

Jackson Heart Study Protocol

Manual 3

Blood Pressure

Visit 2

Version 2.0

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For Copies, Please Contact:

Jackson Heart Study Coordinating Center  
Jackson Medical Mall  
350 W. Woodrow Wilson Dr.  
Jackson, MS 39213



## 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 and 4 describe the operation of the Cohort Procedures, Blood Pressure and Events Ascertainment Components of the study. Detailed Manuals of Operation for specific procedures, including those for Blood Pressure and Quality Assurance, make up Manuals 4 and 5. The Data Management System is described in Manual 6. The Central Laboratory and Specimen Repository is described in Manual 7. Manual 8 is designed to provide volumetric CT image data for measuring coronary and abdominal aortic calcified plaque as well as measuring body composition in the abdomen.

### JHS Study Protocols and Manuals of Operation

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1	General Description and Study Management
2	Cohort Component Procedures
3	Blood Pressure
4	Cohort Events Ascertainment
5	Quality Assurance
6	Data Management
7	Central Laboratory and Specimen Repository Collection and Processing
8	CT Scan

## Manual 3 Blood Pressure

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## **1.0 SITTING BLOOD PRESSURE PROTOCOL (RANDOM ZERO SPHYGMOMANOMETER)**

### **1.1 Introduction**

As blood pressure rises, so does risk of ischemic heart disease and its complications. The range of normal blood pressures is wide. Even within the "normal" range, risk increases as the upper limits are approached. Usually, blood pressures are expressed as systolic pressure/diastolic pressure; values exceeding 140/90 mmHg are considered to be hypertensive for adults. Classification and staging of hypertension are more precise where systolic rather than diastolic is the principle criterion. Both systolic and diastolic blood pressure elevations are associated with increasing risk for cardiovascular disease. Middle-aged persons with a diastolic blood pressure of 90-104 mmHg (so-called "mild" hypertension) have a risk of heart attack that is about 70 percent higher than that of persons with a diastolic pressure under 80 mmHg (optimal value). Persons with a diastolic blood pressure exceeding 104 mmHg (moderately severe to severe hypertension) have a risk more than twice that of those with a normal value. Hypertension is an especially strong risk factor for stroke and, to a lesser extent, for peripheral vascular disease. Most of the knowledge of the consequences of high blood pressure arises from studies of sitting arm blood pressure, as described in this section.

Sitting blood pressure in the first exam (Visit 1) is measured in a resting state, using 2 measurements with a random zero sphygmomanometer. The random zero machine has two advantages over the fixed zero manometer. Digit preference does not appear in the data. It may still exist in the reading itself, but it is "removed" from the data by the use of the randomly chosen zero point. More importantly, it prevents the blood pressure technician from knowing the actual value, and therefore removes judgements about blood pressure levels for readings close to critical values such as 90 diastolic. It should be noted, however, that the random zero machines tend to yield blood pressures which are about 1.5 mmHg less than those obtained when using a fixed zero machine. Within person variation in blood pressure is substantial, even within a few minutes and particularly under conditions perceived as stressful. Use of two replicate readings tends to reduce this short-term variation.

### **1.2 Standardized Clinic Procedures**

Correct measurement of blood pressure is of the utmost importance to the success of this study. It is essential that the procedure described below for measuring blood pressure be followed exactly. Major differences in blood pressure measurement methodology among health professionals from several countries have been observed despite the fact that a joint committee of the American Heart Association and the Cardiac Society of Great Britain and Ireland established international recommendations on blood pressure measurement in 1939. Precision is essential for valid comparisons of blood pressure between groups of people and in individuals on different occasions.

### **1.3 Description of the Equipment**

#### **1.3.1 Stethoscope**

A standard Littman stethoscope with a bell is used. Korotkoff sounds, described as Phase 1 through Phase 5, are best heard with the bell because of their low pitch. Stethoscope tubing should be about 10-12 inches from the bell piece to "Y" branching. This length provides optimal acoustical properties and allows the observer to read the sphygmomanometer at eye level and in a comfortable position. Earpieces should fit comfortably and snugly in the ears. Four points should be observed in using the stethoscope.

The earpieces should be directed downwards and forwards into the external ear canal.

1. The earpieces should be tight enough to exclude outside sound but not so tight that they cause discomfort.

2. The valve between the bell and the diaphragm should be turned in the correct direction.
3. The bell of the stethoscope should be placed lightly on the skin overlying the brachial artery - immediately below the cuff and medial to the cubital fossa above the medial epicondyle of the radius and posterior to the biceps muscle. Light pressure accentuates low-pitched sound and avoids compression murmurs. Pressing too heavily with the stethoscope over the brachial artery causes turbulent flow in the artery and a murmur can be heard which may prolong the apparent duration of phase 4.

### **1.3.2 Sphygmomanometers**

Standardized Hawksley random-zero instruments are used for all clinic visits. Standard Baum manometers are used for determining peak inflation level.

The mercury manometer consists of a screw cap, a face with numbers, a lined glass column, a reservoir containing mercury, rubber tubing, and a metal case. The rubber tubing from the mercury manometer connects to the rubber tubing from the inflatable rubber bladder of the cuff. As the inflatable rubber bladder is filled with air, the air pressure in the bladder travels through the connecting rubber tubing. The pressure pushes the mercury out of the reservoir and into the lined glass column. The number for each line is read when the rounded top of the mercury, the meniscus, is level with it. If the meniscus is exactly between the lines, the reading is made from the line immediately above, i.e., rounded up to the nearest even number.

### **1.3.3 Random-Zero Mercury Manometer**

The random-zero (R-Z) manometer has all the parts of the standard mercury manometer. In addition, it has a device built into the box-shaped back that changes the level of mercury in the calibrated glass tube. The device includes a second mercury reservoir the size of which can be changed to hold a larger or smaller amount of the mercury and therefore allow different amounts of mercury to remain in the calibrated glass tube and the outside reservoir. Turning a wheel on the side of the wooden box changes the size of the second reservoir. The second reservoir is opened and closed with a bellows control valve on the face of the manometer.

### **1.3.4 Cuffs and Bulbs**

Proper size of the cuff is essential for accurate blood pressure measurement. The Examination Center has four standardized cuffs available - small adult, adult, large adult, and thigh cuff. The standardized cuffs (provided are by the Baum Company) are used for the measurement of sitting blood pressure.

The range markings on commercial cuffs overlap from size to size and do not offer a precise guideline. In the JHS Study arm size is measured, and the cuff size is selected as illustrated in Table 1, below.

**Table 1. Determination of Cuff Size Based on Arm Circumference**

<b>Cuff Size</b>	<b>Arm Circumference</b>
Small Adult	< 24 cm
Adult	24 to 32 cm
Large Adult	33 to 41 cm
Thigh	> 41 cm

#### **1.4 Blood Pressure Measurement Instructions**

Standardizing the measurement technique and the environment in which the measurement is made controls some of the many extraneous factors influencing blood pressure. Uncontrolled factors (temperature, time of day, arm circumference, recent use of caffeine, and identity of the observer) are recorded, so that they can be taken into account during analysis.

JHS participants are reminded during the scheduling of Visit 1 to avoid caffeine (from tea, coffee, chocolate, and soft drinks), eating, heavy physical activity, smoking and alcohol intake for twelve hours prior to the clinic visit. Current drug intake, including medications affecting blood pressure and non-prescription drugs, is recorded on the day of the examination. A detailed history of alcohol intake history is also recorded.

#### **1.5 Staff Preparation for Participant Visit**

In relating to the JHS participants, remember that participation in the study is voluntary. Participants are given full explanation and instructions about the preparation for the blood pressure examination and an opportunity for questions. The setting in which blood pressure measurements are made is standardized and takes place in a separate, quiet room where no other activity is taking place, and where temperature fluctuations are minimal. Clinic scheduling procedures establish consistent appointment times to minimize as much as possible the impact of daily blood pressure variation.

#### **1.6 Measurement Procedures**

The sitting arm blood pressure is measured two times at Exam 2. It takes approximately 10 minutes to make two blood pressure measurements including the initial five-minute rest.

Once the participant is given instructions and explanations, and the equipment has been checked, blood pressure measurement begins. The following steps must be followed precisely. The procedure is described here employing the JHS paper form. When using the JHS Direct Data Entry System, calculations are performed by the system.

1. If the participant indicates that there is a medical or post-surgical reason for not having the blood pressure measured on the right arm (or if the right arm is missing), reverse chairs and proceed with the left arm. Indicate on the Itinerary Form and on the Sitting Blood Pressure form Note Log that the left arm is used. If in doubt, or if the participant prefers not to have a blood pressure taken on either arm, consult with the supervisor.
2. Determine the arm circumference using the following procedure.

The participant stands facing away from the observer with the right arm flexed at 90 degrees at the elbow, hand across midsection. The observer determines and marks the tip of the olecranon (elbow).

The participant straightens the arm, allowing it to hang loosely at the side. The observer then determines and marks the posterior tip of the acromion process (shoulder bone). Using a centimeter tape, the observer measures the length of the upper arm between the two marks and marks the midpoint (+).

The observer wraps the tape around the arm over the midpoint mark, making sure that the tape is level. The arm circumference is measured to the nearest centimeter, and is recorded.

3. Seat the participant with right arm on table. The bend at the elbow (cubital fossa) should be at heart level. Legs should be uncrossed and feet comfortably flat on the floor, not dangling. Be sure that the chair head support is comfortable and the participant is able to relax the neck and shoulder muscles as much as possible.

4. Palpate the brachial artery (just medial to and above the cubital fossa), and mark this location for stethoscope placement. Choose the correct cuff size and wrap the cuff on the arm with the center of the bladder over the artery. If the participant seems particularly apprehensive, delay wrapping the cuff until after the five-minute wait.

5. Record the time. Start five-minute timer. **Allow a five-minute wait before taking the blood pressure.** Conversation should be limited. However, a brief explanation of the procedure can be repeated at this time if necessary. The smoking and fasting questions may be asked after timing is begun.

6. After the 5-minute rest, check and record the 30-second heart rate. Then, connect the cuff to a standard manometer and establish the pulse obliteration pressure by slowly inflating while palpating the radial artery until pulse is no longer felt. Deflate and disconnect the cuff. Record the pulse obliteration pressure. Record the R-Z maximum zero number (found next to mercury column). Calculate and record the peak inflation level (i.e., pulse obliteration pressure + R-Z maximum zero number + 30).

7. Measurement 1: Connect the cuff to the random-zero manometer. Open the bellows control valve and wait until the mercury settles. Using downstrokes only turn the thumbwheel two or three times. Note: Do not spin the thumbwheel. Place the bell of the stethoscope on the brachial artery. Inflate rapidly to the R-Z peak inflation level. Holding the pressure constant with the bulb, wait 5 seconds. Close the bellows control valve. Slowly deflate the cuff (2 mm per second) while listening. Record the 1st and 5th phases, reading the pressure in mmHg to the nearest even number. The first sound heard in a series of at least two sounds is recorded for systolic blood pressure (phase 1). The first silence in a series of at least two silences is recorded for diastolic blood pressure (phase 5), not the last sound heard. Disconnect the cuff and record the zero reading.

8. Measurement 2: Have the participant raise measurement arm for five seconds. After waiting another 25 seconds with the participant's arm on the table, repeat the measurement as in step 7 above and disconnect cuff.

Blood pressure calculations are made for the first and second readings. When using paper forms, subtract the zero value from the readings to get the actual (corrected) systolic and diastolic blood pressure measurement. This is done on the worksheet at the end of the form. Because of the importance of the blood pressure averages, to inform the participant and for the purpose of referral, all arithmetic is done with a calculator.

If for any reason the observer is unable to complete, or has forgotten to complete any portion of the exam (and the participant is gone), draw two horizontal lines through the space(s) on the form, if using

paper forms. This is the correct way to indicate missed information. If an entire reading is missed and the participant is still sitting at the blood pressure workstation, completely deflate the cuff and start over with a replacement reading. However, under no other circumstances may a replacement reading be obtained. Always wait at least 30 seconds between readings.

### 1.7 Procedure for Changing the Peak Inflation Level

Occasionally the Korotkoff sounds may be heard as soon as one places the stethoscope over the brachial pulse. If this happens, the peak inflation level used was too low. The observer immediately deflates the cuff by releasing the thumbscrew and disconnecting the cuff tube. Then have the participant hold the cuff-wrapped arm vertically for five seconds. As shown below in Table 2, draw a line through the previously recorded Pulse Obliteration Pressure and Peak Inflation Level. Increase each number by ten and write the new number above the original one, as shown below. When using the Direct Data Entry system, the Peak Inflation Level values change automatically when the Pulse Obliteration Pressure is changed. Proceed with blood pressure measurement, starting at the new Peak Inflation Level.

**Figure 1. Changing the Peak Inflation Level on paper forms.**

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	130
Pulse obliteration pressure	<del>120</del>
R-Z maximum Zero	<del>+ 22</del>
	<del>+ 30</del>
	=182
Peak Inflation Level (Random-Zero)	<del>172</del>

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### 1.8 Reporting the Blood Pressure Results to the Participant

Using a calculator, average the first and second corrected R-Z readings and record the average on the form if using paper forms. Record this average on the transmittal slip or itinerary form in the participant's folder, and mention the results to the participant. State clearly the systolic and diastolic pressure, and indicate that the participant will receive a written report with these values at the end of the visit.

### 1.9 Stopping Rules for Elevated Blood Pressure

The classification of blood pressure for adults is summarized in Table 3. The medical care referral guidelines for elevated blood pressure are summarized in Table 4. When a person has one or more sitting blood pressure measurements where the systolic reading exceeds 260 mm Hg **or** the diastolic reading exceeds 130 mm Hg (emergency referral), the JHS physician is consulted and the arrangements are made to transport the person to an emergency care facility. The JHS physician is also consulted and the participant is advised to seek immediate medical care (same day) when one or more systolic blood pressure measurements are between 210 and 259 mm Hg or the diastolic pressure is between 120 and 129 mm Hg (immediate referral). In both circumstances, the remaining procedures and interviews in Visit 1 are cancelled and Visit 1 is rescheduled as appropriate. When one or more systolic blood pressure levels are between 180 and 209 mm Hg or the diastolic is between 110 and 119 (urgent referral); the JHS physician is notified for urgent referral unless the physician recommends otherwise.

**Table 5.1 Classification of Blood Pressure for Adults, Based on Joint National Committee on Detection, Evaluation and Treatment of High Blood Pressure (JNC-VII, 2003) Guidelines**

Category*	SBP (mm Hg)		DBP (mm Hg)
Normal	<120	and	<80
Pre Hypertension	120-139	or	80-89
Stage 1 Hypertension	140-159	or	90-99
Stage 2 Hypertension	≥160	or	≥100

\*When SBP and DBP fall into different categories, use the higher category.

**Table 5.2 Medical Care Referral Guidelines for Blood Pressure, Based on Joint National Committee on Detection, Evaluation and Treatment of High Blood Pressure (JNC-VII, 2003) Guidelines**

Referral Classification	Examination Findings	Recommendation to Participant <sup>1</sup>	Explanation to Participant
Emergency Referral	SBP ≥ 260 or DBP ≥ 130	Transportation to emergency care facility. Stop exam and reschedule clinic visit	Your BP is very high.
Immediate Referral	SBP 210-259 or DBP 120-129	Consult with JHS MD. Refer to source of care immediately (today). Stop exam and reschedule clinic visit	Your BP is very high.
Urgent Referral	SBP 180-209 or DBP 110-119	Consult with JHS MD and proceed unless otherwise indicated. Refer to source of care within 1 week	Your BP is high.
Routine Referral	SBP 160-179 or DBP 100-109	Refer to source of care within 1 month	Your BP is elevated.
	SBP 140-159 or DBP 90-99	Refer to source of care within 2 months	Your BP is elevated.
	SBP 120-139 or DBP 80-89	Recheck in 1 year (no JHS referral)	Your BP is in the pre-hypertension range
	SBP < 120 <sup>2</sup> or DBP < 80	Recheck in 2 years (no JHS referral)	Your blood pressure is normal

<sup>1</sup> If the systolic and diastolic categories are different, follow recommendations for the shorter time follow-up (e.g., 160/85 mm Hg should be evaluated or referred to source of care within 1 month). <sup>2</sup> Unusually low readings should be evaluated for clinical significance.

## **1.10 Sitting Blood Pressure Training and Certification**

At the Examination Center a minimum of five clinic staff persons are trained for measuring sitting blood pressure. They need not be health professionals, but they must be trained and certified by JHS in the blood pressure measurement technique. Observers should also have experience in relating to people.

The first training session begins with a description and demonstration of the correct blood pressure measurement procedure. Trainees listen to the 1st (training) audiocassette tape, taking the test sequences until they are confident they can identify 1st and 5th phase Korotkoff sounds. Then, they use the 2nd tape until they have passed the test. After passing the second test, they are given the 3rd tape test. Alternated with the tapes are actual practice sessions with live subjects under the instruction and observation of the training supervisor. Some live practices may be done with a standard stethoscope, but most employ the Y-tube stethoscope. After the first day of training, each trainee is given a cuff and manometer (no stethoscope) to take home and practice control of the valve. This is done by wrapping the cuff on a jar or bottle and alternately pumping up and dropping the mercury at a steady rate of 2 mm per second. After two or three sessions, trainees are also given a stethoscope to practice on family or friends. Out-of-class practice is very important to build confidence. Practice time allowed in class is not enough without outside practice time. Once each trainee has passed the third tape test, he or she does at least two live readings with the training supervisor on the Y-tube stethoscope. The readings must agree within 4 mm and the average must agree within 3 mm. If they do not, the trainee needs additional practice with tapes and live subjects. The training supervisor also verifies that the trainee understands and follows proper procedures.

Additional time is allowed for instruction and mastering the use of the Random-Zero device. Trainees are certified after passing tape tests 2 and 3 (tape 4 is held in reserve for recertification) and at least 2 live readings. Observers are recertified every six months by taking and passing tape 3 or 4 and two readings with the blood pressure supervisor on an Y-tube stethoscope.

It is the responsibility of the Examination Center to conduct recertification procedures and report to the Coordinating Center when the procedures are complete.

### **1.10.1 Tapes**

The JHS Study uses four tapes of Korotkoff sounds. Tape 1 is a training tape. Tape 2 is a practice tape. Tapes 3 and 4 are test tapes. A new trainee listens to tape 1, goes to tape 2 and repeats it as often as necessary. Tape 3 is taken as a test. It, too, may be repeated if necessary. Tape 4 is held in reserve for the six-month recertification. Tapes 3 and 4 are alternated thereafter for recertification.

### **1.10.2 Using the Cronus Stop Watch with the Prineas Blood Pressure Tapes**

The Cronus stopwatch, model 3-S, is an interval timer and is the preferred timing device to be used with the training tapes. Of the various options, it seems to be the simplest and easiest to read. It is generally available at a local sporting goods store. The address of the manufacturer is:

Cronus Precision Products, Inc.  
2895 Northwestern Parkway  
Santa Clara, CA 95051 USA

If only Phase 1 and Phase 5 are learned, two ordinary stopwatches may be used. Using one in each hand, both are started at the beep; one is stopped when the first Korotkoff sounds are heard and the other stopped at Phase 5. The interval watch is preferred even if Phase 4 is not being recorded because it is much easier to change one's mind if sounds change, and it is easier to read.

1. Turn on the stopwatch and press the reset button.
2. Start the tape, wearing headphones. At the beginning of each tape is a timing sequence, with no Korotkoff sounds. When the beep is heard, start the watch by pressing the button at the top. Stop the watch with the button at the top when the second beep is heard. Record the time elapsed to the nearest 10th of a second on the top of the student form.
3. Press reset button. When the tape announces sequence 1, start the watch at the beep.
4. When the first Korotkoff sound is heard, stop the watch with the button at the top. Record the time elapsed to the nearest 10th of a second. The watch continues to run internally.
5. When the Phase 5 (disappearance) is heard, stop the watch. Record the time elapsed to the nearest 10th of a second. Press reset. Repeat steps 3 through 5 for each sequence. Remember that the tapes were designed for a special timing device. The answers given are double the stop watch values. At the end be sure to turn off the stopwatch in order to save batteries. To score the tests, add all the sequences, and divide by the number of sequences. The average should be within plus or minus one second.

### **1.10.3 Y Tube Stethoscope Observations**

Y Tube stethoscope observations are made in conjunction with the blood pressure tapes during initial training and for biannual quality control. The trainer has the observer-trainee go through the entire blood pressure measurement procedure using a quality control checklist. The observer and trainer listen with the Y Tube and record the values on separate sheets. Two measurements on one subject are obtained. Measurements by the trainer and the trainee should agree within 4 mmHg on any one reading (systolic or diastolic) and averages should agree within 3 mmHg.

### **1.11 Quality Control**

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

1. recruitment of the most qualified personnel
2. standardized training and certification
3. retraining and recertification
4. biannual observation of data collection by supervisors, using the checklist given in Appendix 3. One checklist is used for each technician and sent to the Coordinating Center 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 Coordinating Center
8. biannual simultaneous Y Tube observation of each technician by the blood pressure supervisor
9. equipment maintenance program

### **1.12 Technician Training and Quality Control**

Blood pressure technicians are trained by the clinic coordinator or their designee prior to participant recruitment. New technicians hired after the start of the study are trained locally by the Study

Coordinator 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 Coordinating Center 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.

### **1.13 Equipment Maintenance**

The Examination Center is responsible for the proper operation and maintenance of its equipment. Maintenance responsibility is assumed by the blood pressure supervisor 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 Appendix 4.

#### **1.13.1 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, 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 Appendix 4.

### **1.14 Referral of Hypertensives**

As shown in Table 3, blood pressure referral levels are made based on the findings of the JHS examination which are consistent with the recommendations given in the seventh report of the Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure (2003). The average of the first and second resting blood pressure readings is used.

## 2.0 SITTING BLOOD PRESSURE (OMRON HEM-907XL) BLOOD PRESSURE PROTOCOL AND BLOOD PRESSURE COMPARABILITY STUDY PURPOSE

This protocol is written for use with the *Omron* HEM907XL automated BP monitor. Special attention must be placed on assessment and maintenance of the instrument's accuracy as per the manual that accompanies the instrument (Appendix).

The design and operation of the *Omron* HEM907XL are based upon the combined principles of compression of the brachial artery under an elastic, inflatable cuff and estimation of the systolic and diastolic BP levels by oscillometric methods. All readings are to be recorded to the nearest digit.

The *Omron* HEM907XL unit will undergo and Blood Pressure Comparability study to assure comparability between measures of blood pressure taken with this equipment and that taken using the Random Zero sphygmomanometer. The purpose of this comparability study is to assure that blood pressure taken by either type of equipment can be considered equivalent for data analysis purposes for the JHS. Once the comparability study is complete, and reliability of measurements determined, the *Omron* HEM907XL equipment will be used for all off-site examinations conducted as a part of Exam 2.

### 2.1 Equipment

The following equipment will be required for BP and pulse measurement:

1. One *Omron* HEM907XL automated BP monitor.
2. BP cuffs in four sizes: S, M, L, XL
3. One *Gulick II* tape (or *Gulick II Plus*)
4. A chair with arm support for BP measurement, or a chair and table (table must provide for a comfortable resting posture of the arm with the cubital fossa at the level of the 4<sup>th</sup> intercostal space at heart level)
5. One black pen (marking on skin) and one No. 2 pencil (completing the form)



### 2.2 Exclusions

1. Persons with rigid arteries such that an occlusion pressure cannot be reached. If the artery cannot be occluded before the mercury column reaches 300 mmHg, the participant is excluded.
2. Persons with bilateral amputations of arms.
3. Subjects who fit any of the above categories are recorded as missing data.
4. If a subject has undergone a mastectomy of the right breast or has other reasons to omit right arm pressures, the left arm will be used for measures.

## 2.3 Set-Up Procedure

The proper cuff size must be used to avoid under- or over-estimation of BP. Cuff size refers to the cuff's bladder, not the cloth. A copy of the chart below should be attached to the sphygmomanometer for easy reference. In addition, the cuffs must be HEM907 XL-compatible (see manual in Appendix). If the right arm cannot be used, the left may be used. This change must be noted on form.

**Table 2. Determination of Cuff Size Based on Arm Circumference**

Cuff Size	Arm Circumference	Bladder Size
Small Adult	< 24 cm	9.0
Adult	24 to 32 cm	12.0
Large Adult	33 to 41 cm	15.0
Thigh	> 41 cm	17.5

Measurement of arm circumference. The participant should remove his/her upper garment, or clear the upper arm area so that an unencumbered measurement may be made. The technician should:

1. Have the participant stand, with the right arm hanging and bending the elbow so that the forearm is horizontal (parallel) to the floor.
2. Measure arm length from the acromion (bony protuberance at the shoulder) to the olecranon (tip of the elbow), using the *Gulick II* anthropometric tape.
3. Mark the midpoint on the dorsal surface of the arm.
4. Have the participant relax arm along side of the body.
5. Draw the tape snugly around the arm at the midpoint mark.  
**NOTE:** Tape should be horizontal and should not indent the skin.
6. Noting the arm circumference indicated by the tape, use the criteria above for determining cuff size.

## 2.4 Procedure

### 2.5.1 Wrapping the Blood Pressure Cuff around the Arm

The technician should:

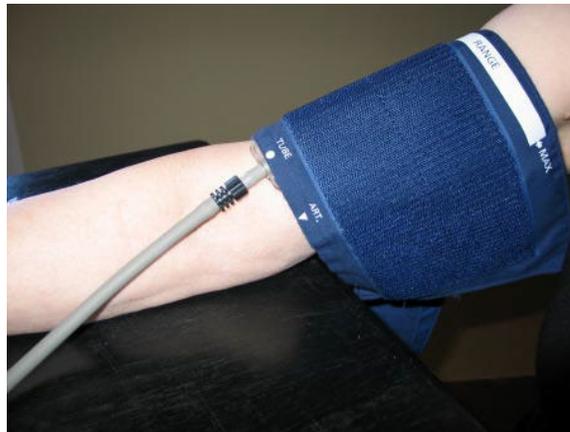
1. Ensure the participant is seated, legs uncrossed, in a quiet room, with the elbow and forearm resting comfortably on the armrest of the BP measurement chair (or table), with the palm of the hand turned upward. The area to which the cuff is to be applied must be bare (free of clothing).
2. Locate the brachial artery by palpation and mark the skin with a small dot, using a black pen. (The brachial artery is usually found just medial and superior to the cubital fossa, posterior to the biceps muscle and slightly toward the body). For brachial artery palpation, fingertips or thumb may be used (see figures to the right).
3. Place the appropriate cuff around the upper right arm so that:



- i. The midpoint of the length of the bladder lies over the brachial artery.
- ii. The cubital fossa is at heart level.

**NOTE:** The midpoint of the length of the bladder should be confirmed by folding the bladder in two. The marking on the cuff should not be trusted.

4. Place the lower edge of the cuff, with its tubing connections, about 1 inch above the natural crease across the inner aspect of the elbow (the cubital fossa).
  5. Wrap the cuff snugly about the arm, with the palm of the participant's hand turned upward, making sure the long edges of the cuff lie on top of each other as the cuff is wrapped around.
  6. Secure the wrapped cuff firmly by applying pressure to the locking fabric fastener over the area where it is applied to the cuff.
- NOTE:** The cuff should not be wrapped too tightly around the arm.



#### 2.4.2 General Guide to Blood Pressure Readings

1. Following any previous inflation, wait at least 30 seconds after cuff has completely deflated.
2. By closing the thumb valve and squeezing the bulb, inflate the cuff at a rapid but smooth continuous rate to the maximal inflation level (30 mmHg above systolic pressure). This measure is described in greater detail below.
3. The examiner's eyes should be level with the mid-range of the manometer scale and focused at the level to which the pressure will be raised.
4. By opening the thumb valve slightly, and maintaining a constant rate of deflation at approximately 2 mmHg per second, allow the cuff to deflate.
5. Listen throughout the entire range of deflation, past the systolic reading (the pressure where the first regular sound is heard) for 10 mmHg. Two subsequent beats should be heard for any valid systolic blood pressure reading.
6. Deflate the cuff fully by opening the thumb valve.
7. Neatly enter systolic readings in the spaces provided on the form.

#### 2.5 Blood Pressure Comparability Study Methods

The BP Comparability Study is done with a subset of JHS participants who are willing to participate in this extra measurement. Participants with an arm circumference exceeding 50 cm and requiring the use of a thigh cuff are ineligible to participate in the BP Comparability Study.

##### 2.5.2 Equipment

1. Standard sphygmomanometer
2. Standard cuffs
3. Single stethoscope with bell
4. Double Y-stethoscope with bell

5. *Omron* HEM907XL
6. Random Zero
7. Y-connector
8. *Omron* cuffs

### 2.5.2 Staff

Two BP technicians: Each will record three measurements on the BCF form for use by the Random Zero (RZ) technician and the *Omron* technician. Two BP measurements will be made on each BP Comparability Study participant. The technicians will alternate observations using the RZ and *Omron*. Technician No. 1 will measure a participant's BP twice with the RZ, and Technician No. 2 will measure the participant's BP twice with the *Omron*. The next participant would have Technician No. 2 measure BP twice with the RZ, and Technician No. 1 measure BP twice with the *Omron*. During the comparability study, *Omron* measurements are made with the setting on **MANUAL**. The *Omron* technician listens with the same double stethoscope as the RZ technician.

### 2.5.3 Random Zero Technician Procedures

The RZ technician should:

1. Enter his/her Technician ID in the space provided at the bottom of the BCF form.
2. Measure and record participant's arm circumference with *Gulick II* tape.
3. Select and apply an appropriate sized standard cuff according to the participant's arm circumference measurement.
4. Determine and record the **Pulse Obliteration Pressure** using the standard sphygmomanometer and a standard cuff with the technician's hand on the participant's radial pulse.
5. **Add and record 30 mm** to the Pulse Obliteration Pressure.
6. Switch from the standard sphygmomanometer to the RZ. (*Omron* technician will remove standard cuff and apply *Omron* cuff.)
7. **Record the RZ maximum value** for the RZ in use. Enter Item 15 (sum of Pulse obliteration, maximum zero + 30 values) to determine the peak inflation value for the ***Omron* P-Set level (Q4) setting**.
8. Attach Y-connector to the RZ, the *Omron*, and the *Omron* cuff. The small connector on this cuff should be removed so that the tubing can be attached to a Y-connector.
9. Turn the bellows valve dial on the RZ to **OPEN**, after the *Omron* technician has set up and turned on the *Omron*,.
10. Place the double Y-stethoscope earpieces into ears (at same time as other technician).
11. Observe the other technician press the **START** button on the *Omron*, ensuring it inflates the cuff for both devices, and that the mercury column in the RZ rises.

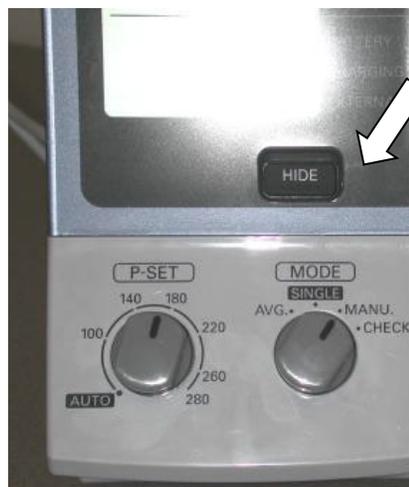


12. Turn the RZ dial to **CLOSE**, when the mercury column on the RZ has dropped 20 mm from its highest point.
13. Listen for the onset of the 1<sup>st</sup> sounds and 5<sup>th</sup> (disappearance) Korotkoff phase sounds.
14. Record readings from the RZ, when the cuff is completely deflated, and subtract the RZ level from the RZ systolic and diastolic readings, recording the corrected measurement.
15. Open the RZ dial and turn the thumb wheel.

#### 2.5.4 Omron Technician

The *Omron* technician should:

1. Enter his/her Technician ID in the space provided at the bottom of the BCF form. Remove the standard cuff, after the RZ technician has completed the peak inflation level measurement, and apply the appropriate sized *Omron* cuff to the participant's arm with the arrow at the brachial artery.
2. Turn on the *Omron* (It is best to have the *Omron* connected to the main power supply, rather than relying on the battery power). Turn the P-SET dial on the *Omron* to the P-Set level estimated in [2.6.3(7)], above. PLEASE NOTE: If using *Omron* equipment without prior Random Zero methods, enter the P-Set level as the pulse obliteration level + 30.
3. Turn the MODE on the *Omron* to **MANUAL**.
4. Place the double Y-stethoscope earpieces into his/her ears (at same time as other technician) and hold the bell over the participant's artery.
5. Press **START** on the *Omron*. The *Omron* will inflate the cuff for both devices.
6. Watch the *Omron* and listen for the onset of 1<sup>st</sup> (sounds) and 5<sup>th</sup> (disappearance) Korotkoff phase sounds, noting the pressure levels.
7. Record the systolic and diastolic BP levels from the *Omron*, when the cuff is completely deflated and the *Omron* is at "0."



#### 2.5.5 Second Blood Pressure Measurements

The above steps should be repeated, starting at Step 2.6.3.(7) for the RZ technician and Step 2.6.4.(5) for the *Omron* technician. Each technician should take both measurements with the same device. The RZ technician will continue to record the measurements in the Random Zero section of the BCF form and the *Omron* technician will continue to record measurements in the OMRON section of the form.

#### 2.5.6 Measurements Using Omron Only Equipment

When taking measurements using ONLY the Omron equipment, follow all the instructions above for the Omron Technician except:

1. only one technician is required

2. Set the P-SET value to AUTOMATIC and record the maximum inflation on the monitor before the monitor begins automatic deflation as the P-set value.
3. Set the MODE to AVG. The monitor will automatically take two measurements one minute apart displaying the first, second, and average blood pressure readings. Record each as directed in the SBP QxQs for the relevant items.

## **2.6 Quality Assurance**

### **2.6.1 Training Requirements**

Staff performing the ankle-arm index measurements should be research technicians or clinicians previously trained in taking research blood pressure measurements. In addition, training should include:

- Read and study manual
- Attend Jackson Heart Study training session on techniques (or observe administration by experienced examiner)
- Practice on volunteers
- Compare measurements with those made by experienced colleagues (Goal: obtain measurements within  $\pm 2$  mm Hg of that observed by a trainer)
- Discuss problems and questions with QC officer

### **2.6.2 Certification Requirements**

- Complete training requirements
- Recite exclusion criteria
- Conduct exam on two volunteers while being observed by QC officer listening with Y stethoscope

### 3.0 SELF MONITORED BLOOD PRESSURE

#### 3.1 Introduction and Equipment

The self monitored blood pressure component of Exam 2 includes instructing the participant in the use of the Omron HEM-780 *Intellisense* Automatic Blood Pressure Monitor and providing opportunity for the participant to satisfactorily measure her/his blood pressure prior to leaving the clinic. This monitor is ideal for self monitoring as it uses oscillometric methods of blood pressure measurement to detect blood movement through the brachial artery and converts these movements to a digital reading. Thus, no stethoscope is needed simplifying the use of this equipment.

The HEM-780 comes with the following components:

Monitor	ComFit Cuff
AC Adapter	4 "AA" Batteries
Storage Case	Instruction Manual

##### 3.1.1 Preparation in Advance of Clinic

Clinic staff will prepare each monitor in advance of the clinic session by setting the date and time following the instructions in the HEM-780 Instruction Manual (Appendix). This will shorten the time needed for the participant's to learn to use the equipment for blood pressure measurement.

- 1) Press the Date / Time Setting button. The Year flashes on the display.
- 2) Setting the Year. The year can be set between 2004 and 2030. If you accidentally advance to 2030, it will return to 2004. Press the ► memory up button to advance by increments of one year. Press the Date / Time Setting button. The Month flashes on the display
- 3) Setting the Month. Press the ► memory up button to advance by increments of one month. Press the Date / Time Setting button. The Day flashes on the display.
- 4) Setting the Day. Press the ► memory up button to advance by increments of one day. Press the Date / Time Setting button. The Hour flashes on the display.
- 5) Setting the Hour. The Time is set using AM or PM. Press the ► memory up button to advance by increments of one hour. Press the Date / Time Setting button. The Minute flashes on the display.
- 6) Setting the Minutes. Press the ► memory up button to advance by increments of one minute. Press the Date / Time Setting button to set the current minute. The Year flashes on the display.
- 7) Press the START / STOP button to turn the display off.

#### 3.2 Participant Instructions

Participants will be instructed in the proper application and removal, blood pressure measurement, use of the memory function, care and maintenance, and trouble shooting for common error codes of the Omron 780-HEM SMBP device during the clinic visit. Safety features will be reviewed. Review the SMBP Instructions to Participants and the HEM-780 Instruction Manual with participants.

Provide participants with a copy of the SBPM Participant Instructions and the JHS Blood Pressure Diary. Inform participants that they will be called in 2-6 weeks to assure that they are having no difficulties with SMBP measurement and to obtain their most recent readings from their monitor's memory.

##### 3.2.1 Preparing to Take a Measurement

Instruct participants to follow these recommendations in order to ensure a reliable blood pressure reading:

- 1) Avoid eating, smoking, and exercising for 30 minutes before taking a measurement. Rest for at least 5-15 minutes before taking the measurement
- 2) Avoid taking measurements during stressful times as stress may elevate the blood pressure
- 3) Take measurements in a quiet place
- 4) Remove tight fitting clothing from the right upper arm (Please note with the participant that this is DIFFERENT from what is written in the Instructions Manual accompanying the monitor)
- 5) Sit in a chair with your feet flat on the floor resting your right arm on a table so that the cuff is at the level of your heart
- 6) Remain still and do not talk during the measurement
- 7) Try to measure your blood pressure at the same time of day each time you measure it
- 8) Take three measurements one or more minutes apart at one sitting
- 9) Make sure to wait at least 1 minute between readings to allow arteries to return to pre-blood pressure measurement condition
- 10) Keep a record of readings from blood pressure and pulse for your health care provider.
- 11) Use the HEM-780 memory function to obtain an "average" of the last three blood pressures taken at one sitting
- 12) Record the average on the Blood Pressure Diary

Place the blood pressure main using on the table. Insert the AC Adapter into the back of the unit and plug it in to a 120V AC wall outlet. When disconnecting the AC Adapter, unplug it from the back of the monitor prior to unplugging it from the wall outlet.

### 3.2.2 Applying the Arm Cuff

The HEM-780 SMBP device is supplied with a ComFit cuff that accommodates all but the very largest arm sizes. Plug the air plug securely into the main monitor on the left side of the unit. The arm cuff will be applied to the participant's RIGHT arm, unless there are compelling reasons to do otherwise (for example, amputation, mastectomy, dialysis shunt, etc). Turn the palm of the right arm upward. Holding the grip on the cuff securely with the left hand, apply the cuff to the right upper arm so that the blue strip is on the inside of the arm and aligned with the middle finger. The bottom of the cuff should be approximately ½ inch above the elbow. Wrap the cuff firmly in place using the Velcro strip. Be careful not to rest the arm on the air tube as this will restrict the flow of air to the cuff, preventing it from inflating.

### 3.2.3 Taking a Measurement

1. Initiate a reading by pressing the START/STOP button. All display symbols will appear on the face of the monitor and the cuff will start to inflate automatically

SPECIAL CONDITIONS: If the participants' systolic blood pressure is known to be more than 220 mm Hg, press and hold the START/STOP button until the monitor inflates to 30 or 40 mm Hg higher than the suspected systolic blood pressure, taking care not to apply more pressure than necessary.

2. Inflation stops automatically and the measurement is started. As the cuff deflates, decreasing numbers appear on the display and the Heart Symbol (♥) flashes at every heart beat
3. The arm cuff completely deflates when the measurement is complete
4. The blood pressure and pulse are displayed
5. Press the START/STOP button. Rest for 1-3 minutes with feet flat on the floor and without talking or moving
6. Initiate a second and third reading by pressing the START/STOP button and following steps 1-4 above.
7. Press the ◀ memory down button. The average value symbol will display on the screen with the average blood pressure reading.
8. Record this reading in your Blood Pressure Diary

### 3.2.4 Using the Memory Function

The date and time is alternately displayed with the measurement values selected. Press the ◀ memory down button to display the most recent measurement value on the screen. Press the ▶ memory up button to display the oldest measurement values. Continue to press the down (or up) button repeatedly to display the next most recent (or next oldest) values.

To delete all values in the memory, hold the ◀ memory down button AND the STOP / START button at the same time for more than 2 seconds.

### 3.2.5 Error Codes

The monitor is designed to illustrate a pictorial code if there is a problem in taking a measurement. The following list contains a brief description of the event codes which appear on the monitor display.

**Table 5. Omron 780-HEM Error Codes, Causes, and Solutions**

Symbol	Cause	Correction
E	Monitor did not detect pulse rate	Remove the arm cuff. Refer to 13 in the Instruction Manual—“Applying the Arm Cuff.” Wait 2-3 minutes. Take another measurement.
EE	Cuff under-inflated	Remove the arm cuff. Read p 16 in the Instruction Manual – “Taking a Measurement.” Wait 2-3 minutes. Take another measurement.
E E	Cuff over-inflated	Remove the arm cuff. Read p 16 in the Instruction Manual – “Taking a Measurement.” Wait 2-3 minutes. Take another measurement.
	Batteries are worn	Replace the 4 batteries. Refer to p 8 in the Instruction Manual for battery installation directions.

Other troubleshooting tips include:

**Table 6. Omron 780-HEM Troubleshooting Tips**

Problem	Causes and Solutions
No power	Replace worn batteries
No display appears on unit	Check the battery installation for proper placement of the battery polarities
Measurements appear too high or too low	Blood pressure varies constantly. Many factors including time of day, how you wrap the cuff, stress may affect your blood pressure. Review the sections “Before Taking a Measurement” and “Taking a Measurement” in your Instructions Manual

### 3.2.6 Care and Maintenance of the Monitor

Instruct the participant to follow the directions listed below to keep her/his blood pressure monitor in the best condition and to protect it from damage

- 1) Keep the monitor in its storage case when it is not in use. Make sure that the AC Adapter is placed under the main unit so that it does not damage the display screen
- 2) Do not forcefully bend the arm cuff or the air tube. Do not fold tightly

- 3) Clean the monitor with a soft dry cloth using no abrasive or volatile liquids. Do not attempt to clean the cuff. Never immerse the unit or any of its components in water
- 4) Store the unit in a clean, dry place and do not subject it to extremes of heat or cold, humidity, or direct sunlight
- 5) Try not to subject the unit to strong shocks, such as dropping it on the floor
- 6) Remove the batteries if the unit is not used for 3 or more months
- 7) Use the unit in accordance with the Instruction Manual and only use authorized parts and accessories

### **3.2.7 Safety Information**

The Omron HEM-780 blood pressure monitor should be used only in accordance with the Instruction Manual accompanying the unit for the purpose of measuring blood pressure and pulse. The participant should complete the Product Registration form within 10 days of receiving the unit and mail it to:

Omron  
PO Box 174378  
Denver, CO 80217-4378

This will register the unit and enable the product warranty. Any attempt to disassemble or repair the unit or its components will void the user warranty.

Instruct the participant to follow her/his health care provider's recommendations regarding blood pressure. The unit is only intended for use in adults and should not be used with children or infants or persons who cannot express their intentions.

Instruct the participant not to:

- Use a cellular phone near the unit as it may result in operational failure
- Plug or unplug the AC Adapter unit with wet hands

### **3.3 Participant SMBP Follow Up**

The SMBP nurse will complete a telephone follow up with each participant to assure that s/he is not having any difficulties with using the equipment. During that call, the participant will be asked to provide information on the most recent readings taken with their monitor. Information regarding participant use of equipment, satisfaction, and blood pressure readings will be recorded on the Post Self Monitored Blood Pressure (ASB) form in accordance with the QxQs (Forms Appendix).



## APPENDICES



## Appendix 1 Check Procedures and Maintenance Instructions Random Zero Sphygmomanometer

1. Check cap of manometer column to be sure it fits properly and is tight. The O ring or seal must be seated correctly. Clean cap of any mercury (Hg) beads or dust. The cap should be firmly finger tight. Any time the mercury seems to 'bounce' in the column of either a standard manometer or random zero (R-Z) manometer, it may be due to a loose cap. Check the opening. If it becomes blocked, the mercury column falls too slowly due to a vacuum effect. This may result in false high readings and an erratically oscillating column. This procedure should be carried out for both standard manometers and R-Z's.
2. Remove back of case (two screws at top of face and two at bottom rear of case). Swing back from the left around the thumbscrew on the right side. Check for spring placement - it should be in line. Tighten all screws except the one holding the bellows plate in place.
3. Wrap an arm cuff around a bottle or can.
4. With reservoir valve open (newer models do not have a reservoir valve) and bellows valve closed, pump mercury to top of column (270-290 mmHg). If the mercury holds at a steady level for 15 seconds or drops 2-4 mm, that system is airtight.
5. With the high pressure still in the system, close the reservoir and disconnect cuff to see if that valve holds steady pressure. If a leak is discovered in the reservoir valve, remove hose and valve (with Allen wrench). Valve handle unscrews or lifts off. There are two O rings on the valve stem. Clean stem and replace O rings. Use stopcock grease in O rings and valve.
6. If the closed reservoir valve is tight, but there was a leak with it open, check the inflation assembly. There may be a leak in the bulb, valve, or cuff. To test the inflation assembly, immerse each section, especially valves and tubing connections in water while the pressure is high and watch for air bubbles. To test the tubing of the Hg reservoir, put soapy water on it. Most leaks occur at or near tubing connections or from valves. If a valve leaks sometimes a shot of silicone lubricant on the thumbscrew and worked in will solve the problem. Otherwise it may need to be replaced. Tubing leaks near a connector can be repaired by removing the connector, cutting off 1/2 to 3/4 inches and replacing the connector. Lubricate a sharp knife with soapy water to make the cut, and lubricate the cut tube to make it easier to reattach.
7. Turn R-Z with back toward you. With bellows valve open, retract mercury to just below the plexiglass valve chamber. Close the bellows valve, pump mercury to top and visually check that leakage does not occur at that valve point. If Hg rises into the chamber, the valve needs repair. Replacing O rings on that valve can be done locally if someone is qualified to do it. It is a more difficult job than on the reservoir valve. Otherwise it should be sent to Baum. A serious leak in this valve can affect blood pressure readings. Whenever the manometer tube seems dirty in the area of the 'zeros' or if the Hg seems to hang up there, the tube should be cleaned. A dirty tube can affect 'zero' readings. To clean tube, set cam at lowest zero. Pump up, close bellows valve, and release pressure. This leaves little mercury in the column. Tilt manometer, getting rest of mercury out of glass and into reservoir. Close reservoir valve. Lean manometer at angle so that no mercury is in glass. Remove the tube and clean tube and seats. Check to be sure that the rubber gaskets are seated properly. Replace tube. Only a qualified person in a controlled setting should do this procedure. The manometer is set in a catch basin so that no mercury can escape. There should be a rap-type vacuum pump available to pick up any small spills.

8. Check "maximum" and "minimum" zeros and of bellows and cam function. (This must be done only if there are doubts about the values of those zeros or functions; or if Hg has been added or lost.)
  - a. Release all pressure and open the bellows valve. The large thumb wheel with the black rubber "tire" and the cam against which it is pressed should turn freely without binding. If they do bind, bring in the R-Z.
  - b. Inflate the system while watching the large (about 2-1/4" diameter) disc above and to the left of the bellows valve chamber. (Bellows valve is still open.) As pressure rises one can see the disc, a piston, pushed toward the back plate until a ring around the center of the disc touches the forward rim of the cam. That rim is tapered, and thus determines how far the piston can move, depending on the position of the taper in relation to the ring at the center of the piston - a matter of change in normal operation of the R-Z. The distance that the piston can move before being stopped by the cam determines the volume of Hg in the bellows chamber; hence the volume of Hg left in the rest of the manometer.
  - c. To read "maximum" zero, release pressure with bellows valve still open. Turn the cam so that the point of its taper nearest the piston will be hit by the ring of the piston. (It may take an inflation and deflation or two before you find the correct cam position, which allows the minimum volume of Hg in the bellows chamber, hence maximum Hg in the rest of the system.) Inflate to about 200 mmHg, close the bellows valve, release pressure and read the zero as usual; this is the "maximum". Repeat the procedure once or twice, checking the cam position to make sure you get the same reading. Note that this is not a fixed value for if you were to inflate to 300 before closing the bellows valve, the reading would be lower; and inflation to 120-130 would give a higher value. For this reason, always record the maximum zero reading when taking blood pressures.
  - d. "Minimum" zero is measured as in c above, except that the cam is turned so that the piston can travel its maximum. It is usually nearly 20 mm lower than the "maximum" and should not be closer than about 4 mm to the 0 on the manometer tube scale.
  - e. Replace the rear case, putting it over the thumb wheel first. Start all four screws before tightening any. Take care not to cross thread.
  - f. After a series of blood pressure readings or before transport, open the bellows valve to drain Hg from that chamber, then close it and the reservoir valve. Between readings, the bellows valve should be left on "open" so that pressure on the bellows is not left in the device.

## Appendix 2 Maintenance Procedures for Standard Sphygmomanometer

The following checks should be conducted at least every month, and a log kept of the dates and the people carrying out the troubleshooting (see Appendix 4).

1. With the instrument placed flat on the table, and the inflation system disconnected, the level of mercury should read zero in the standard instrument. If the reading is either above or below the zero mark, mercury should be added or withdrawn until it does read zero. The top of the meniscus is on the zero line when the eyes are level with this line and the mercury is correctly adjusted.
2. The inflation system should then be reconnected, and the cuff rolled around a bottle and secured. The valve should be closed on the Air Flo system, and the instrument inflated until the mercury rises to 240 mmHg. The Air Flo valve should then be slowly opened and the mercury allowed to fall to 200 mmHg. The valve should then be closed; at which time the mercury column should remain stable. If the column continues to fall, there is an air leak, and the following step should be taken:
3. The system should be reinflated until the column rises to 200 mmHg. The tubing should be pinched at various locations to localize the area of the leak. Appropriate replacement of the tubing, cuff, or valve should be performed.
4. With the instrument inflated above full calibration, the screw cap should be examined for mercury leaks. If this happens, the screw cap should be tightened. If the leak persists or the mercury is seen at the bottom of the tube, the silicone rubber, which provides a seat for both ends of the glass tube, should be replaced.
5. With time, the mercury will become dirty and an oxide layer will be deposited on the inside of the glass tube. The instrument should be laid nearly on its side (on a tray) so that the mercury will return to the reservoir and none can be seen in the glass tube. The tube should be removed carefully and cleaned out using the long pipe cleaner supplied with the instrument. The tube should then be replaced and the zero level rechecked.

Since mercury is a toxic substance all maintenance procedures must be performed carefully and with attention to safety. Mercury should not be allowed to get in contact with rings and other jewelry.

(Maintenance instructions for the standard sphygmomanometer are adapted from those given for the MRFIT study in Controlled Clinical Trials, Vol. 7, No. 3 (Supplement), Sept. 1986.

### **Appendix 3 Check Procedures for Maintenance of the Omron HEM907XL Blood Pressure Equipment**

The following checks should be conducted at least every month, and a log kept of the dates and the people carrying out the troubleshooting (see Appendix 4).

1. Assemble the following equipment:
2. Connect the manometer, inflation bulb, cuff, and the monitor with the T-tube (see p 26 of the Omron HEM907XL Instruction Manual.
3. Tightly wrap the cuff over a sturdy cylinder
4. Release the valve of inflation bulb to remove the air inside the cuff completely
5. Set the MODE to "CHECK"
6. Close the valve of inflation bulb and inflate the cuff to the pressure to be checked, based on the manometer read
7. Compare the pressure values displayed on the monitor with the one on the manometer

**CHECK RESULT:** The accuracy of the monitor should be validated to  $\pm 3$  mmHg or 2% of standard manometer reading. If the result shows a difference exceeding this tolerance, contact Omron repair department (1-877-216-1336).

#### Appendix 4 Checklist for Biannual Observation of BP Technicians by BP Supervisor

BP Technician Code # \_\_\_\_\_ Observer Code # \_\_\_\_\_

Date Observed \_\_\_\_/\_\_\_\_/\_\_\_\_

Instructions: For each item, check "yes" or "no" in the space provided to indicate if the procedure is carried out correctly. Record any comments in the blank line between that item and the next. For certain items specific parts of the procedure which are important are listed separately. Supervisor should recheck all measurements and procedures.

	Yes	No
<b>ALL:</b>		
Measures arm for correct cuff size	( )	( )
Palpates brachial artery	( )	( )
Marks pulse point	( )	( )
Wraps cuff center of bladder over brachial pulse	( )	( )
Leaves subject for five minutes rest	( )	( )
Instructs on Posture	( )	( )
Full five minutes for rest allowed	( )	( )
Work station free of excessive noise	( )	( )
Explanation	( )	( )
Count radial pulse 30 seconds, record reading	( )	( )
<b>RANDOM ZERO AND COMPARABILITY STUDY</b>		
Finds Pulse obliteration point using standard manometer	( )	( )
Calculates peak inflation, standard manometer	( )	( )
Calculates peak inflation, R-Z	( )	( )
If computer is down use the formula (pulse obliteration pressure + R-Z maximum zero number + 30)		
Explanation	( )	( )
Connects R-Z tube to cuff	( )	( )
Sure reservoir lever open (newer devices have no lever)	( )	( )
Opens bellows valve and waits full 3 seconds for mercury to settle	( )	( )
Turns thumb wheel (down strokes only)	( )	( )

	<b>Yes</b>	<b>No</b>
Places stethoscope in ears	( )	( )
Inflates rapidly to R-Z peak	( )	( )
Counts full 5 seconds with pressure steady	( )	( )
Closes bellows knob	( )	( )
Places bell on brachial pulse	( )	( )
Deflates cuff 2 mmHg per second	( )	( )
Deflates cuff after 2 absent sounds	( )	( )
Records readings	( )	( )
Disconnects tubes	( )	( )
Reads zero value	( )	( )
Subtracts zero value from <u>each</u> BP reading, if using paper form	( )	( )
Instructs to hold arm vertical for full 5 seconds	( )	( )
Waits at least 30 seconds before proceeding	( )	( )
Repeats R-Z readings	( )	( )
Informs participant of average readings	( )	( )
<b>OMRON</b>		
Assure unit is properly plugged into wall unit	( )	( )
Push ON/OFF button to turn on power	( )	( )
Set the MODE for AVG (if off site)	( )	( )
Set the MODE for MANU if on site		
Set the P-SET to AUTO (if off site)	( )	( )
Set the P-SET to = Item 15 SBP-B (if on site)		
Wrap the proper size cuff on arm	( )	( )
Press the START button to take measurement	( )	( )
Records the first measurement	( )	( )
Records the second measurement	( )	( )
Records the average measurement (if off site)	( )	( )
Push the ON/OFF button to turn the power off	( )	( )

Inform the participant of the average reading ( ) ( )

Special Comments:

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**Appendix 5 JHS Monthly Log for Sitting Blood Pressure Station**

Month \_\_\_\_\_ Year \_\_\_\_\_

Weekly Check Procedures:

		Week				
		1	2	3	4	5
1.	Random-Zero Sphygmomanometer:					
	Date of Check	_____	_____	_____	_____	_____
A.	Check Tube for Oxide Dust	_____	_____	_____	_____	_____
B.	Check Cap for Tightness	_____	_____	_____	_____	_____
C.	Check Omron for Accuracy	_____	_____	_____	_____	_____

Procedures performed only if there appear to be problems:

- C. If mercury bounces even though the cap appears tight, remove cap, clean of any mercury beads, and check opening at top of tube for dust

Check Needed and Performed during weeks      1          2          3          4          5  
 (Circle number of weeks applicable)

- D. If tube appears "dirty" (oxidized mercury) remove cap, tip manometer to retract mercury, run pipe cleaner down, replace cap

Needed and Performed during weeks                      1          2          3          4          5  
 (Circle number of weeks applicable)

- E. List the problem encountered, the date, and the actions taken below:

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Monthly Check Procedures:

A. Accuracy Check on Random-Zero Sphygmomanometer (to be performed every 2 months):

Date last accuracy check performed: \_\_\_\_\_

Is an accuracy check due this month? ( ) Yes ( ) No

Date accuracy check performed, if due: \_\_\_\_\_

Problems found on accuracy check? ( ) Yes ( ) No

If yes, list problems found and corrective action taken:

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Random Zero Sphygmomanometer Check

Standard	200	170	140	100	60
Random Zero	_____	_____	_____	_____	_____
Zero	_____				
Corrected R-Z Measure*	_____	_____	_____	_____	_____

Corrected R-Z measure = [(Random-Zero) - Zero]

Note that this corrected R-Z measure must be within 2 mmHg of the standard.

B. Standard sphygmomanometer check (to be performed every two months)

Date of check: \_\_\_\_\_

A. Check cap for tightness \_\_\_\_\_

B. Check tube for oxide dust \_\_\_\_\_

C. Check that mercury is at zero with no pressure \_\_\_\_\_

List any problems found and corrective action taken:

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C. Accuracy check for Omron monitor (to be performed every two months)

Date of Check: \_\_\_\_\_

Problems found on accuracy check? ( ) Yes ( ) No

If yes, list problems found and corrective action taken:

\_\_\_\_\_  
\_\_\_\_\_

D. Measuring tape for arm circumference worn or stretched

Tape measure has been tested as part of Anthropometry station procedures. ( ) Yes ( ) No

If no, perform tape measure calibration check:

Check by holding the zero mark of the tape against the ruler used to measure standing height at the 150 cm. mark. If the 30 cm. mark on the tape used for arm circumference falls outside the range 119.5 to 120.5 on the standing height ruler it should be replaced.

Date of check: \_\_\_\_\_

Point on height ruler where 30 cm. on tape falls \_\_\_\_\_

## Appendix 6 Accuracy Check on the Random-Zero Sphygmomanometer

This check should be performed every two months, using a standard manometer and an Y connector. Check that the mercury level of the standard device reads zero with no pressure in the system. If it does, it should be treated as accurate and having an adequate supply of mercury.

To perform the accuracy check on the R-Z instrument, attach the two arms of the Y connector directly to the reservoirs of the R-Z and standard devices, using Latex tubing. Attach the base of the Y connector to a cuff with an Air Flo control valve and bulb. To attach the Latex tubing to the reservoirs or to a valve, it may be helpful to moisten the openings of the tubing to allow the tubing to slip onto the desired parts. Wrap the cuff around a bottle or can.

First open the Air Flo valve to insure that all pressure is out of the system. Check the zero level of the standard device. Next, turn the R-Z valve to the OPEN position. Close the Air Flo valve and inflate both machines until the mercury level in the standard device is at the 250 mmHg level. After 5 seconds, close the R-Z valve. Allow the mercury in the standard manometer to drop to 200 mmHg. Record the exact levels of mercury in the RZ and standard device. Repeat the procedure at 170 mmHg, 110 mmHg, 80 mmHg and 60 mmHg. Release the air from the Air Flo valve. When the mercury in the R-Z instrument has stabilized and the standard is at zero, record the zero reading from the R-Z. Subtract this value from the R-Z readings.

The results should agree with the comparable readings on the standard instrument within  $\pm 2$  mmHg. If this agreement is not found at all levels, repeat the procedure. If the disagreement is constant, stop using the instrument and contact the manufacturer.

Worn parts should only be changed as necessary (when there is disagreement between the R-Z and standard devices). Only those parts in the parts kit should be changed. No attempt should be made to change the rubber diaphragm or bellows.

Note: These instructions are adapted from the procedures employed by the MRFIT study, described in Controlled Clinical Trials, Vol. 7, No. 3 (Supplement), September 1986.

**Appendix 7 Form for Recording Simultaneous Blood Pressure Observations on a Volunteer by Two Technicians**

Instructions:

Biannually, each technician should be part of a pair of technicians who simultaneously measure blood pressure using an Y-tube on a volunteer (not a JHS participant). Each technician should separately record his/her measurements on a standard paper JHS SBP form. The blood pressure supervisor should then transfer the results to this form and calculate the differences between the two sets of measurements. If the difference on any individual measurement is greater than 4 mmHg, or if the averages of the two readings for each technician differ by more than 3 mmHg, the supervisor should indicate the corrective action taken on this form. Any further sets of simultaneous measurements for a given pair should appear on a new form.

Technician IDs: 1st ID: \_\_\_\_\_ 2nd ID: \_\_\_\_\_ Date: \_\_\_\_\_

	1st Technician	2nd Technician	Difference
a. Initial arm circumference (cm)	_____	_____	_____
b. Initial cuff size selected	_____	_____	_____
c. Pulse Obliteration Pressure	_____	_____	_____
d. First SBP	_____	_____	_____
e. First DBP	_____	_____	_____
f. First Zero Reading	_____	_____	_____
g. First Net SBP Corrected for Zero	_____	_____	_____
h. First Net DBP Corrected for Zero	_____	_____	_____
i. Second SBP	_____	_____	_____
j. Second DBP	_____	_____	_____
k. Second Zero Reading	_____	_____	_____
l. Second Net SBP Corrected for Zero	_____	_____	_____
m. Second Net DBP Corrected for Zero	_____	_____	_____
n. Average Net SBP	_____	_____	_____
o. Average Net DBP	_____	_____	_____

ACTION TAKEN IF DIFFERENCES BETWEEN TECHNICIANS EXCEED LIMITS SPECIFIED:

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**APPENDIX 8                    JHS OMRON AND RZ COMPARISON CHECK SHEET****1. Equipment:**

- Standard sphygmomanometer
- Single stethoscope with bell
- Double Y-stethoscope with bell
- Y-connector
- Random Zero
- Standard cuffs
- *Omron* HEM907XL
- *Omron* cuffs

**2. Staff:**

Two BP technicians: Each will record three measurements on Form 2C for use by the Random Zero (RZ) technician and the *Omron* technician. Three BP measurements will be made on each BP Comparability Study participant. The technicians will alternate observations using the RZ and *Omron*. Technician No. 1 will measure a participant's BP three times with the RZ, and Technician No. 2 will measure the participant's BP three times with the *Omron*. The next participant would have Technician No. 2 measure BP three times with the RZ, and Technician No. 1 measure BP three times with the *Omron*.

**3. Procedures:**

Follow procedures on the other side of this card. Repeat steps for measurements 2 and 3 and record readings on Form 2C where indicated for 2<sup>nd</sup> and 3<sup>rd</sup> measurements.

<b>RZ Technician</b>	<b>Omron Technician</b>
1 Measure and record participant's arm circumference (Q5) with <i>Gulick II</i> tape.	
2 Select and apply appropriate size standard cuff according to the participant's arm measurement.	
3 Determine and record the <b>Pulse obliteration level</b> using the standard sphygmomanometer and cuff with fingers on the radial artery (Item 13).	
4 <b>Add 30 mm</b> to the Pulse Obliteration level and record (Item 14).	
5 <b>Record the RZ maximum value</b> for the RZ in use (#3). Sum the values from Item 13 and Item 14 to determine the <b>Peak Inflation level</b> for the <b>Omron P-Set level setting</b> (Item 15) (Done automatically by Data Entry System if using direct data entry).	Apply the <i>Omron</i> appropriate sized cuff to the participant's arm with the arrow at the brachial artery (same size used during the core exam Blood Pressure measurement).
6 Attach Y-connector to the RZ, the <i>Omron</i> , and an appropriately sized <i>Omron</i> cuff with small connector removed so that the tubing can be attached to a Y-connector.	
7 After the <i>Omron</i> is turned on, turn the bellows valve dial on the RZ to <b>OPEN</b> .	Turn on the <i>Omron</i> . Turn the P-SET dial on the <i>Omron</i> to the P-Set level estimated in #5 (RZ) above. Turn the MODE on the <i>Omron</i> to <b>MANUAL</b> .
8 Place the double Y-stethoscope earpieces into ears.	Place the double Y-stethoscope earpieces into ears, holding the bell over participant's artery.
9 <i>Omron</i> will inflate the cuff for both devices, and the mercury column in the RZ will rise.	Press <b>START</b> on the <i>Omron</i> , cuffs will inflate.
10 When the mercury column on the RZ has dropped 20 mm from its highest point, turn the RZ dial to <b>CLOSE</b> .	Watch the <i>Omron</i> .
11 Listen for the onset of the 1 <sup>st</sup> (sounds) and 5 <sup>th</sup> (disappearance) Korotkoff phase sounds.	Listen for the onset of 1 <sup>st</sup> (sounds) and 5 <sup>th</sup> (disappearance) Korotkoff phase sounds.
12 When the cuff is completely deflated, record readings from the RZ (Q6 for 1 <sup>st</sup> reading). Read and record the RZ (Q7) and subtract it from the RZ systolic and diastolic readings, recording the corrected measurement (Q8).	When the cuff is completely deflated and the <i>Omron</i> is at "0," record the systolic and diastolic BP levels from the <i>Omron</i> (Item 24 for 1 <sup>st</sup> reading).
13 Open the RZ dial and turn the thumb wheel.	

Appendix 9

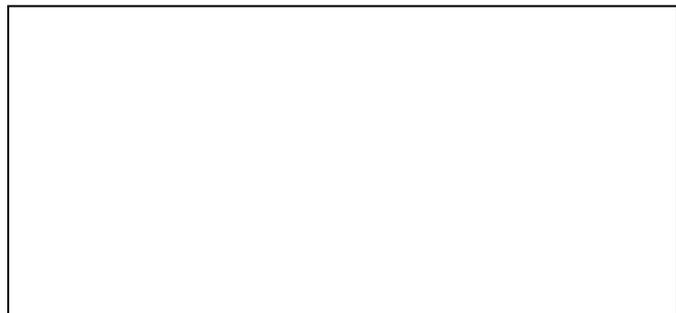
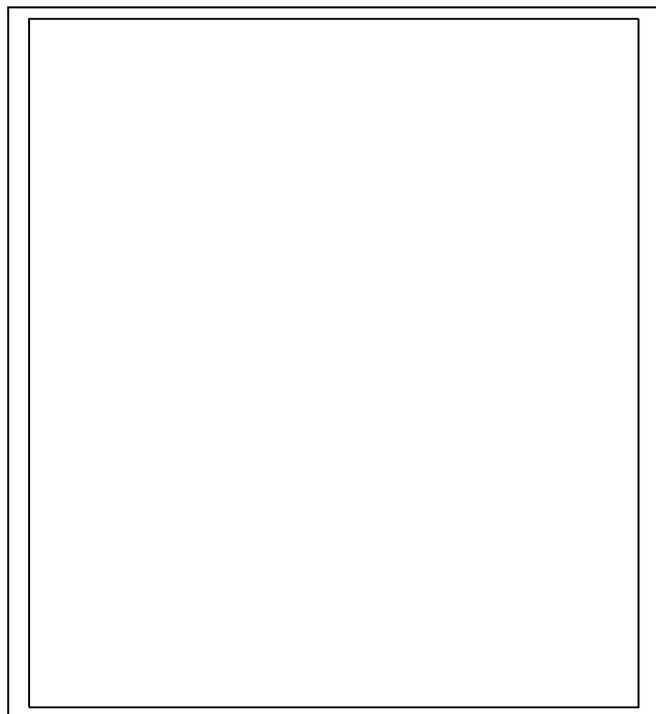
# OmRON®

## INSTRUCTION MANUAL

### IntelliSense™ Blood Pressure Monitor Model HEM907XL

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## EXEMPTIONS

OMRON does not accept liability and warranty becomes void under the following circumstances:

1. When persons, not authorized by OMRON, perform repairs or modifications of this product.
2. When use and/or operation of this device is adversely effected by a device not manufactured by OMRON.
3. When use and/or operation of this device is adversely effected by use of parts, not authorized by OMRON, to repair or modify this product.
4. When Notes on Safety or Instructions for Use contained in this manual are not followed.
5. When use and/or operation of this device is effected by an act of God, such as fire, earthquake, flood or other natural disasters.

1. The product and contents of this Instruction Manual may be changed without prior notice.
2. We have prepared the contents of this Instruction Manual thoroughly. However, if an inadequate description or error is found, please let us know.
3. Reproducing or copying any or all of this Instruction Manual without OMRON's written consent is prohibited.

## NOTES ON SAFETY

- The warning signs and the sample icons shown here are listed to insure safe and accurate use.
- The icons and meanings are as follows.

Warning sign	Contents
	Indicates matters in which death or severe bodily damage may arise as a result of incorrect handling.
	Indicates matters in which bodily harm or material damage* may arise as a result of incorrect handling.
* Natural disasters refers to a wide range of damage involving your house, household goods, domestic animals, and pets.	
<b>Examples of signs</b>	
	The  icon indicates caution (including warning and danger). Matters involving actual caution are indicated by text or pictures in or near  . The pictured icon refers to "caution for flammability".
	The  icon indicates prohibitions (what you cannot do). Matters involving actual prohibitions are indicated by text or pictures in or near  . The pictured icon refers to "prohibition to disassemble".
	The  icon indicates something that is compulsory (always follow). Matters involving actual compulsory actions are indicated by text or pictures in or near  . The pictured icon refers to "unplugging the power source plug".
<b>Warning</b>	
	Self diagnosis of measured results or treatment is dangerous. Please follow the instruction of the doctor or healthcare provider.
	If cuff inflation does not stop, remove the cuff or pull out the air tube from the main unit.
	If battery fluid gets into your eye or comes in contact with skin, wash the effected area with water repeatedly. Immediately consult a doctor for treatment.
	Do not wrap the cuff over an arm to which intravenous injection or transfusion is being conducted, or when otherwise contraindicated.
	Do not connect the air tube or the cuff to other equipment which is connected to an intracorporeal organ. Air embolisms may result.
	Do not use this unit in the presence of flammable gas or anesthetics or in a high pressure oxygen room or oxygen tent.
	Do not use the battery pack for devices other than for this unit.
	Do not disassemble the battery pack.
	Do not touch the AC adapter with wet hands.

## NOTES ON SAFETY

<b>⚠Caution</b>	
<p>Unplug the AC adapter from the electric outlet if this unit is unused for an extended period of time.</p> <p>Unplug the AC adapter from the electric outlet when installing, removing, or cleaning the unit.</p>	
<p>Confirm readings with a stethoscope when an irregular pulse wave is displayed or when the measured value is questionable or erratic.</p> <p>Use an AC adapter indicated for use with a power supply of 110 VAC.</p> <p>Do not share an electric outlet with other unit or electric appliance.</p> <p>After cleaning this unit, dry it well before plugging the AC adapter in the electric outlet.</p> <p>If this unit fails to perform as indicated, discontinue use, turn off the unit, unplug the AC adapter from the electric outlet, and contact OMRON's repair department.</p>	
<p>Do not disassemble or modify this unit.</p>	
<p>Do not use any cuff other than the models exclusive for this unit.</p> <p>Do not use this unit on infants.</p> <p>Do not use this unit on patients using a pump oxygenator.</p> <p>Do not use an AC adapter or battery pack not specified for this unit.</p>	

## NOTES ON SAFETY

<b>⚠Caution</b>	
<p>Do not use a cellular phone near this unit.</p> <p>Do not use this unit in a vehicle.</p> <p>Do not install the parts and/or instruments not specified for this unit.</p> <p>Do not use a broken power cord or AC adapter.</p>	
<p>Do not install or store this unit where it may come in contact with water or liquid medication.</p> <p>This is a Class II device with double isolation. Earth pin is not for protective purposes.</p>	
<b>General advice</b>	
<p>Do not place or put anything on this unit.</p> <p>Do not drop this unit.</p> <p>Turn off power to the unit and unplug the AC adapter from the electric outlet before moving the unit.</p> <p>Read the instruction manual of the other devices to be used at the same time with this unit, to understand and be aware of the interaction between the devices.</p> <p>When using the unit</p> <ul style="list-style-type: none"> <li>• Do not inflate the cuff without being wrapped over the arm.</li> <li>• Do not use a damaged cuff</li> <li>• Be sure that patients do not touch the Buttons of this unit.</li> </ul> <p>After using the unit</p> <ul style="list-style-type: none"> <li>• Do not disinfect this unit by autoclave or gas sterilization (ETO, glutaraldehyde, or high concentration ozone).</li> </ul> <p>Do not install or store this unit in the following places.</p> <ul style="list-style-type: none"> <li>• Under the direct sunlight,</li> <li>• Dusty or salty environment</li> <li>• Places having slope, vibration, and/or shock</li> <li>• Storage of chemicals or where combustible gas may be generated,</li> <li>• Under high temperature and high humidity.</li> </ul>	

## NOTES ON SAFETY

### Maintenance and inspection

1. Check the unit operation on regular basis.
2. If this unit has not been used for more than three months, be sure to check that this unit operates normally and safely before use.

### Troubleshooting

If device error 9 (Erf) occurs, take the following procedure promptly:

- (1) Remove the cuff from the patient's arm.
- (2) Turn off the power of the unit and unplug the AC adaptor from the electric outlet.
- (3) Display "Out of use" on this unit so that it cannot be used.
- (4) Contact Omron for repair service (1-877-216-1336).

## FEATURES OF THE PRODUCT

OMRON IntelliSense™ Blood Pressure unit, Model HEM-907XL is developed to measure blood pressure and pulse rate accurately and simply in a doctor's office, examination room, or patient bedside.

### • One-button operation

Simply wrap the cuff and push the START Button. Blood pressure and pulse rate are automatically measured by the oscillometric method.

### • Automatic pressure setting

When the P-SET (Pressure Setting) Knob is set to "AUTO," the unit will automatically inflate the cuff to the optimal pressure according to each patient's blood pressure. Pre-setting inflation level is not necessary.

### • Noiseless operation

This unit operates so quietly that it can be used in the patient room at night.

### • Average Mode (AVG Mode)

In the AVG Mode, this unit will automatically measure for two or three times. The average of systolic and diastolic blood pressures and pulse rate are displayed. Each measurement can also be shown individually. The number of measurements, waiting time before first measurement, and the interval can be changed.

### • Auscultation Mode (MANU Mode)

You can measure auscultatory blood pressure by using a stethoscope, with automatic cuff inflation and deflation by this unit. Because the cuff pressures during deflation are displayed digitally and synchronized with the heart beat, they can be read with accuracy. After taking systolic reading you can accelerate cuff deflation to shorten measurement time.

### • Large and easy to read display

Large and easy to read figures are displayed on the LCD display.

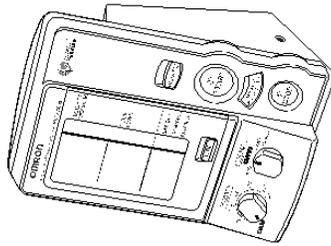


The IntelliSense™ Monitor inflates the cuff to the ideal level with each use. No adjustments are required by the user to select an inflation level. This is especially convenient for hypertensive users and for people with certain arrhythmia or heart disorders, because their blood pressure is likely to fluctuate. The advantage is Personalized Inflation for maximum comfort.

# COMPONENTS OF THE PRODUCT

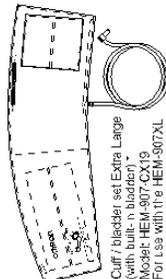
## Main unit

IntelliSense™ Blood Pressure Monitor, Model HEM-907XL

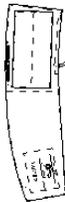


## Accessories

(Included and also available separately)



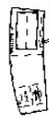
Cuff / bladder set Extra Large with built-in bladder\*  
Model: HEM-907-CXL19  
For Use with the HEM-907XL unit only.  
Applicable arm circumference: 17" to 20" (42 to 51 cm)



Cuff / bladder set Large (with built-in bladder)\*  
Model: HEM-907-CL19  
Applicable arm circumference: 13" to 17" (32 to 42 cm)



Cuff / bladder set Medium (with built-in bladder)\*  
Model: HEM-907-CR19  
Applicable arm circumference: 9" to 13" (22 to 32 cm)

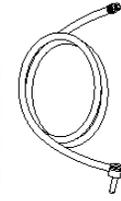


Cuff / bladder set Small (with built-in bladder)\*  
Model: HEM-907-CS19  
Applicable arm circumference: 7" to 9" (17 to 22 cm)

AC adapter  
Model: HEM-AC-J

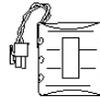


Air tube 1.0 m (33.13")\*  
Model: HEM-TUBE-100X



The air tube is available for the large, medium or small cuff size. It is NOT for use with the exchange cuff size.

Battery pack (48H607H)  
Model: HEM-907-PBAT



Instruction Manual

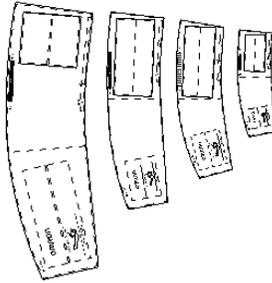


Items identified with an asterisk (\*) are consumables and not covered by the guarantee.

# COMPONENTS OF THE PRODUCT

## Options (no. included)

Cuffs without bladder\*



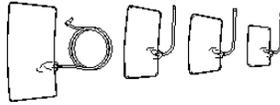
Extra Large Cuff  
For use with the HEM-907XL only.  
Model: HEM-907-CUJFX

Large Cuff  
Model: HEM-907-CUJFL

Medium Cuff  
Model: HEM-907-CUJFM

Small Cuff  
Model: HEM-907-CUJFS

## Bladders\*

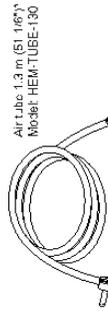


Extra Large Bladder  
For use with the HEM-907XL only.  
Model: HEM-907-BLDRX

Large Bladder  
Model: HEM-907-BLDRL

Medium Bladder  
Model: HEM-907-B-DRM

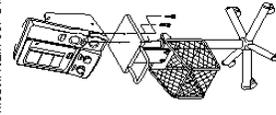
Small Bladder  
Model: HEM-907-BLDSB



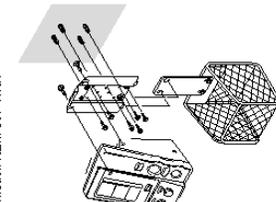
Air tube 1.3 m (51.183")  
Model: HEM-TUBE-130

The air tube is available for the large, medium or small size cuff. It is NOT for use with the extra-large cuff size.

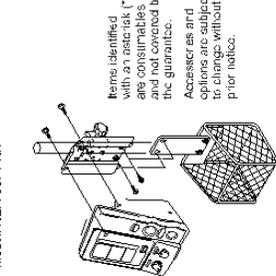
Exclusive Stand  
Model: HEM-907-STAND



Wall hanging kit  
Model: HEM-907-WKIT



Pole mounting kit  
Model: HEM-907-PKIT

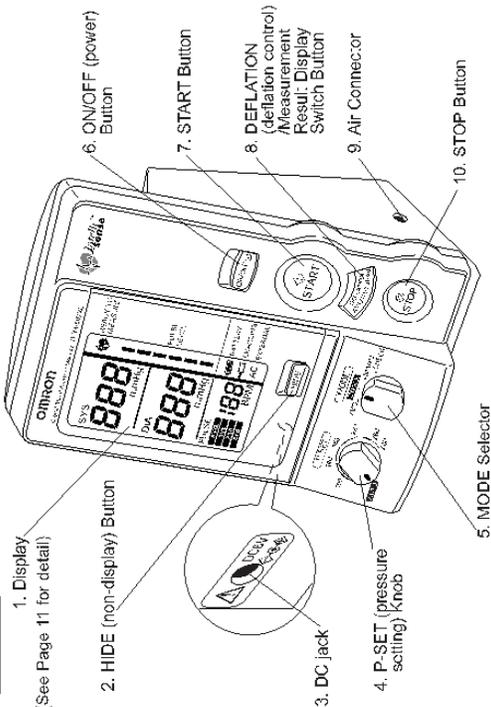


Items identified with an asterisk (\*) are consumables and not covered by the guarantee. Accessories and options are subject to change without prior notice.

# FEATURES AND FUNCTIONS

## Names of the Parts

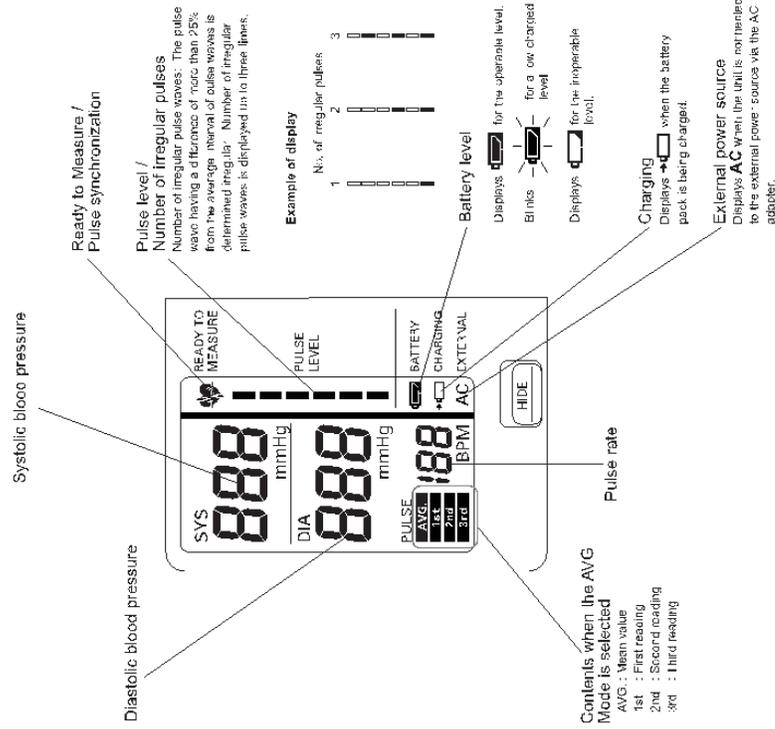
### Main unit



1. **Display:** Displays blood pressure and, pulse rate readings, and oscillation pulse level.
2. **HIDE Button:** Switches display and non-display of measured results.
3. **DC Jack:** Connects the AC adapter.
4. **P-SET (pressure setting) Knob:** In the AUTO position, inflation level is automatically set. Otherwise, inflation level can optionally be set manually between 100 and 280 mmHg.
5. **MODE Selector:** Selects the operation mode.
  - One-time Measurement Mode (SINGLE Mode): Measurement with automatic inflation.
  - Average Mode (AVG. Mode): Automatically measures two (or three) times consecutively.
  - Auscultation Mode (MANU Mode): Automatic inflation, automatic deflation, and pressure display for auscultation (does not measure blood pressure).
  - Check Mode (CHECK Mode): Checks the accuracy of pressure display. Displays only pressure.
6. **ON/OFF (power) Button:** Turns on or off the unit.
7. **START Button:** Starts the measurement.
8. **DEFLATION (deflation control) / Measurement Result Display Switch Button:**
  - In the MANU Mode, deflates the cuff by approximately 5 to 10 mmHg with each push during deflation.
  - In the AVG Mode, switches the display of average values and the measurement results with each push.
9. **Air Connector:** Connects the air tube.
10. **STOP Button:** Stops the measurement and deflates air rapidly.

# FEATURES AND FUNCTIONS

### Display



# FEATURES AND FUNCTIONS

## Functions setting

### (1) Inflation level setting

**AUTO (Automatic setting):** Can be used when the SINGLE, AVG, or MANU Mode is selected. The unit estimates the systolic blood pressure during inflation and inflates to a proper cuff pressure (approximately 30-40 mmHg above the patient's systolic pressure).

**Manual level setting:** Inflation level can be set manually between 100 and 280 mmHg. Set the level to 30 to 40 mmHg higher than the expected systolic pressure.

- To set the P-SET to "AUTO", turn the P-SET Knob counterclockwise as far as it goes until you can hear a click.
- If the inflation level may not be set automatically when the systolic blood pressure is more than 220 mmHg. Use the manual level setting.
- If the cuff has not been inflated to the necessary level, it may be inflated automatically.

### (2) Non-display function

Use to prohibit the display of measurement results. However, the cuff pressure during measurement is displayed. This function can be used in the SINGLE and AVG Modes.

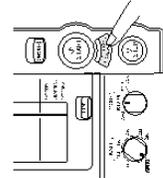
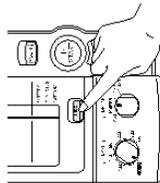
By pushing the  Button, display or non-display of status is switched alternately.



### (3) Manual deflation control

Accelerate deflation by pushing the DEFLECTION (deflation control) / Measurement Result Display Switch Button during deflation in the measurement by the MANU Mode.

With each push of the  Button, cuff is deflated rapidly in increments of 5 to 10 mmHg.



# FEATURES AND FUNCTIONS

List of Functions for each Mode

Function	Single (SINGLE) Mode	AVG Mode	MANU Mode	Check (CHECK) Mode
Inflation level setting	●	●	●	—
Man. deflation control	—	—	—	●

### (4) AVG Function setting

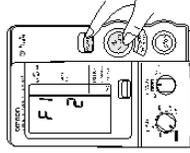
You can set the number of measurements, the waiting time until the 1st measurement, and the measurement interval for the AVG Mode.

Function #	Items to set	Set value
F1	Number of measurements	2 times or 3 times
F2	Waiting time until the start of 1st measurement	0 sec, 3 min, 5 min, or 10 min.
F3	Measurement interval	5 sec, 30 sec, 1 min, or 2 min.

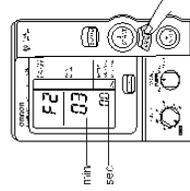
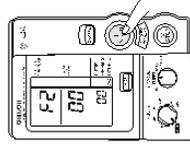
Note: The bold letters represent the factory-set values.

### Procedure to change the set values

1) When the power is OFF, push the ON/OFF (power) Button for more than three seconds while holding the START Button; F1 is displayed.



2) Push the START Button and select the function to set from F1 to F3. Each time you push the START Button, the functions change in the order of **F1** → **F2** → **F3**.



3) Push the DEFLECTION (deflation control)/Measurement Result Display Switch Button and change the set values.

4) When the setting is finished, push the ON/OFF (power) Button to turn off the power. The setting is changed.

## HOW TO APPLY THE CUFF

The cuff of OMRON IntelliSense™ Blood Pressure Monitor HEM-907XL plays an important role of collecting the information on blood vessels. Please wrap the cuff according to the procedure, below.

**Warning**

- Do not wrap the cuff over an arm to which intravenous injection or transfusion is being conducted, or when otherwise contraindicated.
- Do not connect the air tube or the cuff to other equipment which is connected to intracranial organ. Air embolisms may result.

**General advice**

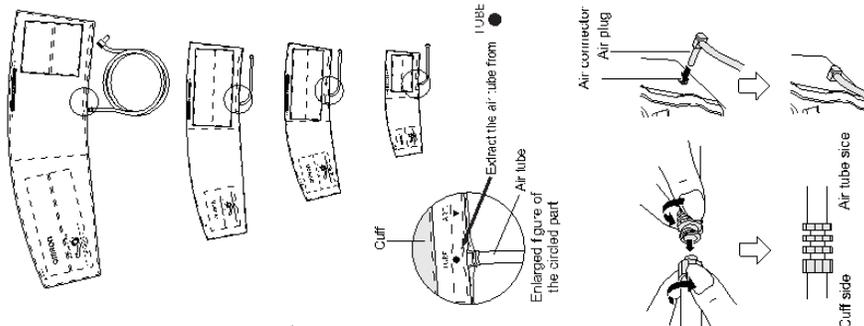
- Do not inflate the cuff without being wrapped over the arm.
- Do not use a damaged cuff.

1. Select the cuff according to the arm size

Arm circumference	Name of the cuff
(7" - 9") 17-22 cm	F-EM-907-CS19 (Small)
(9" - 13") 22-32 cm	F-EM-907-CR19 (Medium)
(13" - 17") 32-42 cm	F-EM-907-CL19 (Large)
(17" - 20") 42-50 cm	F-EM-907-CX19 (Extra Large)

• Check the following before applying the cuff.

- 1) The bladder is correctly installed in the cuff.
- 2) The bladder is not twisted inside the cuff.
- 3) The bladder tube is protruding from the cuff as shown in the Figure on the right.



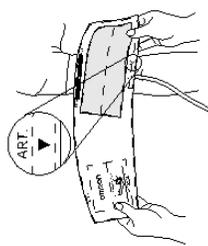
2. Connect the air tube securely.

