manager	Quarterly	Yes
Family /Cohort:					
• DNA & blood samples	QA	Check processing & storage procedures	CC/Reading Center	Monthly	No
• Genotype	QA	Check for maker-typing incompatibilities	CC/Genetics Consultants	Quarterly	Yes
Specimen Repository	QA Equipment Maintenance	Check Freezer Temp, refrigerator & centrifuge(s)	Reading Center	Quarterly	Yes

2.0 OPERATION OF QUALITY ASSURANCE AND QUALITY CONTROL ACTIVITIES

2.1 Quality Assurance Monitoring Process for Recruitment

There will be ongoing evaluation of Annual Follow-up Research Interviewers (AFU Interviewers) for assurances that the interview processis being followed as specified in the manuals of operations. For purposes of monitoring quality each Research Interviewer is observed by the Director of Retention.

In order to monitor 5% of the average number of annual follow-up interviews completed, two Research Interviewers per week will be randomly selected by the CC. Observations will be done by the Director of Retention to determine if the protocol as articulated in the MOO are being followed correctly. A checklist will be used to determine satisfactory performance (Appendix). Biannually, the CC/EC Liaison will conduct a random selection of AFU Interviewers on a rotating cycle to assess protocol adherence and interviewing techniques. Deviations from the protocol and possible remedial actions are discussed with the Director of Retention and the staff at that time. Major deviations are brought to the attention of the Retention and Events Monitoring subcommittees, the EC Co-PI and the SQA. Data quality is monitored by the SQA quarterly.

2.2 Interviews in the Baseline Exam Visit

With participant approval, most interviewer-administered forms are taped for quality control. A non-systematic sample of forms is reviewed monthly by the Clinic Manager and/or CC/EC Liaison. For purposes of monitoring quality each clinc staff is observed by the Clinic Manager. Adherences to the manuals of operations and interviewing techniques are reviewed at least biannually by CC/EC Liaison. Minor deviations from the manuals of operations are discussed with the Clinic Manager and staff at that time for possible remedial action. Major deviations, such as not following the QxQ to clarify questions of the participants, are brought to the attention of the JHS Clinic Operations Committee Data quality is monitored by the SQA quarterly.

The Exam Center Co-PI is responsible for ensuring that the medical data review, referrals and reporting of results are done according to procedures in the JHS manuals of operation by clinic manager (primary) or the research nurse (secondary). The CC/EC liaison will be responsible for checking to ensure that the EC Co-PI is monitoring the medical data review, referrals and reporting of results. The CC will perform Quarterly assesment to determine which participants have or have not received their clinic results. A written report will be submitted to the SQA. .

The Participant Evaluation of Clinic Visit (PEC) is considered an essential component of overall quality control for the JHS Exam 2. A PEC report is generated each month by the Data Manager and forwarded to the Clinic Operations Committee for monthly review and determination of any needed actions. Actions will be presented to clinic staff by the Clinic Manager at regular clinic staff meetings. In the event that there are implied data quality issues cited in the report, that aspect of data quality will be referred to the SQA for review.

2.3 Quality Assurance for Cohort Procedures

There will be ongoing evaluations of clinic staff to ensure that the manuals of operations are being followed in the clinic. For quality purposes the Clinic Manager will evaluate each staff per cohort procedure; performance of the staff in these evaluations will be used in the annual for re-certification of staff..

On a monthly basis, two clinic staff members are observed to determine quality assurance of the various clinic procedures. The staff person will be observed on two areas of clinic exam component to determine satisfactory performance. A rotating cycle of staff observation will be done monthly. The EC/CC liaison will monitor clinic operations using designated evaluation tools in Appendix III of this manual. Review of

tape interviews will be done biannually or on as needed basis and outcome of the evaluation will be utilization in the certification of technicians. Monthly, the EC/CC liaison will conduct QA checks on equipment maintenance logs for blood pressure, body composition and lipid and glucose testing. Weekly QA monitors involve overall operation of the clinic. Quality control observations of technicians by an observer are also performed biannually by Examination Center staff in January and July of each year and documented on the Report on Use of Observation and Equipment Checklist (See Appendix IV - Evaluation/Certification/Site Visit Checklist). These are sent to the JHS Coordinating Center for review. Deviations from the protocol are brought to the attention of the Cohort Operations Committee and the EC Director/Co-PI. Data quality is monitored by the SQA quarterly. Frequency distributions of consent preferences recorded on the Informed Consent Form (ICF) are monitored by the SQA on a semi-annual basis.

