Jackson Heart Study Protocol

Manual 8

Quality Control

Visit 3

Version 1

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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 Central Laboratory and Specimen Repository Components of the study. Manuals 5 and comprise Electrocardiography and Magnetic Resonance Image studies, respectively. . Manual 7 comprises of Morbidity and Mortality Classifications. Manual 8 articulates the quality assurance and control activities of JHS Examination 3 components. 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 9.

JHS Study Protocols and Manuals of Operation

| MANUAL | TITLE |
|---|---|
| 1 | General Description and Study Management |
| 2 | Cohort Component Procedures |
| 3 | Blood Pressure |
| 4 | The Central Laboratory and Specimen Repository |
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**Manual 8 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 providing refresher training sessions every six months or as needed basis, which review the protocol and update personnel on any changes which have occurred.

3) Certification. Criteria to examine the adequacy of an individual's training have been established. Individuals meeting these criteria are qualified to execute a protocol or a segment of it. Certification and periodic re-certification indicate that an acceptable performance standard has been mastered or an adequate knowledge of material has been achieved. The Coordinating Center (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 field centers and by monitoring visits from the CC and various central agencies. 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 or not being followed. Also, periodic monitoring visits are made to the Examination Center (EC) by Coordinating Center (CC) staff to observe actual clinic activities. Detailed checklists are used to assess strict adherence to protocol. Immediate feedback is given, and general recommendations for improvements are sent to the Steering Committee for action.

2) Interview monitoring Another form of observation in the JHS study takes place with the interview portion of the protocol. A supervisor reviews the tapes on a random basis, reviewing at least one of each tape per month. The supervisor checks for adherence to protocol and for accuracy of recorded responses. The director of annual follow-up and surveillance conducts weekly over-the-shoulder observation of recruiters in the field. Two recruiters are randomly selected for each week. In addition to field observation of the annual follow-up interviewers, the director for annual follow-up and surveillance conducts weekly phone calls to a random subset of participants to obtain feedback on their recruitment experience. The subset of participants chosen is from the pool of participants interviewed by the recruiters who are not chosen for field observation that week. The data collection instruments for field observation and phone calls to participants are in Appendix II.

3) 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. Digit preference in anthropometry or blood pressure measurement is monitored with study data.

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

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

### 1.1 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 Committee (SQA) is the designated committee to coordinate and direct the quality control activities. THE SQA subcommittee comprises of representation from all three local partnering institutions (Jackson State University, Tougaloo College, and University of Mississippi Medical Center), and reading centers and laboratories. The SQA subcommittee meets every two months (January, March, May July, September, and November) of the year. Off schedule meeting are to be arranged to deal special needs or emergent issues that need immediate attention. The two workgroups (QC and Statistics) of the subcommittee serve as taskforces to the subcommittee and their meetings are recommended to be off-schedule meeting months of the subcommittee or on as needed basis. The SQA is charged with the responsibility to review all reports with specific attention given to deviation from protocol, recurrent problems and trends or shifts in data over time. The 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), reading centers, or laboratories as needed, to advise them of a problem and to discuss the mechanism for correction. Central logs of data and management quality problem are reviewed by the SQA.

- 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, consisting of tabulated data and summary statistics, identify specific QC problems. The JHS CC, via its CC-EC liaison, maintains contact with the EC to confirm that it has been notified of a problem and that 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. In response to requests from the SQA, the CC replicates pertinent sections of quality control reports prepared by reading centers/laboratories. Some external quality control programs for the reading centers/laboratories are administered by the CC and reported to the SQA. The reading centers/laboratories are to generate and disseminate to the CC QC reports on a quarterly basis.