- To use the cuff in small, medium or large size
  - Connect the air tube to the main unit by securing the air plug to the base of the air connector.
  - Securely connect the air tube and the cuff/bladder set by rotating the luer connection as shown in the Figure on the right.
- To use the cuff in extra large size only
  - The extra large cuff comes with an air tube with an integrated air plug. Connect the air tube of the cuff to the air connector securely when connecting to the main unit.

## HOW TO APPLY THE CUFF

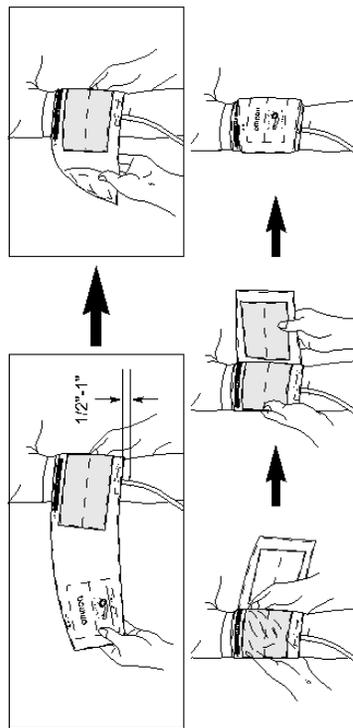
3. Place the right or left hand of the patient with the palm of hand facing upward.

4. Align the Artery Position Mark  with the brachial artery.



5. Wrap the cuff snugly using both hands and securely fasten it with the Velcro™ tape. At this time, the lower edge of the cuff must be placed 1/2" to 1" above the inner side of elbow joint.

- If the INDEX is positioned outside the RANGE, select the cuff suitable for the patient's arm circumference and wrap it again.
- Wrap the cuff so that you can insert only one finger between the cuff and arm.



6. Keep the level of the cuff at the same level as the heart during the measurement.

## HOW TO USE THE POWER SOURCE

### How to use the AC adapter

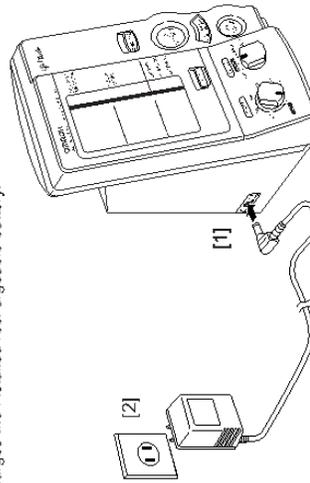
<b>⚠ Warning</b>	Do not use this unit in the presence of flammable gas, or anesthetics, or in a high pressure oxygen room or oxygen tent.
<b>⚠</b>	Do not touch the AC adapter with wet hands.

<b>⚠ Caution</b>	Be sure to use the AC adapter from the power supply of 110 VAC.
<b>⚠</b>	Do not install or store this unit where it may come in contact with water or liquid medication. This is a Class II device with double insulation. Earth pin is not for protective purposes.

<b>General advice</b>	<ul style="list-style-type: none"> <li>Read the instruction manual of the other devices to be used at the same time with this unit to understand and be aware of the interaction between the devices.</li> </ul>
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Connect the AC adapter to the DC jack of the main unit [1] and the electric outlet [2].

NOTE: When the AC adapter is connected and the unit is turned off, the AC adapter charges the installed rechargeable battery.

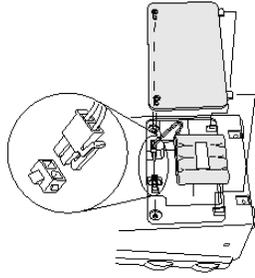


## HOW TO USE THE POWER SOURCE

### Installation and Replacement of Battery Pack

<b>⚠ Warning</b>	If battery fluid gets into your eye or comes in contact with skin, wash the affected area with water repeatedly. Immediately consult a doctor for treatment.
<b>⚠</b>	Do not use the battery pack for devices other than for this unit. Do not disassemble the battery pack.

1. Remove both screws on the upper portion of the battery cover of this unit, and remove the cover.
2. Disconnect the old battery pack from the connector and replace with a new one.
3. Install the battery cover and fasten it with both screws. Be careful not to pinch the lead wire.
4. Connect the main unit to the AC adapter to charge the new battery. The battery is not charged when you purchase the monitor. When you use the battery for the first time, charge it for more than twelve hours before use.



## HOW TO USE THE POWER SOURCE

### Battery life

- You can use the unit for approximately three hundred measurements with one charge.
- Approximate life of battery is two years. However the battery life from each charging may be shortened depending on the state of using. If the interval between charging becomes short and the  icon appears frequently, replace it.

### Charging time

- At approximately five seconds after connecting the AC adapter, the unit will start battery charging automatically.
- While the battery is being charged, the  icon turns on.
- The battery can be completely charged in approximately twelve hours.

### Battery low

- When the  icon starts to blink, twenty to thirty measurements remain on the battery. However if the Battery Low Mark starts to blink, charge it soon.
- If the  icon is displayed, the battery is low and the unit cannot operate. Please charge the battery.

### Automatic Power Off

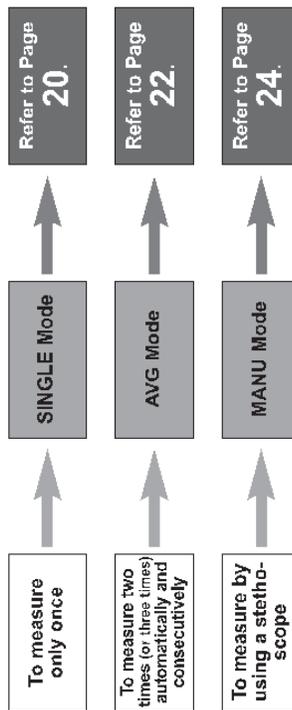
- When using the unit with the battery, the unit will turn off automatically after five minutes of inactivity.
- While the AC adapter is connected, the Auto Power Off function does not work.

## HOW TO MEASURE BLOOD PRESSURE

<b>⚠Warning</b>	<b>!</b>
If cuff inflation does not stop, remove the cuff or pull out the air tubes from the main unit.	
<b>General advice</b>	
• Patients should not touch the unit.	

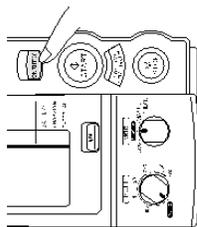
<b>⚠Caution</b>	<b>!</b>
Confirm readings with the stethoscope when an irregular pulse wave is displayed or when the measured values are questionable or erratic.	
Do not use a cellular phone near this unit. Do not use this unit in a vehicle.	

### List of Measurement Modes

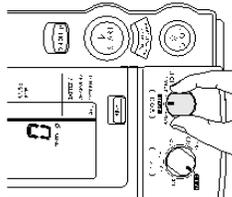


## HOW TO MEASURE BLOOD PRESSURE (IN SINGLE MODE)

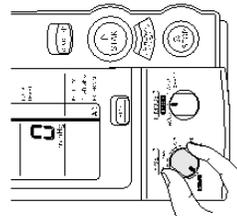
1. Push the ON/OFF (power) Button to turn on the power.



2. Set the MODE Selector to "SINGLE".



3. Set the P-SET (inflation level) Knob to "AUTO" or to the target pressure value.

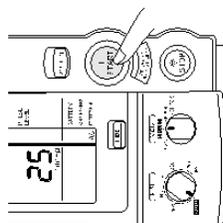


4. Measure the patient's arm size, and wrap appropriate cuff over the patient's arm. (Refer to Pages 14 and 15.)

## HOW TO MEASURE BLOOD PRESSURE (IN SINGLE MODE)

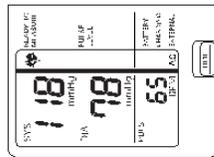
5. Push the START Button to start the measurement.

- Do not push the START Button without wrapping the cuff.
- If you want to stop measurement, push the STOP Button. The cuff will rapidly deflate.

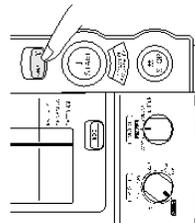


6. The measurement results are displayed.

- While the battery pack is in use, the monitor will turn off automatically after five minutes of inactivity and the display (measurement results) will disappear. (Automatic Power Off)

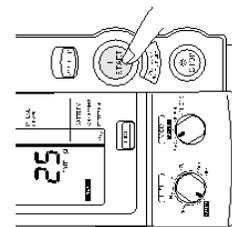


7. Push the ON/OFF (power) Button to turn off the power.



If the monitor determines that the pressure value is not correct, an error display appears (Er1 to 9). In this case, refer to Page 28 and start the measurement again.

## HOW TO MEASURE BLOOD PRESSURE (IN AVERAGE MODE)

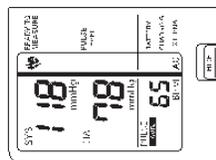


5. Push the START Button to start the measurement.

After the pre-select waiting time, the unit takes the 1st measurement.

After displaying the results of 1st measurement, subsequent measures occur automatically at the specified intervals.

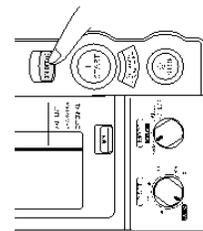
- For setting the number of measurements, the waiting time until the 1st measurement, and the interval, refer to Page 13.
- If you want to stop measurement, push the STOP Button. The unit will rapidly deflate.
- If an error occurs during measurement, the monitor will automatically start measurement again. If a second error occurs, measurement will automatically stop.
- Do not push the START Button without wrapping the cuff.



6. The measurement results are displayed.

After all the measurements are finished, average values will be displayed.

Each time the DEFLATION (deflation control) / Measurement Result Display Switch Button is pushed, the measurement results for each reading and the average value will be displayed.



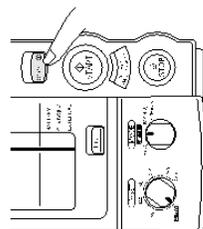
- While the battery is in use, the monitor will turn off after five minutes of inactivity and the display (measurement results) will disappear. (Automatic Power Off)

7. Push the ON/OFF (power) Button to turn off the power.

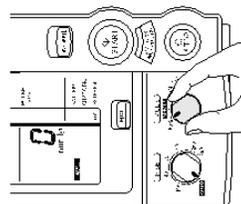
If the monitor determines that the pressure value is not correct, an error display appears (Er1 to 9). In this case, refer to Page 28 and start the measurement again.

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## HOW TO MEASURE BLOOD PRESSURE (IN AVERAGE MODE)



1. Push the ON/OFF (power) Button to turn on the power.

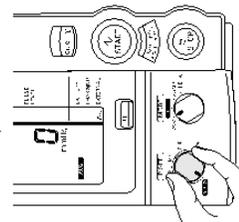


2. Set the MODE Selector to "AVG".

The factory-set values are set as follows:

- Number of measurements: 2
- Waiting time until the 1st measurement: 0 sec.
- Interval: 1 min.

To change these factory-set values, refer to Page 13.



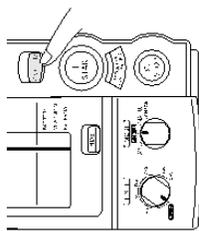
3. Set the P-SET (inflation level setting) Knob to "AUTO" or the target pressure value.

4. Measure the patient's arm size and wrap appropriate cuff over the patient's arm. (Refer to Pages 14 and 15.)

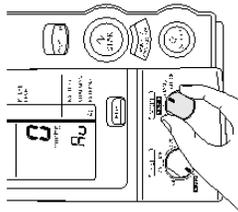
22

## HOW TO MEASURE BLOOD PRESSURE (IN MANUAL MODE)

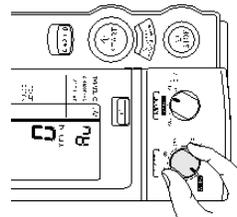
1. Push the ON/OFF (power) Button to turn on the power.



2. Set the MODE Selector to "MANU".



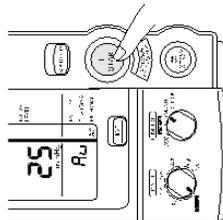
3. Set the P-SET (inflation level setting) Knob to "AUTO", or the target pressure value.



4. Measure the patient's arm size and wrap appropriate cuff over the patient's arm. (Refer to pages 14 and 15.)

## HOW TO MEASURE BLOOD PRESSURE (IN MANUAL MODE)

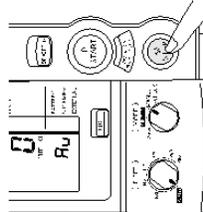
5. Place the stethoscope on the patient's arm.



6. Push the START Button to start the measurement.

- Do not push the START Button without wrapping the cuff.
- Do not squeeze or press the cuff during the measurement.
- If you want to inflate again after the start of deflation, push the START Button.
- If you want to accelerate deflation after the start of deflation, push the DEFLATION (deflation control) / Measurement Results Display Switch Button. Each time the Button is pushed, cuff is deflated rapidly in increments of 5 to 10 mmHg.

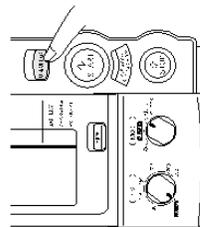
7. Take the readings.



8. Push the STOP Button to remove air inside the cuff.

- The unit does not automatically deflate in the MANU Mode.

9. Push the ON/OFF (power) Button to turn off the power.



If the monitor determines that the pressure value is not correct, an error display appears (Er1 to 9). In this case, refer to Page 28 and start the measurement again.

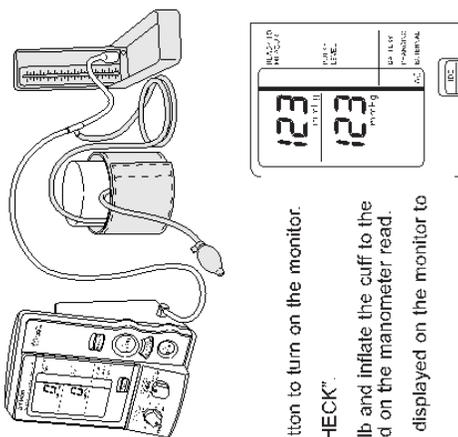
## HOW TO CHECK PRESSURE ACCURACY (IN CHECK MODE)

Accuracy of pressure display can be checked in the CHECK Mode.  
**What you need to prepare**

- (1) Calibrated mercury manometer (including inflation bulb), (2) T-tube, (3) two air tubes, and (4) a sturdy cylindrical shaped object on which the cuff is wrapped.

### How to check

1. Connect the manometer, inflation bulb, cuff, and the monitor with the T-tube as shown in the figure on the right.
2. Tightly wrap the cuff over a sturdy cylinder.
3. Release the valve of inflation bulb to remove the air inside the cuff completely.
4. Push the ON/OFF (power) Button to turn on the monitor.
5. Set the MODE Selector to "CHECK".
6. Close the valve of inflation bulb and inflate the cuff to the pressure to be checked, based on the manometer read.
7. Compare the pressure values displayed on the monitor to the one on the manometer.



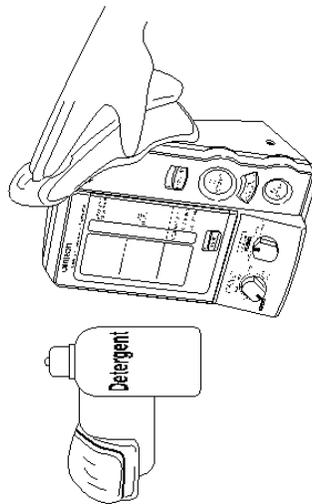
### Check result

Accuracy of the monitor is validated to be  $\pm 3$  mmHg or 2% of standard manometer reading. If your result shows a difference exceeding the tolerance, contact Omron repair department (1-877-216-1335).

## HOW TO CLEAN THE UNIT AFTER USE

	<b>Caution</b>		<b>General advice</b>
When cleaning this unit, unplug the AC adaptor from the electric outlet.		• Do not clean this unit with gasoline, paint thinner, or high concentration alcohol. • Do not disinfect this unit by autoclave or gas sterilization (EO, glutaraldehyde, or high concentration ozone).	
After cleaning this unit, dry it well, before plugging the AC adaptor in the electric outlet.			

1. Wipe the monitor with a soft, damp cloth diluted with disinfectant alcohol, or diluted detergent.
2. Complete cleaning by wiping the monitor with a soft, dry cloth.



## LIST OF ERROR CODES

Error code	Explanation	How to correct
E-r-1	Inflation error <ul style="list-style-type: none"> <li>When the pressure does not exceed 12 mmHg within the set time after the start of inflation</li> <li>When the inflation does not reach the set cuff pressure within the specified time after the start of inflation</li> </ul>	<ul style="list-style-type: none"> <li>Confirm that the air tube connecting the cuff and the main unit is connected securely.</li> <li>Confirm that the air flow in the air tube connecting the cuff and the main unit isn't being restricted.</li> <li>Confirm that the cuff is wrapped correctly (refer to pages 14 and 15).</li> <li>Check bladder for leaks and, if necessary, replace the bladder with new one (option).</li> </ul>
E-r-2	Deflation error <ul style="list-style-type: none"> <li>When the deflation speed is too fast during the measurement</li> <li>When the deflation speed is too slow during the measurement</li> <li>When the measurement does not finish within the specified time after starting the measurement</li> </ul>	<ul style="list-style-type: none"> <li>Confirm that air flow in the air tube connecting the cuff and the main unit isn't being restricted.</li> <li>If the measurement is made by setting the P-SET to "AUTO", ask the patient not to move during the inflation.</li> <li>Confirm that the P-SET is securely set to "AUTO". Turn the Knob counterclockwise as far as it goes until you can hear a click sound.</li> <li>If the measurement is made by manual inflation level setting, set the value to 30 to 40 mmHg higher.</li> </ul>
E-r-3	Overpressure error <ul style="list-style-type: none"> <li>The cuff pressure exceeded 299 mmHg.</li> </ul>	<ul style="list-style-type: none"> <li>Confirm that air flow in the air tube connecting the cuff and the main unit isn't being restricted.</li> </ul>
E-r-4	Insufficient inflation error <ul style="list-style-type: none"> <li>Blood pressure could not be measured due to insufficient inflation level.</li> </ul>	<ul style="list-style-type: none"> <li>If the measurement is made by setting the P-SET to "AUTO", ask the patient not to move during the inflation.</li> <li>Confirm that the P-SET is securely set to "AUTO". Turn the Knob counterclockwise as far as it goes until you can hear a click sound.</li> <li>If the measurement is made by manual inflation level setting, set the value to 30 to 40 mmHg higher.</li> </ul>
E-r-5	Indeterminable blood pressure error <ul style="list-style-type: none"> <li>Blood pressure could not be measured even when the cuff pressure reached the specified pressure.</li> </ul>	<ul style="list-style-type: none"> <li>Confirm that the cuff is wrapped correctly (refer to pages 14 and 16).</li> </ul>
E-r-6	Low pulse level error <ul style="list-style-type: none"> <li>Pulse wave was too small.</li> </ul>	<ul style="list-style-type: none"> <li>Confirm that the cuff is wrapped correctly (refer to pages 14 and 15).</li> </ul>
E-r-7	Blood pressure error <ul style="list-style-type: none"> <li>Relationship between systolic and diastolic pressures was abnormal</li> </ul>	<ul style="list-style-type: none"> <li>Ask the patient not to move during the measurement.</li> <li>Check the patient for arrhythmia.</li> </ul>
E-r-8	Pulse rate error <ul style="list-style-type: none"> <li>Pulse rate did not stay within the range of 30 to 199 beats/min.</li> </ul>	
E-r-9	Device error <ul style="list-style-type: none"> <li>Main unit malfunction.</li> </ul>	<ul style="list-style-type: none"> <li>Contact Omron's repair department toll-free at (1-877-276-1336).</li> </ul>

## TROUBLESHOOTING

If the unit malfunctions during use, please check the following:

Trouble	What to inspect	How to correct
The unit inflates to abnormally high (low) pressure.	Is the cuff wrapped correctly?	Wrap the cuff correctly, and measure again. (Refer to Page 14 and 15.)
	Is the patient moving during inflation?	Ask the patient not to move during measurement, and measure again.
	Does this patient have arrhythmia?	Set the P-SET to 30 to 40 mmHg higher than estimated systolic pressure of the patient, then measure.
The monitor cannot measure blood pressure. Measured values are abnormally high (low).	Check the patient's condition.	After checking the patient with the stethoscope refer to the "list of error codes". (Refer to Page 28.)
	Is the patient moving during the measurement?	Ask the patient not to move during measurement, and measure again.
	Does the patient have an arrhythmia?	Set the P-SET to 30 to 40 mmHg higher than estimated systolic pressure of the patient, then measure.
The monitor cannot measure blood pressure. Measured values are abnormally high (low).	Is the size of the cuff correct and is it wrapped correctly?	Select the cuff according to the patient's arm circumference, wrap it correctly, then measure again. (Refer to Pages 14 and 15.)
	Is the level of the brachium to which the cuff is wrapped at the same level as the heart?	Keep the level of the brachium to which the cuff is wrapped at the same level as the heart, then measure again.
	Are the patient's clothes restricting normal blood flow to the arm?	Remove the clothing and measure again.

# FIVE YEAR LIMITED WARRANTY

Your HEM-907XL IntelliSense™ Automatic Blood Pressure Monitor is warranted to be free from manufacturing defects for a period of five years under normal use. The five year warranty excludes the monitor cuff. The cuff is warranted for a one year period. This warranty extends only to the original retail purchaser.

Should repair be needed within the warranty period, ship the unit prepaid to **Omron Healthcare, Inc., 300 Lakeview Parkway, Vernon Hills, IL 60061, Attn: Service Dept.**, together with \$3.00 for return shipping and insurance. Be sure to include the model number of your unit and your phone number on any correspondence.

We will either repair or replace (at our option) free of charge any parts necessary to correct defects in the materials or workmanship. The above warranty is complete and exclusive. The warranty expressly disclaims liability for incidental, special, or consequential damages of any nature. (Some states do not allow the exclusion or limitation of incidental or consequential damages, so the above warranty may not apply to you.)

Any implied warranties arising by the operation of law shall be limited in duration to the term of this warranty. (Some states do not allow limitations on how long an implied warranty lasts, so the above limitation may not apply to you.)

This warranty gives you specific legal rights, and you may have other rights which vary from state to state. As a condition to operation of your warranty, the enclosed registration card must be completed and sent to us within 10 days from the date of purchase.

FOR CUSTOMER SERVICE CALL TOLL FREE:  
1-877-216-1336

# SPECIFICATIONS

<b>Name:</b>	OMRON Digital Automatic Blood Pressure Monitor
<b>Model:</b>	HEM-907XL
<b>Display:</b>	Digital display
<b>Measurement:</b>	Oscillometric method
<b>Measurement Range:</b>	Pressure: 0 to 299 mmHg Pulse rate: 30 to 199 beats/min
<b>Accuracy:</b>	Pressure: Within ±3 mmHg or 2% Pulse rate: Within ±5% of reading
<b>Inflation:</b>	Automatic inflation with pumping
<b>Deflation:</b>	Automatic deflation by electromagnetic control valve
<b>Air Release:</b>	Automatic rapid air release by electromagnetic control valve
<b>Pressure Detection:</b>	Electrostatic capacity sensor, conductivity sensor, sensor
<b>Power supply:</b>	AC adapter (120 VAC, 60 Hz, 20 VA) or Battery pack (4.8 VDC, 6Wh)
<b>Electric Shock Protection Method:</b>	Class II B type
<b>Operating Temperature and Humidity:</b>	50°F to 70°F (10 to 40°C), 30 to 85% RH, IPX 0 Rating
<b>Weight of Main Unit:</b>	Approx. 32 oz (910 g)
<b>External Dimensions:</b>	Approx. 5 1/2" (W) x 8" (H) x 5 1/8" (D) 139 (W) x 203 (H) x 131 (D) mm
<b>Accessories:</b>	Cuff / bladder set Extra Large, Cuff / bladder set Large, Cuff / bladder set Medium, Cuff / bladder set Small, AC adapter, Battery pack, air tube (1.0 m), Instruction Manual (with guarantee card)
<b>Options:</b>	Cuff Extra Large (without bladder), cuff Large (without bladder), cuff Medium (without bladder), cuff Small (without bladder), bladder Extra Large, bladder Large, bladder Medium, bladder Small, air tube 1.3 m (51 1/8")

\* Please note that specifications may be changed without prior notice.

# CAUTION

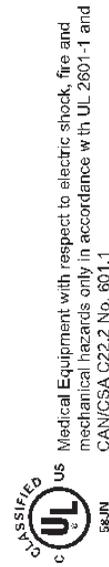
**CAUTION:** Changes or modifications not expressly approved by Omron Healthcare, Inc. could void the user's authority to operate this product.

**POTENTIAL FOR RADIO/TELEVISION INTERFERENCE (for U.S.A. only)**  
This product has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC rules.  
These limits are designed to provide reasonable protection against harmful interference in a residential installation. The product generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If the product does cause harmful interference to radio or television reception, which can be determined by turning the product on and off, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the product and receiver.
- Connect the product into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

**POTENTIAL FOR RADIO/TELEVISION INTERFERENCE (for Canada only)**  
This digital apparatus does not exceed the Class B limits for radio noise emissions from digital apparatus as set out in the interference-causing equipment standard entitled "Digital Apparatus", ICES-003 or the Canadian Department of Communications.

Cet appareil numérique respecte les limites de bruits radioélectriques applicables aux appareils numériques de Classe B prescrites dans la norme sur le matériel brouilleur: "Appareils Numériques", NMB-003 édictée par le ministre des communications.



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300 Lakeview Parkway  
Vernon Hills, Illinois 60061  
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HEM-907XLINST Rev A

**Appendix 10 Omron HEM-780 Instruction Manual**



























**Appendix 11 Self Monitored Blood Pressure Teaching**















































Jackson Heart Study Protocol  
Manual 7  
Central Laboratory and Specimen Repository  
Specimen Collection and Processing  
Visit 2

Version 1.0  
September 13, 2006

For Copies, Please Contact:  
Jackson Heart Study Coordinating Center  
Jackson Medical Mall  
350 W. Woodrow Wilson Dr.  
Jackson, MS 39213



## 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 and 4 describe the operation of the Cohort Procedures, and Events Ascertainment Components of the study. Detailed Manuals of Operation for specific procedures, including those for Blood Pressure and Quality Assurance, make up Manuals 3 and 5. The Data Management System is described in Manual 6. The Central Laboratory and Specimen Repository are described in Manual 7. Manual 8 is designed to provide volumetric CT image data for measuring coronary and abdominal aortic calcified plaque as well as measuring body composition in the abdomen.

### JHS Study Protocols and Manuals of Operation

<u>MANUAL</u>	<u>TITLE</u>
1	General Description and Study Management
2	Cohort Component Procedures
3	Blood Pressure
4	Morbidity and Mortality
5	Quality Control
6	Data Management
7	Specimen Collection and Processing
8	Computed Tomography (CT) Scan
9	MRI Forthcoming

**Manual 7. Central Laboratory and Specimen Repository  
Specimen Collection and Processing**

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## 1.0 PURPOSE

The Jackson Heart Study (JHS) provides a framework for research into the genetic, biochemical, epidemiological, and physiological causes of cardiovascular disease in African-Americans. The study participants will include 5,600 African-Americans between the ages of 35-84 years. Female and male participants will be equally represented. Blood and urine samples and other information on these individuals will be extensively analyzed to determine how best to prevent and treat cardiovascular disease.

Jackson, MS is the site of the only Exam Center involved. The technicians at the exam center collect blood and urine specimens, process them, and ship them to the Central Laboratory at Fairview-University Medical Center in Minneapolis, MN. Specimens collected for immediate testing and specimens collected for long-term storage are both sent to the Central Laboratory.

The Central Laboratory performs general blood and urine chemistry tests, routine plasma lipid tests (cholesterol, triglycerides, and HDL-cholesterol), and other more specialized analyses. A complete list of tests performed is located in Appendix 1.

The foundation on which all of these tests are based is the blood and urine samples that are collected and processed by the technicians at the Exam Center. Probably the most important step (and potentially the most variable) is the collection and processing of the samples. Laboratory tests can be repeated, but if the sample itself is NOT correctly collected and processed, the laboratory results may be precise, but perhaps not reflective of the *in vivo* state. It is important that this study measures true differences between participants rather than differences in collection procedures. The JHS depends heavily on the Exam Center technicians who perform the blood and urine collection and sample processing. It is important that these people be not only well trained and competent at drawing blood and processing the blood and urine, but also willing to take pride and responsibility in their work.

## **2.0 PREPARATION**

### **2.1 Participant Contact**

Since the study depends on the voluntary participation of participants, every effort must be made to make the entire procedure as easy and painless as possible for them. The technicians must remain calm and project an attitude of competence even when faced with the most nervous or inquiring participant. The best way to achieve this is for the technicians to be thoroughly knowledgeable about all aspects of the procedures. The JHS involves the collection of 30-40 mL of blood from each participant. Three or four tubes of blood are collected. The fourth tube (CPT) will be collected from all participants who did NOT have that tube collected at visit 1. Any participant who is concerned about the volume of blood should be reassured that the total amount of blood drawn is only about two ounces, although it may look like more. The technician may also assure participants that they donate 11 times as much blood (450 mL) when they donate a pint of blood. Participants will also be asked to provide a random urine specimen during their visit. The technicians and the clerk should be wearing a clean laboratory coat.

### **2.2 Staff Certification Requirements**

A certified JHS technician at the Exam Center performs the blood drawing and blood and urine processing. Technicians complete a training course taught by certified laboratory staff. Each technician must complete the training and pass both written and practical exams before becoming JHS-certified. Re-certification takes place annually and is authorized by supervisory personnel.

### **2.3 Blood Collecting Trays and Tubes**

Prior to venipuncture two trays are prepared for each participant. One tray holds the Vacutainer tubes used in the blood collection. The other tray holds the various plastic microvials which contain the final serum, plasma, and urine aliquots that are sent to the Central Laboratory and local laboratory for analyses. The collection tubes and storage microvials are labeled with LABID numbers. A list of equipment, suppliers, and vendors is provided in Appendix 2.

#### **2.3.1 Blood Collection Tray**

First, the technicians organize and prepare the blood collection tray. The tray itself should be made of hard plastic, which is unbreakable and can be easily cleaned. The tray has individual compartments, filled with the following supplies.

- A test tube rack to hold the three or four blood collection tubes drawn from each participant. These tubes are described in detail in the next section.
- Sterile, disposable 21 gauge butterfly needles
- Plastic Vacutainer tube guides
- Vacutainer Luer adapters
- Sterile alcohol swabs
- Gauze sponges
- Tourniquets

- Bandages ("Band Aids")
- Smelling salts, ice packs, and wash cloths should be readily available in the specimen collection area for patients who become faint during the blood draw

### 2.3.2 Blood Collection Tubes

Draw 30-40 mL of blood from each participant using three or four Vacutainer tubes. Specimens from these blood collection tubes are used in approximately seven different biochemical assays. It is important that the technicians know more than just the arrangement of the blood collection tubes and the sequence of tube collection. They should also be familiar with the purpose of each tube, the type of anticoagulant in each tube, and possible sources of error in the handling of each tube. These tubes are organized in the test rack in the following sequence:

**Tube #1** is a 10-mL red and gray-stoppered tube filled with 9.5 mL of blood. This tube does NOT contain anticoagulant, so it does NOT need to be mixed following collection. After drawing, allow the blood to clot at room temperature for 30 minutes. Following centrifugation, the serum is frozen and sent to the Central Laboratory. One potential problem with the processing of this tube is that one of the tests it is used for is a blood glucose determination. If the serum is allowed to remain in contact with the red cells for much longer than 30 minutes, the serum glucose levels can be artifactually decreased.

**Tubes #2 and #3** are 10-mL lavender-stoppered tubes containing the liquid anticoagulant EDTA. The whole blood from this tube is used to measure glycosylated hemoglobin and for DNA extraction. The plasma is used for future testing. After each tube is fully filled with blood, invert four times then place into a room temperature rack until centrifugation.

**Tube #4** is 8.5 mL black-and-blue-stoppered tubes containing citrate anticoagulant and ficoll hypaque cell separation media (Cell Preparation Tube or CPT). It is collected only from participants who did NOT have this tube collected at visit 1. This tube is used to isolate lymphocytes for cryopreservation and, ultimately, transformation. After this tube is fully filled with blood, invert four times then place into a room temperature rack until shipment. These tubes are not centrifuged.

### 2.4 Blood Collection Tubes: Labeling and Set-up

Three or tubes are drawn in the following sequence:

Tube #1:	9.5-mL red and gray-stoppered tube
Tube #2 and #3:	10-mL lavender-stoppered tube (EDTA)
Tube #4:	8.5-mL black and blue-stoppered tube (CPT)

Attach pre-numbered adhesive LABID labels to each Vacutainer tube and each plastic microvial prior to blood collection. Place the labels on the tubes so that the barcoded ID number is positioned vertically. Arrange the set of tubes in a test tube rack. When the participant arrives for the Exam Center visit, place a LABID label on the Venipuncture form along with the participant's JHS ID number. Handle only one participant's specimens at a time so the chance of mislabeling is minimized. Each center must keep a permanent record of the matching of the JHS ID number to the laboratory ID number (e.g., participant log).

Select a number of JHS participants to donate duplicate samples for analysis. Assign duplicate samples a unique laboratory ID number and ship to the Central Laboratory one week later. This is described more completely in the Quality Control Section.

## 2.5 Sample Aliquot Tubes: Labeling and Set-up

The technician prepares a tray of the plastic microvials that will contain the final samples that will be assayed locally or shipped to the Central Laboratory for each participant. Each type of microvial has a corresponding color-coded screw cap that fits onto it. The technicians should be trained to organize the tray for the sample processing as follows:

### 2.5.1 Sample Tray

The tray itself should be a flexible sponge test tube rack that will fit tubes from 10-16 mm in diameter. The tray has 5 rows and 10 columns. The columns are numbered 1-10 from left to right. The rows are lettered A-E from top to bottom.

### 2.5.2 Organization

The technician needs the following supplies for each sample tray:

- 5 - 2.0-mL polypropylene vials (red top)
- 5 - 2.0-mL polypropylene vials (purple top)
- 5 - 2.0-mL polypropylene vials (clear top)

Vertically label the microvials with the LABID number (letter designator at bottom) and arrange in the sample tray in the following order:

- Col 1: 2.0-mL red top vials (rows A-E)
- Col 2: empty
- Col 3: 2.0-mL purple top vials (rows A-E)
- Col 4: empty
- Col 5: 2.0-mL clear top vials (rows A-E)
- Col 6: empty
- Col 7: empty
- Col 8: empty
- Col 9: empty
- Col 10: empty

All extra labels are returned to the Central Laboratory with the weekly specimen shipment.

## 2.6 Preparation for Specimen Collection

Prepare for specimen collection in the following manner. In the early morning, prior to drawing blood from the participants:

1. Check to make sure the blood collection tray is properly equipped. Every item on the checklist must be ready before proceeding.
2. Check that each Vacutainer tube is properly labeled with the appropriate LABID number.
3. Check that the sample processing tray is properly equipped. Every item on the checklist must be ready and in its proper position.
4. Check that each microvial is labeled with the appropriate laboratory number.
5. Check that a urine collection container is labeled with the appropriate laboratory number.
6. Perform and record quality control (QC) check on centrifuge temperature ( $4^{\circ}\text{C} \pm 2^{\circ}\text{C}$ ).

7. Perform and record QC check on refrigerator temperature ( $4^{\circ}\text{C} \pm 2^{\circ}\text{C}$ ).
8. Perform and record QC check on freezer temperature ( $-70^{\circ}\text{C} \pm 10^{\circ}\text{C}$ ).
9. Perform and record QC check on room temperature.

At participant arrival:

1. Place the LABID label (labeled on the collection tubes and aliquot vials) on the Venipuncture Form. Make sure the JHS ID number on the Venipuncture Form is correct.
2. Check that Quality Control tubes are prepared and labeled, if needed (see Quality Control section of this manual for details).

## **2.7 Venipuncture Form and Urine Collection Form**

Enter the participant's JHS ID Number and name on the Venipuncture form when the participant arrives for the visit. At the completion of specimen collection and processing, the entire original Venipuncture Form is kept on file at the Exam Center.

The original Urine Collection Form is also kept on file at the Exam Center.

### **3.0 VENIPUNCTURE**

#### **3.1 Precautions for Handling Blood Specimens**

Handle all specimens as potentially infectious for laboratory workers. OSHA rules mandate that technicians must always wear disposable protective gloves when collecting and processing specimens.

Use 0.5% sodium hypochlorite (household bleach diluted 1:10) to clean up any spills of blood, plasma, or serum.

OSHA regulations require that all needles and sharp instruments be discarded into puncture resistant containers.

Avoid formation of potentially infectious aerosols when removing the rubber stoppers from Vacutainer tubes. In addition to wearing protective gloves, hold a piece of gauze over the stopper while slowly removing it from the tube.

Place all used Vacutainer tubes and blood-contaminated products in biohazard bags for proper disposal.

#### **3.2 Phlebotomy Room**

The blood drawing takes place in an isolated room or in an area where participants are separated by room dividers.

#### **3.3 Participant Preparation**

Informed consent must be obtained from the participant before drawing blood and collecting urine. This procedure is followed to ensure that the participants understand the purpose of blood drawing and the possible complications of venipuncture. A standard informed consent has been prepared for this study. With regard to laboratory procedures, the consent statement informs study participants that although there may be some minor discomfort, their blood will be drawn by trained technicians. The consent statement also states that a copy of clinically relevant test results is sent to their physicians and that they will be contacted if clinically important tests are abnormal, if so desired by the participant.

Complete the JHS Venipuncture Form with the participant.

Blood drawing is standardized to the sitting position

Give the participant enough time to feel comfortable after the blood collection, as well. In many cases the most memorable part of the experience for participants will be the contact with the technicians who draw the blood and their general attitude and competence.

If the participant is nervous or excited, the technician briefly describes the procedure, e.g., "I am going to be drawing about three ounces of blood. This blood will be used in tests for lipids (or fats) and cholesterol and other chemistry tests. We hope to be able to use the results of these tests to determine some of the causes of heart disease."

**HANDLING PARTICIPANTS WHO ARE EXTREMELY APPREHENSIVE ABOUT HAVING BLOOD DRAWN:** Do NOT under any circumstances force the participant to have blood drawn. It may help to explain to the participant that the blood drawing is designed to be as nearly painless as possible. It is sometimes best to let the participant go on with another part of the visit. It may also be helpful to

have the participant relax just so the phlebotomist can check the veins in the participant's arms, without actually drawing blood.

Provide participant with a labeled urine collection container and instructions for specimen collection. If possible, obtain this specimen prior to blood collection. The urine specimen may then be processed with the blood specimens.

### 3.4 Venipuncture

Before applying the tourniquet, screw the Luer adapter into the plastic Vacutainer tube guide. Insert the butterfly tubing onto the adapter.

With jacket or sweater removed, have the participant sit with the sleeves rolled up to expose the antecubital fossa (elbow). The preferred arm to draw from is the left arm. The right arm should be used only if blood collection is NOT possible from the left arm. This does NOT mean you must stick the left arm. Only do so if an adequate vein is apparent.

**PRECAUTIONS WHEN USING A TOURNIQUET:** The tourniquet should be on the arm for the shortest time possible. Never leave the tourniquet on for longer than two minutes. To do so may result in hemoconcentration or a variation in blood test values. If a tourniquet must be applied for preliminary vein selection, and it remains on the arm for longer than two minutes, it should be released and reapplied after a wait of two minutes. Instruct the participant that he/she should not clench their fist prior to the venipuncture. Doing so could cause fluctuations in the results in several of the analytes being measured. Specifically, it could artifactually raise the serum potassium level. If the participant has a skin condition, put the tourniquet over the participant's shirt or use a piece of gauze or paper tissue so as NOT to pinch the skin. Wrap the tourniquet around the arm 3 to 4 inches (7.5 to 10.0 cm) above the venipuncture site.

Identify the vein, then cleanse the venipuncture site.

1. Remove alcohol prep from its sterile package.
2. Cleanse the vein site with the alcohol prep using a circular motion from the center to the periphery.
3. Allow the area to dry to prevent possible hemolysis of the specimen and a burning sensation to the patient when the venipuncture is performed.
4. If venipuncture becomes difficult, the vein may need to be touched again with your hand. If this happens, cleanse the site again with alcohol.

Perform venipuncture.

1. Grasp the participant's arm firmly, using your thumb to draw the skin taut. This anchors the vein. The thumb should be 1 or 2 inches (2.5 or 5.0 cm) below the venipuncture site.
2. With the needle bevel upward, enter the vein in a smooth continuous motion.
3. Make sure the participant's arm is in a flat or downward position while maintaining the tube below the site when the needle is in the vein. **DO NOT HAVE THE PARTICIPANT MAKE A FIST IN THE HAND OF THE ARM FROM WHICH BLOOD IS TO BE DRAWN.**
4. After blood has appeared in the butterfly tubing insert tube #1 into the plastic vacutainer tube holder. Grasp the flange of the tube holder and push the tube forward until the butt end of the needle punctures the stopper, exposing the full lumen of the needle. The tube should begin filling with blood.

5. Once the draw has started, do NOT change the position of a tube until it is withdrawn from the needle. If blood is flowing freely, remove the tourniquet after two minutes. A tourniquet may be reapplied during the collection to spare the participant a restick, but the tourniquet must NOT be on for more than two minutes.
6. Keep a constant, slight forward pressure on the end of the tube. This prevents release of the shutoff valve and stopping of blood flow.
7. Fill each Vacutainer tube as completely as possible; i.e., until the vacuum is exhausted and blood flow ceases. If a Vacutainer tube fills only partially, remove the tube and attach another without removing needle from vein.
8. When the blood flow into the collection tube ceases, remove the tube from the holder. The shutoff valve covers the point, stopping blood flow until the next tube is inserted (if necessary). Tubes which require mixing (#2 through #4) should be gently inverted four times immediately following removal of the tube from the adapter, then placed into a room temperature rack.

If a blood sample is NOT forthcoming, the following manipulations may be helpful.

1. Turn needle slightly or lift the holder in an effort to move the bevel away from the wall of the vein.
2. Move needle slightly in hope of entering vein. Do NOT probe. If NOT successful, release tourniquet and remove needle. A second attempt can be made on either arm. The same technician should NOT attempt a venipuncture more than twice. If a third attempt is necessary, a different phlebotomist should attempt the venipuncture.
3. Loosen the tourniquet. It may have been applied too tightly, thereby stopping the blood flow. Reapply the tourniquet loosely. If the tourniquet is a Velcro type, quickly release and press back together. Be sure, however, that the tourniquet remains on for no longer than two minutes at a time.

At the conclusion of the blood draw:

1. Remove the last collection tube from the Vacutainer tube holder prior to removing the needle from the participant's arm. Lightly place clean gauze over the venipuncture site. Remove the needle quickly and immediately apply pressure to the site with a gauze pad. Discard the butterfly needle, adapter and Vacutainer tube holder into a needle box. **DO NOT ATTEMPT TO RECAP NEEDLES!** Have the participant hold the gauze pad firmly for one to two minutes to prevent a hematoma.
2. If blood flow stops before collecting tube #4, repeat the venipuncture, collecting only the unfilled tubes from the previous attempt. A tourniquet may be applied in this case but should be released if possible as soon as blood flows into the first tube. As always, the tourniquet must never be on for longer than two minutes.

Bandaging the arm.

1. Under normal conditions:
  - a. Slip the gauze pad down over the site, continuing mild pressure.
  - b. Apply an adhesive or gauze bandage over the venipuncture site after making sure that blood flow has stopped.
2. If the participant continues to bleed:

- a. Apply pressure to the site with a gauze pad. Keep the arm elevated until the bleeding stops.
- b. Wrap a gauze bandage tightly around the arm over the pad.
- c. Tell the participant to leave the bandage on for at least 15 minutes.

**PRECAUTIONS - WHEN A PARTICIPANT FEELS FAINT OR LOOKS FAINT FOLLOWING THE BLOOD DRAWING:**

1. Take an ampule of smelling salts, crush it, and wave it under the person's nose for a few seconds.
2. Provide the person with a basin if he/she feels nauseous.
3. Have the person stay seated or lying down until he/she feels better.
4. Have someone stay with the person to prevent them from falling and injuring themselves if they should faint.
5. Place a cold wet cloth on the back of the person's neck or on their forehead.
6. Once the episode has passed, some fruit juice may be given to the participant in order to counteract any possible hypoglycemia due to their pre-clinic visit fast.
7. If the person continues to feel sick, take a blood pressure and pulse reading. Contact a medical staff member, who will advise you on further action.

### **3.5 Blood Mixing During Venipuncture**

To invert tubes, hold the tube horizontal to the floor. Slowly tip the stopper end down while watching the air bubble rise to the butt. Now, lower the butt end slightly while watching the bubble float to the stopper (1st inversion). Invert each tube, except #1 and #2, four times. Four inversions should take 6 to 8 seconds.

1. Draw tube #1 (10-mL red and gray top). Place the tube in a rack at room temperature.
2. Draw tubes #2 and #3 (10-mL lavender top). Invert four times and place in room temperature rack.
3. Draw tube #4 (8.5 mL black and blue top). Invert four times and place in room temperature rack

### **4.0 Blood and Urine processing**

Processing of the various blood samples is divided into 3 stages.

#### **4.1 Stage One: Immediate Processing**

Tube #1 remains at room temperature for thirty minutes to allow the blood to clot (blood at 4°C clots extremely slowly). Set a timer for 30 minutes as a reminder to centrifuge this tube.

##### **4.1.1 Whole blood for glycosylated hemoglobin and DNA isolation**

Tube #3 is placed into the refrigerator until shipment. It is NOT centrifuged. This tube must be shipped within 48 hours of collection.

#### **4.1.2 Centrifugation**

Place tube #2 in the centrifuge trunion. Balance the centrifuge then spin these tubes at 3,000 x *g* for 10 minutes at 4°C.

Wait for centrifuge to come to a complete stop. Remove the tubes from the centrifuge as soon as possible. Proceed to stage two processing.

#### **4.1.2 Urine specimens**

1. Thoroughly mix the random urine specimen.
2. Using a plastic transfer pipet, deliver 2 mL of urine to each of the five labeled microvials in column 5.
3. Screw clear plastic caps onto each vial, and leave the sponge rack at room temperature.
4. Re-attach the screw cap to the collection container, and hold it at room temperature until all vials are safely frozen.

#### **4.2 Operating the Centrifuge**

Refer to Centrifuge Operating Manual for specific operating and balancing instructions. In order to achieve a 3000 x *g* centrifugal force within the centrifuge, the corresponding revolutions per minute (RPM) will vary from centrifuge to centrifuge depending on radius of the centrifuge's rotor. Consult the centrifuge's operating manual for the appropriate RPM for each centrifuge.

#### **4.3 Stage Two:**

Approximately 15 minutes after venipuncture.

##### **4.3.1 Lavender-stoppered Tube (Tube #2)**

1. Remove tube from the centrifuge and put it in the sponge test tube rack holding the microvials labeled with the corresponding laboratory number. Remove the stopper.
2. Using the plastic transfer pipette, and being careful not to disturb the cell layer, remove the clear plasma supernatant from tube #2. The pipette tip should NOT get any closer than one-half inch from the cells. Equally transfer the plasma into the five 2.0-mL microvials in column 3.
3. Fasten the purple screw caps onto the microvials in column 3, and leave them in the sponge rack.
4. Re-stopper collection tube #2, and discard it in a biohazard waste bag.
5. Leave the sponge rack holding the filled aliquot vials at room temperature until it is time to remove the serum from tube #1. The EDTA plasma vials must NOT be refrigerated. They are to remain at room temperature until placed in the freezer.

#### **4.4 Stage Three**

Stage three begins approximately 30 minutes after venipuncture.

As soon as possible after the 30 minutes timer goes off, and NOT longer than 45 minutes after blood collection, centrifuge tube #1 at 3,000 x *g* for 10 minutes at 4°C.

#### **4.5 Final Blood Processing**

1. Remove the red and gray top tube from the centrifuge and place it in the sponge test tube rack.
2. Remove the stopper from tube #1. Using a plastic transfer pipette, aliquot all of the serum equally into the five tubes in column 1.
3. Fasten red screw caps on each of these vials.
4. Replace the stopper on the red and gray-stoppered blood collection tube and discard it in a biohazard waste bag.
5. Refrigerate one of the urine vials for local testing, then place the foam rack holding the remaining 14 specimen vials in the -70°C freezer.

##### **4.1.5 Black and blue-stoppered tubes (#4)**

1. This tube is to be shipped to the Central Laboratory without centrifugation.
2. Shipments of tube #4 must occur daily, and the specimens must be stored at ambient temperature.
3. Tube #2 (see above) may be shipped within 48 hours of collection.

#### **4.6 Freezing**

When all of the blood and urine specimens have been aliquotted into their respective microvials, and the microvials have been replaced in the sponge rack, the entire rack is placed upright in the -70°C freezer for a minimum of 30 minutes. Samples must be placed into the freezer within 90 minutes from venipuncture time. Samples must be thoroughly frozen before packaging them for storage and shipping. Record the time that the samples are placed in the freezer on the Venipuncture form.

Once the specimens are safely stored in the freezer, the urine may be discarded. The urine can be poured down a sink with copious amounts of water, or it can be flushed down a toilet. The empty collection jug should be discarded in accordance with local biosafety guidelines.

### **5.0 STORAGE AND SHIPPING**

#### **5.1 Storage**

##### **5.1.1 Frozen Specimens**

Place all of the frozen serum and plasma vials from a single participant into a 5" x 8" zip-seal storage bag. Place all of the frozen urine vials from a single participant into a separate 5"x 8" zip-seal storage bag. Check again to make sure all tubes are numbered. Press the air out of the bag and seal. Place these bags in the Central Laboratory box in the -70°C freezer and do NOT remove it until the time of shipment. This shipment is prepared weekly.

##### **5.1.2 Ambient Specimens**

Ambient specimens (CPT tubes) are stored at room temperature until shipment. The CPT shipment is prepared daily.

### **5.1.3 Refrigerated Specimens**

There are two types of refrigerated specimens: whole blood to be sent to the Central Laboratory (one tube per participant) and urine to be analyzed in the central laboratory (one vial per participant). Maintain a separate rack for each vial in the refrigerator until shipment. The whole blood EDTA tube (#3) may be shipped within 48 hours of collection. and urine is delivered to the local laboratory daily.

## **5.2 Shipping**

All frozen specimens collected and stored within the last workweek are shipped to the Central Laboratory on Monday, with the exception of Quality Control sera, as discussed in the Quality Control section below, by overnight courier. If very few participants were seen in the Exam Center during a week, two or three weeks of frozen specimens can be combined into one shipment.

Ship CPT specimens daily, even if only one participant was seen on a given day.

Ship refrigerated whole blood EDTA specimens (tube #3) within 48 hours of collection.

If there is any deviation from the regular shipping schedule contact the Central Laboratory to notify them of any changes.

Weigh all packages before shipping, if possible. It is important to record an accurate weight on the Federal Express airbill. Do NOT over-estimate the package weight.

### **5.2.1 Packaging Instructions (frozen specimens)**

The bags of frozen specimens are packed and shipped in styrofoam boxes. Packaging instructions are as follows:

1. Place a layer of dry ice on the bottom of the styrofoam box.
2. Put half of the bags of specimens into the styrofoam box on top of the dry ice.
3. Layer more dry ice on top of and around the sample bags.
4. Put the remaining specimen bags into the styrofoam box on top of the dry ice.
5. Layer more dry ice on top of and around the sample bags. The amount of dry ice in the shipping box should total at least five pounds.
6. Place packing material (e.g. bubble wrap) on top of the dry ice to fill the box.
7. Place the paper shipping forms on top of the packing material. The shipping forms and instructions are shown in Appendix 3.
8. Seal the outer box tightly with strapping tape. Affix UN3373 label to outside of box.
9. Address the box and contact Federal Express for pickup.
10. If necessary, more than one box may have to be shipped per week.

### **5.2.2 Packaging Instructions (ambient specimens)**

1. Place ambient specimens into a foam-lined mailer. More than one mailer may be required for all of the specimens.

2. Close the mailer and place it inside a large zip-seal storage bag. Press the air out of the bag and seal.
3. Place the mailer inside a larger styrofoam shipping box. Add room temperature freezer packs and other packing material (e.g. bubble wrap) to occupy extra space.
4. Place the paper shipping forms on top of the packing material. The shipping forms and instructions are shown in Appendix 3.
5. Seal the outer box tightly with strapping tape. Affix UN3373 label to outside of box.
6. Address the box and contact Federal Express for pickup.
7. If necessary, more than one box may have to be shipped per day.

### **5.2.3 Packaging Instructions (refrigerated specimens)**

1. Place refrigerated specimens into a three-tube foam mailer system. Place the mailer in a zip-seal bag.
2. Press the air out of the bag and seal.
3. Place the mailer inside a small styrofoam shipping box. Add a previously frozen freezer pack and other packing material (e.g. bubble wrap) to occupy extra space.
4. Place the paper shipping forms on top of the packing material. The shipping forms and instructions are shown in Appendix 3.
5. Seal the box tightly with strapping tape. Affix UN3373 label to outside of box.
6. Address the box and contact Federal Express for pickup. This shipment occurs on Tuesdays and Thursdays.

### **5.2.4 Mailing Instructions**

All shipping containers are sent to the Central Laboratory by overnight courier (Federal Express) to ensure receipt within 24 hours. The empty styrofoam containers are returned to the Exam Center via UPS.

Containers shipped to the Central Laboratory are addressed as follows:

JHS Central Laboratory  
University of MN Medical Center, Fairview  
Room L275 Mayo  
420 Delaware Street S.E.  
Minneapolis, MN 55455  
Telephone: (612) 273-3318 (office)  
Telephone: (612) 273-3645 (lab)  
FAX: (612) 273-3489  
Email: [grynder1@fairview.org](mailto:grynder1@fairview.org)

## **6.0 QUALITY CONTROL**

### **6.1 Venipuncture and Equipment Records**

In the Exam Center there are two different aspects of quality control. One is the daily or monthly record of the performance of the refrigeration equipment and centrifuge. This is most easily kept as a check sheet with the daily or monthly records, as described below. The other aspect of quality control is the Venipuncture Form that is part of each participant's records. It shows the number of attempts it takes to achieve a successful venipuncture and the code number of the technician who performs the venipuncture. This record provides needed documentation that the blood was drawn in a standardized manner and that the equipment was functioning properly. This quality control documentation is the best evidence that all specimens in the Exam Center are being drawn and processed identically. Differences in the way the samples are collected or processed could potentially create a significant difference in assay results, which could seriously compromise the laboratory test data. It is very important that the quality control records of the procedures and the equipment be properly maintained.

For the equipment, daily records should be kept on all refrigerators and freezers. The temperature of the refrigerated centrifuge must be recorded daily. See Appendix 4 for a sample form. In addition, the actual speed of the centrifuge needs to be checked and recorded annually with a tachometer. A sample Quality Control Checklist is enclosed in this manual (see Appendix 5). The local blood processing certifier will fill out this sheet monthly, certifying that daily checks have been performed properly and describing any problems in this area. The Monthly Quality Control Checklists should be kept in a permanent file in the Exam Center.

### **6.2 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 and sent out under the same QC ID number. For data analysis, results on each laboratory measurement are matched to the appropriate participant results.

All QC samples (except the refrigerated whole blood tube) are stored an extra week at the Exam Center and then sent to the Central Laboratory with a regular shipment.

Ideally the QC samples are drawn on three separate days. For example, on Monday draw Tube 1 (chemistry); on Tuesday, draw Tube 2 (glycated hemoglobin); and on Wednesday, draw Tube 3 (special chemistries). Tube 4 is NOT collected as part of the QC program. The QC urine duplicate can be collected on Thursday or Friday.

#### **6.2.1 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. An example of the checklist is given below:

**Figure 1. Weekly Blood QC Sample Checklist**

Week of: \_\_\_\_\_

<u>Day</u>	<u>Tubes</u>	<u>Laboratory</u>	<u>Sample collected?</u>
Monday	1	Chemistry	_____
Tuesday	2	Gly. Hgb	_____
Wednesday	3	Special chemistry	_____
Thursday or Friday	Urine	Chemistry	_____
			_____

**6.2.2 Preparation for Drawing and Processing QC Samples**

Blood Drawing Tubes: Each morning the blood drawing technician prepares an extra blood collection tube for the QC sample 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, five extra tubes for the urine QC duplicates should be set out and labeled with the urine QC ID number. One participant per week is chosen for use as the urine QC duplicate.

**6.2.3 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 refrigerated whole blood QC specimen is shipped along with its mate within 48 hours of collection.

The four urine QC samples should be placed into the freezer at the same time as their matched participant specimens. 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. A separate JHS study ID is NOT assigned to the QC specimen set. It is NOT assigned a study ID.



processing of samples, without performing any actual venipuncture. Mock venipuncture is performed with the Vacutainer system. A piece of latex tubing with a knot in one end leading to a glass of water is used as a target vein. Practice tubes are collected in the correct order, then placed at their proper positions. The sample is processed from start to finish exactly as if real blood were being used. Each technician performs a minimum of two mock draws from beginning to end. Although the mock draws take time, they provide hands-on experience and allow the technician to become comfortable with the procedures before proceeding to live participants.

At this point the technicians are ready to practice on live volunteers. The technicians practice at least once with just one volunteer at a time and again process the blood entirely by themselves from start to finish. If the technicians do NOT feel comfortable, they can repeat the process with dummy tubes. If enough volunteers are available, it may be beneficial to repeat this several times. Any questions or problems that the technicians have must be solved before the technicians proceed to drawing the JHS participants. Before the technicians draw blood from any JHS participant, they must take and pass the practical and written tests included at the end of this manual. After passing the tests and evaluation of their instructor, they may proceed to drawing blood from JHS participants.





## APPENDICES

### Appendix 1 JHS Laboratory Tests

Traditional Risk Factors (performed on all participants):

- Glucose (serum)
- Glycosylated hemoglobin (whole blood)
- Cholesterol (serum)
- Triglyceride (serum)
- HDL-Chol. (serum)
- Calc. LDL-Chol. (serum)
- DNA isolation (whole blood)
- C-reactive protein (serum)

Newer Risk Factors (performed on a focused subset or subsets of participants):

- Lymphocyte cryopreservation (whole blood)
- Lymphocyte transformation (whole blood)



## Appendix 2 Equipment and Supplies

Supplies to be obtained by Exam Center:

Supplier	Catalog no.	Description	Usage/week
Sarstedt	72.609	Microsample Tubes 500/pk	1260
"	65.716.003	Red Screw Caps 1000/pk	450
"	65.716.008	Purple Screw Caps 1000/pk	270
"	65.716.	Clear Screw Caps 1000/pk	225
Allegiance	B3036-4	Butterfly Needles, 21G x 3/4", BD #367250	45
"	B3062	Alcohol Swabs 2,000/cs	45
"	B3063-5	Gauze Sponges 200/pk	45
"	B3063-70	Band Aids 100/pk	45
"	B3060	Tourniquets	n/a
"	B3035-4	Vacutainer Tube Holders 10/pk	45
"	P5214-12	Transfer Pipettes 500/pk	270
Obtain locally		Freezer Bags 5" x 8"	47
Obtain locally		Freezer Bags, Large	40
Allegiance	S9221-1	Sponge Tube Rack	n/a
Obtain locally		Dry Ice (approximately 9 lbs./shipment)	
Allegiance	B3062-40	PDI Ammonia Inhalant	n/a
		<u>Vacutainer Tubes 100/pk</u>	
Allegiance	B2970-32	9.5 mL, SST, red/gray top, BD #366510	90
"	B2991-54	10 mL, EDTA, lavender top, BD #366457	135
"	B2973-3	8.5 mL, CPT, black/blue top, BD #362761	90
"	B2922-1	Blood Collection Trays	n/a
"	T2050-1	Thermometers -20 C - +110 C	n/a
"	1550SD*RS	Harvard Trip Balance (Ohaus 1550SD)	n/a
"	C6510-1	Timer - 3 channel digital	n/a
Polyfoam Packers	325	Styrofoam shipping box	10
"	409/410	Large 5-tube mailer/sleeve	45
"	364/365	Small 3-tube mailer/sleeve	15
"	414	Gel packs, 24 oz., +30°F	10
UAL Med Prod	BH302CL	Biohazard labels 320/roll	10

Equipment purchased and maintained by Exam Center:

Table-top refrigerated centrifuge capable of producing 3,000 x g

Freezer capable of maintaining -70°C

Refrigerator 4°C











## CONTENTS SHEET INSTRUCTIONS

The contents sheets list the complete inventory of specimens in a shipment. The original form is sent to the Central Laboratory with the specimen shipment, and a copy is filed at the Exam Center. More than one contents sheet may be used in each shipment, depending on the number of specimens enclosed. The number of pages attached and each page number are filled in at the top of the contents page (e.g. "page 1 of 5"). This form is filled out at the Exam Center as the specimens are collected and stored. This form must be checked against the specimens when packed for shipment. Record the date of shipment.

The LABID number is entered in the left hand column of the contents sheet. This is most easily done by attaching one of the adhesive LABID labels in the space provided. The Study ID label should also be applied in this section. This should be done at the time of collection. It is suggested that a second person check these IDs against the IDs on the vials to correct any errors.

The tubes comprising a complete set are listed in the upper left hand corner of the sheet. Under the category SET COMPLETE?, YES or NO should be marked for each participant to indicate whether the correct number of tubes has been shipped. If there is some deviation from the correct count, "NO" should be marked, and a description of the problem should follow in the column headed MISSING VIALS. The number of missing tubes and the color of their caps should be recorded here.

COMMENTS on the quality of the specimens upon receipt are recorded at the Central Laboratory.







**Appendix 5. JHS Monthly Equipment Quality Control Checklist**

CENTER \_\_\_\_\_  
 DATE \_\_\_\_\_  
 TECHNICIAN \_\_\_\_\_  
 ID NUMBER \_\_\_\_\_

(S)atisfactory/(U)nsatisfactory      Comments

**SET UP**

- 1. Daily QC records
  - refrigerator temperature      \_\_\_\_\_
  - centrifuge temperature      \_\_\_\_\_
  - freezer temperature      \_\_\_\_\_
  - room temperature      \_\_\_\_\_
- 2. Annual QC records
  - centrifuge tachometer check \_\_\_\_\_
- 3. Equipment and Supplies
  - refrigerated centrifuge \_\_\_\_\_
  - refrigerator      \_\_\_\_\_
  - 70°C freezer      \_\_\_\_\_
  - stopwatch      \_\_\_\_\_
  - timer      \_\_\_\_\_
  - Vacutainer needles      \_\_\_\_\_
  - tourniquet      \_\_\_\_\_
  - Vacutainer tubes      \_\_\_\_\_



## Appendix 6 JHS Venipuncture and Processing Procedures Certification Checklist

VENIPUNCTURE		Satisfactory/ Unsatisfactory	Comments
1.	Labels checked	_____	_____
2.	Participant prepared and procedure explained.	_____	_____
3.	Venipuncture Form filled.	_____	_____
4.	Tourniquet application and release	_____	_____
5.	Venipuncture technique	_____	_____
6.	Tube collection sequence	_____	_____
7.	Inversion technique	_____	_____
8.	Tube incubation location	_____	_____
9.	Stasis obtained	_____	_____
10.	Needle disposal	_____	_____
PROCESSING			
1.	Knowledge of centrifuge operation	_____	_____
2.	Aliquotting supply set-up	_____	_____
3.	Stage I tube spin	_____	_____
4.	Stage II aliquotting	_____	_____
5.	Stage III tube spin	_____	_____
6.	Vials sealed	_____	_____
7.	Final processing stage	_____	_____
8.	VPT Form completed	_____	_____
9.	Freezer organization	_____	_____
10.	Time constraints	_____	_____
11.	Disposal of contaminated supplies	_____	_____
PACKAGING AND SHIPPING			
1.	Specimens bagged	_____	_____
2.	Adequate dry ice used in shipping	_____	_____
3.	Shipping paperwork	_____	_____
MISCELLANEOUS			
1.	Incident Form	_____	_____
2.	QC Procedure	_____	_____
3.	Containers correctly labeled for shipping	_____	_____



## **Appendix 7 Sample Exams for Certification**

### **PRACTICAL EXAM FOR JHS BLOOD DRAWING TECHNICIAN**

1. Place the following four blood collection tubes in the correct set-up order and location for the venipuncture: 1-10 mL red and gray top, 2-10 mL lavender tops, 1-8.5 mL black and blue tops.
2. Specify which tube(s) remain at room temperature after collection.
3. Remove the appropriate tubes from the tray, balance them and place them in the centrifuge. How long should they spin? At what speed?
4. Set up a sponge tray with the appropriate number and order of specimen storage tubes. Indicate the colors of screw caps and the types of specimen put into these tubes.
5. Place the collection tubes in front of their respective sample tubes. Describe what further processing is required of each collection tube before it is aliquotted into its respective sample tube.
6. Organize the color-capped sample tubes and prepare them for shipment.
7. Describe the quality control for each piece of equipment.

SAMPLE WRITTEN EXAM

1. When handling biological specimens, what type of protective apparel must always be worn?  
\_\_\_\_\_
2. What is the recommended solution for use in cleaning an area where blood or urine has spilled?  
\_\_\_\_\_
3. Is it acceptable for the participant to make a fist in the hand of the arm from which the blood specimen is being collected? If so, when? \_\_\_\_\_  
\_\_\_\_\_
4. During a typical week, how many JHS participants will have additional blood specimens collected to be used as part of the phantom duplicate?
  - a) 5
  - b) 4
  - c) 3
  - d) 0
5. From which tubes are the packed cells used?
  - a) None
  - b) All
  - c) #1
  - d) #2, #3, #4 and #5
6. How long should tube #1 sit at room temperature before centrifugation?
  - a) 5 minutes
  - b) 30 minutes
  - c) 2 hours
  - d) No waiting time required
7. Why is this step (un)necessary? \_\_\_\_\_
8. Which tube is drawn last?
  - a) A 10 mL lavender-stoppered
  - b) An 8 mL black and blue-stoppered
  - c) A 10 mL red and gray-stoppered
  - d) A 7 mL lavender-stoppered

9. For what type of tests will the 10-mL lavender-stoppered tubes be used?
- a) Special Chemistry
  - b) Lipid
  - c) Hypertension
  - d) Special coagulation
10. When is the tourniquet removed?
- a) after tube #1 fills
  - b) after the tourniquet has been attached for two minutes
  - c) after all tubes fill
  - d) it does not matter
11. How many JHS participants will provide duplicate QC urine samples weekly?
- a) 0
  - b) 1
  - c) 2
  - d) 4



## Appendix 8 JHS Quality Control Phantom Participant ID Form

### JHS QUALITY CONTROL PHANTOM PARTICIPANT ID FORM

Note: This form should be sent to the Coordinating Center within two weeks of the first entry for a QC phantom.

Phantom Participant Laboratory ID Number \_\_\_\_\_

Date ID Assigned: \_\_\_\_ / \_\_\_\_ / \_\_\_\_ ID of Person Assigning ID: \_\_\_\_\_

### Phantom QC Log

<b>Tube</b>	<b>Matching Laboratory ID</b>	<b>Date Collected (Mo/Day/Yr)</b>	<b>Technician ID</b>
1	_____	____ / ____ / ____	_____
2	_____	____ / ____ / ____	_____
3	_____	____ / ____ / ____	_____
Urine	_____	____ / ____ / ____	_____





Jackson Heart Study

Manual 2

Cohort Procedures

Version 2.0

September 15, 2005

For Copies, Please Contact:

Jackson Heart Study Coordinating Center  
Jackson Medical Mall  
350 W. Woodrow Wilson Dr.  
Jackson, MS 39213



## 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 and 4 describe the operation of the Cohort Procedures, Blood Pressure and Events Ascertainment Components of the study. Detailed Manuals of Operation for specific procedures, including those for Blood Pressure and Quality Assurance, make up Manuals 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	Cohort Events Ascertainment
5	Quality Assurance
6	Data Management
7	Central Laboratory and Specimen Repository' Specimen Collection and Processing



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## Manual 2 Cohort Procedures

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## INTRODUCTION

The JHS cohort is comprised of 5,302 African-American adults residing in the Jackson, MS Metropolitan Statistical Area. Of those, most were between the ages of 35-84 at the initiation of Exam 1, though some members of the Family Study component of the cohort were younger (21-35) or older (85+).

Chapter 1 of this manual describes the procedures for retaining the cohort including scheduling the second examination (1.2), conducting off-site examinations (1.3), and ongoing contact with the cohort.

Chapter 2 provides an overview of the design, objectives, and content of the second clinical examination (Exam 2) and describes the logistics for setting up the clinical examination (Sections 2.2). The training and certification required to administer the forms as well as the quality assurance activities for all baseline interviews are described in the next sections (Section 2.3-2.5).

Chapter 3 provides the background, rationale and description of each interview, the training and certification required to administer the form, the quality assurance activities, and the data collection instruments and procedures.

Chapter 4 provides similar information for the procedures performed during Exam 2.

Chapter 5 describes the rationale and procedures of the medical data review performed before the participant leaves the Examination Center.

Chapter 6 covers the study's referral and review guidelines, including activities associated with reporting results to participants and her/his health care providers.

Chapter 7 outlines the procedures at the Examination Center to ensure participant safety.

Chapter 8 describes procedures for annual telephone follow-up of the cohort.

Chapter 9 introduces the procedures for surveillance and monitoring events of the cohort and refers the reader to the detailed information contained in Manual 4: Events Ascertainment.

## 1.0 RETENTION OF PARTICIPANTS FOR EXAM 2 (CONTACT YEAR 06 EXAMINATION)

### 1.1 Introduction and Overview of Retention Focus

Retention of the cohort is a continual focus within the JHS. Maintaining contact with participants is critical so that they are available for re-examination as the study progresses. The Examination Center unit (retention/TRIPP [Translating Research into Prevention and Practice], annual follow up, and clinic) works very closely with the Community Outreach unit of the Coordinating Center to bring back a high percentage of the cohort for Exam 2. The retention plan for Exam 2 is designed to maximize the number of participants re-examined ~ 4 years after their baseline examination in Exam 1. The target is to re-examine at least 85% of the original cohort. While the 85% return goal is set as the target, every attempt will be made to maximize the return at Exam 2. The JHS is well aware of the need to obtain as high a rate of return as possible in order for the study to assess the natural history and/or evolution of cardiovascular disease and its risk factors in the cohort. Making accurate inferences regarding risk factors changes and disease prevalence / incidence demands the retention of sufficient numbers of the cohort. The plan provides for extensive monitoring of the process. These efforts will include coordinated and community-driven strategies derived from the prerecruitment study (Participant Recruitment Study) and the lessons learned in Exam 1.

#### 1.1.1. Building on Lessons Learned in Exam 1: Community Driven Strategies

##### 1.1.1.1 Gathering the JHS Family

An important Exam 1 lesson was that by engaging participants as member of the “JHS family”—not only did they come to clinic, they recruited other household and family members as well. Exam 2 retention activities capitalizing on this lesson include:

- Hosting “family days” in the clinic when we focus scheduling to accommodate entire families (or households) to attend.
- Incorporating special recognition for families with the most clinic attendees
- Offering a digital family photo
- Including a “family history” format to encourage families to learn and record more about the personal and health histories of their families. This will be disseminated via the newsletter, community gatherings, and the JHS web page.

Similarly, involving the Council of Elders (with IRB clearance and approval) in contacting participants and discussing the importance of the study and their individual participation was effective in increasing clinic attendance. Activities for Exam 2 will include:

- A coordinated retention effort from the Council of Elders targeted for each specific age / gender / SES group
- Focus on multiple methods of contact including mail or phone, and in some cases in person e.g. to provide transportation or other needed services to assist cohort members to keep their clinic appointments.
- Identify a small group of young males who might be willing to assist in similar targeted retention activities with this high-risk group.

Active involvement of the investigators, particularly the PI, in contacting participants who had missed one or more clinic appointments was effective for some. Repeating this positive activity during Exam 2, we will:

- Generate a monthly list of persons who are more than one month post clinic exam date for PI/investigator phone calls or home visits to express appreciation for and personally invite **their continued** participation

Specific strategies for retention will focus on *overcoming barriers, enhancing the clinic as the “home” of the JHS family, and maintaining ongoing contact/communication.*

Barriers: Barriers included transportation, child care, work, health care providers, health services, and time constraints. The retention plan will continue to:

- Provide transportation to anyone who needs it via a contract with a local cab company; utilize the Council of Elders for personal transportation when persons are unwilling to use commercial cab services. We will pay transportation costs (mileage) for all other participants driving their own vehicles who so request this.
- Provide child care services in the JHS “children’s” space during the time of clinic examinations. The Council of Elders as well as high school volunteers have provided this service during the summer months.
- Negotiate time off work with agreeable employers of participants using targeted communication from the three institutional leaders and the JHS PI discussing the importance of heart health in our community, and their potential contribution by providing paid leave for the clinic examination.
- Negotiate continued support of participant health care providers using targeted communications (including personal visits from the Social Worker and / or Outreach staff) to request their supportive communication with patients regarding JHS participation.
- Provide JHS results reporting of abnormal results at the request of the participant. Participants are encouraged to share their results with their health care providers. The Social Worker will develop and maintain an extensive resource directory for use by participants and will proactively provide assistance to all participants in obtaining affordable health care services.
- Reduce time constraints by limiting the exam length to 2 hours, providing advance notification of pending examination schedule and flexible scheduling of examinations.
  - Annual personalized letter at time of Family Reunion / Birthday Celebration to provide updated information on the status of their clinic examination (e.g. due this year, due next year, etc).
  - Reconsider evening clinics
  - Provide split clinics for rescheduling incomplete exams
  - Conduct off site exams at the participant’s home or other convenient location should they be unable to schedule a convenient clinic visit. We anticipate up to 10-15% of the cohort may benefit from this alternative (N ~ 750 persons).

Enhancing the Clinic as the “Home” of The JHS: will continue to focus on aesthetics, communication with the staff, participant comfort, and clinic flow / examination time.

- Clinic aesthetics
  - Painting and routine maintenance
  - African American art work from Tougaloo and Jackson State art departments,
  - Reading material, information on heart disease and heart health promotion, a pleasing “snack” environment where participants can mingle and talk with each other, as well as receive a nutritious snack will be a high priority.
  - Exam rooms serve as “office” JHS staff with personalized decorative items to create a mutually comfortable feeling for participants and staff
- Enhance participant physical comfort by providing
  - Lockers for personal belongings
  - Modest clinic clothing
  - Temperature control--provide robes for participants for warmth
- A personable, communicative and caring clinic staff is essential to retention.
  - Include the Council of Elders in personnel interviewing and new staff training
  - Ongoing staff training
- Timely participant flow
  - 2 hour exam

- Provide JHS videos, heart health education, and other useful information for use as during any potential time in the waiting area or snack area
- Video of the self-monitored blood pressure teaching
- Flexible clinic scheduling
  - To achieve 5 completed exams daily, we will schedule up to 10 exams, with the potential for up to 15 if this level of over scheduling is approved by the Clinic Manager.
  - Saturday clinics
  - Off site examination options

Maintaining ongoing Contact and Communication with the JHS family is also essential to retention. Participants are more likely to remain committed long-term if they can identify with the study. Just as family members stay in touch with each other to hear about day to day activities and important events in each others' lives, give and receive advice / recognition / gratitude, and learn new things, the JHS stays in touch with the participants regularly to provide an ongoing flow of information and recognition intended to provide a "lifeline" to the JHS.

- Sending birthday cards and holiday mailings
- A certificate of JHS membership
- Monthly raffle and end of clinic "trinkets"
- JHS Newsletter semiannually
- JHS Family Reunion and Birthday Party each September
- Annual\_Celebration of Life sponsored by the Coordinating Center
- Community Monitoring Board, held annually in December
- Participant link on the JHS web site
- Extending the number of contact attempts to > 6-8 as needed
- Active efforts for participant conversion of missed appointments/contacts or refusals
- Well trained clinic and AFU staff
  - Skill training
  - Interpersonal relationships
  - Supervision
  - Quality control

#### **1.1.1.2 Safeguarding Concerns**

Maintaining a timely examination and providing immediate feedback on results are important ways of safeguarding participant concerns.

- Provide same day feedback on all elements of clinic examination with option for notification of health care provider for abnormal results
- Ongoing involvement of cohort in development of consent forms
- Continue innovative "pledge of the investigator" initiated in Exam 1 consent
- Initiating formal "process" consent form with review of prior consent documents as part of each exam cycle
- Ongoing community workshops and educational offerings, particularly concerning genetics
- Community Monitoring Board

#### **1.1.1.3 Building Community Partnerships**

As we have learned from the Participant Recruitment Study and Exam 1, support of family and community is crucial to ongoing participation. The feeling that there is benefit to the entire community, not just the individual participant, is an important lesson. Several activities of the Community Outreach arm of the JHS have been instrumental in recruitment and will be essential for ongoing retention. Most notable is the development of the Community Health Advisor (CHA) Network for the JHS in each of the three counties.

- CHAs will continue to serve as community ambassadors for the JHS, sponsoring and participating in JHS and community activities
- “Red Hat Society” will continue to visit area churches on a regular basis—wearing a red hat or a red tie highlighting ongoing participation and providing timely information about the study and its many community activities to church attendees
- Target specific demographic and health groups ongoing study involvement
- Continue community health fairs and screenings targeted in the most densely populated JHS participant communities, as well as to areas with a high concentration of potential “difficult to retain” participants
- Community JHS presentations to include the following topics: KYN, obesity, managing stress, genetics and other subject matter related to cardiovascular disease
- Community Outreach office will continue a well-articulated public relations and media campaign with targeted television, radio and print activities, when appropriate.

### **1.1.2 Overview of Protocol for Retention**

The protocol for participant retention includes detailed instructions to staff regarding participant scheduling. Special instructions are included for:

- persons who have moved > 50 miles since Exam 1
- an initial contact letter followed by telephone contact during Annual Follow Up
- scheduling confirmation
- reminder telephone calls
- detailed plans for no shows and rescheduling incomplete examinations
- off-site examinations

Extensive tracking of each phase of the protocol is included and will be carefully monitored by the Participant Retention Committee, the Administrative Team, and the Steering Committee at their regular monthly or bi-weekly meetings.

The JHS web site will serve as a central information source for participants regarding their current “phase” in the study. They will be able to schedule upcoming clinic exam or AFU calls via this mechanism. In addition, all participants will receive annual updates in conjunction with mailings for the Annual Birthday Party and Family Reunion. Included in this mailing will be information that alerts them to the upcoming examination cycle and provides an approximate date and year for their pending individual examination. The mailing will be merged from the Participant Scheduling List (see below) to obtain accurate scheduling information. This will be updated each year to reflect their exam status, either thanking them for having completed their exam, or letting them know when they may expect to be contacted. This communication will also include the invitation for the participant to schedule her / his examination with the Examination Center by phone or web site in advance of receiving a call from JHS.

## **1.2 Scheduling Clinic Appointment (CLA)**

### **1.2.1 Eligibility for Exam 2 Scheduling**

All participants in the CY06 who completed all or part of the baseline clinic examination (Exam 1) are eligible for continuation in Exam 2. Timing of Exam 2 scheduling is an approximately equidistant time from the Exam 1 clinic visit, taking into account modifications to accommodate a shorter exam cycle. If the participant is not seriously injured or ill and is willing to come for the exam, s/he should be scheduled. Participants can complete the second exam with broken limbs as long as one arm is unbroken for completion of the blood pressure measurement.

For female participants who are in the age range where pregnancy could be a possibility, probe to determine pregnancy status. Inform them that while they can come in while pregnant as there are no tests that could be detrimental to their pregnancy, we would prefer, if possible, to examine the women when they are NOT pregnant. Explain that this is because there are important changes in

women's blood chemistries during pregnancy (such as glucose) that may not be within their normal range.

### **1.2.1.1 Participant Scheduling List**

The Examination Center Data Manager will run a Participant Scheduling List from the program provided by the Coordinating Center for that purpose. The Participant Scheduling List orders participants by their expected Exam 2 exam date in keeping with the order of their participation in Exam 1. This program will accommodate changing the exam window such that the 3 ½ year cycle for Exam 1 is compressed into 3 years for Exam 2 and participant flow is equalized across the three years.

### **1.2.1.2 Greater than 50 Mile Scheduling List**

Also, the Coordinating Center has provided a program for identifying persons who have moved > 50 miles from their home address at the time of Exam 1. The Data Manager will run the > 50 Mile List as a subset of the Participant Scheduling List.

The primary purpose of the > 50 Mile List is to enable the research interviewer to efficiently begin contacting and scheduling these participants in the most cost-effective manner. The goal is to bring them back for the second exam without having to pay high travel costs. To do this requires flexibility on the acceptable travel interval between the first and the second examination. Contact should be initiated at least 4 months in advance of their target date to give the best chance of arranging travel within a month of their date.

### **1.2.2 Participant Contact (ARC)**

Initial contact letters (Appendix) will be mailed to participants selected from the Participant Scheduling List *at least* one week prior to initiating scheduling attempts and to the >50 Mile List with one of the first mailings. For most participants, contact should be initiated approximately 4-8 weeks in advance of their target exam date. As noted above, for those participants on the > 50 Mile List, contact should be initiated immediately upon receipt to allow for the most flexible scheduling possible over the duration of the three year exam cycle. Early contact could facilitate bringing them in during a planned family visit or for vacation sometime over the exam period, but who otherwise would not be returning. Start with those whose target appointment date is in September 2005, and then move to each succeeding month.

The Research Interviewer will make contact attempts with participants selected from these lists as part of their AFU calls, and invite them to come to Exam 2. This initial telephone contact will include:

- an introduction and description of Exam 2
- invitation / scheduling
- arrangements for expense reimbursement / transportation / child care
- arrangements for reminder telephone call
- review of pre-exam instructions
- any special arrangements for participants now living > 50 miles away.

Participants will be directed to the JHS web site at the interviewer's discretion for additional information.

Results of all initial telephone contacts will be recorded in the DMS using the ARC (Annual Follow Up Record of Calls) form (Forms Manual for form and question by question [QxQ] instructions; Section 8.0, Manual 2 for more detailed information).

### 1.2.3 Participant Scheduling

#### 1.2.3.1 Making the Clinic Appointment

Clinic appointments are made by the research interviewer at the completion of the Annual Follow Up interview using the Clinic Appointment Form (CLA). Detailed QxQ instructions are specified in the Forms Manual. Upon completion of the interview and appointment scheduling, the interviewer accesses the web based scheduling system, enters the participant's JID, and the date and time of the clinic appointment.

The interviewer is to assist the participant to make an appointment for a date and time that is most convenient for her/him during her/his target exam week. If a participant is unable to schedule an appointment at that time, schedule an appointment for another time—keeping it as close as possible to the target week. The participant may make a tentative appointment date with the understanding that s/he will be called back within 7-10 days to confirm. If the participant is willing to come for the exam but is unwilling to schedule a specific appointment date, ask him/her to indicate a specific week or month when he/she thinks he/she might be able to take the exam. Arrange to recontact them approximately 2 weeks prior to that week (or month) to schedule a definite appointment. If the participant expects to move and/or not be in the area of the Examination Center during the Exam year for another reason, use the special procedures for participants who are >50 miles, below.

Review the pre-exam instructions with the participant as noted in the CLA form. After determining that he/she can fast (CLA), please stress fasting for 12 hours (nothing except water and all medications, including blood pressure medications) since both of these were a problem for some persons during Exam 1. Also, stress the importance of bringing ALL medications, including over the counter, herbals, and so forth, as well as prescription medications.

Indicate that the participant will be contacted during the week before the exam date, and again the day before as a reminder. Ask her/him to place the date and time on her/his calendar while you are talking with them.

Also, participants may make their own appointments separate from the Annual Follow Up process by using the JHS web-based appointment scheduling system. Specific instructions for using the system are mailed to the participant with the initial contact letter. Participants go to the JHS web site at [www.jsums.edu/~jhs/](http://www.jsums.edu/~jhs/) and select the Participant button. The scheduling system is then selected and s/he follows the instructions for scheduling an appointment.

The Data Manager will run a daily update to the Participant Scheduling List and the web-based appointment scheduling system to capture all activities of that day and to generate the list of participants scheduled to be examined for the next day(s).

#### 1.2.3.2 Special Arrangements

##### 1.2.3.2.1 Transportation

The JHS will provide or reimburse transportation to the JHS Examination Center for completion of the clinic examination. Special arrangements are available with a contract taxi service to pick up and return the participant to her/his home or place of departure. Inform the participant that this is available. Also inform the participant that if s/he would like to be reimbursed for travel, a travel reimbursement form will be available in the clinic and will require an exact address for calculation of mileage. Mileage will be paid at the current state mileage rate, but not to exceed \$40.

### 1.2.3.2.2 > 50 Mile Arrangements

If the participant lives > 50 miles away, JHS will also reimburse costs for travel to the Examination Center as possible, determined on an individual basis. However, whenever possible, the interviewer should attempt to schedule the Exam 2 visit at a time when the participant will be in Jackson for family or other business. If this is possible, make an appointment during that time. If this is not possible and the participant is unwilling to travel at her/his own expense to complete the exam, advise the participant that the JHS has limited funds for assistance with actual travel costs for cases such as this. Negotiate with the participant at this point to determine how to accommodate the most economical travel costs from her/his destination to the JHS Examination Center. The Director of Retention, in consultation with the Exam Center Director, will determine the allowable travel reimbursement for such participants within budget limits.

The interviewers should schedule each of the >50 mile participants according to the following list of priorities:

- 1) Schedule the participant's appointment within one month of the target date with no reimbursement for actual travel expenses above usual and customary mileage for a clinic exam visit.
- 2) Schedule the participant's appointment for ANY TIME during the three year exam cycle with no reimbursement for usual and customary mileage for a clinic exam visit.
- 3) In consultation with the Director of Retention and the Exam Center Director, arrange for participant to return to Examination Center with reimbursement for actual travel expenses within a budgetary constraint. In general, the JHS will use the following general guidelines in determining allowable expenses, though these may be individually negotiated: a) up to \$250 for train, plane, or bus fare; b) state gasoline reimbursement rate per mile for driving (not to exceed \$250); c) \$65 for one night's lodging, and d) \$30 per diem for two days. The suggested maximum total per any one participant is \$375. (DO NOT QUOTE NUMBERS TO PARTICIPANTS).
- 4) Arrange for the participant to have an off-site examination in a locale within the tri-county area with no reimbursement for actual expenses above usual and customary mileage for a clinic exam visit,  
(NOTE: These costs may need to be adjusted during the time frame of the exam to accommodate changes in air fares and gasoline rates)

If the JHS is to pay travel costs for > 50 Mile participants, assure that they understand that receipts are necessary to be reimbursed. Tell the participant to bring all receipts with him/her to the clinic visit and that s/he will be mailed a check after the clinic exam is completed.

PLEASE NOTE THAT NO ADDITIONAL TRAVEL MONIES SHOULD BE SPENT ON PARTICIPANTS THAT ARE EXCLUDED FROM THE EXAM 1 DATA ANALYSIS—SEE LIST PROVIDED BY THE COORDINATING CENTER FOR THIS PURPOSE.

### 1.2.3.2.3 Child or Adult Care Arrangements

If the participant needs assistance with child or adult care, inform the participant that the JHS will either provide that care at the clinic (preferable) or, if we cannot locate appropriate volunteers to do so, we will reimburse the participant for those costs for the time of the clinic visit (not to exceed \$30). This reimbursement should not be offered unless it is clear that there are no other options available to bring the participant to the clinic. In that instance, attempt to make an appointment for an off-site clinic visit (Section 1.3, below).

### 1.2.3.3 Confirmation of Clinic Appointment

Confirmation letters, including pre-examination instructions (PART-Participant Instruction Sheet; MIN-Medication Instruction Sheet), a plastic bag for transporting all medications to the JHS clinic,

and a Health Care Provider (REQPC-Request Health Care Provider Contact Information) and Contact worksheet, are sent to participants one to two weeks before their exam is scheduled. The JHS web site link with instructions for access, and a Consent Brochure for the appropriate exam year are also included in the confirmation letter. If, in the judgment of the interviewer, the participant would benefit from viewing the JHS consent video in advance of the clinic visit, this may also be included in the mailing.