3.0 DESCRIPTION OF THE QC SYSTEM FOR REPEATED MEASUREMENTS

In several areas, repeated measurements during a clinic examination are taken for quality control purposes and are recorded on study forms separate from the participant's original forms. These forms are designated as belonging to phantom participants. The phantom participants are approximately 10% of assigned study IDs for finger stick. The 10% of the total sample of 5,302 participants translated to 530 participants. The sampling of these 530 participants is weighted heavily in the earlier phase of the Exam 2 clinic visits and reduced over time once sufficient data has been collected, analyzed and reviewed. Details of sample size and the methodology for carrying out repeated measures for all replicate procedures are given below. The EC with the assistance of the CC creates phantom participant folders when needed, and initializes a phantom participant diskette. As a safeguard against gathering unnecessary data on the phantom participant forms, only a subset of the usual study forms is included for QC repeated studies. The data collected on the phantom form is later keyed into ClinTrial. Repeat measurements are then entered, by the technician making the measurements, the phantom forms just as regular study data, as explained below, and the folders are processed as regular study data. There is one extra form in the QC phantom participant's folder, the JHS QC Phantom Participant and Non- Participant ID Form (PNP: Exam 2 Forms Manual), which is used to match the phantom ID to the IDs of the JHS participants contributing repeat measurements. This form is also used to record IDs used for data collected on persons who are not JHS study participants (e.g., monitors from the CC. This form is sent to the CC with a copy kept in the phantom participant's folder. Non JHS study participants might be new clinic staff members who might need to go through the study better understand clinic flow and the various clinic procedures as articulated in the manuals of operation. As a further backup, the QC phantom ID is entered on a form in the associated JHS participant's folder, as explained below.

The procedures for using the QC phantom participant folders are:

1) The study coordinator creates phantom folders, putting the QC phantom participant labels on the Phantom Participant Form, and the forms of the cohort procedures being repeated, and places these in the folders. When QC phantom participant IDs are assigned, the person making the assignment does the following on the Quality Control Phantom Participant and Non-Participant ID Form:
    a) Places the label for the ID assigned to the QC phantom in the space provided at the top of the form;
    b) Circles "1" for "A QC Phantom Participant" on the form;
    c) Fills in their own ID and the data the QC phantom ID was assigned in the spaces provided.
2) As JHS participants contribute replicate data, the matching JHS participant labels are affixed to the QC Phantom Participant Log for the data that are contributed.
3) After all needed repeat measures are recorded on the phantom's forms, the designated EC staff inserts the folder in the regular stream of participant folders as if the Exit Interview had just finished. It is processed as usual, except the QC Phantom Participant A designated EC staff will copy the log and place in the folder, with the original sent to the CC.

It is desirable to utilize each phantom participant ID for gathering all replicate QC entries in order to use fewer JHS IDs. Since different measurement groups in body composition may be sampled at different rates, the number of IDs needed to record all body composition repeats data groups will not be balanced.

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

1) The clinic manager assigns a JHS phantom ID to a given phantom .
2) As soon as the ID is assigned, a label for that ID is placed in the box marked "Phantom Participant ID Number" on the QC Phantom Participant and Non-Participant ID Form, and "N", for "An ID Used for a Non- Participant" is circled.
3) Also as soon as the ID is assigned, the person making the assignment records the date and their own ID number in the spaces provided.
4) Once the QC Phantom and Non-Participant ID Form is completed it will be photocopied. The copy is retained at the EC, and the original is sent to the JHS CC for data entry and filed.

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

1) Forms filled out to record the IDs used for non-participants in the JHS cohort study should be sent to the CC at the end of the same week in which they are collected.
2) For quality control phantoms, the folder for the phantom should go to the EC data manager for routine processing of any clinic procedure form filled out on a phantom.

3.1 Replicate Clinic Procedures

The purpose of the replicate studies is to ensure that the quality of data collected in the JHS is high and comparable across measures.

The following clinic procedures are being included for the replicate studies: Anthropometry and Sitting Blood Pressures. Participants will receive a Phantom ID for their repeated measure of any given test. The data collected in the replicate studies will be for sole purpose of QC analysis.

For each of the proposed replicate clinic procedures, the Study Plan will entail the following:

Task (Activities)
Target Sample (including sample size)
Selection and Assignment Study units

3.1.1 Study Plan – Body Composition and Sitting Blood Pressures

- **Task (Activities) –** The following measures listed under selected measures will be repeated on a random selection of JHS participants. Fifty percent of the replicate study participants will have their repeated measures conducted by the same technician and the other 50% by a randomly selected technician. The Clinic Manger (or designate) will be given random selection schemes. One scheme will assist the Clinic Manager (or designate) in identifying the randomly selected participant for a given clinic day and whether or not the second measurement will be done by the same technician or by a different technician. The second scheme will assist the Clinic Manager (or designate) to randomly select a second technician for repeated measurement.

- **Target Sample –** The sample size for these repeated measures was arrived using data from JHS participants who had clinic visit between September 2000 and September 2001. In addition to setting the significance level (α) at 5% and a power greater than 90%, it was assumed that the mean difference of these measures for each pair would not exceed 5%. For body composition measures the sample sizes ranged from 140 to 200 for each of the measures. The sample sizes for the sitting blood pressures ranged from 150 to 200. We will over sample to accommodate refusals and to gather enough data at the onset to ensure an adequate sample size to detect data problems and implement corrective actions early on.

- **Selection & Assignment Study units –** Study subjects will be pre-selected at random prior to their clinic visit. Suppose the goal is to select the 360 subjects over 36 months (144 weeks) after the start date then an average of 2.5 (≅ 3) subjects per week will need to be assigned for repeated measures. Hence if three JHS participants are randomly assigned to participate in repeated measures for any of selected body composition or blood pressure replicate measures, there will be a resultant sample size of 432. The over sample of 72 participants will address refusals and provide adequate sample size to detect data problems and implement corrective actions early on in the study.