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 and/or reading centers are given the responsibility of reading, implementing corrective action, and responding to the reports in their respective area. Monitoring reports for protocol deviations, recurrent problems, or temporal trends is the responsibility of the SQA. Immediate QC problem sent to the appropriate centers including the EC directly

for correction with a record kept by the reading center/laboratory/CC. The distribution of periodic reports described latter in this manual is as follows:

1) QC reports on technician-specific performance are sent quickly to the EC principal investigator, and the SQA within a week of generating the report.
2) Summary QC reports without technician-specific data are sent to the Steering Committee through the SQA. The following centers and committees have responsibility for responding to the reports as follows:
    a) EC Co-PI, study coordinators, local certifiers/trainers. Review each QC and monitoring report, including those with technician-specific quality; identify a solution to each problem; implement corrective action; report corrective action to CC monitor.
    b) Principal Investigators of laboratories and reading centers directors. Review each QC and monitoring report for their laboratory/center; identify a solution to each problem; implement corrective action; report corrective action to SQA.
    c) Statistics and Quality Assurance Subcommittee (SQA). Review each QC and monitoring report with attention to deviation from protocol, recurrent technician or field center problems and temporal trends; direct exam center, interviewing staff/reading center/laboratory attention to problem and recommend additional corrective action if they persist; monitor the implementation of corrective action; contact and coordinate study agencies and investigators to review data quality problem and solutions; prepare summary reports and recommendations for the Steering Committee.
    d) Steering Committee. Review QC summary reports; monitor data quality trends; direct the QC in areas needing special attention; responsible for changes in protocol.

## SCHEDULE OF QUALITY ASSURANCE AND QUALITY CONTROL ACTIVITIES

**Table 1: Schedule of Quality Assurance Activities**

| Procedure | Quality Assurance or Quality Control | Monitoring Methods | Responsible | Reporting Frequency | Written Report to CC & SSQC |
|---|---|---|---|---|---|
| AFU Interviews | QA<br>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 | 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<br>Re-certification of technicians | CC | Quarterly Semi-annually | Yes |
| Omaron BP Machines<br>Tanita 300A | QA **Equipment Maintenance** | ➢ P-Set<br>➢ inspection<br>➢ Standardization of manometer | Clinic Staff | ➢ Weekly<br>➢ Monthly | ➢ No<br>➢ 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 & centrifuge(s) | Clinic Manager | Monthly | Yes |
| Blood Analysis Lab | QC | Condition of arrival<br>Analytes Means & SDs; check extreme values with lab | Lab & CC | Monthly | Yes |
| MRI | QC | Range Checks, Descriptive statistics & Trend Analysis | Lab & CC | Monthly | Yes |

## 2.0 OPERATION OF QUALITY ASSURANCE AND QUALITY CONTROL ACTIVITIES

### 2.1 Quality Assurance Monitoring Process for Retention

Ongoing evaluation of Annual Follow-up interviewers will occur to ensure protocol adherence for all AFU interviews. Each research interviewer is monitored per observation by the Director of Retention using random in line listening equipment for quality control and re-certification purposes.

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 research protocols are being followed. A checklist will be used to determine satisfactory performance (Appendix). Random selection will be done on a rotating cycle to monitor all Research Interviewers in an ongoing manner. Protocol adherence and interviewing techniques are reviewed at least biannually by the CC/EC Liaison. Deviations from protocols 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 and the EC Co-PI. Data quality is monitored by the SQA quarterly through reports submitted to the subcommittee. Recommended corrective actions will be sent to the respective unit to address the concerns or issues at hand. The SQA will also inform the Steering Committee of its recommended corrective actions to data quality issues.

### 2.2 Interviews Exam 3 Visit

With participant approval, five per technician, interviewer-administered forms are taped for quality control every six months. This translates to about one taping per technician per month. A non-systematic sample of forms is reviewed by the Clinic Manager and/or Clinic Liaison monthly. Routine quality assurance is provided through observation by the Clinic Manager. Protocol adherence, and interviewing techniques are reviewed at least biannually by Clinic Liaison. Deviations from protocols and possible remedial actions are discussed with the Clinic Manager and staff at that time. Major deviations are brought to the attention of the JHS Clinic Operations Committee and the EC Co-PI. 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 protocol. The CC/EC liaison will be responsible for conducting a random exit interview with participants related to medical data review and referrals. In terms of reports, the CC will perform a bimonthly analysis to determine which participants have or have not received their clinic results. A written report will be submitted to the SQA subcommittee.

### 2.3 Quality Assurance for Cohort Procedures

There will be ongoing evaluations of clinic staff to ensure quality assurance of protocols being followed in the clinic. For quality purposes each staff is monitored per cohort procedure by the Clinic Manager yearly for re-certification purposes.