Specific instructions include:

- Appointment time and date
- Directions to the clinic (a map) and to parking facilities (JHS provides free parking)
- Preparations
  - No blood donation within 7 days of visit
  - 12 hour fast
  - No tobacco or vigorous activity
  - Clothing to wear for the visit
- Things to bring
  - Eyeglasses for reading
  - Name and address of health care provider
  - Name, address, and phone number(s), email of contact persons
  - Medications
    - A script describing the need for medication information is on the Annual Follow Up forms and is read to the participant at the time of scheduling. The reminder sheet also indicates which medications should be brought. A bag is provided in which to carry the medication.
- Clinic Operation
  - Clinic hours and phone number
  - Length of exam (no more than 2 hours)
  - Snack is provided after finger stick blood
- Transportation
  - The JHS will provide transportation and arrange for participant pick-up for those participants who need this service
  - Those who drive are asked to record mileage for reimbursement or bring their exact address for web-based calculation of mileage
- Optional contact by JHS Council of Elders for additional information about participation

When appropriate, a letter is sent to the participant's employer explaining the JHS and requesting time off during working hours (Appendix: Employer Letter)

#### **1.2.3.4 Reminder Telephone Calls**

The evening Patient Representative in the Examination Center makes reminder telephone calls to participants three and one day before their scheduled clinic appointment. Confirmation of transportation and child care needs will be made on the final reminder call. If a participant has moved and is traveling to attend the clinic, this phone call will be made in keeping with the participant's travel schedule.

#### **1.2.3.5 Rescheduling Missed Appointments**

After the scheduled clinic date for the participant has passed and the clinic examination has not been noted as Complete, the tracking system report will identify participants who have missed their appointments. When possible, the Clinic Receptionist / Patient Representative should call the participant ON THE SAME DAY as the missed appointment to attempt to reschedule. Otherwise, initiate calls the day following the missed appointment and follow the procedures for scheduling a clinic appointment. At that time, the scheduler attempts to address any concerns or fears that the participant may still have. A volunteer Council of Elders contact may also be

initiated. When necessary, the Clinic Manager or one of the investigators may also talk with the participant.

After several unsuccessful reschedule attempts, or missed appointments, attempt to schedule an off-site examination appointment for the participant.

### **1.3 Off Site Examinations**

Every effort will be made to maximize the return rate of the JHS cohort for Exam 2. These efforts will include performing an off site examination with participants who refuse or are unable to travel to the Examination Center, but are willing to provide information at home or some other convenient locations. Implementation of this option will not be started until there is sufficient documentation of the inability to schedule the participant for an on site examination. When an off site examination is scheduled, a member of the Examination Center clinic staff will travel to the off site location and complete all Exam 2 components. When this occurs, the Tanita Bioimpedance scales and height measures will be used for height and weight measurement (as well as for their usual measurement of body composition parameters). As well, blood pressure will be measured using digital equipment rather than random zero mercury manometers.

In addition to individual off site examinations, on occasion, the Examination Center will set up off site examinations in a convenient community based locations to accommodate groups of participants who live at a significant distance from the Examination Center. These will be scheduled well in advance and participants residing in that locale with pending clinic examinations will be notified of this option for completing their Exam 2 clinic visit.

### **1.4 Recognition of Participant Ongoing Personal Contact**

A personal thank you is sent to each participant immediately following each AFU interview (see Appendix). At the time of the clinic visit, each participant receives a small gift of appreciation for taking part in the exam as well as a more substantial gift or \$25 as selected by the participant. Another thank you and formal recognition as a participant in the JHS is mailed immediately after completion of the baseline exam and 24-hour measures. This recognition is a certificate of membership in the JHS cohort that is suitable for framing (see Appendix).

The Examination Center maintains personal contact with each participant throughout the year on special occasions such as birthday, holidays and special cultural events significant to the African-American community. The Office of Community Partnership issues a semi-annual JHS Participant Newsletter mailed to all cohort participants updating them on study progress including new and emerging findings.

### **1.5 Participant Follow-up and Satisfaction**

A "Comments and Suggestions" box is prominently located in the reception area of the Examination Center clinic. Forms and pencils are provided for participants to comment on their clinic visit. A Participant Evaluation of Clinic Visit (PEC) (see Forms Appendix; section 3.10) is conducted at the conclusion of the clinic visit to obtain a global rating of the visit and suggestions for improvement. A Participant Satisfaction Survey (see Forms Appendix) is conducted by telephone on a 5-10% random sample of the cohort at periodic intervals. This satisfaction instrument is designed to gather information about all components of the clinic scheduling, clinic examination, and annual follow up. Additionally, in-depth interviews regarding the experience of participating in the JHS may be conducted with a designated percentage of the cohort on occasion. Interviewer/recruiters and clinic staff will notify the Examination Center co-PI of any participants who have had particularly notable experiences for follow-up interviews. These interviews will provide ongoing information for quality improvement and retention of the JHS cohort. Findings from the satisfaction surveys and in-depth interviews will be reviewed regularly

by the Council of Elders, Participant Recruitment, and Clinic Operations Committees who will advise on strategies to improve study performance.

## 2.0 EXAM 2 DESIGN, LOGISTICS, TRAINING, AND QUALITY CONTROL

### 2.1 Introduction

During the annual follow up interview, cohort members in the Contact Year 06 are invited to return for a second clinical examination (Exam 2). As envisaged during the initial design of the JHS, a core component of the cohort examination has remained constant to allow for comparability. As with Exam 1, measurements of blood chemistry (glucose, lipids), blood pressure (sitting), body frame / size (anthropometry) are included in Exam 2. Core interviews are continued to document relevant / incident cardiovascular disease, symptoms and medical care, fasting status prior to blood draw, use of medications (prescriptions, over the counter, herbals, vitamins and mineral supplements, and gonadal hormones in women), menstrual status in women, and prevalent / incident cerebrovascular disease (stroke / TIA).

In addition to these core components some additional JHS procedures and interviews have been included to supplement this information. New procedures in Exam 2 include the documentation of body composition, including percent body fat as well as the addition of hip circumference to the determination of body frame / size. As it is anticipated that mercury blood pressure manometers may be phased out of clinical use, a blood pressure comparability study is included to allow for validation of digital measurement in comparison with the gold standard random zero mercury manometer used in Exam 1. Exam 2 blood pressures will continue to be taken with the random zero equipment; however, some participants whose examinations are conducted off site may have digital blood pressure measurement, after assuring measurement comparability. Similarly, a comparability study will be conducted using the gold standard standing balance beam scale and standing height measurement and the Tanita TBF 300A body composition analyzer equipment. As with blood pressure measurement, participants having off site examinations will have their height and weight measured using the Tanita equipment, after assuring measurement comparability.

New interviews in Exam 2 include a more extensive documentation of renal medical history, as well as additional information on having been breastfed as an infant, weight at birth, age 18, and other factors related to weight control and perception.

Table 2.1, below, provides a summary of the core components of Exam 2 identifying the activities at each work station and cross referencing each procedure with its respective location in the Manual of Operations. Table 2.2 provides a summary of the two comparability studies included in Exam 2 which are being conducted to assure measurement comparability using different equipment.

<b>Table 2.1 Core Components of the Exam 2 JHS cohort examination, listed in alphabetical order, and location of the procedure / interview in the Manual of Operations</b>		
<b>Exam Component</b>	<b>Description</b>	<b>Manual_section</b>
Anthropometry	Measure height, weight, waist and hips.	M2_3.2
Body Composition	Measure percent body fat, free fat mass, total body water, basal metabolic rate, and desirable range for percent body fat and fat mass	M2_3.2
Informed Consent	Obtain informed consent for core Exam 2 examination including authorization for collection of study data, access to medical records, release of study data, data sharing, and reaffirmation of continuing use of Exam 1 study data	M2_3.3, 3.4

Interviews	Collect medical, health, stroke /TIA, and renal history; medication/vitamin use	M2_3.0
Finger Stick (Digipuncture) Laboratories	Collect by digipuncture fasting glucose and lipids (total cholesterol, Triglycerides, HDL, LDL, VLDL)	M2_4.3
Medical Data Review	Ascertain the completeness of the exam and verify abnormal results. Review results of medical history with participant and provide a written summary report of clinical examination findings. Refer participant for diagnosis or treatment if needed. Return medications, answer questions. Meet with social worker for assistance with locating medical care and completion of satisfaction interview. Thank participants. Reschedule for missed procedures.	M2_5.0, 6.0
Reception	Greet the participant, collect Participant Contact Information form, and verify identifying information. Obtain informed consent, collect medications, and determine fasting status.	M2_3.1
Self- Monitored Blood Pressure	Participants will be given a home blood pressure monitor and taught to use it. Initial readings will be obtained in clinic with follow up self-report readings 2-6 weeks post clinic visit	M2_4.5 M4
Sitting Blood Pressure	Assess sitting blood pressure using random zero sphygmomanometer and / or Omron HEM-907XL (comparability study or off site measurement); average of two measurements	M2_4.1 M4
Snack	Provide heart healthy snack with no stimulants	M2_4.4

<b>Table 2.2 Components of the Comparability Studies in the JHS Exam 2 and their location in the Manuals of Operation</b>		
<b>Comparability Component</b>	<b>Description</b>	<b>Manual_Section</b>
Blood Pressure	Comparability between two measures of sitting blood pressure: random zero sphygmomanometer and Omron HEM-907XL digital manometer on 300 participants at the beginning of Exam 2	M2_4.1 M4
Height	Comparability between two measures of height obtained with traditional wall mounted tape devise and Tanita TBF 300A height rod on 300 participants at the beginning of Exam 2	M2_3.2
Weight	Comparability between two measures of weight obtained with standing balance beam scale and Tanita TBF 300A Body Composition Analyzer scale on 300 participants at the beginning of Exam 2	M2_3.2

Annual follow up telephone contact is a continuing component of Exam 2 using core procedures identical to those used in the ARIC study. It is intended to obtain updated information regarding participant vital and health status, medical history, diagnostic and invasive procedures, and hospitalizations. If the participant has either died or been hospitalized, surveillance activities are triggered. In addition to the core procedures, Exam 2 includes documentation of additional information on an annual basis to identify symptoms of congestive heart failure, identify reasons for cardiovascular diagnostic procedures, update family history, track psychosocial parameters, and any changes in insurance or health access status.

Cohort surveillance is also continued using core procedures identical to the ARIC study cohort surveillance activities. It is intended to gather key event information by abstracting medical records for all cohort hospitalizations. For cohort deaths, surveillance includes contacting next of kin, coroners, and attending health care providers, as well as obtaining a death certificate to allow determination of cause of death. Table 2.3 summarizes the core components of annual follow up and surveillance, identifying the activities and cross referencing each procedure with its respective location in the Manual of Operations.

<b>Table 2.3 Components of Annual Follow Up (AFU) and Surveillance in the JHS Exam 2 and their location in the Manuals of Operation</b>		
<b>Component</b>	<b>Description</b>	<b>Manual Section</b>
AFU ID information	Update Contact (CON) form	M2_8.5
AFU Interview	Annual telephone call to ascertain: 1) correct contact information, 2) update tracing information on 3 contact persons, 3)ascertain participant's vital status, 4) document medical events, life events, and functional status	M2_8.0
Annual Follow Up Additional Questions	Additional questions administered at the time of AFU contact to document: 1) CHF symptoms, 2) update family history, 3) ascertain cardiovascular invasive procedures / diagnostic tests and their indications, 4) update psychosocial parameters, 5) update health access and insurance status	M2_8.5
Surveillance	Ascertainment of cohort events by: 1) abstracting hospitalizations each year, 2) obtaining information from death certificates and key informants (next of kin, coroner, health care provider) on cause and circumstances of death	M2_9.0 M4

This chapter provides an overview of the design and objectives of the second cohort examination for the JHS (Exam 2). It describes the logistics for setting up the examination as well as the overall training and quality control. Chapters 3-9 of this manual provide the details of the second cohort examination including procedures for administering participant interviews and conducting exams, annual follow up, and cohort surveillance; references to the pertinent manuals of the protocol for those examination procedures not covered in detail in Manual 2; and references to appendices of forms and question by question (QxQ) instructions for their administration. Chapter 3 provides the rationale and describes the Exam 2 clinic interviews, the training and certification required to perform the interview, the quality assurance activities, and the data collection instruments and processes. Chapter 4 provides similar information for the procedures performed during Exam 2. Chapter 5 describes the activities associated with reporting results. Chapter 6 details the referral and review guidelines for abnormal clinic examination findings. Chapter 7 outlines the procedures at the Examination Center to ensure participant safety. Chapter 8 provides the rationale and describes the Annual Follow Up interviews, the training and certification required to perform the interview, the quality assurance activities, and the data collection instruments and processes. Chapter 9 refers the reader to the Cohort Surveillance / Events Ascertainment Manual of Operations for similar information regarding surveillance.

In general, the numbering of the sections within Chapters 3-6 and 8 follows a standard format: a description of the rationale for the interview, procedure, or activity (.1), operational procedures (.2), training requirements (.3), the certification criteria (.4), routine quality assurance activities (.5), and data collection procedures (.6).

The rationale (.1) for core interviews, measurements, and procedures briefly summarizes the major premise(s) for its inclusion in the JHS and its continued use in Exam 2. A more detailed rationale is provided for the new components in Exam 2.

The section on operational procedures (.2) describes in detail the procedures for administering the interviews, conducting examinations or taking measurements, or gives a reference to the appropriate manual of operations for the procedures with their own separate protocols. Standardized definitions or terms for use by the interviewer or respondent in an interview or instructions for administering or filing in individual questions on the data collection forms for each interview, measurement or procedure are provided in the QxQ instructions which are located in the appendix Forms Manual immediately following the individual data collection form.

Training requirements (.3) and certification criteria (.4) are listed separately from their traditional rubric of quality assurance to provide easier reference for study personnel. Training materials additional to those in this manual of operations on data management, general interviewing techniques, the administration of all interviews, the measurement techniques were compiled for the Exam 2 central training workshop and are available in a separate notebook.

To reduce the use of repetitive statement for each procedure in the sections on training and certification for interviews and procedures, it is understood that the minimum training and certification requirements / criteria for all Exam 2 interviewers, technicians, and clinicians are a command of the pertinent protocol sections and forms, and demonstrated proficiency on the JHS direct data entry/management system (DMS) or back-up procedures for completing paper forms. Detailed instructions for completing paper forms and for standardized interviewer techniques are found in the Appendix.

Table 2.4 lists the personnel responsible for the training or each interview / procedure at the outset of Exam 2. The Quality Assurance section (.5) briefly summarizes and /or references the additional quality control activities that are carried out by Examination Center personnel and globally by the Coordinating Center (see Manual 5, Quality Assurance and Quality Control).

The final section in each section is on Data Collection (.6) which briefly summarizes the standard and backup operation procedures for data collection using both the direct and delayed entry systems. A separate manual, Manual 6: Data Management serves as the official reference document for all data collection and systems management procedures.

The appendices for this manual provide support material for Chapters 1-8 containing, among other items, prototypes for all participant results reports and quality control checklists. Forms and QxQs are maintained in a separate Forms Manual that also serves as an Appendix to this manual.

<b>Table 2.4 Training and Certification Criteria for JHS Exam 2 Interviews and Procedures</b>				
<b>COMPONENT</b>	<b>CERTIFICATION REQUIREMENT</b>	<b>CERTIFIER OR REVIEWER</b>	<b>RECERTIFICATION REQUIREMENTS</b>	<b>RECERTIFIER OR REVIEWER</b>
AFU (CY06-09) Annual Follow Up – typically done by telephone	Review of AFU procedures	Director AFU or Interviewer team leader/CC Central Trainer	Annual Rose Questionnaire Exercises Annually, 1 taped participant interview	Supervisor or Interviewer team leader
ANTHROPOMETRY / BODY COMPOSITION  Height Weight Waist Hip % Body Fat Fat Mass	Technicians certified at CC training; Clinic Manager leads all other training  1cm of trainer 1 cm of trainer 1 cm of trainer 1 cm of trainer Agreement with trainer Agreement with trainer	Clinic Manager or interviewer team leader/CC Central Trainer	Biannually (January/July), results sent to CC annually  Annual recertification for lead technician during annual CC monitoring visit	Supervisor or Interviewer team leader  Monitor
BLOOD PRESSURE, SELF-MONITORED	SMBP lead technician  1 acceptable group and individual class	Clinic Manager or lead technician	Biannually (January / July), results sent to CC annually  Annual recertification for lead technician during annual CC monitoring visit	Clinic Manager  Monitor
BLOOD PRESSURE, SITTING   2 replicate measures	Lead technician (Clinic Manager) certified, all others training by Clinic Manager   < 4 mm Hg/reading < 3 mm Hg/average	Lead technician   Coordinating Center	Biannually (January / July), results sent to CC annually  Annual recertification during annual CC monitoring visit  Continuous	Lead technician  Monitor  Coordinating Center

<b>Table 2.4 Training and Certification Criteria for JHS Exam 2 Interviews and Procedures</b>				
<b>COMPONENT</b>	<b>CERTIFICATION REQUIREMENT</b>	<b>CERTIFIER OR REVIEWER</b>	<b>RECERTIFICATION REQUIREMENTS</b>	<b>RECERTIFIER OR REVIEWER</b>
Digit preference mean values	None			
CONSENT	Adequate technique on 5 taped consent	Clinic Manager / EC Director	Biannually (January / July) Methods reviewed annually during CC monitoring visit	Clinic Manager and CC monitoring round robin Monitor
DIGIPUNCTURE	Training by Clinic Manager / lead technician who are certified; 2 acceptable draws/processing	Clinic Manager / Lead technician	Biannually (January / July) Annual CC monitoring visit	Lead Technician Monitor
LETTERS/REPORTS Participant results reports	Steering Committee approval	Clinic Manager or EC Director / PI	Methods reviewed annually during CC monitoring visit	Monitor
MEDICATION SURVEY Interview	Adequate technique on 5 taped interview	Clinic Manager or lead interviewer	Annually, 1 taped participant interview included in round robin	Clinic Manager and CC monitoring round robin
Transcription	80% correct on supervisor review	Clinic Manager	Methods reviewed annually during CC monitoring visit	Monitor
Coding	80% correct on coding exercises	Coordinating Center		
MEDICAL DATA REVIEW	Steering Committee approval	EC Director / JHS PI	Methods reviewed annually during CC monitoring	Supervisor or Interviewer Team Leader and Monitor
MEDICAL HISTORY interview	Adequate technique on 5 taped interviews	Clinic Manager or Interviewer team leader	Annually, 1 taped interview included in round robin review	Clinic Manager
PHYSICIAN REVIEWS	Adequate technique on 5 reviews	Exam Investigator	Annually, 1 complete review	Exam Investigator

<b>Table 2.4 Training and Certification Criteria for JHS Exam 2 Interviews and Procedures</b>				
<b>COMPONENT</b>	<b>CERTIFICATION REQUIREMENT</b>	<b>CERTIFIER OR REVIEWER</b>	<b>RECERTIFICATION REQUIREMENTS</b>	<b>RECERTIFIER OR REVIEWER</b>
PARTICIPANT SATISFACTION interview	Adequate technique on 5 taped interviews	Clinic Manager or Interviewer team leader	Annually, 1 taped interview included in round robin review	Clinic Manager
PARTICIPANT SAFETY	Local review of safety procedures	Clinic Manager	Annual safety review	Clinic Manager
RECEPTION interview	Adequate technique on 5 taped interviews	Clinic Manager or Interviewer team leader	Annually, 1 taped interview included in round robin review	Clinic Manager
RENAL DISEASE interview	Adequate technique on 5 taped interviews	Clinic Manager or Interviewer team leader	Annually, 1 taped interview included in round robin review	Clinic Manager
RESULTS REPORTING	Adequate technique on 5 reports	Committee Chair or Interviewer team leader	Annually, 1 complete review	Committee Chair or Interviewer team leader
REFERRALS AND REVIEW GUIDELINES	Adequate technique on 5 referrals	Committee Chair or Interviewer team leader	Annually, 1 complete review	Committee Chair or Interviewer team leader
STROKE SYMPTOMS interview	Adequate technique on 5 taped interviews	Clinic Manager or Interviewer team leader	Annually, 1 taped interview included in round robin review	Clinic Manager
SURVEILLANCE	Central and local review of surveillance procedures	Surveillance Supervisor or Lead Records Administrator	Exercises annually at Exam Center and University of North Carolina Collaborative Coordinating Center certification training	Supervisor or Lead Records Administrator UNCCC Monitor

## 2.2 Participant Flow

The participant flow is based on a paradigm modified from its long term successful use in the ARIC study for use in Exam 1 of the JHS. The schedule is divided into fixed and non-fixed sequences to accommodate legal requirements, scientific constraints of which measurement cannot precede another, the daily fluctuations in Examination Center staffing patterns, and unforeseen number of participants who keep scheduled appointments, the configuration of the Examination Center physical layout, equipment availability and function, and allowing for the future integration of ancillary studies, and so forth. Participant flow and the approximate time associated with each workstation are outlined in Table 2.5.

<b>Table 2.5 Participant Flow, JHS Exam 2</b>	
<b>Procedures / Workstations</b>	<b>Approximate Time</b>
<b>FIXED SEQUENCE #1<sup>1</sup></b>	
RECEPTION Informed Consent Informed Consent Form Update Contact Information Fasting Status Collect Medications CHANGE OF CLOTHES	15 minutes
ANTHROPOMETRY SITTING BLOOD PRESSURE	6 minutes 6 minutes
DIGIPUNCTURE	5 minutes
SNACK	8 minutes
<b>FLEXIBLE SEQUENCE<sup>2</sup></b>	
BODY COMPOSITION	5 minutes
STAFF ADMINISTERED QUESTIONNAIRES Health History Medical History Renal Disease Stroke Symptoms	40 minutes
SELF MONITORED BLOOD PRESSURE TEACHING	20 minutes
<b>FIXED SEQUENCE #2<sup>1</sup></b>	
DATA INVENTORY (staff activity) CHANGE CLOTHES MEDICAL DATA REVIEW	5 minutes 10 minutes
<b>TOTAL TIME</b>	<b>2.0 hours</b>

<sup>1</sup>Components in the Fixed Sequence #1 and #2 are considered first priority should a participant be unable to complete Exam 2 in one visit

<sup>2</sup>Components in the Flexible Sequence can be rescheduled for a second visit should the participant be unable to complete Exam 2 in one visit

### **2.2.1 Rationale**

The fixed components of scheduling participant flow reflect the requirement to initiate the examination with the administration of informed consent, the scientific constraints which establish the grouping of procedures which require fasting, and the logistical necessity of conducting medical data reviews after all other procedures have been completed. The flexible components reflect the advantages of having the interviews and examinations conducted in accordance with the Examination Center physical layout and the scheduling patterns for participants. This approach is intended to minimize participant burden to approximately 2 hours and reduce variability in study measurements.

### **2.2.2 Fixed Sequences**

Exam 2 always begins with the administration of the informed consent at the reception workstation and always ends with the reporting of clinical examination results at the medical data review workstation. An outline of the components and the order in which they must be scheduled is provided in Table 2.5. After the participant has been welcomed and has signed the consent form, s/he is asked to change into a surgical scrub suit, provided by the Examination Center. The Examination Center provides a safe place to store clothing and valuables for the duration of the visit. After changing, anthropometry and sitting blood pressure are measured prior to digipuncture. Because the measurement of sitting blood pressure requires knowledge of the circumference of the right arm in order to select the appropriate blood pressure cuff size, anthropometry is generally performed prior to sitting blood pressure, and is generally performed at the same workstation. Digipuncture must be done while the participant is in a fasting state and could affect the participant's blood pressure. Therefore digipuncture is generally performed immediately after anthropometry and sitting blood pressure measures and at the same workstation.

Following digipuncture, the participant is shown to the snack area and provided with a caffeine-free, heart healthy snack.

### **2.2.3 Flexible Sequences**

The interviews and the body composition measures are scheduled in the non-fixed portion of the exam.

The Participant Itinerary Form (PIN) (Forms Manual) serves as a summary of clinically relevant data, either from participant self-report at the initiation of the exam visit or from the Coordinating Center from Exam 1 data, for use during reception, interviews, procedures, and medical data review. The PIN serves as a summary of procedures and interviews performed during Exam 2 and is either direct entered into a PDA format using a small portable computer (PDA) and subsequently downloaded to the DMS, or using a paper form and subsequently direct entered into the DMS. The PIN has several purposes: to monitor the amount of time it takes to complete each component for the examination to provide staff with information about where the participant is in the process, or to establish the participant's sequence of procedures and interviews based on the daily staffing patterns. It also serves as a single source to identify the completion status for each exam component. The paper version of the PIN stays on the front of the participant record as s/he moves from one workstation to another.

The participant's record of data acquisition is documented on the JHS Cohort Inventory (CXI) (Forms Manual) from within the DMS. The CXI is completed as a report from the DMS as each interview or procedure is completed and monitors the completion of data collection forms.

## 2.3 Training

The Examination Center staff is trained before the baseline exam to use a standardized technique for administering all Exam 2 interviews. Central training conducted by the Coordinating Center liaison in coordination with the Examination Center unit managers (Clinic Manager, Data Manager, Director of Retention and Annual Follow Up, and Surveillance Supervisor) includes an overview of the JHS Exam 2 components; an update overview of epidemiological cohort research methods; instructions in research interviewing techniques: communication, respecting cultural diversity and in specific forms completion including:

1. a thorough review of the forms, instructions and protocol to promote adherence to the protocol
2. practice in the use of non-judgmental attitude
3. practice with the degree and nature of prompting permitted dealing with problem interview situations
4. use of response cards
5. practice handling participants' comments and recording relevant information on the note logs
6. review of post interview responsibility for the data

For clinic staff, the Clinic Manager and interviewer team leader are responsible for training new staff based on standardized interview techniques (see Appendix), QxQ instructions for each form, practice scripts, and role playing. For Annual Follow Up staff, the Director of Retention and Annual Follow Up and interviewer team leader are responsible for similarly training new staff. For surveillance staff, the Surveillance Supervisor is responsible, in conjunction with the ARIC Coordinating Center, for training in methods of abstraction and out-of-hospital death interviewing techniques.

The Clinic Manager is responsible for training the clinic staff to perform each exam procedure by the Clinic Manager, assisted by appropriate study investigators as needed.

## 2.4 Certification

Table 2.4 summarizes certification and re-certification criteria for all elements of the JHS Exam 2 interviews and procedures. Interviewers are certified by the interviewer trainer at the successful completion of training. Certification is achieved by the demonstration of adequate technique on five taped interviews, reviewed and approved by the Clinic Manager (for exam interviews), Director of Retention (for annual follow up interviews), Surveillance Supervisor (for out-of-hospital death interviews) or interviewer team leader. Re-certification is completed annually and requires the successful completion of one taped interview. With participant approval, all interviews are taped for quality control. All tapes are included in the round robin and are reviewed by the interviewer supervisors selected to monitor each year's round robin. Special certification criteria beyond these tape reviews are described below with the appropriate exam component.

## 2.5 Quality Assurance

With participant approval, most interviewer-administered forms are taped for quality control. A non-systematic sample of forms is reviewed by the Clinic Manager / interviewer team leader and/or Coordinating Center training liaison monthly. Routine quality assurance is provided through observation by the Clinic Manager. Protocol adherence and interviewing techniques are reviewed at least biannually by Coordinating Center examination monitors. 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 Cohort Operations Committee. Data quality is monitored by the Quality Control Committee semi-annually.

### **3.0 INTERVIEWS IN THE JHS EXAM 2 CLINIC VISIT**

#### **3.1 Reception**

The reception workstation welcomes the participant to the clinic and initiates the baseline exam interviews and clinical measurements at the Examination Center. Prior to the participant's arrival, an Exam 2 folder is assembled which contains labeled data collection forms: the most recent annual follow up Record of Calls and Clinic Appointment Scheduling (CLA) forms (these may also be filed in a separate, recruitment folder at the discretion of the Examination Center, but are available for use during the JHS exam), the Participant Itinerary Sheet (PIN), and blank copies of the JHS Exam 2 informed consent form and a print out of the participant's Exam 1 ICF form. Folders also contain ALERT/REFERRAL logs for use in baseline exam. The PIN is attached to the outside of the clinic visit folder. Paper versions of all DMS forms are readily available for staff use should the DMS be inaccessible.

For off site examinations, participant folders are assembled to include the above plus a paper copy of all Exam 2 data clinical exam data collection forms. Specifically, the file would include the CON (contact), ICF (Informed Consent Form), FTR (Fasting Tracking), BCF (Body Composition Form), SBP (Sitting Blood Pressure), FST (Finger Stick Form), HHX (Health History Form), MHX (Medical History Form), RDF (Renal Disease Form), SSF (Stroke Symptoms Form), SMP (Self Monitored Blood Pressure), and a blank copy of the medical data review form.

On arriving at the Examination Center, the participant is greeted and welcomed. Travel reimbursement and participant payment information is obtained. Approach to Life and Health Care Provider Contact forms are collected and checked for completion. If incomplete, assistance is offered.

Informed Consent for the full JHS exam (see Appendix) is obtained before administering any other JHS interviews. Participant questions are answered. Demographic and tracking information (CON Form) are updated. Fasting status (FTR form) is determined. Consent to tape interviews for quality assurance assessment is requested and documented on the Itinerary sheet (see Forms Appendix). The Informed Consent Form (ICF) is completed either during or after the participant has left the reception workstation. Medication bags are logged and labeled.

General instructions on how to administer each interview are given in the text of Chapter 3 under the name of the data collection form. Specific instructions for completing each item on the data collection form are given in the QxQ instructions that follow each individual form in the Forms Manual Appendix.

The receptionist informs the participant that s/he will receive the results of Exam 2 at the conclusion of the exam before the participant leaves the Examination Center. Results of all studies done during the visit are reviewed by the JHS clinician after the participant has left the Examination Center (see Appendix). The participant is requested to take study results to her/his health care providers. Final results reports will only be mailed to health care providers if an alert finding is identified (see Chapter 6: Referrals and Review Guidelines; Appendix: Alert Letters).

When Informed Consent and the Fasting forms have been administered, the participant is shown where to change into an examination gown/robe, asked to remove all jewelry, and to place clothing and valuables in a secured locker.

Staff is trained for the reception workstation at central training and by the Clinic Manager at the Examination Center. Certification requirements include the successful completion of training on general interviewing techniques, Informed Consent, the Fasting/Tracking form, direct data entry for the DMS, and use of the web-based Participant Scheduling and Tracking System. Although no formal certification schedule has been established, interviewers working at the reception workstation are observed by the Clinic Manager for quality assurance and standardization.

## **3.2 Informed Consent**

Administration of Informed Consent precedes all other activities at the Examination Center. The core content and consent options of the Exam 2 informed consent documents comply with the National Institutes of Health and the National Heart, Lung, and Blood Institute guidelines on the protection of human subjects, the American Society of Human Genetics' statement on informed consent for genetic research and the approval of the JHS Steering Committee. The Institutional Review Boards of Jackson State University, Tougaloo College, and the University of Mississippi Medical Center have approved the study protocol and informed consent procedures, maintaining annual review.

The JHS consent includes two sections: the Consent Information and the Statement of Participation (Appendix). After reading the Consent Information, the participant is asked to select the specific items that s/he agrees to participate in and sign the Statement of Participation. The JHS consent form is available in written and audio recorded versions. Though the font size of the document is large, some participants may have difficulty reading the form. If requested, a magnifying glass is available for participant use or a staff member will read the document to the participant. In advance of the JHS Exam 2 clinic visit, participants received a consent brochure that provided key information regarding the exam.

The JHS consent form includes two unique components. The first is an investigator pledge to the participant to maintain confidentiality of the participant's data. This was initiated in Exam 1 and continues with the Exam 2 form. Exam 2 initiates a formal mechanism that provides participants the opportunity to review their prior consent statements and reaffirm or modify them in keeping with current preferences. As an addendum to the consent documents, the participant will receive a print out of her/his Exam 1 consent preferences for review. Also, a consent brochure from Exam 1 will be available should the participant wish to review or clarify aspects of that exam. The Clinic Manager and a study investigator are available to answer any questions the participant may have.

### **3.2.1 Rationale**

The primary objective of administering the Exam 2 informed consent is to affirm that the participant understands (1) the purpose of the research; (2) what data collection procedures are used; (3) the risks and benefits of participation; (4) alternatives to participation (5) what procedures are in place to protect confidentiality; (6) that s/he is free to participate, refuse any procedure or answer any question, and to withdraw at any time; (7) that withdrawing carries no penalties; and (8) that s/he may affirm or modify prior consent choices. The informed consent has a record of the JHS Principal Investigator and the name of a staff contact person (witness). Signing permits the participant to indicate her/his current preference for the use and disposition of study data, including genetic materials, and to change her/his preference at a future date; affirms permission to release clinically relevant study data to the health care provider of her/his choice, and gives the participant's permission to abstract her/his medical records in the event of hospitalization or death.

### **3.2.2 Administration**

The Informed Consent is administered as the first component of the baseline exam as part of the fixed sequence #1. The goals of JHS at the baseline exam are reviewed with the participant prior to the administration of any other data collection instrument. Consent to participate in the second JHS examination is documented on the Informed Consent Form (ICF) (see Forms Appendix). Written, audio and visual consent forms are available. Time is allowed for the person to read and ask questions about the informed consent documents in a confidential setting. If the participant is visually handicapped or otherwise incapable of reading the study description and informed consent page, the narrative portion is read to her/him and then the person is asked to sign the

document. The original Informed Consent documents are filed in the participant's JHS study folder. A copy of the informed consent and signature page is given to the participant.

### **3.2.3 Training**

Interviewers are centrally trained in general interviewing techniques and the goals and objectives of informed consent, including role play. The Clinic Manager or interviewer team leaders are responsible for providing staff training for new staff.

### **3.2.4 Certification**

Certification requires adequate technique on 5 informed consents with annual recertification during monitoring visit and completion of consent exercises. Interviewers who administer informed consent are observed by the Clinic Manager or interviewer supervisor.

### **3.2.5 Quality Assurance**

Routine quality assurance is provided at the Examination Center by means of observation by the Clinic Manager. Administrative techniques and adherence to protocol are also monitored at least semi-annually by Coordinating Center monitors; frequency distributions of consent preferences recorded on the Informed Consent Form (ICF) are monitored by the Quality Control Committee on a semi-annual basis.

### **3.2.6 Data Collection**

Descriptions of the study and the signature pages acknowledging informed consent for the second exam are paper forms. The participant receives a copy of the full informed consent document and the signed consent statement. In all cases, the original signature page must be kept at the Examination Center and stored in the participant's JHS study folder.

## **3.3 Informed Consent Form (ICF) and Informed Consent Tracking (ICT) Form**

The Informed Consent Form (ICF) form is an internal form that applies to the written consent given by cohort members at the time of the second clinic visit to participate in the regular JHS study. It serves to identify the restriction, if any, on exam procedures or use of study data by directly entering the items on the Statement of Participation from the signed consent document. The form is completed by JHS staff, and NOT administered to participants.

The Informed Consent Tracking (ICT) Form is an internal document that applies to any modifications of consent restrictions between exam cycles. It serves to identify any modifications in restrictions that a participant may notify the JHS s/he wishes to make.

### **3.3.1 Rationale**

The purpose of the form is to document and track in the JHS central database the level of consent given at Exam 2, and subsequent (if any) changes to, participants' restrictions on the use of her/his study data, including DNA, by JHS and other investigators.

### 3.3.2 Administration

All items on the ICF form are completed by an interviewer at the reception workstation after participants have read and signed the baseline exam Informed Consent form. QxQ instructions are provided in the Forms Manual Appendix.

All items on the ICT form are completed by an interviewer either at Annual Follow Up or at the clinic reception workstation when a participant notifies the study of a desire to either change her/his type of consent or access to medical records, or to withdraw from the study. QxQ instructions are provided in the Forms Manual Appendix.

### 3.4. Fasting Tracking

The Fasting Tracking (FTR) form is a core data collection form which confirms the participant has had nothing to eat or drink for 12 hours before the baseline visit. The form is administered at reception.

#### 3.4.1 Rationale

The participant's fasting status affects the measurement of glucose and lipids, as well as body composition. To standardize measurements, participants are requested to take nothing by mouth except water for 12 hours prior to arriving at the Examination Center.

#### 3.4.2 Administration

The FTR is completed for all participants during the reception for the baseline exam (fixed sequence #1). QxQ instructions for administering the FTR form are provided in the Forms Manual Appendix. The participant's fasting status is verified. Strict fasting is defined as nothing taken by mouth, except water, for the preceding 12 hours. However, for purposes of results reporting of the clinical chemistries, participants can be considered fasting if they have fasted for at least 10 hours or if they have ingested no more than one cup of black, unsweetened coffee/tea within the past 10 hours. Ingestion of more substantive liquids or solids constitutes breaking the fast. The participant's fasting status is recorded in number of hours on the FTR form, but the consumption of coffee/tea is recorded in a note log.

Finger stick samples are drawn on all participants, regardless of fasting status. If the participant has not fasted for 10 hours, the participant is also offered the opportunity to repeat finger stick blood drawing in the fasting state at a later date. The FTR is completed; the non-fasting state and rescheduled date of digipuncture are noted on the Participant Itinerary Form. When the participant returns in the fasting state for digipuncture, the questions concerning fasting status and recent blood donation on the FTR form are updated and the data on the Finger Stick Form (FST) are updated.

The FTR form also documents whether the participant has given blood within the last 7 days. It is assumed that very few cohort members will have donated blood within the last week as they are reminded during both the scheduling calls not to do so, or to reschedule her/his clinic visit if they have had to give blood. Recent donors are not rescheduled once they come for baseline exam; the response to question 6 on the Fasting/Tracking form is recorded to reflect the recent blood donation and the individual is sent to the digipuncture workstation.

### 3.5 Medication Survey and Follow Up

The Medication Survey (MSR) is part of the core data collection instruments and is administered to all participants during Exam 2 as part of the fixed sequence #1. The survey covers the use of any prescribed or over-the-counter medications, including vitamins, mineral supplements or other herbals or home remedies, used within the two weeks prior to the participant's interview as well as the current and regular use of aspirin and non-steroidal anti-inflammatory drugs in the JHS population. It also queries usual medication – taking practices of participants.

As some participants do not bring all medications with them to the examination, a Medication Survey Follow Up (MSR-FUP) form is used to document information obtained from the participant after completion of Exam 2. It is an exact duplicate of sections B (Medication Transcription) and C (Interview) of the MSR, thus supplementing any missing information from that form. This form can be completed up to 3 months following the date of Exam 2.

### **3.5.1 Rationale**

The goal of the MSR and MSRFUP is to ascertain medication usage by coding prescription and nonprescription drugs, home or folk remedies, used by the respondent within the two weeks preceding the interview. This information assists in measuring patterns of medication use in the study communities, temporal changes in medical care practice, diagnostic classification of cardiovascular diseases, interpretation of laboratory results, and predictors of study end points. A second goal for the MSR is to document individual medication-taking practices to assist in determining adherence to prescribed regimes.

### **3.5.2 Administration**

The MSR is divided into five major sections. QxQ instructions are located in the Forms Appendix. During reception, the interviewer determines and records in Part A of the form whether the participant has brought in all medications taken within the last two weeks. Identification labels are placed on the participant's medication bag and MSR form. If the participant has not brought in any (all) medications, inquiries are made to differentiate between non-compliance with pre-visit instructions or non-use of medications in the prior two weeks. In case of inadvertent omissions, arrangements are made for obtaining the information, usually by telephone interview. The deliberate omission to bring medications to the Examination Center is recorded on the MSR and on the Participant Itinerary Sheet (Forms Appendix) and conversion is attempted later with the participant during the review of medical data. Subsequent parts of the MSR can be administered during reception (if the area affords the opportunity for maintaining confidentiality) or later, by trained interviewers or the JHS nurse/clinician in areas in the Examination Center usually designated for conducting interviews.

Before starting Part B of the MSR, the name on the medication bag is checked against the name on the MSR. Medication containers are removed from the participant's medication bag and the medication name and concentration are transcribed into column (a) of Section B on the form. Medications that are not in a container are examined only in front of the participant, with her/his permission. When there are more than 26 medications, recording the name and concentration is continued on the back of the page if a paper form is used. If the Medication Survey DMS form is used and more than 26 medications need to be entered, the name and concentration of the additional medications are written on a piece of paper labeled with the participant's ID, and filed in the participant's folder for future coding. See below for coding instructions. If the name of the medication exceeds the number of fields in the DMS, the name is abbreviated on the screen.

When more than 26 medications have been recorded, the priority algorithm for data entry and coding of the medications is as follows: prescription medications first; aspirin and aspirin-containing medications (aspirin, Alka Seltzer®, headache powders, cold medications, medication for arthritis, etc.); anti-inflammatory drugs (ibuprofen, Motrin®, Nuprin®, etc.); then over-the-counter-medications, followed by vitamins and food supplements.

To administer Parts B and C, a trained interviewer or the JHS nurse/clinician shows each container of medication to the participant, transcribes its name in column (a) of Section B (MEDICATION RECORDS), records medication's concentration in column (b), the instructions for administration in column (c), and asks and records in column (d) whether the medication was used within the last 24 hours, and asks and records in column (e) the reason the participant takes this medication.

When preparing to ask the participant about each medication, the interviewer removes all containers from the bag and sets them in front of the participant. As each medication is reviewed,

it is shown to the participant while keeping the other medications in view. After the participant answers the questions for each medication, its container is placed back in the carrying bag to minimize confusion and to assure that all medications are returned.

The interviewer verifies the transcription of medication names and makes corrections on the paper (or DMS) form as required. Use the American Drug Index and Physician's Desk Reference for unknown and incomplete names.

Part C of the MSR ascertains (1) whether any of the participant-reported medications were used to treat cardiovascular diseases or symptoms (high blood pressure; high blood cholesterol; angina; arrhythmia; heart failure; blood thinning; diabetes; stroke; intermittent claudication) or (2) whether aspirin or aspirin-containing medications were used in the last two weeks and the reason for her/his use; current, regular use (at least once per week for several months) of aspirin or other non-steroidal anti-inflammatory drugs.

[Parts B and C correspond to Parts A and B on the MSR FUP form. If the participant returns to the clinic to bring her/his medications, the same procedures are used as in the MSR to record information regarding each medication as above. If the participant is contacted by telephone, ask the participant to spell the name of the medication exactly as written on the bottle and record in column (a), the medication dosage in column (b), and the instructions for administration in column (c). Ask the participant if s/he has taken the medication in the past 24 hours and record in column (d) and the reason for taking the medication recording the response in column (e). Continue to the Interview questions to clarify the reasons for taking medications in the past two weeks by reading the questions and recording the respondent's responses.]

Part D of the MSR ascertains any reasons the participant may have for not taking her/his prescription medications as prescribed. It also requests information on the participant's current or regular use of either aspirin or non-steroidal inflammatory agents.

Part E asks the participant to identify any folk medicine, herbals, roots or teas that they may have used for medicinal purposes in the last two weeks. A separate question ascertains whether such remedies have ever been used and for what health-related reason.

### **3.5.3 Certification**

Certification to administer the MSR and MSR FUP is achieved by the demonstration of adequate technique on 5 taped interviews, reviewed and approved by the supervisor or interviewer team leader. Re-certification is required annually, and requires the successful completion of one taped interview of an actual participant. This tape is included in the round robin that is reviewed by the four interviewer supervisors selected to monitor each year's round robin tapes.

Separate certification is required for medication coding, based on a minimum of 80% correct responses on the certification test provided by the Coordinating Center and administered at central training. Re-certification for medication coding is also required annually. For the Medication-Coding Specialist, this includes coding a set of selected medication names circulated for this purpose and adequate performance on blinded re-coding of medications recorded during the previous year. Re-certification criteria for medication coders require meeting minimum standards of coding repeatability (by interviewer/transcriptionist) and a review at the Coordinating Center of the accumulated performance on quality control repeat medication coding.

### **3.5.4 Quality Assurance**

For each person certified to code medications a ten percent sample of medication coding records is identified by the Coordinating Center for blinded repeat coding at the Examination Center.

### **3.6.5 Data Collection**

The six digits medication code numbers are listed in a hard copy or DMS version of the Medication Coding Dictionary. The Medispan code in part (c) can be matched to the drug name

while transcribing the name of the drug in part (a) into the DMS screens, or can be ascertained later. Drug names are listed alphabetically. The medication code of a drug not listed in the dictionary is left blank, and its status code is always set to "Q" (questionable) so that the pharmacist at the Coordinating Center can develop a code number and update the dictionary. Detailed instructions for coding medications are provided in the QxQ instructions for the MSR.

### **3.6 Health History**

The Health History (HHX) is a core data collection form, administered during the flexible sequencing component of Exam 2. It serves to update information obtained as part of the Exam 1 Home Induction Interview in the Personal and Family History (PFH-A) form. Information included from the PFH is self-perceived health status, personal health history, and health care access. Additionally the HHX adds new items to further characterize self-perceived health status (comparison with self this time last year), and reproductive status (currently pregnant, ever tubal ligation or vasectomy), as well as to assess weight at key points over the participant's lifetime (birth, age 18, perception of current weight status), having been breast fed or not as an infant, and several health behaviors related to weight management (diet, exercise).

#### **3.6.1 Rationale**

An extensive, well-accepted body of data supports the relationship between health history and risk for development of CVD. Self-perceived health status has likewise been positively correlated with disease likelihood. We hypothesize that these strong relationships will continue with the JHS. That is, the more extensive the history of CVD and other metabolic conditions, the more likely the person is to develop CVD over her/his lifetime. Further, this relationship will be moderated by a variety of socioeconomic and psychosocial variables, e.g., discrimination, stress, social support, coping, SES, health care access, and so forth.

There is an evolving body of literature that relates having been breast fed, birth weight, and weight at age 18 (approximate correlate to weight at high school graduation) to adult weight and the development of obesity. As obesity and its impact on CVD is a major emphasis in the JHS, additional items to characterize weight over a lifetime, including health behaviors to manage it, and individual perception of current weight are anticipated to improve our understanding of these factors in the JHS cohort.

#### **3.6.2 Administration**

The HHX is administered to all participants during the Exam 2 clinic visit by a trained and certified interviewer. The time reference for all health history questions (section B) is since the time of the baseline clinic visit (Exam 1). Detailed instructions for administering each question are contained in the QxQ instructions. Questions on deaths of family members may be considered sensitive by participants and care must be exercised to administer each item in a non-judgmental and caring manner.

### **3.7 Medical History**

The Medical History (MHX) form is a core data collection form, administered during the flexible sequencing component of Exam 2. It serves to update from the baseline examination potential sleep apnea or other sleep disturbance as well as a number of specific cardiovascular symptoms. Chest pain, possible infarction, intermittent claudication (peripheral vascular disease), and congestive heart failure are each detailed. The occurrence of the participant-reported chest pain is confirmed as positive angina and/or myocardial infarction by London School of Hygiene criteria. The questionnaire also documents the occurrence of procedures to diagnose or treat cardiovascular disease.

### 3.7.1 Rationale

A major objective of the JHS is the assessment of CHD in the study population at each clinical examination and across time beginning from the baseline examination. This is done, in part, by the documentation of the symptoms of heart disease and exposure to diagnostic and therapeutic procedures of each participant at each visit and annual follow-up call. Another objective is a similar assessment of peripheral vascular disease (PVD). Questions on claudication provide updated information on PVD symptoms. Another major contributor to CHD is sleep apnea. Data also suggest a relationship between sleep quality irrespective of sleep apnea, as a correlation with CHD.

### 3.7.2 Administration

The MHX form is administered during the Exam 2 clinic visit by trained and certified interviewers with an understanding of the medical terms and diagnostic procedures referred to in this instrument. The frame of reference for questions in section A (chest pain on effort) and sections B and C (invasive/non-invasive diagnostic and therapeutic cardiovascular procedures) is the time period since the baseline JHS examination. Detailed procedures for administering the form are provided in the QxQ instructions immediately following the form in the Forms Appendix.

## 3.8 Renal Disease Form

Renal disease is an important correlate of cardiovascular disease. In Exam 1, data was obtained regarding dialysis. Exam 2 extends that data collection by including information on a wide variety of symptoms of renal disease in addition to overt kidney failure indicated by dialysis. Items for the Renal Disease Form (RDF) were modified from the National Kidney Foundation's KEEP (Kidney Early Detection Evaluation Program) [1] and are administered during the flexible sequencing component of Exam 2.

### 3.8.1 Rationale

The extraordinarily high rates of renal insufficiency and failure among the African American population [2] warrant the focus of the JHS. Renal disease is both an important co-morbidity as well as a key determinant of cardiovascular disease occurrence and outcome. Renal disease shares risk factors (such as obesity, diabetes, hypertension, hyperlipidemia) with cardiovascular disease and is also an important marker of cardiovascular disease prognosis. In a recent survey of 680 Mississippians (515 AA, mostly from Jackson), the Mississippi Affiliate of the National Kidney Foundation found that 67% of the participants learned for the first time that they might have kidney disease [3]. This data suggests that African Americans who are enrolled in the JHS may be unaware that they actually have kidney disease that can progress toward end stage renal disease. This potential lack of awareness underscores the importance of renal disease symptoms makes it imperative to include questions regarding potential renal disease symptoms as well as acute or chronic renal insufficiency.

#### References:

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2. Norris, KC, Agodoa, LY, Race and kidney disease: the scope of the problem. *Journal of the National Medical Association* 2002; 94(8 Suppl):1S-6S
3. National Kidney Foundation Mississippi Affiliate KEEP Executive Summary for 2001-2003. March, 2004.

### **3.8.2 Administration**

The RDF is administered by trained interviewers as part of the flexible sequence of Exam 2.

## **3.9 Stroke Symptoms**

The Stroke Symptoms Form (SSF) is one of the core data collection instruments to assess the symptoms of stroke and transient ischemic attack. The interview is administered during the flexible component of the JHS exam.

### **3.9.1 Rationale**

Stroke and transient ischemic attack (TIA) are identified as end points in the JHS study. A baseline history of stroke symptoms was collected during baseline exam and is updated during Exam 2. The time frame for this form is since the last JHS exam (Exam 1).

### **3.9.2 Administration**

The SSF administered by certified interviewers. Positive symptoms are recorded during the standardized interview along with her/his speed of onset, duration, and co-morbid manifestations. QxQs instructions are in the Forms Appendix. Section A of the form documents the participant's medical history of a stroke. The subsequent sections cover six neurological symptoms which are associated with strokes and TIAs and are administered in a standardized format. Descriptors of the neurological symptoms (earliest, longest and worst) often require probing, but the definitions are left to the respondent.

## **3.10 Participant Evaluation of Clinic Visit**

The Participant Evaluation of Clinic Visit (PEC) is continued from Exam 1 to ascertain participant's global perspective of the clinic visit. It is intended to provide participants with the opportunity to express any concerns or issues they may have had with the visit and provides input into their overall satisfaction with the procedures and approaches used in the clinic, including staff encounters and information received.

Additionally, a small percentage (5-10%) of the cohort may be called to complete a more extensive Participant Satisfaction Survey (PSS) to ascertain their satisfaction with all elements of the JHS Exam 2 components, including scheduling, annual follow up, clinic visit, and ongoing contact with the cohort. Participants who have expressed particularly good or particularly troublesome experiences with the JHS may be asked to take part in an in-depth interview with an investigator to engage in mutual dialogue regarding their experience.

### **3.10.1 Rationale**

As detailed in the Retention Plan in section 1.0, the JHS is dedicated to providing a positive experience for all JHS participants. Close monitoring of participant satisfaction can provide essential input for maintaining that experience for the vast majority of the JHS cohort.

### **3.10.2 Administration**

The PEC is administered during the Exam 2 clinic visit as a part of the fixed sequence #2 components. It is conducted by a trained and certified social worker (or designee) at the end of the clinic visit. In addition to completing the PEC, the Social Worker is assuring that participants have access to needed health care or other social services, making arrangements to assist the participant as needed in these areas.

### **3.10.3 Training**

See below.

### **3.10.4 Certification**

See below

### **3.10.5 Quality Control**

The 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.

### **3.10.6 Data Collection**

The PEC is a self-administered paper form completed by the participant. If needed, the Social Worker may collect data via interview. No identifying information is included on the form and it is direct data entered into the DMS. QxQs are included in the Forms Appendix.

## **4.0 PROCEDURES IN THE JHS EXAM 2 CLINIC VISIT**

### **4.1 Body Composition (Height, Weight, Waist / Hip Girth, Body Fat, Fat Mass)**

Height, weight, waist / hip girth, and body composition (body fat and fat mass) are measured during baseline exam. All measurements are recorded on the Body Composition Form (BCF) (see Forms Appendix). Procedures for measuring the height, weight and waist and neck girths are provided below. Separate instructions for completing the data collection form are provided in the BCF QxQ instructions (Forms Appendix). At the option of the Examination Center, the circumference of the right upper arm (to determine blood pressure cuff size) can also be measured at this workstation and recorded on the Sitting Blood Pressure (SBP) form.

#### **4.1.1 Rationale**

Overweight and obesity are associated with morbidity and mortality from cardiovascular disease, and their prevalence is increasing at a remarkable rate in all ages in the US population. Over 60% of the JHS cohort was either overweight or obese at baseline. Common assessment of overweight and obesity relies on the use of anthropometry in the form of body mass index (BMI), skinfold thicknesses, and body circumferences. These anthropometric approaches, though useful indicators, have limits in their ability to differentiate between levels of fatness and leanness. [1,2] More complete measures are needed for accurate assessment of body fat; fat free mass (FFM) – which can be further separated into lean soft tissue, including water and bone; and total body water (TBW): the components of body composition.

Bioelectrical impedance analysis (BIA), a practically useful indirect method for assessing body composition, has gained in use over the last decade. BIA methods assume the body to be a cylindrically-shaped ionic conductor where the extracellular and intracellular non-adipose tissue compartments act as resistors and capacitors, respectively. By introducing a small alternating electrical current passed across two body parts and measuring the potential (voltage) difference that results, the electrical impedance (or resistance and capacitance) of the body is measured. BIA has been used as an indirect measure of body composition in large scale studies, including NHANES III, 1988-94) [3] as well as a number of other studies where it has been shown to quantify FFM, body fat, and TBW reliably when compared with more direct measures of densitometry [4], deuterium isotope dilution [5,6] and dual energy X-ray absorptiometry (DXA) [7,8] across normal, obese, and diabetic individuals. [9,10]

BIA was used in the JHS as it has been determined to be safe, is noninvasive, has no associated discomfort, and required little respondent burden, and could potentially provide valid predictions of major body compartments, specifically TBW, FFM, and % body fat. A single frequency 50-kHz leg-to-leg BIA system combined with a digital scale that uses stainless steel pressure-contact foot pad electrodes was selected for use in the JHS as an indirect measure of body fat. This method offers operational advantages over the traditional arm-to-leg approach which requires gel electrodes and has been shown to be comparable with the traditional method and reliable in assessing body composition in a variety of populations [11,12] The anterior and posterior portions of each foot pad comprise two separate electrodes with current applied via the anterior portion of the foot pad electrodes and the voltage drop across the posterior (heel) portion is then measured. Leg to leg impedance and body mass are simultaneously measured as the participant's bare feet come in contact with the electrodes. FFM and body density are then calculated using prediction equations provided by the manufacturer (Tanita Corporation of America, Inc., Arlington Heights, IL) which use weight, age, and an impedance index,  $\text{height}^2/Z$ . Percentage of body fat is estimated using the equation of Brozek et al. [13]

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#### **4.1.2 Procedures**

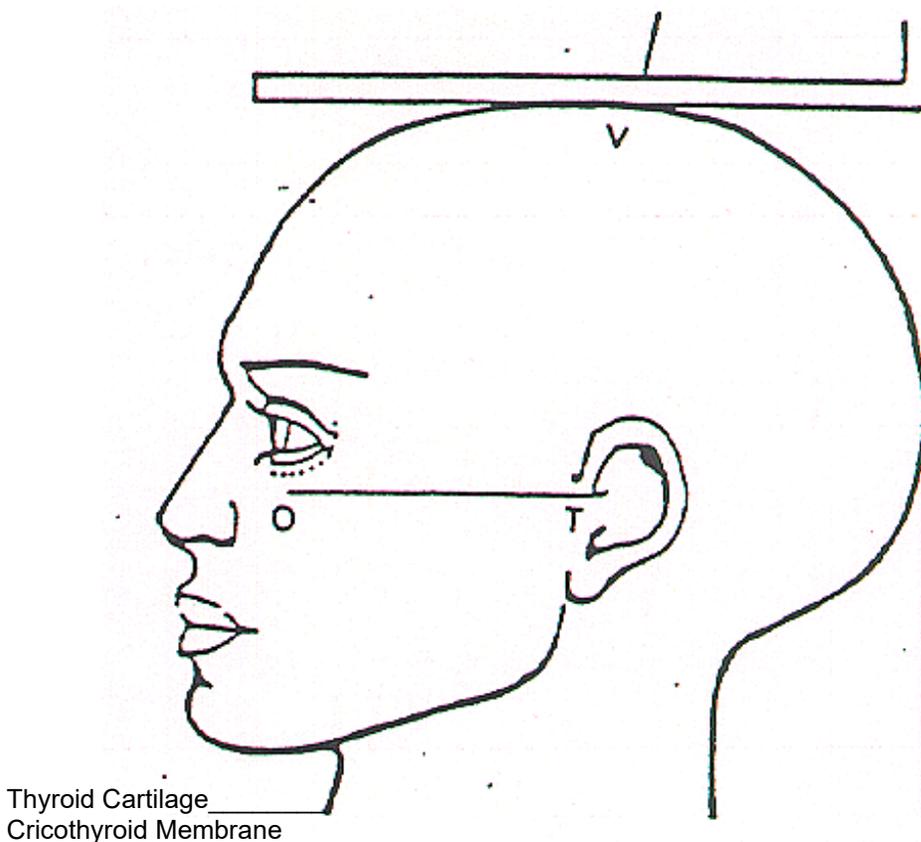
Anthropometry and determination of body composition are performed as part of the fixed sequence #1 before the clinic snack and after the participant has changed into a scrub suit or examination gown and been given the opportunity to empty her/his bladder. All measurements are made with the participant wearing light-weight, non-constricting underwear. Participants wearing nylon hose or other forms of constricting undergarments are instructed to remove them. Weight and height are measured without shoes. Technicians complete the procedures on every participant by following the general checklist for performing anthropometric measurements (Forms Appendix).

All anthropometric measurements are taken by either a team of two persons (one serving as observer; the other as recorder) or by one technician using a full length mirror to aid in the appropriate placement of the tape measure to record the girths. Using the team approach, the observer calls out the name of the next measurement, takes the measurement, and keeps the measuring instrument in place until the recorder repeats the number. The recorder checks the position of the examinee and verifies the horizontal placement of the measuring instrument during each procedure, and records the result. When a single technician performs the measurements, s/he verifies the horizontal placement of the measuring instrument (using the mirror when appropriate) for each measurement and records each measurement immediately after it is taken.

##### **4.1.2.1 Standing Height**

The participant stands erect on the floor or the horizontal platform with her/his back against the vertical metal centimeter ruler mounted on the wall. The heels are placed together and positioned against the vertical ruler. The participant is instructed to stand as straight as possible, but with feet flat on the floor. The participant looks straight ahead with her/his head in the Frankfort horizontal plane (i.e., the horizontal plane which includes the lower margin of the bony orbit -- the bony socket containing the eye -- and the most forward point in the supratragal notch - - the notch just above the anterior cartilaginous projection of the external ear) (Figure 4-1). The right angle is brought down snugly, but not tightly, on the top of the head. A footstool is used if the examiner is shorter than the participant, such that the examiner's view is level with the point of measurement on the head of the participant. The certified technician follows a checklist for height measurement (Forms Appendix) which outlines the procedures for checking the equipment and measuring the participant's height and enters study data on the Anthropometry form. The participant's height is recorded to the centimeter. The conversion chart in Table 4-1 is provided to assist in the converting to and from metric measures. A chart converting centimeters to inches is available for use in informing the participant of her/his height in inches (Table 4-2) and weight in pounds (Table 4-3).

**Figure 4.1 Frankfort Plane for Measuring Body Height**



ORBITALE: Lower margin of eye socket

TRAGION: Notch above tragus of ear or at upper margin of zygomatic bone at that point

FRANKFORT PLANE: Orbitale-tragion line horizontal

THYROID CARTILAGE: Firm, cartilaginous prominence on neck

CRICOTHYROID MEMBRANE: Below thyroid cartilage

**Table 4.1 Converting To and From Metric Measures**  
**Conversion from Metric Measures**

Symbol	When you Know	Multiply by	To Find	Symbol
Height				
Cm	Centimeters	0.3937	inches	in
Weight				
Kg	Kilograms	2.2046	pounds	lb

**Conversion to Metric Measures**

Symbol	When you Know	Multiply by	To Find	Symbol
Height				
In	Inches	2.54	centimeters	cm
Ft	Feet	30.7	centimeters	cm
Weight				
Lb	Pounds	0.454	kilograms	kg

**Table 4.2 Body Size Measurements: Body Height in Centimeters and Inches**

Centimeters	Inches		Centimeters	Inches
122	48.0		165	65.0
123	48.4		166	65.4
124	48.8		167	65.7
125	49.2		168	66.1
126	49.6		169	66.5
127	50.0		170	66.9
128	50.4		171	67.3
129	50.8		172	67.7
130	51.2		173	68.1
131	51.6		174	68.5
132	52.0		175	68.9
133	52.4		176	69.3
134	52.8		177	69.7
135	53.1		178	70.1
136	53.5		179	70.5
137	53.9		180	70.9
138	54.3		181	71.3
139	54.7		182	71.7
140	55.1		183	72.0
141	55.5		184	72.4
142	55.9		185	72.8
143	56.3		186	73.2
144	56.7		187	73.6
145	57.1		188	74.0
146	57.5		189	74.4
147	57.9		190	74.8
148	58.3		191	75.2
149	58.7		192	75.6
150	59.1		193	76.6
151	59.4		194	76.4
152	59.8		195	76.8
153	60.2		196	77.2
154	60.6		197	77.6
155	61.0		198	78.0
156	61.4		199	78.3
157	61.8		200	78.7
158	62.2		201	79.1
159	62.6		202	79.5
160	63.0		203	79.9
161	63.4		204	80.3
162	63.8		205	80.7
163	64.2		206	81.1
164	64.6		207	81.5

**Table 4.3 Body Size Measurements: Body Weight in Kilograms and Pounds**

Kilograms	Pounds		Kilograms	Pounds
48	105.8		81	178.6
49	108.0		82	180.8
50	110.2		83	183.0
51	112.4		84	185.2
52	114.6		85	187.4
53	116.8		86	189.6
54	119.0		87	191.8
55	121.3		88	194.0
56	123.5		89	196.2
57	125.7		90	198.4
58	127.9		91	200.6
59	130.1		92	202.8
60	132.3		93	205.0
61	134.5		94	207.2
62	136.7		95	209.4
63	138.9		96	211.6
64	141.1		97	213.8
65	143.3		98	216.1
66	145.5		99	218.3
67	147.7		100	220.5
68	149.9		101	222.7
69	152.1		102	224.9
70	154.3		103	227.1
71	156.5		104	229.3
72	158.7		105	231.5
73	160.9		106	233.7
74	163.1		107	235.9
75	165.3		108	238.1
76	167.6		109	240.3
77	168.8		110	242.5
78	172.0		111	244.7
79	174.2		112	246.9
80	176.4		113	249.1

The height rule is observed weekly to see that it (a) touches the hard-surfaced floor or platform on which measurements are done, and (b) is perpendicular to the floor. This weekly check is recorded on the Anthropometry Equipment Calibration Log (see Appendix).

#### 4.1.2.2 Body Weight

Using the balance beam scale--Before a participant is weighed, the scale is balanced so that the indicator is at zero when no weight is on the scale. The scale must be level and on a firm surface (not a carpet). The participant is instructed to stand in the middle of the platform of the balance scale (Detector, model #437) with head erect and eyes looking straight ahead. Weight is adjusted on the indicator until it is balanced. Results are recorded to the nearest kilogram. A chart converting kilograms to pounds is available for use in informing the participant of her/his weight in pounds (Table 4-1).

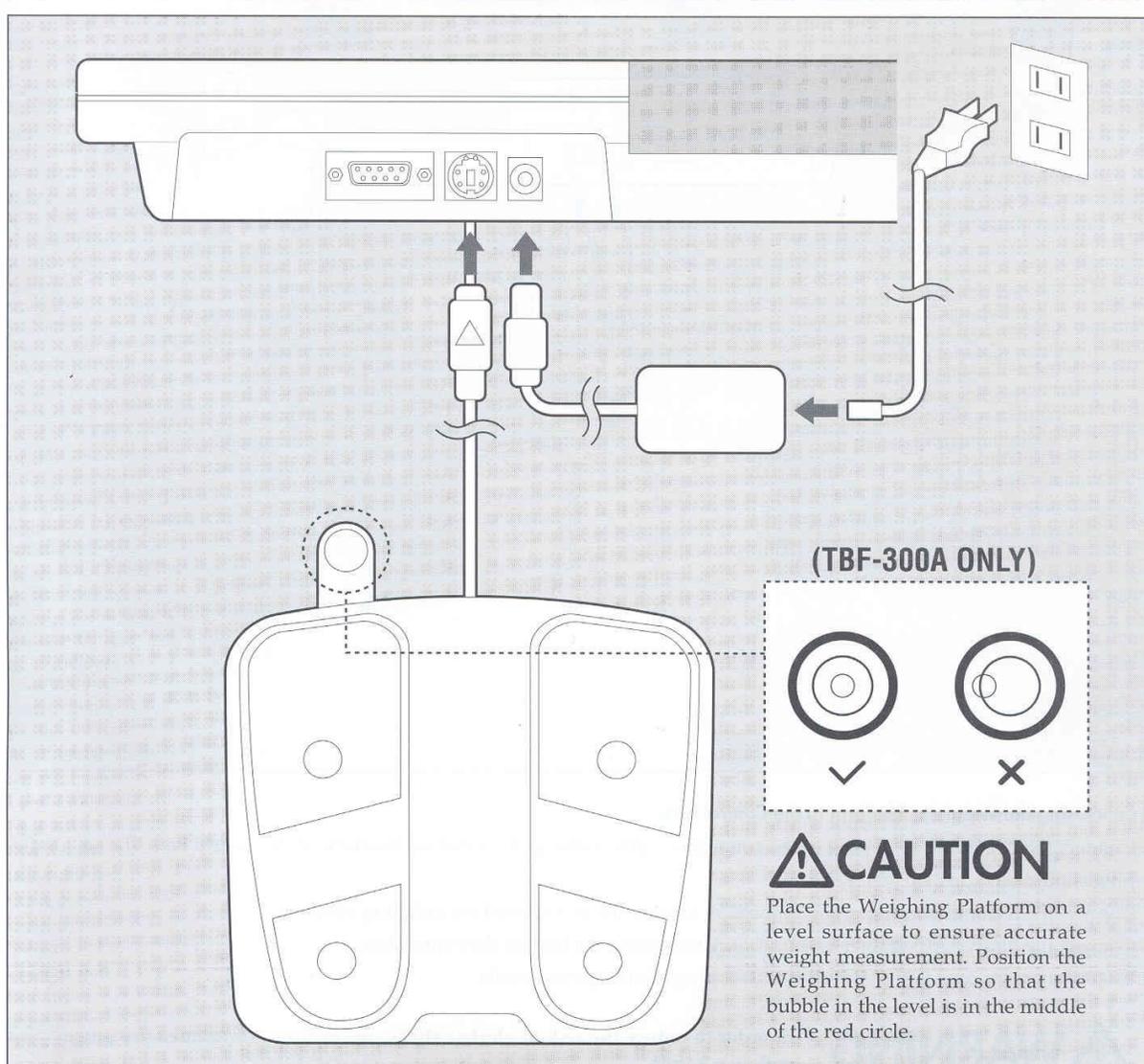
To maintain accuracy, the scale is zero balanced daily and calibrated with a known weight (50 lbs) every week or whenever the scale is moved. The daily zero balance and the weekly scale calibration are documented on the Anthropometry Equipment Calibration Log (see Appendix). The scale is professionally calibrated and serviced annually. The certified technician follows a

checklist for weight measurement (Forms Appendix) which outlines the procedures for checking the equipment and measuring the participant's weight and enters study data on the BCF.

Using the Tanita TBF 300A Body Composition Analyzer. Before starting, connect the cable from the weighing platform to the jack located on the back of the control box. The ▲ on the plug should be facing up when inserted. Connect the plug of the AC adapter to the DC jack located in the back of the control box. Insert the power cord to the AC adapter, and plug it into a power outlet. Use only the Tanita AC adapter provided with the unit and assure that the weighing platform is on a flat, level surface.

The Tanita unit should be preset to start up in the Goal Setter Mode. This mode controls the type of output that the unit provides and is accomplished by pressing the [8] key immediately after turning on the power. When this input has been completed, the unit is preset to start in this mode with each use.

**Figure 4.2 Set Up, Tanita TNF300A Body Composition Analyzer**



■ Connecting the Weighing Platform to the Control Box

Turn the unit on by pressing the ON/OFF key. If there is no printer paper in the feeder, "P-End" will flash on the LCD.

If you DO NOT want to use printer paper, press the [CE] key to continue measurement with no printer paper. When there is no "P-End" message, but the printer fails to print, the chosen number of print outs may be "0". Select a number of print outs greater than "0".

See Operating Instructions Manual for the Tanita located in the Appendix for details on Loading Printer Paper (p 16 of Manual)

Set the number of printouts and the printing language. Press and hold the [0] key and press the [ON/OFF] key once. Release the [0] key after "Prt-1" is displayed on the screen. Using the number keys, enter '3' to obtain 3 printouts (one for participant, one for provider, one to be filed in participant chart). The LCD will then automatically advance to language selection. Select [1] for English. When input has been completed, the unit will automatically switch to the measurement section. If further changes are needed, turn off the unit, and repeat the steps for setting number of printouts and language.

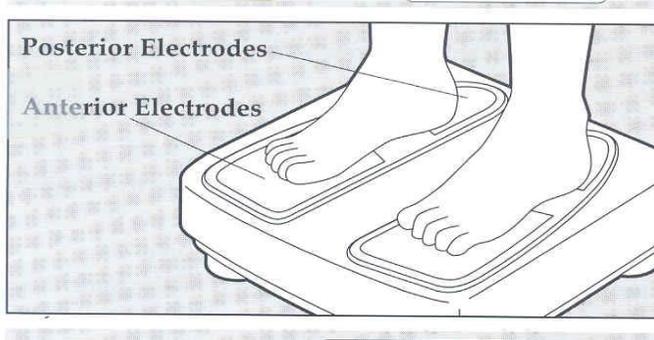
Once all presets have been completed, after a momentary delay, the ◀ mark and "0.0" will appear on the LCD. If measuring units need to be changed, do so at this time by pressing the [kg/lb] key. An arrow on the LCD will follow the selection of weighing units. Throughout the data entry, mistakes may be corrected by pressing the [CE] key. Follow the flashing arrow on the LCD for proper sequence. The following additional steps must be completed BEFORE the participant steps on the scale:

- Enter the Clothes Weight. This function will automatically subtract the chosen amount of clothes weight. Enter Clothes Weight to the nearest decimal point, or the flashing light will not advance. Clothes Weight can be entered by 0.1kg /0.2lb increments. In order to allow comparability between the weights obtained via the standard balance beam scale and the Tanita, no allowance will be made for clothes weight. ENTER "0.0".
- Enter Gender and Body Type. Select from one of the four body types: Standard Male, Standard Female, Athletic Male, Athletic Female. For most participants, you will select the "Standard" mode. The Athletic key should be used for individuals over the age of 17 and under the following conditions:
  - Tanita defines "athlete" as a person involved in intense physical activity of at least 10 hours per week and who has a resting heart rate of approximately 60 beats per minute or less. Tanita's athlete definition includes "lifetime of fitness" individuals who have been fit for years but currently exercise less than 10 hours per week. Tanita's athlete definition does not include "enthusiastic beginners" who are making a real commitment to exercising at least 10 hours per week but whose bodies have not yet changed to the required Athlete mode.
- Enter Age. Enter age using two digits.
- Enter Height. Using feet and inches to the nearest 0.5 decimal point, enter the height obtained from either the wall mounted metal ruler or, if doing an off site examination, the height obtained from the Tanita height ruler. Height will automatically be rounded up or down to the nearest 0.5 or whole number
- Set the Target % body fat. Acceptable levels of body fat for men range between 18-25% and for women between 25-31%. Explain to the participant that you are selecting the mid/upper level of the acceptable range by entering 24% for men and 30% for women. You may also inform them that the "fitness" levels for men are between 14-17% and 21-24% for women and that the "essential" fat that is necessary for men is 2-4% and for women is 10-12%.

Check the participant's feet for calluses. If the participant has thick calluses on her/his feet, place 0.5cc of a conductant (saline, water) in the center of each electrode. After assuring that the

participant's feet are clean (have them use a wipe to cleanse the bottom of their feet), ask the participant to step onto the scale when the flashing arrow appears next to STEP ON and the LCD screen displays "88888". Instruct the participant to make sure the heels are placed on the posterior electrodes and the front part of the feet is in contact with the anterior electrodes as indicated in the Figure. The weight will be displayed on the upper portion of the LCD screen. Record it on the BCF form in item 13.

**Figure 4.3 Foot Placement for Body Composition Measurement, Tanita TNF 300A Body Composition Analyzer**

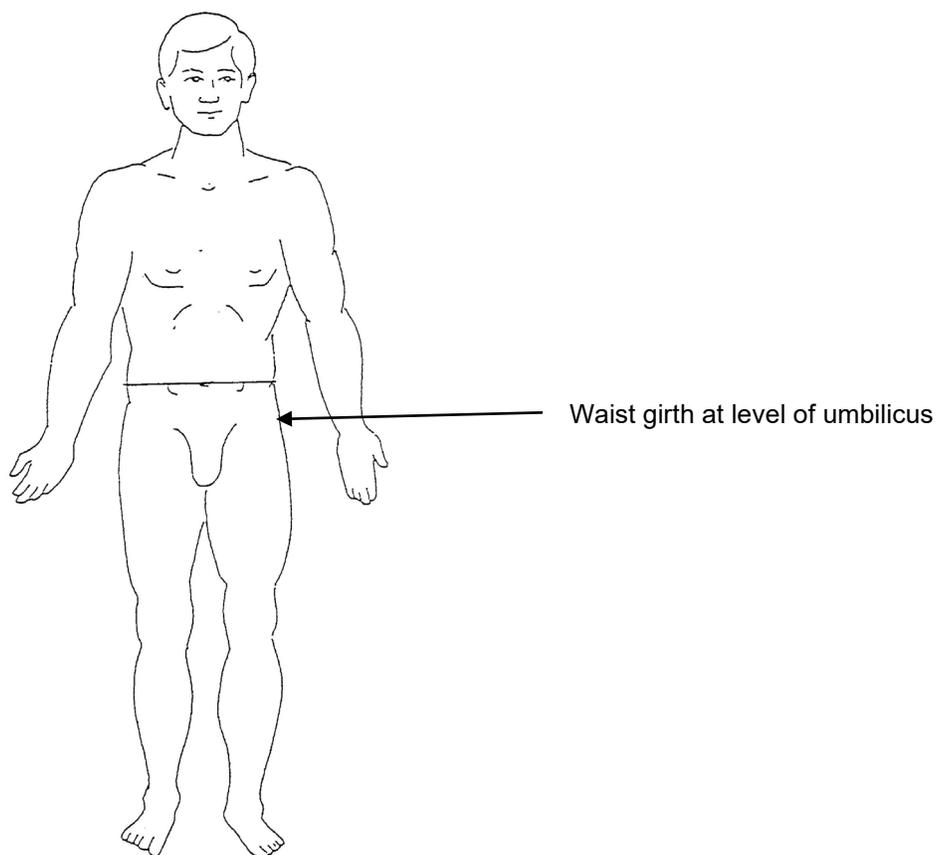


7

#### 4.1.2.3 Abdominal (Waist) Girth

The participant is instructed to stand erect and relaxed with the feet approximately 6 inches apart and the weight equally distributed on both feet. The participant is asked to lift the scrub suit top just high enough to make the area visible (hands must not go above waist level). An anthropometric tape is applied at the level of the umbilicus (navel) and the participant is instructed to breathe quietly. The tape should be snug, but not so tight as to compress tissue (Figure 4-4). The full length mirror or recorder verifies that the participant is standing erect and that the tape is horizontal. The measurement is recorded to the nearest centimeter at the point of relaxation end exhalation. The technician follows a checklist for the measurement of the maximal abdominal girth (Forms Appendix).

**Figure 4.4** Location of Waist Girth Measurement



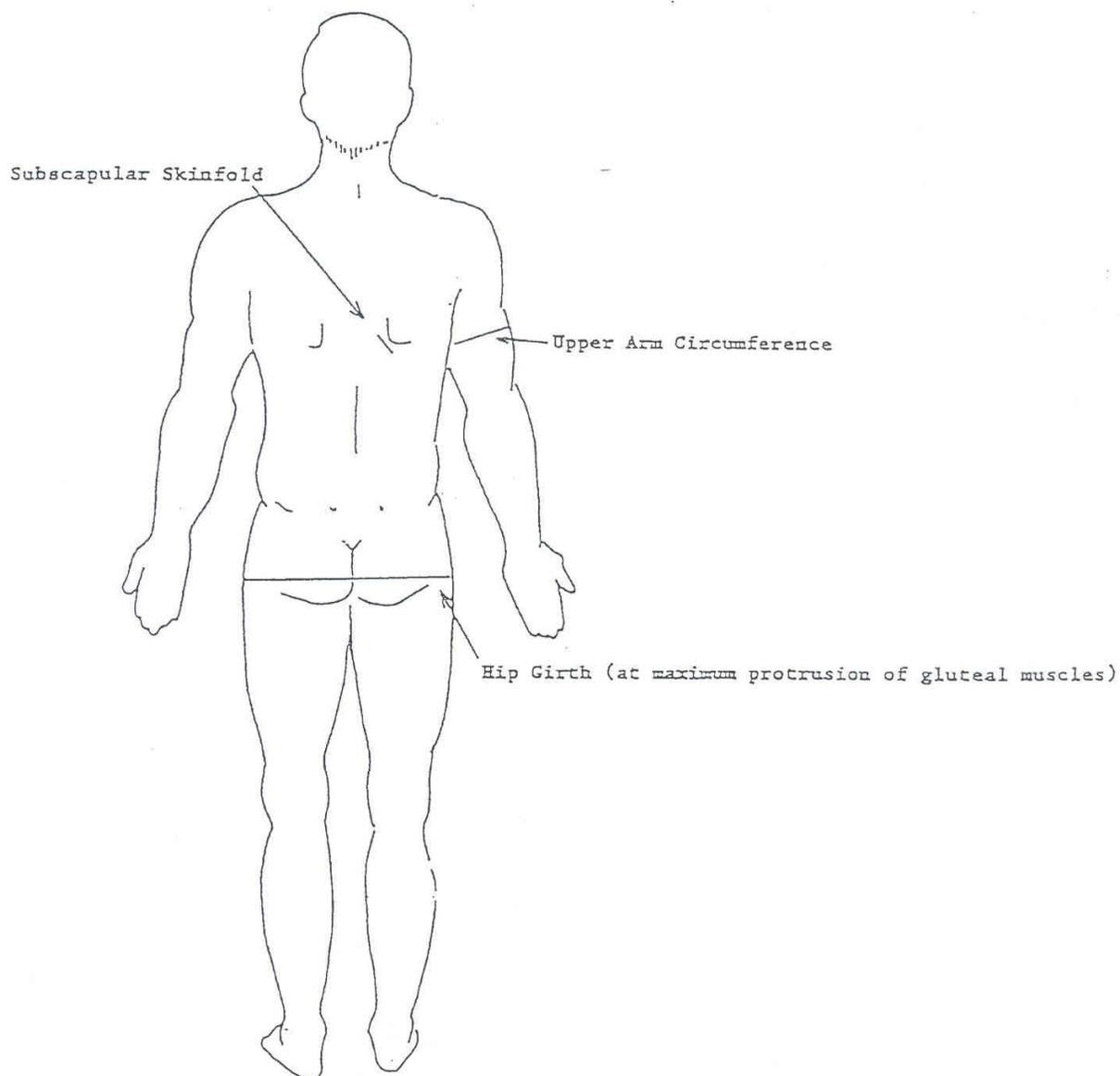
#### **4.1.2.4 Hip Circumference**

The participant stands erect, yet relaxed, with weight distributed equally over both feet and with the feet together. The hip girth is measured at the level of the maximal protrusion of the gluteal muscles (hips) (Figure 4-5). The tape is placed horizontally level around the participant's gluteal muscles (hips) at the level of maximal protrusion. The position is verified by passing the tape measure above and below the observed maximum. The tape is kept horizontal at this level and the measurement is recorded to the centimeter, rounding down.

A checklist for maximal hip circumference measurement (Appendix) is used for measuring each participant. The most common source of error for this measurement is due to not having the tape horizontal and not verifying that the maximum width is being measured. The position of the tape is checked from both the front and the back.

The tapes used for measuring girth are calibrated monthly against the metal height rule, as indicated on the Anthropometry Equipment Calibration Log (Appendix). Tapes that show damage or wear or that do not measure within the required range are replaced.

**Table 4.5 Location of Hip and Upper Arm Girth Measurements and Subscapular Skinfold**



#### **4.1.2.5 Arm Circumference**

The participant stands facing away from the technician with the right arm flexed at 90 degrees at the elbow, hand across midsection. The observer determines and marks the tip of the olecranon (elbow). Bony landmarks for measuring the circumference of the right arm are depicted in Figure 4-6. The participant straightens the arm, allowing it to hang loosely at the side. The technician then determines and marks the posterior tip of the acromion process (shoulder bone). Using a

centimeter tape, the technician measures the length of the upper arm between the two marks and marks the midpoint (+).

The technician wraps the tape around the arm at the midpoint mark, making sure that the tape is level. The arm circumference is measured to the nearest centimeter, rounding down, and is recorded in Item 8 on the Sitting Blood Pressure (SBP) form.

#### **4.1.2.6 Body Fat Percentage and Fat Mass**

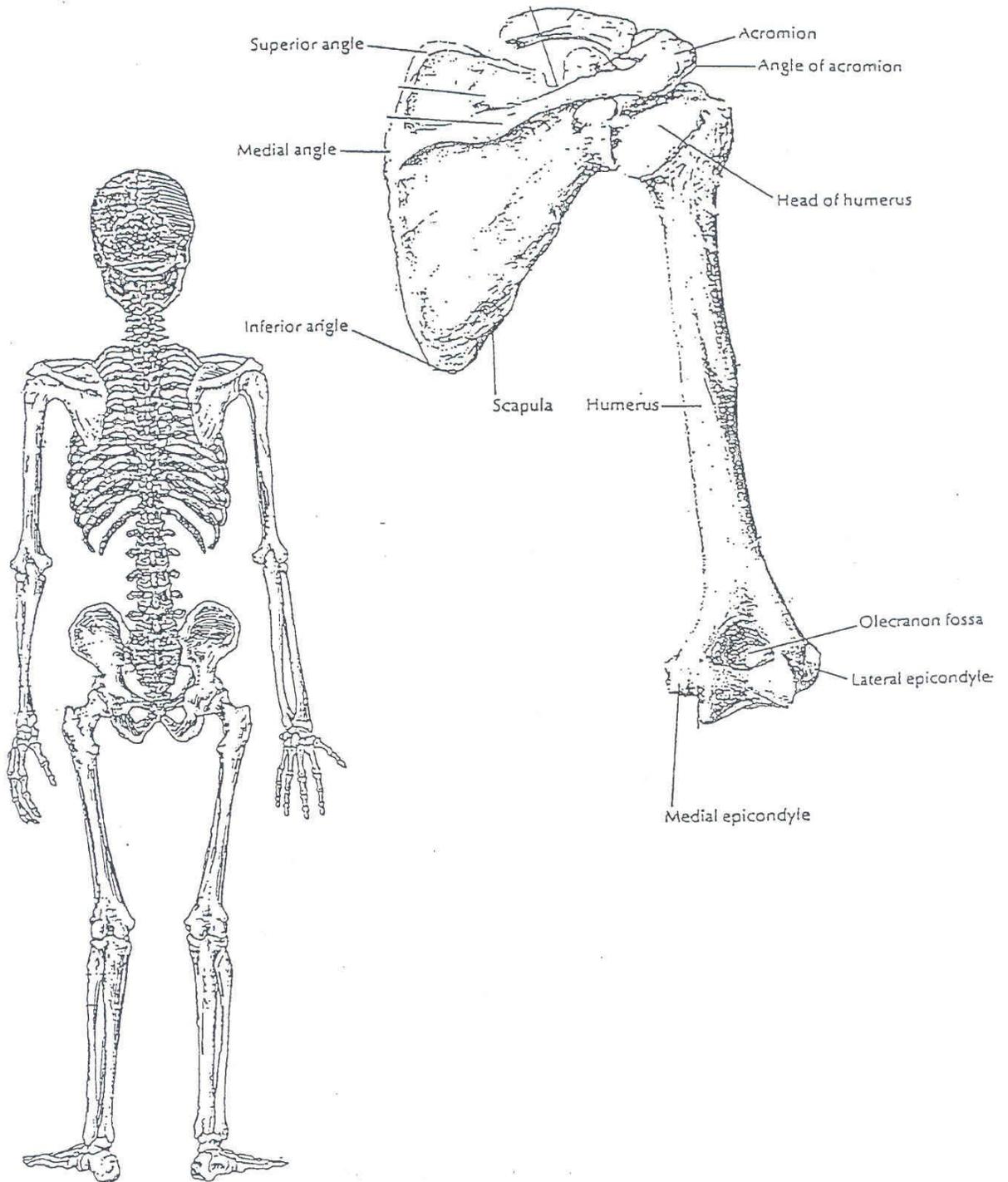
Body fat percentage and fat mass are automatically measured once the weight measurement has stabilized on the Tanita TBF300A Body Composition Analyzer scale. The participant continues to stand with her/his heels and front part of the foot in contact with the posterior and anterior electrodes of the scale unit as described in 4.1.2, above. After the weight stabilizes, the

impedance measurement is taken. This is denoted by four “bubbles” □□□□ which appear on the bottom half of the LCD. As the measurement is being made, each of the bubbles will disappear one by one. It is important that the participant not step off the scale until the last bubble has disappeared and the display emits a short BEEP.