Selected Measures –

Procedures	Measures (Variables)
Anthropometry	Height (BCFA8), Weight (BCFA 9), Girth-Waist (BCFA 5), Hip Girth (BCFA6) & Body Fat % (BCFA15)
Sitting Blood Pressure	Heart Rate (SBPB8), First Systolic BP (SBPB13), First Diastolic BP (SBPB14), First zero reading (SBPB15), Second Systolic BP (SBPB16), Second Diastolic BP (SBPB17) & Second zero reading (SBPB18).

3.1.2 Study Plan – Finger Stick

- **Task (Activities) –** The following measures listed under selected measures will be repeated on a random selection of JHS participants. The Clinic Manger (or designate) will be given random selection schemes. One scheme will assist the Clinic Manager (or designate) in identifying the randomly selected participant for a given clinic day and whether or not the second measurement will be done by the same technician or by a different technician. The second scheme will assist the Clinic Manager (or designate) to randomly select a second technician for repeated measurement.

- **Target Sample –**The total sample size for this study is 360.The goal is to compare the comparability of the test devices.

- **Selection & Assignment Study units –** Study subjects will be pre-selected at random prior to their clinic visit. Suppose the goal is to select the 360 subjects over 36 months (144 weeks) after the start date then an average of 2.5 (≅ 3) subjects per week will need to be assigned for repeated measures. Hence if three JHS participants are randomly assigned to participate in repeated measures for additional blood draw, there will be a resultant sample size of 432. The over sample of 72 participants will address refusals and provide adequate sample size to detect data problems and implement corrective actions early on in the study.
-

Selected Measures –

Procedures	Measures (Variables)
Lipids	Total Cholesterol, LDL Cholesterol, HDL Cholesterol, Triglyceride
Glucose	Fasting or non-fasting glucose

3.1.3 Schematic of Repeated Measures per Week

This schematic is based on: a) a five-day clinic week, b) repeating measures on first three participants per each clinic day, and c) replicating on a total of 7 measures. The first three participants will be used for two reasons. The reasons are: 1) It is being assumed that the arrival of the participants at the clinic is random; and 2) Though the number of participants per day will fluctuate, the minimum per day should not be less than three. The measures are numbered in Tables 2 and 3 below. This schematic will be generated by the CC for the Clinic Manager every two months. This will help maintain the random assignment of repeated procedure to participants. The repeats of procedures 1 – 7 each contributed by an individual to makeup a phantom are collected on the same clinic visit of a participant.

Table 2: Assignment of Repeated Procedure to Participants per Week

Day of Clinic Visit	Combination of Repeated Measure & Participant (M, P)		
1	(6, 3)	(5,2)	(4, 1)
2	(3,3)	(1,2)	(2,1)
3	(5,1)	(7,3)	(1,2)
4	(7,2)	(5,3)	(2,1)
5	(6,1)	(4,2)	(3,3)

***Note**: M=denotes the number of the repeated measure; P=denotes the number of a participant in the order in which he/she arrives in the clinic(1 = 1st participant and 3 = 3rd participant).*

Table 3: Numbering and Description of Repeated Clinic Procedures

Procedure Number	Description
1	Height
2	Weight
3	Waist Girth
4	Hip Girth
5	Body Fat %
6	Heart Rate & 1st & 2nd Sitting BP
7	Finger Stick (lipid and glucose)

4.0 ANALYSIS OF STUDY DATA FOR QUALITY CONTROL PURPOSES

The methods to monitor the quality of the JHS data collection process include analyses of the study data itself. This section provides a summary and discussion of the analysis of the study data for quality control purposes. To monitor the data entry process, most variables in the JHS database are analyzed periodically, by the CC, in terms of:

1) Status of the variables for each participant record (no problem, skipped due to skip rule, problem with the entry).
2) Frequencies for categorical variables, or means, standard deviations and selected percentiles for continuous variables.
3) Frequency of digit preference analysis.
4) Quality control charts or plots.
5) Univariate and comparative analysis of current data and previous finger stick data on a monthly basis.

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

Summary statistics by technician by period of observation (quarterly) are generally not sufficient for quality control purposes, due to the large amount of explained variation in a small amount of data. For example, the means of weight measurements made by two technicians may differ simply because of age or sex differences between the two groups examined. In order to adjust for such known sources of variation, the CC periodically examines selected items of study data in terms of age- and sex-adjusted means by technicians.

In addition to looking at differences among technicians within the EC in a given reporting period, the CC also looks at trends in adjusted means and in variability after adjustment, over time. Relatively sudden shifts in the mean for a given technician or increases in measurement variability after adjustment may indicate that changes in measurement technique have occurred which should be examined. Certain measurements, which involve a degree of subjective judgment by technicians, such as blood pressure or body composition data, are commonly subject to digit preference. The CC periodically analyzes such data for digit preference, by technician. Technicians will be provided feedback on their performance of quality data collection.

Certain items of data (e.g. fasting time before blood drawing) give information on protocol adherence and the validity of data obtained from each participant. The CC periodically analyzes these data items; trends in this data will be assessed over time. The CC monitors on a monthly basis the frequency with which each technician performs specific procedures in participant exams, comparing this frequency with the minimum number of exam required to maintain proficiency.