On a monthly basis, two staff members are selected randomly on a rotating cycle for observations by the EC/CC liaison to determine quality assurance protocol. The EC/CC liaison will provide both verbal reports at Clinic Operations Subcommittee meetings monthly and quarterly written report to the Statistics and Quality Assurance Subcommittee. The staff person will be observed on two areas of clinic exam components to determine satisfactory performance. The EC/CC liaison will monitor clinic operations using designated evaluation tools in (Appendix). 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. The various cohort procedures will be assessed for a given clinic staff by the Clinic Manager or a designated evaluator on the specific time frame in Table 1 of the manual. The corresponding instrument for each procedure is provided in Appendix – Evaluation/Certification/Site Visit Checklist. Deviations from protocols and possible remedial actions are discussed with the Clinic Manager and staff at that time. Major deviations are brought to the attention of the JHS Clinic Operations Committee and the EC Co-PI. Data quality is monitored by the Quality Control Committee quarterly.

## 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 venipuncture. To test reliability of newly developed instruments and for the purpose of reproducibility of measurement the JHS pilot testing cohort (n=21) will be utilized in replicating the entire cohort except for MRI. Ten percent of the total sample of 5,000 participants (excluding deceased participants) translated to 500 participants. The sampling of these 500 participants is weighted heavily in the earlier phase of the Exam 3 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, entering 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 3 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. 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 research nurse 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 that the assembled data will correspond to a 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 measurements of body composition may be sampled at different rates, the number of IDs needed to record all body composition of a given phantom will not be balanced.

*Alternative Use of the Phantom and Non-participant Form*: When new clinic staff or other JHS staff persons who are not JHS participants go through all or some of the JHS examination procedures, they are assigned a JHS cohort ID, which are recorded on the Quality Control Phantom Participant and Non-Participant ID Form. The range of IDs used by the non-participants is classified as Phantom and Non-Participant IDs. The following procedure should be used:

1) The research nurse assigns a JHS cohort ID at the start of their visit.

2) As soon as the ID is assigned, a label for that ID is placed in the box marked "Phantom Participant ID Number" on the QC Phantom Participant and Non-Participant ID Form, and "N", for "An ID Used for a Non- Participant" is circled.
3) Also as soon as the ID is assigned, the person making the assignment records the date and their own ID number in the spaces provided.
4) The same week the non-participant is seen, the QC Phantom and Non-Participant ID Form will be photocopied. The copy is retained at the EC, and the original is sent to the JHS CC

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 study coordinator 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 *(Sitting & Ankle-Brachial)*

- **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 by the CC. The Data Manager/Senior SAS Programmer at the CC generates the list. 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 will assist the Clinic Manager (or designate) to randomly select a second technician for repeated measurement.

- **Target Sample** The target sample size was arrived using data from JHS participants who had clinic visit between September 2005 and September 2008. In addition to setting the significance level ($\alpha$) 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. Over sampling will accommodate refusals and gather enough data at the onset to ensure an adequate sample size to detect data problems at the onset and thus correcting any identified issues.

- **Selection & Assignment Study units –** Study subjects will be pre-selected at random prior to their clinic visit. Three hundred thirty-six subjects will be selected over 36 months (144 weeks) after the start date. An average of 2.5 ($\cong$ 3) subjects per week will need to be assigned for repeated measures. Hence, 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 – over sampling of 20%. Hence if a randomly selected participant refuses to participate, there will be no need to replace that individual. This based on the assumption that the refusal rate will be below 20%.