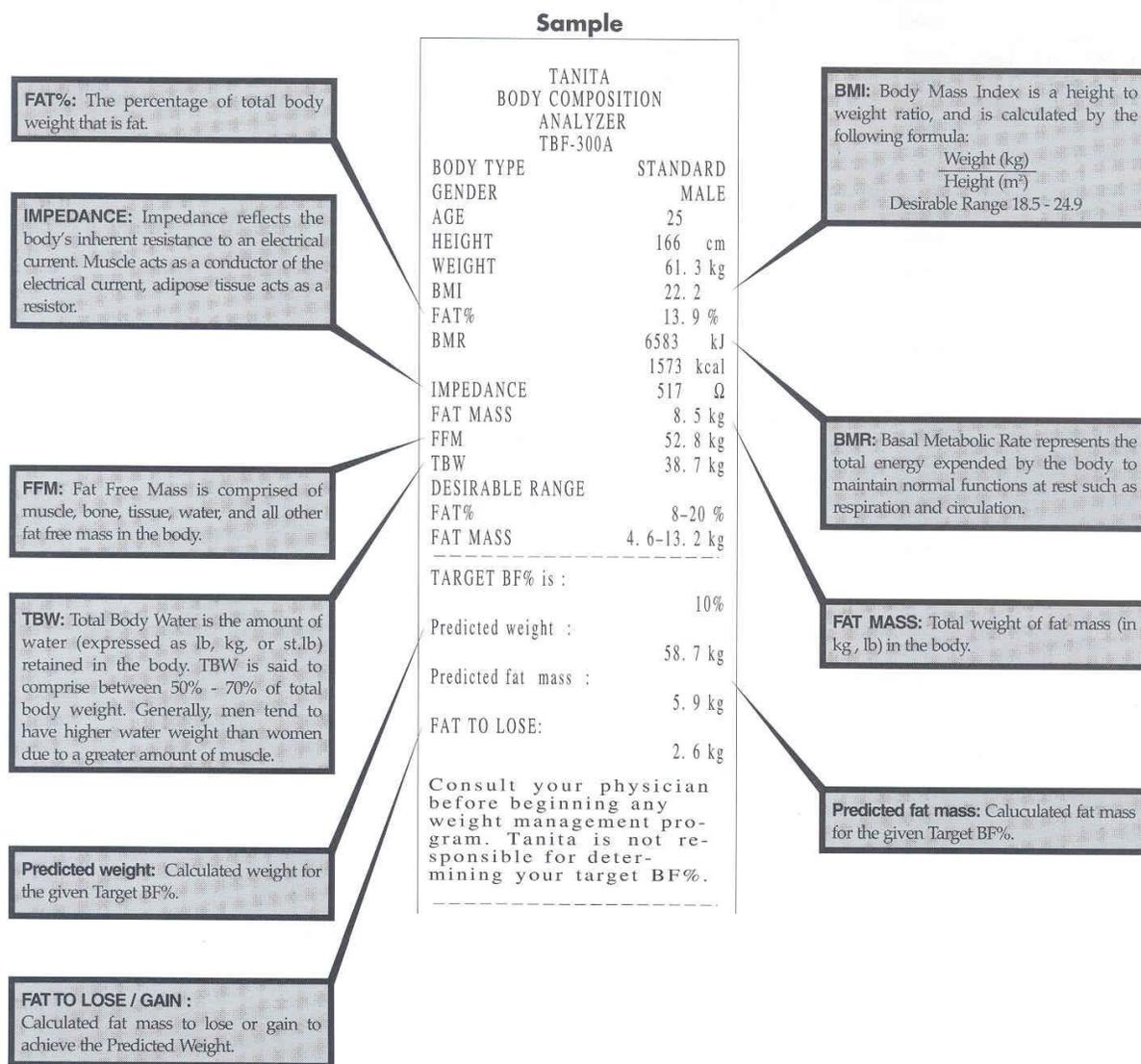
When measurement is complete, both weight and percent body fat will be displayed on the LCD, and detailed results will automatically print out. The LCD will then return to the Gender and Body Type screen in about 10 seconds, making it ready for the next participant.

Figure 4-6 provides shows an example printout with explanations. The printout includes a summary of Body Type, Gender, Age, Height, Weight, BMI (calculated), Fat %, Fat Mass. A TARGET section follows and contains: Target Body Fat%, Predicted Weight, Predicted Body Fat, and Fat to Lose. These measures are recorded from the printout on the BCF Items 14-25, as indicated in the QxQs (Forms Appendix).

**Table 4.6 Bony Landmarks for Anthropometric Measures**



**Figure 4.7 Sample Tanita TNF 300A Body Composition Print Out**



#### 4.1.3 Training

Technicians are trained by the Clinic Manager and the Coordinating Center training liaison and are responsible for training of newly hired technicians (observers) and recorders. Training includes an (1) introduction to the rationale for body size measurements, the expected limits of reproducibility, and usual errors; (2) a demonstration of proper and improper procedures; (3) practice on volunteers; and (4) testing on volunteers with four different body types—lean, obese, athletic, and aged.

#### 4.1.4 Certification

Common criteria are used for initial certification and recertification for anthropometry and body composition determination. Examination Center supervisors and technicians are certified after participating in central training by the Clinic Manager and Coordinating Center liaison with investigator oversight / assistance as needed. All observers are recertified bi-annually (January and July) by the local expert. Each technician practices on volunteers with a variety of body shapes for the assessment of certification and recertification, measures one volunteer, meeting the following criteria:

- The standing height measurement must agree within 1.0 cm of the trainer/certifier
- The waist and hip circumference measurements must agree within 1.0 cm of the trainer/certifier
- Weight must agree within 1kg (or 1 pound) of the trainer/certifier

Recertification is performed every 6 months. The following additional certification criteria for each type of measurement used must be met”

- Absence of digit preference for more than 6 months during one year
- Absence of systematic differences in mean values
- Adequate performance on replicate measurements

#### 4.1.5 Quality Assurance

In addition to annual recertification, protocol adherence in the performance of each procedure is reviewed at least annually by the Coordinating Center monitors. Deviations from protocol and possible remedial actions are discussed with the Clinic Manager and staff at that time. 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). These are sent to the JHS Coordinating Center for review. Major deviations from the protocol are brought to the attention of the Cohort Operations Committee.

Anthropometry equipment is calibrated frequently and results are recorded on an Anthropometry Equipment Calibration Log (see Appendix). 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 on Use of Observation and Equipment Checklist (see Appendix) and sent to the Coordinating Center biannually.

Digit preference, systematic differences in location statistics, completion of checklists/logs according to schedule are analyzed by the Coordinating Center. Important quality assurance/control measures analyzed include training/certification, instrument checks, random repeatability studies and biannual observations of technicians by other technicians and Coordinating Center monitors are monitored and reviewed by the Quality Control Committee. Refer to Manual 5 for a detailed description of quality assessment procedures.

#### 4.1.6 Data Collection

The BCF is collected by either the technician (observer) or recorder by direct data entry on a data entry screen or on a paper form (see Forms Appendix) for delayed data entry according to QxQ instructions.

## **4.2 Sitting Blood Pressure**

Sitting Blood Pressure (SBP) is performed as part of the fixed sequence #1 during the Exam 2 clinic visit. See Manual 3, Blood Pressure. See Forms Appendix for SBP form and QxQ instructions.

## **4.3 Finger Stick Laboratories**

Measures of fasting glucose and lipids are obtained via finger stick (digipuncture) blood samples using the Cholestech LDX analysis system. The Cholestech LDX Manual is found in the Appendix.

### **4.3.1 Rationale**

Glucose and lipids are well known risk factors for heart disease and their measurement is continued in Exam 2 to provide immediate information to participants regarding their values.

### **4.3.2 Administration**

The FST form is completed by trained and certified technicians during the fixed sequence #1 component of the Exam 2 clinic visit to record results of the glucose and lipids (Cholesterol, Triglycerides, HDL, LDL, VLDL) obtained by the Cholestech system. The FST and QxQ instructions for completion are contained in the Forms Appendix.

### **4.3.3 Training**

### **4.3.4 Certification**

### **4.3.5 Quality Control**

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 Standardization 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 (Appendix). Instructions for completing the Cholestech LDX Optics Check can be found in the Appendix: Cholestech Manual, p 13-14.

Good Laboratory Practice principles suggest that external controls must be run whenever the laboratory director has any question about test system integrity or operator technique (e.g., when

reagents may have been stored or handled in a way that can degrade their performance or when operators have not performed a particular test in recent weeks). Controls should be run

- With each new shipment of cassettes (even if cassettes are from the same lot previously received)
- With each new lot of cassettes
- As otherwise required by your laboratory's standard Quality Control procedures
- If you are not running the Cholestech L·D·X System under CLIA waived status, or if your local or state regulations require more frequent testing of quality control material, then quality control must be performed in compliance with those regulations.

If the controls do not perform as expected, repeat the test or contact our office for more help. Toll Free 1-877-WILBURN

As soon as the LDX cassettes are received, they should be placed in the refrigerator. When stored refrigerated at 2-8°C (36°-46°F) the cassettes are stable and can be used until the expiration date printed on the cassette pouch and box. Cassettes can be taken out of the refrigerator and stored at room temperature for thirty (30) days. Once the cassettes have been removed from the refrigerator, and have reached room temperature, the room temperature timing starts. The cassettes cannot be returned to the refrigerator to extend the dating to the expiration date on the label once they have reached room temperature. A Quality Control Log for Cholestech cassettes can be found in the Appendix.

#### 4.3.6 Data Collection

Finger stick is standardized to the upright position. If the participant is nervous or excited, the technician briefly describes the procedure, e.g. "I am going to be sticking your finger once to obtain a few drops of blood to check your sugar (glucose) and blood fats (lipids). You will feel a quick prick, then I will massage your finger to obtain sufficient blood to accomplish the tests. You will know the results of your tests in just a few minutes. This information is important for your health and the JHS will be able to use the results of these tests to determine some of the causes of heart disease."

**HANDLING PARTICIPANTS WHO ARE EXTREMELY APPREHENSIVE ABOUT HAVING A FINGER STICK.** Do not under any circumstances force the participant to have a digipuncture. It may help to explain to the participant that the finger stick is designed to be as painless as possible. It may help to have the participant go on to another part of the exam. It may be useful to have the participant relax for a short time before the finger stick.

Use the third finger of the participant's left (or nondominant) hand for the digipuncture. Cleanse the digipuncture site with a sterile alcohol prep using a circular motion from the center to the periphery. Allow the area to dry. Perform the digipuncture using the equipment for that purpose. Grasp the participant's finger firmly, using your thumb to draw the skin taut. With the lancet firmly inserted in the digipuncture device, enter the finger in a smooth continuous motion.

The Cholestech LDX system uses reflectance photometry (the amount of light reflected from a solid surface) to measure the amount of substances in the blood. The analyzer measures color changes of the 4 reagent pads that is then converted to mg/dL or U/L and displayed on the Liquid Crystal Display (LCD) screen.

The Cholestech system should be operated in an environment with a room temperature between 68-87 degrees centigrade, has a stable work surface, and no direct heat or bright light. Check that the ROM pack is inserted and the clip is in place.

**Important: Do not remove the ROM pack while the analyzer is plugged in or it will lose its optical calibration and stop working!**

Insert the power plug in the back of the analyzer and plug into the wall (see Appendix, Cholestech Manual, p 9). The following messages will appear on the screen:

Testing Memory

Selftest running

Selftest OK

Should these messages fail to appear, or a message that says: Calibration Fail...Call Tech Service, call for technical service.

Prior to using the Cholestech monitors, assure that the Configuration Menu has been completed and the Optics Check Testing procedure has been completed for the day (see above). See Appendix: Cholestech LDX Manual, p 10 for directions.

### **Testing Procedure:**

Remove the Cholestech test cassette from its pouch, assuring that it has warmed to room temperature (at least 10 minutes after removing from refrigerator) before using. **DO NOT TOUCH THE BLACK BAR OR MAGNETIC STRIPE.** Wear gloves at all times when collecting blood specimens.

#### *Performing Finger Stick:*

Have the participant sit quietly for 3-5 minutes before collecting the finger stick sample. Place a capillary plunger into the end of a Cholestech capillary tube with the red mark. The participant's hands should be warm to the touch. If they are not:

- Wash hands with warm water
- Apply warm compress for several minutes
- Gently massage finger from base to tip

Clean the site with alcohol swab and thoroughly dry the site

Perform fingerstick with deep, firm pressure. Gently squeeze finger to obtain drop of blood. Wipe away the first drop

Squeeze the finger again, holding it downwards until a second drop appears

Hold the capillary tube horizontally by the end with the finger and touch it to the drop of blood without touching the skin. **DO NOT COLLECT AIR BUBBLES.** If necessary, collect another drip of blood in order to fill the capillary tube in 10 seconds.

Wipe off excess blood and have participant apply pressure with swab until bleeding stops

#### *Performing the Test:*

Three buttons [RUN, DATA, STOP] control all the steps needed for operation of the analyzer.

1. Press RUN to complete the selftest
2. The cassette drawer will open and the screen will display: Load cassette and press RUN
3. Use the Cholestech LDX Capillary Tube to place sample into the test cassette sample well (See Appendix: Cholestech Manual, pp 19-22 for additional information)
4. **Fingerstick sample must be applied within 5 minutes after collection or blood will clot**

5. Keep the cassette level once sample applied and IMMEDIATELY place the cassette into the drawer of the analyzer with the black reaction bar facing toward the analyzer and the brown magnetic stripe on the right.
6. Press RUN and the drawer will close, displaying: Test running
7. Place all materials coming in contact with blood samples or control in biohazards waste container
8. Analyzer will beep when test is complete and display: Test= ### units
9. Press DATA to view the calculated results
10. The machine will display results outside the normal range with a <### or >### sign
11. Problems will result in a text message referring you to the Troubleshooting section of the Cholestech Manual (Appendix, pp 38-43)
12. The drawer will automatically open. Remove the cassette and discard in biohazards waste container
13. Record results on the FST form

The Cholestech measuring range for each analyte is as follows:

- Total Cholesterol 100 -500 mg/dL or 2.59 - 12.93 mM/L
- HDL Cholesterol 15-100 mg/dL or 0.39-2.59 mm/L
- Triglycerides 45-650 mg/dL or 0.51 - 7.34 mm/L
- Glucose 50-500 mg/dL or 2.78 - 27.75 mm/L
- ALT 10-400 U/L, 37°C

Results outside these ranges will be reported as less than (<) the lower limit or greater than (>) the upper limit. If repeat testing gives the same < or > result the sample should be sent to a clinical lab for testing. If Triglycerides are > 400, the LDL cannot be calculated and the results will be reported as NA.

#### **4.4 Snack**

A light snack is scheduled as soon as possible after digipuncture during the flexible sequence for the Exam 2 clinic visit. Caffeine-free refreshments are provided, including decaffeinated coffee and tea, fruit juices and reduced fat or skim milk. Menus are determined by the Examination Center staff, but will include heart-healthy alternatives.

#### **4.5 Self-Monitored Blood Pressure**

See Manual 3, Blood Pressure. See Forms Appendix for Self-Monitored Blood Pressure (SMP) and Post Self Monitored Blood Pressure (ASB) forms and QxQ instructions.

### **5.0 MEDICAL DATA REVIEW**

Through the participant informed consent, the medical data review, and the cover letters for any alert results reports sent to participant health care providers it is made clear that the interviews and exam components are not a substitute for regular medical care. One of the benefits to participants, however, is the summary of clinically relevant results distributed by the Examination Center at the conclusion of Exam 2. At the end of the Examination Center visit, participant interview and examination data are reviewed by the trained staff to provide the participant with a summary of study results for height, weight, BMI, sitting blood pressure, glucose, lipids (cholesterol, triglycerides, HDL, LDL, VLDL) percent body fat, fat mass, and target body fat/body mass goals (see Appendix). Participants are reminded that they should take their results to their health care provider and are provided with a duplicate copy for that purpose.

Three procedures are included in Medical Data Review: Data Inventory, Participant Medical Data Review Exit Interview, and Clinician Reviews.

## 5.1 Rationale

The primary objectives of the Medical Data Review are to safeguard participant safety and to inform the participant of findings detected during the clinical components and through responses to the interview/questionnaires. Clinical and interview data are reviewed with participants to confirm selected positive symptoms reported during the interviews/exams and to determine if these appear to warrant immediate (same day), urgent (same week) or routine medical follow-up. Conditions requiring emergency referral are dealt with as soon as observed and, in general, have been dealt with before the Medical Data Review takes place. For example, blood pressure readings  $\geq 210/120$  mm Hg are attended to as soon as observed. Table 5-1 indicates the classification of blood pressure for adults. The JHS physician is consulted, the clinic visit terminated, the person referred for immediate medical care, and a return visit to complete missed procedures and interviews is scheduled as appropriate. Persons with elevated blood pressures less than 210/120 mm Hg are referred to her/his source of medical care at the Medical Data Review following the guidelines shown in Table 5-2.

When clinically relevant finger stick laboratory data is identified during the examination, the data are again reviewed prior to producing summary reports for participants and her/his physicians. As part of this review, JHS clinical personnel may recommend follow-up again if symptoms/conditions appear to warrant further medical attention.

At the Examination Center, participants' clinically relevant data are reviewed at two levels. The first review takes place during the Medical Data Review (see below, section 5.3), which is conducted after all interviews and physical exams have been completed and data have been assembled as part of the data inventory step (section 5.2). The second level of medical data review takes at the end of the clinic visit during the exit interview.

**Table 5.1 Classification of Blood Pressure for Adults, Based on Joint National Committee on Detection, Evaluation and Treatment of High Blood Pressure (JNC-VII, 2003) Guidelines**

Category*	SBP (mm Hg)		DBP (mm Hg)
Normal	<120	and	<80
Pre Hypertension	120-139	or	80-89
Stage 1 Hypertension	140-159	or	90-99
Stage 2 Hypertension	$\geq 160$	or	$\geq 100$

\*When SBP and DBP fall into different categories, use the higher category.

<b>Table 5.2 Medical Care Referral Guidelines for Blood Pressure, Based on Joint National Committee on Detection, Evaluation and Treatment of High Blood Pressure (JNC-VII, 2003) Guidelines</b>			
<b>Referral Classification</b>	<b>Examination Findings</b>	<b>Recommendation to Participant<sup>1</sup></b>	<b>Explanation to Participant</b>
Emergency Referral	SBP $\geq$ 260 or DBP $\geq$ 130	Transportation to emergency care facility. Stop exam and reschedule clinic visit	Your BP is very high.
Immediate Referral	SBP 210-259 or DBP 120-129	Consult with JHS MD. Refer to source of care immediately (today). Stop exam and reschedule clinic visit	Your BP is very high.
Urgent Referral	SBP 180-209 or DBP 110-119	Consult with JHS MD and proceed unless otherwise indicated. Refer to source of care within 1 week	Your BP is high.
Routine Referral	SBP 160-179 or DBP 100-109	Refer to source of care within 1 month	Your BP is elevated.
	SBP 140-159 or DBP 90-99	Refer to source of care within 2 months	Your BP is elevated.
	SBP 120-139 or DBP 80-89	Recheck in 1 year (no JHS referral)	Your BP is in the pre-hypertension range
	SBP < 120 <sup>2</sup> or DBP < 80	Recheck in 2 years (no JHS referral)	Your blood pressure is normal

<sup>1</sup> If the systolic and diastolic categories are different, follow recommendations for the shorter time follow-up (e.g., 160/85 mm Hg should be evaluated or referred to source of care within 1 month). <sup>2</sup> Unusually low readings should be evaluated for clinical significance.

## **5.2 Procedures**

### **5.2.1 Data Inventory**

The data inventory step initiates the last fixed component #2 of the Examination Center examination sequence and is done after all interviews and examination procedures have been completed in preparation for the Medical Data Review. Participant data are collected by various means during the course of the baseline exam and require summarization and placement in the participant's folder for nurse/clinician review.

Although the JHS study does not diagnose or treat any medical condition, the participant's health and safety is of paramount concern. Therefore, data collected during the examination that could indicate the need for immediate (same day), urgent (within one week) or routine (within one to two months or first convenient appointment) referral for medical care are put together into one document, the Medical Data Review Printout (see Appendix), and reviewed with the participant prior to the completion of the examination.

A staff person reviews the participant itinerary (PIN) to determine that all interviews and procedures have been completed and checks participants' folders to verify that they contain the paper versions of the forms to be completed by JHS staff. After completion of the baseline exam and confirmation of quality control procedures, participants are invited to change back into street clothes while the data are being prepared for the medical data review.

### **5.2.2 Participant Medical Data Review Exit Interview**

Trained staff conducts the medical data review as part of the fixed sequence #2 at the end of the Exam 2 clinic visit to:

- summarize the results of selected measurements obtained during the Exam 2 exams/interviews
- identify potential medical problems
- answer participant questions

In summary, factual information is given to participants about her/his results during the Medical Data Review, identifying abnormalities and recommending referral as needed, but avoiding medical advice about prognosis, prevention or therapy. Physician back-up is available at all times.

### **5.2.3 Clinician Reviews**

Clinician reviews of medical data reports are conducted one week after the participant's Exam 2 clinic visit by the Clinic Manager with back up of the Clinic RN and oversight by the Examination Center Director/co-PI and JHS PI. This step in the Medical Data Review process is to assure that all alerts have been recognized and adequately managed by Examination Center staff.

The Clinic Manager review is an ongoing activity at the Examination Center. Once a week, the Clinic Manager reviews the data of participants seen in the preceding week. This procedure includes the information initially reviewed during the Medical Data Review and serves as a quality control to assure that all alert values have been appropriately identified and processed. After the examination of the participant's Medical Data Review printout, the Clinic Manager records the interpretation of the Medical Data Review printout and reviews the preliminary interpretation. The Clinic Manager also confirms the results for alert values. Any referrals made during Medical Data Review are reviewed at this time, and sent to a JHS physician for review. This general medical review provides a clinical staff's interpretation of the study results and an overview of referrals and reports from the Examination Center.

## **5.3 Training**

Staff is trained for the data inventory and assembly of study materials for the Medical Data Review, as well as the Medical Data Review tasks by the Examination Center Clinic Manager. The Clinic Manager is trained to perform the clinician review by the Examination Center Director/Co-PI and/or the JHS PI.

## **5.4. Certification**

Certification for data inventory is the responsibility of the Clinic Manager. Annual recertification is required, and staff performance is monitored by the Clinic Manager. The Examination Center Clinic Manager is responsible for certification of the clinicians responsible for Medical Data Review.

## 5.5 Quality Control

Quality assurance consists of observation by the supervisor and retraining or corrective action, as required. The Examination Center PI is responsible for ensuring that the medical data review, referrals and reporting of results are done according to procedures in the JHS protocol.

## 6.0 REFERRALS AND REVIEW GUIDELINES

### 6.1 Rationale

Participants are referred based on the guidelines for alerts referral listed below (Table 6.1). Prior to the Medical Data Review (described in section 5.0), a DMS utility system retrieves affirmative responses (from the questionnaires) to key items indicative of hypertension, diabetes, ischemic heart disease, hypercholesterolemia, cancer, chest pain on effort, congestive heart failure, TIA/stroke, and intermittent claudication. Guidelines for conducting the Medical Data Review are provided in the Medical Data Review instructions.

Referrals for follow-up care can be made at the Medical Data Review or in subsequent communications. Uniform criteria for emergency, immediate, urgent and routine referrals have been established, (section 6.2), and are summarized in Tables 6.1 and 6.2. Sources of medical care for participants who do not have a health care provider will be identified in consultation with the representatives of the local medical community. All referrals are documented on a separate Report/Referral Form (REF) and the JHS Alert/Referral log (ALT) (see Forms Appendix). Detailed QxQ instructions are specified in the Forms Appendix.

### 6.2 Procedures

Referrals are made during the Medical Data Review or upon receipt of the study's clinically relevant data, which follow the criteria listed below.

1. Emergency Referral. Transportation to the nearest emergency care facility is provided or an emergency squad is called.
2. Immediate Referral. The participant is urged to see her/his health care provider within one day.

The nurse/clinician consults with the JHS physician, and the participant's health care provider is called. The participant's health care provider is also sent a letter of explanation (see Appendix).

Participants who have no health care provider are referred based on consultation with a provider in the community.

3. Urgent Referral. The participant is asked to see her/his health care provider in one week.

The nurse/clinician confirms the decision with the JHS physician, and explains the reason(s) for an urgent referral to the participant. This usually occurs during the Medical Data Review, but can occur when alert values are returned to the Examination Center from a central agency. The JHS physician calls the participant's health care provider and sends a referral letter (see Appendix). Follow-up letters are also sent to the participant (see Appendix).

Participants who have no health care provider are referred based on consultation with a provider in the community.

4. Routine Referral. The participant is asked to see her/his health care provider at the first convenient appointment.

The nurse/clinician advises a visit to the participant's health care provider. A referral letter is sent to the participant (see Appendix) and her/his health care provider (see Appendix) as a cover letter for the final results report.

5. No Referral. The study results are summarized for the participant and her/his health care provider and sent along with cover letters (see Appendix).

Procedures/symptom-specific guidelines are summarized in Tables 6.1 and 6.2. The types of participant and health care provider referral and results letters used for each of the five referral categories are summarized in Table 6.2; examples of the texts of these letters are provided in the Appendix.

<b>Referral Classification</b>	<b>Examination Findings</b>	<b>Recommendation to Participant</b>	<b>Explanation to Participant</b>
IMMEDIATE Referral	*SBP $\geq$ 210 mm Hg or DBP $\geq$ 120 mm Hg	See health care provider today	BP very high
URGENT Referral	*SBP $\geq$ 180-209mm Hg or *DBP $\geq$ 110-119mm Hg	See health care provider within a week	Your BP high.
ROUTINE Referral	*SBP 160-179 mm Hg or DBP 100-109 mm Hg  *SBP 140-159 mm Hg or DBP 90-99 mm Hg  *SBP 120-139 mm Hg or DBP 80-89 mm Hg	See health care provider within one year	Your BP is high  Your BP is high  Your BP is borderline high
NO Referral	* SBP 130-139mm Hg or DBP 85-89mm Hg  *SBP $\leq$ 140mm Hg and DBP $\leq$ 90mm Hg  Height, weight	Recheck in one year  Recheck in two years  None	Confirm only  Confirm only Your reading is high normal  Report only

\*Interview items/measurements require confirmation during Medical Data Review

TABLE 6.2 SUMMARY OF PROCEDURES FOR ROUTINE REPORTING AND IDENTIFICATION, NOTIFICATION, AND DOCUMENTATION OF ALERTS					
Exam	ACTION SEQUENCE FOR ROUTINE RESULT REPORTING	Action Sequence for Identifying Abnormal / Alert Result	ABNORMAL / ALERT VALUE BY CATEGORY OF REFERRAL	ACTION SEQUENCE FOR REPORTING ABNORMAL / ALERT RESULT	ALERT / REFERRAL DOCUMENTATION
BP	<p>BP Technician informs participant of BP</p> <p>↓</p> <p>Clinic nurse discusses findings and gives instructions for follow up at exit interview.</p> <p>↓</p> <p>Social Work referral to assist with HCP or other identified social needs as indicated.</p> <p>↓</p> <p>Weekly Clinic Manager review of <u>all</u> results from preceding week with review of appropriate alert action for previously identified alerts. Any new alerts identified initiate Alert Action sequence for participant and HCP notification.</p> <p>↓</p> <p>Weekly EC clinician review of <u>abnormal</u> results from preceding week with review of appropriate alert action.</p> <p>↓</p> <p>Comprehensive <u>abnormal</u> results reporting to HCP (if requested) within 2 weeks following clinic visit.</p>	<p>BP Technician identifies alert value</p> <p>↓</p> <p>Notifies Clinic RN/Manager</p> <p>↓</p> <p>Confirms reading</p> <p>↓</p> <p>Contacts JHS Medical Officer or EC Clinician on-call</p> <p>↓</p> <p>Initiates Alert Action procedure</p>	<p><u>Emergent:</u> SBP≥260 DBP≥130</p> <p><u>Immediate:</u> SBP 210-259 DBP 120-129</p> <p><u>Urgent:</u> SBP 180-209 DBP 110-119</p> <p><u>Routine 1:</u> SBP 160-179 DBP 100-109</p> <p><u>Routine 2:</u> SBP 140-159 DBP 90-99</p>	<p>Stop clinic exam and transport to local ER. Notify participant and HCP by telephone.</p> <p>Continue with clinic exam. Notify participant and HCP at exit interview. If no HCP, use Referral Procedure and make appointment for same day.</p> <p>Continue with clinic exam. Notify participant at exit interview and HCP by letter (M2Appendix) for 1-week appointment. If no HCP, use Referral Procedure and make appointment for one week.</p> <p>Continue with clinic exam. Notify participant at exit interview and HCP by letter (M2Appendix) for one-month appointment. If no HCP, use Referral Procedure and make appointment for one month.</p> <p>Continue with clinic exam. Notify participant at exit interview and HCP by letter (M2Appendix) for two-month appointment. If no HCP, use</p>	<p>Record alert value, referral action, notification method and date of notification on ALT (Alert and Referral Log) at time of action.</p>

TABLE 6.2 SUMMARY OF PROCEDURES FOR ROUTINE REPORTING AND IDENTIFICATION, NOTIFICATION, AND DOCUMENTATION OF ALERTS					
Exam	ACTION SEQUENCE FOR ROUTINE RESULT REPORTING	Action Sequence for Identifying Abnormal / Alert Result	ABNORMAL / ALERT VALUE BY CATEGORY OF REFERRAL	ACTION SEQUENCE FOR REPORTING ABNORMAL / ALERT RESULT	ALERT / REFERRAL DOCUMENTATION
			<p><u>Routine 2:</u> SBP 120-139 DBP 80-89</p>	<p>Referral Procedure and make appointment for two month.</p> <p>Continue with clinic exam. Notify participant at exit interview and HCP by letter (MSAppendix) for one year appointment. If no HCP, use Referral procedure and make appointment for one year.</p>	
Lab	<p>Lab Technician collects samples</p> <p>↓</p> <p>Clinic nurse informs participant at exit interview findings.</p> <p>↓</p> <p>Weekly Clinic Manager review of <u>all</u> results from preceding week with review of appropriate alert action for previously identified alerts. Any new alerts identified initiate Alert Action sequence for participant and HCP notification. Retain paper file of lab results for back up until completion of comprehensive reporting.</p> <p>↓</p> <p>Weekly EC clinician review of <u>abnormal</u> results from</p>	<p>Lab Technician identifies alert (Panic) value immediately</p> <p>↓</p> <p>Notifies Clinic RN/Manager</p> <p>↓</p> <p>Reviews reading</p> <p>↓</p> <p>Contacts JHS Medical Officer or EC Clinician on-call</p> <p>↓</p> <p>Initiates Alert Action procedure</p> <p>↓</p> <p>Repeat finger stick provides repeat confirmation of alert result</p>	<p><u>Emergent:</u> None</p> <p><u>Immediate:</u> Glucose: &lt; 45 or &gt;500</p> <p><u>Urgent:</u> Gluc: 45-60 or 200-500 TotChol: &gt; 360 HDL: &lt; 20 LDL: &gt; 260 TG: &gt;1000</p>	<p>Notify participant and HCP by telephone on day alert received. FAX complete lab results to HCP. If no HCP, use Referral Procedure and make appointment for same day.</p> <p>Notify participant in clinic and HCP by letter (M2Appendix) for 1-week appointment. Enclose copy of alert lab value and complete finger stick lab results to HCP. If no HCP, use Referral Procedure and make appointment for one week.</p>	<p>Record alert value, referral action, notification method and date of notification on ALT (Alert and Referral Log) at time of action.</p>

<b>TABLE 6.2 SUMMARY OF PROCEDURES FOR ROUTINE REPORTING AND IDENTIFICATION, NOTIFICATION, AND DOCUMENTATION OF ALERTS</b>					
<b>Exam</b>	<b>ACTION SEQUENCE FOR ROUTINE RESULT REPORTING</b>	<b>Action Sequence for Identifying Abnormal / Alert Result</b>	<b>ABNORMAL / ALERT VALUE BY CATEGORY OF REFERRAL</b>	<b>ACTION SEQUENCE FOR REPORTING ABNORMAL / ALERT RESULT</b>	<b>ALERT / REFERRAL DOCUMENTATION</b>
	preceding week with review of appropriate alert action.		<u>Routine:</u> All other abnormal values not classified as alert value	Notify participant in clinic and HCP by letter (M2Appendix) for 1-week appointment. Enclose copy of alert lab value and complete finger stick lab results to HCP. If no HCP, use Referral Procedure and make appointment for one week.	

## 7.0 PARTICIPANT SAFETY

The safety and welfare of the JHS participants is protected by:

- specific measurements taken in the design or conduct of the examination for her/his safety;
- the mechanisms established for handling potential emergencies;
- routine notification of participants and her/his health care providers regarding the results of the examination, and
- the procedures JHS staff use to review all potentially medically important results and make the appropriate referrals.

An important factor in participants' welfare involves her/his expectations regarding the examination. If they believe the JHS examination is a substitute for a clinical examination, delay in seeking needed medical care could occur. Therefore, the provision of adequate information is a requisite to the JHS informed consent procedures (described in section 3.2).

### 7.1 Measures to Protect the Participant

Examination procedures which convey potential risk to participants include the fasting requirement and digipuncture. Methods by which participant risk is minimized (more fully described elsewhere in JHS Manuals) include the following:

- The possibility of hypoglycemia with a 12-hour fast is diminished by routine inquiry about reasons that should exempt the participant from fasting during the scheduling of baseline exam. Other medical conditions or dietary restrictions, which may be incompatible with the snack provided in the clinic, are also ascertained.
- Hematomas or prolonged bleeding may result from digipuncture. These are usually avoided if well-trained technicians follow the procedures for finger stick. Prior to digipuncture, the participant is asked: "Do you have any bleeding disorders?" If the participant answers affirmatively or is uncertain, s/he is asked about whether s/he has had blood drawn previously and if so, whether there were any problems such as swelling or continuing to bleed at the digipuncture site. If the answer to this question is "yes," the Clinic Manager is summoned to approve the digipuncture. Occasionally, with any participant, bleeding persists after the digipuncture. If the participant continues to bleed:
  - Apply pressure to the site with a gauze pad. Keep the hand and arm elevated until the bleeding stops
  - Wrap a gauze bandage around the finger over the pad.
  - Tell the participant to leave the bandage on for at least 15 minutes

If the measurements taken have not stopped all bleeding within 30 minutes, and there is no obvious explanation for the prolonged bleeding, a medical referral is made. Also, the participant is instructed to seek medical care promptly if bleeding recurs after leaving the JHS clinic.

- Participants may experience dizziness or syncope during the digipuncture. When a participant feels faint or looks faint following finger stick, follow the rules for a minor emergency, below (section 7.3.2). Additionally,
  - Have someone stay with the person to prevent them from falling and injuring themselves if they should faint
  - Place a cold wet cloth on the back of the person's neck or on their forehead

- Once the episode has passed, some fruit juice may be given to the participant in order to counteract any possible hypoglycemia due to their pre-clinic visit fast
- If the person continues to feel sick, take a blood pressure and pulse reading. Contact a medical staff member, who will advise you on further action

## 7.2 Stopping Rules for Interviews and Procedures

Participant safety and comfort during the clinical examination are monitored throughout the clinic visit. Interviewers and technicians observe participants for signs of fatigue or physical and/or emotional discomfort. When any one of these conditions is observed, participants are offered the opportunity to discontinue the interview or procedure, and are given an opportunity to rest before the next procedure. Persons incapable of completing the entire clinical exam are invited to change back into her/his street clothes and participate in the medical data review and reschedule the clinic exam on another day.

For persons with conditions which require emergency and immediate referrals, such as cardiac events, unstable angina, or blood pressure  $\geq 210/120$  mm Hg (see Tables 16 and 17), the JHS physician is consulted immediately, the clinic exam is terminated as soon as the condition is observed, and another appointment for baseline exam rescheduled as appropriate. For blood pressures requiring referral within one week (SBP 180-209 mm Hg or DBP 110-119 mm Hg; the urgent referral category in Table 20), the JHS physician is also consulted, and the clinic exam is either continued and the participant advised to seek medical care within one week or the clinic exam is terminated and rescheduled, based on the JHS physician's recommendation. The termination of any interview or procedure is documented on the Participant Itinerary Sheet (PIN).

## 7.3 Methods for Handling Emergencies

While all life-threatening emergencies (e.g., acute MI) require immediate evaluation of the participant at an acute care facility, some emergency measures may be required in the clinic before departure (e.g., cardiac arrest). In addition, there are minor emergencies (hypotension, fainting, etc.) which may require treatment in the clinic only. Although most emergencies are of the less severe nature, the JHS Examination Center is prepared for both types.

### 7.3.1 Major Emergencies

In a serious event the primary concern of the Examination Center staff is to implement pre-established procedures to get the participant to the nearest medical facility. The JHS clinic is located within a few city blocks of a large, general, and acute-care hospital. A staff person with certification in basic life support is on duty and physically present at every clinic session. Needed life support procedures are continued until emergency care arrives or the participant is transported to a hospital. The JHS Examination Center has specific emergency procedures which define:

- Who is in charge during the emergency
- Who is to administer treatment
- Who is to be notified
- What action clinic staff is to take
- Which reports are to be filed

In addition to trained personnel and emergency equipment, the Examination Center has posted in a conspicuous place (e.g., the reception area): phone number of police and fire stations, ambulance services, and specific phone numbers or codes to alert medical teams, if applicable.

In each participant's folder, the name and phone number of her/his health care provider or usual source of medical care and the home and work telephone numbers of one or more contact person are available on the CON form. The Examination Center is required to have either a physician or a registered nurse on site at all times when participants are interviewed and examined.

All emergency situations are coordinated by the staff person designated, a priori, or by a physician if present. The Examination Center has a designated physician on duty for each clinic session. If not physically present in clinic, s/he is within immediate reach by phone or paging system and within a short distance to the clinic. The physician duty roster is posted with the clinic secretaries and in the office of the nurse/clinician so that the name of the responsible physician is readily accessible. However, in no case is emergency referral and/or care deferred while staff is attempting to locate a clinic doctor.

JHS staff is trained to carry out her/his specific responsibility during an emergency. Retraining is the responsibility of the Examination Center, following institutional guidelines.

All emergencies, whether serious or minor, are documented. This requires filling out an institutionally-approved form identifying the type of emergency. This is done by the person in charge at the time, and all reports are co-signed by a clinic physician and are filed at the Examination Center.

### **7.3.2 Minor emergencies**

The most common minor emergency is simple syncope (fainting) and near syncope. These events may occur during digipuncture. Many syncopal episodes can be prevented if clinic staff is alert to early signs. In any situation in which syncope is likely, e.g., after the digipuncture, staff verifies that the participant does not look or feel faint. If the participant looks faint or feels faint in the digipuncture area:

1. Have the person remain in the reclining position or in the chair, sitting with head between the knees
2. Crush an ampoule of smelling salts and wave it under the participant's nose for a few seconds
3. Provide the participant with a basin and a towel if s/he feels nauseous
4. Have the participant stay in the reclining position or chair until s/he feels better and her/his color returns

If the participant continues to feel sick, recline the chair, place a cold wet towel on the back of the person's neck, and notify the supervisor. If a participant feels faint, s/he is cautiously lowered to the supine position on the floor and one attendant immediately calls for an in-house nurse/clinician to assist the patient. The remaining attendant raises the participant's legs above the plane of the body to increase venous return. Prior to this, the staff member momentarily palpates for a carotid pulse and checks to be sure the subject is breathing. If life support measures are needed, the procedures outlined in section 7.3.1 are followed.

### **7.4 Emergency equipment**

A basic first aid kit is maintained at the Examination Center. The kit contains a reference guide of its contents, and is checked every year and immediately after each use. The Clinic Manager identifies a person responsible for this task.

## **8.0 FOLLOW UP OF THE JHS COHORT**

## **8.1 Introduction**

Annual Follow Up (AFU) interviews are conducted for the purpose of reviewing the health-related developments occurring since the last contact with the JHS. Each follow up is completed by telephone (preferred) or in person (if necessary). The follow up call is preceded by a letter sent by mail about two weeks in advance of the call (Appendix: AFU Contact Letter). Information for this letter is taken from the study data base and is merged into the letter using mail merge procedures.

Each study participant is recontacted approximately every 12 months on a time schedule based on the date of the baseline clinic examination. This date has been adjusted for Exam 2 to accommodate an examination of shorter duration (three years) and to equalize the distribution of participants across the three years of the exam cycle. This will mean that some participants will be contacted sooner, while others will be contacted later, than they might otherwise have been with the new time windows.

## **8.2 Training and Certification**

AFU interviewers are trained and certified in general interviewing techniques and the administration of all relevant AFU interviews. This requires familiarity with the contents and procedures for administering the forms, assigning contact and appointment status codes on the Record of Calls (ARC) form, scheduling a clinic appointment for Exam 2, verifying contact information on the CON form, and recording any changes in consent restrictions on the Informed Consent Tracking (ICT) form.

Staff is certified in administering all forms and questionnaires after review of a standardized protocol. Satisfactory completion of two annual follow up interviews is necessary for certification on any new form or interview. Recertification is required annually with the recommendation of a periodic refresher course and retraining if quality assurance analysis indicates poor performance or inconsistent results.

## **8.3 Quality Assurance**

Individual interviewer performance is reviewed regularly by the Director of Retention / Annual Follow 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.

## **8.4 Annual Follow Up**

### **8.4.1 Eligibility Requirements for Annual Follow Up Interviews**

Participants who completed at least part of the baseline clinic examination are contacted annually. Individuals excluded from annual follow-up (AFU) and subsequent examinations at the beginning of the study are only those enumerated residents who completed the home interview, but did not sign the informed consent form at the Examination Center examination (baseline exam).

Unless requested otherwise by the participant, or a participant is lost to follow-up, an attempt is made annually to contact all surviving JHS cohort members. This includes participants who have moved away from the community in which they were recruited. Telephone AFU interviews can be conducted anywhere in the continental U.S. Addresses and telephone numbers of cohort members with multiple residences are kept on file to contact participants on her/his target anniversary date.

### 8.4.2 Time Window for Annual Contacts between Examinations

Study participants are recontacted annually on or near the anniversary date of her/his initial examination date, adjusted for Exam 2 modifications in duration and equalizing participants across years. The target date for the AFU interview is this adjusted baseline visit date. Contact years are numbered sequentially with the date of the baseline visit as CY01 assigned regardless of the calendar years in which that visit was completed (Table xx).

**Table 8-1. Contact Years by Visit Dates**

Contact Year 01 Baseline Exam	Contact Year 02 AFU 1	Contact Year 03 AFU2	Contact Year 04 AFU 3
9/26/2000-9/25/2001	3/26/2001-3/25/2002	3/26/2002-3/25/2003	3/26/2003-3/25/2004
9/26/2001-9/25/2002	3/26/2002-3/25/2003	3/26/2003-3/25/2004	3/26/2004-3/25/2005
9/26/2002-9/25/2003	3/26/2003-3/25/2004	3/26/2004-3/25/2005	3/26/2005-3/25/2006

Because recruitment is done over a three-year period, all participants will be in any one of three JHS baseline examination contact years during the calendar year in which annual contact interviews are conducted. Regardless of the contact year, the optimal time for placing the initial call each year for annual contact is generally not more than three weeks before the target (anniversary) date. A one year window, up to 6 months before and 6 months after the target date, is the maximum allowed for each annual contact. This window will allow accommodation of ARIC with JHS AFU.

When the contact window expires and no contact is made, a final result code for that window is entered on the Annual Follow-Up Record of Calls (see Appendix), and a new window begins.

The contact year to which a participant death is assigned is determined by two factors: the date of death and whether or not the participant had already been interviewed during the contact year in which the death occurred. For example, if the death is determined during or prior to the regularly scheduled AFU interview, the death is assigned to the contact year in which the AFU form was administered. If however, a participant is interviewed in Contact Year 02, dies a short time afterwards, and the family notifies the Examination Center of the death, the death is assigned to the next contact year, i.e. Contact Year 03.

#### 8.4.2.1 Modified Windows for Exam 2 Scheduling

In order to accommodate the reduced length of time allocated for the conduct of Exam 2 (3 years instead of 3 ½ as required for Exam 1), all participant annual follow up windows have been modified. Additionally, windows have been modified to accomplish an approximate equal number of participants across each month and year of clinic scheduling. Table x below provides details on the reallocation of participant Exam 2 dates based upon the date of the baseline examination (Exam 1). A similar collapsing of participant windows was first accomplished for the JHS cohort as part of the Interim Clinic Protocol (2004-2005) in the year between Exams 1 and 2 (see ICP Manual of Operations) to allow all participants to be contacted by telephone during a one year time frame. Based on this table, we anticipate approximately 150 participants to be scheduled each month for the three years from September 2005 through September 2008.

**Table 8.2 JHS Exam 2 Revised Scheduling Windows**

Exam 2 DOV	Exam 1 DOV	N	cum(n)
09/26/05-12/31/05	09/26/00-04/21/01	441	441
01/01/06-03/31/06	04/22/01-08/22/01	446	887

04/01/06-06/30/06	08/23/01-01/23/02	443	1330
07/01/06-09/30/06	01/24/02-04/29/02	447	1777
10/01/06-12/31/06	04/30/02-07/10/02	443	2220
01/01/07-03/31/07	07/11/02-09/27/02	448	2668
04/01/07-06/30/07	09/28/02-01/07/03	444	3112
07/01/07-09/30/07	01/08/03-03/28/03	444	3556
10/01/07-12/31/07	03/29/03-06/27/03	446	4002
01/01/08-03/31/08	06/28/03-10/21/03	446	4448
04/01/08-06/30/08	10/22/03-02/03/04	440	4888
07/01/08-09/25/08	02/04/04-03/31/04	419	5307
<b>TOTAL</b>		5307*	

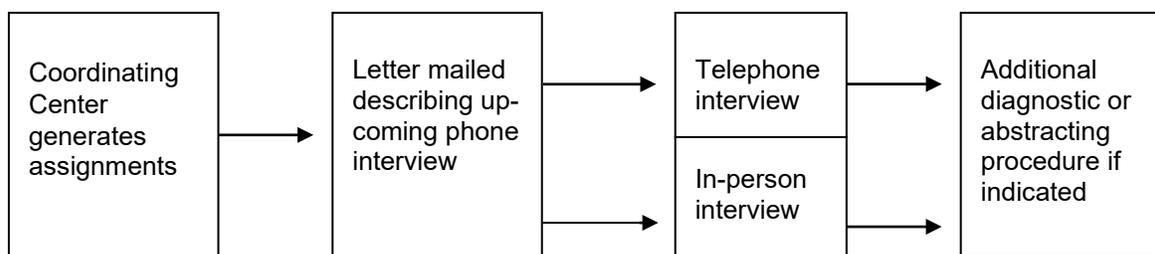
\*Total enrolled participants exceeds total participants for data analysis

### 8.4.3 Follow Up Procedures

Annual follow-up of cohort members is used to (1) maintain contact and correct address information on cohort participants, (2) update tracing information on three contact persons, (3) ascertain the participant's vital status (4) document interim medical events/hospitalizations, life events and functional status between the three-year comprehensive examinations, and (5) obtain additional sociocultural information.

There are four primary components to annual follow-up: (1) the generation of scheduling material by the JHS Coordinating Center; (2) the scheduling of the AFU interview by Examination Center staff; (3) the administration of the AFU interview; (4) the ascertainment of medical information relating to hospitalizations for cardiovascular disease and documentation of fatal events. It is anticipated that the scheduling of a Examination Center examination every third contact year will occur during the annual follow up call in AFU Year 03 (Contact Year 04). These steps are summarized in Figure 8.1 and described in the following sections.

**Figure 8-1. Interim Contact Procedures between Clinical Examinations in the JHS Cohort Study**



#### 8.4.2.1 Scheduling Annual Follow Up Interview

The Coordinating Center initiates the AFU procedures by generating several times a year AFU materials for use in scheduling and conducting the AFU interview. These materials include the Participant Tracing Information Sheet (see Forms Appendix). The list of participants includes the participant name, participant ID, date of baseline exam, and date of Visit 2 (optional), sorted in the order requested by the Examination Center. The Participant Contact Information Sheet includes the participant's name, address, telephone number(s); gender, date of birth, state of birth, social security number; employer's name and address; date of baseline exam; and the names, addresses, and

telephone numbers of two contact persons, and the personal health care provider. The Contact (CON) form lists the current data on file for the names and addresses of the participant and her/his three contact persons.

The scheduling of AFU interviews at the Examination Center is done year round and involves identifying the participants who require scheduling, establishing contact, administering the AFU form, and recording participant-reported medical events to JHS surveillance staff. The procedures for scheduling baseline exam and event classification are described in sections 1.2 and Manual 4: Cohort Surveillance / Events Ascertainment, respectively.

Participants who do not have phones, have trouble communicating by phone, or have special needs are not contacted by telephone but are visited in-person. If these participants can be identified in advance, the letter indicates that an interviewer will visit the home, and AFU interviews take place there.

#### **8.4.2.2 Conducting Annual Follow Up Interviews (AFU and AFO)**

In Contact Year 06 forward, version "B" the AFU and Version C of the Annual Follow-Up Other (AFO) forms are administered along with AFU Year 1, 2, 3, or AFE supplementary questions for any persons who have not previously completed them. QxQ instructions for the Record of Calls and version "B" of the AFU and version "C" of the AFO forms and prototype scripts for their administration have been prepared for the AFU interview (See Forms Appendix). The interview includes the use of three forms (CON, ARC and AFU) which update address and tracing information of cohort participants (See Forms Appendix); and ascertains her/his vital status (AFU, section A), death information (AFU, section B); perceptions of general health (AFU, section C); chest pain on effort (AFU, section D); possible infarction (AFU, section E); intermittent claudication (AFU, section F); TIA/stroke (AFU, section D); hospitalizations (AFU, sections H and K); and functional status, weight loss, and life events (AFU, section I) (See Forms Appendix, Annual Follow-up form). The Record of Calls (ARC) is used throughout the contacting process to log each participant's interim and final contact and appointment status (when applicable). At some point after the AFU interview, every participant-reported hospitalization is verified and the discharge diagnoses recorded. Potential cardiovascular events are reviewed further by the abstraction of participants' hospital records to document the presence/absence of JHS Study end point criteria. Detailed information on diagnostic criteria and event determination of the cardiovascular events is provided in Manual 4, Cohort Surveillance / Events Ascertainment Component Procedures.

The components of the AFU interview are usually done in the following order: (1) completion of the Record of Calls; (2) administration of the AFU questionnaire; (3) documentation of the participant's hospitalizations during the past year - section K of the AFU form; (4) completion of the AFO questionnaire; (5) completion of any incomplete AF1, AF2, AF3, or AFE forms; (6) scheduling of the appointment for Visit 2 exam (Contact Year 06); (7) updating of the contact information (CON form; and, if indicated, updating of the informed consent information (ICT form).

The Record of Calls (ARC form) is used to keep track of attempts to contact a participant. The participant's name, ID, contact year, and contact year date ranges are pre-printed at the top of the form. Space is provided to document contact attempts, pertinent information for future contacts, and the outcome of the contact. There are 26 contact RESULTS CODES. The final result code is circled and entered into the data entry system. The paper copy of the form is kept in the participant's folder to assist in future contacts. The results codes are as follows:

- 1 Annual Follow-Up Notification Letter Sent – Letter notifying participant that s/he will be contacted by the JHS in the near future for the annual follow-up call.
- 2 No Action taken – No attempt has yet been made to contact the participant.
- 3 No Answer – No answer after 10 rings

- 4 Busy – Busy signal
- 5 Answering Machine – Message left on answering machine for participant.
- 6 Privacy Block – Phone with privacy block on all calls
- 7 Disconnected/Non-Working Number – Recording from phone company or fast busy signal.
- 8 Recording/ # Change – Recording from phone company of number change. Record new number in notes section and retry.
- 9 Participant Does Not Live Here/Never Heard Of – Phone answered, name does not reside here or denies knowledge of name.
- 10 Participant Lived Here, But Moved Permanently – Phone answered, person has moved. New contact information, if available, recorded in notes section and retry.
- 11 Tracing – Attempts are being made to locate the participant, but so far neither the participant nor a reliable source have been contacted.
- 12 Physically/Mentally Incompetent – Participant was successfully contacted by phone, letter or in person, but has a physical or mental impediment to communication (e.g. slurred speech, hearing impaired).
- 13 Language Barrier – Participant was successfully contacted by phone, letter or in person, but interviewer was unable to understand the respondent, or the participant was unable to understand the interviewer.
- 14\* Contacted, Interview Complete – Participant was successfully contacted by phone or in person and the entire interview, including the questionnaires (AFU, AFO, AF1, 2, or 3) and hospitalization was completed.
- 15\* Contacted, Interview Partially Complete or Rescheduled – The participant was successfully contacted by phone, letter or in person, but the interview is incomplete or was not done at all. This may be a temporary code if it is possible that the interview may be completed at a later date within the same contact year.
- 16\* Contacted, Interview Refused – Participant was successfully contacted by phone, letter or in person, but the interview was not done and will not be completed at a later date within the same contact year.

- 17\* Reported Alive, Will Continue to Attempt Contact This Year – Reliable information (e.g., from employer, relative, etc.) indicates that the participant is living, but direct contact has not yet been made. It is possible that contact will be made during this same contact year through further efforts. For example, “temporarily away”, would fit in this category. Record date of return in notes section and retry.
- 18\* Reported Alive, Contact Not Possible This Year – Reliable information indicates that the participant is living, but direct contact has not yet been made. This code should be used only if repeated contact attempts have been made, or when it has been determined that it is not possible that contact will be made during this same contact year.
- 19\* Reported Deceased – Reliable information indicates that the participant has died.
- 20\* Unknown – Neither the participant nor another source of information has been contacted in a manner sufficient to provide reliable vital status data during the specified date range.
- 21\* Does Not Want Any Further Contact – Participant has requested that s/he does not wish to be contacted any more by the JHS. This code alerts staff that no additional contacts should be attempted during the same contact year. Notes should be kept on the ARC to describe the nature of the refusal. The Director of Recruitment determines the type of action to be taken at the following contact anniversary date, e.g., a polite letter, post card or an alternative that is sensitive to any known reasons for this participant’s desire not to be contacted again by the study.
- 22 Other – Any other results not covered by specified RESULTS CODES.
- 23 ARIC AFU – This participant has completed the ARIC AFU conducted by ARIC interviewers
- 24 Exam scheduled --Exam 2 has been successfully scheduled. Enter the date and time in the NOTES boxes.
- 25 Clinic Exam not scheduled, pending – Participant is willing to schedule clinic exam, but unable to do so at time of AFU call. Indicate in the NOTES boxes the plans for further contact regarding scheduling.
- 26 Clinic Exam not scheduled, refused – Participant indicates that s/he is not willing to schedule Exam 2 visit. This code requires an entry in the NOTES box to indicate whether the refusal is considered to be a “soft” or a “hard” refusal. A “hard” refusal generates mailing of a “refusal” letter to the participant while a “soft” refusal is followed by supervisor contact to attempt to convert the participant to a successful scheduling. Please refer to the section on Off Site Examinations is necessary to retain participation.

Codes 1-13 and 22 are interim codes. Codes 14 – 20, 21, and 23 are final codes. See Forms Appendix for detailed instructions for completing the form, and a description of the Results Codes for contacts. It should be noted that these codes are required for all AFU contacts, in contrast to the APPOINTMENT CODES (24-26) which are only used in the Contact Years in which the participant is scheduled for a clinic visit.

Note that comments are required in the NOTES for codes 8,10,11-15, 18, 21, 22, and 26.

#### 8.4.2.2.1 Annual Follow Up (AFU)

Once contact has been made, the entire AFU interview is administered to surviving participants. When a participant has expired prior to the annual contact, the relevant portions of the AFU form (Sections A, B, H and K) are administered to a member of the participant's household (or a contact person) in order to officially record the death and to obtain the date and location of death and other relevant medical information.

Section A of the AFU form documents the participant's vital status and the date on which the status determination was made. The criteria for establishing participant vital status are defined in the form's instructions. Section B is completed on individuals who have died and records demographic information necessary for obtaining a copy of a death certificate. Sections C-G are administered to all surviving participants and document perceptions of health and interim (since the previous AFU interview) medical events; the majority of the questions were taken from the London School of Hygiene Questionnaire for chest pain on effort, possible infarction, and intermittent claudication. Guidelines for administering this section are provided below, in Section 7.4.2.2.1.1. Sections H and O on the AFU form are administered to all respondents (participants and proxies) to document overnight hospitalizations in acute or chronic medical care facilities. The surveillance staff is notified of every cohort hospitalization and an event investigation is initiated. Section I is administered only to surviving participants. Section J is administered to all respondents to ascertain any changes in stress, coping and social support and negative emotions of anxiety or depression. Section L is administered to all respondents to ascertain any change in employment status. Table 8.2 summarizes the data collected in each of the versions of the AFU interview since study inception in 2000.

**Table 8.3 Summary of Data Collected During Annual Follow-Up (AFU) Interview From JHS Cohort Members**

Data Item	JHS/ AFU Form Version		
	A	B	C
DATE OF STATUS DETERMINATION	X	X	X
VITAL STATUS	X	X	X
DEATH INFORMATION			
Date of death	X	X	X
Location of death	X	X	X
COMPARISON OF HEALTH TO OTHERS ONE'S OWN AGE	X	X	X
STROKE/TIA	X	X	X
HOSPITALIZATIONS	X	X	X
FUNCTIONAL STATUS	X	X	X
MARITAL STATUS	X	X	X
RESIDENCE WITHIN ARIC STUDY BOUNDARIES	X	X	X
NURSING HOME ADMISSIONS	X	X	X
HISTORY OF CARDIOVASCULAR AND RELATED DISEASES	X	X	X
DIAGNOSTIC PROCEDURES FOR CVD	X	X	X
INVASIVE PROCEDURES/TREATMENT FOR CVD	X	X	X
CURRENT MEDICATIONS FOR HYPERTENSION, HYPERCHOLESTEROLEMIA, DIABETES	X	X	X
REGULAR OR CURRENT USE OF ASPIRIN	X	X	X

Data Item	JHS/ AFU Form Version		
	A	B	C
HISTORY OF HRT USE OR GYNEGOLOGIC SURGERY	X	X	X
CURRENT CIGARETTE SMOKING	X	X	X
CURRENT EMPLOYMENT STATUS	X	X	X

#### 8.4.2.2.1.1 Administration of London School of Hygiene Questionnaire

The questions in Sections D-F (CHEST PAIN ON EFFORT, POSSIBLE INFARCTION, and INTERMITTENT CLAUDICATION) of the AFU form are based on the London School of Hygiene Questionnaire. The purpose of the London School of Hygiene Questionnaire (generally referred to as the 'Rose Questionnaire') is to standardize the identification of 'angina on effort' as defined by Dr. Geoffrey Rose. It is not the purpose of the questionnaire to arrive at a medical diagnosis. The questionnaire will fail to identify angina pectoris in some participants whose pains are regarded by the physician as genuinely ischemic. It may categorize other cases as pain due to a quite different cause. Any special effort, however, to alter the conduct of the interview in such instances would destroy the basic purpose of the questionnaire technique, which is to insure uniformity in the eliciting of defined symptoms.

Questions must be put to the participant exactly as they are printed: small changes can make unexpectedly large differences in responses. Unequivocal answers must be recorded as such, whether they seem reasonable or not. Supplementary questions (probing) should rarely be used. When they have to be asked, they should depart as little as possible from the wording of the initial question, and must not be such as to suggest any one particular answer to the participant.

If serious doubt arises about the correct interpretation of a particular answer, it is recorded in such a way as to exclude the suspected condition. An example of this type of situation is demonstrated in the following question and hypothetical response.

{Question} "Do you get it when you walk uphill or hurry?"  
 {Response} "Well, I think I might, but I really can't remember."

This answer is recorded as NO and no probes are employed.

An exception is made to this rule only if a negative response to the lead-in question is an interpretation or denial of a positive response.

{Question} "Have you ever had any pain or discomfort in your chest?"  
 {Response} "No. Only indigestion."

The answer is recorded as YES, because the participant's interpretation of the symptom is disregarded.

A frequently made error in the administration of the Rose Questionnaire is to extrapolate the participant's response to similar, but not defined, situations in the question.

{Question} "Do you get it when you walk uphill or hurry?"  
 {Response} "Yes, the chest pain occurs when I cut the grass."

The answer to this question is recorded as NO, i.e., a strict interpretation is required. If pain is experienced only during some other form of exertion (e.g., cycling, stair climbing, lawn mowing, etc.) it must always be recorded NO. The response 'NEVER HURRIES OR WALKS UPHILL' can

only be coded if the participant specifically denies walking uphill or hurrying.

For the remaining questions, unequivocal answers need not be probed. However, responses qualified by terms describing frequency of events, such as 'occasionally' or 'sometimes' should be probed by a question such as 'Does it happen on most occasions?' Individual QxQ instructions are provided in the Forms Appendix.

#### **8.4.2.2.2 Annual Follow Up Other (AFO)**

The AFO form is administered to determine recent medication use related to chest pain or some other heart condition, whether the participant has experienced any of the signs or symptoms of congestive heart failure, had any invasive procedures or diagnostic tests with their associated indication (reasons), update family history, assess the degree of global psychosocial experiences over the previous year, and health care access.

If the additional year questions for Contact year 02, 03, 04, and 05 were not administered in the corresponding Annual Follow-Up year 1, 2, 3, or 4 (forms AF1, AF2, AF3, AFE), these forms should be administered during the current Contact year..

#### **8.4.2.2.2.1 Congestive Heart Failure Questions**

Detailed information on congestive heart failure (CHF) symptoms that may have been experienced in the past year, since the last JHS contact, is assessed as part of the AFO form. Participants are asked about possible symptoms of CHF as detailed in the table below. Difficulty breathing or swelling of the feet or ankles are common symptoms that are assessed by a series of questions that request information about shortness of breath when at rest or that awakens the person at night, needing extra pillows to improve their breathing, night time cough, or lower extremity swelling. The items included in this battery were derived from several standardized sources used by Multiethnic Study of Atherosclerosis (MESA), Framingham and Cardiovascular Health Study (CHS) (1-4).

**Table 8-4. Congestive Heart Failure Criteria Symptoms List**

Paroxysmal nocturnal dyspnea Orthopnea Dyspnea on exertion Shortness of breath (dyspnea at rest) Night Cough Bilateral lower extremity edema
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#### **8.4.2.2.2.1 Background, Rationale, and Hypotheses**

Congestive heart failure (CHF) is a syndrome that disproportionately affects African Americans (5-6). National Health Surveys were unable to document differences in self-reported heart failure between blacks and whites (7), but there is evidence that African American ancestry is a major risk factor for hypertension and hence congestive heart failure (6). CHF is lethal in African Americans, and contributes significantly to high prevalence of cardiovascular disease morbidity and mortality in African Americans nationally (7-8). African Americans appear to develop asymptomatic left ventricular dysfunction (ALVD) which is a precursor for the development of symptomatic congestive heart failure (9). It also appears that African American males are at a greater risk of developing ALVD (10). Risk factors for the development of CHF are numerous, but two major ones are hypertension and coronary heart disease (9). Congestive heart failure mortality rate increases with age in African Americans and at every age mortality rates for African Americans exceed rates for the white population (11). CHF may occur earlier in life in African Americans because of the high prevalence of hypertension in this group (12). National surveys reported that African

Americans have higher prevalence and incidence of hypertension and heart failure across every age group when compared to whites (13). Most of these studies also reported that CHF is at least 50% higher in African Americans than in whites. Overall, the heart failure rates are 3 to 7 times higher in African Americans when compared to other ethnic groups nationally.

The management of heart failure is characterized by high rates of hospital admission and readmission. For African Americans the most practiced self-care behavior for heart failure is the use of prescribed medications, with the least practiced behavior of symptom monitoring and management (14) of the contributable risk factors such as coronary heart disease and hypertension. This suggests that African Americans respond more to intervention than prevention and this may account for high readmission rates into hospitals (5). Clinical studies reported higher rate of readmission in elderly African American patients with CHF when compared with whites, but case fatality CHF mortality rates are similar (8).

CHF mortality rates in Mississippi are about 4 to 6 times higher than US National rates for ages 20-64 (15). Finally, the CHF mortality rates in African Americans in Mississippi are increasing, according to the most recent available data (11). Data on incidence and prevalence of CHF in African Americans is limited or unavailable. JHS is all African American study and will be an excellent resource for studying CHF in African Americans. The CHF questions will collect incident data on CHF in cohort participants during the annual follow-up interview. The next phases (II and III) of the JHS will include CHF event ascertainment. This will parallel the current system that is utilized by JHS to identify, classify, review and adjudicate both coronary heart disease (CHD) and stroke.

#### 8.4.2.2.1.2 References

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#### **8.4.2.2.2.2 Diagnostic Tests / Invasive Procedures Questions**

These items are included to assess the type and reasons for any cardiovascular diagnostic tests or procedures the participant may have had in the previous year. They are intended to update and supplement information previously gathered during the baseline and Exam 2, as well as in earlier annual follow up interviews. Of particular note beginning with Contact Year 06, items have been added to assess the participant's awareness of the rationale or indication for each test or procedure conducted. A series of likely clinical indications are included for each relevant test / procedure. Items are based upon standard clinical care practices for cardiovascular disease diagnosis / intervention.

##### **8.4.2.2.2.2.1 Background, Rationale, and Hypotheses**

Capturing these data may be very important. Cardiac catheterizations are done very frequently, and coronary disease is clearly the leading killer of the JHS cohort. But, paradoxically, there are unresolved questions about the high rate of negative catheterizations (i.e., catheterizations that don't lead to definitive interventions like PTCA or surgery) in African American patients (vs the rates of procedures in whites). The whole notion that blacks were somehow "immune" to coronary disease found support in the high frequency of negative catheterizations seen studies like the National Heart Lung and Blood Institute's CASS Study (which set the standards for bypass surgery that are followed by most surgeons today). An increasing number of cardiac catheterizations are done outside the hospital. Our data MAY shed some light on this as we collect these data points longitudinally.

##### **8.4.2.2.2.2.2 References**

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##### **8.4.2.2.2.3 Update Family History Questions**

This section of the AFO provides an update on family history items initially obtained in the Home Induction Interview. The intent is to determine if there have been any deaths or new diagnoses among natural parents, full siblings, or natural children of cohort members since the last JHS contact. The items were modified from those asked in the Personal and Family History (PFH) form, Exam 1. Original items were modified from those used in ARIC. Additional questions were added in the JHS on the health history of full siblings and natural children to assure that a wide range of essential family health data can be captured.

#### **8.4.2.2.3.1 Background, Rationale and Hypotheses**

An extensive, well-accepted body of data supports the relationship between health history and risk for development of CVD. We hypothesize that strong relationships will continue with the JHS. That is, the more extensive the history of CVD and other metabolic conditions, the more likely the person is to develop CVD over her/his lifetime. Further, this relationship will be moderated by a variety of socioeconomic and psychosocial variables, e.g., discrimination, stress, social support, coping, SES, health care access, and so forth.

#### **8.4.2.2.2.4 Update Global Psychosocial Questions**

Five questions will be used to assess global psychological functioning each year at annual follow-up. Participants will be asked to rate her/his response to each question on a 6-point Likert-type scale. The specific psychological domains assessed include: major stressors, depressed mood, anxiety, coping, and social support.

#### **8.4.2.2.2.4.1 Background, Rationale and Hypotheses**

Epidemiologic and clinical studies have identified a number of psychosocial risk factors that appear to influence the incidence, morbidity, and mortality associated with cardiovascular disorders. Measures of each of these psychosocial domains are assessed at baseline. An annual global assessment will provide valuable information on change over the year's time.

Hypotheses include:

1. Greater global distress will be associated with an increased risk of hypertension and CHD events independent of the contribution of traditional CHD risk factors.
2. The relationship observed between global psychological distress, hypertension, and CHD events will be moderated by global social support, global coping, SES, and education.

#### **8.4.2.2.2.4.2 Scoring/Coding**

Each item is read to the participant and requires a rating on a 6-point Likert-type scale. One score is derived for each of the Psychosocial Annual Follow-up Questions. Each rating scale ranges from 0 (assigned 0 points) to 5 (assigned 5 points).

#### **8.4.2.2.2.5 Access to Care Questions**

Items 11 through 29 were included to supplement the information collected at the baseline and subsequent visits regarding participant access to health care resources. These questions will be provide ongoing information regarding the status of JHS participants in terms of type and stability of health insurance coverage, prevalence of prescription medication insurance coverage, out of pocket expenditures for medications, prevalence of health care access barriers, interactions with health care providers, and satisfaction with health care. These items were derived from items frequently used in population-based surveys such as the Medical Expenditure Panel Survey [1], National Health Interview Survey, Community Tracking Survey [2], which are frequently used to inform policy makers, legislators, and the public regarding health care access and utilization issues in the United States.

#### **8.4.2.2.2.5.1 Background, Rationale, and Hypotheses**

Health insurance status is an important determinant of health care access and satisfaction with health care. Numerous researchers have determined that regardless of race, the lack of health insurance status is associated with poor health outcomes, decreased use and expenditures for a

variety of health services, increased prevalence of experiencing health care access barriers, decreased satisfaction with care, decreased quality of health care, and increased financial burden [3-5].

Simply asking questions regarding current health insurance coverage with each round of data collection does not address the considerable changes in health insurance status that can occur between data collection periods. Health insurance coverage instability can occur when a person gains or loses coverage as well as when the person experiences changes in coverage such as reduced benefits or increased co-payments. Instability in coverage has been associated with same health care access barriers experienced by persons who are uninsured. Furthermore, asking uninsured persons about the length of time uninsured is important since longer time uninsured associated with increased financial burden and access barriers [6].

Clearly, a means of measuring health insurance instability is needed to accurately determine the impact of health insurance status on health care access, utilization, and the health of JHS participants. The prevalence of health insurance instability among JHS participants is unknown. Asking annually about current health insurance coverage, the type of coverage, gaps in coverage, and the length of time not covered will provide information about the current health insurance status as well as stability of coverage over time.

Health insurance coverage does not always include coverage for prescription medications. Recent changes in Medicare prescription coverage have sparked interest in examining how elderly Americans cope with prescription medication expenditures. Co-payments and restrictions in coverage influence participants' ability to purchase medications and other health services. Out of pocket expenses for prescription medication affect use of medications and ultimately health. However, not much has been written regarding factors that influence prescription medication use and expenditures for African Americans or non-elderly Americans. Asking questions about the status of insurance coverage for prescription medication and the OOP associated with prescription medication use will allow investigation of factors influencing prescription medication expenses and the affect of these expenses on the lives of JHS participants [7,8].

Few questions were asked at the baseline visit regarding health care access barriers and the use of health services. The AFO delves more deeply into use of primary care services and the existence and nature of health care access barriers experienced by JHS participants. Self report of the number of primary care visits has been shown to be fairly reliable measure of the level utilization. In addition to asking about problems getting care the participant is asked about whether he or she/ as gone without care, the type of care foregone, and confidence with getting high quality care. The inclusion of these measures of realized health care access will allow analyses of the relationship between primary care use, health insurance status, and health status [8,9].

The relationship of the JHS participant and health care providers is an important aspect of health care access. Being listened to and respected, having thing explained, and having the provider spend enough time with a person are important aspects of these relationships which can have an impact on a person's perception of how they are treated by health care professionals as well as trust and satisfaction with health care. These attitudes can also influence JHS participants' willingness to access the health care system [10].

Hypotheses that can be examined with these health care access measures include:

- Health insurance status (including instability in coverage) will be associated with the use of primary care services, prevalence of having unmet health care needs, satisfaction with care, confidence with getting care, prevalence of symptoms indicating angina or heart failure exacerbation, and level of stress and anxiety.
- Prescription medication coverage status will be associated with the use of medications to treat chest pain and heart failure and OOP expenditures for prescription medications.

- Out of pocket expenditures for prescription medications will be associated with use of medications to treat chest pain and heart failure.
- Interactions with health care providers will be associated with use of and satisfaction with health care.

#### 8.4.2.2.5.2 References

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#### 8.4.2.3 Updating Contact Information

Tracing information listed on the computer-generated Participant Contact Information Sheet is verified at the conclusion of the AFU form using the CON form (see Forms Appendix). Instructions for administering the form and a prototype script are provided at the end of the annual follow-up instructions. Any changes to tracing information recorded on the paper form during the telephone interview are recorded on the computerized version of the CON form by staff certified in the use of the JHS Data Entry System. Prior to making any changes in the DMS, a hard copy of the current version is printed, dated, and placed in the participant file for future reference.

#### 8.4.2.4 Tracing Participants Unable to Contact

Participants found to have moved or who are otherwise lost to follow-up are traced using the tracing information obtained at baseline exam and during subsequent annual follow-up contacts or other local sources of information, such as the telephone directory, city directory, etc. By using the Contact Form, Examination Center staff can call or write to the family members, friends, employers, or physicians the participants identified as contact persons during previous interviews. By using Social Security numbers, periodic searches of the National Death Index are done. Every attempt is made to schedule and complete an AFU interview for each participant.

#### **8.4.2.5 Informed Consent Tracking**

See Informed Consent Tracking, section 3.3

### **9.0 SURVEILLANCE / EVENTS ASCERTAINMENT**

See Manual 4, Cohort Surveillance/Events Ascertainment Component Procedures for a complete review of the procedures and protocol associated with cohort surveillance and events ascertainment.

## **Appendices**

### **APPENDIX 1 RETENTION OF PARTICIPANTS FOR EXAM 2**

- Appendix 1.1 Prototype Participant Letter: Cohort Notification of Exam 2
- Appendix 1.2 Prototype Participant Letter: Notification of Upcoming Annual Follow Up Interview and Exam 2 Scheduling Call
- Appendix 1.3 JHS Information / Consent Brochure
- Appendix 1.4 Prototype Participant Letter: Refusal Conversion
- Appendix 1.5 Prototype Employer Letter: Request for Release from Work
- Appendix 1.6 Prototype Employer Letter: Institutional Heads Request for Collaboration with JHS to Release from Work
- Appendix 1.7 Prototype Health Care Provider Letter: Request for Continued Collaboration / Support of JHS Participation
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### **APPENDIX 2 EXAM 2 DESIGN, LOGISTICS, TRAINING, AND QUALITY CONTROL**

- Appendix 2.1 Standardized Interview Techniques
- Appendix 2.2 Instructions for Completing Paper Forms

### **APPENDIX 3 INTERVIEWS IN EXAM 2**

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- Appendix 4.1 Tanita TNF 300A Manual
- Appendix 4.2 Cholestech LDX Manual
- Appendix 4.3 Anthropometry Equipment Calibration Log
- Appendix 4.4 Cholestech Optics Check Log/ Cassette Quality Control Log
- Appendix 4.5 Checklist for Anthropometry Measurement
- Appendix 4.6 Checklist for Height Measurement
- Appendix 4.7 Checklist for Weight Measurement
- Appendix 4.8 Checklist for Maximal Waist Measurement

- Appendix 4.9 Checklist for Maximal Hip Circumference Measurement
- Appendix 4.10 Report on Use of Observation and Equipment Checklists

**APPENDIX 5 MEDICAL DATA REVIEW**

- Appendix 5.1 Prototype Medical Data Review Print Out and Information Sheet
- Appendix 5.2 Tanita Patient Education Handout
- Appendix 5.3 Cholestech Patient Education Handout

**APPENDIX 6 REFERRAL AND RESULTS REPORT**

- Appendix 6.1 Prototype Health Care Provider Results Reporting Letter: Health Care Provider Designated
- Appendix 6.2 Prototype Health Care Provider Results Reporting / Referral Letter: No Health Care Provider Designated
- Appendix 6.3 JHS Alerts and Referrals Procedures
- Appendix 6.4 JHS Resource Manual

**APPENDIX 1 RETENTION OF PARTICIPANTS FOR EXAM 2**

## Appendix 1.1 Prototype Participant Letter: Cohort Notification of Exam 2

(The mailing envelope for this letter will include one of the following statements:

Help us fight heart disease!  
Thanks....we need your help again!

[DATE]

[NAME]

[ADDRESS]

[ADDRESS]

Dear [Mr. Ms. Name]

I would like to share some exciting news with you. The Jackson Heart Study (JHS), the medical research project in which you are participating, is celebrating continuation for the next 8 years! You may have seen me in the recent news making this wonderful announcement. On behalf of the JHS staff, and the many people who benefit from the knowledge gained as a result of your continued participation, I want to thank you for being a loyal participant. As a member of this ongoing study, you contribute valuable information in our search for causes and prevention of heart disease in African Americans. Without dedicated people like you, this would not be possible.

Between 2000-2004, you completed your first JHS clinical examination. We are pleased to invite you for your second visit approximately five years after the time of your first exam. Your expected return visit will be the week of [DATE}. This second visit will be much shorter than the first (only about 2 hours) and will include some special teaching about taking your own blood pressure at home. You will receive your own personal home blood pressure monitor, and a \$25 check or equivalent gift (your choice) in appreciation for your time..

Please, choose one of the following options for scheduling your second clinic visit:

- Call the office at 601-815-5050 or 1-866-680-0660
- Access our web-based scheduling system at [www.jsums.edu/~jhs/](http://www.jsums.edu/~jhs/) and sign in with your personal JHS identification number, JXXXXXX.
- Allow your JHS interviewer to schedule your appointment when she calls to conduct your annual follow-up interview.

We thank you for your continued participation in the Jackson Heart Study.

Sincerely,



Herman A. Taylor, MD, MPH,  
Principal Investigator

Sonja R. Fuqua, PhD, RN  
Director of Retention

**Appendix 1.2 Prototype Participant Letter: Notification of Upcoming Annual Follow Up Interview and Exam 2 Scheduling Call**

[DATE]

[NAME]

[ADDRESS]

[ADDRESS]

Dear [Mr. Ms. Name]

It has been almost a year since the Jackson Heart Study (JHS), the medical research project in which you are participating, conducted your annual follow-up telephone interview. As in the past, a JHS interviewer will be calling to gather information about your health status over the past year. If you have had any hospitalizations or illnesses during the past year, please gather information regarding the date and type of illness or hospitalization so it is available when the JHS interviewer calls. The interview will take about 15 minutes.

This year, we are pleased to invite you to your second clinic examination. It has been almost 5 years since your first exam, and we are excited about the new tests that we believe you will find both interesting and useful. You will be taught to take your blood pressure and will receive a blood pressure monitor for your personal use. You will also receive a \$25 check or equivalent gift (your choice) in appreciation for your time. The exam will be much shorter—taking no more than 2 hours. Upon completing your interview, the interviewer will schedule an appointment. Please have your calendar ready to select a convenient day and time for your visit.

MAKEABA an interviewer will call you in the near future or you may telephone the JHS office at 601- 368-4618 or 1-866-680-0660 to set an appointment for your interview and second clinic examination. Your identification number is JXXXXXX, please have it available when you call.

We thank you for your continued participation in the Jackson Heart Study.

Sincerely,



Director of Retention

**Appendix 1.3 JHS Information Brochure / Consent**

**INSERT WHEN COMPLETED**

#### Appendix 1.4 Prototype Participant Letter: Refusal Conversion

[DATE]

[NAME]  
[ADDRESS]  
[ADDRESS]

Dear [Mr. Ms. Name]

Recently, you indicated that you did not want to participate in the current Jackson Heart Study (JHS) examination. I appreciate all the time you have already given us both on the phone and in the JHS clinic. On behalf of all the JHS staff and investigators, and all the people who benefit from the knowledge gained as a result of your participation thus far, I want to thank you for being a loyal participant. As a member of this ongoing study you contribute valuable information in our search for causes and prevention of heart disease in African Americans, but we know that it is only possible because you have been willing to sacrifice some of your time and tell us about yourself.

Thank you again, and should you reconsider, we would be more than happy to hear from you. If your schedule permits, we can offer to come to your home to conduct the interviews and brief physical examination. As you know, we are also including instruction on how to take your own blood pressure and a home blood pressure monitor will be given to you. This should take no more than 90 minutes of your time, at most.

Again, we are sad to lose you after so many years. If you should change your mind, please call me at 601.815.5050 or access our web-based scheduling system at [www.jsums.edu/~jhs/](http://www.jsums.edu/~jhs/) and sign in with your personal JHS identification number, JXXXXXX. Any time you give us will be of great benefit to the study and the people whose health may be improved as a result of JHS findings.

With best regards,

Herman Taylor MD, MPH

Mary Crump RN, MSN

Director and Principal Investigator

Clinic Manager

**Appendix 1.5 Prototype Employer Letter: Request for Release from Work**

DATE

EMPLOYER NAME

ADDRESS

Dear Employer:

Your employee, [NAME], is a participant in an important medical research project called the Jackson Heart Study (JHS). This project is sponsored by the National Heart, Lung, and Blood Institute in the Jackson Metropolitan area. It is being conducted by Jackson State University, Tougaloo College and the University of Mississippi Medical Center. The purpose of the study is to better understand characteristics which may predispose African-Americans to heart or blood vessel diseases.

The JHS requires a two examination now and in three to four years to collect the medical information. We hope you will allow your employee time off to complete this examination—hopefully without having to take personal or vacation time to do this. Her/his participation is important to the study. If you have any further questions you may call me at [telephone number].

Thank you.

Sincerely,

Herman A. Taylor, Jr. MD, MPH  
Principal Investigator

**Appendix 1.6 Prototype Employer Letter: Request for Collaboration with JHS to Release  
from Work**

Date

Business Leader/Employer Name  
Business Leader/Employer Address

Dear NAME BUSINESS LEADER/EMPLOYER:

I would like to extend my thanks and appreciation for your continued support of the Jackson Heart Study (JHS). As a business leader in Hinds, Madison and/or Rankin Counties, your advocacy in and support of the Study remains critical.

Cardiovascular disease is still the number one killer of African Americans in Mississippi and the nation. The JHS is the first large scale epidemiologic observational study on African Americans and heart disease. Between September 2000 and March 2004, the JHS recruited over 5,300 participants aged 21 and over. During this time, the business community demonstrated support by allowing potential participants time off without having to use company personal leave or vacation time. A collaborative effort with the business leadership will again allow maximization of our efforts to reach participants. JHS's 2<sup>nd</sup> exam cycle will occur over a period from September 2005 through September 2008, during which time each participant will undergo one brief exam. By allowing your employees time off for their exams, once again you are providing support needed to achieve our research goals.

We look forward to your continued support and involvement with the JHS. Should you need to talk with me or require further information, I can be reached at (601) 368-4650. Thank you for your continued support of the JHS.

Regards,

Herman A. Taylor, MD, MPH, FACC  
Director/Principal Investigator

**Appendix 1.7 Prototype Health Care Provider Letter: Request for Continued Collaboration /  
Support of JHS Participation**

Date

Health Care Provider Name  
Health Care Provider Address

Dear NAME HEALTH CARE PROVIDER

I would like to extend my thanks and appreciation for your continued support of the Jackson Heart Study (JHS). As a health care provider in Hinds, Madison and/or Rankin Counties, your advocacy in and support of the Study remains critical.

Cardiovascular disease is still the number one killer of African Americans in Mississippi and the nation. The JHS is the first large scale epidemiologic observational study on African Americans and heart disease. Between September 2000 and March 2004, the JHS recruited over 5,300 participants aged 21 and older. During this time, the health care provider community demonstrated support by distributing study information and discussing the importance of research participation with their patients. A collaborative effort with the health care providers will again allow us to maximize our efforts in reaching participants, as well as allow us to offer health care resources when needs are identified. JHS will begin the 2<sup>nd</sup> exam cycle in September 2005 and it will continue through September 2008. By continuing to support this important research investigating the high rates of heart disease in our community, you significantly contribute to the cardiovascular health of all African-Americans.

We look forward to your continued support and involvement with the JHS. Should you need to talk with me or require further information, I can be reached at (601) 368-4650. Thank you for your continued support of the JHS.

Regards,

Herman A. Taylor, MD, MPH, FACC  
Director/Principal Investigator

**Appendix 1.8 Certificate of JHS Membership**

## **Appendix 1.9 Prototype Participant Birthday Card**



**Appendix 1.10 Prototype Participant Holiday Card / Calendar**

**Appendix 1.11 Prototype Condolences Letter**

DATE

NAME [Family Member of Deceased JHS Participant]

ADDRESS

Dear NAME [Family Member of Deceased JHS Participant]

On behalf of the Jackson Heart Study family of participants, staff, and researchers, I wanted to express my deepest sympathy on the death of [Name – JHS Participant]. No words can do justice to the profound sadness that we share with you in this time of loss. We are grateful that [name-participant] was part of the Jackson Heart Study. Please know that by [her/his] participation in the Jackson Heart Study, [s/he] will continue to leave a Legacy of Health for African Americans through [her/his] contribution to understanding and reducing the heavy burden of heart disease in African Americans.

Our thoughts and prayers are with you and your family.

Sincerely,

Herman A. Taylor, Jr. MD, MPH

Principal Investigator

**Appendix 1.12 Prototype JHS Participant Newsletter**











## **Appendix 1.13 Prototype Annual Family Reunion and Birthday Celebration**





**Appendix 1.14 Prototype JHS Participant Web-based access**

















**APPENDIX 2 EXAM 2 DESIGN, LOGISTICS, TRAINING, AND QUALITY CONTROL**

## Appendix 2.1 Standardized Interview Techniques

### I. Overview of Interviewing

#### A. Interviewer bias – includes anything that creates a systematic difference between responses obtained by different interviewers

- 1 Respondent's perception of the interviewer and his/her reaction to that.
- 2 Interviewer's perception of the respondent and his/her reaction to that.

#### B. Characteristics of a good interview

There is an appropriate atmosphere

- friendly, but businesslike

1. The respondent is at ease
  - female interviewers may be perceived as less threatening
  - ensure confidentiality of participant
  - someone much older than respondent may be viewed as more judgmental
  - space for interviewing is appropriate, quiet, friendly
2. The interviewer obtains the answer to the question that is asked
  - proper use of probes
  - repeats question, rather than interpreting it
3. Clarification is obtained for confusing answers
4. The interviewer gives only neutral responses to the respondent's answers
5. The response is recorded accurately

#### C. Specific skills required for interviewers

1. Be able to ask questions at the correct pace and in a conversational tone
2. Know the questions and response categories well enough to keep the interview flowing smoothly
3. Know when there are probes that can be used, and know how to use them
4. Be able to think as an interviewer, and put aside other roles (researcher, and health care provider, etc.) for the time being
5. Be able to maintain a positive attitude about the interview so that respondent feels that the interview is important
6. Be able to keep some level of control over the interview process, e.g. by rewarding the respondent for answering questions, and not for other behavior

7. Neat, pleasant, professional dress; not too timid, not too aggressive

## **II. Administration of Interviewing**

### **B. Administration of work**

1. Supervisor
  - a. One supervisor for each ten interviewers
  - b. Importance of prompt review of work, and quick feedback
  - c. Face-to-face conference with each interviewer once a week
2. Other considerations
  - a. Good pay and working conditions help keep up morale
3. Tracking procedures
  - a. Response rate, overall and by interviewer
  - b. Reasons for non-response
  - c. Length of interview, overall and by interviewer

### **B. Interviewer training**

1. Must cover all aspects of the interview
  - a. Introducing yourself
  - b. Handling people who are reluctant
  - c. Following instructions for administration of interview form
  - d. Obtaining consent
  - e. Answering consent
  - f. Obtaining privacy for the interview
  - g. Setting respondent at ease
  - h. Administering the interview
  - i. Ending the interview
  - j. Importance of role playing, using both standard and problematic situations
  - k. Discuss problems that arose

**C. Quality control of field work**

1. Observation
  - a. Supervisor going with interviewer
  - b. Tape recording
  - c. Monitoring telephone interview
2. Editing
  - a. Field editing
  - b. Editing by supervisor – edit first few interviews, if no problems then only need edit a sample of remaining interviews
3. Validation
  - a. That interview was done – by re-interview, telephone call, or sending a letter

**D. Ways to reduce the standard errors from interview effects by 10% for at least the one-third of items most affected by interviewers (Source: Fowler FJ, Mangione TW)**

1. Increase effective sample size by about 20% (if simple random sample)
2. If interviewers receive less than 1 day of basic training, increase by a day or two
3. Tape all or a sample of interviews; review one a week per interviewer, provide feedback
4. Rewrite questions to reduce the need for probing and make administration and reading of questions easier
5. Reduce the number of interviews per interviewer by 20% by using 20% more interviewers

**Reference**

Fowler FJ, Mangione TW. Reducing Interviewer effects on health survey data – Executive Summary. Center for Survey Research – Univ. of Massachusetts/Boston. Report No. NCHSR 86-8. U.S. Department of Health and Human Services.

## Appendix 5.3 Jackson Heart Study Interviewer Techniques

### 1. Standardized Interviewing Techniques

The Jackson Heart Study is a single site study being conducted in the Jackson Mississippi area, with African-American persons aged 35-84. The aim is to produce a study that represents 6,500 people throughout the Jackson area in Madison, Rankin and Hinds counties.

In order to produce valid and reliable data, the study designers must pay attention to the training and the methods in which the data are collected. Thus, a standardized approach to interviewing and the training of interviewers is necessary. The study is standardized through the use of scripts in training, centralized training of supervisors, setting of qualifications for supervisors, reviewing of data that is collected, listening to tapes that are produced at interviews, and finally observing the interviewer in the field.