The IDs of technicians for the various procedures will be crossed checked with the procedures that the Techs have been certified in. Violation of protocol will be communicated to the Director or Co-PI of the EC. This check is to ensure that only certified technicians for specific procedures are involved in the data collection for those procedures.

5.0 QUALITY CONTROL REPORTS FOR THE COHORT COMPONENT

A large number of reports are generated as part of quality assurance of JHS data. Thus, in order to spread out the workload and the distribution of the reports, a schedule for the Cohort Component reports has been developed. The schedule for the Cohort Components reports are subject to modification by the CC or by directives from the SQA.

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

The standard QC reports generated for the categories within the Cohort Component are outlined below.

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

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

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

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

4) Finger Stick
    a. Distribution of number of stick attempts, means and distribution of filling and processing time (every two monthly)
    b. Repeated measures (semi-annually)

For repeated measures technicians who consistently (2 consecutive analysis) have clinical and/or statistical significant difference in the repeated measures will receive written communication of the significant differences in the repeated measures of the specific measurements. If these differences

persist for a given technician then the SQA will recommend that the technician be subject to retraining of that (those) procedures.

6.0 SPECIAL STATISTICAL ANALYSES IN QUALITY CONTROL REPORTS

6.1 Monitoring for Digit Preference

Monitoring for digit preference for blood pressure and for body composition is done by the CC every quarter. Summary reports are sent to the SQA, and reports of individual technicians are sent to the EC. The actual technician specific frequencies of final digits recorded are not revealed to the EC, to prevent technicians from over compensation to avoid digits that they had preferred in previous reports. For blood pressure only final digits 0, 2, 4, 6, 8 are possible, while for anthropometry 0, 1, 2, 3, 4, 5, 6, 7, 8, 9 are all possible. 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 (where k is 5 and 10 for blood pressure and anthropometry, respectively). The statistic is calculated as:

$$\chi^2 = \frac{\sum_{i=1}^{k} (O_i - N/k)^2}{N/k}$$, where O_i is the observed frequency of the ith possible digit $N=\sum O_i$ (i=1,2, .., k).

For large N, this statistic is distributed approximately as a chi-square distribution with k-1 degree of freedom. Also, $\chi^2 = 0$ if the observed numbers for each possible digit is equal to N/k. For validity of this test $N \geq 25$ for blood pressure and $N \geq 50$ for anthropometry are required. A significance level of 0.05 ($p < 0.05$) 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, JHS has adopted the use of "digit preference score (DPS)" used in ARIC. This score, DPS, is expressed as follows:

$$DPS = 100\sqrt{\chi^2/(k-1)N}$$

This score can be shown to have values between 0 and 100 (It is 0 when all observed digit frequencies (O_i; i=1,2, .., k)are N/k and is 100 when all observed frequencies are all in one cell). Using the cut off point used by ARIC; a $DPS \geq 20$ is the threshold for marked digit preferences. 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 and 50 for anthropometry); (2) the p-value for χ^2 statistic is < 0.05; and (3) the digit preference score (DPS) is greater than or equal to 20. The Table below illustrates a technician specific report as is pertains to digit preference.

Table 4: Clinic Visit – Blood Pressure (BP) Digit Preference on Three BP Readings. Data Received at CC for << Date – Month & Year>>

Technician Code =

Measurement	N	Most Freq.	2nd	3rd	4th	Least Freq.	Probability*	Digit Preference Score (DPS)
Systolic BP								
Diastolic BP								
Random Zero								

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

If digit preference persists over a number of months, it is requested that the technician be re-trained. Digit preference monitoring is also used in determination of re-certification.

6.1.1 Replicate Data Analysis

Paired t-tests will be used to determine whether or not the difference between the repeated measures is significantly different from zero. If there is no significant difference (i.e. $p > 0.05$), it implies the net difference between the repeated measures is not statistically different.

Reliability Coefficient (R) is one of the quantities of interest in considering data quality. It is expressed as: $R = \sigma_b^2 / (\sigma_b^2 + \sigma_e^2)$ which is one minus the proportion of total variance due to lab variation. It can also be shown that R is the correlation coefficient between two laboratory measurements made on the same (split) sample. This coefficient, R may be estimated in two ways: (1) from the replicate data alone, using the technique of one-factor random effects ANOVA, divide the total variance in the replicate data into estimates of σ_b^2 and σ_e^2; (2) by combining the information from the replicates with the information from the total JHS study data set. From the sample variance of the study data, S_T^2, we may obtain good estimate σ_T^2. Then, σ_b^2 is estimated by $S_T^2 - \sigma_e^2$, so that the estimate of R is given by

$$R = 1 - (\sigma_e^2 / S_T^2)$$

R is useful for overall assessment of the reliability of the measurement method. For routine monitoring of the data collection process, the standard deviation σ_e is most closely watched. In monitoring laboratory data, σ_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 of the laboratory SD,, which are more than twice the target SD are considered cause for concern.