**Selected Measures –**

| Procedures | Measures (Variables) |
|---|---|
| **Body Composition** | Height (BCFB8), Weight (BCFB 9), Girth-Waist (BCFB 5), Hip Girth (BCFB6) & Body Fat % (BCFB15) |
| **Sitting Blood Pressure** | Heart Rate (SBPC8), First Systolic BP (SBPB13), First Diastolic BP (SBPB14), Second Systolic BP (SBPB16), Second Diastolic BP (SBPB17) & Second zero reading (SBPB18). |
| ***Ankle-Brachial Blood Pressure*** | Max. Inflation level (ABBB6), Brachial (ABBB7), Right posterior tibia (ABBB8), Left posterior tibia (ABBB9), Left posterior tibia (ABBB10), Right posterior tibia (ABBB11) & Brachial (ABBB12) |

3.1.2 Study Plan – Electrocardiography:

- **Task (Activities) –** The replicate study in this case with utilize repeating scans for a random subset of JHS participants. This will not be done routinely but once a year as part of re-certification of ECG technicians. Each technician will have to complete 5 QC scans as part of the re-certification process. Individuals selected for the scan will be done at random. In addition to these yearly QC scans; ECG scans sent in from hospitals (as part of surveillance) can also be evaluated for QC. There will no re-reads of blinded images because all ECG scans are machine-read.

  **Target Sample –** The sample size will be 60 participants for the entire recruitment period. This translates to 20 participants per year (5 participants per technician per year).
- **Selection & Assignment Study units -**

  The CC, working in conjunction with the EC and the ECG Reading Center, will design a randomization scheme to carry out this aspect of the ECG replicate study. The study will be designed such that the scans will address inter- and intra-reliability.

3.1.3 Study Plan – Magnetic Resonance Imaging (MRI):

**Task (Activities) –** Given the time requirement and participants' willingness to participate in a repeated study, participants will not be re-scanned as part of the replicate studies. However, replicate studies will be conducted by re-reads of blinded MRI scans.
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**Target Sample –** The sample size will 10% of the total scans (n=2500), which is 250 re-reads.

**Selection & Assignment Study units -** The CC, working in conjunction with the MRI Reading Center, will design a randomization scheme to carry out this aspect of the MRI replicate study. The study will be designed such that the scans will address inter- and intra-reliability.

3.1.4 Study Plan – Venipuncture and Urine:

- **Task (Activities) –R**eplicate QC blood-drawing tubes will be assigned to each of three phantom participants per week. The blood draws are on three different participants whose clinic visits are on the same day. The urine collection will be on a fourth person other than the three individuals that had blood drawn. The clinic manger (or designate) will be given random selection scheme. For a given clinic day, the scheme will assist the clinic manager (or designate) in identifying the randomly selected participant and with blood tubes need to be drawn. The scheme will also be used to randomly select a participant for repeated urine collection.
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- **Target Sample –** The target sample for this replicate study will JHS participant. The total sample size for this study is 250 (5% of the total cohort of 5000).

- **Selection & Assignment Study units –** Study subjects will be pre-selected at random prior to their clinic visit. The goal is to select the 250 subjects over 36 months (144 weeks) after the start date. An average of 1.8 (≅ 2) subjects per week will need to be assigned for repeated measures. Hence, three JHS participants are randomly assigned to participate in repeated measures for additional blood draw; there will be a resultant sample size of 288 – over sampling of 9%. If a randomly selected participant refuses to participate, there will be no need to replace that individual.

**Selected Measures –**

| **Procedures** | **Measures (Variables)** |
|---|---|
| **Tubes & Spot Urine** | Analytes corresponding to tubes 1, 2 and 3; and spot urine sample. |

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 four 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 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) | (2,4) | (4, 1) |
| **2** | (3,3) | (1,2) | (7,4) | (6,1) |
| **3** | (5,1) | (2,3) | (3,4) | (4,2) |
| **4** | (7,2) | (1,3) | (5,4) | (2,1) |
| **5** | (6,1) | (4,2) | (7,4) | (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 & Weight |
| 2 | Girth: Waist & Hip |
| 3 | Body Fat % |
| 4 | Heart Rate & 1st & 2nd Sitting BP |
| 5 | Max Inflation, 1st & 2nd Ankle-Brachial BP |
| 6 | Venipuncture |
| 7 | Urine |

## 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) Digit preference analysis for blood pressure and anthropometry/body composition measures.
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 (monthly) or 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. Similar analyses of trends in the study data's summary statistics monitor laboratory data for signs of measurement drift or reduced measurement precision. Certain measurements, which involve a degree of subjective judgment by technicians, such as blood pressure or anthropometry data, are commonly subject to digit preference. The CC periodically analyzes such data for digit preference, by technician. Technicians will be provided feedback on their performance of quality data collection. A sample report is provided in the Appendix.