Scripts are used to teach you techniques in probing as well to determine how well you are following skip patterns in the forms and adhering to the various aspects of protocol. Scripts are specifically used in the Rose Questionnaire. All of your interviews will be taped and you will gain knowledge about how to do this talking with experienced interviewers who are systematically reviewed by your supervisor to determine that you are asking the questions as written and are not leading the study respondent or providing answers for them. You will occasionally be observed through monitoring visits.

The study is further standardized in centralizing training for supervisors and where possible for the interviewers. The study initially will train local interviewer supervisors who will be responsible for training on site as the need for new personnel is required.

### 2. Dealing with the Sample Population

The sample members for Jackson Heart Study will include a variety of persons who, generally, will have characteristics similar to those encountered with any household survey. Some of the situations you may encounter at the household, along with suggestions for dealing with them appropriately, follow:

1. Fear of Being Victimized – Some of your respondents may refuse to participate in a survey because they are afraid of being victimized in some way. It is your responsibility to assure the sample member of the legitimacy of your call/visit and intentions and to make the respondent feel secure. Your identification badge and letter will aid you in reassuring the respondent.
2. Handicaps – If a sample member seems to have a handicap that will interfere with proper completion of the interview, would cause undue stress for the sample member, or prevent the sample member from completing the clinic/examination, do not attempt to complete the interview with her/him. Determine if there is a person available who is knowledgeable about the sample member's health and tactfully obtain information which will help determine if the sample member should be excluded from the study. If such a person does not exist, thank the sample member for his/her time and terminate the interview. Code the result appropriately and provide explanatory notes so that your supervisor can evaluate the case.
3. Difficulty Understanding Questions – Some of your respondents may have difficulty in comprehending the questions slowly and allow the respondent adequate time to respond.

Repeat the question, if necessary. (Unless specifically allowed by the specifications, do not define and explain, which may result in obtaining a biased response.)

4. Tendency to Stray from the Topic – Some respondents will welcome the opportunity to talk with someone who is neutral about their health problems. Attempts to explain their problems or vent their feelings may cause them to stray from the questions being asked. You must be careful to control the interview situation, while not alienating the respondent.
5. Tendency to Respond in a Socially Desirable Manner – Some of the respondents will rely on you to help with a response or offer responses that they think are what you or the government would like to hear rather than expressing their knowledge or opinion about a given subject. Keep in mind that we are trying to gather objective data on the sample members' health. Reassure sample members that there are no right or wrong answers to the questions and encourage them to respond according to their experience and knowledge.

### 3. Interviewing Guidelines

The survey response rate and the quality of the data collected depend on how well you handle various interview situations. Every interview situation will be different, and it is impossible to enumerate every possible situation that you might encounter and suggest ways for handling those situations. There are, however, some basic guidelines presented in this section that, if followed, will assist in obtaining a sample member's participation in the survey and obtain accurate data.

### 4. Contacting the Respondent

- **Official Notification:** Jackson Heart Study staff will have notified appropriate law enforcement personnel, post offices and community leaders of the study. If interviewer/recruiters are questioned in the field, show their ID badge (which should always be worn in the field) and other identifying information.
- **Leaving Messages:** Interviewer/recruiters will leave door hangers along with business cards. This will provide an opportunity for someone in the household to directly contact the Interviewer/recruiter or Jackson Heart Study center staff to schedule an appointment.
- **Interviewing People You Know:** Interviewer/recruiters are not allowed to conduct interviews with friends, relatives or acquaintances. If the Interviewer/recruiter discovers that the respondent is someone s/he knows, inform her/him of the Jackson Heart Study policy and record on HEF form. Jackson Heart Study wants to be able to ensure confidentiality to all respondents and to maintain a professional relationship in the interview setting.
- **Your Introduction:** Initial contacts with sample members will be made in person (or by the printed Jackson Heart Study door hanger). When you meet with a sample member, read the introduction as it is printed. The focus of the introduction is to identify the Interviewer/recruiter, the organization you represent and the purpose of your visit. Attitude: Approach each respondent with a positive, self-assured and matter-of-fact manner. Friendliness, not familiarity, is an asset.

### 5. Obtaining Participation

You will be provided with the following materials to motivate sample members to participate in the study:

- Introductory letter,
- Study brochure, and
- Copies of local newspaper clippings and endorsements.

You may, however, encounter questions about the survey or objections to participation. A list of possible questions and suggested answers appear below.

## 6. Commonly Asked Questions

- “Will I have to take any drugs and/or medications?”** Explain to the respondent that there will be no drugs or medication administered during the clinic visit -- only related tests, such as EKG, Lab test, Physical Examination.
- “How often and how long are the clinic visits?”** Explain clinic visits are (1) once every three years, (2) clinic visit will last approx. 2-4 hours.
- “What type of tests will be administered?”** Name all tests that will be administered.
- “Will transportation be provided?”** Transportation will be provided as needed.
- “Are child accommodations provided?”** Yes.
- “How do I know you and the survey are legitimate?”** Repeat your introduction and give the respondent the introductory letter and brochure. Suggest that the respondent call the number on the brochure for information and verification. Also point out that the local health officials are aware of the survey and show the sample member local newspaper clippings and endorsements. Above all else, always wear your picture ID badge in the field and have it visible.
- “What’s this survey about?”** Explain that we are interviewing approximately 5,300 participants in the Jackson Heart Study who live in 3 counties in the state of Mississippi, Hinds, Madison and Rankin, to collect data about their health. The data collected will help the National Institutes of Health, and local area health professionals to understand better, the factors associated with heart disease.
- “I don’t want to buy anything!”** “We are not selling anything. We are doing an important research study for the National Heart, Lung and Blood Institute.”
- “Why interview me?”** “Researchers used scientific sampling procedures to select a random sample of the people in your community. It is important that you participate because we can’t replace you with someone else if you don’t.”
- “Who’s paying for this study?”** The National Heart, Lung and Blood Institute is sponsoring the study.
- “I’m too busy”** “Then let’s make an appointment for some other time that is more convenient for you. We can make the appointment now.” Note: If the participant does not make an appointment then and request for you to call back, tell them you can call back tomorrow morning, afternoon, or evening. “Which would you prefer?”
- “My answers won’t be of any help.”** Explain that there are no right or wrong answers and their opinions and experiences will be helpful to the study.

- M. **“I don’t want everybody to know my personal information.”** Advise that “Your answers will be kept fully confidential. The information that you give us will be analyzed statistically, and there will be no way that your name will be connected with your answers. Your name, address, and phone number will be separated from your answers, and all identifying information will be destroyed when the study results are reported. Your answers will not be given to your doctor or anyone else responsible for your health care without your permission and will not, in any way, affect the care you receive from them.”
- N. **“I can’t help you because I never had heart problems.”** Explain that you still need to talk to them about their health and that the study is based on selecting people from the general population, most of whom will not have heart problems. Also, explain that if a question is asked for which they don’t know the answer, they can simply say “don’t know” and you will move on to the next applicable question.
- O. **“Will this affect my medical care?”** Assure the sample member that participation in this study will not affect any medical care s/he now receives or might receive in the future. Also, explain that participation in the survey is voluntary and that all data collected will be kept fully confidential.
- P. **“My doctor may not want me to be in the study.”** Inform the sample member that area physicians are in support of Jackson Heart Study and show her/him copies of local endorsements. Suggest that the sample member complete the home interview, and if s/he still feels uncomfortable about the clinic examination, s/he may contact his/her physician to discuss the study.
- Q. **“What do I get out of the study?”** “There are several things that you will get from the study. You will receive free of charge a medical examination and a free home blood pressure cuff with instructions on its use. You may find out that you have a medical condition you have been unaware of and you will be able to get treatment from your personal physician for it earlier. You will also have an opportunity to participate in one of the most important health studies ever conducted. *Legacy of Health.*”
- R. **“How long will this take?”** The telephone call today will take about 15-20 minutes, depending on your answers. Let me start and I’ll move through the interview as quickly as I can” (Immediately ask the first question).
- S. **Request for information that you are unable to provide.** If you are unable to answer a sample member’s question about the study, advise her/him that you will talk to your supervisor to get the needed information, and that you will be back in touch in a day or so. Then talk to your supervisor as soon as possible.
- T. **“What will the clinic visit involve?”** If this question is asked during annual follow up call, provide the respondent with a brief explanation, such as: “The clinic visit will involve a physical examination by highly trained clinic staff using modern equipment and an interview.” If this question is asked later during the visit, interviewer/recruiters will review the Jackson Heart Study brochure with the respondent. The Jackson Heart Study brochure will consist of the clinic scheduled activities and a brief description of the major tests that will be conducted at the clinic.
- U. **“Will I get results of my test?”** “Any abnormal findings will be made known to you, as well as either complete results or a summary of results of important tests. For example, we will provide the actual blood pressure values, blood cholesterol and fasting blood sugar results, and many more. Your lab results will be given to your primary physician also.”

- V. **“Where did you get my name or why have you come to my house.”** You are already identified as a participant in the JHS and came to the clinic approximately 4 years ago.
- W. **“I would like to participate but I can’t take that much time off work.”** Tell the respondent that the Jackson Heart Study project has received extensive community support and that Jackson Heart Study staff will be happy to send a letter to the employer requesting time off (see attached letter). Be sure to note that the respondent has requested this letter and inform your supervisor as soon as possible.
- X. **“I heard you can get AIDS from blood tests.”** Explain that the clinic uses only sealed, disposable needles and that only a finger stick will be done in Exam 2. The needles will not be “shared”; therefore there is not a known risk for AIDS from blood drawing.
- Y. **“I don’t like the idea of blood tests.”** “I don’t like to have my blood drawn. The clinic staff is very well trained and performs finger sticks with a minimum of discomfort. The blood tests are one of the most important parts of the Jackson Heart Study and are needed to compare with your other study results.”

NOTE: If the respondent refused to have blood drawn, consider that a refusal for the clinic appointment. Try, however, to obtain a home interview without scheduling the appointment.

- Z. **“I just told you the answer to that question.”** “I’m sorry I repeated the question. I don’t want to rely on my memory to record your information correctly.” Note that this can be avoided if you realize the respondent has answered the question by a lead-in such as “I know this sounds repetitive but could you tell me...” or “You may have told me this before but just to make sure I have it right...”

The important point to remember when answering questions or overcoming objections is to try not to alienate the respondent. If you feel that you are unsuccessful in countering the respondent’s objections, politely thank her/him for his/her time and terminate the interview. Try to “leave the door open” for someone else to talk to the sample member and encourage her/him to participate.

## 7. Conducting the Interview

The interviewer must help the respondent to feel at ease and comfortable with the interview. During the initial contact and throughout the interview, you should:

- Maintain a positive attitude.
- Repeat that any information the respondent gives you will be kept confidential if s/he appears to be apprehensive about providing information,
- Maintain control of the interview.
- Assume a nonjudgmental, noncommittal, neutral approach to the respondent and the subject matter, so that the sample member will feel comfortable answering the questions truthfully.

The process of asking the questions, probing, and recording responses correctly is crucial to obtaining usable, high-quality data. The standard practices listed below must be followed.

## 8. Asking the Questions

- Ask the questions using the exact words printed in the questionnaire.
- Ask the questions in the exact sequence in which they appear or as instructed. Whenever you are not to ask questions in sequence, a skip instruction will appear beside the response categories for the question asked. (Skip routing instructions are discussed in more detail later in this chapter.)
- Ask every question specified even when a respondent has seemingly provided the answer to the question when another question was asked. The answer received in the context of one question may not be the same answer that will be received when the other question is asked.
- If the answer to a question indicates that the respondent did not understand the intent of the question, repeat the question.
- Read the questions at a moderate speed, preferably at a pace of about two words per second.
- Avoid suggesting answers to the respondent. As noted elsewhere in this manual, the sample members may rely on you to help with an answer to a question. As the interviewer, your job is to ask the questions, make sure the respondent understands the questions, and then record his/her responses. Do not assist the respondent in selecting responses.
- Read transition statements just as they are printed in the questionnaire. Transition statements are designed to inform the respondent of the nature of a question or a series of questions, to define a word, or to describe what is being asked for in the question.
- Sensitive questions should be asked in a neutral manner, which should not differ from the normal professional flow of the interview. The respondent may be more comfortable if you avoid eye contact when asking sensitive questions.
- Read questions in a natural tone, following the punctuation in the question. Only emphasize words that are underlined or appear in bold. When response categories are to be read, put a brief pause between the options so the participant knows what the choices are.
- Do not show the questionnaire to the respondent. You do not want the respondent to see the questions and response categories of the questionnaire. For this reason, you will want to arrange the seating so that you are sitting across from the respondent. When it is appropriate for the respondent to see the response categories to a question, the questionnaire will instruct you to guide the respondent to look at a designated RESPONSE CARD.

## 9. Probing

You will be required at times to probe to obtain a more complete or more specific answer from a respondent. Chapters 3 and 4 provide explanation of the questions you will ask. When you know the objective of a question, you will be able to judge whether a response is adequate or inadequate. In order to elicit complete, adequate answers, you often will need to use an appropriate neutral or

non-directive probe. The important thing to remember when probing is that you must not suggest answers or lead the respondent. General rules for probing follow.

- Use neutral questions or statements to encourage a respondent to elaborate on an inadequate response. Examples of neutral probes are “What do you mean?”, “How do you mean?”, “Tell me what you have in mind.”, “Tell me more about...”.
- The silent probe, which is pausing or hesitating to indicate to the respondent that you need more or better information, is a good probe to use after you have determined the respondent’s response pattern.
- Clarification probes should be used when the response is unclear, ambiguous or contradictory. Be careful not to appear to challenge the respondent when clarifying a statement and always use a neutral probe.
- Repeat the question if the respondent misunderstood or misinterpreted the question. After hearing the question the second time, the respondent will likely understand what information is expected.
- Unless you have been provided with a response code of “Don’t know”, the “I don’t know” response almost always requires a probe since this response can mean one of several things:
  - The respondent doesn’t understand the question and says “Don’t know” to avoid saying s/he doesn’t understand;
  - The respondent is thinking the question over and says “Don’t know” to fill the silence and gain time to think;
  - The respondent may be trying to evade the issue because s/he feels uninformed, is afraid of giving a wrong answer or the question seems too personal; or, the respondent may really not know.

Some of the questions in the Jackson Heart Study ask about recall of events over time. You may assist the respondent without violating probing rules by working with her/him on math or pinpointing dates or events (such as age a parent was diagnosed with a specific disease). Another way to help pinpoint more accurate information is to ask respondent to think about time of year or season when an event occurred.

## 10. Recording Responses

Most of the questions in the Jackson Heart Study instruments have precoded responses. There are a few questions, however, that are open-ended – that is, you must write in a response to the question. Some questions have pre-coded responses as well as an “Other (Specify)” category. If the respondent’s answer does not fit into a pre-coded answer, you must specify the response. The recording practices below must be followed at all times to assure that the response recorded accurately reflects the respondents’ answers and to assure that questionnaire data can be converted to machine-readable form. Detailed Instructions for Completing Paper Forms may be found in Appendix 10.

## 11. Instrument Conventions

Certain conventions are used consistently in the Jackson Heart Study instruments. Familiarity with these conventions will help you use the instruments with ease and confidence.

**12. Instructions to the Interviewer**

Your instructions are always in CAPITAL LETTERS, and they are not to be read to the respondent. Often, your instructions are also in brackets. For example:

37. Have you ever smoked a pipe regularly?  
 [CODE "NO" IF LESS THAN 12 OZ. IN A  
 LIFETIME] .....Yes Y  
Go to Item 44 ——— No N

Instructions to interviewers may also appear in boxes. Boxed material in capital letters are interviewer instructions. Other statements which are in boxes but are not capitalized are to be read to the respondent. An example of each type of boxed statement appears below.

Did your natural father ever have or does he now have any of the following diseases? [READ EACH RESPONSE CATEGORY]

26a. Cancer? ..... Yes Y  
 No N  
 Don't know D

26b. Diabetes? (sugar in the blood) ..... Yes Y  
 No N  
 Don't know D

26c. High blood pressure or  
 hypertension (high blood)? ..... Yes Y  
 No N

	Don't know	D
26d. Stroke? .....	Yes	Y
	No	N
	Don't know	D
26e. Heart attack? .....	Yes	Y
	No	N
	Don't know	D

If "No" or "Don't Know", Go to Item 28

I would like to ask you a few questions about your parents' health.

The first box consists of an interviewer instruction; the second of a lead-in statement which is to be read to the respondent.

**13. Questions**

Questions are printed in upper and lower case type. Answer choices and codes are printed below the question. Answer choices are never read to the respondent unless they are included in the body of the question or unless you are instructed to do so. In Example 1 below, the answer choices are not read to the respondent; In Examples 2 and 3, they are read because they are included in the question or because you are instructed to do so.

**EXAMPLE 1**

14. What was the cause of your natural mother's death? .....	Cancer	C
	Heart attack	A

Stroke	S
Unknown	U
Other (Specify)	O

Specify: \_\_\_\_\_  
 \_\_\_\_\_

### EXAMPLE 2

1. Compared to other people your age, would you say that your health is excellent, good, fair, or poor? .....
- |           |   |
|-----------|---|
| Excellent | E |
| Good      | G |
| Fair      | F |
| Poor      | P |

### EXAMPLE 3

36. (Do/did) you inhale the cigarette smoke?  
 [READ RESPONSE CATEGORIES] .....
- |            |   |
|------------|---|
| Not at all | N |
| Slightly   | S |
| Moderately | M |
| Deeply     | D |

### 14. Alternate Wording

Where you must choose the correct wording for a question, a choice of words or phrases is given in parentheses. The choice you make depends upon previous answers from that respondent. For example:

57. What (is/was) your (current/most recent) occupation? [IF MORE THAN ONE JOB, RECORD OCCUPATION FOR JOB FOR MOST HOURS WORKED PER WEEK.]

For currently employed respondents you would read "What is your current occupation?"  
 For unemployed respondents, you would read, "What was your most recent occupation?"

**15. Word Insertion**

Many questions in the Jackson Heart Study survey instruments contain capitalized words or phrases within brackets. For these questions, you must insert the appropriate name, date, place, etc., as required by the questions. For example:

[IF YES TO ANY DISEASES IN QUESTION 26, ASK FOR EACH DISEASE.] How old was he when he was first told he had [NAME OF DISEASE]? [ENTER "99" FOR "DON'T KNOW"; "98" FOR AGES 98 AND OLDER.]

	<u>Age</u>			
27a. Cancer:	<table border="1" style="border-collapse: collapse; width: 100px; height: 25px;"> <tr> <td style="width: 50%;"></td> <td style="width: 50%;"></td> </tr> </table>			
27b. Diabetes:	<table border="1" style="border-collapse: collapse; width: 100px; height: 25px;"> <tr> <td style="width: 50%;"></td> <td style="width: 50%;"></td> </tr> </table>			
27c. High Blood Pressure:	<table border="1" style="border-collapse: collapse; width: 100px; height: 25px;"> <tr> <td style="width: 50%;"></td> <td style="width: 50%;"></td> </tr> </table>			
27d. Stroke:	<table border="1" style="border-collapse: collapse; width: 100px; height: 25px;"> <tr> <td style="width: 50%;"></td> <td style="width: 50%;"></td> </tr> </table>			
27e. Heart attack:	<table border="1" style="border-collapse: collapse; width: 100px; height: 25px;"> <tr> <td style="width: 50%;"></td> <td style="width: 50%;"></td> </tr> </table>			

53. How long have you lived in [NAME OF COMMUNITY]? ..... 

--	--

  
YEARS

In the first example, you would insert the name of each disease specified in the preceding question. In the second example, you would read the name of your study community, e.g. Mississippi.

## **16. Skip Instructions**

Skip instructions direct you to the next applicable question or item in the instrument. As with other interviewer instructions, they are in capital letters and appear with arrows, brackets, or as a lead-in to a specific question. Since skip instructions are crucial to the accurate administration of the questionnaire, see example below.

**EXAMPLE 1**

12. Have you ever taken birth control pills to prevent pregnancy?.....Yes Y

No N  
 **Go to Item 17**

13. At what age did you start taking birth control pills for the first time? .....    
age

14. Are you currently taking birth control pills?.....Yes Y  **Go to Item 16**  
No N

15. At what age did you stop taking birth control pills? .....    
age

16. For how many years altogether have you used birth control pills? .....    
Years

**C. HORMONE USE**

17. Have you ever taken female hormone pills, skin patches, shots, or implants, including birth control pills for reasons other than preventing pregnancy?.....Yes Y

No N  
 **Go to Item 30**  
 Don't Know D

## Appendix 2.2 Instructions for Completing Paper Forms

### I. Instructions for Completing Paper Forms General

#### A. Background

The Jackson Heart (JHS) Study utilizes computer-assisted direct data entry as its primary mode of data collection. Nevertheless, the existence of paper forms is necessary for situations in which direct data entry is not possible. In such instances, data is collected on paper forms and then entered on the computer at some later time. The purpose of this document is to provide instructions for completing these paper forms. It should be read carefully prior to working with any forms. Specific sets of instructions associated with each form (QxQ's) should then be read for those forms that are of interest.

#### B. Form Structure

Most of the paper forms in JHS are designed to correspond exactly to the computer screens used for data entry. However, the quantity of text showing on one paper page will not usually match the quantity of text on a screen. For example, the first page of a form may show items 1 to 10, while the first screen of the form may show items 1 to 8.

Most forms are structured as follows:

First page:

- a. Form Title
- b. "Header" Information
  1. Participant's ID Number
  2. Contact Year
  3. Form Code (preassigned 3-letter code)
  4. Version (1-letter code and date)
  5. Participant's Last Name and Initials
- c. Summarized Instructions
- d. First Screen of the Form

Following pages:

- a. Form Title, Code, and Version
- b. Successive Screens

#### C. General Instructions for Completing and Correcting Items on the Forms

All items fall into two main categories: (1) fill in the boxes, and (2) multiple choice. Techniques for completing each of these types of items, as well as making corrections, are described below. A general rule is to record information only in the spaces provided (except for some error corrections).

##### 1. Fill In The Boxes: Recording Information

When alphabetic information is required, print the response beginning in the leftmost box using capital letters. Punctuation may be included.

Example: If the participant's last name were O'Reilly, it should be entered as follows:





If an item of this type (either alphabetic or numeric) *does not apply* to the subject being interviewed, leave it **blank**. For example, if the participant does not have an "other" phone number, that item is left blank. Similarly, if the form provides spaces for three measurements, but only two are taken, the third space is left blank.

If the item *does apply*, but the response is unknown, mark through the box(es) with two horizontal lines.

Example: The question "How old were you when you had your first heart attack?" is asked, but the participant does not recall how old s/he was. The question *does apply* because it has been established that the participant has had a heart attack, but the *answer to this question is not known*. In this case, the response would look like:

How old were you when you had your first heart attack? 

--	--

#### 4. Multiple Choice: Recording Information

In this type of question several alternatives are given for the answer, each having a corresponding letter. When it is decided which alternative is most appropriate, circle the corresponding letter in the space provided. Always circle one letter only.

Example: If the participant indicates that they have never had chest pain or discomfort, the response would look like:

Have you ever had any pain or discomfort in your chest?	Yes	Y
	No	N

#### 5. Multiple Choice: Correcting Mistakes

If a response is coded incorrectly, mark through the incorrectly coded response with an "X" and circle the correct response.

Example 1: The actual response is No, but Y was circled incorrectly. The correction looks like:

Yes	Y
No	N

Example 2: If a mistake is made, corrected, and then it is discovered that the correction is incorrect, make a second correction as shown below:

Yes	Y
No	N

#### 6. Completing "Header" Information

The following guidelines should be observed in filling out the "header" information located at the top of the first page on all forms:

**ID NUMBER:** Write in the participant's 7-digit ID. The first box contains the letter J, followed by the 6-digit numeric portion of the ID number.

Example: ID NUMBER: 

J	9	9	9	9	9	9
---	---	---	---	---	---	---

**CONTACT YEAR:** Fill in the appropriate contact year for the form. Use leading zeroes. Note: This item may be pre-coded on some forms.

**LAST NAME:** Code the response beginning in the leftmost box using capital letters. If the name contains more letters than there are boxes, beginning with the first letter enter as many letters as there are boxes. Punctuation (e.g., apostrophes and hyphens) and blanks may be entered as part of the last name. Follow the guidelines and examples given above for alphabetic "fill in the boxes" items.

**INITIALS:** Record the participant's first initial in the first box and middle initial in the second box. If a female participant is married and uses a "maiden" name (father's surname) as a middle name, use that initial as the second initial. Otherwise, if the participant has more than one middle name, record only the first initial and the second initial. If there is no middle name, record the first initial in the first box and leave the second box blank.

Example 1: A participant's first initial is K, but he has no middle name. The entry would be as follows:

INITIALS: 

K	
---	--

Example 2: If the participant's full name is John Oscar Van Camp, Jr., and the participant specifies that his last name is "Van Camp", it should be entered as:

LAST NAME: 

V	A	N		C	A	M	P				
---	---	---	--	---	---	---	---	--	--	--	--

 INITIALS: 

J	O
---	---

## 7. Skip Patterns ("Go to" Boxes)

Skip patterns occur in many multiple choice type items. Here, if a certain response is selected, it is necessary to skip over one or more items to the next applicable item. This is indicated by an arrow from the response which necessitates a skip to a box containing a "go to" statement. If that response is selected, the next item to be asked is the one indicated in the box. If the other response is selected, always proceed to the next item unless otherwise directed. The box will also indicate the screen containing the "go to" item if that item is not on the current screen.

Example: 7. Since we last contacted you, have you had any pain or discomfort in your chest?

Yes Y

No N

Go to Item  
20. Screen 5

In this case, if the response is "No", skip to Item 20 on screen 5. If the response is "Yes", proceed to the next question, Item 8.

Occasionally, a skip pattern will occur in a fill-in type item. In those instances, specific instructions are provided on the form. Again, if the skip criteria are not satisfied, continue with the next item.

A few items will trigger a skip regardless of the response. For these, follow the instructions on the form.

## **II. General Instructions: Completing Computer Data entry Screen**

SEE MANUAL 6, DATA MANAGEMENT

## **III. Instructions for Recording Responses that Do Not Match Precoded Response Categories**

Most of the questions in the JHS instruments have precoded responses. There are a few questions, however, that are open-ended that is, you must write in a response to the question. Some questions have precoded responses as well as an "Other (SPECIFY)" category. If the respondent's answer does not fit into a precoded answer, you must specify the response. The recording practices below must be followed at all times to assure that the response recorded accurately reflects the respondent's answers and to assure that questionnaire data can be converted to machine-readable form.

- You must listen to what the respondent says and record the appropriate answer if the response satisfies the objective of the question.
- In recording answers to open-ended questions or "Other (SPECIFY)" categories, print the response verbatim.
- Record the response immediately after it is given.
- Use a black ball point pen provided by the Exam Center.
- Record in the white space below the questions any responses that "don't quite fit" in one of the response categories. Your notes will help the analysts in understanding points of confusion, difficulty, etc.
- Print or write legibly.
- If a respondent refused to answer a question, write "refused" in the left margin beside the question.
- A single answer choice code must be circled in each question to represent the respondent's answer. The only deviation from this rule is for disease questions which are subdivided into several diseases and an answer code is to be circled for each disease listed.

**APPENDIX 3 INTERVIEWS IN EXAM 2**



### Appendix 3.1 Consent Form

Title of Investigation: The Jackson Heart Study  
Principal Investigator: Herman A. Taylor, MD, MPH

**Introduction:** As one of more than 5,000 persons who took part in Exam 1 of the Jackson Heart Study (JHS), you are being invited to continue your participation in this study, which may include future examinations, telephone, or mail contacts. Please ask us about anything in this document or that we tell you that you do not understand.

**Purpose:** The Jackson Heart Study is a medical research study to identify the risk factors and causes of high blood pressure, heart or other cardiovascular disease, obesity, diabetes, kidney disease, or lung disease in African Americans. It is conducted by Jackson State University, Tougaloo College, and the University of Mississippi Medical Center, and sponsored by the National Heart, Lung, and Blood Institute (NHLBI) and the National Center on Minority Health And Health Disparities (NCMHD).

**Procedures:** Your study participation will last several years. This exam will take no more than 2 hours of your time and includes:

- An **interview** with questions about your health, health care, lifestyle and family medical history. To assure that all the questions are asked in the same way of everyone, some interviews may be tape-recorded.
- An **examination** to measure your blood pressure, height, weight, waist and hip size, and body composition using a special scale.
- **Laboratory blood tests** for cholesterol (lipids and blood fats) and sugar levels. A few drops of blood will be taken by pricking your finger.
- You will be given a **home blood pressure monitor** and taught to use it.

After the examination, you will be contacted by telephone one or more times each year:

- 2-6 weeks after your visit to ask a few questions (5 minutes or less) about follow up of your examination and home blood pressure monitoring, and may also be asked about your experience and satisfaction with the JHS either at the end of the clinic visit (2 minutes or less) or by telephone after the visit (10 minutes or less).
- Yearly, to ask about your health during that year and getting copies of hospital and physician's medical records for any diagnosis or treatment of conditions including blood pressure, heart or other cardiovascular disease, obesity, diabetes, kidney disease, or lung disease and risk factors for these diseases. In the event of your death, information will be sought from your relatives or other informants including coroner's reports and information from the state health department.

Future JHS examinations will occur approximately every 3 years. The next JHS exam cycle will be from 2009-2012. Also, you may be asked to take part in other studies conducted by JHS or collaborating investigators outside the regularly scheduled JHS exam cycle.

**Risks:** All of the tests included in this study are routinely included as part of standard health screenings and are considered safe. There will be slight discomfort when your finger is pricked for blood testing. No materials will be injected into your body; blood will only be withdrawn. There may be some discomfort and annoyance from the repeated blood pressure measurements. You might experience some embarrassment or anxiety from answering any sensitive background questions or have concerns about learning of some health condition that you did not know you had. This is a concern to some people who would rather not know, or who do not have insurance or a regular source of health care. If you have any of these concerns, a JHS social worker will be available to talk with you.

**Benefits:** You may or may not receive a direct benefit from being in this study. You will be given a summary report of all of your results from this examination, including your blood pressure, blood cholesterol, blood sugar, BMI, and body composition percentages. Since this is a research study, and the examination you receive is not a substitute for care you would receive from your health care provider, we cannot make a diagnosis, provide treatment, or give medical advice related to any condition. We, therefore, encourage you to share your summary report of results with your health care provider and, with your permission, abnormal results will be sent to her/him. Should you not have regular health care, or be unable to afford such care, the JHS will assist you in locating affordable health care. All study participants will also receive a regular newsletter updating them on the overall findings of the JHS.

**Alternatives:** You may decide not to take part in the clinical examination. Even if you decide not to take part in the examination, you may continue as a JHS participant by responding to annual follow up calls, and by participating in any future JHS clinical examinations.

**Costs:** There will be no costs to you for participating in this study.

**Research-related injury:** In case of injury or illness resulting from your participation in this study, medical treatment is available to you at the University of Mississippi Medical Center. You will be charged the usual and customary charges for any such treatment you receive.

**Compensation:** You will receive your choice of \$25.00 in cash or gifts in appreciation for taking part in the study. Transportation, if needed, will be reimbursed or provided. The JHS will provide a taxi service if needed. Should you require reimbursement for use of personal transportation, documentation of mileage from your home address to the JHS will be used to determine actual reimbursement costs, not to exceed \$20.00. Child care will be provided, if needed, at the JHS clinic.

**Participation is voluntary:** Your participation in the JHS is completely voluntary and you are free to withdraw your consent and to stop taking part at any time, without affecting any future relationship for you or your relatives with the JHS, Jackson State

University, Tougaloo College, the University of Mississippi Medical Center, or the Jackson Medical Mall. You may decide not to answer any question or complete any examination.

**Withdrawal from the study:** You may choose to stop your participation in this study and withdraw at any time. If you decide to withdraw the information already collected about you may still be used in this study unless you request that your records, and test results obtained from this exam or prior exams be removed from study files. You may also request that your DNA and blood samples and cell lines be destroyed or that all identifiers be removed (including code numbers) from such samples. Your decision to stop your participation will have no affect on the quality of your medical care.

**New Information:** You will be told of any information we learn during your participation in this study that may affect your willingness to participate.

**Confidentiality:** The confidentiality of your information is a top priority for the JHS. Every effort will be made to keep the information we learn about you private. All information collected during this research--including interviews, laboratory data, or examination findings--will be kept confidential and results will not be disclosed to anyone without your permission except as described below. Information may be released to other researchers for scientific purposes, but only after removing your name and all other personal identifiers. Research may be done for conditions not directly related to the heart and blood vessels. Researchers from private companies, under conditions of data confidentiality specified by the JHS and the Institutional Review Boards reviewing the JHS, may have access to your information or samples, in a way that cannot identify you. Please note that neither the JHS investigators, nor you, nor your family would benefit financially from this.

Study records may be reviewed by the Food and Drug Administration (FDA), the Office for Human Research Protections (OHRP), and the Institutional Review Boards (IRB) of the University of Mississippi Medical Center, Jackson State University, and Tougaloo College and Office of Compliance of the University of Mississippi Medical Center. Study data may be submitted to regulatory agencies in other countries but you will not be identified. If the National Heart, Lung, and Blood Institute or the National Center for Minority Health and Health Disparities shares this information with others, the information is no longer covered by the federal privacy regulations. To help insure your privacy, a Certificate of Confidentiality has been obtained from the National Heart, Lung, and Blood Institute for this study. This Certificate is intended to help protect against the involuntary release of information collected during this study. The researchers can make disclosures of information only in very special cases (for example, if they think that a participant or someone else is in serious danger or harm).

**Protected Health Information:** Protected Health Information is any personal health information through which you can be identified. The data collected in this study includes all the interviews, examinations, laboratory tests, genetic (inheritance or DNA) analyses, and review of records as described in this form. A decision to participate in this research means that you agree to the use of your health information for the study described in this form. This information will not be released beyond the purposes of conducting this study. The information collected for this study will be kept indefinitely. While this study is ongoing you may not have access to the research

information beyond the summary report of your clinic examination results. This summary report may be released to your health care provider only upon your special request to do so.

Your information will be grouped with that of all other persons taking part in the JHS and will be used only for statistical analysis to further medical knowledge without disclosing your personal identity. When results of this study are published, presented at medical or research meetings, or to the Jackson community, only group findings will be presented.

**Questions:** Any questions about the study, the specific interviews, examinations, laboratory tests, or record reviews, or any questions about the findings of the study can be answered by the Director of the Jackson Heart Study, Dr. Herman A. Taylor. He can be reached at the Jackson Medical Mall offices of the Jackson Heart Study, 350 W. Woodrow Wilson Drive, Suite 701, Jackson, MS 39213, (601) 815-5050. A pager number is provided through the voice mail for after hours and on weekends.

This research study has been reviewed by the Institutional Review Boards (IRBs) of Jackson State University, Tougaloo College, and The University of Mississippi Medical Center. Any questions about your rights as a research participant can be addressed to one of the following persons:

Richard Ogletree, Pharm.D.  
Chair, IRB  
**Univ. of MS Medical Ctr**  
2500 North State Street  
**Jackson, MS 39216-4505**  
(601) 984-2815

Marlene Setze, Ph.D.  
Chair, IRB  
**Jackson State University**  
1400 J.R. Lynch Street  
**Jackson, MS 39217**  
(601) 979-2931

Shaila Khan, Ph.D.  
Chair, IRB  
**Tougaloo College**  
500 West County Line Rd  
**Jackson, MS 39174**  
(601) 977-7737



## STATEMENT OF PARTICIPATION

I have been told about my continued participation in the Jackson Heart Study and the possible risks and benefits. My participation is voluntary and I may withdraw at any time without any penalty or loss of benefits to which I am entitled, including medical care at the University of Mississippi Medical Center. By signing this form, I confirm that I have read the preceding consent information (or it has been read to me) and that I understand the contents. A copy of the consent information will be given to me for my records.

The JHS investigators and the scientists with whom they are collaborating will use the information and samples that have been collected from me (including the results of questionnaires, clinic examinations, and blood tests) for heart disease risk factor and related disease research purposes. My name or other information that could identify my family or me will not be released.

I have VOLUNTARILY agreed to any of the following conditions marked with an X or  $\checkmark$  in the “Yes” column.

- | Yes                      | No                       |  |
|--------------------------|--------------------------|--|
| <input type="checkbox"/> | <input type="checkbox"/> | I agree to participate in the clinic and annual interviews, clinic examinations, blood pressure teaching and record review.  |
| <input type="checkbox"/> | <input type="checkbox"/> | I give my permission for JHS investigators to review a copy of my medical records.   |
| <input type="checkbox"/> | <input type="checkbox"/> | I would like to receive JHS results from the clinic examinations.  |
| <input type="checkbox"/> | <input type="checkbox"/> | I give permission for JHS to provide my health care provider with my examination results, if they are outside the normal range.  |
| <input type="checkbox"/> | <input type="checkbox"/> | I agree to allow my study data / samples to be used for future other research by scientists studying diseases not directly related to heart disease risk factors and related diseases.   |
| <input type="checkbox"/> | <input type="checkbox"/> | I agree to have my study data or samples released researchers from for profit organizations who wish to develop diagnostic laboratory tests, medications, or other therapies that could benefit many people. (Note: Neither you nor your heirs will benefit financially from this, and your cell line or DNA will not be sold to anyone for profit.) |



**APPENDIX 4 PROCEDURES IN EXAM 2**

**Appendix 4.1 Tanita TNF 300A Manual**











































































**Appendix 4.2 Cholestech LDX Manual**













































## Appendix 4.3 Anthropometry Equipment Calibration Log

## ANTHROPOMETRY EQUIPMENT CALIBRATION LOG

Deliver to Coordinating Center on Friday afternoons. Keep photocopy in Exam Center.

Week of \_\_\_\_\_  
(Monday's date)

## DAILY CHECKS (at beginning of day)

	M	T	W	Th	F
1.a. Scales Read Zero	—	—	—	—	—

## WEEKLY CHECKS

## 1. Scales

A. Calibration check of scales with 50 lb weight

Date \_\_\_\_\_

Time \_\_\_\_\_

Reading of scales with 50 lb weight \_\_\_\_\_

If reading outside of 49.5 to 50.5 range, scale should be Serviced.

If service is REQUESTED, give Time \_\_\_\_\_ Date \_\_\_\_\_

RECALIBRATION by independent Service technician Time \_\_\_\_\_ Date \_\_\_\_\_

## B. Repeat calibration because of moving scales

Scales moved: 1. Date \_\_\_\_\_ 2. Date \_\_\_\_\_

Time \_\_\_\_\_ Time \_\_\_\_\_

Calibration: 1. Date \_\_\_\_\_ 2. Date \_\_\_\_\_

Time \_\_\_\_\_ Time \_\_\_\_\_

## 2. Height Rule

a. Touches hard-surfaced platform on which measures are done \_\_\_\_\_

b. Perpendicular to floor \_\_\_\_\_

## MONTHLY CHECKS

1. Check Measuring Tape: Date \_\_\_\_\_

a. Excess wear or damage found (Y or N) \_\_\_\_\_

b. Height above floor (to nearest cm) on \_\_\_\_\_  
height rule of the 30 cm mark of the  
tape when the zero mark of the tape  
is aligned with the 150 cm mark of the  
height rule

Note: If this measure is outside the 119.5-120.5 cm range,  
the tape should be replaced.

c. Height above floor (to nearest cm) on \_\_\_\_\_  
height rule of the 100 cm mark of the  
tape, with the tape aligned as above.

Note: If this measure is outside the 49.5-50.5 cm  
Range, the tape should be replaced.

d. Tape replaced (Y or N) \_\_\_\_\_ Date replaced \_\_\_\_\_  
Time replaced \_\_\_\_\_

Technician doing weekly check:

ID# \_\_\_\_\_ Signature \_\_\_\_\_ Date \_\_\_\_\_

**Appendix 4.4 Cholestech Optics Check Log / Cassette Quality Control Log**



## Appendix 4.5 Checklist for Anthropometry Measurement

### CHECKLISTS FOR ANTHROPOMETRY MEASUREMENTS

Date of Visit: \_\_\_\_\_

Technician: \_\_\_\_\_ I.D. # \_\_\_\_\_

Supervisor: \_\_\_\_\_ I.D. # \_\_\_\_\_

This booklet contains a checklist for each anthropometry measurement and equipment calibration. The purpose of these checklists is to help train technicians to take uniform and accurate measurements using calibrated measuring equipment. Each checklist leads you through a series of steps to obtain and to record a measurement. All measurements are done on the right side, unless the limb is missing, atrophied or injured.

	<u>Item</u>	<u>Yes</u>	<u>No</u>
A.	Anthropometry is done BEFORE the Snack.	_____	_____
B.	Prepare participant for anthropometry: (May be done by the receptionist or technician).	_____	_____
	1) If the participant is wearing any nylon hose other than knee highs, the participant is instructed to remove hose.	_____	_____
	2) Participant is wearing light-weight, non-constricting underwear.	_____	_____
	3) Participant is wearing scrub suit.	_____	_____
	4) Participant has removed shoes.	_____	_____
	5) Participant has emptied bladder.	_____	_____

**Appendix 4.6 Checklist for Height Measurement**

**CHECKLIST FOR HEIGHT MEASUREMENT**

<u>ITEM</u>	<u>YES</u>	<u>NO</u>
1. Participant is prepared.	_____	_____
2. Procedure is explained to participant.	_____	_____
3. Participant's spine and heels are placed against the wall.	_____	_____
4. Participant's eye to ear plane is horizontal (i.e., Frankfurt plane).	_____	_____
5. Measurement is taken with triangle or measuring block.	_____	_____
6. Recording is completed.	_____	_____
7. Data are recorded accurately to the nearest centimeter, rounding down.	_____	_____

Technician: \_\_\_ \_\_\_ cm

Supervisor: \_\_\_ \_\_\_ cm

8. Other: \_\_\_\_\_

**Comments:**

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Appendix 4.7 Checklist for Weight Measurement

CHECKLIST FOR WEIGHT MEASUREMENT

<u>ITEM</u>	<u>YES</u>	<u>NO</u>
<b>A. PROCEDURE</b>		
1. Participant prepared and procedure explained	_____	_____
2. Position of participant on center of scale	_____	_____
3. Balance achieved	_____	_____
4. Recordings completed	_____	_____
5. Data recorded accurately to the pound, rounding down	_____	_____
Technician:   ___ ___ ___ lbs		
Supervisor:   ___ ___ ___ lbs		
6. Other _____	_____	_____

**Comments:**  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

Appendix 4.8 Checklist for Maximal Waist Measurement

CHECKLIST FOR MAXIMAL WAIST MEASUREMENT

<u>ITEM</u>	<u>YES</u>	<u>NO</u>
1. Subject stands erect, yet relaxed, with weight equally distributed on both feet.	_____	_____
2. Measuring tape is placed around subject's waist at the level of the umbilicus (navel).	_____	_____
3. Recorder or another observer verifies horizontal position of tape, both front and back of the subject, or uses mirror to check tape.	_____	_____
4. Subject takes a normal breath and gently exhales holding breathe in in a <u>relaxed</u> manner at the end of exhalation.	_____	_____
5. Tape is horizontal and snug, but not tight enough to compress tissue. (Invert tape, <u>if needed</u> , to insure reading edge of tape is snug to skin for measurement).	_____	_____
6. Reading is recorded to the nearest centimeter, rounding down, at point of <u>relaxed</u> and exhalation.	_____	_____

Technician: \_\_\_ \_\_\_ \_\_\_ cm

Supervisor: \_\_\_ \_\_\_ \_\_\_ cm

Comments:

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Appendix 4.9 Checklist for Maximal Hip Circumference Measurement

CHECKLIST FOR MAXIMAL HIP CIRCUMFERENCE MEASUREMENT

<u>ITEM</u>	<u>YES</u>	<u>NO</u>
1. Subject stands erect, yet relaxed, with weight equally distributed on both feet and feet together.	_____	_____
2. Measuring tape is placed horizontally and level around the subject's gluteal muscles (hips) at the level of maximal protrusion of the gluteal muscles. Verify this position by passing the Tape above and below the observed maximum.	_____	_____
3. Recorder or another observer verifies horizontal position of tape, both front and back of the subject, or uses a mirror to check tape.	_____	_____
4. 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.	_____	_____
5. The measurement is made at the participant's side.	_____	_____
6. Tape is read to the centimeter, rounding down.	_____	_____

Technician: \_\_\_\_\_ cm

Supervisor: \_\_\_\_\_ cm

Comments: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Appendix 4.10 Report on Use of Observation and Equipment Checklists

REPORT OF USE OF OBSERVATION AND EQUIPMENT CHECKLISTS

DATE: \_\_\_\_/\_\_\_\_/\_\_\_\_ (Month/Day/Year)

Biannually: \_\_\_\_ January \_\_\_\_ July (20\_\_\_\_)

This form should be completed biannually and sent to the Coordinating Center (by the end of January and July).

<u>Form Type</u>	<u>Observer ID</u>	<u>Observed ID</u>	<u>Date (MM/DD/YY)</u>
Anthropometry	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
BP Observation	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____

**REPORT ON USE OF OBSERVATION AND EQUIPMENT CHECKLISTS (Cont'd)**

<b><u>Form Type</u></b>	<b><u>Observer ID</u></b>	<b><u>Observed ID</u></b>	<b><u>Date (MM/DD/YY)</u></b>
<b>BP Tape Test</b>	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
<b>BP Double Stethoscoping</b>	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
<b>Digipuncture</b>	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____

**REPORT ON USE OF OBSERVATION AND EQUIPMENT CHECKLISTS (cont'd)**

**Tanita  
Bioimpedance  
Monitor**


## REPORT ON USE OF OBSERVATION AND EQUIPMENT CHECKLISTS (cont'd)

Individual checklist for equipment should be filled weekly or monthly, according to the requirement of the checklist, and kept in the Field Center.

Key: N = Expected total number of checks needed:  
 n = Number of checks done:  
 % = % of checks done.

Checklist	Frequency	N	n	%
<b>Anthropometry Equipment Calibration Log</b>				
(1) Scale Read Zero	Daily			
(2) Weight Scales	Weekly			
(3) Height Rule	Weekly			
(4) Measuring Tape	Weekly			
<b>Sitting Blood Pressure Monthly Log for BP Station</b>				
	Weekly			
	Monthly			
Appendix 4.3 Anthropometry				
<b>Equipment Calibration Log</b>				

**APPENDIX 5 MEDICAL DATA REVIEW**

## Appendix 5.1 Prototype Medical Data Review Print Out and Information Sheet

### MEDICAL DATA REVIEW REPORT FOR EXAM 2

1. Name (CONA 1, 3, 4, 2):
2. JHS ID (CON)
3. Birth date (ELGA 5a):
4. Exam date
5. Physician name (CONA 34B,A):
6. Age in years (FTRA1, ELGA5A):
7. Height in feet & inches (ANTA/B1):
8. Weight in pounds (ANTA/B2):
9. BMI (BCF 8)
10. % Body Fat (BCF 12)
11. Avg. Sitting BP (SBPB 22, 23)
12. Taking antihypertensives (MSRA30a)

#### Possible Angina

13	Ever had chest pain (MSR B8)	Yes	No
14	HTN diagnosis (HHX 8A)	Yes	No
15.	Diabetes diagnosis (HHX 12a)	Yes	No
16.	High Cholesterol diagnosis (HHX 9a)	Yes	No
17.	Pain more frequent past 2 months (MHX B 20)	Yes	No
18.	Pain more severe past 2 months (MHX B22)	Yes	N

#### Possible Congestive Heart Failure:

19.	Slept on 2+ pillows to breathe (MHX B47)	Yes	No
20.	Awakened by breathing trouble (MHX B48)	Yes	No
21.	Had swelling of feet or ankles (MHX B49)	Yes	No
22.	Decreased swelling overnight (MHX B50)	Yes	No

#### Recognized TIA or stroke

23.	Stroke diagnosis (SSF B1)	Yes	No
24.	Date of first stroke (DDFB 2A, 2B)		
25.	Leg pain with walking (MHX B37)	Yes	No

**Cardiovascular surgery**

23.	Heart or arterial surgery (MHX B51)	Yes	No
24.	Coronary bypass (MHX B 52 A)	Yes	No
25.	Other heart procedure (MHX B52 B1)	Yes	No
26.	Other revascularization (MHX B52 E1)	Yes	No
27.	Specify (MHX B42 E2)	Yes	No
28.	Other Heart, neck or leg (MHX B52 F)	Yes	No
29.	Balloon angioplasty (MHX B53)	Yes	No
30.	Coronary angioplasty (MHX B54 A)	Yes	No
31.	Neck angioplasty (MHX B54 A)	Yes	No
32.	Lower extremity angioplasty (MHX B54 C)	Yes	No

**Catheterization**

33.	Heart catheterization (MHX B55 A)	Yes	No
34.	Carotid artery catheterization (MHX B55 B)	Yes	No
35.	Other arterial catheterization (MHX B55 C1)	Yes	No
36.	Specify (MHX B55 C2)		

**Diagnostic procedures**

37.	Echocardiogram (MHX B56 A)	Yes	No
38.	ECG (MHX B56 B)	Yes	No
39.	Treadmill or stress test (MHX B56 C)	Yes	No
40.	MRI of Brain (MHX B56 D)	Yes	No

**Laboratory Values**

41.	Glucose (FST A5)
42.	Cholesterol (FST A6)
43.	Triglycerides (FST A7)
44.	HDL (FST A8)
45.	LDL (FST A9)
46.	VLDL (FST A10)

**Administrative**

47. Code of person Completing Medical Data 

--	--	--

48. Date of Medical Review 

		/			/				
M	M		D	D		Y	Y	Y	Y

52. Code of clinician Reviewer: 

--	--	--

53. Date of review by clinician: 

		/			/				
M	M		D	D		Y	Y	Y	Y

**Appendix 5.2 Tanita Patient Education Handout**



**Appendix 5.3 Cholestech Patient Education Handout**



**APPENDIX 6 REFERRAL AND RESULTS REPORT**

**Appendix 6.1 Prototype Health Care Provider Results Reporting Letter: Health Care  
Provider Designated**

DATE

Provider's name

Provider's address:

Dear Provider Name:

Your patient, PATIENT'S NAME, is a participant in the Jackson Heart Study and was seen at our Exam Center on VISIT DATE. During the course of our evaluation, the following abnormality was identified. We believe that this requires your attention.

**ABNORMAL RESULT: [LIST RESULT]**

The Jackson Heart Study routinely offers to send all clinically relevant data to the participant's health care provider. PATIENT'S NAME has requested that we send the result to you, and we have also provided a report to her/him.

The Jackson Heart Study procedures are designed exclusively for epidemiological research. Our study procedures do not substitute for a clinical examination. The study does not provide any diagnosis or medical treatment. We have recommended that Mr./Mrs./Ms. PATIENT'S NAME that s/he contact you to determine how to follow up on these results.

Should you have any questions, please feel free to contact us at 601-815-5050.

Sincerely,

Mary E. Crump RN, MSN  
Clinic Manager

**Appendix 6.2 Prototype Health Care Provider Results Reporting/ Referral Letter: No Health Care Provider Designated**

DATE

Provider's name

Provider's address:

Dear Provider Name:

Thank you for agreeing to see, PARTICIPANT'S NAME, a participant in the Jackson Heart Study who was seen at our Exam Center on VISIT DATE. PARTICIPANT'S NAME does not have a regular health care provider. During the course of our evaluation, the following abnormality was identified. We believe that this requires your attention.

**ABNORMAL RESULT: [LIST RESULT]**

PATIENT'S NAME has requested that we send the result to you, and we have also provided a report to her/him.

The Jackson Heart Study procedures are designed exclusively for epidemiological research. Our study procedures do not substitute for a clinical examination. The study does not provide any diagnosis or medical treatment. We have recommended that Mr./Mrs./Ms. PATIENT'S NAME that s/he contact you to determine how to follow up on these results.

Should you have any questions, please feel free to contact us at 601-815-5050.

Sincerely,

Mary E. Crump RN, MSN  
Clinic Manager

## Appendix 6.3 JHS Alerts and Referrals Procedures

### CLINIC PROCEDURES –EXAM 2 MEDICAL DATA REVIEW AND RESULTS/ALERTS REPORTING

#### I. Overview

The purpose of medical data review and results/alerts reporting is to provide timely information regarding the results of the JHS clinic examination to participants and, if requested or indicated, their health care provider (HCP). Additionally, medical data review is conducted to identify and provide timely notification of any alert findings that require emergent, immediate or urgent attention by a HCP. This process is a major component of assuring participant safety.

Results that are immediately available during the clinic examination (blood pressure, anthropometrics, body fat, glucose, and lipids) are reviewed with the participant at the end of the clinic visit during the exit interview. Any abnormal or alert values will result in an appropriate level referral based on the categorization of findings as emergent, immediate, urgent or routine as identified in Manual 2: Cohort Procedures. Participants without a HCP, but needing referral, will be assisted in that process.

The Medical Data Review and Results/Alerts Reporting Form (ALT) are used to track all results reporting activities.

Table 6.2 provides a summary of procedures for routine results reporting and identification, notification and documentation of alerts. Each column of this summary table is reviewed below.

#### II. Medical Data Review: Action Sequence for Routine Results Reporting

This section details the action sequence for routine results reporting for each examination component reportable to participants and their HCP (if requested) presented in Table 6.2, column 2. As the same series of steps is listed for each component in the table, this section provides a common overview of the entire process applicable to all procedures.

A medical data review is conducted in several steps for each participant. The first step occurs during the clinic visit at the time of the exit interview. The next step occurs during a weekly review as the Clinic Manager performs quality control to assure that all abnormal results were properly handled. Results of the medical data review process are documented on the ALT and maintained in the Data Management System (DMS).

##### A. End-of-Clinic Medical Data Review

The end-of-clinic medical data review serves to summarize the results of selected measurements obtained during the baseline exams/interviews, identify potential medical problems and answer participant questions. It is important to note that the intent of this review is to provide factual information about results, identify abnormalities and recommend referral as needed, while avoiding medical advice about prognosis, prevention or therapy. All such medical advice is in the purview of the participant's HCP and is not within the scope of the JHS.

##### 1. Medical Data Review print out

The Medical Data Review (MDR) print out is generated at the end of the clinic visit (Appendix). This print out contains relevant participant personal (birth date, age) and medical history (taking hypertensive medications, history of hypertension, diabetes, elevated cholesterol, stroke, chest pain, coronary bypass surgery, balloon angioplasty or

cardiac catheterization, undergoing dialysis, menstrual bleeding); indication of identified HCP as well as values from the clinic examination (height, weight, sitting blood pressure).

## 2. Nurse Manager/Clinic RN review

Using the information contained in the MDR print out, the Clinic Manager or RN conducts an exit interview with the participant at the conclusion of the clinic examination visit. During this exit interview, all known findings from the clinic exam/questionnaires are reviewed with the participant to confirm selected positive symptoms reported during the interviews/exam and to determine if these appear to warrant immediate (same day), urgent (same week) or routine medical follow-up. Specifically, the Clinic Manager or RN reviews anthropometrics, blood pressure, body fat, fasting blood glucose and lipids. The information on the MDR print out provides background information to assist the nurse in determining the urgency of any abnormalities. For example, should the participant have an elevated blood pressure, the Clinic Manager or RN will determine from the print out and confirm with the participant that s/he takes blood pressure medication. Ascertaining whether medications have been taken that day, if the participant knows her/his normal blood pressure reading, and the last time s/he was seen by a HCP will be instrumental in subsequent follow-up actions. Guidelines for abnormal and alert referrals are summarized in Table 1 and detailed below.

A printed summary of the exam results that are immediately available from the Clintrial DMS is completed during the end-of-clinic medical data review and given to the participant. This includes BP, height, weight and calculated body mass index, body fat, blood glucose and lipids. In addition, the participant receives a copy of her/his Tanita Bioimpedance monitor print out and a summary health education handout that explains these findings. Any remaining participant questions are answered during this interview.

At the conclusion of the end-of-clinic medical data review, the participant is directed to the Social Worker who conducts the Participant Evaluation of Clinic Visit on as many participants as possible during each clinic day. When it is not possible for the Social Worker to conduct the evaluation interview, participants will be asked to complete the 5-item evaluation on their own.

In the event the participant has social service needs, does not have a HCP and either needs alert / routine referral or requests assistance with locating health care, the Social Worker is consulted to assist with the referral process.

## B. Daily and Weekly Review

Designated lead technicians conduct a daily review of examination results to detect and initiate action on alert findings. The Clinic Manager conducts a weekly review of all available examination results for participants completing clinic examinations during the preceding week. The purpose of this examination is to assure that all alerts have been identified and handled according to the results and alerts reporting protocol. Information needed to complete this weekly review includes 1) appointment listing for previous week, 2) a copy of the MDR and ALT completed at the time of the Exam 2 visit. A notation of review is indicated in the upper right or left hand corner of the result report.

### 1. Appointment listing

The Data Manager prints a query report from the Participant Itinerary Form for the specified week. This report includes all participants who have completed all or part of a clinic examination during the specified time frame. Specific exam components not completed or refused by each participant are identified in this report.

The Clinic Manager uses this report to assure that the reports provided for weekly review are complete.

2. Compilation of reports

The Clinic Receptionist creates a Results Reporting file with name and J number for each participant at the time of clinic file generation on the morning of the clinic visit. This file is placed in alphabetical order by day of the week in the Weekly Review filing space in the JHS file storage room. The MDR Report and the ALT printout are placed in the individual participant Result Reporting file.

3. Notation of review

a. Daily review. All abnormal values are recorded on the ALT form by the lead technician at the time of the daily review and entered in the Medical Data Review and Alerts/Referral Log (ALT) in the DMS (see section D1, below).

b. Weekly review. The Clinic Manager affixes a check ( ✓ ) followed by her/his initials, the date of review and an indication of the level of reporting to each report reviewed. For normal values, no further annotation is included. For abnormal values, results that require routine reporting are indicated by the letters RR; those requiring alert reporting are indicated by the letters AR.

The Clinic Manager affixes a check ( ✓ ) followed by her/his initials beside each name on the weekly appointment list that accompanies the weekly compiled results. The placement of initials indicates completion of the weekly medical data review. Using this checklist, the Clinic Receptionist enters confirmation of completion of the weekly medical review in the Medical Data Review and Alerts/Referral Log in the DMS (see section D2, below).

C. Comprehensive Results Report

A comprehensive report of participant examination results is generated by the Coordinating Center and delivered to the Exam Center at the time of the exit interview (Medical Data Review printout). In addition to the reportable examination findings, this report includes information necessary for completing the review process, e.g. participant name, J number, gender, HCP status, and whether or not s/he is taking medications for hypertension.

Also, a final packet, including an appropriate cover letter for the participant HCP, two copies of the results report, an explanations booklet, and a risk factor analysis is generated for distribution to each participant.

A dual process of clinic staff and Clinic Manager review of all results reporting letters and results is completed to assure accuracy prior to mailing. Designated clinic staff review the comprehensive results reports generated each week to assure accuracy and subsequently completes the documentation process using the ALT form (see Forms Manual and QxQs for each form). A final quality control review is conducted by the Clinic Manager prior to mailing any abnormal results to the participant's designated HCP (with permission of participant).

For participants who request that abnormal results be mailed to their health care provider, the Examination Center will mail a complete set of findings to the designated HCP two weeks of the clinic visit date.

1. Distributing reports
  - a. Initial review. Designated clinic staff review letters and reports for 8-10 participants each week to assure accuracy and to complete the ALT forms for each participant.
  - b. Quality review. The Clinic Manager completes a final quality control review of each participant report packet to assure that the information matches the actual results for each participant and that the correct information is attached to each letter for each participant.
  - c. Participant reports. The Clinic Receptionist makes a duplicate copy of the complete participant report (letter, results report, explanations) for both the participant and HCP. The copy is filed in the participant JHS file.

#### D. Annotating Routine Medical Data Review

Any abnormal result found at any stage of the medical data review process (end-of-clinic, daily review, weekly review, comprehensive review) is annotated on the Alert and Routine Referral Log (ALT) and entered into the DMS. Likewise, the confirmation of completion of each of the weekly review and comprehensive results reporting procedures is annotated in the Medical Data Review printout and maintained in the participant paper record.

##### 1. ALT form

The Alert and Routine Referral Log (ALT) form is used to record all abnormal findings and subsequent referral action for any reportable result from the clinic examination. The form includes space for recording information on abnormalities in blood pressure, body fat, body mass index, blood glucose and lipids. For each exam component, space is provided to record the date the abnormal finding was received, the alert item/value, the date of referral action, the JHS code of the person completing the review, the type of referral action taken, the referral source and the method of notifying both the participant and her/his HCP. Specific instructions for completing the ALT form are included in the Forms Manual for Manual 2.

The paper version of the ALT is maintained in the participant's file.

The Data Manager queries the Alerts Reporting Crystal Reports provided by the Coordinating Center to generate a monthly report of Alert and Referral actions on a designated date each month. This report is transmitted electronically to the Clinic Manager, the Chair of the Clinic Operations Committee, and the Director of the Exam Center for inclusion in the monthly agenda of appropriate committee meetings (e.g. Clinic Operations, A Team, Steering Committee).

### III. Medical Data Review: Action Sequence for Identifying and Reporting Abnormal Results

This section details the action sequence for identifying (Table 6.2, column 3), reporting (Table 6.2, Column 5) and documenting (Table 6.2, column 6) abnormal results for each examination component reported to JHS participants and their health care providers (HCP) (See Manual 2 v2.0, section 6: Results and Alerts Reporting). Table 6.1, column 4 summarizes the range and categorization of abnormal values for quick reference. Definitions for each of the identified alerts categories: Emergent, Immediate, Urgent and Routine, are provided.

#### A. Definitions of Results Categories

1. Alerts are those results that require participant notification and referral to HCP within a time period prior to the usual results reporting schedule (within 2 weeks after the clinic examination). There are three categories of alert referrals:
  - a. Emergent referrals are those immediate or urgent clinical findings identified during the clinic examinations that are accompanied by life-threatening (e.g. hemodynamic instability) findings. In all such instances, the clinic examination is stopped and the participant is transported to the nearest Emergency facility. Emergency procedures are outlined in Section 7 of Manual 2 v2.0, Cohort Procedures. Chapter 4 of the EC Clinic Procedure Manual outlines the protocol for handling emergencies, including those that do not fall in any of the alert categories.
  - b. Immediate referral is made for specified abnormal findings that require immediate (same day) attention. When identified during the clinic examination or exit interview, the participant must be notified and notification of her/his HCP is initiated before the participant leaves the clinic. Contact is made with a selected HCP if the participant does not have an established provider.
  - c. Urgent referrals are made for specified abnormal findings identified during the clinic exam. They require participant notification and HCP referral within one week.
2. Routine referral occurs for those abnormalities that are unlikely to result in an adverse affect within several weeks of the clinic examination. These results are reported routinely with comprehensive reporting of results to participants in clinic and HCP (if requested).

## B. Identifying and Reporting Clinic Alerts

### 1. Blood Pressure

The technician completing the BP measurement during the clinic examination identifies abnormalities in blood pressure and notifies the Clinic RN or Clinic Manager. S/He repeats the BP reading to confirm the abnormality and identifies the alert category. The nurse assesses the participant's clinical status.

BP alert values in accordance with Joint National Commission VII guidelines are summarized below:

<b>Medical Care Referral Guidelines for Blood Pressure, Based on Joint National Committee on Detection, Evaluation and Treatment of High Blood Pressure (JNC-VII, 2003) Guidelines</b>			
<b>Referral Classification</b>	<b>Examination Findings</b>	<b>Recommendation to Participant<sup>1</sup></b>	<b>Explanation to Participant</b>
Emergency Referral	SBP $\geq$ 260	Transportation to emergency care	Your BP is

<b>Medical Care Referral Guidelines for Blood Pressure, Based on Joint National Committee on Detection, Evaluation and Treatment of High Blood Pressure (JNC-VII, 2003) Guidelines</b>			
<b>Referral Classification</b>	<b>Examination Findings</b>	<b>Recommendation to Participant<sup>1</sup></b>	<b>Explanation to Participant</b>
	or DBP $\geq$ 130	facility. Stop exam and reschedule clinic visit	very high.
Immediate Referral	SBP 210-259 or DBP 120-129	Consult with JHS MD. Refer to source of care immediately (today). Stop exam and reschedule clinic visit	Your BP is very high.
Urgent Referral	SBP 180-209 or DBP 110-119	Consult with JHS MD and proceed unless otherwise indicated. Refer to source of care within 1 week	Your BP is high.
Routine Referral	SBP 160-179 or DBP 100-109	Refer to source of care within 1 month	Your BP is elevated.
	SBP 140-159 or DBP 90-99	Refer to source of care within 2 months	Your BP is elevated.
	SBP 120-139 or DBP 80-89	Recheck in 1 year (no JHS referral)	Your BP is in the pre-hypertension range
	SBP < 120 <sup>2</sup> or DBP < 80	Recheck in 2 years (no JHS referral)	Your blood pressure is normal

<sup>1</sup> If the systolic and diastolic categories are different, follow recommendations for the shorter time follow-up (e.g., 160/85 mm Hg should be evaluated or referred to source of care within 1 month). <sup>2</sup> Unusually low readings should be evaluated for clinical significance.

If the alert value is determined to be Emergent or Immediate, the JHS Medical Officer or EC Clinician on call is notified immediately (prior to participant leaving the clinic). S/He reviews and confirms this level of alert finding and provides instructions to initiate participant and HCP notifications according to protocol definitions (described above) including any further recommendations.

Participant notification of BP value occurs at the time of measurement and is discussed and explained at the medical data review conducted at the end of the clinic visit. If the alert is Emergent, the participant is transported to the nearest emergency facility and her/his HCP is notified by telephone. If the alert is Immediate the participant's HCP is notified by telephone at the time of the medical data review at the completion of the clinic visit. If the alert is Urgent, an alert letter (M2A6.1-6.2) is sent to the HCP. If the alert is Routine level 1 or 2, a letter is sent to the HCP (M2A6.1-6.2) recommending a one or two month appointment, respectively.

If the participant does not have a HCP, the Social Worker is consulted and a referral process is initiated.

## 2. Laboratory

The laboratory technician receives panic and routine laboratory reports immediately from the Cholestech monitor reading at the time of the finger stick. The technician screens the results, identifies abnormalities and notifies the Clinic RN or Clinic Manager of the alert value. The Clinic RN or Clinic Manager reviews the laboratory results and confirms the alert category.

The Cholestech alert values are as follow:

<b>Alert Category</b>	<b>Glucose</b>	<b>Lipids</b>
Emergent:	None	None
Immediate:	Glucose: < 45 or >500	None
Urgent:	Gluc: 45-60 or 200-500	TotChol: > 360 HDL: < 20 LDL: > 260 TG: >1000
Routine:	Any abnormal value not classified as an alert	TotChol: >200 < 360 HDL: >20 < 35 LDL: >100 < 260 TG: >200 <1000

If the alert value is determined to be Immediate, the JHS Medical Officer or EC Clinician on call is notified immediately (prior to participant leaving the clinic). The technician provides an immediate repeat finger stick analysis (if necessary, using a different monitor) of any results reported as a panic value. The JHS Medical Officer or EC Clinician reviews and confirms this level of alert finding and provides instructions to initiate participant and HCP notifications according to protocol definitions (described above) including any further recommendations. If the alert is Immediate, the participant's HCP is notified by telephone on receipt of the abnormal value. The full laboratory report is Faxed to the HCP. If the alert is Urgent, an alert letter that includes the alert lab value is sent to the participant HCP (M2A6.1). If the participant has no HCP, s/he is notified by letter (M2A6.2) and instructed to call for HCP referral, if needed.

If the participant does not have a HCP, the Social Worker is consulted and a referral process is initiated.

## C. Generating Alerts Reports

Alert values for reportable clinic examination findings are identified and addressed in the clinic at the time of the exam. The weekly medical data review also serves to identify any alert values that may not have been identified in earlier reviews. As described above, technicians conducting each element of the clinic examination identify alerts and notify the Clinic RN or Manager. The JHS Medical Officer or EC Clinician on call reviews alerts with the clinic nurse and directs alerts actions. Participant and HCP telephone calls are initiated by the Clinic RN with directions to the Clinic Receptionist to provide appropriate reports via Fax to the HCP. The Clinic Receptionist generates participant and HCP alert letters and examination results. The Clinic Manager reviews all alert letters and accompanying results for accuracy prior to mailing.

1. Compiling information

Information for alerts reports is compiled by the appropriate technician as described above and delivered to the Clinic RN or Clinic Manager for review and confirmation of alert category.

2. Categorizing alert values

The lead technician or Clinic Manager/RN, in consultation with the JHS Medical Officer or EC Clinician on call, categorizes the alert value(s) following identified protocol for each exam component (see above). The Clinic Manager or RN initiates the process of participant and HCP notification, making telephone calls and directing distribution of Fax reports to the identified HCP for Emergent or Immediate alerts. The lead technician or nurse notifies the Clinic Receptionist of the alert categorization.

3. Generating cover letters and results report

The Clinic Receptionist will generate the appropriate alert letter as specified above for each exam component requested by the lead technician, Clinic Manager or RN. Once the letter and copy of result report are generated, the Clinic Receptionist delivers it to the Clinic Manager for review prior to mailing and documentation in the Medical Data Review and Alerts Referral/Reporting Log (ALT) in the DMS (see section D2, below).

4. Distributing reports

The Clinic Manager reviews each participant / HCP letter and enclosed results report for accuracy prior to mailing. This quality control review is conducted to assure that the information matches the actual results for each participant and that the correct information is attached to each letter for each participant. Following this review, the letter is returned to the Clinic Receptionist for mailing.

Prior to mailing the alert results report, the Clinic Receptionist makes a duplicate copy of the complete mailing (letter, results report, explanations) to both the participant and HCP. The copy is filed in the participant JHS file.

D. Documenting Clinic Alerts and Referrals

Any abnormal result found at any stage of the medical data review process (end-of-clinic, weekly review, comprehensive review) is annotated on the Alert and Routine Referral Log (ALT) and entered into the DMS.

## 1. ALT form

The Alert and Routine Referral Log (ALT) form is used to record all abnormal findings and subsequent referral action for any reportable result from the clinic examination. The form includes space for recording information on abnormalities in blood pressure, body mass index, body fat, blood glucose and lipids. For each exam component, space is provided to record the date the abnormal finding was received, the alert item/value, the date of referral action, the JHS code of the person completing the review, the type of referral action taken, the referral source and the method of notifying both the participant and her/his HCP. Specific instructions for completing the ALT form are included in the Forms Manual for Manual 2.

The paper version of the ALT is maintained in the participant's file.

The Data Manager queries the Alerts Reporting Crystal Reports provided by the Coordinating Center to generate a monthly report of Alert and Referral actions on a designated date each month. This report is transmitted electronically to the Clinic Manager, the Chair of the Clinic Operations Committee, and the Director of the Exam Center for inclusion in the monthly agenda of appropriate committee meetings (e.g. Clinic Operations, A Team, Steering Committee).

# Jackson Heart Study

## *Resource Guide*



- How to stay well in Mississippi
- Things you can do for yourself and others
- Where to find help in your community

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**To Find the Subject You Want**

- Look through the list on page 4-5
- For general topics see page 2

**To Find Community Services**

Local Phone Numbers for Community Services Agencies are listed at the back of the Guide.

For Community Services that are not listed in this guide, please look in the table of contents in the Yellow Pages of the phone book under Social Services.

Local numbers for many types of Services are in the Government Pages or White Pages in your phone book.

**Free Statewide Phone Numbers**

- Toll-free (800) numbers are included in the back of this Guide.

**You are welcome to contact the Jackson Heart Study Social Worker to assist you in obtaining other information or needed services. You can reach her by calling 601-815-5050.**

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# Basic Needs



## Basic Needs

Everyone has basic needs, like food, clothing and a safe place to live. Without them, you can't survive. Yet sometimes these needs can be hard to meet.



This chapter contains ideas about things you can do for yourself and where to find help in your community.



### Food

Emergency Food is available from community pantries, community centers, senior meal programs and churches.

Government Food Programs, such as Food Stamps, School Breakfast and Lunch Programs, and the Women, Infants, and Children Program (WIC) are other resources for the low-income.

### Things You Can Do

- Look for places with low prices
- Find out about local community food programs.
- Cut out coupons from the newspapers.
- Add more whole grains and beans to your diet
- Eat a wide variety of foods each week.
- Eat fresh fruits and vegetables each day
- Eat less fat, avoid fried foods and pastries
- Eat nourishing soups.

### Where To Find Help

#### Local Phone Numbers

City of Jackson Senior Services	(601) 960-0454
New Dimension Food Pantry	(601) 969-9856
DHS (Food Stamp Office)	(601) 362-9892
WIC office	(601) 364-2666
Meals n Wheels	(601) 960-0438



## Housing

Good housing can be expensive. Many people are homeless, or just one paycheck away from it. There are not many resources, but low-income housing is available for senior citizens and the disabled.



There are also agencies that help with utility bills.



### Things You Can Do

#### Looking for a home to Rent

You cannot legally be turned down for housing because of race or a disability. For advice, call the Fair Housing Authority.

#### Neighborhood Problems

Streetlights out? Too Noisy? Talk to neighbors, or call the City of Jackson.

#### Homeless

In the Jackson area there are emergency shelters for the homeless. Some shelters offer counseling and other services.

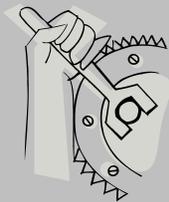


## Where To Find Help

### Local Phone Numbers

Human and Cultural Services	(601) 960-0335
Jackson Housing Authority	(601) 362-0885
Regional Housing Authority	(601) 373-7040
Hinds Co. Human Resources (Homeless Support Services)	(601) 354-3857
Veterans Homeless Services	(601) 362-4471





## Work

A job with fair pay is a basic need. Unemployment offices help people find jobs, and get benefits.

### Things You Can Do

- Attend adult education classes to complete a GED program
- Take classes at a community college or university.
- Job training programs, such as Job Corps.
- Temp agencies can help; look in the Yellow Pages
- Veterans can get special help.
- Stay healthy at work by taking regular breaks.
- Report discrimination to the Equal Employment Opportunity Commission (EEOC).
- Report dangers at work to management or the Occupational Safety and Health Organization (OSHA).
- If you are injured at work, discuss with management how to apply for worker's compensation benefits.

### Where To Find Help

#### Local Phone Numbers

Duling GED program	(601) 987-3695
EEOC	(601) 965-4537
Vet Center	(601) 965-5727
WINN Job Center	(601) 321-7931
Unemployment Insurance Office	(601) 321-7937
OSHA	(601) 965-4606



## Medical Care

Do you need to see a doctor or some other kind of health care provider? Do you know where to go? Medical care can be very expensive. If you do not have health insurance or money to pay for medical care, you can get low-cost treatment at the community clinic or a hospital. The JHS Social Worker can also help you. **See page 29**



Medicare covers seniors and people with disabilities.

Medicaid covers certain individuals and families with low incomes and resources who need help paying for medical care.

### Things You Can Do

#### To Find Medical Care

Community clinics serve almost anyone, even if you have no insurance and do not qualify for Medicare and Medicaid. Private clinics serve people who can pay or have insurance.

Medicare pays medical costs for some people over 65, and some people with disabilities. You can buy “Medigap” insurance to cover costs not covered by Medicare. Sometimes you get Medicare automatically; other times you have to apply.

Children’s Health Insurance Program (CHIP) provides free medical and dental check –ups for children from low-income families.

#### Private Health Insurance

Insurance is expensive and you usually have to pay part of the treatment cost. There are agencies that assist county residents who are uninsured or underinsured. **See page 29**

## Where To Find Help

### Local Phone Numbers

Medicaid

(601) 961-4361

Medicare

(601) 965-6273

Medicaid (CHIP)

(601) 359-6050



# Staying Well

We can prevent a lot of illness and suffering by learning to take better care of ourselves and each other.

***Think about your life and the people you live and work with. What are some changes that you would like to make?***

This chapter offers helpful information about diet, exercise, drugs, physical disability, mental health problems, violence and dying.



Some problems we can solve alone, if we take the time to make a change. For other problems, we need help from a friend, a family member, professional, or a small support group.

# Stress

## Are You Stressed?

The signs vary.

**Are you:**

- ❖ Moody or depressed?
- ❖ Getting aches and pains?
- ❖ Having problems eating?
- ❖ Not sleeping well?
- ❖ Eating too much?
- ❖ Drinking or smoking a lot?
- ❖ Getting violent?



### Life can be demanding!

Family, work, commuting to work and money issues can add to the stresses of daily life, and can cause a non-stop kind of stress that wears you down

Times of major change are the hardest, like divorce, or losing your job, or the death of someone you love. Even happy changes, like the birth of a baby can be stressful.

**Stress may mean you need to make some changes. Ignoring the signs can lead to bigger problems, even serious illness. Think about what stresses you. Find ways to make a change. Help yourself feel better. Changing the way you live can be very difficult. It takes hard work and patience. You may need help. Talk to friends and family. If you can't cope, there are counselors and others in your community who can help.**

## Coping With Stress

### Things You Can Do To Prevent Stress

Think about what stresses you:

- Learn your signs of stress. When they appear:
- Take a break
- Talk to a friend
- Make a change you think could help you
- Learn about deep relaxation
- Avoid debt. Don't buy what you can't pay for.
- Stand up for yourself
- Find time for yourself every day
- Take up a hobby
- Try to keep a sense of humor

### Resist Illness: Adopt a Healthy Lifestyle

- Nutritious Meals eaten slowly can be calming.
- Exercise can give you some relief from stress.
- Drugs and alcohol can make things worse.
- Make sure to get enough sleep.

### Trouble Coping Alone? Get Help.

- For help solving a family problem — seek counseling
- Need a professional therapist? Call a mental health clinic.
- Very depressed, even suicidal? Call Contact Crisis Line.



## Where To Find Help

### Local Numbers

The Crisis Line	(601) 713-4357
Healing Hearts First Baptist Church	(601) 949-1949
Central Mississippi Medical Center	(601) 376-2600
Mississippi Department of Mental Health	(601) 369-1288
Mississippi Mental Health Association	(601) 351-8503



## Healthy Eating For Cardiovascular Health

Eating well may help prevent serious illnesses like diabetes, cancer and heart disease. The kind of foods you choose, and how much of them you eat are both important. Most experts agree that we should eat more whole grains, vegetables and fruit and less fat, sugar and salt.

Enjoying your food is important, but remember:

- Eat only when you are hungry
- Choose a place where you can eat in peace
- Stop when you feel full.

Steaming, stir- frying, baking and micro waving meats and vegetables are healthier than deep- frying.

Add pepper, lemon juice, or other spices rather than lots of salt. Mrs. Dash's is a healthy alternative to salt.

It is important to remember these food safety tips

- Meat, milk and eggs should be kept in a cold place.
- Always rinse fruits and vegetable before use.



## Eating Well

### Things You Can Do

- Eat a Variety of Foods
- Use whole grain breads and cereals
- Try to eat five servings of vegetables and fruits daily
- Select low-fat or non-fat dairy products
- Trim the fat from beef and pork
- Skin chicken and turkey to reduce their fat content
- Drink water or fruit juice instead of sodas, coffee and alcohol
- Check food labels for fat, fiber, sugar and salt content.



### Cooking

- Cut down on deep-fat frying, try stir-frying, baking or broiling
- Use vegetable oil, like corn, canola or olive
- Use less salt; too much can raise your blood pressure
- Wash fresh fruits and vegetables to remove chemicals
- Cook and eat with family or friends

## Eating Problems

Many people eat too much because they are bored, lonely, or depressed, or they are addicted to certain foods. Others eat only small meals or make themselves throw up their food. These habits can be dangerous and hard to change. Join a support group like Overeaters Anonymous.



## Exercise

no matter how old you are, exercise and relaxation can help you stay well, look good and live longer.

Some kinds of exercise make you flexible. Some make you strong. Others give you stamina. You need all three.

Regular exercise is best – several days a week, if you can, there are many ways: swimming, gardening, walking, jogging—each helps the body in different ways. Some people join a group; others exercise alone.

Relaxing is also important. Read. Sing. Walk the dog. Play music. Write a letter. Get together with friends. Even making a small change in your daily routine can be relaxing. It's never too late to start.



## Exercise and Relaxation

### Things You Can Do

#### Exercise Regularly

- Make exercise a regular part of your life
- Check with your health care provider about safe exercises
- Start slowly; forcing your body could cause an injury
- Exercise should be fun, so enjoy yourself
- Exercise for 20-30 minutes, at least three times a week
- Try different kinds of exercise
- Instead of elevators, use the stairs



#### Take Time to Relax

- Find a quiet safe spot to sit or lie down
- A few deep breaths can help release tension
- Take a leisurely walk. Or talk to a friend
- Ten minutes of exercise can also ease tension
- Relax with music, movies, reading, or by playing with a pet
- Take a hot shower or bath
- Soak your feet in warm water
- Take at least one day of rest every week



#### Other Places to Go

- Classes at a YMCA or health club
- A local library museum, or community center
- A park, beach, swimming pool or recreation center

### Where To Find Help

#### Local Numbers

YMCA (601) 948-3091  
 Baptist Healthplex (601) 925-7900  
 Parks & Recreation Office (601) 960-0471



## Mental Health

Many people experience severe mental distress at some point in their lives. It may last only a few days or weeks; it may be there most or all the time. It can make you feel very alone.

The signs vary. You could feel:

- overwhelmed or confused
- frightened or angry
- worthless or depressed
- others do not understand you
- everyone is against you
- you cannot take care of yourself
- you are going to hurt yourself, or someone else.

Get help ignoring the signs, or denying there is a problem, can make matters worse.

For serious mental illness, try to find a mental health specialist. Public mental health programs offer some services and referrals, but treatment is not always easy to get. Family and friends may also be able to help. Self-help groups, counselors and clergy offer important kinds of guidance and support.

## Where To Find Help

### Local Phone Numbers

Central MS Medical Center	(601) 376-2600
St. Dominic Behavioral Health	(601) 200-3090
Brentwood Behavioral Healthcare	(601) 936-2024
MS State Hospital	(601) 351-8000
Region 8 Mental Health Center	(601) 825-8800



## Mental Distress

### Things You Can Do

#### Do You Have a Mental Health Problem?

- Learn to recognize the signs that you are becoming sick
- Keep a journal: write down your symptoms and feelings
- Tell friends your trouble signs; let them warn you.
- A support group may help. **See page 34**
- Be hopeful; don't be ashamed.
- You are entitled to respect like everyone else.

#### Finding Help in a Crisis

Call a mental health center. In a serious emergency, Call 9-1-1

#### Spending Time With People in Distress?

- Be patient. Recovery takes time.
- Be sensitive. Treat the person with respect.
- Take care of yourself too; take time away.
- Encourage the person to continue treatment of some kind.
- If the treatment is not helping, try to find an alternative.
- Be understanding; invite them to do things with you.
- Encourage the person to be independent.

#### Treatment

The main treatments are counseling and medication. Both can help people to lead a normal life, though drugs may have unwanted side effects. Most insurance plans don't cover all the costs of treatment for mental health problems—so make sure to check your coverage.

## Disability

There are many kinds of disabilities, and many causes. Some of us are born with them. Others are disabled by illness or injury. Physical disabilities limit the full use of your body, while people with developmental disabilities, may be mentally challenged or have problems communicating.

Being disabled does not mean the person is sick or helpless. People with disabilities can be as healthy and capable as anyone else. Many organizations offer services ranging from job training and housing to transportation and sports.

## Things You Can Do

### Disability Services

Independent Living Centers help with counseling, job training, housing, benefits counseling, peer support, living skills classes and legal advice.

#### Other Services and Benefits

- For medical help, call the health department. **See page 30**
- To find out if you are eligible for S.S. I. assistance, call the Social Security Administration office.
- For self-help groups. **See page 34**



## Where To Find Help

### Local Phone Numbers

Social Security Administration  
Vocational Rehabilitation

(601) 965-5377  
(601) 853-5100



## Alcohol and Drug

Many people use some kind of drug. It could be tobacco or alcohol, a prescribed medicine or an illegal drug. Regular use of many kinds of drugs can lead to addiction.

The first step towards healing is to admit that you have a problem and need to make a change. Then you need to find help. Ask a health care provider or counselor who knows about addiction. Drug treatment programs offer chances to start living without alcohol or drug; support groups can help you stay off them.



### Things You Can Do

#### For help with a Drug Problem

- Realize that you are not alone
- There are many people like you.
- Find out about support groups. **See page 32.**
- Seek counseling or a drug treatment program
- Be patient. Recovery takes time.

Tobacco is also a health hazard. Quitting is hard, but not impossible.



## Where To Find Help

### Local Phone Numbers

ACT Tobacco Center

Baptist Behavioral Health Services

Brentwood Behavioral Health

St. Dominic Chemical Dependency Treatment Center

(601) 815-1181

(601) 968-1102

(601) 936-2024

(601) 200-3090



## Violence and Abuse

There are many types of violence and abuse. They include:

- Domestic violence
- Child abuse
- Neighborhood Violence
- Abuse in a Nursing Home or at Work

### Things You Can Do

If you are attacked

- Go to a safe place
- Call 9-1-1.
- For a place to stay, call an emergency shelter.
- For general help, find a counselor
- To report child abuse or elder abuse, contact the Department of

## Where To Find Help

### Local Phone Numbers

(DHS) Child Abuse Hotline

(601) 359-4991



## Growing Older

### Care For the Elderly

Growing older can bring happiness and satisfaction, but can also be difficult. You may be living alone, just when you are having trouble taking care of yourself. You may have health or money problems. There are many Community Services that the elderly may need at this time in their lives. They range from medical care, prescription assistance, financial planning, legal services, and other senior services. The Aging and Adult Services agency can assist seniors



### Things You Can Do

- Work to maintain a healthy lifestyle, by eating right and staying active.
- Get financial advice. Try to save money.
- Contact the local senior service agency for help with resources, such as food, clothing, shelter, utilities, etc.
- To get help applying for Social Security, Medicare or Medicaid.
- To get help paying for prescriptions.
- To get information about home care, senior housing, and live- in facilities, such as personal care homes or nursing homes.
- Protect Your Wishes about medical care.
- Have a 'Durable Power of Attorney for Health Care'
- Have a will stating where you want your property to go.

## Where To Find Help

### Local Phone Numbers

Deliver Me (Senior Support Services)	(601) 354-4646
Social Security Administration	(601) 965-5377
City of Jackson Senior Services	(601) 960-0454
Medicaid	(601) 961-4361
Medicare	(601) 965-6273
Aging and Adult Services	(601) 359-4929

Exam



## JHS Network Providers

The JHS Network Providers are a group of health care providers who have agreed to see Jackson Heart Study participants who do not have a regular source of health care and need treatment for abnormal JHS examination results. The JHS Social Worker can assist you to select a provider and to obtain affordable health care. This list is constantly updated, so make sure to contact the JHS Social Worker for assistance in obtaining a referral.

### Internal Medicine

Arhin Akwasi, M.D.	500 W. County Line Rd. Tougaloo, MS 39174 (601) 957-6776
Natalie Brookins- Reddix, M. D.	5903 Ridgewood Rd. Suite 310 Jackson, MS 39211 (601) 899-3310
Zina Lee, M.D.	5429 Robinson Rd Ext. Jackson, MS 39204 (601) 914-0163
Maurice McShan, M.D.	5908 Ridgewood Rd. Jackson, MS 39211 (601) 899-3310
Denzel Robertson, M. D.	1134 Winter St. Jackson, MS 39204 (601) 948-5572
Adesola Shekoni, M.D.	5160 Galaxie Drive Jackson, MS 39206 (601) 713-0890
Nurudeen Shekoni, M.D.	5160 Galaxie Drive Jackson, MS 39206 (601) 713-0890
Robert Smith, M.D.	1134 Winter St. Jackson, MS 39204 (601) 948-5572

Rosie Walker- McNair, M.D.