Coefficient of Variation (CV) is another index of reliability often used in epidemiologic studies. It is standard deviation (S.D.) expressed as a percentage of the mean value of two sets of paired observations. In an analysis of reliability data, it is calculated for each pair of observations and then averaged over all pairs of original and repeated measures. The lower the CV, the less variation there is between the replicate measurements. Obviously, if there are no differences whatsoever between paired values (perfect agreement), the CV value would be zero.

Outliers are extreme observations in a set of data points. Using the maximum normal residual (MNR), sometimes called the extreme studentized deviate (ESD) we will detect outliers. These values will be double checked with the EC to ensure that they are not due to data entry error or that they are not clinically plausible, thus they are true outliers.

Descriptive statistics will be generated to examine the distribution of the various means. These statistics will give us a clear sense of our data in very simplistic terms.

Control quality control charts will be used to assess the quality of the data. Using the SAS/QC procedures a number of these charts or plots will be constructed.

7.0 QUALITY CONTROL ANALYSES ON THE VARIOUS CLINIC PROCEDURES/MEASURES

7.1 Finger Stick and Equipment Records

- For equipment, daily records should be kept on all glucose and lipid testing machines.
- Daily logs of glucose and lipid equipment will be sent to the CC for review and analysis.
- The monthly Quality Control Checklists should be kept in a permanent file in the EC.

7.2 Sitting Blood Pressure

7.2.1 Quality Control

To ensure the accuracy of the blood pressure measurements throughout the study, quality control measures are developed at the CC and applied at the EC. These measures include:

1. Recruitment of the most qualified personnel
2. Standardized training and certification
3. Retraining and re-certification
4. Quarterly observation of data collection by supervisors, using the checklist given in Appendix. One checklist is used for each technician and a copy sent to the CC each quarter.
5. Frequent staff meetings to provide feedback
6. Editing of data, both manual and by computer
7. A quality assurance program administered by the CC
8. Quarterly simultaneous Y Tube observation of each technician by the Clinic Manager
9. Equipment maintenance program

7.2.2 Technician Training and Quality Control

Blood pressure technicians are trained by the certified trainer, Clinic Manager or their designee prior to start of Exam 2. New technicians hired after the start of the study are trained locally by the EC Co-PI or a designated "Blood Pressure Supervisor". Recertification occurs every six months. Prior to certification, each technician is required to have a clinical hearing test.

The CC directs a blood pressure quality assurance program to review six-monthly data. This includes quality analysis and review of blood pressure data, comparing means for each technician with the values for all technicians. These statistics are adjusted for weight, age and sex of the participants. Digit preference is also monitored for each technician.

7.2.3 Equipment Maintenance

The EC is responsible for the proper operation and maintenance of its equipment. Maintenance responsibility is assumed by the Clinic Manager and all staff are instructed to report any real or suspected equipment problems to that person promptly.

All checks, inspections, cleanings and problems indicated are documented and recorded by date in a permanent log. Problems and solutions are also recorded. A copy of this log is given in the Appendix. The EC will submit a copy of this log to the CC for its file and review.

Anthropometry equipment is calibrated frequently and results are recorded on an Anthropometry Equipment Calibration Log. Scales are zero balanced daily and calibrated weekly or when moved. Measuring tapes are checked monthly and replaced as needed. The number of above measurements are recorded on the Report Use of observation and Equipment Checklist and sent to the Coordinating enter biannually.

7.2.3.1 Random Zero and Standard Sphygmomanometers

The Random Zero manometer is inspected once a week and the standard manometer once a month. These inspections include a check of:

1. the zero level of the standard manometer
2. mercury leakage

3. manometer column for dirt or mercury oxide deposit
4. condition of all tubing and fittings.

The equipment is cleaned if inspection indicates it is needed, or at least once a year. Specific instructions for the random zero device are provided in Appendix 1 of Manual 3 (BP Manual), and for the standard manometer in Appendix 2. In addition, every two months the accuracy of the random zero instrument is checked using a standard manometer and an Y connection, as described in the Appendix 4 of Manual 3.

7.2.3.2 Omro n – Quality Assurance Activities

In summary the QA activities involves initial certification of the use of the equipment and comparing the reading of technicians in the replicate studies.

7.2.3.3 The Cholestech L·D·X System

The Cholestech L·D·X System requires no user calibration. The calibration information for running a test is encoded on the brown mag stripe on each cassette and is read each time a cassette is run. Since calibration differences between methods can play a role in the variation in results between methods, the National Cholesterol Education Program (NCEP) established the Lipid Standardized Panel (LSP) to look at improving the accuracy and precision of lipid methods. To make it easier for vendors, such as Cholestech, to standardize their methods, a national network of laboratories (The National Cholesterol Reference Method Laboratory Network) was set up with lipid methods standardized to the CDC (Centers for Disease Control and Prevention) reference methods for lipids. The Cholestech Total Cholesterol, HDL Cholesterol and Triglyceride methods on the test cassettes are standardized to the CDC through one of the network laboratories. The Glucose method is standardized to a hexokinase method at a reference laboratory.

The Cholestech Controls are run to assure that all parts of the Cholestech L·D·X System – the cassettes, the analyzer, the pipette and the operator – are functioning properly. Together the Optics Check Cassette and the controls give you assurance that your test results are accurate, precise and reliable.