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 by EC. 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 procedures 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 by QC work. In order to spread out the workload and the distribution of the reports, a schedule for the Cohort Component reports has been developed.

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 body composition is not feasible on a monthly basis, but can usefully be done each quarter. Digit preference analyses 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) Laboratory (lipids, hemostasis, clinical chemistries, hematology)
    a. Repeated measures (monthly)
    b. Condition of sample on arrival (monthly)
    c. Analysis of QC samples from frozen storage (semi-annually)
    d. Internal QC results (quarterly)
    e. External QC results (frequency varies)

5) Venipuncture

    Distribution of number of stick attempts, means and distribution of filling and processing time (every two monthly)

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 SSQC 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 SSQC, 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 i[th] possible digits and $N = \sum_{i=1}^{k} O_i$

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:

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

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 $\chi^2$ 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 | | | | | | | | |
| Peak Set | | | | | | | | |

* 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.

In addition to the use of paired t-test to analyze replicate QC data the following modeling methodology. The total variance of the study data ($\sigma_T^2$) can be partitioned into two components: the measurement error component ($\sigma_e^2$) and the true variation between and within individuals in the study populations ($\sigma_b^2$), so that $\sigma_T^2 = \sigma_b^2 + \sigma_e^2$. Hence, the 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 total variation. It can also be shown that R is the correlation coefficient between two laboratory measurements made on the same (split) sample. The components of variance will be estimated from the replicate data using maximum likelihood (ML) or restricted maximum likelihood (REML).

R is useful for overall assessment of the reliability of the measurement method. For routine monitoring of the data collection process, the standard deviation $\sigma_e$ is most closely watched. In monitoring laboratory data, $\sigma_e$ 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 of the laboratory S.D., 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 Venipuncture and Equipment Records

- For equipment, daily records should be kept on all refrigerators and freezers.
- The temperature of the refrigerated centrifuge must be recorded daily.
- The speed of the centrifuge must be checked and recorded annually by a tachometer.
- The local blood processing certifier will fill out the Quality Control Checklist (Appendix 6) monthly, certifying that daily checks have been performed properly and describe any problems in this area.
- Daily checks of freezer alarm.
- Daily checks of the back-up generator to the freezer.
- Daily logs of lab 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 Exam Center.

## 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 3. 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 is 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.

## 8.0 SPECIMEN REPOSITORY QA ACTIVITIES

### 8.1 *Quality Control Duplicate Blood and Urine Samples*

As part of the overall quality control program for laboratory analyses, duplicate specimens are sent to the laboratory, with one half of each specimen pair sent under the participant's regular JHS 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 upon JHS participants, no one person is asked to contribute sufficient extra blood to make a complete set of duplicates for all tests. Instead, extra blood is drawn from three participants per week and sent out under the same QC ID number. The rational is to use different of examination components of several participants to construct QC data that represent a one (QC) participant. For data analysis, results on each laboratory measurement are matched to the appropriate participant results.

#### *8.1.1 Weekly Blood and Urine QC Sample Checklist*

The JHS Exam Center venipuncture technicians maintain a weekly checklist posted in their work area of the QC samples to be collected during the week. As each sample is drawn and processing completed, it is checked off. On Friday morning, this checklist is consulted to see if there were any additional samples needed to make up the complete set of QC samples.

#### *8.1.2 Preparation for Drawing and Processing QC Samples*

Blood Drawing Tubes: Each morning the blood drawing technician prepares extra blood collection tubes for the QC samples to be drawn that day. Each tube is labeled with the QC ID number to be used that week. In addition, the technician may wish to mark QC tubes "QC" in a clearly visible fashion, to reduce the chance that these tubes might be mixed up with the regular blood collection tubes during processing. The QC tubes are set in the same rack used to hold the regular blood collection tubes, in a separate row from the other tubes.

Sample Aliquot Tubes: Each morning a separate foam block is prepared for each set of QC blood tubes that the technician plans to draw that day. The foam block contains all the storage vials needed to process the day's quality control samples. The tubes in each block are labeled in advance with the QC ID number being used that week. Care must be taken during processing that the labels on the sample aliquot tubes match the label on the QC blood collection tubes.