1600 N. State St.  
Suite #301  
Jackson, MS 39202  
(601) 352-3440

Indira Veerisetty, M.D.

12 Professional Pkwy  
Ridgeland, MS 39157  
(601) 856-2460

## **Family Practice**

Hursie Davis-Sullivan, M.D.

1814 Hospital Drive  
Jackson, MS 39204  
(601) 373-2940

Shunda Garner, M.D.

187 Doctor's Drive  
Pearl, MS 39208  
(601) 939-8921

115 W. Madison St.  
Bolton, MS 39041  
(601) 866-7723

Don Gibson, M.D.

811 Hwy 49 S.  
Richland, MS 39218  
(601) 932-5060

Wesley Granger, M.D.

12 Professional Pkwy  
Ridgeland, MS 39157  
(601) 856-2460

Samuel Okoye, M.D.

4304 Hwy. 80 W.  
Jackson, MS 39209  
(601) 922-4722

Joyce Olutade, M.D.

1815 Hospital Drive  
Jackson, MS 39204  
(601) 815-5700

Andrea Phillips, M.D.	909 Westland Service Drive Jackson, MS 39202 (601) 948-8501
Earnest Rankin, M. D.	2570 Bailey Ave. Suite F Jackson, MS 39213 (601) 366-1693
David D. Richardson, M.D.	1551 E. County Line Rd. Jackson, MS 39211 (601) 957-2273
Harvey Sanders, M.D.	5429 Robinson Rd. Ext. Jackson, MS 39204 (601) 914-0163
	1134 Winter St. Jackson, MS 39204 (601) 948-5572
Selika Sweet, M.D.	4635 Hwy 80 E Pearl, MS 39208 (601) 936-3833
Cassandra Thomas, M.D.	514C E. Woodrow Wilson Jackson, MS 39216 (601) 981-7198

## **General Practice**

Oliver Cunnigen, M.D.	1134 Winter St. Jackson, MS 39204 (601) 948-5572
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## Specialty Clinics

### Cardiology

Myrna Alexander, M.D.

971 Lakeland Dr., Suite 850  
Jackson, MS 39216  
(601) 981-8543

Tellis Ellis, M.D.

971 Lakeland Dr., Suite 850  
Jackson, Ms 39216  
(601) 981-8543

Richard Rayford, M.D.

971 Lakeland Dr., Suite 850  
Jackson, Ms 39216  
(601) 981-8543

Malcolm Taylor, M.D.

971 Lakeland Dr., Suite 850  
Jackson, MS 39216  
(601) 981-8543

### Gastroenterology

Mark Wilson, M.D.

1421 North State St. Ste. 203  
Jackson, MS 39202  
(601) 355-1234

### Nephrology

Gary Davis, M.D.

5903 Ridgewood Rd, Ste 340  
Jackson, MS 39211  
(601) 899-3340

Hollye Johnson, M.D.

5903 Ridgewood Rd, Ste.340  
Jackson, MS 39211  
(601) 899-3340

Tunde Olutade, M.D.

5903 Ridgewood Rd, Ste 340  
Jackson, MS 39211  
(601) 899-3340

**Podiatry**

Willie James Lewis, DPM

128 Poindexter St.  
Jackson, MS 39203  
(601) 355-0026

Robert Woodruff, DPM

3855 Azalea Drive  
Jackson, MS 39206  
(601) 366-7063

**Pulmonary**

Obie McNair, M.D.

1134 Winter St.  
Jackson, MS 39204  
(601) 948-5572

Joyce Wade, M.D.

1151 N. State St. #301  
Jackson, MS 39202  
(601) 352-0041

**Urology**

Ronald Davis, M.D.

971 Lakeland Drive, Ste. 315  
Jackson, MS 39216  
(601) 982-0982

Lionel Frasier, M.D.

971 Lakeland Drive, Ste. 315  
Jackson, MS 39216  
(601) 982-0982

Felix Gordon, M. D.

971 Lakeland Drive, Ste. 315  
Jackson, MS 39216  
(601) 982-0982

# Community Healthcare Resources

## Resources in Hinds County for the Uninsured

Health Care Referrals for uninsured/underinsured participants, who are residents of Hinds County, are made to the Hinds County Health Alliance (HCHA). The HCHA located at the Jackson Medical Mall, is a nonprofit organization that assists Hinds county residents obtain health care. The Hinds County Health Alliance coordinates care services that include: 1) primary care at a discounted cost, 2) prescription drug assistance, 3) transportation assistance, and 4) case management. The address and phone number is:

**Hinds County Health Alliance**

350 W. Woodrow Wilson, Suite 615  
Jackson, MS 39213  
(601) 362-3010

**Jackson Hinds Comprehensive Health Center**

3502 W. Northside Drive  
Jackson, MS 39213  
(601) 362-5321

**UMC Adult Medicine Clinic**

Jackson Medical Mall  
350 W. Woodrow Wilson Blvd.  
Jackson, MS 39213  
(601) 815-1420

**Hinds County Health Department**

350 W. Woodrow Wilson Drive, Suite 411-A  
Jackson, MS 39213  
(601) 364-2666

### *Healthcare Resources in Madison County for the Uninsured*

Health Care Referrals for uninsured/ under-insured participants who are residents of Madison County are made to G.A. Carmichael Clinic located in Canton. The type of assistance offered includes: medical, dental and eye exams, pharmacy, lab work, WIC, diabetic foot care, immunization, medical screening, and transportation. The address and phone number is:

**G.A. Carmichael Clinic**

1668 Peace St.  
Canton, MS 39046  
(601) 859-5213

**Madison County Health Department**

317 N. Union Street  
Canton, MS 39046  
(601) 859-3316

### *Healthcare Resources in Rankin County for the Uninsured*

**Family Health Care Clinic**

4635 E Hwy 80  
Pearl, MS 39208  
(601) 933-2500

**Family Health Care Clinic**

1551 W. Government St.  
Brandon, MS 39042  
(601) 825-3163

**Rankin County Health Department**

100 Tamberlin St.  
Brandon, MS 39042  
(601) 825-2141

## HEALTH ASSOCIATIONS

Alzheimer's Association  
877-525-4357

American Red Cross  
601-353-5442

American Cancer Society  
601-362-8874

Arthritis Foundation, MS Chapter  
601-206-7726

American Diabetes Association  
601-932-1118

Diabetes Foundation of MS, Inc.  
601-957-7878

American Heart Association  
601-321-1200

Epilepsy Foundation of MS  
601-936-5222

American Lung Association  
601-362-5453

Lupus Foundation of America  
601-366-5655

American Parkinson's Disease Association  
800-223-2732

Muscular Dystrophy Association  
601-936-6862

### Community Support Services

Catholic Charities 601-355-8634  
Mon. – Fri. 8:30 a.m. – 5:00 p.m.  
Services include: homemaker and  
caregiver services.

Department of Human Services  
601-362-9892  
477 Medgar Evers Blvd.  
Jackson, MS 39213  
Services provided: public assistance

### Clinton Community Christian Corporation

601-924-9436  
Services Provided: Group Meals, Home  
Delivered Meals, Transportation  
Meal Site: 2001 Northside Dr., Clinton

### Deliver Me Senior Support Services

601-354-4646  
Services Provided: Financial Assistance for  
medicine, eyeglasses, food, etc.

### Madison County Meals on Wheels

601-859-5747  
Service provided: Meal delivery to seniors

## HOSPITALS

### Hinds County

**Baptist Medical Center**  
1225 North State St.  
Jackson, MS 39202-2002  
601-968-1000

**St. Dominic**  
969 Lakeland Drive  
Jackson, MS 39216  
601-200-2000

**Central MS Medical Center**  
1850 Chadwick Drive  
Jackson, MS 39204  
601-376-1000

**University Medical Center**  
2500 N. State Street  
Jackson, MS 39216  
601-984-1000

**River Oaks Hospital**  
1030 River Oaks Drive  
Jackson, MS 39208  
601-932-1030

**Women's Hospital At River Oaks**  
1026 Flowood Drive  
Jackson, MS 39232  
601-932-1000

### Madison County

**Madison County Medical Center**  
Hwy 16 East  
Canton, MS 39046  
601-898-4049

### Rankin County

**Rankin Medical Center**  
350 Crossgates Blvd.  
Brandon, MS 39042  
601-825-2811

## **SUPPORT GROUPS**

### **Alzheimer's Support Groups**

University Medical Center Alzheimer's Support Group  
601-815-8498

VA Hospital Alzheimer's Support Group  
601-362-4471 ext. 11038

### **Cancer Support Groups**

Cancer Masters First Baptist Church  
601-949-1949 or 601-939-7251

Central MS Medical Center  
601-376-1172

Chapel of the Cross General Cancer  
Support Group 601-856-2593

C.O.P.E (Cancer Outreach Provides Empathy)  
Methodist Medical Center  
601-376-1163

Leukemia Society Support Group  
601-948-6262

MS Baptist Medical Center Support Groups  
601-948-6262

St. Dominic Cancer Support Group  
601-364-3979

### **Caregiver Support Groups**

Baptist Adult Day Care  
601-956-7794

St. Dominic Caregivers Support Group  
601-200-6468

**Grief Support Groups**

Bereavement Education/ Support Group  
Hospice Ministries 601-989-1053

Friends in Crisis  
601-936-9492

Healing Hearts  
First Baptist Church 601-949-1949

St. Dominic Behavioral Health Services  
601-200-3110

**Literacy Support Groups**

Jackson Program For Adult Readers  
601-987-3695

Literacy Programs Governor's Office of Literacy  
601-432-6591

Reading Help Program  
601-981-359-3778

**Stroke Support Groups**

Stroke Support Group  
Methodist Rehabilitation Center  
601-981-2611

**Self Help Groups**

Alcoholics Anonymous  
(601- 982-0081

Gamblers Anonymous  
601- 471-4333

Overeaters Anonymous  
601- 957-0321

Narcotics Anonymous  
601- 949-9499

## Prescription Resource Information

The Medicare Discount Card (1-800-633-4227) is only one of a number of programs available to help Medicare beneficiaries receive discounts on the price of their prescription drugs. Other Drug Discount Cards may be used as well.

Some of the other Discount Drug Cards are:

- Share Card (Pfizer) 1-800-717-6005
- Lilly Answers Card (Lilly) 1-877-795-4559
- Care Card (Novartis) 1-866-974-2273
- Orange Card (GlaxoSmithKline) 1-888-672-6436
- The Merck Assistance Program 1-800-727-5400
- The Nordisk Patient Assistance Program 1-800-727-6500
- Bayer Patient Assistance Program 1-800-998-9180

Discount Drug Cards to help the uninsured/underinsured are:

- Partnership for Prescription Assistance 1-888-477-2669
- Together RX Access Program 1-800-444-4106
- My Free Medicines 1-800-620-7620

In addition, there are some web sites dedicated to helping patients in getting the medicines they need. Some of those web sites are:

- [www.pparx.org](http://www.pparx.org)
- [www.HelpingPatients.org](http://www.HelpingPatients.org)
- [www.rxassist.org](http://www.rxassist.org)
- [www.rxhope.com](http://www.rxhope.com)
- [www.benefitscheckuprx.org](http://www.benefitscheckuprx.org)
- [www.needymeds.com](http://www.needymeds.com)
- [www.Qdrug.com](http://www.Qdrug.com)
- [www.themedicineprogram.com](http://www.themedicineprogram.com)
- [www.resourcesforseniors.com/prescript.html](http://www.resourcesforseniors.com/prescript.html)
- [www.myfreemedicine.com](http://www.myfreemedicine.com)
- [www.together-rx.com](http://www.together-rx.com)

JHS participants can work with their health care provider and local pharmacies to determine which discount drug card best suits their needs.

## **Acknowledgements**

This Wellness Guide was adapted from the Wellness Guide Project, School of Public Health, University of California at Berkeley, Berkeley, California.

Jackson Heart Study (JHS)

Manual 8

CT Scan Site  
Manual of Operations

Visit 2

Version 1.0

January 12, 2007

For Copies, Please Contact:

Jackson Heart Study Coordinating Center  
Jackson Medical Mall  
350 W. Woodrow Wilson Drive  
Jackson, MS 39213



## 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 and 4 describe the operation of the Cohort Procedures, Blood Pressure and Events Ascertainment Components of the study. Detailed Manuals of Operation for specific procedures, including those for Blood Pressure and Quality Assurance, make up Manuals 3 and 5. The Data Management System is described in Manual 6. The Central Laboratory and Specimen Repository is described in Manual 7. Manual 8 is designed to provide volumetric CT image data for measuring coronary and abdominal aortic calcified plaque as well as measuring body composition in the abdomen.

### JHS Study Protocols and Manuals of Operation

MANUAL	TITLE
1	General Description and Study Management
2	Cohort Component Procedures
3	Blood Pressure
4	Morbidity Mortality Classification Manual /Cohort Events Ascertainment
5	Quality Assurance
6	Data Management
7	Central Laboratory and Specimen Repository Collection and Processing
8	Computed Tomography (CT) Scan
9	MRI Forthcoming



## Manual 8 CT Scan

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## 1. Introduction

The Jackson Heart Study (JHS) is a single-site prospective epidemiologic investigation of cardiovascular disease (CVD) among African-Americans from the Jackson, Mississippi metropolitan area. This study represents an expansion of one of the study sites of the [Atherosclerosis Risk in Communities \(ARIC\) Study](#) which included four geographically diverse communities in the U.S. (northwestern suburbs of Minneapolis, Minnesota; Washington County, Maryland; Forsyth County, North Carolina; and the city of Jackson, Mississippi).

### TRAINING OF TECHNOLOGISTS

Dr. Carr has performed on-site training January 10-12, 2007. The training sessions included didactic, small groups and hands on training. Following the course the technologists will complete the certification test and observe CT scans of participants and QC procedures. They will leave with a comprehensive understanding of the CT protocol. It is anticipated that upon completion they will be "Provisionally Certified". They will have knowledge and training material for the other technologists at their site. During the pilot phase the technologists will complete the 3 certification exams on their CT system. Each of these scans will also be rated on technical quality criteria and immediate feedback will be provided. These exams will be reviewed by the CTRC personnel and either further training for full certification will occur.

## 2. CT Exam Protocol and Procedures

### 2.1 Field Center Scheduling

The JHS local investigators will arrange details of scheduling participants for the CT exam. Scheduling details will be mutually agreed upon between the CT scanning center and Field Center. ***A Field Center interviewer/scheduler will be responsible for explaining and obtaining consent for the CT examination including pregnancy screenings.*** Participants will be scheduled for a certain date and time, and escorted to the CT scanner. The Field Center will take the participant and ***CT Scan Worksheet*** (see Appendix B) which identifies the participant by name. The CT Technologists need to have the individual's real name to confirm identity. The CT Scan Worksheet provides the detailed information required by the CT scanning sites for labeling and performing the CT exam (See Appendix B).

Required information for the CT scheduling form includes the participant's name (for scheduling and greeting purposes only), participant's weight (as recorded at the clinic visit), and date of birth, JHS study ID and a secondary identifier called the ***"alpha code"*** which will replace the participant's real name.

### 2.2 CT Exam Overview

The CT examination is designed to provide volumetric CT image data for measuring coronary and abdominal aortic calcified plaque as well as measuring body composition in the abdomen. The exam consists of scout images and one ECG gated series of the entire heart and a series through the lower abdomen. On average, 15 minutes of participant time will be spent within the CT scan suite; this includes instructions, setup and imaging. In rare cases, the exam may require 20 minutes. In many cases, the examination will be completed in less than 10 minutes. Participants will have ECG electrodes attached (according to your vendors recommendations) for cardiac gating and be instructed as to a standardized breath holding instructions.

**Figure 1 CT Exam – Detail of CT scan Series:**

Series	Description	No. of images	Scan time	ECG gating
Series	Description	No. of images	Scan time	ECG gating
1	Scout	2	< 8 sec	no
2	Heart / Coronary arteries	50	15 sec	yes
3	Lower abdomen /L3-S1	44	20 sec	no

<sup>1</sup>Scout images will consist of a frontal and lateral low energy 2D scanogram when possible

<sup>2</sup>Duplicate scans will not be obtained of the coronary circulation since previous studies have demonstrated minimal add value.

<sup>3</sup> Additional reconstructions will be made using a display field-of-view (DFOV) of 50 cm for the measurement of subcutaneous fat. These require no additional radiation exposure and simply represent additional copies of the already acquired data.

### 2.3 Entering Participant Identifying Information

The CT scanners to be used in this study store demographic, detailed scan technical information and the raw image data in the standard DICOM file format. Participant identifying information will be encrypted at each CT site for the following reasons: Safeguard participant confidentiality.

Comply with federal requirements for medical information, Health Insurance Portability and Accountability Act of 1996 (HIPAA).

Provide positive and redundant participant identification for CT image files now and in the future. The data coordinating system has assigned a unique study identification number for each participant. The exact method will be decided upon by the coordinating center and CT scan site. Below is a method we have successfully used in prior studies.

*The Jackson Heart Study - study identification number ("J" + 6 digits) will be entered in the field on the CT scanner where the local medical record numbers is typically placed. An "alpha code" (5 letters) will be entered in the name field. The participant's weight, date-of-birth, ordering physician (Dr. Herman Taylor, interpreting physician (Dr. Mike Doherty), will be entered on the demographics page of the GE Lightspeed Pro 16 after pressing the "New Exam" button.*

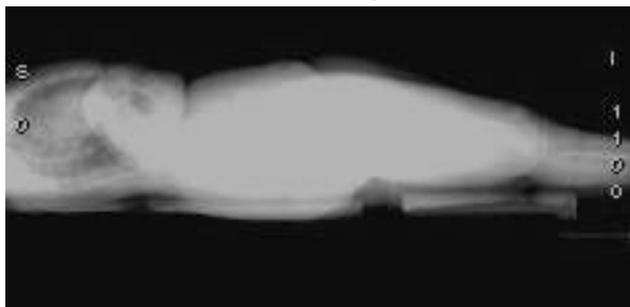
\*\*\* It is very important that you enter your technician ID initials on this screen. This may vary between CT vendors, but most systems have a field for entering the CT technologists name/initials. Please type your tech ID in this location. If you do not have a field for this on your CT scanner please call the CTRC for additional help in resolving this issue.

#### Example CT Data Entry:

Name	BJDEC (Exact format TBD)
ID number:	J123456
Date of Birth	03 MAR 1947
Technologist	JJC

Gender	Male
Weight	175
Ordering Physician	Dr. H. Taylor
Interpreting Physician	Dr. M. Doherty
History	JHS research CT exam

The series number and time stamp on each CT image will ensure proper identification of the respective series of the coronary and abdominal aorta CT scans. Scan technical data (site, CT scanner, kV, mA, fov, slice thickness, spatial resolution, kernel etc.) are automatically stored within the DICOM header as part of the DICOM standard for each image recorded and tracked by the CTRC.



stored within header as part standard for file and will be tracked by the

## 2.4 Pre-CT Exam Activities

Subjects weighing more than 350 lbs (~160 kg) will be excluded from the CT exam. This exclusion is secondary to technical difficulties related to imaging individuals of this size and greater.

**Pregnancy Screening:** The field center personnel will ask women if they have the potential to be pregnant and complete pregnancy screening process as detailed in the Clinic Exam procedures.

### CT inclusion criteria:

Enrolled in JHS study, eligible for the CT exam with signed consent obtained.  
Pregnancy screen completed if applicable

### CT exclusion criteria:

1. Weight greater than 350 lbs (~160 kg).
2. Pregnant or pregnancy status unknown
3. Female participant < 40 years of age
4. Male participant < 35 years of age

## 2.5 Participant Preparation at the CT Scan Site

### The CT Tech:

1. Reviews the CT Scan Worksheet with the JHS Study ID and alpha code.

The technologist will instruct the subject on the importance of breath holding and immobility during scanning. The technologist will attach 3 electrocardiography electrodes under the right and left clavicle and on the left side of the thorax near the axilla (to maximize ECG signal) or as instructed by your equipment provider.

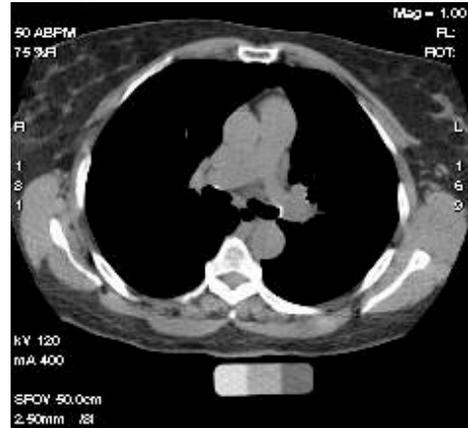
## 2.6 Positioning the Participant and Calcium QCT Phantom on the CT couch

The participants will be positioned for the study feet first. The rectangular 3 sample calcium calibration QCT Phantom (Image Analysis, Columbia, KY) will be placed underneath the participant and is long enough that it can extend from the top of the chest to the sacrum (or tail bone). The phantom will not need to be repositioned between the

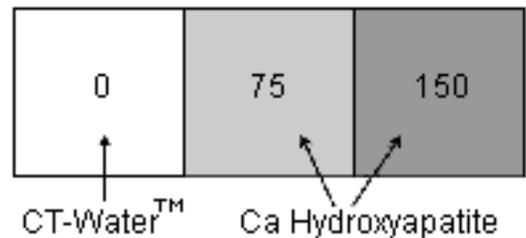
cardiac and abdominal CT scans. The QCT phantom will be inside the special padded cushion to make it comfortable for participants. The long axis of the QCT phantom should parallel the participant's spine. The phantom is made of tissue equivalent plastic with rods of hydroxyapatite of known radiographic density. The density is demonstrated in the figure below:

## 2.7 Scout Image of the Thorax

The technologist will instruct the participant about the importance of holding still and holding their breath when instructed during the CT exam. The standard breathing instructions, (at end-inspiration), have been pre-recorded using the auto-voice feature. This standard voice will be used during the scouts, cardiac and limited scan of the abdomen. Two scout images of the thorax (Frontal and lateral scout images, ka scanograms or tomograms) which will include the entire chest, abdomen and pelvis will be obtained. (see adjacent figures).



The technologist performing the scan will check participant centering and position of the Calcium CT Calibration Phantom. The technologist will then choose the start position for just above the carina of the trachea. The end location of the volume acquisition will be beyond the diaphragmatic aspect of the heart so that the entire coronary arterial system will be imaged. The CT couch will be moved to the start position. The technologist will confirm correct positioning of the calcium phantom on the scout image, correct prescribing of the start and end scan locations and appropriate ECG gating and if all are acceptable will then precede with scan.

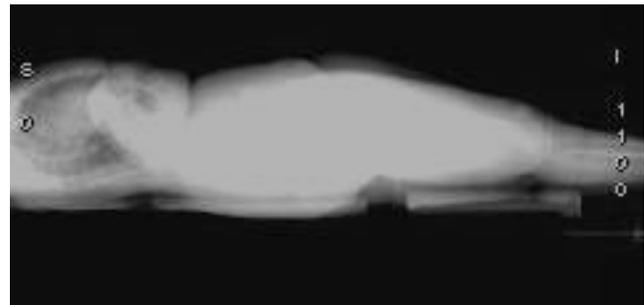


## 2.8 Heart 1 CT Scan Series

Scanning procedure for cardiac gated CT scans of the coronary arteries are based on the standard protocols developed as part of the NHLBI's MESA and CARDIA studies (Carr et. al. Radiology 2005; 234(1):35-43.) . To ensure complete coverage of the entire heart, a minimum of 10.5 cm of image data in the z direction (head-to-foot) will be acquired with each scan. This coverage results in 44-60 slices depending upon the length of the heart.



The heart scans will be reconstructed centered on the heart using a



display field-of-view of 35 cm. This will include the Calcium QCT phantom within the images as well as the majority of the lungs.

\*\*\*\* One of the CT quality factors is inclusion of the phantom on the cardiac CT images – the technologist should confirm that the entire QCT phantom (i.e. all four cylinders) are visible on each slice – if not reconstruct the images altering the left-right or anterior-posterior positioning while maintaining a 35 cm DFOV to include the entire phantom. \*\*\*\*\*

Technical Parameters for each CT system is in Appendix C.

### Participant Weight and the CT exam:

*Participants weighing more than 350 lbs (~160 kg) will be excluded from the CT exam. As individuals become larger more X-ray photons are stopped or attenuated by their tissue. This means that there are fewer photons making the trip through the participant to make an image. This results in decreased image quality. To compensate, the tube current (or mA) will be adjusted upwards (25%) for participants who weigh more than 100 Kg (220 lbs.) at their clinic visit. This is why clinic personnel must record weight on the CT completion form, in addition the CT tech must append the weight after the name.*

This adjustment, although imperfect, will maintain a more constant signal-to-noise ratio (or photon flux) across participants of varying weights and result in improved image quality and calcium measurement. Note that this along with all the additional technical and demographic information including individual time stamps for the scan, scan series and individual image is recorded in the DICOM header which is part of each image and will be available on the CT image library of all the JHS studies as part of our quality control procedures.

### Reconstruction Parameters:

The following technical parameters should be entered into a memorized protocol on each CT system, which should greatly facilitate protocol compliance. All series will be performed using the large scan field-of-view. This may also be referred to as the “body” as opposed to the “head” scan field-of-view. The technologist will reconstruct using a display or reconstruction field-of-view of 35 cm (or 350 mm). **Why are we scanning the heart with a 35 cm fov?** By reconstructing with a 35 cm fov we insure that the QCT phantom is included in the reconstructed images. **It is very important when prescribing the scan to make sure that the anterior-posterior center is such that the entire phantom is included in the image. You will have to center AP behind the heart on individuals with very large chest. If while reviewing your images you see that the phantom is partially clipped off, reconstruct the series with the appropriate AP offset. Be sure to check this on all studies and if necessary reconstruct to include the phantom on the images.** The standard reconstruction kernel will be used for the two cardiac series. For the cardiac series, the 240 degree (cardiac CINE) segmented scan reconstruction algorithm will be used.

**Additional Reconstructions:** Two additional reconstructions of the same scan data will be made for measurements of surrounding tissues.

1. “Hi-res Recon” Thin slice reconstruction at 1.25 mm – these images allow better definition of potential plaque by using thinner slices and may be useful for future analyses related to plaque characterization.
2. “Max 50 cm Recon”. These images can be used along with the scout in future studies to obtain information about body composition with attention directed to the chest wall, muscles and fat.

### Figure 2 - Table CT Image Reconstruction Parameters

Series	Scan FOV	Display FOV	Kernel	Recon. type
Heart 1	Large / Body	350 mm	GE=standard Siem=b30f Imatron=Sharp	240° (partial) <input type="checkbox"/> quick scan

## 2.9 Breathing Instructions

All CT scan sequences will be performed with suspended respiration and a single breath hold. The cardiac scan series will require participants to suspend respiration a variable amount of time, ranging from 10 to 15 seconds, depending upon the combination of heart rate and heart length. The technologist will instruct the participant as described above and then a standardized digitally recorded voice will provide breathing instructions. Breathing will be suspended at end inspiration to depress the diaphragm and liver for improved imaging of the heart.

### Standardized Script for breathing instructions:

"Take a deep breath in... <5 sec. pause>  
 "Blow it all the way out... <5 sec. pause>  
 "Take a deep breath in... <5 sec. pause>  
 "Blow it all the way out... <5 sec. pause>  
 "Take a deep breath in and hold your breath .....

<15 second scan acquisition>  
 "Breathe and relax"

Though total imaging time will be less than 15 seconds, it will require about 5 to 7 minutes to complete.

## 2.10 Limited Lower Abdominal Aorta CT series (L3-S1) Scanning Procedures for the Aorta:



The scanning procedure described below will require approximately 5-10 minutes of the participant's time. The technologist *proceeds directly to prescribing the abdominal aorta scan from the initial scout image*. The abdominal aorta protocol requires a lateral scout image to identify the disk spaces and vertebra of the lumbar spine. The technologist will identify the three lower lumbar vertebra and scan from mid L3 through S1. (See adjacent figure with the start and end locations designated by the thick red lines).

**Helical Scan Acquisition of the Abdominal Aorta:** The abdominal aortic scan will be prescribed graphically based on the location of L3 and S1 vertebra from the lateral scout image.

*Why are we using S1 as at landmark?* The Lumbosacral junction is the most easily identifiable and consistent landmark identified in the abdomen/pelvis. Our objective is for you to scan the entire aspect of the two lowest lumbar vertebra, typically L4 and L5. The protocol is designed to avoid imaging the true pelvis where in females the ovaries are located. We performed a study and have determined that 150 mm superior to S1 is above the renal arteries in all participants in our sample population. Other landmarks like the top of the diaphragm and counting the vertebral levels are variable between people and we believe are less reproducible. The CT scanners will be set at the technical parameters specified in the table below. Like in the cardiac scan we will adjust up the mA for those individuals that weigh more than 220 lbs.

**Figure 3 CT Technical Parameter for the Abdominal Aorta Scan:**

CT System	Mode	FOV	Pitch <sup>1</sup>	Kernel /recon	KV	mA	time	mAs <sup>2</sup>
GE LightSpeed Plus (WFU/MGH/UT)	Helical	35 & 50 cm	4i 3:1 HQ	Std /□full	120	300 or □51 5	0.5 s	<del>200</del> 150

<sup>1</sup>Note pitch on multidetector CT systems have been described with competing conventions by different vendors, thus for the Siemens & Marconi systems the pitch can be explained as 3:1 [7.5 mm table travel per rotation over a 2.5 mm slice collimation] or alternatively as 0.75:1 [7.5 mm table travel per rotation over a beam collimation of 10 mm (i.e. in 4 slice mode 2.5 mm x 4 = 10 mm beam collimation)].

<sup>2</sup>mAs for the Abdominal Aorta scan was reduced (decreasing participant exposure) in May 2002 after review of the initial images from the pilot / vanguard phase of the study.

Abdominal Aorta CT scan series will be acquired in the helical mode, full or 360° recon mode with a 2.5 mm slice collimation and a scan pitch of 3:1 or 0.75:1 depending upon the definition of pitch chosen by the CT scanner manufacturer for a particular system. A detailed definition of pitch is provided in the note below the table on technical factors. The CT Reading Center will confirm through the quality assurance scans performed on phantom objects that all protocol parameters are set appropriately. Human and software will check each pilot and participant scan for the key technical parameters related to image quality and radiation exposure to insure protocol compliance. Scans will be obtained during suspension of breathing. Technologist should instruct participants and use the same breathing script as used for the heart 1 and heart 2 series.

#### **Abdominal Aorta Reconstruction Parameters:**

The technologist will use the 35 cm field of view and the standard reconstruction kernel at 2.5 mm slice thickness. In addition, a retrospective reconstruction into a 500 mm (50cm) display fov will be performed so that we include the entire body in this set of images and an additional reconstruction at the 35 cm DFOV will be made using 1.25 mm slice thickness. Because of significantly reduced motion of the abdominal aorta relative to the coronary arteries, the full or 360 degree reconstruction rather than the partial scan reconstruction algorithm will be used for the aorta scans. Cardiac gating is not required and will not be used in imaging the abdominal aorta. The images will be obtained with participant's holding their breath and using the standard breathing instructions (autovoice).

### 3.0 Radiation Dose Estimates for the JHS CT EXAM

#### 3.1 Introduction

The CT exam involves the use of ionizing radiation (X-rays) to generate images of the participants, which are then analyzed to provide quantitative information for scientific investigation. The level of exposure utilized in the CT exam is on the same magnitude as that typically used in diagnostic imaging. The next section describes the potential risks of exposure to low levels of radiation and how this exposure compares to the average natural exposure of 3.6 mSv annually. The radiation exposure in this CT exam is well below the threshold for any observable direct dose related effects of ionizing radiation. Therefore the concerns of low-level radiation exposure for participants are the potential for (1) hereditary defects, (2) developmental defects for exposure of a fetus/embryo in utero and (3) cancer induction. The CT Exam is designed to minimize or eliminate these potential risks. Specifically the following steps have been implemented:

1. To reduce the risk of any radiation induced hereditary effects, the gonads (testes and ovaries) are not directly irradiated in the CT exam.
2. To, in all likelihood, eliminate the potential risk of any radiation induced developmental defects to an embryo/fetus as a result of a research CT exam, female participants who have the potential to be pregnant (i.e. functioning ovaries and uterus) will be required to have a pregnancy test prior to being eligible for an research CT exam. In addition, the true pelvis which contains the uterus and ovaries receives negligible exposure related only to scatter photons since it is not directly imaged in the CT protocol.
3. To further reduce the low risk of any radiation induced cancer, we are using as low a radiation exposure scan as possible to obtain the information necessary to accomplish the goals of this research.

Participants in this study will receive a one-time exposure of less than 6.6 mSv. This level of radiation exposure is equivalent to less than two years of average annual background exposure (secondary to natural and man-made sources of radiation), less than the 7 mSv annual exposure of residents of Denver, Co, and much less than the 50 mSv annual exposure allowed for radiation workers.

#### 3.2 Radiation Exposure and Dose Calculation by Exam Component

As specified in the preceding sections of this MOP, participants will have a CT exam that consists of the following components:

Series	Description	No. of images	Scan time	ECG gating
Series	Description	No. of images	Scan time	ECG gating
1	Scout	2	< 8 sec	no
2	Heart / Coronary arteries	50	15 sec	yes
3	Lower abdomen (L3-S1)	44	20 sec	no

The heart scan is comparable to those currently in use in both the NHLBI-funded CARDIA and MESA studies. The lower abdomen scan is less coverage and thus lower exposure than the scan of the abdomen that is used in the NHLBI MESA, FHS-SCAN and Framingham Heart Studies.

Participants undergoing the Entire CT exam will have the following:

1. Peak radiation dose of approximately 2.5 rad (25 mGy) at the peripheral position (essentially the skin) of the patient.
2. Highest doses to radiosensitive organs are approximately 0.65 rad or 6.5 mGy) to the lungs and slightly less than the skin dose (1.25 rad or 12.5 mGy) to the female breast.
3. An estimate of effective dose would be 3.5 to 3.9 mSv for the entire CT exam and is itemized by scan series below:

**Figure 4 – Summary of Effective Dose Estimates**

Sequence	Description	Deff [mrem]	Deff [mSv]
1	Scout	NA	NA
2	Heart / Coronary arteries	150 to 190	1.5 to 1.9
3	Lower abdomen /Abdominal Aorta	200	2.0
<b>Total</b>		<b>350 to 390</b>	<b>3.5 to 3.9</b>

Note: Dr. McNitt-Gray, expert in medical physics and imaging states that the radiation exposure related to the low energy scouts / topograms are inconsequential in dose compared to the above series, as a result they are not detailed in the above table.

These estimates of effective dose can be compared to the annual average effective dose from background radiation, which is 3.6 mSv/year and the annual whole body effective dose that a radiation worker (medical personnel, nuclear chemist or other radiation worker) is allowed on an annual basis (50 mSv/year).

### 3.3 Detailed Discussion of Dose Estimates

#### Exam description

The CT exam will consist of the series of scans described above with repeat series (total of 2) through the coronary arteries using standard techniques.

#### Technical factors for each series used in the dose estimates

##### 1. Coronary Scans 1 and 2 (which are identical sequences)

Using the GE LightSpeed multidetector scanner, the standard protocol will be employed:

- 8 x 2.5 mm collimation (8i axial) mode with 20 mm table increment (contiguous scans)
- Prospective EKG gating; x-ray beam is only on 2/3 of a scan rotation
- 120 KVp, 400 mA, 0.26 second scan time = 104 mAs  
Scan Coverage: 2 cm below the carina extending to the base of the heart.

#### Peak Radiation Dose

Estimated radiation dose (CTDI) is reported below using the technical factors described above for each sequence. These values were calculated based on measured values using a standard test object (CTDI 32 cm-diameter body phantom) in comparable scanners (GE LightSpeed) at UCLA:

For one prospectively ECG gated low dose heart scan the peak dose is 12.5 mGy (1.25 rad).

### 3.4 Effective Dose Calculations

Effective Dose is the sum of the weighted absorbed doses for all irradiated tissues, where the weighting factors represent the different risk of each tissue to mortality from cancer and hereditary effects. These weighting factors are higher for the gonads and lower for less sensitive organs (such as the extremities).

These estimates were obtained by finding the average dose to each radiosensitive organ (based on the phantom radiation dose measurements described above and anatomical coverage for each sequence). The weighting factors were then applied according to the description in the International Council on Radiation Protection Report 60. These estimates were performed for each sequence and then summed to obtain the results for the entire exam. The results are summarized in table 2 above.

For each coronary scan, the estimated effective dose is estimated to be 1.5 mSv (150 mrem) for men and 1.9 mSv (190 mrem) for women. The difference is that the breast is irradiated in this scan, and because the breast dose carries a weighting factor of .05 of the total effective dose, the effective dose is higher for women. A similar effective dose was calculated for the abdominal scan used in FHS-SCAN and MESA studies of 2.7 mSv for both women and men is noted since neither gender's gonads are directly irradiated. In this protocol the majority of the abdomen was imaged. In the Jackson Heart Study we are reducing the scan coverage by 30% and removing the liver, kidneys and marrow of the upper spine from the imaged region. Thus the a conservative estimate of the effective dose for this more limited scan area is 2.0 mSv.

For the entire exam, the estimates of effective dose range 3.5 mSv for men to 3.9 mSv for women. These values would compare with 3.6 mSv annual background exposure in the U.S to radiation and the 50 mSv whole body exposure annual limit for radiation workers.

**Therefore, the total effective dose from these scans for an average Jackson Heart Participant is significantly less than that allowed for radiation workers on an annual basis and is equivalent to about 1.1 times annual background exposure. However, because these estimates are based on population averages, these estimates should not be taken to provide an estimate of risk for any individual patient.**

### 3.5 Informing Participants of Radiation Exposure:

To provide participants with a concise and understandable explanation of the radiation involved with the CT exam we have chosen to present the effective dose. The effective dose estimates the exposure by organ irradiated and allows the values to be compared directly with the annual exposure to natural sources of radiation (3.6 mSv) and the annual allowance for radiation workers(50 mSv). We believe that the alternatives of (1) simply providing a number out of context or (2) comparing the dose to other medical procedures, while informative to scientists and healthcare professionals, is less informative to the lay public. The following language is recommended to the field centers for informed consent concerning the CT exam. Local requirements or standard language may require modifications as appropriate.

Recommended Language for Informed Consent

**The estimated amount of radiation (effective dose) the average participant in this study will receive is less than 4 mSv. This amount of radiation exposure can be compared to the amount of radiation exposure you get each year from natural and man made sources which is 3.6 mSv (average annual background exposure to radiation in the U.S.). The actual amount you receive for the whole CT exam depends on several factors such as how big you are and if you are a man or women. People who have jobs in which they work with radiation have a yearly limit of 50 mSv. This CT exam is about 8% of the yearly amount of radiation exposure a worker is allowed to receive each year.**

We believe the above language accurately and conservatively presents the information related to radiation exposure with the research CT exam and will allow our participants and potential participants to make an informed decision about involvement in this study.

The investigators are aware that local review and approval of the CT protocol, as for other aspects of the study, must be made through the appropriate local Investigational Review Boards (IRB). In some cases additional review by radiation safety committees may be required. The CT Reading Center will provide assistance and the material contained in the manual of operation to the field center principal investigator and imaging investigator to facilitate and enhance the process as requested.

#### **4.0 CT Scan Site Procedures for Secure Networking of CT image to Wake Forest University CTRC**

The JHS CT Data Acquisition Center is located in the Jackson Medical Mall. The specific CT system is a GE Healthcare Lightspeed 16 Pro. The standardized protocol has been stored on the CT system during Dr. Carr's training visit and this protocol includes automatic routing from the CT scanner to the Wake Forest Univ. CTRC using secure networking protocols over the internet. The system uses Medical Imaging Resource Center (MIRC) software developed with support from the Radiological Society of North America (<http://www.rsna.org/mirc/>) in an open source environment. The software has been specifically designed to meet the needs of clinical trials and has been incorporated in the National Cancer Institute's CA-BIG project. Dr. Carr has collaborated in the development of the clinical trials software applications. A computer with the MIRC Field Center software has been installed in the CT control room at the Jackson Medical Mall. Upon completion of each exam the images are automatically networked to the MIRC PC. The MIRC Field Center System is set up to receive DICOM images from imaging modalities and forward these images to Wake Forest University's research PACS. In order to ensure HIPPA compliance, this system is configured to de-identify patient health information before forwarding the images. Furthermore, the forwarding mechanism is based on the secure HTTP protocol using SSL networking. The cryptographic keys use the RSA/DES3 algorithms and are 2048 bits long and provide industrial strength security. The CTRC can receive images continuously and simultaneously from the JHS CT scanner 24 hours a day, 7 days a week. In addition the images are archived redundantly to prevent loss of image data during the transfer (CT scanner holds a temporary copy, UMMC sends the images to two independent PACS archives, the MIRC field center applications maintains a copy of all images until received successfully at WFU CTRC and once received we have extensive backup procedures detailed in the CTRC MOP.

### **5. CT Scanner Quality Assurance Procedures**

#### **5.1 CT Scanner Certification and Quality Assurance**

The CT Scanners will complete a certification process prior to the pilot exam. During this process measurement of scan quality will be obtained concerning spatial resolution and contrast resolution with particular attention directed to the calibration of CT numbers.

### **CT Certification Process:**

1. CT images will be sent to the CTRC to provide format of DICOM header and additional CT scanner specific information.
2. CTRC will ship the Cardiac CT phantom (QRM-Germany) to the site and a series of scans of this phantom will be obtained (This was completed on Jan. 11, 2006).
3. The QCT phantom & torso phantom to be used throughout the exam will be scanned according to protocol (This was completed on Jan. 11, 2006).

The purpose of the CT scanner certification process is to validate the CT scanners ability to measure the known amounts of simulated calcified plaque contained in the standard QCT phantom (Image Analysis, Columbia, KY). We will then use this information to fine-tune the CT protocol for the CT system. It will also allow us to ensure comparability to other CVD disease research studies that use CT such as MESA and the Framingham Heart Study.

### **CT Calibration**

Calibration to Air (Baseline, then daily) - An initial baseline followed by daily scans will be obtained. This calibration is part of the daily scanner start-up routine. These procedures will follow the manufacturer's recommended procedure.

#### **Calibration to Water (Baseline)**

An initial baseline calibration will be obtained and analyzed using a water phantom. These procedures will follow the manufacturer's recommended procedure and will include zeroing and calibrating the scanner unit.

#### **Calibration to Calcium (Baseline, 1st and 15th of each Month)**

Each CT scanning site will be provided a standardized Calcium QCT Calibration Phantom which includes a Torso QA phantom for scanner calibration (Image Analysis Inc, Lexington, KY). The center plug of the Torso QA phantom contains a region with a known concentration of calcium hydroxyapatite (100mg/ml). The Calcium QCT Calibration phantom contains four cylindrical rods with the following concentrations of calcium: 0, 50, 100, 200 mg/ml calcium hydroxyapatite. On the first and 15<sup>th</sup> of each month quality assurance scans of the torso phantom will be performed at the CT scan site. The analysis of these scans by the CT Reading Center allows convenient and quick verification of accuracy and precision of the CT scanners at different sites.

#### **Positioning the Calibration and Torso Phantoms.**

The table height of the CT couch will be positioned such that the center of the Torso Calibration phantom will be located at isocenter of the scanner field of view.

Place the torso phantom on top of the calibration phantom (positioned in couch pad) and using your laser alignment light; adjust the table height until the torso center insert is at the location of isocenter on the CT scanner. This is the table height you will use for QA scans with your Torso phantom.

#### **Scanning the TORSO QA Phantom**

After the correct position has been determined, take a vertical axial slice through the center of the TORSO phantom. Use the same parameters as with participant exams. Each site will perform a scout of the phantom followed by an axial scan (identical parameters to the heart series). Reconstruction should be done with the same parameters as in scanning study subjects. Then display your axial image on your CT monitor and examine it to ensure that it is free of artifacts, such as air gaps and streaks. Ensure that the calibration phantom is included in

the field of view. If there are significant artifacts over the calibration phantom, you should discard the image and rescan the phantom.

Using your CT software place ROIs on the calibration phantom reference samples (0, 75 150 mg/mL). The 0 sample will be an apparent blank space on one end of the calibration phantom. Then place an ROI in the TORSO vertebral sample. The ROIs should be as large as practical while remaining completely within the reference cylinder. (We recommend ROIs about 70% of the sample area.) Record the five mean CT numbers within these five ROIs and send these numbers by FAX or E mail to the CARDIA reading center (Email, fax) using the standard QA forms provided (attached QA Data Sheet). Record the mean CT numbers within these ROIs. The QA data sheet will then be filed in the local study 3-ring binder for your records.

The QCT & Torso phantom scans provide valuable information concerning the CT scanner and any change over time (temporal drift). It is critical that these scans be performed and the results & images be sent to the CTRC.

**\*\*\*\*\* Torso QCT scans will be performed on or about the 1<sup>st</sup> & 15<sup>th</sup> of each month\*\*\*\*\***

Some common sources that cause poor results include: inappropriate table height (TORSO plug should be at isocenter when scanned); mal-positioning of the phantom; old or improper CT calibrations; use of improper scan parameters.

## **6.0 CT Technologist Training Material**

CT protocol training material will be provided for all technologists from each field site. The curriculum for the CT Training is presented in Appendix A and a draft of the electronic education material is in Appendix D.

The instructional material will provide the technologist who will perform the CT studies an overview of the study objectives, study organization and an introduction to the CT Reading Center personnel. It will detail the study protocol and quality control procedures. It will complement this manual of operation and provide pictures to facilitate learning the CT protocol.

The experience in MESA and CARDIA with CT technologists is that in some cases multiple technologists at each site are performing protocol exams as part of their work schedule. Although it is desirable to minimize the number of technologists involved, this is, in most cases, outside the ability of investigators to designate. The WFU Reading Center has designed a program to accomplish the following:

1. Identify the technologist performing each CT study
2. Train and maintain skills of each CT technologist
  - a. Train a "Master" technologist from each site at WFUHS CTRC
  - b. Provide pre-certification material and exam for each technologist
  - c. Provide Preliminary Certification until completion and review of the 3 studies on protocol.
  - d. Time-limited certification for 6 months
3. Provide feedback to CT technologist on an individual and by site basis
4. Identify protocol variances / violations /and violations impacting participant safety

- a. Retrain / enhanced training as needed
- b. Stop CT exams if needed to resolve problem

The training material will consist of a CD with a PowerPoint presentation, this CT manual of operations and a pre-certification exam. Technologists will be required to read the PowerPoint training material and answer the pre-certification exam. Hypertext links will allow the technologist to link directly to the relevant material in the MOO. The pre-certification exam will allow the Reading Center to assign a unique technologist identification which will be entered on every scan performed by the technologist. After successful pre-certification, the next three exams will be performed in conjunction with the Master technologist. After these have been reviewed and accepted, the technologist will be given full certification for 6 months. Every 6 months the Reading Center will create a new training presentation in PowerPoint focusing on core issues and any potential problems identified across all scan sites in the study. A brief questionnaire directed at these issues must be completed by each technologist and returned to the Reading Center to maintain certification. If problems are identified at a specific site, additional training by Dr. Carr may be required. He will review selected studies completed to date and discuss issues related to protocol compliance. Feedback will be provided to the technologists concerning their scan technique for the heart. Questions and issues they may have will be discussed and resolved as appropriate. These visits will take one working day each and will concentrate on obtaining adequate and optimal scan images using the CT scanning protocol.

## Appendices

## Appendix A

The central training curriculum for CT Technologists:

**Jackson Heart Study  
Technologist CT Training Course  
Schedule & Itinerary  
Jackson Medical Mall, Jackson, MS  
January 10-12, 2007**

1. Dr. Carr meets with JHS & UMMC personnel
2. Dr. Carr meets with UMMC CT technologists and reviews training PowerPoint presentation, including interactive Q&A period.
3. Hands on training with phantoms, QC, forms
4. Calibration scans for testing CT scanner performance.

**CT Reading Center and Jackson Heart Study Site Visit  
January 10 – 12, 2007  
Jackson, MS**

**Itinerary for Dr. Jeffrey Carr**

**Wednesday, January 10**

12 noon	Arrive at Jackson Airport
12:45 – 1:15 p.m.	Arrive at Jackson Medical Mall (JMM) Jackson Heart Study (JHS) Meet with Dr. Taylor
1:15 – 1:50 p.m.	Meet with Directors Council Members & Tour JHS JHS Conference Room
2:00 – 3:30 p.m.	Meet with Data Acquisition Center, CC & EC Staff JHS Library
4:00 p.m.	Check into Marriott (downtown) 200 Amite Street Jackson, MS 601-969-5100
7:00 – 9:00 p.m.	Dinner with JHS Investigators

**Thursday, January 11**

8:00 – 9:00 a.m.	Prep meeting with Data Acquisition Center Staff JMM - CT Station
9:00 – 9:15 a.m.	Break
9:15 – 12 noon	Training of CT Technicians and Pilot Testing *

## CT Station

- |                  |   |
|------------------|---|
| 12 noon – 1 p.m. | JHS Seminar – Topic: “Medical Implications of Calcium Score”<br>Presenter - Dr. Jeffrey Carr<br>UMC Conference Room<br>(Lunch will be provided) |
| 1:15 – 4:00 p.m. | Pilot Testing (continuation) *<br>CT Station  |
| 4:00 – 4:10 p.m. | Break   |
| 4:10 – 5:15 p.m. | Debriefing of Pilot Testing* and Review of Protocol<br>JHS Conference Room  |
| 5:15 p.m.        | Activities Adjourn – Leave for Hotel  |

**Friday, January 12**

- |                   |   |
|-------------------|---|
| 8:00 a.m.         | Check out of hotel  |
| 8:30 – 10:30 a.m. | Debriefing of Pilot Testing* and Assessment of Readiness<br>for CT Studies<br>JHS Conference Room |
| 10:45 a.m.        | Leave for Airport<br>Flight leaves around 12 noon   |

**\*NOTE:** Since the CT Scan Protocol had not been approved by the UMMC IRB, Pilot Testing was replaced with the use of 3 volunteers, who are not JHS participants, to allow Dr. Carr to train technologists on body positioning and related skills. UMMC Radiology Department will conduct Pilot Testing after IRB approval of the CT Scan protocol.

## Appendix B – CT Scanning Worksheet

### CT Scanning Worksheet

To Be Completed by CT Scheduler		
Last Name	First Name	MI
Date of Birth	Weight	Sex
		DR. H. TAYLOR Dr. M. DOHERTY
CT Scan Date	CT Scan Time	Referring Physician

JHS Study ID	JHS Name Code

To Be Completed by CT Technologist		
Series Description:	Series Number:	Number of Images
Scout		
Heart: 35 cm FOV @ 2.5 mm		
Heart Retrorecon: 27 cm FOV @ 1.25 mm		
Heart Retrorecon: 50 cm FOV @ 2.5 mm		
Aorta: 35 cm FOV @ 2.5 mm		
Aorta Retrorecon: 27 cm FOV @ 1.25 mm		
Aorta Retrorecon: 50 cm FOV @ 2.5 mm		

Table Height:: 150 or _____	mA: 400 or 515 (if > 220 lbs) (circle one)	
Exam Number:	Local Archive:	Tech ID#

<b>Comments:</b>	
------------------	--

## Appendix C

### Appendix C: The CT Technical Parameters for each CT system

System	Mode	FOV	Multi- <input type="checkbox"/> slice	Kernel / <input type="checkbox"/> recon	time	ECG <input type="checkbox"/> gating
GE LightSpeed 16 Pro	Axial/CI NE	35 cm	8 slice by <input type="checkbox"/> 2.5 mm	Std / <input type="checkbox"/> Partial <input type="checkbox"/>	0.5 s	Prospective 70%

Heart Scans: Adjusting mA / mAs based on Weight					
System	KVp	Gantry <input type="checkbox"/> speed [s] <input type="checkbox"/>	Exposure Time [s]	Weight < 220 lbs	Weight = > 220 lbs
GE LightSpeed 16 Pro <input type="checkbox"/>	120	0.50 s <input type="checkbox"/>	0.33s	320 mA 106 mAs	400 mA 133 mAs

**Note: The Siemens and Philips systems will enter mAs values while the GE systems will enter mA values. The appropriate value has been made bold in the above table.**

### CT Technical Parameter for the Abdominal Aorta Scan:

CT System	Mode	FOV	Pitch <sup>1</sup>	Kernel /recon	KV	mA	time	mAs <sup>2</sup>
GE LightSpeed Plus (WFU/MGH/UT)	Helical	35 & 50 cm	4i 3:1 HQ	Std / <input type="checkbox"/> full	120	300	0.5 s	<del>200</del> 150

<sup>1</sup>Note pitch on multidetector CT systems have been described with competing conventions by different vendors, thus for the Siemens & Marconi systems the pitch can be explained as 3:1 [7.5 mm table travel per rotation over a 2.5 mm slice collimation] or alternatively as 0.75:1 [7.5 mm table travel per rotation over a beam collimation of 10 mm (i.e. in 4 slice mode 2.5 mm x 4 = 10 mm beam collimation)].

<sup>2</sup>mAs for the Abdominal Aorta scan was reduced (decreasing participant exposure) in May 2002 after review of the initial images from the pilot / vanguard phase of the study.

\*\*\*\* During Protocol Development and Training final adjustment to scanning protocols will be made \*\*\*\*

### Table CT Image Reconstruction Parameters

Series	Scan FOV	Display FOV	Kernel	Recon. type
Heart 1	Large / Body / 55 cm	350 mm 500 mm (retro)	standard	240° (partial)
Abd. Aorta	Large / Body / 55 cm	350 mm 500 mm (retro)	standard	360° (full)







Jackson Heart Study Protocol

Manual 6

Data Management System

Visit 2

Version 2.0

February 15, 2006

For Copies, Please Contact:

Jackson Heart Study Coordinating Center  
Jackson Medical Mall  
350 W. Woodrow Wilson Dr.  
Jackson, MS 39213

## 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 and 10 describe the operation of the Cohort and Surveillance Components of the study. Detailed Manuals of Operation for specific procedures, including those of reading centers and central laboratories, make up Manuals 3 through 9 and 11.

### JHS Study Protocols and Manuals of Operation

<u>MANUAL</u>	<u>TITLE</u>
1	General Description and Study Management
2	Cohort Component Procedures
3	Blood Pressure
4	Morbidity and Mortality Classification Manual
5	Quality Control
6	Data Management System

## MANUAL 6. Data Management System

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## 1.0 INTRODUCTION

### 1.1 Overview

The Data Management System (DMS) is used to collect, process, and store information about participants in the Jackson Heart Study (JHS). This user guide describes the steps in the collection and management of data entered in the DMS during a center exam interview, from paper forms, or through batch-loading of an ASCII file.

The JHS DMS was developed using the Clintrial™ 4 (hereafter referred to as Clintrial) clinical research system software. Clintrial consists of a set of integrated core modules for data collection, management, and retrieval. This document specifically discusses the tasks using the Clintrial Enter module and Clintrial Manage module.

Clintrial Enter allows for data entry, editing, verification (double data entry), and storage of data in a JHS study database. Data checks are automatically performed during data entry by a check of a data value against predetermined edit specifications, and any value that fails a data check can be corrected immediately or flagged for future resolution. Built-in Clintrial reports and custom reports are available to check status of data entered and to look for any data inconsistencies.

Data are entered into update tables and are referred to as unmerged data in Clintrial while in the update tables. The data manager using the Clintrial Manage module moves data to the data tables. The update and data tables are in an Oracle database, and Clintrial handles the storage and use of these data tables in a way transparent to the user.

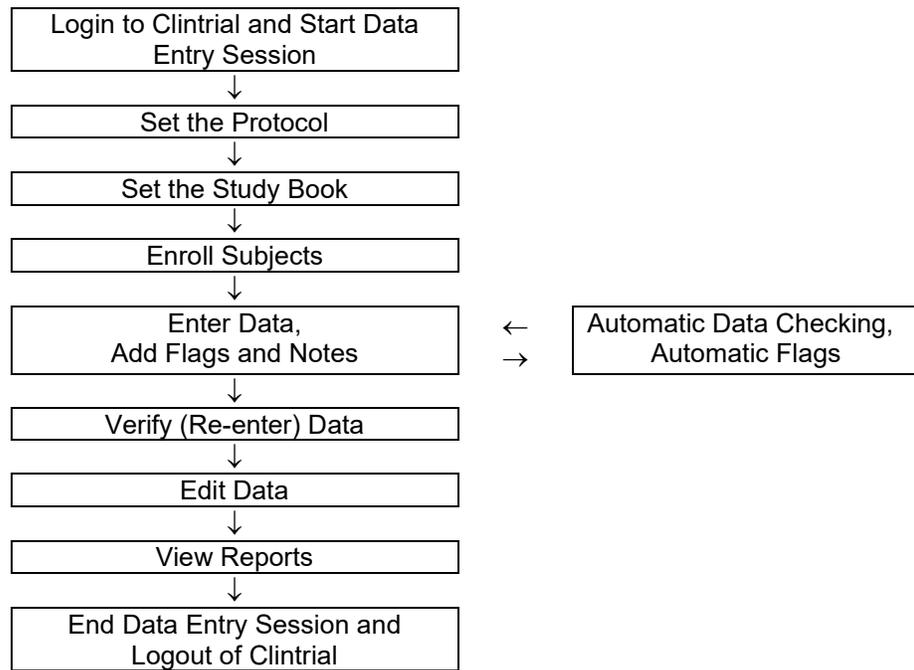
Using the Clintrial Manage module, a data manager can perform additional tasks in the management of the JHS data. The person in this role has extended access rights to the study data tables and familiarity with the Clintrial database structures. Tasks within the Manage module include batch-loading laboratory or ancillary data from an ASCII file, manual coding of medication data from industry-standard dictionaries, moving data from update tables to data tables, making global changes or deletions across multiple records, and reviewing processing logs and error or change reports.

### 1.2 Sample Data Management Workflow

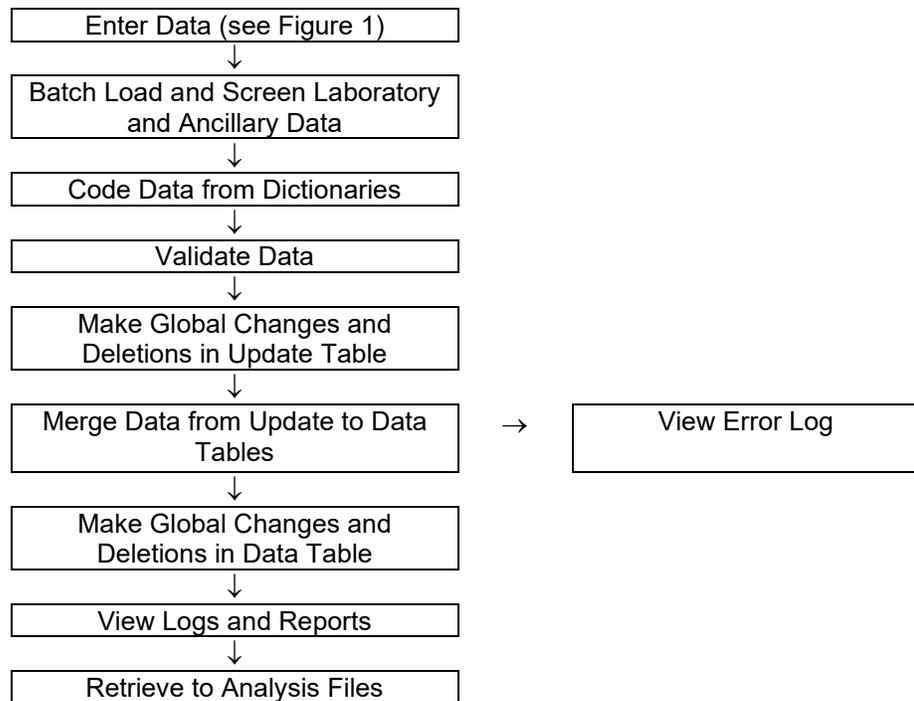
Section 2 of this document provides the step-by-step instructions on each task for data entry. **Figure 1** gives a visual representation of the data entry workflow.

Section 3 of this document describes other tasks that are performed in the management of the JHS data. **Figure 2** shows a data management workflow of the data entry and management tasks for the DMS.

**Figure 1 Data Entry Workflow**



**Figure 2 Data Management Workflow**



### 1.3 Data Entry Help Menu and Glossary of Terms

The Help menu includes step-by-step instructions to perform tasks in Clintrial along with overviews of concepts and descriptions of the menus and options. A glossary provides an extensive dictionary of special Clintrial terms.

To search for information in Help:

1. Select **Help > Help Topics**.
2. To find a topic in the Help Topics dialog box:
  - a) Click on the **Contents** tab for topics by category.
  - b) Click on the **Index** tab for index entries.
  - c) Click on the **Find** tab for a search on specific words.
3. For the glossary of terms, click on the **Contents** tab and then double-click on **Glossary** at the top of the list.

Additionally for help on an open window or dialog box, press **F1**.

Some of the Clintrial terms and their descriptions that are found in this document are as follows:

**Protocol** – a Clintrial account that consists of the data and other components used by the DMS for a research study.

**Study Book** – an online representation of a list of the data collection forms. Each study book contains an ordered list of study pages grouped into blocks.

**Block** – a group of related study pages in a study book, usually representing a visit or contact occasion.

**Study Page** – a data entry window that usually corresponds to a single data collection form, however some forms have multiple study pages because of a length limitation of the data entry window template.

**Study Page Number** – a sequential number assigned to the study pages in their alphabetical order (usually) by form-version.

**Repeating Page** – a single block of study pages that can be repeated multiple times for repeated visits (only twice in the JHS DMS). A repeat visit is optional and rare for the baseline visit. A block repeat key value uniquely identifies a repeat of a block and is stored in the block repeat key item that is a visit-related context (key field) item. The block repeat key value is entered during data entry for a repeated visit from a drop-down list of values.

**Subject** – a participant in a research study for whom data are entered in the DMS.

### 1.4 References

Information for this instruction manual for JHS comes from the Clintrial™ 4 Release 4.2 software manuals and from the Clintrial 4.2 Design Training Guide published by Domain Pharma Corporation. Clintrial is a trademark of Domain Pharma Corporation.

The current release of Clintrial 4.2 stores data in an Oracle8 database. Oracle is a registered trademark of Oracle Corporation.

The SAS® System Version 8 from SAS Institute Inc. is used in writing the custom reports and for the data retrieval process in the JHS DMS.

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## 2.0 DATA ENTRY GUIDE

### 2.1 Starting a Data Entry Session

#### 2.1.1 Logging In

You must login to a Clintrial session to access the JHS DMS for data entry. The steps to login and start a data entry session is as follows:

1. From the Windows **Desktop**, double-click on the **JHS Data Entry** icon. As an alternative, select **Start > Programs > Clintrial 4.2 > Clintrial Enter**.
2. The **Database Connection** dialog box is displayed. Login to Clintrial, as follows, with the information that was set up for your user account:
  - a) Enter your **Clintrial User Name**.
  - b) Enter your **Password**.
  - c) Enter the character string **@ORCO** for Database.
3. Click **OK** to leave the dialog box.

The first time you start a Clintrial session, the fields in the Database Connection dialog box are empty. The next time you start a session, the user name and database that you last used to start Clintrial are displayed as defaults in the dialog box.

On a successful login, you are in the **Clintrial Enter** window.

#### 2.1.2 Changing a Password

If you want to change your Clintrial password for any reason, do the following:

1. From the **Clintrial Enter** window, select **File > Password**.
2. In the **Password** dialog box, follow the instructions to set up a new password. Click on **OK** to finish.

A password must conform to the Clintrial password minimum length currently set at 6, must consist of alpha and/or numeric characters (other symbols and spaces not allowed), and cannot begin with a number. A password is not case sensitive.

If you have any difficulty getting started in Clintrial or forget your current user name and/or password, see your Database Administrator (DBA).

## 2.2 Selecting the Protocol and Study Books

### 2.2.1 Overview

This DMS organizes data for the different components of this study into **protocols**. One protocol named **JHS\_COHORT** comprises the data from the Baseline Visit (enumeration, home induction interview, center exam, and 24-hour exam) and the annual contacts (annual contact details are not yet available). The Surveillance and Family Study components of this study will be organized into two additional protocols (details are not yet available).

The data in JHS\_COHORT are organized into **study books**. A study book represents the collection of data collection forms called **study pages** grouped into visits called **blocks**. The study books in JHS\_COHORT are as follows:

- **INTERVIEW** (enumeration and home induction interview data)
- **EXAM** (center exam and 24-hour exam data)

- **ANNUAL** (annual follow-up data, not yet available)

An enrollment study book named **ENROLL** is available exclusively to enroll new study participants. A participant must be enrolled before any data can be entered for that participant.

## 2.2.2 Setting the Protocol and Study Book

The first time you start the JHS DMS for data entry, you must set the protocol and study book.

To set the protocol, do as follows:

1. In the **Set Protocol** dialog box, click to highlight the protocol in which you want to work, for example, **JHS\_COHORT**.
2. Click on **OK** to continue.

The next time you start the DMS, Clintrial automatically selects the protocol that you last used and asks if you want to use the protocol selected. Click on **Yes** to select the protocol; click on **No** to enter the **Set Protocol** dialog box to select another protocol.

After setting the protocol, set the study book as follows:

1. The **Set Study Book** dialog box opens automatically after you set the protocol. Click to highlight the study book in which you want to work, for example, **INTERVIEW**.
2. Click on **OK** to continue.

Clintrial automatically chooses the study book that you used during your last session on subsequent logins to the DMS. A message is displayed asking you to confirm that this is the study book you want to use. Click **Yes** to select the study book; click **No** to enter the **Set Study Book** dialog box.

## 2.3 Accessing Forms Using the Clintrial Navigator

### 2.3.1 Overview

The best method to access forms within each study book is by using the Clintrial **Navigator**. The Navigator is a browser that graphically displays the **blocks**, **study pages**, and **subjects** in a **study book**. The Navigator uses **icons** to uniquely identify these objects, and a double-click on an icon opens that object in the Navigator. **Figure 3** shows the Navigator in the navigation order of **Navigate by Page**.

In the Navigator for the JHS DMS, the study pages are listed in ascending order of their study page number. Note that some forms have multiple study pages (indicated as Part 1, Part 2, etc.) due to a length limitation in the design of the data entry window templates.

The Navigator menu commands offer another method to navigate through the sequence of forms and subjects in a study book. A description of the menu commands is in **Figure 4**.

The Help menu provides more detailed instruction in the use of the Clintrial Navigator.

Figure 3 The Navigator (Navigate by Page)

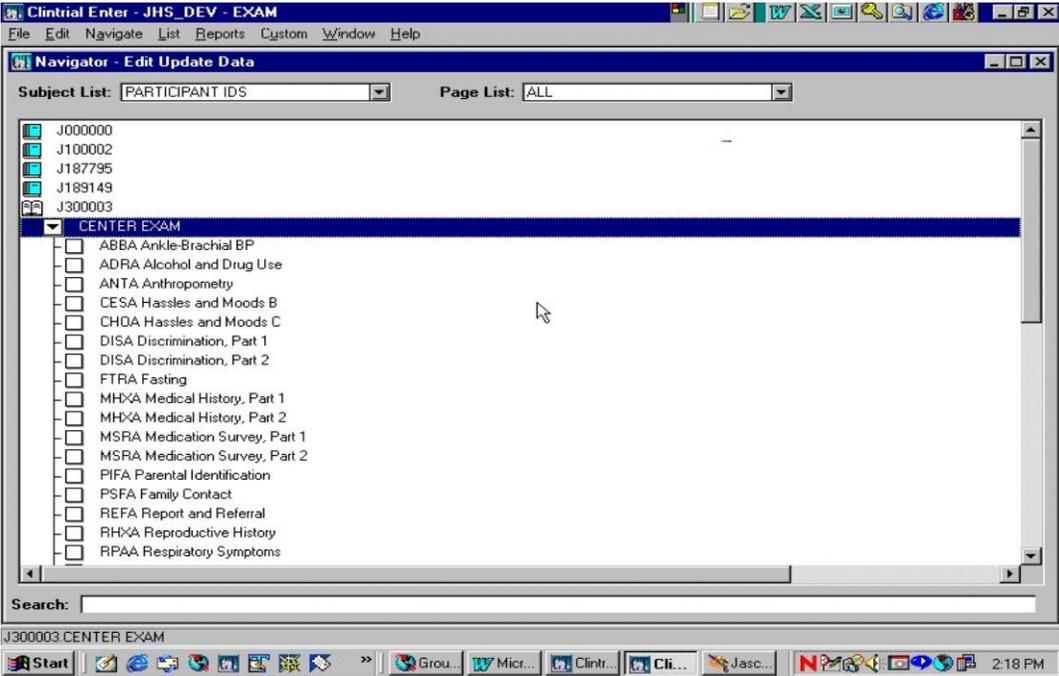


Figure 4 Navigator Menu Commands

Menu command	Description
<b>Go To</b>	Open a form by using the <b>Go To</b> dialog box. Enter ID NUMBER, CONTACT YEAR, and PAGE number.
<b>Go To Selected</b>	Go to the study page highlighted in the Navigator.
<b>Next*</b>	Go to the next study page in the navigation order.
<b>Previous*</b>	Go to the previous study page in the navigation order.
<b>Next Subject</b>	Go to the current study page for the next subject.
<b>Next Page</b>	Go to the next study page for the current subject.
<b>Previous Subject</b>	Go to the current study page for the previous subject.
<b>Previous Page</b>	Go to the previous study page for the current subject.
<b>Navigate by Subject</b>	Set the navigation order to By Subject (list of subjects under each study page).
<b>Navigate by Page</b>	Set the navigation order By Page (list of study pages under each subject).
<b>Expand</b>	Expand the selected Navigator order.
<b>Collapse</b>	Collapse the selected Navigator order.
<b>Sort Subjects</b>	Set the sort order for subjects in Navigator as ascending or descending.
<b>Navigator</b>	Open the Navigator.

\*Depending on the Navigation order selected, **Next** or **Previous** opens either the next or previous page for the current subject (**Navigate by Page**), or opens the current page for the next subject (**Navigate by Subject**).

### 2.3.2 Using the Navigator

For the JHS DMS, the Navigator is set to open automatically whenever you open a study book. If Navigator does not open automatically, select the **Navigate > Navigator** menu commands.

This section describes the Navigator in navigation order **Navigate by Page** that is the recommended navigation setting for the JHS DMS. For Navigate by Page, the Navigator **icons** as shown in **Figure 3** are as follows:

- Subject – a **book** (closed if collapsed, open if expanded)
- Block – a **boxed arrow** (right arrow if collapsed, down arrow if expanded)
- Study page – a **page**
- Repeating page – **overlapping pages**

An icon is shaded if any data are present.

As displayed in **Figure 3**, the study book **EXAM** is open and contains one block called **CENTER EXAM** with the study pages grouped under each subject. For JHS, the study pages are listed in alphabetic order by form code. To expand or collapse a subject, block, or study page, double-click on its icon.

The Contact Information form in the INTERVIEW study book is designed as a **repeating page** to allow for the possibility of additional data from a repeat contact with a subject. For the first Contact Information form, enter the repeating page number as 0 (zero) when prompted. Enter repeating pages as consecutive numbers 1, 2, etc.

## 2.4 Enrolling Subjects

### 2.4.1 Overview

A new subject must be enrolled in a protocol before any data can be entered for that subject. The DMS allows for enrollment of new subjects either in the ENROLL study book or within a study book prior to entry of any data. *It is recommended to enter a new subject within a study book from the File menu due to current Clintrial limitations that may cause loss of data using the ENROLL study book.*

Enrollment data are the subject-related items ID NUMBER, LAST NAME and INITIALS appearing at the top of the first page of each form. These are required fields in the DMS, and the fields must contain data to continue data entry.

### 2.4.2 Adding New Subjects

#### Enrolling subjects in a data study book (recommended)

If you are only adding a few subjects at a time along with their data, you can enroll the new subjects from within a data study books.

To enroll a new subject, do as follows:

1. Select the **File > New Subject** menu commands to open the **New Subject** dialog box.
2. Enter **ID NUMBER, LAST NAME** and **INITIALS** in the Enrollment Information section.
  - a) ID NUMBER is a unique subject identifier. If you enter a non-unique subject identifier into the DMS, Clintrial displays a message that you cannot enroll the subject since the subject has already been enrolled.
  - b) Since these are required fields, if INITIALS or LAST NAME is not available then enter X's in the field. For example, enter the household last name for LAST NAME and X's for INITIALS for enrollment of a Household ID.

- c) Use the **Tab** key to move from one field to another. If you use the Enter key, Clintrial attempts to leave the New Subject dialog box, and if any fields are blank, it displays a message to enter data in the highlighted fields which you must do before you can leave this dialog box.
3. After completing the subject enrollment information, click one of the following:
  - a) **Go To Page** to save the subject information and to go to the subject's first study page.
  - b) **Add Next** to save the subject information and add another new subject (repeat items 2 and 3).
  - c) **OK** to save the subject and to close the New Subject dialog box.

To modify or delete any subject information in the New Subject dialog box that have not yet been saved, do one of the following:

1. To modify the subject information, place the cursor in the field you want to modify, delete the old information and enter the new information.
2. To delete the subject information, click on **Cancel** to delete the information and exit from the New Subject dialog box.

### Enrolling subjects in the enrollment study book (not recommended)

The enrollment study book contains only one study page that opens automatically when you open the ENROLL study book. Using the enrollment study book is most effective when you are enrolling a group of subjects prior to entry of any data, or when you want to view or print a list of enrolled subjects.

To enroll a subject in the enrollment study book, do as follows:

1. Select the **File > Set Study Book** menu commands. Highlight **ENROLL** and click **OK** to continue.
2. The **SQL Restriction Clause Builder** window automatically opens. Click **Cancel** or **OK** to continue. SQL restrictions are not being used at this time.
3. The cursor is on the first field to enter a new subject. Enter **ID NUMBER, LAST NAME** and **INITIALS**. Use either the **Tab** or **Enter** key to move to the next field.
4. To enter additional new subjects, press **Ctrl-A** or select the **Edit > Add Subject** menu commands. Enter each new subject as in step 3. Repeat these steps until you enter the last subject.
5. Close the enrollment study page by clicking on the (X) windows button for the page or select the **File > Close** menu commands.

To modify or delete any subject information in the enrollment study book that have not yet been saved, do one of the following:

1. To modify the subject information, place the cursor in a field belonging to the subject you want to modify, delete the old information and enter the new information.
2. To delete the subject information, place the cursor in a field belonging to the subject you want to delete and select **Edit > Delete Subject** from the menu commands.

### Modifying and deleting subject information after data have been saved

Once a subject's enrollment data have been saved by either enrollment method, you cannot modify the enrollment data in the Clintrial Enter module. Modification to saved enrollment data must be done in the Manage module by the Data Manager.

## **2.5 Entering Data**

### 2.5.1 Overview

Data are entered in a study page that is a representation of the data collection forms. Some forms have multiple study pages due to form length limitations in the design of the data entry screen templates. Flags and notes are information about data that can be attached to fields or a study page during data entry.

Figure 5 shows an example a study page open for data entry.

Figure 5 Study page

The screenshot shows a software window titled "Clintrial Enter - JHS\_DEV - EXAM" with a menu bar (File, Edit, View, Navigate, List, Flags, Notes, Discrepancies, Reports, Custom, Window, Help). The main window title is "J300003.CENTER EXAM.FTRA Fasting (UPDATE)".

Form fields include:

- ID NUMBER: J300003
- CONTACT YEAR: 1
- PAGE NUMBER: 610
- LAST NAME: ANDERSON
- INITIALS: NC
- PAGE REPEAT: (empty)

The "FTR Fasting Form" section contains the following questions and input fields:

1. Date of clinic visit: (mm/dd/yyyy)
2. Date of fasting determination: (mm/dd/yyyy)
- 3a. Time: (hh:mm)
- 3b. AM/PM: (A/P dropdown)
4. When was the last time you ate or drank anything except water?
  - 4a. Day last consumed: (Today, Yesterday, Before Yesterday dropdown)
  - 4b. Time last consumed: (hh:mm)
  - 4c. AM/PM: (A/P dropdown)

The taskbar at the bottom shows the Start button, several application icons, and the system clock at 2:19 PM.

## 2.5.2 Adding New Data

### 2.5.2.1 Characteristics of Form Fields

#### Field Types

Several types of fields appear in a study page:

- **Enterable fields** are fields in which you can enter data. These fields have a white background and can accept the cursor.
- **Non-enterable fields** are fields in which you cannot enter data. These fields have a colored background (usually gray) and will not accept the cursor. Examples are computed fields and skipped fields that follow a skip trigger field.

#### Data Types

Each field has been assigned a **data type** attribute. The following data types are used in the JHS DMS:

Field Type	Data Type	Description and Example
Numeric	FIXED	An integer that cannot include a decimal point. The integer can be prefaced with a plus or minus sign. Example: 100.

Numeric	FLOAT	A number that can include a decimal point. The number can be prefaced with a plus or minus sign. Example: 25.6
Date	DATE	A date in the format mm/dd/yyyy (month/day/year). Leading zeroes are accepted but not required for month and day. Missing date parts must be estimated, e.g., 01 for missing month or day. Enter a slash or hyphen as the delimiter separating date parts. Example: 06/20/2000
Character	TEXT	A character string that can include letters, numbers, punctuation marks, spaces, and special characters. Enter character strings in upper case. Partial dates (mm/yyyy) and times (hh:mm) are entered as character strings since Clintrial does not have a comparable data type. Examples: J123456, ASPIRIN, 09/2001, 04:45

Note the following for date field types:

- From the Clintrial Help menu, “Years can be entered as two digits or four. When a two-digit year is entered, Clintrial stores numbers 00 to 49 as 21st century (2049) and numbers 50 to 99 as 20th century (1950).” It is important to enter year as a 4-digit number to ensure the correct century.
- Although the Clintrial date uses the DATE data type, a date is stored with the DATETIME data type in the Oracle database. In rare cases during data entry, you may see a date field type displayed in DATETIME format.

### Value Ranges

Most numeric and date fields have lower and upper bounds. You must enter a value within the specified limits. However, if the correct value is outside these bounds, the JHS DMS has been designed to allow you to enter a value that overrides these bounds.

If you enter a value outside the bounds, Clintrial issues a message that the item value is outside the range and asks if you want to override and accept this value. You can accept or not accept the value, with the following actions:

- If you do accept this value, Clintrial will attach a flag to the field and a red flag icon will appear to the right of the field (see Using Flags for more information). The cursor will move to the next field.
- If you do not accept this value, the value of the field will return to its previous state (either blank or a previously entered value), and the cursor will move to the next field (unfortunately a Clintrial feature with the autoskip functionality). You must return to the previous field that invoked the message by pressing Ctrl-Tab or clicking on the field to enter the correct value.

### Drop-Down Boxes

Drop-down boxes are used for fields that have a list of acceptable values, such as a list containing Yes, No and Don't Know. You can only select the values that appear in the list for the field. You can enter a value in the field in one of the following ways:

- Enter the code associated with the value in the list, such as Y for Yes. The value appears in the field.
- Click on the down arrow button to display the list. To select a value, press the keyboard key that corresponds to the value's first letter or click on the value. The value appears in the field. Long lists will have a scroll bar to move down the list of values.

You may encounter a value in a drop-down list that cannot be selected if that value has become obsolete. The value will be displayed as red text.

### Missing Data

There are no special character or numeric entries for missing data in the JHS DMS. Simply leave the value blank. For the JHS DMS, it is recommended to add a flag called PERMANENTLY\_MISSING to the field (see Using flags). Add a comment in the Item Flag dialog box to indicate the reason for permanently missing.

To change a field with data to missing, delete the value in the highlighted field by pressing the keyboard Backspace key or selecting the **Edit > Clear** menu commands. To change data to missing for a field with a drop-down list, select **(None)** from the drop-down list.

### Using Item Help

You can view the attributes of any enterable field on a study page in the Help menu. **Item Help** displays the attributes of a field defined during the development of the DMS. To open Item Help, do the following:

1. Highlight the field whose attributes you want to view.
2. Select **Help > On Current Item** from the menu commands, or press **Shift-F1**.
3. Close the Item Help window by clicking on the (X) windows button.

#### 2.5.2.2 Navigating in a Form

##### Navigating between fields

The following keyboard commands allow you to navigate between fields on a study page:

Command	Description
<b>Tab or Enter</b>	Next field.
<b>Shift-Tab or Shift-Enter</b>	Previous field.
<b>Ctrl-Home</b>	First field in page section (a partition of the study page).
<b>Ctrl-End</b>	Last field in page section (a partition of the study page).

##### Navigating within a single field

The following keyboard commands allow reposition of the cursor and selection of text within a field:

Command	Description
<b>Home</b>	Moves cursor to the beginning of the field.
<b>End</b>	Moves cursor to the end of the field.
<b>Ctrl-Right Arrow</b>	Moves cursor one word to the right.
<b>Ctrl-Left Arrow</b>	Moves cursor one word to the left.
<b>Escape</b>	Restores a non-coded field to its original value.
<b>Shift-Home</b>	Selects text from cursor position to the beginning of the field.
<b>Shift-End</b>	Selects text from cursor position to the end of the field.
<b>Shift-Right Arrow</b>	Selects one character to the right.
<b>Shift-Left Arrow</b>	Selects one character to the left.
<b>Ctrl-Shift-Right Arrow</b>	Selects one word to the right.
<b>Ctrl-Shift-Left Arrow</b>	Selects one word to the left.

##### Autoskip (currently disabled in the JHS DMS)

The JHS DMS uses the Clintrial automatic skipping feature that automatically advances the cursor to the next enterable fields. This feature is not available from fields with drop-down boxes. Autoskip will only advance if the maximum number of characters have been entered in the current field, so if the entry is

less than the maximum length, you will need to advance to the next field using the Tab or Enter key or clicking on the field.

### Go To skips

A field in a form may display an instruction that entry of a particular value for that field causes a skip of one or more fields to a latter field. The field that causes a skip is called a **trigger** field, and the field to skip to is the **target** field. For a trigger field, the paper copy of the form displays a 'Go to' statement beside the trigger value for that field, and the data entry window displays an asterisk (\*) beside the trigger value for that field.

If you enter a trigger value in a trigger field in the DMS, then the cursor goes to the target field and marks the skipped fields as non-enterable fields. If the value of a trigger field is changed, the skipped fields become enterable.

A few exceptions for skips in the JHS DMS are as follows:

- The target field may be too far from the trigger field for a skip in Clintrial. Therefore, a message is displayed to skip to the target field, and then the skip will go to the farthest field it can reach. Use the Tab or Enter keys to go the remaining distance to the target field.
- The skipped fields may not be marked as non-enterable due to Clintrial limitations in certain locations in a page design.

### Scrolling in a study page

As you perform data entry in a study page, the Tab or Enter key move the cursor to the next enterable field on the study page, automatically scrolling down the page and displaying the fields in the data entry window. You can manually scroll down a page by using the vertical scroll bar on the right side of the window.

Some study pages are designed from forms with a landscape layout and require scrolling left to right. The Tab or Enter key moves the cursor to the next enterable field, automatically scrolling to the right on a page and displaying the fields in the data entry window. For these wide pages, a horizontal scroll bar is available at the bottom of the data entry window that you can use to scroll manually from left to right.

### Search field

At the bottom of the Navigator window is a **Search** field in which you can enter text (case sensitive) to search for a particular study page. The search begins at the currently selected icon and proceeds within the hierarchy until the first match is found. You can only search expanded icons.

For example, to find the next occurrence of the SBPE Sitting Blood Pressure study page in the CENTER EXAM block for subject J000000, expand the subject and CENTER EXAM icons and then enter "S" in the Search field. The search begins as soon as you enter any text. Continue to enter additional characters in the text until the search takes you to the SBPE study page.

### Last field action

When the cursor is on the last field of the study page, pressing the Tab or Enter key will move the cursor to the first field of the study page. You do not exit from the study page.

### Printing study pages

You can print study pages from the Navigator without having to open them. Only study pages that contain data can be printed, and only study pages and subjects included in the current subject list and page list can be selected for printing.

The Navigator provides several options to print for selecting one or more individual study pages or subjects or selecting a selected group of study pages or subjects. These options differ depending on the current navigation order setting.

From the Navigator window in the navigation order Navigate By Page, you can select for printing as follows:

1. Select subject(s) or study page(s) to print.
  - a. Selecting an individual subject prints all study pages for the subject
  - b. Selecting one or more individual study pages for a subject prints the individual study page(s) for the subject.
  - c. Selecting the **Edit > Select All** menu command prints all the study pages in the study book.
2. Select **File > Print** from the menu commands. In the Print Options dialog box, you can make further selections on study pages to print, if desired.
3. Click on **OK** to print and to close this dialog box.

### 2.5.2.3 Using flags

Flags can be attached to an individual field as an Item Flag or to a form by way of a Record Flag. Flags are typically used to:

- Label and monitor data quality problems.
- Capture information that cannot be entered in the fields on a screen.

For example, a flag might be added to a field where the data are missing or where the data are outside a specified range of values.

Flags have two parts:

- A **flag category** is used to indicate the type of problem or assertion found with the data, such as ILLEGIBLE or MISSING.
- A **flag name** is associated with a single flag category.

In the JHS DMS, there are four categories of flags with each category associated with a single name (the same value as the category). The categories (and names) and their description are as follows:

<b>FLAG CATEGORY (AND FLAG NAME)</b>	<b>Action</b>
<b>OVERRIDE</b>	Use when overriding an edit range.
<b>PERMANENTLY_MISSING</b>	Use when a field value or form is permanently missing.
<b>CANT_ENTER</b>	Use to indicate when a value cannot be entered into the field (e.g., if a field is too short or if a value is different from the field type).
<b>QUERY</b>	Use only when entering data from paper forms to indicate that a field should be queried.

There are other flag categories supplied by Clintrial that cannot be removed but are not used for JHS. The flag categories to ignore for JHS are CDR, GENERAL, CLASSIFY, and LABLOADER.

To attach a flag to a field, do the following:

1. With the cursor in the field, select **Flags > Item Flag** menu commands.

2. In the Item Flag dialog box, select a **Category** from the list. Select a **Name** from the list (same as Category). Enter text in the **Comment** field to provide a reason for the flag.
3. Click **OK** to continue. The dialog box closes, and a red flag icon appears next to the field.

You attach a flag to a record for a form-level flag, for example, if the entire form is permanently missing. A single form is usually comprised of multiple records appended together, with each record containing a subset of the form fields. Only attach a flag to the first record for a form-level flag. To attach a flag to the first record, do the following:

1. With the cursor in the first field on a study page, select **Flags > Record Flag**. Note that the cursor is automatically positioned in the first field of the study page when the study page is opened.
2. In the Record Flag dialog box, select a **Category** from the list. Select a **Name** from the list (same as Category). Enter text in the **Comment** field to provide a reason for the flag.
3. Click **OK**. The dialog box closes, and a red flag icon appears next to the record (top right of form).

Multiple flags can be attached to an item or a record, but only one red flag icon will appear.

#### 2.5.2.4 Using notes

Notes are used to enter comment fields and 'Other' responses or to make notes about an individual field in a study page or about an entire study page. A note for a field is attached as an Item Note. An example: a note for the reason text to the field 'Other Reason'. A note for a form is added as a Record Note. An example: if a study page cannot be completed, then a record note can indicate why the data are unattainable.

Notes have two parts:

- **Note category** defines the source of the note.
- **Note name** defines a subcategory for the source of the note.

Clintrials supplies two note categories of SPONSOR and INVESTIGATOR, and in INVESTIGATOR, there is one note name. *For JHS, all notes will be note category INVESTIGATOR with note name UNSPECIFIED.* The other note categories are not meaningful in JHS, but cannot be removed in Clintrials.

To attach a note to a field, do the following:

1. With the cursor in the field, select **Notes > Item Note** menu commands
2. In the Item Note dialog box, select **INVESTIGATOR** from the **Category** list. Select **UNSPECIFIED** from the **Name** list. Enter the text in the **Note Text** field to provide a comment or 'Other' reason.
3. Click **OK** to continue. The dialog box closes, and a yellow note icon appears next to the field.