The Optics Check Cassette checks the optical part of the Cholestech L·D·X Analyzer. It should be run each day you run patient samples and the results recorded on the Optics Check Log.

8.0 SPECIMEN REPOSITORY QA ACTIVITIES

8.1 Maintain Plasma Repository

The JHS Specimen Repository Center shall provide facilities and equipment to receive, store, aliquot, and distribute plasma from JHS participants. The facilities must provide aseptic and/or sterile conditions as appropriate (Biosafety Level 2 Containment). The specimens shall be maintained by the contractor in freezers at temperatures between -70 degrees and -80 degrees centigrade. Freezers shall be located in an air-conditioned facility with temperatures maintained between 20 degrees and 25 degrees centigrade (60 degrees to 77 degrees F) when freezers are in operation. The contractor shall supply uninterruptible power to accommodate the refrigerators/freezers and other equipment. Freezers shall be connected to a central alarm system monitored twenty-four hours per day. The JHS Specimen Repository Center shall provide an automated temperature monitoring system composed of individual temperature probes monitored 24 hours a day and controlled by a master computer, and a plan to ensure that necessary personnel are notified in the event of freezer malfunction. Emergency standby freezers shall be available in case of mechanical failure of any portion of storage space. In addition, alternative emergency freezer cooling systems such as a liquid nitrogen system or dry ice must be available. The contractor must have backup electric generators capable of operating all storage equipment for at least 48 hours in the event of utility company power failure. Backup generators must be tested monthly. Specimens will be split into two freezers that a physical located in different locations at the site of the center.

8.2 Preparing Aliquots from Selected Specimens

The JHS Specimen Repository Center shall provide laboratory facilities and personnel for dividing the serum or plasma samples into aliquots. All requests for samples are reviewed by the JHS Steering Committee. Once an original specimen is identified for distribution, it is thawed and divided into aliquots, one of which is sent to the investigator, and the remaining aliquots refrozen for later use. The handling of all biological specimens and Government-owned property under this contract shall be in accordance with all applicable local, state, and federal regulations. In addition, in order to provide safety controls for protection to the life and health of employees and other persons, the contractor shall consult, comply with, and include in all applicable subcontracts, the following standards, as appropriate: 1) Biosafety in Microbiological and Biomedical Laboratories, U.S. Department of Health and Human Services, Centers for Disease Control (CDC) and the NIH, DHHS Pub. No. (CDC) 93-8395. 2) Occupational Safety and Health Administration (OSHA), Publication 29 CFR Part 1910.1030, Occupational Exposure to Blood Borne Pathogens, Final Rule.

8.3 Prepare and Ship Panels of Aliquots or Specimens

The JHS SC reviews requests from investigators for JHS participant plasma specimens. When a request is approved, the JHS CC will provide the identification numbers of the specimens to be provided to the Investigator. Shipments will require preparation of the specimens, packing them in dry ice, packaging in insulated boxes, and express shipment (usually by air) to the investigator). The JHS Specimen Repository Center shall ship all vials C.O.D.; transportation and postage costs are to be paid by the recipients from point of carrier receipt. The JHS Specimen Repository Center shall verify receipt of the panel by the investigator both in writing and by phone. Packaging and shipment shall meet standards for biologically hazardous materials (see publication prepared by the International Air Transport Association (lATA), Dangerous Goods Regulations, 37th edition, 1996 or current edition). It is essential that shipments be coordinated by the JHS Specimen Repository Center so that personnel will be available to receive the arriving packages and transport shipment to the repository for storage at the required temperature.

APPENDICES

Appendix I: Quality Assurance Data Collection Instruments – Observation of Annual Follow-up Interviewers

Form 1: Interviewers Quality Assurance -- Phone Calls of Participants

QA Phone Calls ***Week:*** _____

AFU Interviewers	Participant	Phone #	Comments
207			Prepared Knowledgeable Professional behavior
208			Prepared Knowledgeable Professional behavior
209			Prepared Knowledgeable Professional behavior
262			Prepared Knowledgeable Professional behavior

Note: Research Interviewers' Codes are: 207, 208, 209, 210, 262.

Appendix II: JHS Quality Control Phantom Participant ID Form

- **See the JHS Forms Manual for Examination 2 for a copy.**

Appendix III: Evaluation Tools to monitor Clinic Operations by CC/EC Liaison.

Jackson Heart Study Annual Schedule of Staff Certification, Criteria

Technician ID No._____

Study Component	Certification Criteria	Date Completed	Comments
1. Exam Center Study Procedures/Protocol	Observation by EC Supervisor		
2. Technician Practices/ Performance	Evaluation by Reading Centers		
3. Medical History (MHX)	5 taped interviews by CC		
4. Respiratory Symptoms (RPA)	5 taped interviews by CC		
5. Stroke Symptoms (SSF)	5 taped interviews by CC		
6. Renal Disease History (RDX)	5 taped interviews by CC		
7. Health History Form (HHX)	5 taped interviews by CC		
8. Contact Form (CON)	5 taped interviews by CC		