On the day that the duplicate urine sample is to be collected, three extra tubes for the urine QC duplicates should be set out and labeled with the urine QC ID number. Three participants per week is chosen for urine QC duplicates.

#### *8.1.3 Collecting and Processing QC Blood and Urine*

Selecting Participants for QC Blood Draw: Normally, the QC samples are drawn from the first member of each group of participants whose blood is being processed simultaneously. Based upon the size of their veins, the difficulty of drawing the blood, and the apprehension a participant shows about the blood draw, the venipuncture technician may need to forego the drawing of the QC tube from the first, and draw from another participant instead.

Order of QC Tubes in Relation to Regular Blood Collection: The QC tubes may be added at the end of the blood draw without harming the measurements. This procedure is followed to cause the least disruption of the collection of the regular blood samples. If the blood flow falls off at the end of the draw, so that it would be difficult to obtain the extra QC tubes, a different participant is used to get this blood. A NEW NEEDLE STICK SHOULD NOT BE DONE JUST TO GET MORE BLOOD FOR A QC SPECIMEN.

Processing and Freezing QC Blood and Urine: QC blood samples are processed along with the regular blood samples. After processing is completed for each QC blood collection tube, the microvials are put into the -70°C freezer (for a minimum of 30 minutes). After the samples are thoroughly frozen, they are put into a freezer storage bag. The QC samples should be kept separate from the other samples collected during the week so they are not shipped along with them.

The urine QC samples should be placed into the freezer at the same time as their matched participant pair. As with the blood specimens, the urine samples should be kept away from the other urine specimens collected during the week so they are not included with that week's shipment.

Logging the Match between QC and Regular JHS ID's and Reporting These to the Coordinating Center: The QC Phantom Participant's folder is kept in the blood drawing area during the week the phantom ID number is being used to draw QC blood tubes. In the folder is the JHS Quality Control Phantom Participant Form, which is used to keep track of the match between the QC and regular JHS specimens. A sample copy is shown in Appendix 8. At the top of the log sheet is a space for the QC Phantom Participant's laboratory ID number. As participants donate blood to make up a QC set, labels with their ID numbers are added to the line corresponding to the tubes donated. This step must be done immediately after completing drawing blood for that participant, to minimize the chance of recording the wrong ID number. One such form is recorded for each QC ID number used. As soon as the full set of tubes is completed for each phantom participant (or at the end of the week, if any set is incomplete), the QC phantom participants' folder with this form is given to the receptionist (or other person designated by the Study Coordinator). The folder is processed like other participants' folders, except that the QC phantom participant form is sent to the Coordinating Center and the Exam Center keeps a photocopy of this form in the phantom's folder. Neither a Venipuncture Form nor Urine Collection Form is completed for the phantom duplicate.

## 8.2 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.

### 8.3 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.

### 8.4 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<br>☐Knowledgeable<br>☐Professional behavior |
| 208 | | | ☐Prepared<br>☐Knowledgeable<br>☐Professional behavior |
| 209 | | | ☐Prepared<br>☐Knowledgeable<br>☐Professional behavior |
| 262 | | | ☐Prepared<br>☐Knowledgeable<br>☐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. Venipuncture and Specimen Processing | Review Equipment Checklist<br>Review Blood 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 heels 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 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 <u>compress</u> tissue (Invert tape, <u>if needed</u>, 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 Venipuncture Certification / Supervisor / Site Visit Checklist

**DATE:** ☐ ☐ ☐
**mo** **day** **year**

**Technician ID/Name:** ☐

**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**:

32. ☐ Labels checked.
33. ☐ Venipuncture Form filled.
34. ☐ Tourniquet application and release.
35. ☐ Venipuncture technique.
36. ☐ Tube collection sequence.

**Handling of filled draw tubes:**

37. ☐ Inversion technique.
38. ☐ Tube incubation location.
39. ☐ Stasis obtained.
40. ☐ Needle disposal.
41. ☐ Universal precaution employed.

**Comments:** _____
_____
_____
_____
_____
_____

**Corrective action taken:**_____
_____
_____
_____

*Supervisor / Site Visitor Signature*_____