You attach a note to a record for a form-level note. A single form is usually comprised of multiple records appended together, with each record containing a subset of the form fields. Only attach a note to the first record for a form-level note. To attach a note to the first record, do the following:

1. With the cursor in a field belonging to the record, select **Notes > Record Note**. Note that the cursor is automatically positioned in the first field of the study page when the study page is opened.
2. Select a **Category** from the list. Select a **Name** from the list. Enter text in the **Note Text** field to provide a reason for the note.
3. Click **OK**. The dialog box closes, and a yellow note icon appears next to the record (top right of form).

Multiple notes can be attached to an item or a record, but only one yellow note icon will appear.

#### 2.5.2.5 Saving data and exiting a study page

Data entered in a study page are not permanent until the study page is saved. You can save at any time during data entry in a study page or when you exit from a study page.

The following options are available to save data and/or to exit from a study page:

- Select **File > Save** menu commands to save data without exiting from the study page.
- Select **File > Close** menu commands or click the study page (X) windows button to save data and exit from the study page.
- Select **File > Close Without Saving** to exit the study page without saving data.

### 2.5.3 Creating and Selecting Subject Lists

Long lists of subjects in the Navigator can make data entry cumbersome. To limit the number subjects displayed in the navigation window, such as to those attending the center that day or to those who are in the stack of forms for data entry, you can specify a subset of subjects by using **subject lists**. You can create as many subject lists as needed and save these lists indefinitely.

Every Clintrial protocol has a default subject list called **All** that includes all subjects enrolled in the study. This list cannot be deleted or modified.

You create and modify subject lists using the **List Wizard**. The Wizard is a series of dialog boxes to guide you through the steps of entering or modifying list criteria. To create a list in the Wizard, select specific subjects to include. You can optionally include or exclude subjects based on a SQL restriction. You can also create a list that includes or excludes subjects based upon the presence or absence of flags or notes. Once created, a list can be modified as needed.

To open the List Wizard, select one of the following menu commands appropriate to what you want to do:

- **List > Create List**
- **List > Edit Subject List**

You can select a particular subject list for the Navigator to display, and only those subjects belonging to the list will be displayed. To select a subject list, do one of the following:

- From the **Subject List** drop-down box at the top left of the Navigator window, select the list you want.
- Select **List > Select Lists** from the menu commands. In the Select Lists dialog box, select the subject list you want and click **OK** to continue.

### 2.5.4 Browsing, Changing, Deleting, or Printing Data in the Enter Module

#### Browsing Data

To browse data in a saved study page in the update table, double-click on the study page icon to re-open the study page in the Navigator. Use the scroll bar or the Tab or Enter key to browse through the data, being careful not to change inadvertently any data. Select **File > Close Without Saving** to exit from the study page.

#### Changing Data

There are three edit modes available in an Enter session to change data:

- **Edit Update Data** (default) - enter new data or edit unmerged data.
- **Verify** - perform verification of previously entered data.
- **Edit Merged Data** - edit data that have been validated and merged (moved) to the data table (merging data is described later in Managing Data).

By default, when you start Enter, the edit mode is set to Edit Update Data. If you want to perform verification or edit merged data, you must set the edit mode to one of these other options. All study pages must be closed before you set the edit mode. The name of the current edit mode is displayed in the title bar of the study page. To change the edit mode, select **File > Edit Mode**. Select an edit mode, then click **OK** to continue.

To change data in a saved study page, double-click on a study page icon to re-open the study page in the Navigator. Use the scroll bar or the Tab or Enter key to move through the study page. Select a field to change, then enter the data. Select **File > Save** to save the changed data without exiting or **File > Close** to save and exit from the study page.

### Deleting Data

Depending on the situation, you can delete data in an open study page in following ways:

- Close a study page without saving new or updated data
- Undo data entered since the last save
- Delete data from a field
- Delete all data for a study page

To close an open study page and not save data, select **File > Close Without Saving**. For example, if you inadvertently open the wrong study page from the Navigator, close the study page without saving to avoid creation of any blank records in an update table and to not shade the study page icon.

If you want to undo data entered since last save in an open study page, select **Edit > Undo Page Edits**.

If you want to delete data from a field in an open study page, highlight the field and select **Edit > Clear** or use the **Delete** key. To delete or clear a value from a codelist field, highlight the field and select **(None)** from the drop-down list. Select **File > Save** to save data deletions without exiting or **File > Close** to save and exit from the study page.

If you want to delete all data in a previously saved study page, select **Edit > Delete Page Data** in the open study page and click on **Yes** to confirm the deletion. The study page will automatically close, and the study page icon will not be shaded.

### Printing Data

You can print Clintrial reports, most non-report windows, and study pages. You can open a study page for printing or print from the Navigator window. If the Print or Print Preview command is not available for a displayed window, then that window does not have the print or preview capability.

Select **File > Printer Setup** to specify which local or network printer to use. Depending on your printer, you can also adjust certain printer defaults like page orientation, paper size, and print resolution. Consult your printer's documentation or your Clintrial Data Manager for more information.

To print from within a report, window, or open study page, do as follows:

1. Select **File > Print**.
2. The Print Options dialog box opens. Accept default settings or modify any of these values as needed.
3. Click **OK** to print.

To preview a document, select **File > Print Preview**. Previewing a document before printing lets you see how the text will look when printed, shows certain report features that do not normally display on the screen (e.g., headers and page numbers), and allows an opportunity for an adjustment to page orientation for best printing results.

You can print study pages from the Navigator without having to open them. Only study pages that contain data are printed. Only study pages and subjects included in the current page list and subject list can be selected for printing. However, *use this print capability with caution*. To print multiple study pages at a time is dependent on the number of allowable open study pages set for system parameter ENT\_OPEN\_PAGES (default is 1). *Set ENT\_OPEN\_PAGES temporarily to the maximum of 10 to print study pages from the Navigator*. Otherwise, you will get a Clintrial error that terminates Enter if the number of study pages to print exceeds the number specified by this parameter except if set to 10.

To print study pages from the Navigator, do as follows (assumes Navigate By Page navigation order):

1. Select the page(s) that you want to print in one of following ways:
  - a. Click on one or more individual study pages within a subject (Shift-click for more than one)
  - b. Click on a block (i.e., CLINIC EXAM) to print all study pages in the block for that subject
  - c. Select **Edit > Select All** to print all the study pages for all subjects in the study book
2. Select **File > Print**.
3. The Print Options dialog box opens. Accept default settings or modify any of these values as needed.
4. Click **OK** to print.

## 2.6 Clintrial-Supplied and Custom Reports

### Clintrial-Supplied Reports

Clintrial provides Enter reports that you create through the use of a Report Wizard. Within the Wizard, you enter criteria that determine the report's format and content in a series of dialog boxes.

You can create one of the following reports:

- A Flag Report, which displays information about flags that have been attached to data in the current study book.
- A Note Report, which displays information about notes that have been attached to data in the current study book.
- A Subject Report, which displays information about the status of data entered for study subjects.
- A Verification Report, which displays information about records that have failed to pass blind verification.

The Flags, Notes, and Subject reports are available in two basic formats: detailed and summary. The detailed format provides in-depth information on each record matching the selection criteria. The summary format gives a count and categorical breakdown of records matching the selection criteria.

To create a Clintrial-supplied report, do as follows:

1. To open the Report Wizard, select **Reports** from the Enter menu and then select the type of report: **Subject, Flag, or Note**.
2. Select the criteria for the report. Click **Next** to move to the next dialog box. Click **Back** to return to a previous dialog box to change an earlier entry.
3. Select **Finish** to end your selection and view the report. As soon as the Finish button is available, it indicates that the minimum amount of necessary information has been entered.
4. The report appears on the screen. You can also print the report (**File > Print**) or save the report to a file in a directory of your choice (**File > Save As**).

### Custom Reports

Custom reports developed for JHS such as recruitment status, participant profiles, and lab results can be run from the **Custom** menu in Enter. The Custom menu is a user-modifiable menu in which you can set up shortcuts to Windows applications (e.g., Notepad, Excel), to specific document files (e.g., text files,

spreadsheets), and to the SAS System to run JHS data reports. These applications and documents can be directly opened from Clintrial in the Custom menu.

When creating a shortcut, you can specify whether the shortcut appears in every Clintrial module you use (create in **Common Menu Items**) or in only the module from which it was created (create in **Module Specific Menu Items**). You can create up to eight shortcuts of each type.

*Custom menu items will appear only on the workstation on which they were created since they are stored in the Windows Registry.* For computers running under Windows NT, Custom menu settings are also particular to the user who created them.

## 2.7 Closing Windows

When you have completed data entry using the Navigator or completed other tasks in a DMS window, you need to close the active task window.

To close a window, you can use one of several options:

- Click on the rightmost (X) windows button at the far top right of a window.
- Select the **File > Close** menu commands.
- Click on the **OK** button, if provided (in dialog boxes).
- Click on the **Finish** button, if provided (in List or Report Wizard).

## 2.8 Ending a Data Entry Session

To close the Clintrial Enter window and end your DMS session, click on the rightmost (X) windows button or select the **File > Exit** menu commands.

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## 3.0 PROGRAMMER GUIDE TO MANAGING DATA

### 3.1 Overview

In the Clintrial Manage module, a Clintrial Data Manager can perform data management tasks such as the following:

- batch-load data
- assign codes based on field values from industry-standard dictionaries
- validate data, that is, calculate derived fields and run consistency checks
- merge or move data that have passed validation from update to data tables
- globally change or delete records
- view processing logs and reports
- view error reports and make corrections
- view audit trail reports

A typical data management workflow in the Manage module is displayed in the introduction of this manual.

A person using the Manage module has privileged access rights to the study data tables and has familiarity with the Clintrial database structures.

### 3.2 Batch-Loading Data

#### 3.2.1 Overview

Batch-loading is the process of loading data from ASCII files directly into update tables in the Clintrial database. You can batch-load study data, enrollment data, and thesaurus (dictionary) data.

Enrollment data must be previously entered for a subject whose data are batch-loaded. Either the subject is enrolled in the Enter module, or the enrollment data are batch-loaded, screened, validated, and merged before study data can be entered for the subject.

The input ASCII file contains records composed of data fields. The data fields on a record correspond to items in a pre-defined panel into which the data are batch-loaded. You can only batch-load into one panel at a time. To load data from one input ASCII file into more than one panel is a complicated, multiple control files, multiple runs process not discussed in this manual.

The data fields on a record in the input ASCII file are in either a fixed format or variable format. **Fixed format** records contain data values of specified length beginning in fixed locations in the record with no delimiter separating the values. **Variable format** records contain data values without a specified length and not necessarily in the same location in each record, and these records include a delimiter to separate the values for fields.

A **control file** is created as an interface between the input ASCII file and the Clintrial database table for the batch-loading. The control file interprets the organization and format of data in the input ASCII file and provides the instructions on the loading process.

All batch-loaded data are automatically loaded into the Clintrial database's update tables. The data must pass screening before the data can be edited, coded, validated, and merged to the study data tables. **Screening** is the process that includes updating internal system items to uniquely identify the records, grouping the records into observations (not used in JHS), and applying data checks to data that has been batch loaded into the update table. The data checks confirm that subjects are enrolled and that mandatory items are defined, and they apply the range checks (lower and upper limits) and checklist tests

(checklists not currently used in JHS) for an item. Records that have been batch loaded and screened in Manage appear identical to those records entered interactively in Enter.

Once data have passed screening, the data are ready to be edited, coded, validated, and merged. You can view the results of batch-loading in the SQL\*Load Log from the Reports menu.

### 3.2.2 Preparing Data for Batch Loading

#### 3.2.2.1 Creating a Control File

To create a control file, do as follows:

1. Select **Load > Control File > New** from the Manage window.
2. In the Open dialog box, select the panel for which you are creating the control file and the file format of the input ASCII file (fixed format or variable format).
3. Click **OK** to continue. The default version of the control file is displayed in the Control File window.
4. You can optionally edit the default control file at this time. See edit instructions below.
5. To save the control file, select **File > Save** or **File > Save As** to write the control file to the default C:\CT42 Clintrial directory or a directory of your choice. By default, the file name is panelname.ctl.
6. To close the Control File window, select **File > Close** or click on the window's X button.

To edit the default control file, do as follows:

1. If the Control File window is not opened, select **Load > Control File > Edit** to open the control file for editing. Indicate the directory location and file name in the Open dialog box. Click on **Open** to open the control file in the Control File window.
2. Edit the control file to correspond to the input ASCII file format, as follows:
  - a. Reorder items in the control file to match the order of values in the input ASCII file.
  - b. Delete items for which the input ASCII file does not contain values.
  - c. Add conversion instructions, such as instructions to convert date formats.
  - d. The control file must specify the character used to indicate character strings in the input ASCII file. Change the ENCLOSED By clause to contain this character. Default is the double quotation mark, for example, OPTIONALLY ENCLOSED BY ' " '.
  - e. For a variable format control file, change the default delimiter '@' to the character that is used as a field delimiter in the input ASCII file, for example, FIELDS TERMINATED BY ',' for a comma-separated file (.cvs).
  - f. For a fixed format control file, change an item fixed size if needed.
  - g. By default, a control file includes the line TRAILING NULLCOLS to indicate that, if not enough values are supplied for a record in the input ASCII file, items in the panel will be given the value of Null when the record is batch loaded.
  - h. For probably all date fields, you will want to change the date format of the item. For example, specify the date format as DATE "MM/DD/YYYY" if the input ASCII file contains the date 10/03/2000 (has not yet been tested in JHS).
  - i. For items of data type NUMBER or DATE, the default control file contains a NULLIF clause. The NULLIF clause in the default control file specifies an item as Null if the value in the input ASCII file is blank. Specify another value if the input ASCII file contains a value other than blank for Null, for example, a period (.).
  - j. Items of data type TEXT contain an LTRIM clause to trim leading blanks and a RTRIM clause to trim trailing blanks.
3. Select **File > Save** or **File > Save As** to save the edited control file.
4. Select **File > Close** or click on the window's X button to close the Control File window.

#### 3.2.2.2 Loading the Data

To batch load data requires that the Oracle SQL\*Loader is installed on the computer (use the 32-bit version). Consult Oracle SQL\*Loader documentation for more detailed information on loading data.

It is recommended that you check a batch-load of a sampling of records in the input ASCII file to ensure that positions and formats of fields in the input ASCII file match the corresponding control file.

To batch-load data, do as follows:

1. Select **Load > Load Data** from the Manage window. The Batch SQL Loader dialog box opens.
2. In the dialog box, specify the names and locations of the control file for **Control File** and the input ASCII file for **Data**. Clintrial saves the files specified in this dialog box as defaults for the next session, but you can change these defaults if needed. You can also specify names and locations of files created by the batch-load process: the **Log file**, the **Bad file**, and the **Discard file**. The Log file is a report file of the batch-loading process. The Bad file lists records that were rejected. The Discard file lists records that did not meet the selection criteria for batch loading.
3. If you click **Advanced** in the Batch SQL Loader dialog box, the Advanced Batch Loader Options dialog box opens. You can select addition options as needed such as Records to Skip, Records to Load, Rows per Commit, Maximum Errors, Maximum Discards, and Maximum Bind Array. In most cases, you will probably use the Clintrial defaults. Click **OK** to continue.
4. From the Batch SQL Loader dialog box, click **Load** to batch load the data into an update table. Click **OK** to close message that job was submitted. The Batch SQL Loader dialog box closes after the job has run.
5. From the Manage window, select **Reports > SQL\*Load Log** to view the results of the job run. The Open dialog box opens. Select the path and name of the load log file, then click **Open**. The Oracle Batch Log window opens. For information on the log's entries, see your Oracle documentation. You can print the report from **File > Print**. Close the Oracle Batch Log window from **File > Close** or from the window's X button to return to the Manage window.

### 3.2.2.3 Screening Batch-Loaded Data

You screen records after data are batch loaded into an update table. Screening combines the following processes running concurrently:

- Applies data checks to record data
- Updates the system items
- Groups records into observations as needed (not used in JHS)

The data checks include the same checks applied during interactive data-entry. Records that have been successfully batch-loaded and screened appear identical to records that were entered interactively.

You can only screen records whose **record status** is Unscreened (3) or Screening Error (-3). Records that pass screening are assigned the status Verified (1). Records that fail screening are assigned the status Screening Error (-3).

To screen batch-loaded data, do as follows:

1. Select **Load > Screen** from the Manage window. The Screen dialog box opens.
2. In the Screen dialog box, select the panel(s) from **Panels** that you want to screen. To screen records, check **Release for Validation**. To override data-entry checks on the data, check **Override Checks**. To select records for screening by using a SQL restriction, click **SQL**. To screen data as a batch process, check **Submit Batch**.
3. Click **OK** to screen the records. Click **OK** in the message box at the completion of the screening process.
4. To view the results of screening in Screen Log, select **Reports > Screen Log > View** in the Manage window. The Screen Log is a cumulative report that describes the results of the screening process with entries for each panel that was screened. You can print the Screen Log report from **File > Print** or save from **File > Save As**. Close the Screen Log window from **File > Close** or from the window's X button to return to the Manage window.

Once a record passes screening, it can be edited, coded, validated, and merged.

### 3.3 Coding Data – not available at this time

#### 3.3.1 Overview

#### 3.3.2 Coding Thesaurus

#### 3.3.3 Coding Techniques – Automatic, Interactive

#### 3.3.4 Items To Be Coded

### 3.4 Validating and Merging Data

#### 3.4.1 Overview

Validation is a data cleaning process that checks the integrity of study data in the update tables by finding errors and data inconsistencies. Records must pass validation before they can be merged to the data tables.

Merging is the process of moving data that has passed validation from the update tables to the data tables.

#### 3.4.2 Validating Data

During validation, a validation procedure is run against the data in the update tables. A validation procedure is a PL/SQL procedure that is built automatically from derivations and rules. Derivations and rules are specified during the design of the DMS for a protocol panel. Derivations calculate derived values in the records being validated. Rules check that the data meet certain requirements of the study protocol. There is one validation procedure for each panel.

Records in the update tables must pass validation before they can be merged (moved) to the data tables.

You can view the results of the validation process in the Validation Log. An evaluation of a rule to False during validation also generates an entry in the Error Log. You can then review and edit the record from the Error Log.

To validate data, do as follows:

1. You can select records for validation either by panel (the Clintrial default) or by study page (the JHS DMS preference). To validate records by study page, set the Manage user preference `SELECT_BY_PAGE` to Yes from **File > Preferences** in the Manage window.
2. Select **Manage > Validate** in the Manage window. The Set Study Book dialog box may open if a study book has not been selected (go to 3), otherwise the Validation dialog box opens (go to 4).
3. In the Set Study Book dialog box, select the study book for the data that you want to validate. Click **OK** to continue. The Validation dialog box opens.
4. To validate records by study page, do as follows:
  - a. From the **Page List** drop-down list, select the page list that you want to use. You can create a new list from **List > New List** or edit an existing list from **List > Edit Page List** using the **List Wizard**.
  - b. Select either **All pages** or **Selected pages** to validate. Select the specific pages to validate from the list for Selected pages.
  - c. Optionally you can restrict the data included in the validation as follows:
    - 1) For the date and time that records were last modified, enter a **Date and Time Range**.
    - 2) For record status, select a **Status**.

- 3) For flags present, select one or more **Flags**.
- 4) For notes present, select one or more **Notes**.
- 5) For a SQL restriction, select **Edit > SQL Restriction**.
- d. Check the type of database table(s) you want to validate in **Table(s)**: UPDATE, DATA, or both.
- e. If you are running a test validation, clear the **Release for Merge** check box. Otherwise check Release for Merge.
- f. To run the validation as a batch process, check **Submit Batch**. Otherwise the validation runs interactively.
- g. Select **File > Run**. Click **OK** in the message box at the completion of the validation run. You return to the Validation dialog box.
- h. Select **Reports > Validation Log** to view the results of validation in the Validation Log. You can print the Validation Log from **File > Print** or save from **File > Save As**. Close the Validation Log window from **File > Close** or from the window's X button.
- i. Close the Validation dialog box at the completion of the validation process from **File > Close** or from the window's X button.

### 3.4.3 Merging Data

Once data have been validated, then data can be merged (moved) from the update tables to the data tables where the clean data are stored.

To merge records, do as follows:

1. You can select records for merging either by panel (the Clintrial default) or by study page (the JHS DMS preference). To merge records by study page, set the Manage user preference SELECT\_BY\_PAGE to Yes from **File > Preferences** in the Manage window.
2. Select **Manage > Merge** in the Manage window. The Set Study Book dialog box may open if a study book has not been selected (go to 3), otherwise the Merge dialog box opens (go to 4).
3. In the Set Study Book dialog box, select the study book for the data that you want to validate. Click **OK** to continue. The Merge dialog box opens.
4. To merge records by study page, do as follows:
  - a. From the **Page List** drop-down list, select the page list that you want to use. You can create a new list from **List > New List** or edit an existing list from **List > Edit Page List** using the **List Wizard**.
  - b. Select either **All pages** or **Selected pages** to merge. Select the specific pages to merge from the list for Selected pages.
  - c. Optionally you can restrict the data included in the merge as follows:
    - 1) For the date and time that records were last modified, enter a **Date and Time Range**.
    - 2) For record status, select a **Status**.
    - 3) For flags present, select one or more **Flags**.
    - 4) For notes present, select one or more **Notes**.
    - 5) For a SQL restriction, select **Edit > SQL Restriction**.
  - d. To validate the panels of the selected study pages before merging, if not done in Manage > Validate, check **Validate First**.
  - e. To run the merge as a batch process, check **Submit Batch**. Otherwise merge runs interactively.
  - f. Select **File > Run**. Click **OK** in the message box at the completion of the merge run. You return to the Merge dialog box.
  - g. Select **Reports > Merge Log** to view the results of the merge in the Merge Log. For information on any errors, see the Help menu for the Manage module on Validation and Merging: Error actions. You can print the Merge Log from **File > Print** or save from **File > Save As**. Close the Merge Log window from **File > Close** or from the window's X button.
  - h. Close the Merge dialog box at the completion of the merge from **File > Close** or from the window's X button.

### 3.5 Global Data Changes and Deletions

#### 3.5.1 Introduction

**Global change** is the process of changing one or more values in multiple records simultaneously. You can make global changes to individual or multiple panels, and to records in the update table, data table, or both. You cannot directly change any derived item values.

**Global deletion** is the process of deleting multiple records simultaneously. You can make global deletions to individual or multiple panels, and to records in the update table, data table, or both. You can view the results of global deletion in the Global Delete Log.

Global change and global deletion are powerful processes that alter records irrevocably. Because of this, before you save any global changes or deletions, you should preview the results of the global change or deletion process to ensure that the desired change is made or that the correct records have been selected for deletion. If the preview results are correct, you can then run the global change or deletion process and save the results.

If you want to change or delete enrollment data for study subjects, that is, records in the enrollment panel, you must perform a global change or global deletion. You cannot change or delete enrollment data using any other method. *To change or delete subject item values or any subject-related context items, you must select only the enrollment panel.* If you change or delete the subject item, when the global change is successful, records are changed or deleted in all panels in which the subject item is stored. To change other context item values, select all the panels you want to change, excluding the enrollment panel and any type 0 panels (non-subject data).

You can view the results of global change in the Global Change Log. Errors that occur during global change are recorded in the Error Log with the error types of GLOBCHG.

You can view the results of global deletion in the Global Delete Log. Errors that occur during global deletion are recorded in the Error Log with the error types of GLOBDEL.

#### 3.5.2 Global Change

To make a global change, do as follows:

1. Select **Manage > Global Change** in the Manage window. The Select dialog box opens.
2. In the Select dialog box, select the panels and tables whose records you want to change. When you click **OK**, the Global Change dialog box opens.
3. In the Global Change dialog box, do as follows:
  - a. Select the subjects you want to make changes to, except for type 0 panels. To select the subjects, do one of the following:
    - 1) For all subjects, click **All Subjects**.
    - 2) For individual subjects, click **Selected Subjects**. Select the subjects you want to change.
  - b. Under **Restrict Data**, select records to change as follows:
    - 1) For the presence of flags, select one or more **Flags**.
    - 2) For the presence of notes, select one or more **Notes**.
    - 3) For a SQL restriction, click the **SQL Restriction** box.
  - c. To override data-entry checks on the new values, check **Override Checks**.
  - d. To run the changes as a batch process, check **Submit Batch**. Otherwise global changes are done interactively.
  - e. Enter the new values for the items you want to change in the **Change To** field. To specify global change values, note the following:
    - 1) The new value must match the database format of the item.
    - 2) For items with data type TEXT, you must enclose the new value in single quotes.

- 3) The new value can be a constant, or a calculated value that can refer to other items in the panel.
- 4) To specify a calculated value, enter a valid SQL UPDATE statement. The SQL statement can contain any valid Oracle function or operator.
- f. To preview your changes before running them (recommended), select **View > Preview**.
- i. To run the changes, select **File > Run**. Click **OK** in the message box at the completion of the global change run. You return to the Global Change dialog box.
- g. Select **Reports > Global Change Log** to view the results of a global change in the Global Change Log. You can print the Global Change Log from **File > Print** or save from **File > Save As**. Close the Global Change Log window from **File > Close** or from the window's X button to return to the Manage window.
- h. Close the Global Change dialog box at the completion of the global change from **File > Close** or from the window's X button.

### 3.5.3 Global Deletion

To make a global deletion, do as follows:

1. Select **Manage > Global Delete** in the Manage window. The Select dialog box opens.
2. In the Select dialog box, select the panels and tables whose records you want to delete. When you click **OK**, the Global Delete dialog box opens.
3. In the Global Delete dialog box, do as follows:
  - a. Select the subjects you want to delete, except for type 0 panels. To select the subjects, do one of the following:
    - 1) For all subjects, click **All Subjects**.
    - 2) For individual subjects, click **Selected Subjects**. Select the subjects you want to delete.
  - b. Under **Restrict Data**, select records to delete as follows:
    - 1) For the presence of flags, select one or more **Flags**.
    - 2) For the presence of notes, select one or more **Notes**.
    - 3) For a SQL restriction, click the **SQL Restriction** box.
  - c. To run the deletions as a batch process, check **Submit Batch**. Otherwise global deletions are done interactively.
  - d. To preview your deletions before running them (recommended), select **View > Preview**.
  - j. To run the deletions, select **File > Run**. Click **OK** in the message box at the completion of the global deletion run. You return to the Global Delete dialog box.
  - e. Select **Reports > Global Delete Log** to view the results of a global deletion in the Global Delete Log. You can print the Global Delete Log from **File > Print** or save from **File > Save As**. Close the Global Delete Log window from **File > Close** or from the window's X button to return to the Manage window.
  - f. Close the Global Delete dialog box at the completion of the global deletion from **File > Close** or from the window's X button.

## 3.6 Logs and Reports

Clintrial contains twelve logs and reports in the Manage module that show the results of various data management processes. Logs and reports can be viewed online, printed, and saved to a file.

No JHS DMS custom logs and reports are available at this time.

The Manage logs and reports are as follows:

**Audit History Report** – a report that shows the history of changes to the audit start point for all audited panels, including the current and past audit start points for each panel, and the dates at which the audit start points became effective.

**Audit Notes Report** – a report that shows the changes made to notes attached to records in one panel. It does not show deletions of notes attached to clinical data. For a note to appear in the report, the record to which it is attached must itself be eligible for auditing.

**Audit Records Report** – a report that shows all changes and deletions made to a panel's records after the audit start point has been reached.

**Automatic Coding Log** - a cumulative report that describes the results of the automatic coding process. Contains entries for each panel that was coded automatically.

**Coded Item Report** - a report that provides information about items that were coded interactively for a panel, including the verbatim text, thesaurus term, and code applied for each item.

**Error Log** - a cumulative log of errors that occurred during screening, validation, merging, global change, and global deletion. There is one Error Log per protocol. Errors are displayed in ascending order by panel and subject item. Each row represents a record in the panel. When viewing the Error Log, you can double-click a record to open that record for editing in a study page.

**Global Change Log** - a cumulative report that describes the results of global change processes. Contains entries for each panel and table that was submitted for global change. When you change enrollment records, this log shows only one record modified, however, records in every panel in which that subject item is stored are also modified.

**Global Delete Log** - a cumulative report that describes the results of global deletion processes. Contains entries for each panel and table that was submitted for global deletion. When you delete enrollment records, this log shows only one record deleted, however, records in every panel in which that subject item is stored are also deleted.

**Merge Log** - a cumulative report that describes the results of merging processes. Contains entries for each panel that was submitted for merging.

**Screen Log** - a cumulative report that describes the results of the screening process after a batch-load. Contains entries for each panel that was screened.

**SQL Load Log** – a report that displays the results of batch-loading.

**Validation Log** - a cumulative report that describes the results of the validation process. Contains entries for each panel and table that was validated.

To view a log or report, select **View** from the **Reports** menu for a log. It takes several minutes for a log to display following notification of completion of a batch process. If an open log window is empty, wait another minute and then select **File > Refresh**.

Logs can be filtered to show only specific rows. In the log window, select **View > Filter** to open the Specify Filter dialog box. Click on **Help** for instructions. Click on **OK** to return to the log window.

Logs can be sorted according to criteria you define. In the log window, select **View > Sort** to open the Specify Sort Columns dialog box. Click on **Help** for instructions in sorting data. Click on **OK** to return to the log window.

When viewing a log or report, you can navigate between its pages by using the **View > First Page**, **View > Prior Page**, **View > Next Page**, and **View > Last Page**.

You can purge logs of data at any time. When you purge a log, you can purge all of its records (**Purge All**) or only selected records (**Purge Selected**) from the **Reports** menu for the log.

### **3.7 Closure Checks**

Not available at this time.

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## 4.0 PROGRAMMER GUIDE TO RETRIEVING DATA

### 4.1 Overview

SAS Version 8 is being used for retrieval of study data entered in the JHS DMS and stored in the Oracle database. SAS Version 8 can access the Oracle database directly using the new SAS/ACCESS LIBNAME statement that can take full advantage of SAS Version 7 and Version 8 enhancements.

The SAS data retrieval program and retrieval process described here are for the second release of the JHS\_COHORT protocol distributed on December 14, 2000. The SAS retrieval program will require modification after each protocol release for any new form/version.

Earlier versions of this SAS retrieval program used the SAS/ACCESS to Oracle interface to read the Oracle data tables. Due to retrieval constraints using the SAS/ACCESS interface -- limited to SAS Version 6 naming conventions and restricted to text value lengths no longer than 200 characters -- the program was rewritten to use the new SAS/ACCESS LIBNAME statement to read the Oracle data tables. This enables the use of 32-byte names for SAS variables and enables read/write of character data up to 32,767 bytes using a DBMAX\_TEXT option. And, now there is no creation of access and view descriptor files as an intermediate step to creation of SAS analysis datasets.

As an alternative to the SAS data retrieval procedure, a description of the Clintrial Retrieve Query By Form (QBF) procedure is also provided.

### 4.2 SAS Retrieval for Custom Reports

Not available at this time. Development will be similar to SAS retrieval for data analysis.

### 4.3 SAS Retrieval for Data Analysis

#### 4.3.1 Overview

The SAS data retrieval program reads data directly from the Oracle data tables with the SAS/ACCESS LIBNAME statement and creates output SAS analysis datasets, one dataset per form/version.

Data integrity and security are maintained in this process. The SAS/ACCESS LIBNAME statement requires entry of Oracle username, password, database alias, and protocol name. A parameter specifies access to the Oracle data tables as read-only. **The JHSCC must identify allowable users for data retrieval, and the Database Administrator must provide adequate Oracle access rights for these users. These rights must be similar to the Oracle SYSTEM user account for access to data entered by any user.** The SAS retrieval program delivered to the JHSCC will include the SYSTEM user account as default.

#### 4.3.2 Contents of SAS Retrieval Program

The SAS retrieval program contains the following sections:

1. Documentation block providing a description of the program.
2. SAS environment options.
3. Initialization of program macro variables.
4. Initialization of macro variables for Oracle access.
5. LIBNAME statements for input Oracle data tables and output SAS analysis datasets.
6. Program title and footnote statements.
7. %INCLUDE statement for PROC FORMAT code.
8. Macros:

- a. RETRV reads Oracle data tables and creates output SAS analysis datasets, with conversion of DATETIME variables to SAS DATE variables and with a %INCLUDE statement for FORMAT and LABEL statements by form/version.
  - b. RENAME provides original and temporary variable names for a list of variables to convert from DATETIME to SAS DATE format.
  - c. COUNT counts the number of variables in a list for renaming.
9. Macro calls to RETRV for each form/version. Parameter PAGES is the list of page sections (likewise, data tables) that comprise a single form, and parameter DVARS is the list of DATETIME variables to convert to SAS DATE variables.

#### 4.3.3 Setup of the SAS Retrieval Program

The current version of the SAS retrieval program was developed in SAS Version 8.1 that was installed as a standalone program on a workstation connected to the JHS server containing the Oracle database. This SAS retrieval program does not need to be called from within Clintrial or the JHS DMS.

Steps to set up the SAS retrieval program:

1. Install the SAS System software, Version 8 or later, according to your site's software installation policy.
2. Copy the SAS retrieval program file and accompanying files (%INCLUDE source code) to a directory on your workstation.
3. Edit the SAS retrieval program as follows:
  - a. Modify the 'outds' macro variable to specify the LIBREF name of the LIBNAME statement for the output SAS analysis datasets and modify the corresponding LIBNAME statement with the directory location of the output SAS analysis datasets. The SAS retrieval program delivered to the JHSCC includes the LIBNAME statement as used at the UNC-CSCC.
  - b. Enter the Oracle access information for your site (macro variables 'username', 'userpw', 'database', and 'protocol'). The SAS retrieval program delivered to the JHSCC includes the SYSTEM user account information, the database alias ORC0, and the protocol name JHS\_COHORT.
  - c. Modify the 'home' and 'byformcd' macro variables to specify the directory locations of the %INCLUDE source code. The program delivered to the JHSCC includes the directory locations used at the UNC-CSCC.

#### 4.3.4 Generation of %INCLUDE Source Code for Formats and Variable Labels

A process was established to generate PROC FORMAT statements and FORMAT and LABEL statements from information in the database to include in the SAS retrieval program. A single text file is created of the PROC FORMAT statements for all codelists in the database, and individual text files for each form/version are created of FORMAT and LABEL statements for items in the protocol. In addition, a list of DATETIME variables is generated to update the RETRV macro parameter DVARS for each form/version to convert DATETIME variables to SAS DATE variables.

The steps to generate source code for the SAS retrieval program are as follows:

1. Generate the PROC FORMAT code of all codelists in the database from a Clintrial Retrieve module query. To create a format library text file, do as follows:
  - a. Select any query type from **File > New Query** from the Retrieve browser (for example, select **By SQL**).
  - b. In the query dialog box (for example, Query By SQL dialog box), do as follows:
    - 1) Enter a query. For example, for Query By SQL, enter SQL text 'select \* from JHS\_COHORT.ABBA1\_ALL;'. Entry of a valid query is required to get to the next dialog box to generate the PROC FORMAT code.
    - 2) Select **Results > To SAS Data File**.
    - 3) Select **File > Run Query**.

- c. Now in the Create a SAS File dialog box, do as follows:
    - 1) Check option **Generate SAS Format Library**. You do not need to generate a SAS data file.
    - 2) Click on **Browse** to select a directory path location and to enter a file name (without extension) for the resultant code. The directory path and file name must not contain embedded periods (.), otherwise Clintrial will truncate the path or name at the first period. The output text file will have extension FMT (for example, **FrmtlibV1-2.fmt**).
    - 3) Click **OK** to continue.
    - 4) Close the open windows and exit Clintrial.
  - d. To preserve the original version of **FrmtlibV1-2.fmt**, make a duplicate copy of the file to modify for the SAS retrieval program (for example, **JHSRetrV1-2PrFormat.sas**).
  - e. Edit text file **JHSRetrV1-2PrFormat.sas** to replace single and double quotation marks embedded in the value text string with two single quotation marks. It is not required to remove statements for forms or items not in the current protocol.
  - f. Include this text file in a %INCLUDE statement in the SAS retrieval program.
  - g. Special note: Clintrial uses the following conventions for SAS format names:
    - 1) 8-character maximum.
    - 2) Prefix '\$' if code is TEXT data type.
    - 3) The 6-character codelist SAS name assigned in Design.
    - 4) Suffix 'V' if decoding to values or 'S' if decoding to short label or 'L' if decoding to long label. In JHS, we decode to values.
2. Run the following three SQL SELECT commands (in file **JHSRetrV1-2Selects.sql**) from a SQL command window to create FORMAT statements and LABEL statements for all relevant items in the current protocol. You will need to run these SQL commands using an Oracle user account with access rights like user SYSTEM. The PLSQL Developer software is used at the UNC-CSCC.

For FORMAT statements of character codes:

```
SELECT distinct 'format '||a.item_name||' $'||b.sasname||'V. ;' item_code
FROM ctsdd.item a, ctscodes.code_index b
WHERE a.protocol='JHS_COHORT'
and b.codetype='TEXT'
and a.codename is not null
and a.codename=b.codelist
ORDER BY item_code ;
```

For FORMAT statements of numeric codes:

```
SELECT distinct 'format '||a.item_name||' '||b.sasname||'V. ;' item_code
FROM ctsdd.item a, ctscodes.code_index b
WHERE a.protocol='JHS_COHORT'
and b.codetype='FIXED'
and a.codename is not null
and a.codename=b.codelist
ORDER BY item_code ;
```

For LABEL statements:

(SAS V8 allows up to 40 characters for variable label text. A blank is added as the last character of the label text to handle cases where DESCRIP is null and needs a blank space between double quotation marks as label text.)

```
SELECT distinct 'label '||item_name||'='||substr(descrip,1,39)||' ";' item_label
FROM ctsdd.item
WHERE protocol='JHS_COHORT'
ORDER BY item_label ;
```

- a. Run the SELECT commands. For example, in the PLSQL Developer software, select File > Open > Command File, enter the SELECT commands, and then choose Session > Execute.

- Select all the output statements generated (Edit > Select All) and copy (Edit > Copy) to a single text file (for example, **Parse\_TextV1-2.txt**).
- b. Edit text file **Parse\_TextV1-2.txt** as follows:
    - 1) Modify any variable labels with two consecutive double quotation marks ("" ) indicating no label text by inserting a blank (" "), otherwise a single quotation mark prints as the label text.
    - 2) Replace embedded double quotation marks in the label text with single quotation marks.
    - 3) Remove semicolons embedded in label text.
    - 4) It is not necessary to remove extra lines of text and underscores generated by a SELECT command run, such as the header associated with a page break.
  - c. Continue with step 3.
3. Run the SAS program **Parse\_TextV1-2.sas** to select FORMAT and LABEL statements by form/version from input text file **Parse\_TextV1-2.txt** (created in step 2) and create individual output text files for each form/version. Currently this SAS program adds comment delimiters around the FORMAT statements in the output text files so that codes and not format values are stored in the output analysis SAS datasets.
    - a. Check each output text file and remove any unwanted text. For example, remove any lines that do not begin with 'format' or 'label' or do not contain the comment delimiters.
    - b. Include the individual output text files in a %INCLUDE statement in the SAS retrieval program. A single %INCLUDE statement contains the form/version file name as a macro variable.
    - c. Special note for FORMAT statements: See step 1 for Clintrial's naming conventions of SAS format names.
    - d. Special notes for LABEL statements: LABEL statements for CONTEXT panel items (key field items) are hardcoded in the SAS retrieval program. A label text can contain up to 40 characters in SAS Version 8.
  4. Run the following SQL SELECT command (in file **ItemdateV1-2.sql**) to list all DATETIME variables in the current protocol to convert to SAS DATE variables in the SAS retrieval program. You will need to run the SQL command using an Oracle user account with access rights like user SYSTEM. In the SAS retrieval program, add the variable names to the RETRV macro parameter DVARS by form/version.

```
SELECT item_name
FROM ctsdd.item
WHERE protocol='JHS_COHORT' and dtype in('DATE','DATETIME')
ORDER BY item_name;
```

#### 4.3.5 Special Notes on the Current Version of the SAS Retrieval

1. The program contains retrieval code for forms included in the JHS\_COHORT protocol as of December 14, 2000.
2. The program retrieves data field values only and does not include retrieval of flags and notes.
3. The program includes LABEL statements with the label text from the Clintrial item descriptions used as screen prompts. The item descriptions were assigned when the item was created to accommodate screen design and to match form layout. **It is recommended that the JHSCC staff review and update these variable labels for the SAS retrieval program to meet their analysis needs.** Notes on the labels:
  - a. Label text lengths are limited to 40 characters, so some labels are truncated.
  - b. A label may be blank or abbreviated or the text of an instruction, as per the form layout.
  - c. A label may be incorrect if a change was made to the item but was not made also to the item description. A screen prompt can be revised directly on the page section, not requiring that the item description be changed as well.
4. The program includes codelist codes and values in a SAS FORMAT procedure and in FORMAT statements. The FORMAT statements currently are within comment delimiters so that the data values written to the output SAS analysis datasets are the codes and not the format values.

5. Clintrial's DATE format is stored as a DATETIME format in the Oracle database. The SAS retrieval program converts DATETIME variables to SAS DATE variables using the SAS DATEPART function. Only study data dates are converted, not Clintrial-generated system dates.
6. Although the SAS retrieval program sets the YEARCUTOFF option to 1912 (a UNC-CSCC ARIC statistical programming rule), it can only interpret dates as retrieved from the Oracle database. Note the following year cutoff rule for Clintrial data entry (from Clintrial Help): "Years can be entered as two digits or four. When a two-digit year is entered, Clintrial stores numbers 00 to 49 as 21st century (2049) and numbers 50 to 99 as 20th century (1950)." **The data entry personnel must be instructed to enter dates with a 4-digit year to ensure the correct century.**

#### 4.4 Clintrial Retrieve Query By Form (QBF)

##### 4.4.1 Introduction

Clintrial Retrieve, one of the Clintrial core modules, can be used to access and extract data from the Clintrial database by creating and running queries. To access the Retrieve module, a user account must have the appropriate access rights assigned by the Clintrial Administrator.

Queries are created using the following four types of query tools:

- Query By Form - selecting fields and entering selection criteria directly on a study page (form). Requires familiarity with the study forms and with the data entry standards, but does not require familiarity with either SQL or with the structure of the Clintrial database.
- Query By Panel – defining detailed search criteria through use of SQL. Requires familiarity with panels and items within Clintrial and with simple SQL syntax.
- Query By SQL – creating SELECT and DESCRIBE statements. Requires familiarity with the structure of the Clintrial database and with SQL.
- Ad Hoc Query - creating subject record lists to retrieve data for those subjects. It does not require familiarity with SQL, but does require familiarity with the structure of the Clintrial database.

Query results can be sent to the screen, to an Oracle database table, or to a SAS data file. Then these data can be used in other applications to perform statistical analysis, create reports, or perform other tasks.

You can store the queries in a Query Library where it can be accessed at a later time. You can modify, copy, run, and delete saved queries.

Using the Custom menu in Retrieve and in other modules, a user can access and start up other applications to create reports from the study data. The user has access to the application from within Clintrial, but it executes outside of Clintrial.

##### 4.4.2 Using Query By Form

Query By Form (QBF) is a query method that creates a query directly from the same online study pages used in Clintrial Enter for data entry. For the JHS DMS, a single study page is usually equivalent to one form. However in several cases, a JHS form was split into two study pages due to Clintrial design limitations, i.e., PACA parts 1 and 2, PDSA parts 1 and 2, PFHA parts 1 and 2, DISA parts 1 and 2, MHXA parts 1 and 2, MSRA parts 1 and 2, SSFA parts 1 and 2.

You can create a query from multiple study pages. The number of study pages available at a time is determined by the ENT\_OPEN\_PAGES preference for the Enter module that is set by the Clintrial administrator. For JHS data entry, the preference is set at 1 (allowable range is 1-10) to limit the number of open pages at one time by a single user account in Enter. Once data have been entered and verified,

set the ENT\_OPEN\_PAGES preference to at least 2 for the Retrieve sessions so that you can add multiple study pages to a query for the several JHS forms that are split into multiple study pages.

Below are the steps for using Query By Form. It is suggested to perform a separate query for each JHS form, repeating these steps for each form.

Assumptions are that you have logged into the Clintrial Retrieve module and have selected the correct protocol:

- Start the Clintrial Retrieve module from **Start > Programs > Clintrial 4.2 > Retrieve**. Login to Clintrial with a valid Clintrial user name, password, and database alias (ORC0 for JHS). You are now in the Clintrial Retrieve window.
- From the Retrieve window menu bar, select **File > Set Protocol** and protocol JHS\_COHORT for retrieval of the baseline visit 1 data, if not automatically set at login.

The steps to use Query By Form are as follows:

1. Start Query By Form.

From the Retrieve window menu bar, select **File > New Query > By Form (QBF)** to start Query By Form. The Select Page dialog box opens.

2. Select study pages.

From the Select Page dialog box, select the study page(s) to include in the query. Study pages are added to a query one at a time. These study pages do not need to be in the same block (visit) or study book (INTERVIEW or EXAM).

To select a study page, do as follows:

- a. Select a study book.
- b. Select a study page from the list, or type the study page name in the Page field.
- c. Click OK to continue. A Query By Form window opens, displaying the study page you selected.

To open another study page, select **Edit > Select Additional Page** and repeat a-c above. If multiple study pages are open, you can move to another study page that is open using the commands in the Window menu. If an additional page is selected from the Edit menu that is already open, a new copy of the study page opens.

3. Select fields.

For the study page open in the Query By Form window, select either specific fields or all fields for the study page. The selected fields are highlighted on the study page.

To select or deselect all fields on the study page, select **Edit > Select All**.

To select or deselect a specific field, place the cursor in the field that you want to select or deselect using the Tab key or the mouse and then choose **Edit > Select Item**.

4. Enter criteria in fields to specify a subset of data to retrieve (optional).

If you enter selection criteria for a field, you do not also have to retrieve values for that field when you run the query. Selecting fields and entering selection criteria are separate tasks.

To enter selection criteria for the study page open in the Query By Form window, do the following:

- a. Place the cursor in the field for which you want to enter selection criteria using the Tab key or the mouse.

- b. Enter the selection criteria using one of the following methods:
    - 1) Enter an exact valid value. For a text field, enter the value without quotation marks. For a numeric value, enter a numeric value or function without quotation marks. For a date field, enter a date in a valid date format without quotation marks.
    - 2) Enter a value pattern as an operator and a valid value. No quotation marks are needed for text or numeric types, but they are required for date types.
    - 3) Select a code from the codelist, and optionally add an operator.
  - c. To enter a selection criteria for another field, repeat a and b.
5. Create a sort order of retrieved records (optional).

You create a sorting order for the retrieved records by field values. The default sort order for a field is None. You can specify sort orders for more than one field. Clintrial sorts the results according to the tab order of the fields.

To sort the query results for the study page open in the Query By Form window, do as follows:

- a. Place the cursor in the field whose values you want to sort.
- b. Select **Edit > Sort** to open the Sort Field dialog box.
- c. Select sort order Ascending, Descending, or None, then click OK to continue.

To remove the sort order for a field, do a-c above and select None.

To change the field sort order, do one of the following:

- a. Select **Results > To Window** to display the results on the screen, then run the query from **File > Run Query**. When the results are displayed on your screen, select **View > Sort** to sort the displayed records.
- b. Select **File > Convert to SQL** to convert the query to SQL code, then change the SQL syntax to reflect the order you want.

6. Create flag or note restrictions (optional).

To create a flag or note restriction for the study page open in the Query By Form window, do as follows:

- a. Select **Edit > Flags/Notes Restrictions**.
- b. Select the flag or note category and the flag or note name from the drop down list.
- c. Specify the flag or note level.
- d. Specify the page to which you want the flag or note to be attached. Note for the JHS DMS, the page number is displayed for the open study page and the field is disabled for entry.
- e. If you are creating a restriction at the Item level, specify the item to which you want the flag or note to be attached.
- f. Click Add. Clintrial Retrieve adds the flag or note restriction to the Selection box.
- g. Select whether to retrieve records if the flag or note is present or absent from the drop down list.
- h. To create multiple flag or note restrictions, repeat b-g. A logical operator field appears in the Selection box. Select the flag or note connector from the drop down list.

To remove a flag or note restriction, do as follows:

- a. Select the flag or note restriction to remove by clicking anywhere within the restriction in the Selection box.
- b. Click Delete.

7. Display the query in SQL format (optional).

You can display the SQL for the current query in Query By Form from **File > Convert to SQL** to review a single page query, to review a multi-page query as a whole, or to perform tasks for which you must use SQL. You can display a query in SQL at any time and still return to the Query By Form page(s) *if you do not alter the SQL*. However, if you alter the SQL in the Query By SQL window, you

should not return to the Query By Form page(s). Any changes you make to the SQL cannot display in the Query By Form page(s).

8. Run the query to retrieve the query results, and send the results to various locations in various export formats.

To run a query in the Query By Form window, do as follows:

- a. Select the destination for the query results from the **Results** menu. Options are **To Window**, **To Oracle table**, or **To SAS Data file**.
- b. Select **File > Run Query**.

After the query runs, your results destination does one of the following:

- a. To Window - displays the results in a Query By Form Results window.
- b. To Oracle table – opens the Results to Oracle Table dialog box.
- c. To SAS Data file – opens the Create a SAS File dialog box.

See the section on saving results to a SAS data file below for details on creating an output ASCII file (.DAT) of the study data retrieved from the query and a SAS source code file (.SAS) with the input statement containing the variable names and formats to read the ASCII data file.

9. Print the query.

Select **File > Printer Setup** to specify which local or network printer to use. Depending on your printer, you can also adjust certain printer defaults like page orientation, paper size, and print resolution. Consult your printer's documentation for more information.

To print a report or window from the Query By Form window, do as follows:

- a. Select **File > Print**. At any time the Print command is not available for a displayed window, then that window does not have print capability.
- b. The Print Options dialog box opens. Accept default settings or modify any of the values as needed.
- c. Click OK to print.

10. Save the query to the Query Library for later use by you or other users (optional).

To save a query in the Query By Form window, do as follows:

- a. Select **File > Save Query As**.
  - 1) If you have previously saved this query, Clintrial Retrieve saves the query to the same query name automatically.
  - 2) If you have not previously saved this query, the Save Query As dialog box opens.
- b. In the Save Query As dialog box, do as follows:
  - 1) If you are saving a Query By SQL, select the protocol under which you want to save the query.
  - 2) Enter the query name
  - 3) Enter a description for the query.
  - 4) If you want the security access type for the query to be Public, check Public Query.
  - 5) Click OK.

To access the saved queries in the Query Library, select **File > Query Library** from the Query By Form window.

#### 4.4.3 Saving Results to a SAS Data File

Query results can be saved to a SAS data file from the Query By Form window in one of two ways: save directly to a SAS data file without display, or display and then save to a SAS data file.

To run and save the query results directly to an SAS data file (does not display results), do as follows:

1. From the Query By Form window, select **Results > To SAS Data file** from the menu.
2. Create or select the query you want to run either for selected items (place cursor on item and then select **Edit > Select Item**) or for all items (select **Edit > Select All**).
3. Select **File > Run Query** to run the query and which opens the Create a SAS Data File dialog box.
4. From the Create a SAS Data File dialog box, to save the query results to a SAS data file, do:
  - a. Specify path, file name, label, and record length for the SAS data file. Note that path C:\CT42 is the default.
  - b. To create a PROC FORMAT for this data file (optional), check Make PROC FORMAT.
  - c. Click OK. Clintrial Retrieve displays a confirmation message indicating where the query results are stored; click OK.

To run and display the query and then save the results to a SAS data file:

1. From the Query By Form window, run the query in **File > Run Query** which sends the results to a Query By Form Results window.
2. From the Query By Form Results window, select **File > Save Results As**. The Save Results As dialog box opens.
3. In the Save Results As dialog box, select SAS Data Files [SAS] from the File Format drop down list. The file name in the File Name field changes to \*.SAS, and the SAS fields at the bottom of the dialog box become active. Then, do:
  - a. Specify the path, file name, label, and record length for the SAS data file. Note that path C:\CT42 is the default.
  - b. To create a PROC FORMAT for this data file (optional), check Make PROC FORMAT.
  - c. Click OK. Clintrial Retrieve displays a confirmation message indicating where the query results are stored; click OK.

#### 4.4.4 Setup and Run the SAS Data

If you have saved the query results to a SAS data file, then you have the following two or three text files in the directory that you chose:

1. SAS source code file (.SAS) with a data step that includes an INFILE statement with the location and name of the ASCII data file, an INPUT statement with valid variable names and formats, LABEL statements for the variables (the prompt used in the data entry window), and optionally FORMAT statements for the variables with codelists.
2. ASCII file of SAS data (.DAT) from the query that corresponds to the SAS source code INPUT statement.
3. Optionally, PROC FORMAT code file (.FMT) with the VALUE statements for all the codelists attached to the variables in the query.

To setup a SAS program using these files, do the following:

1. Optionally insert the PROC FORMAT code file into the SAS source code file either directly or with a %INCLUDE statement.
2. Add additional SAS statements to the SAS source code file either to save the data to a permanent SAS dataset, to create a report, or to run data analysis.

You can now run the final SAS source code file in SAS. Consult your local SAS support personnel for information on how to run SAS at your site.

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## 5.0 ADMINISTRATOR GUIDE

### 5.1 Data Entry Workstation Setup

#### Setting year format for dates

The format in which dates are entered and displayed in Clintrial is determined by the Window's date setting. Set the date format (a regional setting) to a four-digit year format (mm/dd/yyyy).

In Clintrial data entry, enter four-digit years for dates to ensure the correct century. If a two-digit year is entered, Clintrial interprets the year as follows:

- 00 through 49 as the 2000's
- 50 through 99 as the 1900's

#### Creating a desktop Enter shortcut icon

To put a shortcut on the desktop, do as follows:

1. In **Start > Programs > Clintrial 4.2**, right-click on **Clintrial Enter** and left-click **Create Shortcut**.
2. Holding down the left mouse button, drag the new shortcut icon, named **Clintrial Enter (2)**, from **Start > Programs > Clintrial 4.2** onto the desktop.
3. To rename the shortcut, right-click the shortcut and left-click **Rename**. Type the new name, and press **Enter**.
4. Double-click the shortcut icon to start the Clintrial Enter module.

To change any settings for the shortcut, right-click the shortcut and then left-click **Properties**.

To delete a shortcut, drag the shortcut to the **Recycle Bin**. The original item still exists on the disk.

#### Screen resolution and window size

The screen resolution and window size for data entry must be set the same as the setting used during the development of the JHS DMS. The settings are as follow:

- Set the screen resolution to 800 by 600 pixels in **Start > Settings > Control Panel > Display**. Click on the **Settings** tab. Under Screen area, click on the left or right of the arrow to get this resolution.
- Set the window size to Maximum. Click the middle windows button on the top right of an open window to toggle between maximum full screen and minimum window display.
- Remove the toolbar buttons to maximize the screen further. In a window, select the **Window > Toolbar** menu commands and click on **Toolbar** to remove the check. Several bugs in Clintrial at the time of this writing affects some of the toolbar buttons, so it is recommended to use the menu commands or to right-click the mouse for selections.

#### Installing and Deinstalling Oracle and Clintrial Client Software

Installing the Oracle Client Software:

1. Insert the Oracle CD into the workstation CD-Rom.
2. Once the Oracle installer main menu appears, click on "Begin Installation". If the Oracle installer main menu does not appear, you can open the Windows Explorer and access the root directory of the Oracle CD-ROM. From the root directory, double-click on SETUP.EXE.
3. You are then asked to confirm the installation default settings, then click OK.
4. You will then be asked to choose the type of installation, click on "Oracle 8 Client" then click on OK.
5. You will then be asked the type of user you are installing for, choose "Application User" and click OK.

6. You will then be asked where the Oracle Documentation should be put, choose "CD-Rom" and click on OK.
7. You will then be asked if you would like to view the Oracle documentation from within your browser, answer No. The Client installation is complete and the Oracle installer will be exited.
8. In order to be able to use Clintrial you must now install the Oracle "Required Support Files 7.3.4.1.1" to do this repeat steps 1 through 3 above.
9. You will then be asked to choose the type of installation, click on "Custom Installation" then click on OK.
10. The Software Asset Manager will appear. Double-click on the All Products entry on the left hand side of the Software Asset Manager window. A scrollable list will be presented; choose "Required Support Files 7.3.4.1.1" by clicking on the entry, then click on Install. This will install the Required Support Files.
11. Upon completion of the installation the Oracle Installer will notify you, at this point you must click on OK, you will be returned to the Software Assets Manager, click on Exit then Yes, to confirm that you would like to exit the Oracle Installer.
12. Reboot your computer after exit from the Oracle Installer with the resultant changes to your AUTOEXEC.BAT (or, you can wait until after Clintrial installation and network connection).
13. You are now ready to install the Clintrial client software on the workstation.

#### Installing the Clintrial Client Software:

1. Insert the Clintrial CD into the workstation CD-Rom.
2. Open the Windows Explorer and access the root directory of the Clintrial CD-Rom. From the root directory double-click on Setup.exe.
3. The Clintrial Welcome screen will appear, click Next.
4. You will be asked for name and company, enter these and click Next.
5. Clintrial will then ask you to confirm that the client software is to be installed in C:\CT42, click Next.
6. Choose Typical as the setup type and click Next.
7. Select Clintrial 4.2 as the Program Folder and click Next.
8. The installation will then take place, at the end of which you will be asked if you would like to view the ReadMe file. Click on Finish.
9. You are now ready to establish your network connection to the computer where the Clintrial database is located.

#### Establishing Network Connection:

1. Start the Oracle Net8 Easy Config module by selecting the following: **Start > Programs > Oracle for windows 95 > Oracle Net8 Easy Config** .
2. Click Yes to continue on past the first dialog box with a warning that comment information in the Network Configuration files may be lost or repositioned when saving your Network configuration.
3. Choose action Add New Service (database alias) and enter a name as the New Service Name. Enter ORC0 as the service name (or the current database alias at your site). Note that .WORLD is automatically appended to ORC0 in the display of available Service Names. Click Next to continue.
4. Choose TCP/IP (Internet Protocol) to connect to and communicate with the Clintrial database you want to use. Click Next to continue.
5. Enter the IP address as Host Name of the computer where the Clintrial database is located. Leave 1521 as the default Port Number. Click Next to continue.
6. Enter ORC0 (or the same name as the current database alias) for the Database SID. Click Next to continue.
7. Click Test Service to test the connection. In the database connection dialog box, enter a valid Oracle database username (for example, SYSTEM) and its password and click Test. After the test is completed, click Done to continue. If the connection test was successful, click Next from the Test Service dialog box to continue; if not successful, click Back to review and correct previous entries.
8. Click Finish to save your service name changes.
9. You are now ready to create new Clintrial user accounts.

### Setting Up Client User Accounts:

1. Start the Clintrial Admin module by selecting the following:  
**Start > Programs > Clintrial 4.2 > Clintrial Admin**
2. In the database connection dialog box, enter the User Name (for example, CTSYS) and Password that was set up with system privileges on installation of Clintrial on the server. For Database, enter your service name added in Oracle Net8 Easy Config preceded by @ ( for example, @ORC0).
3. From the Security menu, select Users to get the User Maintenance window.
4. From the Edit menu, select Add.
5. Enter a name (user account) for the new User Name. A valid user name can be up to 20 characters long, alphanumeric, not beginning with a number, and without spaces or other symbols. User name is not case sensitive.
6. Enter a Password. When you save the window, you will be prompted to re-enter the password for verification. The password must conform to the parameters as set up by the system administrator (currently length set at 6). A password must consist of alpha and/or numeric characters (other symbols and spaces not allowed) and cannot begin with a number. A password is not case sensitive.
7. Accept the defaults, or change the values for :  
Default Tablespace: CT\_USER  
Temporary Tablespace: TEMPORARY  
Profile: DEFAULT
8. From the File menu, select Save to save the window.
9. From the Security menu, select User Access to set access rights and access levels for Protocol, Non-Protocol, and Panel (to be determined). Close the User Access Rights window.
10. From the Parameters menu, select System to define any special characteristics of the work environment for the user. Close the System Parameters window.
11. Close the Clintrial Admin module after the new user accounts have been created with appropriate access rights and system parameter definitions.
12. Optionally you can place a Clintrial 4.2 icon on the Desktop (for Switchboard with access to all Clintrial modules or just for Enter to perform data entry) by doing as follows. Open My Computer or Windows Explorer and select Clintrial 4.2. From the File menu, select Create Shortcut. Select the Clintrial 4.2 shortcut and drag the shortcut onto the Desktop by holding down the left button of the mouse.

### Deinstalling Oracle and Clintrial Client Software:

To delete Oracle and/or Clintrial client software from a computer, say, to restart installation after an unsuccessful attempt, use the following deinstallation instructions.

To deinstall Clintrial Client Software, do the following.

1. Double-click on the icon for My Computer.
2. Double-click Control Panel.
3. Double-click Add/Remove Programs.
4. Select Clintrial 4.2 and click Add/Remove.
5. The directory C:\CT42 can be deleted from Windows Explorer or by the RD DOS command at an MS-DOS command prompt.

To deinstall Oracle Client Software, do the following.

1. Start the Oracle Installer module as follows: **Start > Programs > Oracle for Windows 95 > Oracle Installer.**
2. Select all Oracle modules (shift-down arrow) in the rightmost column labeled "Products Installed at C:\ORAWIN95" and click Remove. The Oracle Installer remains installed and does not need to be deleted if Oracle will be reinstalled.

## 5.2 System Parameters

Clintrials system parameters define the characteristics of the work environment for all users of an Oracle database to which the users connect through Clintrials. These system parameters are set in the Clintrials Admin module from a user account that has the Admin System access right. In Admin and in the following table, system parameters are grouped by the module to which they pertain.

Parameters of type 'System' cannot be overridden. Those of type 'Protocol' can be overridden by modifying protocol parameters within the Design module. Those of type 'User' can be overridden by user preferences for each module (or Group). For JHS, the 'System' parameters are set for the study and do not override the values within protocol or user.

The table below lists the parameter value to be used in JHS and a description of what the value means. If the description is blank, no value has yet been determined.

Group	Type	Name	Value	Description
Admin	System	PASSWORD_ENCRYPTION	No	
	System	SAVE_STATS	Yes	
	System	ACTIV_LOG_END		
	System	ACTIV_LOG_START		
	System	PASSWORD_EXPIRE_DAYS		
	System	PASSWORD_MINIMUM	6	
	System	USR_DB_PROFILE	DEFAULT	
	System	USR_DFT_TSP	CT_USERS	
	System	USR_TMP_TSP	TEMPORARY	
Manage	System	ALLOW_MERGE_TO_VALID	Yes	
	System	AUDIT_REASON_REQD	Yes	
	System	AUTOCODE_FULL_CNT	No	
	Protocol	AUTOCODE_RECODE_ALL	No	
	System	AUTOCODE_SET_FAIL	Yes	
	Protocol	ENCODE_CLEAR_ITEMS	Yes	
	User	SELECT_BY_PAGE	Yes	
	User	AUDIT_ITEM_LIST		
	User	ERRLOG_DISPLAY_ITEM		
Entry	User	DD_BLANKS_IN_PATIENT	No	Blank spaces not allowed in subject item.
	User	ENT_AUTOSKIP_DFLT	No	
	User	ENT_ENTER_AS_TAB	Yes	Enter key acts as Tab key.
	User	ENT_FORM_INSERT	Yes	Data is saved automatically when a page is closed.
	User	ENT_OPEN_NAVIGATOR	Yes	
	User	ENT_TAB_PAGE_FORWARD	No	In last field on page, Tab key moves to first item on current page.
	Protocol	VERIFY_BLIND	Yes	
	System	VERIFY_SHOW_TAGS	Yes	
	User	ENT_ENR_STUDYBOOK		
User	ENT_OPEN_PAGES	1	Number of study pages that can be opened concurrently. Increase to 10 temporarily to print study book or do QBF.	

Design	System	AUDIT_INVNOTES	Yes	
	Protocol	AUDIT_METADATA	Yes	
	System	AUDIT_PROTOCOL_MOD	Yes	
	System	AUDIT_SPONSORNOTES	Yes	
	Protocol	CONNECT_REQD_DD	No	
	Protocol	CONNECT_REQD_FRM	No	
	Protocol	CONNECT_REQD_VLD	No	
	Protocol	CREATE_OBJ_DD	Yes	
	Protocol	CREATE_OBJ_FRM	Yes	
	Protocol	CREATE_OBJ_VLD	Yes	
	Protocol	DD_AUTOVALIDATE	No	
	User	DD_SASNAME_UPDATE	Yes	
	Protocol	DD_STRICT_CODE	No	
	Protocol	DD_STRICT_SEARCH	No	
	User	FRM_CODEENTRY	No	
	User	FRM_OVERRIDE	No	
	User	FRM_USE_DESCRIP	Yes	
	System	AUDIT_START_DEFAULT	MERGE	
	User	DD_DBFMT_FIXED	NUMBER(5)	
	User	DD_DBFMT_FLOAT	NUMBER(6,2)	
	User	DD_DBFMT_TEXT	VARCHAR2(20)	
	Protocol	PROC_ACCOUNT		
	System	PROC_SITE_ACCOUNT	CTSITPROC	
	System	PROT_TMP_TSP	TEMPORARY	
	System	XFER_TABLESPACE		

Retrieve	User	RTV_INCL_SYS	No	
	User	RTV_DEF_DECODE	0	Codelist column used for decoding: 0=code, 1=value.
	User	RTV_SAS_RECLN	80	
	User	RTV_DEF_SOURCE	DATA	From data tables only. ALL includes both update and data tables.
	User	SAS_LIBNAME		

Resolve	System	CTV_USE_ERRORLOG	Yes	
	System	CTV_APPL_RES_CODE		
	System	CTV_AUTOCLOSED_RES		
	System	CTV_OBSOLETE_RES		
	User	CTV_FIRST_HEADER	Company Name	
	Protocol	CTV_FIRST_HEADER_PR		
	User	CTV_REQUESTER		
	Protocol	CTV_REQUESTER_PR		
	User	CTV_SECOND_HEADER	Discrepancy Form	
	Protocol	CTV_SECOND_HEADER_PR		
	Protocol	CTV_SELECT_INVESTIGA	See 1 below	
	Protocol	CTV_SELECT_SUBJECTS	See 2 below	
	Protocol	CTV_SELECT_VISITS	See 3 below	
	Protocol	CTV_SELECT_VISITS_1S	See 4 below	
	User	CTV_STARTUP_VIEW_ALL		
	Protocol	CTV_STARTUP_VIEW_PR		

1) SELECT UNIQUE CT\_RESOLVE\_USER.INV\_ID(<SUBJECTITEM>,  
'<PROTOCOL>') FROM<PROTOCOL>.SUBSTITUTE\*PANEL\_ SUBSTITUTE\*DBTABLE

2) SELECT UNIQUE <SUBJECT\_ITEM> FROM <PROTOCOL>.SUBSTITUTE\*PANEL  
SUBSTITUTE\*DBTABLE  
WHERE CT\_RESOLVE\_USER.INV\_ID(<SUBJECT\_ITEM>, '<PROTOCOL>') =  
'SUBSTITUTE\*INVESTIGATOR'

3) SELECT UNIQUE <BLOCK\_ITEM>  
FROM<PROTOCOL>.SUBSTITUTE\*PANEL\_ SUBSTITUTE\*DBTABLE

4) SELECT UNIQUE <BLOCK\_ITEM> FROM<PROTOCOL>.SUBSTITUTE\*PANEL  
SUBSTITUTE\*DBTABLE  
WHERE <SUBJECT\_ITEM> = 'SUBSTITUTE\*SUBJECT'

Lab Loader	User	CTL_TEST_MODE	No	
	System	CTL_DUPFLAG_LOC	DATA	

Classify	System	CTG_ALLOW_CHANGEVEB	Yes	
	System	CTG_AUTOACCEPT	No	
	System	CTG_EDIT_SYNTAX	No	

### 5.3 Adding New User and Usergroup Accounts and Assigning Access Rights

#### Adding a New User Account

Each Clintrial user must have a user account consisting of an ID and password to work with Clintrial modules. Multiple users with similar access needs (for example, data entry personnel) can be assigned to a usergroup, which allow you to assign and modify their access rights as a single set.

To add a new user, do as follows:

1. Login to the Clintrial Admin module.
2. From the Clintrial Admin window, select **Security > Users**. The User Maintenance window opens.
3. In the User Maintenance window, select **Edit > Add**. The cursor is placed in the User Name field. Do as follows:
  - a. Enter a name for the new user for **User Name**.
  - b. Enter a password for **Password**. When you tab from the field or save the window, you will be prompted to re-enter the password for verification. Follow the password requirements at the beginning of this manual. You may choose to assign a generic temporary password to new users, which they can later change themselves.
  - c. Accept the defaults for the remaining fields.
  - d. Close the window from **File > Close** or from the window's X button to return to the Admin window.

To modify a user password, do as follows:

1. Follow steps 1 and 2 for a new user to login to Clintrial Admin and to open the User Maintenance window.
2. In the User Maintenance window, do as follows:
  - a. Select a user in the **Select User** list.
  - b. Enter a new password. When you tab from the field or save the window, you will be prompted to re-enter the password for verification.
  - c. Close the window from **File > Close** or from the window's X button to return to the Admin window.

To delete a user, do as follows:

1. Follow steps 1 and 2 for a new user to login to Clintrial Admin and to open the User Maintenance window.
2. In the User Maintenance window, do as follows:
  - a. Select a user in the **Select User** list.
  - b. Select **Edit > Delete**.
  - c. Close the window from **File > Close** or from the window's X button to return to the Admin window.

Note that upon deletion, the user will automatically be removed from any associated usergroups.

#### Creating a Usergroup Account

Usergroups are sets of individual user accounts. Grouping of user accounts provides an easy way to manage access rights for multiple accounts with identical access requirements. Once a group is created and its rights defined, its members automatically receive those rights and any subsequent modifications.

Clintrial Help provides the following information about usergroups:

- Belonging to a group does not prevent a user from having individual access rights beyond those of the group.
- Users can be associated with one or more usergroups.

- In the case of a user whose individual access differs from that of the usergroup, or in the case of a user belonging to multiple usergroups with contrasting access rights, the highest access level always takes precedence.
- Deleting a usergroup does not delete its members' individual user accounts.
- When planning a usergroup, consider the following: What Clintrial activities will this group perform? What study data or metadata does this group need access to? For the specified data, what tasks does this group need to perform, for example, read and write tasks?
- Clintrial supplies three predefined usergroups. These groups can be used as is, modified as necessary, or deleted altogether. The groups and their default access rights are as follows:

<u>Group</u>	<u>Module</u>	<u>Type</u>	<u>Access right</u>	<u>Access levels</u>
<b>ADMIN</b>	Admin	Non-protocol	DBA System	Full Full
	Design	Non-protocol	Global System	Full Full
	Tools	Non-protocol	SQL	Full
<b>ANALYSIS</b>	Retrieve	Protocol	Merged Library	Read Write
<b>ENTRY</b>	Enter	Protocol	Unmerged	Full

To create a usergroup, do as follows:

1. Login to the Clintrial Admin module.
2. From the Clintrial Admin window, select **Security > Usergroups**. The Usergroup Maintenance window opens.
3. In the Usergroup Maintenance window, do as follows:
  - a. Select **Edit > Add**. An Add Usergroup dialog box opens. Enter a name for the new usergroup for **Usergroup Name** and click **OK**. A usergroup name can be up to 20 characters long, must be alphanumeric, and cannot begin with a number. A usergroup name is not case sensitive.
  - b. To add or remove group members, see below.
  - c. Close the window from **File > Close** or from the window's X button to return to the Admin window.

To delete a usergroup, do as follows:

1. Follow steps 1 and 2 to create a usergroup to login to Clintrial Admin and to open the Usergroup Maintenance window.
2. In the Usergroup Maintenance window, do as follows:
  - a. Select the group you want to delete from the **Usergroups** list.
  - b. Select **Edit > Delete**.
  - c. Close the window from **File > Close** or from the window's X button to return to the Admin window.

To add or remove group members, do as follows:

1. Follow steps 1 and 2 to create a usergroup to login to Clintrial Admin and to open the Usergroup Maintenance window.
2. In the Usergroup Maintenance window, do as follows:
  - a. Select a group from the **Usergroups** list.
  - b. To add users, select from the **Non-members** list and click <<.
  - c. To remove users, select from the **Members** list and click >>.
  - d. Close the window from **File > Close** or from the window's X button to return to the Admin window.

### Assigning Access Rights

Clintrial Help provides the following information on access rights:

Once a user account or usergroup has been created, the Clintrial administrator must assign access rights for the new account. Access rights determine a user or usergroup's ability to access data and perform tasks in Clintrial.

An access right is composed of the following two parts:

- The **access right**, which specifies the data type or action in question (for example, merged data).
- The **access level**, which specifies what can be done with that right (for example, read or write).

There are the following three categories of access rights:

- **Protocol** access rights control access to data and actions related to a specific protocol.
- **Non-protocol** access rights control access to data and actions independent of specific protocols. For example, the ability to use SQL.
- **Protected Panel** access rights control access to protocol panels that have been designated as "protected" in Design. To work with a panel of this type, the user must have access to both the protocol and the panel itself.

Within each of these three categories, access rights are further grouped by the Clintrial module.

The simplest and most effective way to assign access rights is through usergroups. Once a group is created and its rights defined, its members automatically receive those rights. Rights for a particular user are typically only defined when additional access beyond that of the group is required by a user.

In the case of a user whose individual access differs from that of the usergroup, or in the case of a user belonging to multiple groups with contrasting access rights, the highest access level always takes precedence. For example, if user X has write access to Admin, but X's usergroup access is read-only, the higher (write) access takes precedence.

By default, newly defined users and usergroups have no access rights. Exceptions are Clintrial's predefined user account (CTSUS) and usergroups (Admin, Analysis, Entry).

To assign access rights, do as follows:

1. Login to the Clintrial Admin module.
2. From the Clintrial Admin window, select **Security** and the access action you want to take (**User Access**, **Usergroup Access**, **Protocol Access**, or **Panel Access**). See Clintrial Help for more detail.
3. In an access rights window, select a row to which you are assigning access. For each Clintrial module, select the appropriate access level from the drop-down list. The list displays automatically when you click in a field. The dash (-) signifies No Access. If a user belongs to any usergroups, the usergroups are listed as unavailable rows under the user's name.
4. Close the window from **File > Close** or from the window's X button to return to the Admin window.

To copy settings from one row to another in an access rights window, do as follows:

1. Click a field in the row you want to copy from.
2. Select **Edit > Copy Row**.
3. Click a field in the row you want to copy to, and select **Edit > Paste Row**.

## 5.4 Administering Clintrial and the Oracle Database

This appendix may later include information on topics such as daily monitoring of data table space, installing Oracle and Clintrial service releases, and updating the DMS.

### Typical users and of the Clintrial modules

Clintrial consists of five integrated core modules (listed below) and a Clintrial Switchboard that provides a single point of access to the Clintrial modules. Supplemental modules that extend the basic Clintrial functionality are also available.

<u>Module</u>	<u>Use to</u>	<u>Typical user</u>
Admin	Create user and usergroup accounts. Set up and manage access rights for users, usergroups, and protocols for all Clintrial modules. Set system parameters. Monitor database space. Produce reports about system activities.	Clintrial Administrator or Database Administrator
Design	Design the study database to model your study protocol. Define data structures for storing study data. Create study books that are online representations of a set of data collection forms for data entry.	Designer or Programmer
Enter	Add (enroll) subjects to a study. Enter study data interactively. Verify (re-enter) study data. Edit study data. Add flags and notes to study data. Produce reports about study data.	Data-Entry Operator
Manage	Batch load study data. Code study data using a coding thesaurus. Validate data (run derivations and rules). Globally change or delete records. Edit records based on an Error Log report. Review an audit report of changes to study data.	Data Manager
Retrieve	Extract study data from the Oracle database using SAS. Create simple or complex queries using SQL from Clintrial.	Data Manager or Medical Reviewer

### Monitoring data table space

At installation, Clintrial sets default storage parameters for its Oracle tablespaces. Using the Admin module, the Clintrial Administrator can view and modify these storage parameters and can regularly monitor the growth of the database (e.g., run **Reports > Space Utilization** for tables and indexes).

Frequent monitoring of the tablespaces by the Database Administrator is recommended. Clintrial does not recognize when tablespace limits are approached, and a protocol could be damaged if space allocations are exceeded.

Manuals on Oracle DBA administration are available from the Oracle Corporation. Another source for information is from books by users such as Oracle Performance Tuning by Mark Gurry & Peter Corrigan from O'Reilly & Associates, Inc.

## 5.5 Blind Verification Procedure

### Introduction

Verification or double data entry is the process of re-entering study data to compare the old and new values, checking for data entry errors or value conflicts.

Clintrial supports two types of verification: interactive verification and blind verification.

For the JHS, selected study data are re-entered using blind verification. The forms that are verified are those forms completed on paper (enumeration, home induction interview, Approach to Life A-C, and Hassles and Moods A-D forms).

Blind verification is performed in the Enter module, and reports on verification errors are generated in the Enter module on 'unmerged' data in the update tables.

### JHS DMS Form Design and Its Significance in Verification Error Checking

A single form or study page is usually made up of multiple records (panels or page sections), each containing a unique subset of items (fields) for the form.

Knowing that a form requires verification, the designer sets the Verify attribute for usually all the panels for that form from the Panel Browser in the Design module.

Following blind verification, not all the records (or panels) for a single form may have the same record status. For example, the ELGA Eligibility form is composed of seven records. If only an item contained in the first panel of this form has a value conflict from blind verification, then only the first record for the form containing this item receives a record status of Verify Error; the other records for the same form receive a record status of Verified.

### What is Blind Verification?

In blind verification, Clintrial compares old and new values when you save a study page re-entered in the Verify edit mode. During blind verification, the new values do not overwrite the old ones, nor can you choose which value to retain.

If there is a value conflict, a record status is changed from Unverified to Verify Error, otherwise a record status is changed to Verified. Clintrial also attaches a VERIFICATION/AUTOFLAG flag to an item with a value conflict. The VERIFICATION/AUTOFLAG flag comment contains the original and re-entered values and the user accounts of the data-entry operator(s) who entered the values.

### Reviewing Blind Verification Results

Three Clintrial reports accessed from the Reports menu in the Enter module can provide results on the blind verification. These reports are the Verification Report, Subject Report, and Flag Report. Only subjects in the update tables are included in these reports. Once created, these reports can be viewed online, printed, or saved to a file.

The Verification Report (record level) contains a list of records with a status of Verify Error.

A Detailed Subject Report (record level) can contain a list of all records for a form(s) and their record status.

A Detailed Flag Report (item level) can include items with a VERIFICATION/AUTOFLAG flag, along with the comments containing the original and re-entered values and the user accounts of the data-entry operator(s) who entered the values.

The Flag and Subject reports are available in two basic formats: detailed and summary. The detailed format provides in-depth information on the attributes of each record that it retrieves. The summary format gives a count and categorical breakdown of the records it finds. You can tailor each report by entering criteria prior to generating it using the Report Wizard.

The Clintrial Help menu provides in-depth information on these three reports. Select **Help > Help Topics** in the Enter module. You can find information under the Contents tab in Enter Reports, and you can find information under the Index tab for 'reports'.

*Special note on reviewing verification results:* A form with any of its records and items marked with verification errors should not be changed and set to Verified until all verification results are reviewed for that form. When you open a form in the Navigator after blind verification and set it to Verified on closing, you will lose information on all value conflicts for that form. That is, all VERIFICATION/AUTOFLAG flags on items for the form will be removed and every Verify Error record status for the form will be changed to Verified.

*Special note on Clintrial reports:* The Verification Report and Subject Report may not accurately show a record status of Verify Error when an item in that record has a VERIFICATION/AUTOFLAG flag. The Flag Report appears to be the most accurate listing on blind verification errors. It is advisable to review the Verification Report, Subject Report, and Flag Report together for a comprehensive review of all records entered (Subject Report) and those with verification errors (all three reports but most accurately the Flag Report).

### Performing Blind Verification

In preparation for blind verification, the Enter module VERIFY\_BLIND protocol parameter must be set to Yes in the Admin module by your Clintrial administrator. You can only open a form for blind verification if its panels were set with the Verify attribute in the Design module by the designer. You can only verify forms in the Enter module that are in update tables and that have a panel status of Unverified.

The steps to verify forms using blind verification are as follows:

1. From the **File > Edit Mode** menu, set the edit mode to **Verify**.
2. In the Navigator, select the form (study page) that you want to verify.
3. Enter data in all fields.
4. Save the changes when you are done. Once saved, the record(s) for the form have their status changed from Unverified to Verified or Verify Error, and the form cannot be verified again.

Flags and notes themselves do not need to be verified. However, you can attach, modify, or delete flags and notes during verification if the system parameter VERIFY\_SHOW\_TAGS is set to Yes (all flags and notes are available) in the Admin module by your Clintrial administrator.

During blind verification, Clintrial automatically attaches a VERIFICATION/AUTOFLAG flag to a field if you re-enter a value that is different than the original value or if you leave blank a field that originally had a value. A VERIFICATION/AUTOFLAG flag comment contains the original and re-entered values for the field and the user accounts of the data entry operator(s) who entered the values.

### Modifying Data after Blind Verification and after Verification Results Review

To change a record status from Verify Error to Verified, open the form after blind verification in **Edit Update Table** mode that is set from the **File > Edit Mode** menu in the Enter module. You can add to or change the original values of any fields or retain the original values. When you save the form and set the

form to Verified, then all records for the form receive a status of Verified and all VERIFICATION/AUTOFLAG flags are removed from fields in the form.

When you modify or delete data in the update tables, you may be required to provide a Reason for Change. A Reason for Change is an explanation appended to an individual record explaining why the record was modified. The Reason for Change dialog box opens automatically when you edit a record. Enter an explanation directly into the Reason for Change Text box. To apply the Reason for Change to the current record only, click OK. To apply the Reason for Change to all modified records for a form, click Apply To All Changes.

Jackson Heart Study Protocol  
Manual 1  
General Description and Study Management  
Exam 2

Version 2.0  
September 16, 2005

For Copies, Please Contact:

Jackson Heart Study Coordinating Center  
Jackson Medical Mall  
350 W. Woodrow Wilson Dr.  
Jackson, MS 39213

## 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 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. The other Manuals describe the operations of the Clinic and Surveillance Components of the study. Detailed Manuals of Operation for specific procedures are contained in the other Manuals listed.

### JHS Study Protocols and Manuals of Operation

<u>MANUAL</u>	<u>TITLE</u>
1	General Description and Study Management
2	Blood Pressure
3	Specimen Collection and Processing
4	Cohort Surveillance
5	Quality Control
6	Data Management System
7	Central Laboratory and Specimen Repository
8	CT Scan Site

**Manual 1. General Description and Study Management**

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## 1.0 INTRODUCTION

The Jackson Heart Study is a population-based study of cardiovascular disease in African-Americans sponsored by the National Heart, Lung, and Blood Institute and the National Center for Minority Health and Health Disparities of the National Institutes of Health.

### 1.1 Rationale

Despite encouraging declines over the past three decades, cardiovascular disease (CVD) remains the number one cause of death in the U.S. A number of risk factors for coronary heart disease (CHD) and stroke have been identified; however, relatively few population-based studies have examined CVD in a large group of African-Americans. Existing evidence indicates that death rates for CVD in the U.S. are considerably higher among African-Americans. CVD death rates in Mississippi are the highest in the nation and particularly high among African-Americans. Between 1980 and 1995, the decline in CVD death rates has been the slowest among African-American men and women in Mississippi relative to other groups in the state and nation (Table 1).

**Table 1. Age-adjusted Mortality Rates for Men and Women in the United States (US) and Mississippi (MS), 1997**

Mortality <sup>1,2</sup>	Region	Black		White	
		Men	Women	Men	Women
All Causes	US	1,445	939	1,062	718
	MS	1,630	1,000	1,266	794
CVD	US	540	401	436	300
	MS	683	496	542	365
Hypertension	US	14	12	5	4
	MS	12	13	4	6
Heart Disease	US	414	295	347	223
	MS	548	385	448	285
Stroke	US	206	190	172	169
	MS	233	191	186	174

<sup>1</sup> Age-adjusted death rates to the total US population for year 2000; ages 35-84; annual rate per 100,000.

<sup>2</sup> ICD-9, International Classification of Diseases, Clinical Modification, 9<sup>th</sup> Edition for causes of death listed are:  
 Cardiovascular Disease (CVD) 390-459  
 Hypertension with or without Renal Disease 401, 403  
 Heart Disease 390-398, 402, 404-429  
 Stroke or Cerebrovascular Disease 430-438  
*Source: CDC Wonder Internet Web site (<http://wonder.cdc.gov>)*

## 1.2 Study Objectives

The primary objective of the Jackson Heart Study (JHS) is to investigate the causes of CVD in African-Americans to learn how to best prevent this group of diseases in the future. More specific objectives include:

- (1) Identification of factors, which influence the development, and worsening of CVD in African-Americans, with an emphasis on manifestations related to high blood pressure (such as remodeling of the left ventricle of the heart, coronary artery disease, heart failure, stroke and disorders affecting the blood vessels of the kidney).
- (2) Building research capabilities in minority institutions at the undergraduate and graduate level by developing partnerships between minority and majority institutions and enhancing participation of minority investigators in large-scale epidemiologic studies.
- (3) Attracting minority students to and preparing them for careers in public health and epidemiology.

## 1.3 Study Description

The JHS is a single-site prospective epidemiologic investigation of cardiovascular disease (CVD) among African-Americans from the Jackson, Mississippi metropolitan statistical area. This study represents an expansion of one of the sites of the Atherosclerosis Risk in Communities (ARIC) Study, which included four geographically diverse communities in the U.S. (Northwestern suburbs of Minneapolis, Minnesota; Washington County, Maryland; Forsyth County, North Carolina; and the city of Jackson, Mississippi). The ARIC study included a comprehensive baseline examination (1987-1989) and three subsequent follow-up examinations occurring at approximately three-year intervals (1990-1992, 1993-1995, and 1996-1999). A total of 15,792 individuals between 45 and 64 years of age were initially examined and 3,732 were from the Jackson ARIC cohort.

The JHS includes 5,302 African-American men and women between the ages of 35 and 84 which includes 1,626 of continuing ARIC participants from Jackson along with men and women from a larger tri-county geographic area than the prior study. Non-ARIC participants were selected from the African-American residents of Hinds, Madison and Rankin counties surrounding Jackson, Mississippi. This is an area larger than either Rhode Island or Delaware in square miles. Family members were included in order to permit studies of familial and genetic contributions to CVD. The extensive examination in Exam 1 included a series of questionnaires, physical assessment, and laboratory measurements. Table 2 compares these components with those from the prior ARIC examinations.. Table 3 contains the components of Exams 2 and 3. The information collected included both conventional risk factors and new or emerging factors that may be related to CVD. Some of the newer areas of focus included early indicators of disease, genetics, socio-cultural influences such as socioeconomic status and discrimination, and physiological relations between common disorders such as high blood pressure, obesity and diabetes and their influence on CVD. The initial examination phase of the study was conducted over 3.5 years beginning in the fall of 2000 and concluding in the spring of 2004. This phase of the JHS will include Exam 2 , 2005-2008 and Exam 3, 2009-2012; however, this Manual covers only Exam 2.

The JHS is sponsored by the National Heart, Lung, and Blood Institute (NHLBI) and the National Center for Minority Health and Health Disparities at the National Institutes of Health in partnership with three Jackson, Mississippi institutions: Jackson State University, the University of Mississippi Medical Center, and Tougaloo College. Jackson State University developed a coordinating Center (CC) where all data collected during the study is managed, analysis of data is performed and community involvement is coordinated. Tougaloo college operates an Under graduate Training Center (UTC) where selected students are given the opportunity to take course work in public health and epidemiology and gain

practical experience in health research to help prepare them for potential careers in these fields. The University of Mississippi Medical Center developed an Exam Center (EC) which is responsible for conducting the examinations and retaining the cohort. The JHS offices and clinic facility are located in the main concourse of the Jackson

Medical Mall, which is serving as a centralized location for high quality, efficient health care delivery for the underserved community.