Jackson Heart Study Exam Center Quality Control Weekly Checklist

Study Component	Quality Control Criteria	Date Completed	Comments
1. Body Composition	Review of Logs		
2. Finger Stick and Specimen Processing	Review Equipment Checklist Review Blood and Urine Sample Checklist		
3. Blood Pressure	Review Inventory of Equipment		
4. Informed Consent Forms	Check for Completion		
5. Replicate Studies	Review of the implementation of Replicate studies for compliance		

Appendix IV: Evaluation/Certification/Site Visit Checklist

JHS Data Management Certification / Site Visit Checklist

DATE: ☐ ☐ ☐
Mo Day Year

Manager Trainee Name/ID: ☐

Data Manager Name/ID: ☐

Purpose of Evaluation:

Certification ☐ Site Visit ☐

Please check the appropriate box if manager performance is satisfactory for each line item. Note comments or remedial action taken in 'Comments' section if performance was not satisfactory.

Preparation:

1. ☐ Enrolls participant in Clintrial DMS.
2. ☐ Enters participant contact information using the DMS form.
3. ☐ Enters appropriate DMS forms by direct data entry during participant clinic visit.
4. ☐ Enters clinic paper forms using appropriate DMS forms.
5. ☐ Performs weekly transmission to CC.

Comments: _____
_____
_____

Corrective action taken:_____
_____
_____
_____

Supervisor / Site Visitor Signature_____

JHS Interviewer-Administered Questionnaire Supervisor / Site Visit Checklist

DATE: ☐ ☐ ☐
Mo Day Year

Interviewer Name/ID: ☐

CC Clinic Liaison Name/ID: ☐

Interview/form reviewed (Taped Interviews of Two Questionnaires):

Health History	☐	**Medications**	☐	**Medical History**	☐
Renal Disease	☐	**Respiratory Symptoms**	☐	**Stroke Symptoms**	☐

Purpose of Evaluation:

Certification	☐	Supervisor QC Check	☐	Site Visit	☐

Using the scale key below, evaluate the interviewer's performance based on each of the following criteria. Write any comments in the space provided at the bottom of the page.

Key: N/A – Not applicable
1 – Unsatisfactory (failed to meet standards)
2 – Satisfactory (met standards)
3 – Excellent (distinguished consistently exceeded all standards)

Informed participants of procedures?	N/A	1	2	3
Spoke clearly and audibly?	N/A	1	2	3
Used reasonable voice expression?	N/A	1	2	3
Kept participant focused on the interview.	N/A	1	2	3
Used appropriate vocabulary.	N/A	1	2	3
Established rapport with participant.	N/A	1	2	3
General Overall Rating	N/A	1	2	3

Comments:_____
_____
_____
_____

Corrective action taken: _____
_____
_____
_____
_____

Evaluator Signature: _____
_____

JHS Self-Administered Questionnaire Supervisor / Site Visit Checklist

Date: ☐☐ ☐☐ ☐☐☐☐ (Mo / Day / Year)

Interviewer Name/ID: ☐

Supervisor Name/ID: ☐

Interview/form reviewed:

Informed Consent ☐

Purpose of Evaluation:

Certification: ☐ Supervisor QC Check: ☐ Site Visit: ☐

Using the scale key below, evaluate the interviewer's performance based on each of the following criteria. Write any comments in the space provided at the bottom of the page.

Key: N/A – Not applicable
1 – Unsatisfactory (failed to meet standards)
2 – Below expectation (did not meet some standards)
3 – At expectations (met standards)
4 – Above expectation (met all standards and in some cases exceeded them
5 – Outstanding (distinguished consistently exceeded all standards)

Answers participant's questions and concerns.	N/A	1	2	3	4	5
Speaks slowly and distinctly reading the script of the instructions to the participants at neutral (but expressive) and even pace.	N/A	1	2	3	4	5
Reads script of instructions as written.	N/A	1	2	3	4	5
Completes the editing process and reviews forms.	N/A	1	2	3	4	5
General Overall Rating	N/A	1	2	3	4	5

Comments: _____
_____
_____

Corrective action taken:_____
_____
_____
_____

Supervisor / Site Visitor Signature _____

JHS Anthropometric Certification / Supervisor / Site Visit Checklist

DATE: ☐ ☐ ☐
Mo Day Year

Technician Name/ID: ☐

Supervisor Name/ID: ☐

Measurements:

Weight ☐ **Height** ☐ **Waist** ☐

Purpose of Evaluation:

Certification ☐ Supervisor QC Check ☐ Site Visit ☐

Please check the appropriate box if the procedure was carried out correctly by technician Please note any comments or remedial action taken in 'Comments' section if the procedure was carried out correctly. Items are presented in the sequence of the examination procedure, but may require confirmation before or after examination.

Weight Measurements:

1. ☐ Thoroughly explains the procedure to the participant.
2. ☐ Scale is positioned at zero.
3. ☐ Participant is wearing light gown or scrubs, no shoes.
4. ☐ Participant's feet are both flat on the scale.
5. ☐ The measurement is recorded, rounding down to the nearest tenth of a kilogram (kg).

Height Measurements:

6. ☐ Thoroughly explains the procedure to participant.
7. ☐ Participant is standing erect with his/her back to the ruler with heals together.
8. ☐ Participant faces straight ahead
9. ☐ Examiner's eyes are level with the point of measurement.
10. ☐ Reads and records the measurement to the nearest cm.

Girth-Waist Measurements:

11. ☐ Thoroughly explains the procedure to participant.
12. ☐ Participant is standing erect and facing straight ahead, arms hanging loosely at sides and both feet flat on the floor and six inches apart.

13. ☐ The tape is applied at the level of the umbilicus, and participant is instructed to breathe quietly.
14. ☐ The tape is snug but not tight.
15. ☐ The recorder verifies through viewing in full length mirror, that the participant is standing erect and the tape is horizontal.
16. ☐ The measurement is recorded to the nearest cm.

Girth Hip Measurements:

17. ☐ Thoroughly explains the procedure to participant.
18. ☐ Participant is standing erect an facing straight ahead, arms hanging loosely at sides and both feet flat on the floor and six inches apart.
19. ☐ The tape is placed horizontally and level around the subject's gluteal muscles (hips) at the leve level of maximal protrusion of the gluteal muscles.
20. ☐ Observer verifies horizontal postion of tape both front and back of the subject or uses a mirror to check tape.
21 ☐ Tape is horizontal and snug, but not tight enough to compress tissue (Invert tape, if needed, to insure reading the edge of tape is snug to the skin for measurement.
22. ☐ The measurement is made at the participant's side.
23. ☐ Tape is read to the centimeter, rounding down.
24. ☐ The tape is applied at the level of the umbilicus, and participant is instructed to breathe quietly.
25 ☐ The tape is snug but not tight.
26. ☐ The recorder verifies through viewing in full length mirror, that the participant is standing erect and the tape is horizontal.
27. ☐ The measurement is recorded to the nearest cm.

Comments: _____
_____
_____
_____
_____

Corrective action taken: _____
_____
_____
_____
_____

Supervisor / Site Visitor Signature_____

JHS Sitting Blood Pressure Certification / Supervisor / Site Visit Checklist

DATE: ☐ ☐ ☐
Mo Day Year

Technician Name/ID: ☐

Supervisor Name/ID: ☐

Purpose of Evaluation:

Certification ☐ Supervisor QC Check ☐ Site Visit ☐

Please check the appropriate box if technician performance is satisfactory for each line item. Please note any comments or remedial action taken in 'Comments' section if performance was not satisfactory.

Throughout Exam:

1. ☐ Measures arm for correct cuff size.
2. ☐ Palpates brachial artery
3. ☐ Marks pulse point.
4. ☐ Wraps cuff center of bladder over brachial pulse.
5. ☐ Leaves Instructs on Posture.
6. ☐ Full five minutes for rest allowed.
7. ☐ Places Work station free of excessive noise Explanation.
8. ☐ Count radial pulse 30 seconds, record reading.
9. ☐ Finds Pulse obliteration point using standard manometer.
10. ☐ Calculates peak inflation, standard manometer.
11. ☐ Calculates peak inflation, R-Z.
12. ☐ If computer is down use the formula (pulse obliteration pressure + R-Z maximum zero number + 30 Explanation.
13. ☐ Connects R-Z tube to cuff.
14. ☐ Sure reservoir lever open (newer devices have no lever).
15. ☐ Opens bellows valve and waits full 3 seconds for mercury to settle.
16. ☐ Obtains Turns thumb wheel (down strokes only).
17. ☐ Places stethoscope in ears.
18. ☐ Inflates rapidly to R-Z peak.
19. ☐ Counts full 5 seconds with pressure steady.
20. ☐ Closes bellows knob.
21. ☐ Places bell on brachial pulse.
22. ☐ Deflates cuff 2 mmHg per second.
23. ☐ Deflates cuff after 2 absent sounds.
24. ☐ Records readings.
25. ☐ Disconnects tubes.
26. ☐ Reads zero value.
27. ☐ Subtracts zero value from each BP reading, if using paper form.
28. ☐ Instructs to hold arm vertical for full 5 seconds.
29. ☐ Waits at least 30 seconds before proceeding.
30. ☐ Repeats R-Z readings.
31. ☐ Informs participant of average readings.

Comments: _____
_____
_____
_____
_____
_____

Corrective action taken: _____
_____
_____
_____
_____
_____

Supervisor / Site Visitor Signature_____

JHS Finger Stick Certification / Supervisor / Site Visit Checklist

DATE: ☐ ☐ ☐
Mo **Day** **Year**

Technician Name/ID: ☐

Supervisor Name/ID: ☐

Purpose of Evaluation:

Certification ☐ Supervisor QC Check ☐ Site Visit ☐

Please check the appropriate box if technician performance is satisfactory for each line item. Please note any comments or remedial action taken in 'Comments' section if performance was not satisfactory.

Venipuncture:

1. ☐ Labels checked.
2. ☐ Finger Stick Form filled.
3. ☐ Finger Stick technique.

Handling of blood draw:

4. ☐ Needle disposal.
5. ☐ Universal precaution employed.

Comments: _____
_____
_____
_____
_____
_____

Corrective action taken:_____
_____
_____
_____

Supervisor / Site Visitor Signature_____