**Table 2. The ARIC Study and JHS Exam 1 Component Schedule: Interview and Procedures by Visit**

PROCEDURES	ARIC				JHS
	Visit 1 1987-89	Visit 2 1990-92	Visit 3 1993-95	Visit 4 1996-98	EXAM I 2000-04
<b>ANTHROPOMETRY</b>					
<b>HEIGHT</b>					
Sitting Height	X				
Standing Height	X		X	X	X
<b>FRAME SIZE</b>					
Elbow		X			
Wrist	X				
<b>GIRTHS</b>					
Calf	X				
Neck					X
Hip	X	X	X	X	
Waist	X	X	X	X	X
<b>SKINFOLDS</b>					
Subscapular	X	X			
Triceps	X	X			
<b>WEIGHT</b>	X	X	X	X	X
<b>MALE BALDNESS</b>				X	
<b>BLOOD PRESSURE</b>					
Sitting	X	X	X	X	4
Supine	X		S	S	X
Standing	X		S	S	
Ankle	X		S	S	X

PROCEDURES	ARIC				JHS
	Visit 1 1987-89	Visit 2 1990-92	Visit 3 1993-95	Visit 4 1996-98	EXAM I 2000-04
Ambulatory					X
<b>ECHOCARDIOGRAPHY</b>			X		X
<b>ELECTROCARDIOGRAPHY</b>					
2-minute Rhythm Strip	X		X		
12-Lead	X	X	X	X	X
Heart Rate Variability	S			A	
<b>GLYCEMIC LOAD</b>				X	
<b>INTERVIEWS</b>					
Anger (CHOST, Anger In & Out)					X
Annual Follow-up	X	X	X	X	X
Blood Transfusion				X	
CHD Events/Procedures	X	X	X	X	X
CES-D					X
Cognitive Function		X	S	X	X
Coping Inventory					X
Dietary Intake	X	S	X	S	X
Family History of CHD		X			X
Fasting Status	X	X	X	X	X
Genogram					X
Global Stress					X
Health History	X	X	X	X	X
Home Interview	X				X
Inflammation				X	
Informed Consent	X	X	X	X	X

PROCEDURES	ARIC				JHS
	Visit 1 1987-89	Visit 2 1990-92	Visit 3 1993-95	Visit 4 1996-98	EXAM 1 2000-04
Medication Survey	X	X	X	X	X
Personal History (Smoking, Alcohol, Access)	X	X	X	X	X
Physical Activity	X		X		X
Racism & Discrimination					X
Religion					X
Reproductive History	X	X	X	X	X
Respiratory Symptoms	X	X			X
Social Support		X			X
Socioeconomic Status	X	X	X	X	X
Stress					X
TIA/Stroke	X	X	X	X	X
TIA/Stroke Summary	X	X			X
Tracking	X	X	X	X	X
Trait Anger		X		X	X
Violence					X
Vital Exhaustion		X			
Vitamin Survey			X		X
<b>MEDICAL DATA REVIEW</b>	X	X	X	X	X
<b>MRI, CEREBRAL</b>			X		
<b>PERIODONTAL EXAMINATION</b>				A	
<b>PHYSICAL ACTIVITY MONITOR</b>					X

PROCEDURES	ARIC				JHS
	Visit 1 1987-89	Visit 2 1990-92	Visit 3 1993-95	Visit 4 1996-98	EXAM I 2000-04
<b>PHYSICAL EXAMINATION</b>					
Neck	X	X			
Cardio/pulmonary	X	X			
Lower Extremities	X	X			
<b>PULMONARY FUNCTION</b>					
FEV1.0	X	X			X
FVC	X	X			X
Max. Inspir. Pressure		X			
<b>RETINAL PHOTOGRAPHY</b>			X		
<b>ULTRASOUND, B-MODE</b>					
Carotid Arteries	X	X	S	S	X
Distensibility	X	X			
Popliteal Artery	X				
<b>URINE COLLECTION 24-Hour</b>					X
<b>Spot Urine</b>					X
<b>VENIPUNCTURE</b>					
Chemistries	X	X	X	X	X
Hematology	X	X	O	O	X
Hemostasis	X	X	X	X	X
Lipids	X	X	X	X	X

S=Sample; A=Ancillary study mechanism; O=Optional

Table 3. The JHS Study Component Schedule: Interview and Procedures by Visit

PROCEDURES	JACKSON HEART STUDY		
	EXAM I 2000-04	Proposed for	
		EXAM 2 2005-08	EXAM 3 2009-12
Sitting	X	X	X
ABI	X		X
Ambulatory (24 hour)	X		
<b>CT</b>			
Coronary artery and aortic calcium		X	
Abdominal (visceral fat)		X	
<b>MRI</b>			
Cardiac (structure/function)		X	X subset
<b>ECHOCARDIOGRAPHY</b>	X		
<b>ELECTROCARDIOGRAPHY</b> 12-Lead	X		X
<b>INTERVIEWS</b>			
Anger (CHOST, Anger In & Out)	X		
Annual Follow-up	X	X	X
CHD Events/Procedures	X	X	X
CES-D	X		
Coping Inventory	X		
Dietary Intake	X		
Family History of CHD	X		X
Fasting Status	X	X	X
Global Stress	X		
Health History	X	X	X
Home Interview	X		
Informed Consent	X	X	X
Medication Survey	X	X	X
Personal History (Smoking, Alcohol, Access)	X		X
Physical Activity	X		X
Racism & Discrimination	X		
Religion	X		
Reproductive History	X		
Respiratory Symptoms	X		

PROCEDURES	JACKSON HEART STUDY		
	EXAM I 2000-04	Proposed for	
		EXAM 2 2005-08	EXAM 3 2009- 12
Sleep Quality	X		X
Social Support	X		
Socio-economic Status	X		X
Stress	X		
TIA/Stroke	X	X	X
TIA/Stroke Summary	X	X	X
Tracking	X	X	X
Trait Anger	X		
Violence	X		
<b>MEDICAL DATA REVIEW</b>	X	X	X
<b>PHYSICAL ACTIVITY MONITOR</b>	X		
<b><u>PULMONARY FUNCTION</u></b>			
FEV1	X		
FVC	X		
<b>RESULTS/REFERRAL</b>	X	X	X
<b>SMBP DEVICES (distribute)</b>		X	
<b>ULTRASOUND, B-MODE</b> Carotid Arteries	X		
<b><u>URINE COLLECTION</u></b>			
24 hour	X		
Spot	X	X	X
<b><u>VENIPUNCTURE</u></b>			
<b><u>Electrolytes/Chemistries</u></b>	X	X	X
BUN	x		x
Na/ K / Cl	x		
Creatinine	x		x
Glucose	x	x	x
Uric Acid	x		
<b><u>Hematology</u></b>	X	X	
Hemoglobin	x		
Hematocrit	x		
Hemoglobin A1c	x	x	

PROCEDURES	JACKSON HEART STUDY		
	EXAM I 2000-04	Proposed for	
		EXAM 2 2005-08	EXAM 3 2009-12
B12	x		
Folate	x		
<b>GENETICS</b>			
<b><u>NON-FAMILY COMPONENT</u></b>			
Cryopreservation		X	
<b><u>FAMILY COMPONENT</u></b>			
Family structure	X		
DNA, isolation and purification	X	X	
Cryopreservation	X		
DNA, transformed cell lines	X		
Candidate genes	X	X	X
Genome-wide scan (families)		X	

## 1.4 Study Centers

### 1.4.1 The Coordinating Center

Jackson State University developed a Coordinating Center (CC) where all data collected during the study is managed, analysis of the data is performed and community involvement is coordinated.

The JHS CC operates the Office of Community Partnership. The goal of the Community Partnership is to create an environment of trust and long-term support of the JHS by providing opportunities for substantive community involvement in all phases of the study development, conducting health promotion/education activities, and linking participants to needed services. The Partnership for Community Awareness and Health Education Committee serves as an independent body of community representatives, including political, medical, social, civic, business, health-related government agencies, and grassroots organizations, in order to provide ongoing input into the development and implementation of community outreach and health education activities.

The CC provides centralized administration, planning, and management for many components of the JHS. The core operational and scientific coordinated functions include 1) database management; 2) protocol development; 3) quality assurance; 4) biostatistical analysis; 5) maintenance of phone system, local area networks, e-mail, intranet, and World Wide Web JHS home page; 6) equipment purchasing and maintenance; and 7) administrative support for the JHS and its committees (such as convening meetings, documenting decisions and action items, preparing and distributing meeting minutes and coordinating the work of the various subcommittees). The CC provides technical support for the installation, use and maintenance of local computer equipment and CC staff provides software. The CC serves as the official repository for all JHS Steering Committee records, manuals of operations, data collection instruments, research data and publications.

The CC's responsibility for the centralized management of the study includes the provision and tracking of training and certification; monitoring protocol adherence in the EC and reading centers; the design, implementation and monitoring of quality assurance programs in the EC and reading centers; and data management, including the development of a computerized data collection system, on-site and centralized data processing and data analysis. Training and certification, protocol adherence and quality control are discussed in each of the manuals. The specific procedures for the distributed data management systems and data analysis are described in the following section of this manual. The CC also supports the design, management, and analysis of case-control studies and the publication of results of collaborative studies.

#### **1.4.2 The Examination Center**

The University of Mississippi Medical Center developed an Examination Center (EC), which is responsible for 1) protocol development; 2) conducting the examinations, annual follow-up, and retention of participants; and 3) developing, pilot testing, and conducting surveillance for morbidity and mortality outcomes (events) of all participants. Surveillance includes annual telephone or mail contacts as part of morbidity and mortality follow-up for the entire cohort to ascertain: (a) occurrence of cardiovascular events (including coronary heart disease, cerebrovascular disease, and congestive heart failure), other illnesses, and hospitalizations, including information from participants, personal informants, hospitals and physicians, according to a standard protocol; (b) dates and recorded causes of all deaths, using local vital statistics sources, obituaries, the National Death Index, and other sources; and; (c) circumstances surrounding death, through interview of family members, physicians and review of coroners' and other records; (d) participate in classification of cardiovascular events and conditions, using a standard protocol.

#### **1.4.3 The Undergraduate Training Center**

Tougaloo College created an Undergraduate Training Center (UTC) where selected students are given the opportunity to take course work in public health and epidemiology and gain practical experience in health research to help prepare them for potential careers in these fields.

The specific goals of the UTC are to 1) create a pool of well-trained high school students who upon entering college, can successfully complete undergraduate, graduate or professional degrees in health professions and public health; and 2) introduce a program of college courses to prepare students to pursue advanced studies towards public health and epidemiology, 3) recruit faculty to teach JHS related courses and do collaborative research with other institutions; and 4) participate on various JHS committees. The UTC accomplishes these goals by introducing Outreach to High School students to courses in Science, Language and Mathematics (SLAM) inclusive of pre-college courses. The UTC also implemented a JHS training plan where JHS scholars (freshmen or sophomore undergraduates) act as mentors and tutors to the Outreach high school students; take courses in Public Health, Epidemiology, Biostatistics, and Research Methods; attend Tougaloo College colloquia and the Summer Epidemiology course; and receive didactic academic experience through involvement in the practicum. A modular system for scholar education and associated JHS practica was initiated for Exam 2. The UTC collaborates with the JHS CC and EC and other local and international institutions to provide students with hands-on experiences to create interest in public health careers.

### **1.5 Clinic Examination**

The clinic examination for Exam 2 takes approximately 3 hours. The sequence of the exam is flexible so that up to four participants can be examined concurrently, in accordance with the available personnel and work station configuration. The following sequencing restraints are necessary: (1) Fasting and abstinence from smoking and alcohol is required for not less than 12 hours prior to the venipuncture, spot urine and blood pressure measurements, (2) The venipuncture and spot urine should be done before the sitting blood pressure, (3) Sitting blood pressure must be measured before the body composition (4) Computed Tomography should be done before the snack. (5) Interviewing will precede the distribution of the home blood pressure monitor and related teaching, (6) Medical Data Review must be done prior to the exit

interview. Since participants must fast for not less than 12 hours prior to the examination, a snack is provided during the exam sequence. Table 4 identifies and describes the components of the Examination 2.

**Table 4. Components of the JHS Examination 2**

<b>Procedure</b>	<b>Description</b>
Reception	Greet the participant; determine fasting status; obtain tracking data; collect medications
Informed Consent	Obtain informed consent
Spot Urine	Obtain urine specimen
Venipuncture	Obtain blood specimens for fasting blood glucose, hemoglobin A1c, lipids, C-reactive protein, and DNA
Blood Pressure	Obtain sitting blood pressure
Body Composition	Measure weight and height . Measure waist., neck and hip circumference. Measure % body fat
Computed Tomography	Accompany participant to site for heart x-ray
Snack	Provide a nutritious snack containing no caffeine or stimulants
Interview	Collect medical/health history (medication survey, medical history, health history, renal disease, stroke symptoms)
Self-Monitored Blood Pressure	Distribute home blood pressure monitor. Teach participants to measure blood pressure at home using provided equipment.
Medical Data Review	Ascertain the completeness of the exam and verify abnormal results. Review the results of the medical history and exam with the participant. Refer participant for diagnosis or treatment elsewhere if appropriate.
Exit Interview	Provide clinic summary report and return medications. Provide instructions and thank participant.

### 1.6 Follow-Up

Annual follow-up of the JHS cohort is used to maintain contact, to correct address information of cohort participants and to ascertain medical events between three-year comprehensive examinations.

Follow-up contacts are targeted to occur within a month of the anniversary date of the original visit—adjusted for a three-year exam cycle rather than the 3 ½ year cycle used in Exam 1. Contact letters are on JHS stationery and inform the addressee that s/he will receive a telephone call from JHS asking about interim health problems.

A telephone interview is conducted to ask participants about hospitalizations for illness or surgery, diagnoses and symptoms. If the participant cannot be reached by telephone, a home interview is attempted. The questionnaire queries information on hospitalizations for illness or surgery, diagnoses, medical care and symptoms. The participant is asked the standard Rose questionnaire for angina, possible MI and intermittent claudication, vital status, hospitalizations, and a variety of socio-cultural topics that will change each year. Verification of address and phone number is made along with an update of the other information used to contact the participant. Every attempt is made to identify cohort participants who have died in advance of the annual contact through regular review of obituaries and death certificates.

## **1.7 Clinical Review and Diagnostic Classification**

During the follow-up contact, the cohort participant may indicate that he or she had been hospitalized. Records are obtained for all hospitalizations, which occur after the Exam I visit. Abstracters record all discharge diagnoses and clinical information related to cardiac or cerebrovascular diseases. The participant will have signed a medical release form allowing the study to access medical records.

Similarly, during the obituary review or a follow-up contact, it may be determined that the participant has died. In these cases, the death certificate is obtained and the place of death is determined. For in-hospital deaths, the hospital record is reviewed. For out-of-hospital deaths and decedents admitted without vital signs, the participant's family and physician are contacted to provide information on the circumstances surrounding the death. At entry to the study and with each subsequent clinic visit, the participant will have given consent to contact family members and physicians in the event of his or her death.

A special Events Monitoring Subcommittee reviews the information on hospitalizations and provides the study diagnosis for coronary heart disease or cerebral vascular disease according to defined criteria. The Events Monitoring Subcommittee also provides a classification of cause of death.

## **1.8 Reading Centers**

### **1.8.1 Specimen Repository**

The Specimen Repository (SR) provides facilities and equipment to receive, store, aliquot, and distribute urine, white blood cells, DNA and /or transformed white blood cells from JHS participants. The facilities provide aseptic and/or sterile conditions as appropriate (Bio-safety Level 2 Containment). The SR, like the CL, is at the University of Minnesota Department of Laboratory Medicine and Pathology and the Fairview-University Medical Center. The SR has laboratory facilities and personnel for developing and monitoring the inventory of specimens. The JHS Ancillary Studies Committee reviews all requests for samples.

The SR procedures are detailed in Manual of Operation (MOO) 7. The MOO includes 1) a description of the procedures to be followed for processing, inventory control and delivering samples; 2) procedures for training personnel; 3) a detailed description of computer system and data entry system; and 4) a detailed protocol for long term storage.

## **2.0 DATA MANAGEMENT**

### **2.1 Coordinating Center Data Management System**

The JHS uses state-of-the-art CADC systems during the collection of examination and annual follow-up, in order to maximize data accuracy. A centralized data management system with direct data entry was developed using the software ClinTrial4. This type of system displays screens that resemble paper forms, and eliminates the burden of data entry and editing, reduces data entry turnaround time, and improves the quality of data analysis while minimizing respondent burden. The data collector reads the items from the screen, performs the measurement or

queries the participant, and keys the response into the computer. As data for the EC are entered, they are edited by the system. Values failing the edit checks cause an error message to be displayed and prompts further investigation. In addition to collecting and editing the data, the system permits users to enter text into an electronic "post-it note". This computer assistance rapidly directs the interviewer to the relevant sections of the interview for the particular respondent and provides for very rapid interviewer action, thus lessening the respondent burden.

## **2.2 Examination Center Data Management System**

The EC is responsible for managing the data collected during the cohort examinations and event abstractions. This includes the initial recording, keying, editing, correction, and transmission of data to the JHS CC. It also includes maintaining an inventory of data forms and other materials collected and sent to the JHS Reading Centers and CC.

The CADC workstation allows EC personnel to enter, edit and correct data values directly eliminating the need for paper forms, except as a back up.

The JHS data management system is centrally operated through a local area network that connects workstation microcomputers to a local database computer. The network eliminates the need for individual participant diskettes since the local database is updated from each workstation as participant information is entered. Data records corresponding to each form are written to multiple hard disk files as the data are collected. Thus, a system failure will only affect the current form being entered. In the event that the network is not functioning, participant information is written to the workstation hard disk is used to update the local database once the network is operating properly. If for some reason, such as power failure, the data management system is not functioning, paper forms are available for data collection. These data can then be entered when the data management system becomes operational.

As participant information is entered at a workstation, the local database is updated and automatically encrypted. In addition, a copy of each participant record is written to an encrypted ASCII file on the workstation hard disk. This file serves as a backup from which the local database can be restored, if necessary. If the network is not functioning, this file can be used to update the local database once the network is functioning.

## **2.3 Data Security and Confidentiality**

All investigators maintain data security and confidentiality in accordance with their Institutional Review Board agreement. The Principal Investigator and Center Directors/Co-Principal Investigators maintain data security and confidentiality in accordance with guidelines of the NIH.

All JHS staff is instructed in procedures for maintaining data confidentiality, and sign a form indicating their awareness of the necessity of maintaining confidentiality of data. Staff will be informed that any inappropriate use or disclosure of confidential data is cause for immediate termination of employment.

Certifying Institutional Review Board approvals by each collaborating institution are included in accordance with 45 CFR 46. Participant data are collected and stored by two methods. In addition to the computerized data management system, data may be collected on paper forms or audiotape for quality control, and then stored in locked file cabinets, stored in locked rooms. Since this is a single study center, original data does not leave the premises, and electronic back up of the data is made on a regular basis.

### **2.3.1 Coordinating Center**

Since this is a single study site, the data are entered quickly after collection and do not leave the premises. Data are only made available to persons performing statistical analysis. If outside consultants or investigators with offices outside the study site need access to the data for publications, a data tape or CD-ROM is prepared with no personal identifiers included.

The JHS maintains a "secure data room" that is an interior room within the CC office suite. This room is designed so that it is environmentally controlled with Halon fire protection. This room is used to store original paper forms and data tapes. The room is locked at all times and only select members of the CC computing division have

access to this room. The CC also has procedures for disposal of confidential data, as defined by any medium containing masked information or personal identifiers.

### **2.3.2 Examination Center**

The local area network adds a level of confidentiality since a user must have a special ID and password to log onto the network in order to gain access to the data management system. In addition, another level of security is function-specific, so that interviewers only be allowed to access the specific interviews they were assigned, and staff performing editing, analysis, etc., have another function-specific ID and password. Data is backed-up after each interview is completed, and daily back-ups are performed to the network server to minimize data loss.

Disclosure to the participants regarding confidentiality of their data is completed during reception. The consent form states that information provided by the participant is kept confidential and is only used for scientific research purposes without revealing their name. Individuals are informed that participation in JHS is voluntary, and that they may withdraw from the study at any time. Individuals are informed that the purpose of the survey is to collect information to aid in the understanding of the mechanisms of disease of the heart, lung, and blood vessels, and help physicians treat patients by recommending preventive measures against future disease among healthy individuals.

Individuals are informed that they may refuse to answer any questions or to participate in any of the tests. Refusal to participate or answer any of the questions does not result in any loss of benefits to which they might otherwise be entitled, nor does it adversely affect their medical care. In publications, the individual identities of participants are not disclosed, and data are reported only in aggregate. Abnormal findings are relayed to the participant and his or her physician as agreed to by the participant. EC staff is trained in procedures for insuring confidentiality of participant information.

### **2.3.3 Central Laboratory and Specimen Repository Data Management**

Aliquots of plasma and serum and tubes of whole blood per subject are stored at the CL/SR. An inventory record on paper accompanies each batch of specimens. Specimen analyses are performed on many different instruments with software written for each machine permitting transmittal of results directly to the central computer for the clinical laboratory. Results are then sent from the CL/SR to the CC via file transfer protocol (FTP) for transfer into the main study database.

During Exam 1, inventory records listing participant ID numbers for blood specimens were sent weekly from the EC to the CC. Data backup at the EC included electronic copies of the inventory records of specimens sent. The study elected not to draw extra blood specimens as backup in case of loss or damage during processing or shipping. The CC stored all data received from the CL/SR in the collaborative database and sent a floppy disk to the EC containing study results of its participants in order to update the local databases each week.

Additional tests may be run on selected cases and controls. These results are transmitted from the laboratory's computer via FTP to the CC.

For the first 12 months of Exam 2, no specimens were stored or shipped. Finger stick samples were analyzed at the point of contact using the Cholestech LDX system. This system uses reflectance photometry (the amount of light reflected from a solid surface) to measure the amount of substances in the blood. The analyzer measures color changes of the 4 reagent pads that is then converted to mg/dL or U/L and displayed on the Liquid Crystal Display (LCD) screen. Data from the display screen was recorded directly into the data management system.

Beginning in October 2006 (approximately), blood specimens will be collected via venipuncture. All blood specimens will be processed, packaged and shipped to CL, in accordance with CL instructions. Sample collection, processing, storage and analysis are monitored using an internal and external quality control program through the analysis of blind duplicates. An added check on drift or shifts in laboratory performance is provided by analysis of blood from monthly random sub-samples of the JHS cohort. Laboratory technicians are trained in proper venipuncture and processing methods and are certified and periodically recertified by the chief technologist.

### **2.3.4 Collaborative Database**

The collaborative portion of the database management system is used to store, update, and access the data from the EC and the reading centers. Since each data item is edited, corrected, and verified at the data collection site, editing by the collaborative system largely consists of record level "data base closure" checks, such as ensuring the receipt of all expected records from each exam, contact, hospitalization, and death. The focus of the collaborative DMS is retrieval for analyses. The LDMS directly generates analysis files in SAS data set, BMD save file, and SPSS save file formats. It includes a relational query language, a programming language, and a full-screen forms-oriented retrieval facility. It includes comprehensive security and confidentiality facilities including passwords, encryption, and audit trails. Given the size of the collaborative database, it is maintained on the University's mainframe computer.

## **3.0 STUDY MANAGEMENT**

### **3.1 Introduction**

The JHS Study is funded by the National Heart, Lung, and Blood Institute and the National Center for Minority Health and Health Disparities of the National Institutes of Health, and directed by the Epidemiology and Biometry Program of the Division of Epidemiology and Clinical Applications. The Principal Investigator, Center Directors/Co-Principal Investigators, and their affiliations are listed in Appendix 1. The operations of the study are directed by the JHS Study Steering Committee whose members are the Principal Investigator of the overall JHS, Director/Co-Principal Investigators or two representatives of the EC, CC, UTC, and the NHLBI Project and Field Officers as shown in the organizational chart in Appendix 2.

### **3.1 JHS Director**

The JHS Director actively participates in Monitoring Board, Steering Committee and appropriate subcommittee meetings to develop and implement a coordinated plan to achieve study objectives. The JHS Director acts as chair of the JHS Steering Committee. The Steering Committee is comprised two representatives each from the CC, the EC, the UTC, and the NHLBI Project Officer, the NHLBI Field Site Medical Director and a community representative. The JHS Director has the primary responsibility for planning and facilitating the conduct of the study, responding to issues raised by the Monitoring Board, e.g. protocol design, participant safety, and feasibility, and determining the content and implementation of the study. The JHS Director enlists appropriate senior personnel, either as staff, consultants, or subcontractors, with expertise in cardiovascular epidemiology, behavioral medicine, medical sociology, cardiovascular and renal physiology, medical genetics, clinical cardiovascular disease, noninvasive imaging, laboratory measurements, statistics, and longitudinal studies management to develop the study. The JHS Director fosters an atmosphere among the JHS investigators to work cooperatively with each other and the NHLBI Field Site and Project Office. The JHS Director actively promotes the JHS to the scientific community and the general public.

The Directors' Council (DC) comprising the Center Directors, the NHLBI Field Office Director and the Sr. Operations Manager forms the equivalent of an Executive Committee which meets fortnightly or more frequently if deemed necessary by JHS Director to discuss issues relating to the overall operations and performance of the study.

In view of the emphasis in Exams 2 and 3 on scientific productivity and cohort retention, a small administrative unit has been formed to provide administrative and scientific support to assist the Director in achieving the scientific and operational goals of the JHS through 2013. The JHS Director's Office staff is directly accountable to the JHS Director and is to be specifically responsible for the scientific productivity of the JHS and the oversight of the administrative and fiscal operations of the three JHS Centers. The creation and funding of the Office as a distinct administrative entity within the EC provides the resources to assure scientific productivity through such activities as Invited Collaborators, conferences and convening of an Emerging Science Committee of external experts. Web-based conferences, off-site regional locations and national scientific meeting linkage will be utilized as well as conferences held in Jackson. In addition to accomplishing this plan for scientific productivity, the Office staff will provide the infrastructure and create opportunities to train minority investigators. Ancillary Study instigation and

monitoring will also be a major responsibility of the Office leadership, with these instigation efforts often made in conjunction with the aforementioned Invited Collaborators conferences. Finally, the Office staff will provide essential across center administrative, infrastructure and fiscal coordination. Included among the numerous such responsibilities will be the consistent deliverable content and schedule compliance for all centers.

### **3.3 JHS Study Subcommittee and Charges**

Subcommittees responsible for the details of study design and implementation support the Steering Committee. These committees report and make recommendations to the Steering Committee. The subcommittees and their charges are listed in Append 3. The committees are: the Scientific Directions; Ancillary Studies; Genetics; Clinic Operations and Results Reporting; Events Monitoring; Community Partnership; Retention; Statistics, and Sampling; Academic; Research Training Appointments; and IRB Adherence.

### **3.4 Communications**

#### **3.4.1 Periodic Reports**

The EC and reading centers prepare routine periodic reports to the JHS Study Project Office as contract deliverables which document the progress to date in each major activity, administrative matters, staffing changes, current or anticipated problems, and scientific productivity. The CC also provides reports on the data collection at the EC, quality control findings on examinations, re-abstracted records, re-certification, laboratory determinations, and protocol adherence. Status reports on annual follow up and data collection prepared for the Project Officer are also sent to the EC. Quality control reports are likewise sent to the reading centers.

#### **3.4.2 Newsletters**

The CC prepares and distributes a newsletter to facilitate communication among JHS participants. In general, each edition includes (1) reports from the Project Office, the EC, CC and UTC and the Steering Committee, (2) a description of the facilities and staff (3) general information on data management and (4) a calendar of events. The newsletter also provides reports on issues such as participant follow-up rates and preliminary study results and abstracts.

#### **3.4.3 Electronic Mail**

The EC, reading centers, the CC, some UTC staff, NHLBI Field and Project Office are linked by electronic mail using microcomputers at each center. The electronic mail network is used to facilitate rapid and efficient communication among centers for messages such as announcements, meeting agendas, abstracts for clearance and acknowledgements of receipt of data.

#### **3.4.4 Site Visits**

Project Office staff conduct periodic monitoring visits to the JHS Centers as needed to (1) maintain channels of communication with investigators and staff, (2) solve participant follow-up problems, (3) monitor adherence to the protocol and (4) provide technical support for activities such as data management and quality control.

### **3.5 Publication and Presentation Policy**

#### **3.5.1 Overview**

The Publications and Presentations Subcommittee (PPS) is responsible for overseeing all aspects of study publications and presentations, from the formation of writing groups and approval of manuscript proposals through the final approval of JHS manuscripts prior to journal submission. An overview of the process is shown in Figure 1.

The goal of the PPS is to encourage the preparation of manuscripts and abstracts while providing oversight for their scientific quality and content. The PPS will establish, disseminate and oversee policies for the use of JHS data in abstracts, presentations and publications, and help maintain the publications database at the Coordinating Center.

The PPS is composed of members from the three Jackson institutions, the National Heart, Lung, and Blood Institute (NHLBI) field site, the JHS Director's office, community representatives, and recognized outside scientists. Meetings occur on a regular basis as necessary (e.g. monthly). Abstract approval between meetings takes place by e-mail or fax as necessary to facilitate scientific productivity.

### **3.5.2 Publications Data Base**

A series of tracking tables and data bases maintained by the CC for the PPS are used to monitor the approval and status of new proposals, presentations, abstracts and manuscript publications. A separate listing of all JHS manuscript proposals, abstracts and presentations, and JHS publications (including those in press) is updated quarterly and maintained on the JHS web site (<http://ccaix.jsums.edu/~jhs/>) with subject and author-based search capability. This is true for Ancillary Studies and Genetics Studies as well.

### **3.5.3 Preparation and Approval Process for Manuscripts, Abstracts and Presentations**

**3.5.3.1a. Manuscript proposals.** Manuscript proposals most commonly arise from JHS investigators. A JHS investigator includes Principal Investigators, Co-Principal Investigators and academic staff from the three partner institutions, the JHS Director's office, participating NHLBI staff (field site and project office) and JHS subcontractors. The PPS and the JHS Steering Committee may also designate a topic, select a writing group, and identify its chairperson (lead author). The proposal must include a clear statement of the nature of the publication, its rationale, the hypotheses to be addressed, the analytic approach to be used (types of statistical computations or summarization of data likely to be required) and pertinent references (see Appendix for manuscript proposal form). The lead author initiates the manuscript proposal draft, prepares a list of co-authors, and obtains any suggestions for the proposal. For locally generated proposals, the lead author would in principle strive to include investigators from all local institutions involved in the JHS based on their potential interest and areas of expertise. The writing group should be composed of both interested collaborators and experienced investigators. Interested JHS investigators should have an opportunity to participate. For proposals developed by non-JHS investigators, at least one JHS investigator must be included.

**3.5.3.1b. Format and submission.** The JHS has a standardized form (attached and available electronically on the JHS web site) that is used for proposal submission. Proposals are submitted electronically to the PPS chair and Administrative Coordinator (see contact information at end) who will arrange distribution to the members and maintain appropriate databases.

**3.5.3.1c. PPS Proposal Approval.** The manuscript proposal, including the list of proposed authors, is submitted to the PPS for approval. Review will include assessment of scientific content, potential overlap with previously approved manuscript proposals, priority, and recommendations for members of the writing group.

**3.5.3.1d. Distribution of manuscript proposals to Steering Committee.** After approval by the PPS, manuscript proposals are sent to the JHS Steering Committee for ratification and any additional recommendations that they may wish to make. The Steering Committee meets monthly.

**3.5.4 Data analysis.** The writing group prepares and communicates a detailed plan for data analysis containing computational specifications to the CC, or it prepares statistical computations using the data set distributed by the CC when local analytic assistance is available. In some cases analyses may be done outside the CC (e.g. biostatistical consultants). The CC has representation on the writing group in most cases and this person serves as the liaison to the writing group, both for communications about computing issues and for providing or obtaining appropriate statistical input. The CC performs the specified statistical computations according to priorities set by the PPS.

**3.5.3 Authorship.** The initiator of a manuscript proposal generally assumes first authorship. The PPS will assist in resolving any conflicts or confusion that occurs with respect to appropriate recognition of authorship. The lead author should elicit involvement in the manuscript from the co-authors, circulate drafts for co-author input and coordinate revisions. S/he should determine the order of authorship. Selection of the journal for initial submission is delegated to the writing group with input from the PPS and JHS Steering Committee.

**3.5.4 Abstract approval.** Abstracts should be submitted electronically to the PPS chair and Administrative Coordinator for approval at least 2 weeks prior to the submission deadline. Abstracts will be circulated to PPS members for review and recommendations. After approval by the PPS and incorporation of any revisions, the abstract will be sent by the Administrative Coordinator to NHLBI ([ebpdocs@nhlbi.nih.gov](mailto:ebpdocs@nhlbi.nih.gov)) for rapid review and response (usually takes approximately one-two weeks). In cases where ARIC approval is required, simultaneous submission is made to the ARIC Publications Committee (see section 3.4.7, Coordination with ARIC). Following communication of these approvals (sent by the Administrative Coordinator) the writing group chair may submit the abstract. A copy of the final abstract, notification of acceptance and, if published, its citation, should be sent to the PPS Administrative Coordinator.

**3.5.5. PPS review of completed manuscripts.** The writing group prepares reviews internally, and submits the completed manuscript to the PPS for review and approval. Two JHS reviewers are assigned by the PPS chair to review the manuscript. Ad hoc reviewers with special expertise may be assigned by the chair. Under exceptional circumstances this review may be waived by the PPS with a majority vote. A detailed critique is expected from the reviewers within two weeks. Upon receiving the critiques, two courses of action are possible: (1) if the PPS deems the reviewer suggestions to be mainly editorial in nature, it may approve the manuscript and request that the authors incorporate suggested changes to the final version, or submit in writing reasons for not doing so. No further action is needed from the PPS; or (2) if, in the PPS's judgment, the critiques entail substantive changes, a revised manuscript must be further reviewed by the primary reviewers, before PPS approval is granted. The PPS may recommend data verification by the CC based on reviewer comments and prior experience with JHS data analysis, although this will not be required in all instances. Members of the JHS Steering Committee receive copies of approved manuscripts. Manuscripts should include the phrase: "the Jackson Heart Study" in the title whenever possible and acknowledgement of funding sources for the JHS contract. In the case of genetic or family studies no pedigrees will be published.

**3.5.6 NHLBI review.** NHLBI review of completed manuscripts occurs following PPS approval. The PPS Administrative Coordinator will send the manuscript to NHLBI (see contact information) once the lead author has incorporated any recommended revisions based on the PPS review. Manuscript review may take 2-4 weeks. In cases where ARIC approval is required, simultaneous submission is made to the ARIC Publications Committee (see section 3.4.7, Coordination with ARIC).

**3.5.7 Coordination with ARIC.** Manuscript proposals that involve data from any or all of the four ARIC centers, including Jackson alone, will follow existing ARIC publication policies (<http://www.bios.unc.edu/csc/ARIC/>). If other standard criteria are met, approval by ARIC will generally be granted unless a substantially similar manuscript proposal was already approved by ARIC, in which case modification or withdrawal of the new proposal would be necessary. Approval, along with other comments from the ARIC Publications Committee, will be conveyed to the JHS investigators. In the particular case where proposals include both ARIC and JHS data (e.g. longitudinal designs that include the first JHS exam), formal ARIC consideration will not be required; instead only JHS PPS approval will be necessary. Thus, an exemption from the ARIC review process would be in effect when the manuscript proposal requires JHS data for analysis. The ARIC Steering Committee will send copies of approved proposals and manuscripts to the JHS PPS to facilitate awareness and minimize potential overlap for new proposals. The JHS PPS Administrative Coordinator will submit requests for approval of proposals; abstracts and completed manuscripts involving ARIC data to the designated person at the ARIC Coordinating Center (see contact information).

**3.5.8 Journal submission of manuscript.** After approval and incorporation of recommended revisions, the manuscript is formally submitted to a journal for consideration. The lead author must notify the PPS when the manuscript is submitted, which journal was selected and whether the manuscript was approved or rejected by the journal (e.g. a copy of paper and cover letter will suffice). Once published, a reprint or copy of the manuscript should be sent to the PPS Administrative Coordinator.

**3.5.9 Presentations.** A formal slide or poster presentation at a national or regional scientific meeting can be reviewed by the PPS if desired by the lead author. However, notification of a JHS presentation must be sent to the PPS Administrative Coordinator for tracking purposes and should include the title, authors, name of the meeting,

date and location. In the case of lectures and other informal presentations no formal approval is required assuming initial release of JHS results is not involved.

**3.5.10 Interviews and press releases.** Discussions with the media and press releases should not be used as a forum to release new information, but may be used to clarify scientific findings for the lay public. In general, scientific findings from the JHS made available to the media will involve those findings presented at scientific meetings and published in the literature. Investigators are requested to keep the NHLBI Project Office informed of contacts with representatives of the major national media and of major national media coverage of information that they have supplied. Release of general descriptive information about the JHS for local use (such as a local newspaper, university newsletter or state medical society journal) does not require prior approval. Use of centrally prepared materials for such purposes is encouraged and can be obtained from JHS investigators associated with the partnering institutions, published journal articles, previous abstracts or presentations, and other JHS published materials. A copy of the resultant article should be sent to the Project Office.

### 3.5.11 Contact Information

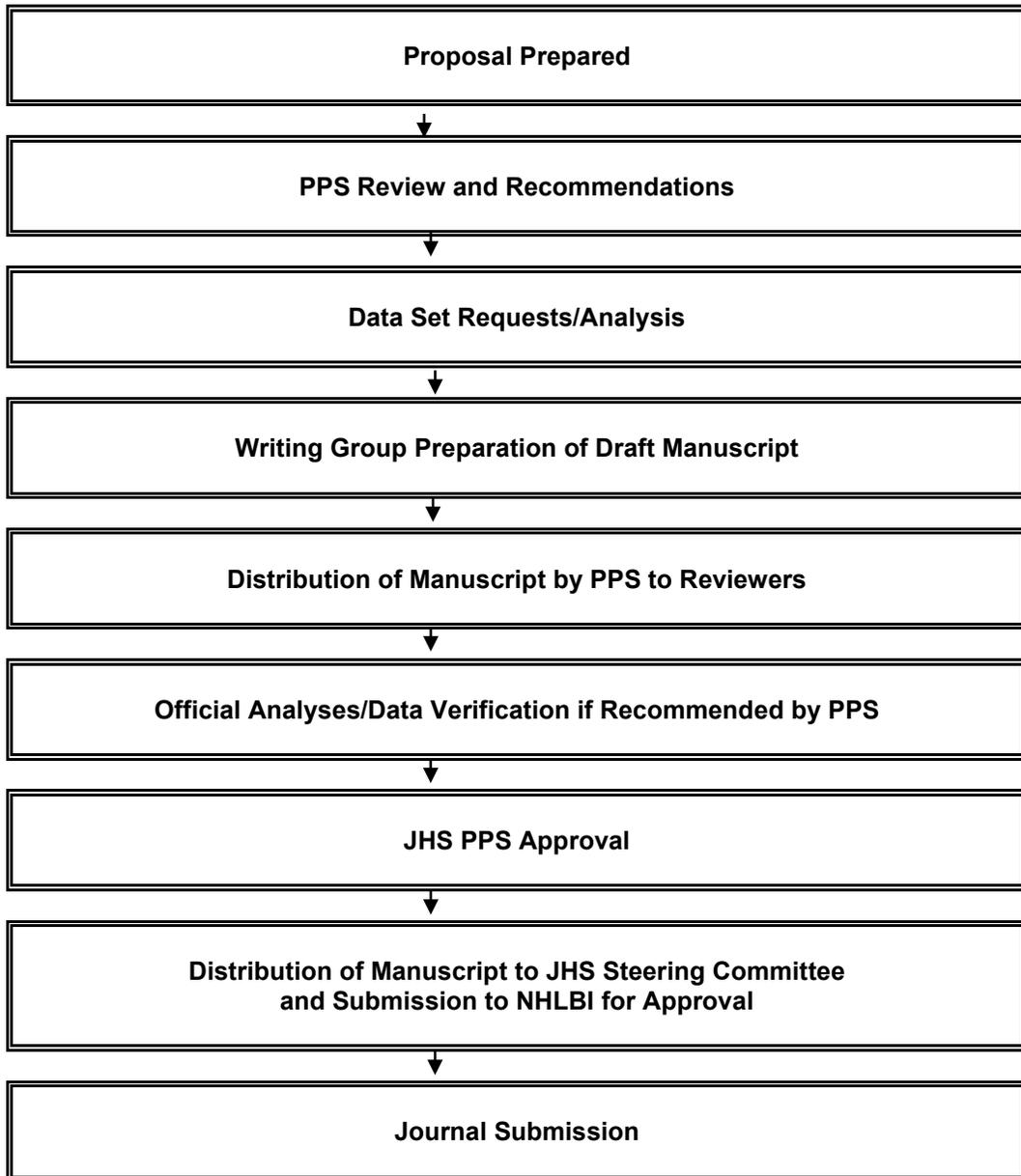
PPS Administrative Coordinator: Brenda Campbell Jenkins, [brenda.w.campbell@jsums.edu](mailto:brenda.w.campbell@jsums.edu)  
Jackson Heart Study Coordinating Center  
Jackson Medical Mall, Suite 701  
350 W. Woodrow Wilson Dr.  
Jackson, MS 39213  
(601) 368-4631 Fax: (601) 982-5421

PPS Chair: Herman A. Taylor, MD, MPH, [htaylor@medicine.umsmed.edu](mailto:htaylor@medicine.umsmed.edu)  
Jackson Heart Study  
Jackson Medical Mall, Suite 701  
350 Woodrow Wilson Drive  
Jackson, MS 39213  
(601) 368-4644 Fax: (601) 982-5421

NHLBI: Shirley Arnold, [arnolds@nhlbi.nih.gov](mailto:arnolds@nhlbi.nih.gov)  
Epidemiology & Biometry Program  
NIH / NHLBI / DECA  
II Rockledge Centre, Room 8170A  
6701 Rockledge Dr., MSC 7934  
Bethesda, MD 20892  
(301) 435-0445 Fax: (301) 480-1455

ARIC Coordinating Center: Debbie Rubin Willaims, [uccdrw@mail.cccc.unc.edu](mailto:uccdrw@mail.cccc.unc.edu)  
University of North Carolina, Biostatistics Department  
Collaborative Studies Coordinating Center  
Bank of America Center, CB#8030  
137 E. Franklin Street, Suite 203  
Chapel Hill, NC 27514  
(919) 962-3246 Fax: (919) 966-3804

**Figure 1. Jackson Heart Study Proposals and Manuscripts**



## **4.0 ANCILLARY STUDIES**

### **4.1 Objectives**

An ancillary study is an investigation, which is not part of the Jackson Heart Study (JHS) protocol but uses all or a subgroup of the JHS cohort, samples, or data collected by JHS. In most cases, an ancillary study will involve acquisition of additional data, which are not compiled as part of the standard JHS data set.

The JHS Steering Committee encourages investigators to propose and conduct ancillary studies. Such studies enhance the value of JHS and ensure the continued interest of the diverse group of investigators who are critical to the successes of the study as a whole. They provide an exceptional opportunity for investigators, either within or outside of JHS, to conduct additional projects within an already existing participant cohort. In general, ancillary studies will require outside (non-JHS) funding.

The objectives of the JHS Ancillary Studies Sub-Committee (ASSC) is to assure the protection of human research subjects as it relates to the JHS, and to assure the integrity of the main goals of the JHS. The aim of the Ancillary Studies Guidelines is to stimulate scientific productivity of the JHS and to stimulate interest in the JHS by a diverse group of investigators.

The guidelines describe the procedures for application, submission, review, approval or rejection of ancillary studies, as well as guidelines for publications and presentations resulting from ancillary studies.

### **4.2 Review Process**

In order to protect the integrity of JHS, all ancillary studies must be reviewed and approved before access to JHS data or participants is permitted. The review process is as follows:

#### **A. Application**

New ancillary study proposals should be sent to the Ancillary Studies Sub-Committee (ASSC) in care of the JHS Coordinating Center. The ASSC will review the proposal to ascertain that it is completed satisfactorily. If the proposal is incomplete, the Principal Investigator (PI) of the ancillary proposal will be notified within five (5) working days after receipt by the JHS Coordinating Center. The ancillary study proposal form and guidelines are available on the Jackson Heart Study Web site (<http://www.jsums.edu/~jhs>) or can be obtained by contacting the JHS Coordinating Center (Phone: (601) 982-1133; Fax: (601) 982-0006).

#### **B. Submission**

Electronic inquiries and submission of applications are encouraged. The ancillary study application should be submitted to Ms. Brenda Campbell, Research Associate at [brenda.w.campbell@jsums.edu](mailto:brenda.w.campbell@jsums.edu) and inquiries about ancillary studies may be directed to the -chair of the ASSC: Dr. James Perkins at [James.Perkins@jsums.edu](mailto:James.Perkins@jsums.edu)

#### **C. ASSC Review**

The ASSC will review the ancillary study proposals to determine if items 1, 2, or 3 below apply. If not, the recommendation of the ASSC will be sent directly to the JHS Director for Steering Committee review.

##### **1. Proposals with New Participant Burden**

If the ancillary study proposal indicates participant burden, the proposal will be sent to the Clinic Operations Committee (COC) for review. The COC will review the proposal within 10 working days and return it to the ASSC Chair with their comments and recommendations.

##### **2. Proposals Requiring Specimen Collection**

If the ancillary study proposal indicates blood use of any kind, the proposal will be sent to the COC for review. The COC will review the proposal within 10 working days and return it to the ASSC Chair with their comments and recommendations.

3. Proposals Involving the JHS Family or Genetics Studies

If the ancillary study proposal indicates the use of family relationship information or the use of genetic material (DNA), the proposal will be sent to the Genetics Subcommittee for review. The Genetics Subcommittee will review the proposal within 10 working days and return it to the ASSC with their comments and recommendations.

D. **Steering Committee Review**

The Steering Committee will review whether the proposed study duplicates existing JHS research, whether it is feasible, and whether the impact of the proposed study on JHS operations and resources is justified by its scientific merit (see below for further discussion of review guidelines). ASSC and COC review comments will be attached to the ancillary study proposal before the proposal is submitted to the Steering Committee. Approval/disapproval will be made by the Steering Committee.

E. **National Heart, Lung, and Blood Institute Project Office Review**

The approved ancillary study proposal will be sent to the National Heart, Lung, and Blood Institute Project Office for review by the JHS Monitoring Board. In the situation where anticipated direct costs exceed \$500,000 in a given year, additional instructions as specified on the National Heart, Lung, and Blood Institute web site [www.nhlbi.nih.gov/funding/policies/500web.htm](http://www.nhlbi.nih.gov/funding/policies/500web.htm)) should be followed with submission directed to Paul Solis, Acting Director, Division of Epidemiology and Clinical Applications.

**4.3 Procedures**

A. **Informed Consent and Institutional Review Board Approval**

If separate informed consent is necessary, this must be obtained from all participants of the ancillary study. This should clearly identify the ancillary study as one being performed in addition to the main study and inform subjects that their participation in the ancillary study is not necessary for them to continue in the JHS. Institutional Review Board (IRB) approval for the ancillary study is the responsibility of the principal investigator of the ancillary study and must be obtained prior to initiation of the study.

B. **Inclusion of JHS Investigators in Ancillary Studies**

A JHS investigator must be included as a co-investigator in every ancillary study proposal. If the CC or EC resources are to be used, arrangements must be made with the Center

Directors/Co-Principal Investigators. Separate funding will usually be required for ancillary study related expenses, such as space rent and support staff. In order to avoid misunderstandings, all communication regarding resources with the JHS Coordinating Center and Examination Center must take place between the senior JHS investigator involved in the ancillary study and the Center liaisons.

C. **Proposal, Data Request, and Funding Source Changes**

Following approval of an ancillary study by the Steering Committee, there can be no substantial changes in the proposal or type or amount of data requested from the Coordinating Center. If major changes are made, the ancillary study must be reconsidered as a revised proposal. Also, if a previously approved ancillary study is to be submitted to a different organization for funding, a revised proposal must be submitted for approval.

D. Time Requirement for Review of Ancillary Studies

Ancillary study proposals should be submitted for review at least 60 days prior to the deadline for the funding application. This will provide time for circulation to appropriate committees, JHS Steering Committee recommendation and NHLBI approval prior to submission to a funding agency. Additional time is required if direct costs exceed \$500,000 in a given year.

E. Ancillary Study Proposal Form

The proposal form must be fully completed by the PI of the proposed ancillary study. The body of the ancillary study proposal must include the following information: 1) investigator information; 2) project sponsoring information; 3) design and methods; 4) assurances that data used by ancillary study PI will be given back to JHS to incorporate into larger JHS data set; 5) data management of the ancillary study project; 6) genetic/family studies information (if applicable); and 7) "other information" regarding the ancillary study. Each section is elaborated in detail on the proposal form which is found on the JHS web site (<http://www.jsu.edu/~jhs>). The completed proposal should not exceed five (5) pages (excluding literature citations and appended questionnaires and forms).

F. Criteria Used to Assess Priority of Ancillary Studies

The JHS Steering Committee will use the ancillary study application to assign priority of the proposed study in relation to the JHS objectives and, most importantly, determine its potential impact on the JHS facilities and operations.

Highest priority will be given to studies which:

- do not interfere with or duplicate the JHS research objectives;
- have the highest scientific merit;
- produce the least burden on JHS participants and the least demand on JHS resources such as blood samples;
- have objectives closest to those of JHS; and
- require the unique characteristics of the JHS cohort.

The Steering Committee will review the proposal primarily to determine that it will not compromise, complicate, or jeopardize the conduct of the JHS. Review of proposed ancillary studies for scientific merit is not the primary responsibility of this review process, but is a necessary consideration for allocating access to scarce JHS resources. All ancillary study

proposals approved by the Steering Committee will also be sent to the NHLBI Project Office and the JHS Observational Studies Monitoring Board for review, comment and approval.

The ASSC will record the progress of approved ancillary studies since the composite impact of the total number of active studies will be difficult to assess without central monitoring. Investigators with approved ancillary studies will report to the Chairperson(s) of the ASSC every six months regarding the status of study funding, initiation and termination dates, success of data collection, and any presentations and publications derived from the ancillary study. A written progress report on ancillary studies will be made twice a year at the request of the ASSC. This written report will be submitted to the Steering Committee.

G. Guidelines for Publications and Presentations from Ancillary Studies

Potential manuscripts from ancillary studies will follow the same procedures as JHS publications and presentations and must adhere to the following guidelines:

1. The ancillary study investigator will submit a formal manuscript proposal to the JHS Publications and Presentations Sub-Committee (PPS), which consists of a title, proposed writing group, introduction and rationale, analysis plan, conclusion, and references.
2. The PPS will submit the proposal to the Steering Committee requesting nominations for the writing group from the JHS investigators who have special expertise in the subject of the manuscript.
3. When the writing group has been finalized, and a memo from the PSS has confirmed the final writing group, the manuscript can be started.
4. The PPS requests that the writing process involves the whole writing group, i.e.; drafts should be circulated regularly to the writing group.
5. The PPS should review the last draft of the manuscript arising from an ancillary study.
6. When approved by the PPS , this draft will be submitted to the JHS Steering Committee and NHLBI for final review.
7. If the data analysis for the ancillary study was not conducted at the JHS CC the analysis may be verified by the CC before submission to a journal.
8. The Chair of the writing group for the paper will be responsible for reporting to the PPS on the paper's progress.
9. A reprint of the final published article must be sent to the JHS CC.
10. Abstracts generated from ancillary studies must follow the same guidelines for all JHS abstracts. The proposed abstract must be sent to the Chair of the PPS:
  - (a) two weeks prior to the deadline for the abstract's submission if data from a JHS paper in progress is used (e.g. abstract is based on paper already reviewed and approved by the PPS); and
  - (b) four weeks in advance if the project has not already been reviewed by the Publications Committee. The proposal should be approved by all co-authors before it is sent to the PPS Chair.

A-1

## Appendix 1 JHS Principal Investigators and Directors

Herman A. Taylor Jr., M.D., M.P.H. JHS Director and Principal Investigator

Jackson Heart Study  
University of Mississippi Medical Center  
Department of Medicine/Cardiology  
350 W. Woodrow Wilson Drive  
Suite 701  
Jackson, MS 39213  
(601) 982-1133  
[htaylor@medicine.umsmed.edu](mailto:htaylor@medicine.umsmed.edu)

Frances Henderson, BSN., PhD

Co-Director Jackson Heart Study Exam Center  
University of Mississippi Medical Center  
Department of Medicine  
350 W. Woodrow Wilson Drive  
Suite 701  
Jackson, MS 39213  
[henfra@att.net](mailto:henfra@att.net)

Ervin Fox, MD., MPH

Co-Director  
Jackson Heart Study Exam Center  
University of Mississippi Medical Center  
Department of Medicine/Cardiology  
350 W. Woodrow Wilson Drive  
Suite 701  
Jackson, MS 39213  
[erfox100@yahoo.com](mailto:erfox100@yahoo.com)

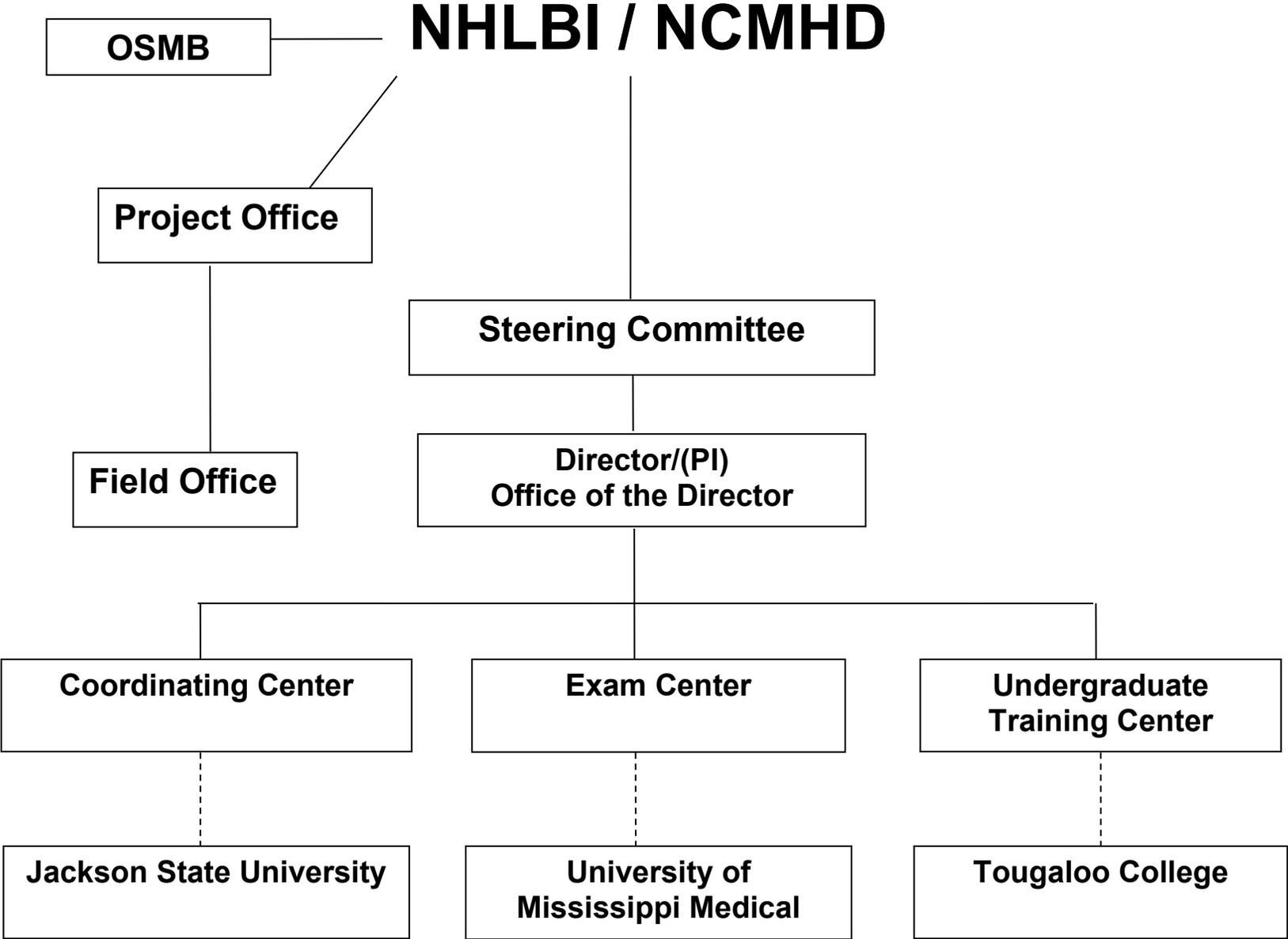
Daniel Sarpong, Ph.D.

Director and Co-Principal Investigator  
Jackson Heart Study Coordinating Center  
Jackson State University  
350 W. Woodrow Wilson Drive  
Suite 701  
Jackson, MS 39213  
(601) 982-1133  
[dsarpong@jsums.edu](mailto:dsarpong@jsums.edu)

Asoka Srinivasan, Ph.D.

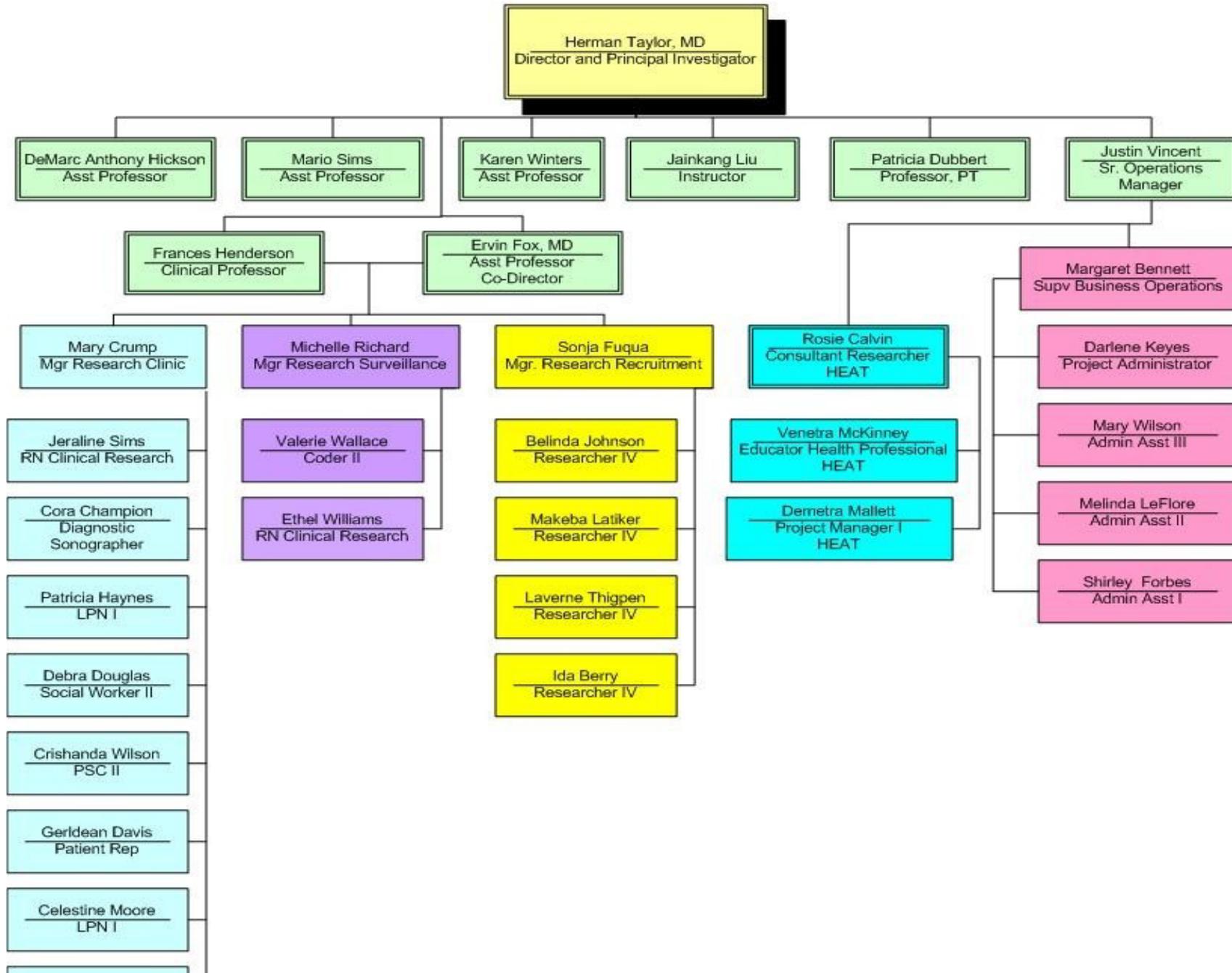
Director and Co-Principal Investigator  
Jackson Heart Study Undergraduate Training Center  
Tougaloo College  
Professor of Biology  
500 West County Line Road  
Tougaloo, MS 39174  
(601) 977-7781  
[asok@juno.com](mailto:asok@juno.com)

Michael Steffes, M.D., Ph.D	Principal Investigator Jackson Heart Study Central Laboratory Reading Center and Specimen Repository Reading Center University of Minnesota Medical School Department of Laboratory Medicine & Pathology 420 Delaware Street, SE Minneapolis, MN 55455-0391 (612) 624-8164 <a href="mailto:Michael.w.Steffes-1@tc.umn.edu">Michael.w.Steffes-1@tc.umn.edu</a>
Evelyn Walker, M.D.	Director, NHLBI JHS Field Site Jackson Heart Study Jackson State University 350 W. Woodrow Wilson Drive <a href="mailto:ewalker@ccaix.jsums.edu">ewalker@ccaix.jsums.edu</a>
Cheryl R. Nelson, M.S.P.H.	NHLBI JHS Project Officer NHLBI 6701 Rockledge Drive Bethesda, MD 20892-7934, <a href="mailto:nelsonc@nhlbi.nih.gov">nelsonc@nhlbi.nih.gov</a>
Paul Solis, PhD	Director, Epidemiology and Biometrics Program, DECA 6701 Rockledge Drive Bethesda, MD 20892-7934, <a href="mailto:manoliot@nhlbi.nih.gov">manoliot@nhlbi.nih.gov</a>
Jennifer Jennings	NHLBI JHS Contracting Officer NHLBI 6701 Rockledge Drive Bethesda, MD 20892-7934 [ <a href="mailto:Jenningsj@nhlbi.nih.gov">Jenningsj@nhlbi.nih.gov</a> ]
Austin Sachs	NHLBI JHS Contracting Specialist NHLBI 6701 Rockledge Drive Bethesda, MD 20892-7934 Sachs, Austin (NIH/NHLBI) [E] [ <a href="mailto:sachsa@nhlbi.nih.gov">sachsa@nhlbi.nih.gov</a> ]

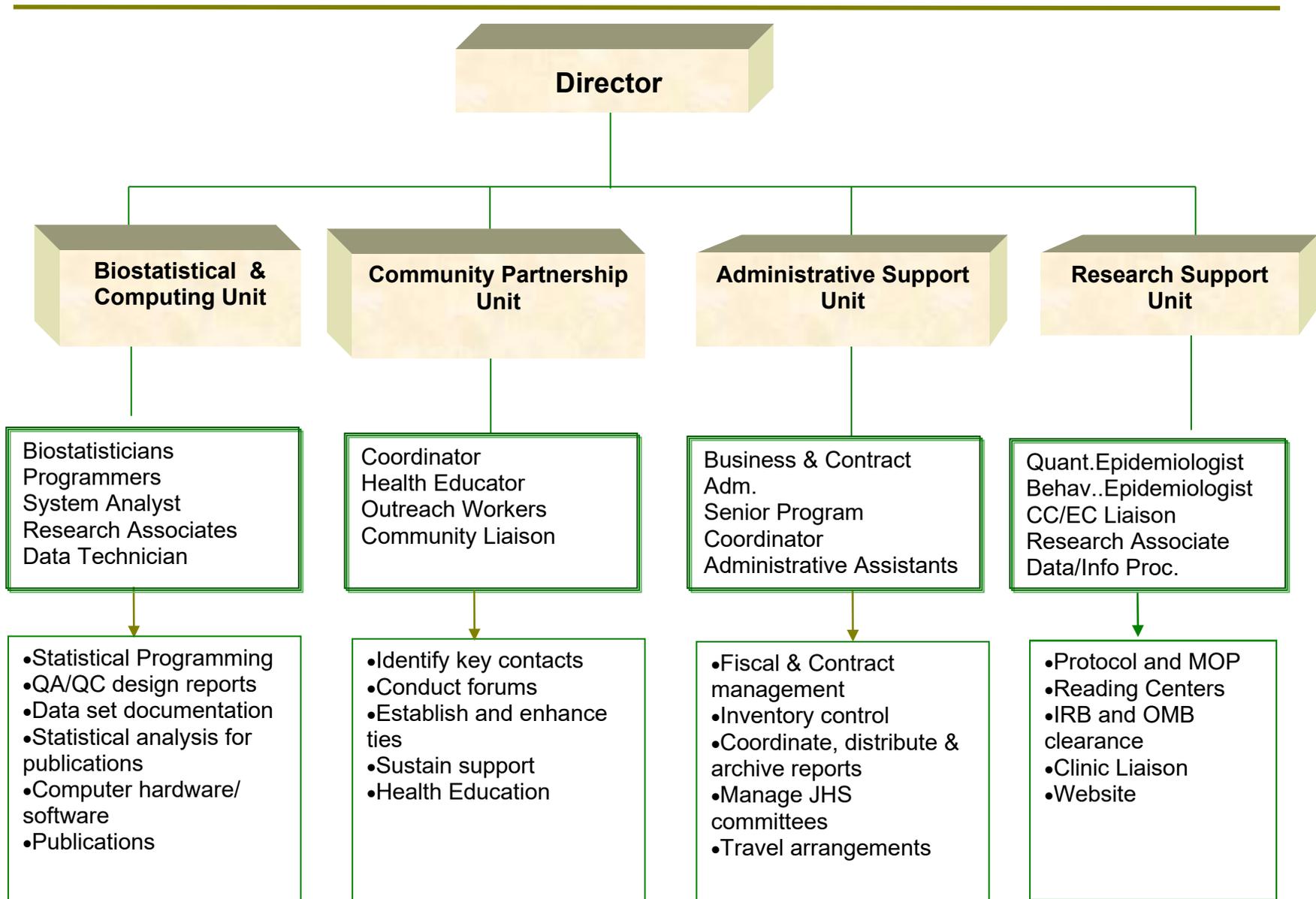


# JHS Coordinating Center Organization Chart

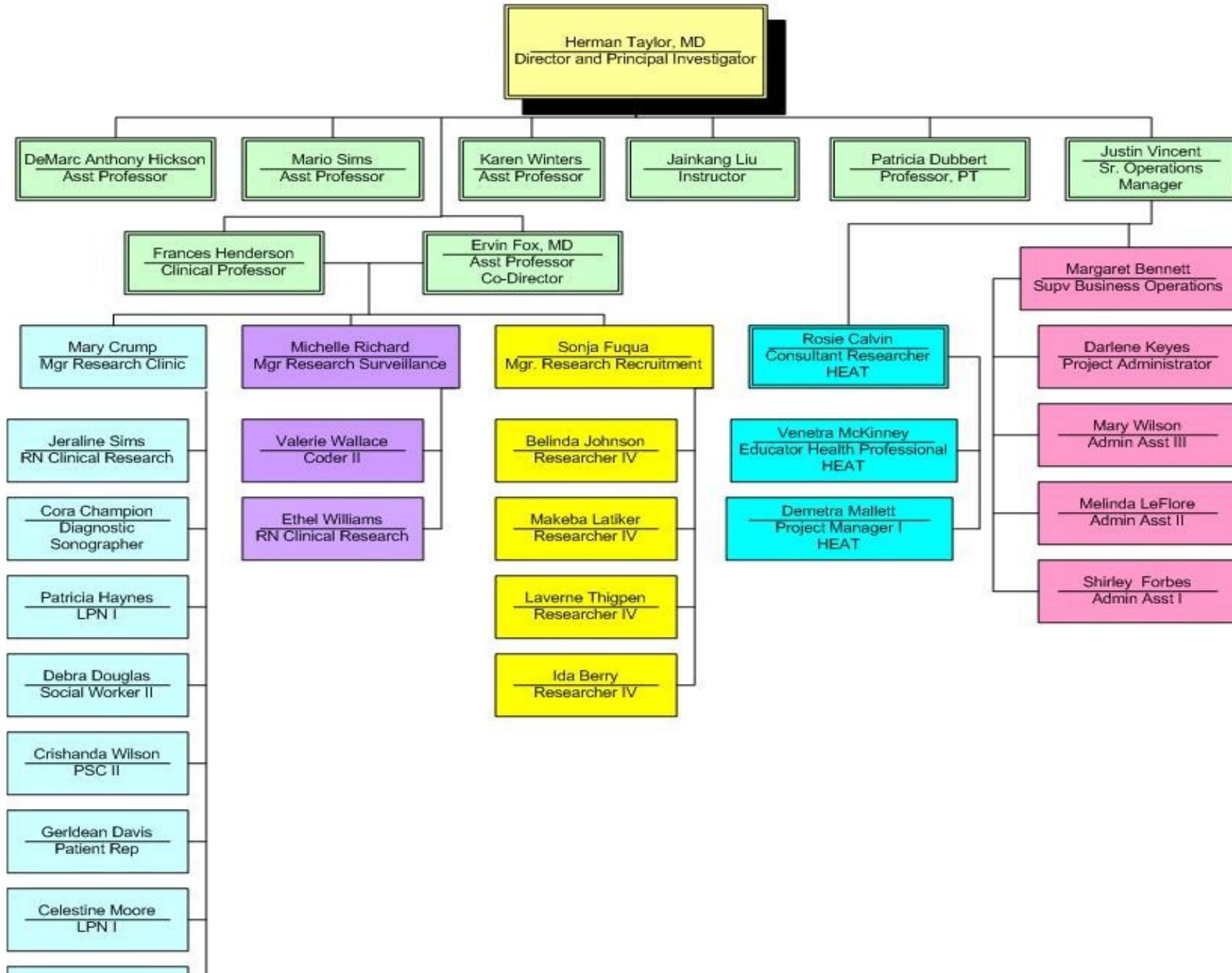
# Jackson Heart Study



Appendix 3 JHS COMMITTEES AND SUBCOMMITTEES



# Jackson Heart Study



Appendix 3 JHS COMMITTEES AND SUBCOMMITTEES

COMMITTEES/SUBCOMMITTEES	CHARGE	CHAIRS & MEMBERS
<p>1.1 1.2 <b>STEERING COMMITTEE</b></p> <p>EXECUTIVE COMMITTEE DIRECTOR'S COUNCIL</p>	<p>Overall planning and conduct of JHS.</p> <p>Development (through subcommittee mechanism) and approval of all aspects of study protocol.</p> <p>Respond to issues raised by the Monitoring Board.</p> <p>Review reports of all major Committees.</p> <p>Review recommendations for Ancillary Studies from Scientific Output and Directions.</p>	<p>1.3 1.4 <b>Herman Taylor, Chair</b> (JHS Director) Frances Henderson – EC Michael Winniford -- EC Emmanuel Keku -- CC Daniel Sarpong -- CC Asoka Srinivasan -- UTC Wendy White -- UTC</p> <p><u>Community Representative:</u> Jermal Clark</p> <p><u>NHLBI Representatives:</u> Cheryl Nelson (Project Officer) Evelyn Walker (Field Site Director)</p> <p>Herman Taylor, Chair (JHS Director) Ervin Fox, EC Frances Henderson, EC Daniel Sarpong, CC Director Asoka Srinivasan, UTC Director Justin Vincent, Sr. Operations Manager Evelyn Walker, Field Site Director</p>
<p>JHS SUBCOMMITTEES</p> <p>IRB Adherence Subcommittee</p> <p>Publications and Presentations Subcommittee</p>	<p><b>Set, disseminate and enforce policies for use of</b></p>	<p>1.17</p> <p><b>IRB Adherence Subcommittee</b> <b>Justin Vincent, Chair</b> Mary Crump Brenda-Campbell Jenkins Melinda Leflore Daniel Sarpong Asoka Srinivasan or Designee</p>

<p>Scientific Directions Subcommittee And Emerging Science</p> <p>Scientific Directions Subcommittee And Emerging Science (Continued)</p>	<p><b>JHS data in abstracts, presentations, and publications.</b></p> <p><b>Maintain updated file of all JHS manuscript proposals, publications, abstracts, presentations and ancillary or sub studies.</b></p> <p><b>Review all manuscript proposals and determine suitability and protect against overlap with other proposed projects and recommend priority for data analysis.</b></p> <p><b>Review abstracts and manuscripts prior to submission.</b></p> <p><b>Continuous review of scientific directions for the JHS to insure innovative scientific hypotheses are addressed and to insure that the most productive approaches are used to test these hypotheses.</b></p>	<p><b>Publications and Presentations Subcommittee</b>  <b>Nimr Fahmy, Chair</b>  <b>Patricia Dubbert</b>  <b>Joseph Maher</b>  <b>Frances Henderson</b>  <b>Gailan Marshall</b>  <b>Neil Powe</b>  <b>Daniel Sarpong</b>  <b>Michael Steffes</b></p> <p><b><u>Ad Hoc:</u></b>  <b>Clifton Addison</b>  <b>Myra Carpenter</b>  <b>Richard deShazo</b>  <b>Ervin Fox</b>  <b>Robert Garrison</b>  <b>Emmanuel Keku</b>  <b>Kent Kirchner</b>  <b>Charles Rotimi</b>  <b>Tandaw Samdarshi</b>  <b>Asoko Srinivasan</b>  <b>James Wilson</b></p> <p><b><u>Community Representative:</u></b>  <b>Richard Sullivan</b></p> <p><b><u>NHLBI Representatives:</u></b>  <b>Cheryl Nelson</b>  <b>Evelyn Walker</b></p> <p><b><u>NCMHD Representative:</u></b>  <b>Jerome Wilson</b></p> <p><b><u>JHS Coordinators:</u></b>  <b>Lynette Ekunwe</b>  <b>Brenda Campbell-Jenkins</b></p> <p><b><u>Scientific Directions Subcommittee</u></b>  <b>,Chair</b>  <b>Ermekgul Akylbekova</b>  <b>Teresa Carithers</b>  <b>Ervin Fox</b>  <b>Celso Gomez-Sanchez</b>  <b>Elise Gomez-Sanchez</b></p>
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<p style="text-align: center;">Ancillary Studies Subcommittee</p> <p>1.4.1.1.1 1.4.1.1.2 1.4.1.1.3</p> <p style="text-align: center;">Ancillary Studies Subcommittee 1.4.1.1.4 <b>(Continued)</b></p>	<p style="text-align: center;"><b>Review ancillary studies for compatibility with JHS goals and make appropriate recommendations to JHS Steering Committee.</b></p>	<p><b>Frances Henderson Robert Garrison Emmanuel Keku Abdul Mohamed Ana Diez-Roux Mario Sims David Williams James Wilson</b></p> <p><b><u>Ad Hoc:</u> Michelle Albert Donna Arnett Gerado Heiss Rick Kittles</b></p> <p><b><u>Community Representative:</u> John Bower</b></p> <p><b><u>Emerging Science I</u> Eric Boerwinkle David Herrington Rick Kittles Bruce Psaty Ellen Wijsman</b></p> <p><b><u>Ad Hoc:</u> Robert Garrison Daniel Sarpong Michael Steffes James Wilson</b></p> <p><b><u>Ancillary Studies Subcommittee</u> James Perkins, Chair Emekgul Akylbekova Ervin Fox William Johnson Anthony Mawson Mario Sims William Woolverton Jiankang Liu</b></p> <p><b><u>Ad Hoc:</u> Asoka Srinivasan or Designee</b></p>
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<p>1.4.1.1.5 1.4.1.1.6 1.4.1.1.7</p> <p>1.4.1.1.8 1.4.1.1.9 <b>Statistics and Quality Assurance Subcommittee</b></p>	<p><b>Establish standard methods for data collection; develop methods for technician monitoring; develop methods for data coding; establish quality control procedures; processing of Coordinating Center statistical requests; oversee quality control and quality assurance, data management systems, and analysis.</b></p>	<p><b><u>Community Representative:</u></b> Charles Spann</p> <p><b><u>NHLBI Representative:</u></b> Cheryl Nelson</p> <p><b><u>JHS Coordinator:</u></b> Brenda Campbell-Jenkins</p> <p><u>Statistics and Quality Assurance Subcommittee</u> William Johnson, Chair <b>Clifton Addison</b> <b>Mary Crump</b> <b>Nimr Fahmy</b> <b>Daniel Sarpong</b> <b>Warren May</b> <b>Gregory Wilson</b></p> <p><b><u>Ad Hoc:</u></b></p> <p><b><u>NHLBI Representative:</u></b> Sean Coady</p>
<p>Genetics Subcommittee</p> <p>Genetics Subcommittee (Continued)</p>	<p><b>Monitor genetic data collection protocols.</b></p> <p><b>Assist in the development of genetics educational materials for the community.</b></p> <p><b>Assist in developing mechanisms for the community to become actively involved in genetics research and in decisions made regarding JHS genetics studies.</b></p> <p><b>Develop and monitor policies to ensure privacy and confidentiality of genetic information, including development of informed consent for genetics.</b></p> <p><b>Assist in the development of policies for sharing genetic information with participants and development of policies to assure access to</b></p>	<p>1.17.1.1.1.1.1</p> <p>1.17.1.1.1.1.2 Genetics Subcommittee Rick Kittles, Co-Chair James Wilson, Co-Chair <b>Ermekgul Akylbekova</b> <b>Errol Crook</b> <b>Joseph Maher</b> <b>Charles Rotimi</b> <b>Charmaine Royal</b> <b>Barbara Wilson</b></p> <p><b><u>Ad Hoc:</u></b> <b>Donna Arnett</b> <b>Sarah Buxbaum</b> <b>Jean MacCluer</b> <b>Asoka Srinivasan</b></p> <p><b><u>Community Representative:</u></b> Bruce Taylor Aneice McLemore</p>

<p>1.4.1.1.10 1.4.1.1.11 1.4.1.1.12 1.4.1.1.13</p> <p>1.4.1.1.14 1.4.1.1.15 1.4.1.1.16 1.4.1.1.17 1.4.1.1.18 1.4.1.1.19 1.4.1.1.20</p> <p>Clinic Operations and Participant Results Subcommittee</p>	<p>genetic data by the scientific community while protecting participants' privacy.</p> <p>Assist in the development of quality control of genetic data and samples.</p> <p>Assist in further refinement of JHS genetics hypotheses and suggest directions for new genetics research.</p> <p>Participate in the review of proposals for new JHS genetics research.</p>	<p><b><u>NHLBI Representative:</u></b> <b>Ebony Bookman</b></p> <p><u>JHS Coordinator:</u> Lynette Ekunwe</p>
<p>1.5 1.6 1.7 1.8 1.9 1.10</p>	<p>Assist with incorporating genetics into the educational aspects of the JHS, including genetic epidemiology into the summer Epidemiology Course and Scholars Program to ensure that scholars have the opportunity to apprentice in an area of genetics research.</p> <p>Monitor and manage operation of clinic and conduct of exams (tracking flow).</p>	<p><b>Clinic Operations and Participant Results Subcommittee</b> Daniel Sarpong, Chair <b>Clifton Addison</b> <b>Michelene Brock</b> <b>Mary Crump</b> <b>Patricia Dubbert</b> <b>Debra Douglas</b> <b>Frances Henderson</b> <b>Wendy White</b></p>
<p>1.11 1.12 1.13 1.13.1.1.1 1.13.1.1.2 1.13.1.1.3 1.13.1.1.4 1.13.1.1.5</p> <p>1.13.1.1.6 1.13.1.1.7 1.13.1.1.8 1.13.1.1.9 1.14</p> <p>Events Monitoring Subcommittee</p>	<p>Develop methods for data coding and transmission in concert with CC (Coordinating Center).</p> <p>Establish quality control procedures for clinic exam and its components in collaboration with Statistics and Quality Assurance Subcommittee.</p> <p>Establish and monitor examination "alert criteria".</p> <p>Develop methods for providing clinical information to participants and their health care providers.</p>	<p><b><u>Ad Hoc:</u></b> Pls of Central Agencies <b>Sonja Fuqua</b> <b>William Rock, Local Lab Reading Center</b> <b>Michael Steffes, Central/Repository Reading Center</b> <b>Minta Uzodinma</b> <b>Justin Vincent</b> <b>Evelyn Walker</b> <b>Gregory Wilson</b></p>
<p>1.15 1.16 1.16.1.1.1</p>	<p>Interface with clinical subcontractors for CC.</p> <p>Develop scientific rationale and protocol for all Interviews, procedures and specimen collection in cooperation with Pls of the appropriate Reading Center, Repository or Laboratory.</p> <p>Ensure appropriate referral for participants requiring medical follow-up.</p>	<p><b><u>NHLBI Representative:</u></b> <b>Cheryl Nelson</b></p> <p><u>Events Monitoring</u> Alan Penman, Chair <b>David Conwill</b> <b>Ervin Fox</b> <b>Sonja Fuqua</b></p>

<p style="text-align: center;">Community Partnership Subcommittee</p> <p style="text-align: center;">Multiple working groups anticipated, focusing on various aspects of charge: media and government relations, student involvement, etc.</p> <p><b>1.16.1.1.2</b></p> <p><b>1.16.1.1.3</b></p> <p><b>1.16.1.1.4</b></p> <p><b>1.16.1.1.5</b></p> <p><b>1.16.1.1.6</b></p> <p><b>1.16.1.1.7</b></p> <p><b>1.16.1.1.8</b></p> <p><b>1.16.1.1.9</b></p> <p><b>1.16.1.1.10</b> <b>Translating Research into Practice and Prevention (TRIPP) Subcommittee</b></p> <p><b>1.16.1.1.11</b></p> <p><b>1.16.1.1.12</b></p> <p><b>1.16.1.1.13</b></p> <p><b>1.16.1.1.14</b></p> <p><b>1.16.1.1.15</b></p> <p><b>1.16.1.1.16</b></p> <p><b>1.16.1.1.17</b></p>	<p><b>Develop and monitor protocols for annual follow up, cohort morbidity and mortality assessment, and events ascertainment.</b></p> <p><b>Establish quality control procedures for events ascertainment in concert with Statistics and Quality Assurance Subcommittee.</b></p> <p><b>Enhance awareness of study among community health care providers/general community.</b></p> <p><b>Develop, implement and evaluate plan for community partnership.</b></p> <p><b>Facilitate community awareness and feedback regarding JHS (including ethical and genetics research issues).</b></p> <p><b>Translate research affiliated with JHS into</b></p>	<p><b>Emmanuel Keku</b></p> <p><b>Michael McMullan</b> <b>Michelle Richard</b> <b>Wayne Rosamond</b> <b>Cynthia Dorsey-Smith</b></p> <p><b><u>Ad Hoc:</u></b> <b>Ermekgul Akylbekova</b> <b>Robert Garrison</b></p> <p><b><u>NHLBI Representative:</u></b> <b>Evelyn Walker</b></p> <p><u>Community Partnership Subcommittee</u> Evelyn Walker, Chair <b>Clifton Addison</b> <b>Sonja Fuqua</b> <b>Donna Antoine-LaVigne</b> <b>Cynthia Dorsey-Smith</b> <b>Justin Vincent</b></p> <p><b><u>Ad Hoc:</u></b> <b>Mary Crump</b> <b>Wendy White</b></p> <p><b><u>Community Representative:</u></b> <b>Jermal Clark</b></p> <p><b><u>NHLBI Representative:</u></b> <b>Cheryl Nelson</b></p> <p><b><u>NCMHD Representative:</u></b> <b>Francisco Sy</b></p> <p><u>Translating Research into Practice and Prevention Subcommittee</u> Frances Henderson, Chair <b>Diane Beebe</b> <b>Kenneth Ray Butler</b> <b>Mary Crump</b> <b>Sonja Fuqua</b> <b>Donna Antoine-LaVigne</b> <b>Rob Rockhold</b> <b>Marjayua Lartey-Rowser</b></p>
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<p>1.16.1.1.18</p>	<p>practice for health professionals and the lay public.</p>	<p>Cythia Dorsey-Smith</p>
<p>1.16.1.1.19 1.16.1.1.20 Academic Subcommittee</p> <p>1.16.1.1.21 1.16.1.1.22 1.16.1.1.23 1.16.1.1.24 1.16.1.1.25 1.16.1.1.26 1.16.1.1.27</p>	<p>Develop the raw materials for two major products: a lay-oriented lecture series and articles for local print media.</p> <p>Identify external funding sources for committee activities.</p>	<p>Debra Sutton Justin Vincent</p> <p><u>Community Representatives:</u> Jermal Clark Margie Cunningham</p> <p><u>NHLBI Representative:</u> Evelyn Walker</p> <p>Academic Subcommittee 1.18 Asoka Srinivasan, Chair Marilyn Houston-Coleman Mary Crump Barbara Dease Candace Jackson Emmanuel Keku Ernest Limbo Richard McGinnis Robin Rockhold</p>
<p>1.16.1.1.28</p>	<p>Conduct major educational activities associated with the JHS.</p>	<p>Ad Hoc Nimr Fahmy Wendy White</p>
<p>1.16.1.1.29 Retention Subcommittee 1.16.1.1.30 1.16.1.1.31 1.16.1.1.32 1.16.1.1.33 1.16.1.1.34 1.16.1.1.35 1.16.1.1.36 1.16.1.1.37</p>	<p>Establish cross-center collaboration for practicum development.</p> <p>Develop summer epidemiology course.</p> <p>Develop seminar series for local investigators in collaboration with the Emerging Science Groups.</p> <p>Develop, update and implement guidelines for individuals seeking JHS appointments that provide skilled-based research training opportunities.</p> <p>Facilitate awareness and development of skilled-based placements within the JHS and among the larger community of educational institutions.</p>	<p><u>Community Representatives:</u> Clyde Christopher Dorothy Williams</p> <p><u>NHLBI Representative:</u> Evelyn Walker</p> <p>Retention Subcommittee _____,Chair Clifton Addison Mary Crump Debra Douglas Sonja Fuqua Frances Henderson Donna Antoine-LaVigne Cynthia Dorsey-Smith Justin Vincent Wendy White</p>



Jackson Heart Study Protocol

Manual 4

Morbidity and Mortality Classification Manual

Version 2.1

March 3, 2006

For Copies, Please Contact:

Jackson Heart Study Coordinating Center  
Jackson Medical Mall  
350 W. Woodrow Wilson Dr., Suite #701  
Jackson, MS 39213

## FOREWORD

Morbidity and Mortality Classification 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. Manual 2 describes all components and procedures carried out with the JHS cohort. Manual 3 provides detailed information about sitting blood pressure measurement. Manual 4 describes cohort surveillance, events ascertainment, morbidity and mortality classification. Manuals 4 and 5 provide information on the quality control and Manual 6 provides information on the data management systems of JHS respectively.

### JHS Protocols and Manuals of Operation

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



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## 1.0 INTRODUCTION

Jackson Heart Study (JHS) cohort morbidity and mortality includes monitoring and validating events among cohort participants. In addition to hospitalized myocardial infarction (MI) and coronary heart disease (CHD) endpoints, clinically recognized strokes among cohort participants are also identified and validated through cohort morbidity and mortality procedures. Hospitalized and outpatient events of congestive heart failure (CHF) among cohort participants are also identified.

The aim of JHS cohort surveillance is to identify all cohort morbidity and mortality events including hospitalizations and out of hospital deaths for cohort participants and to validate the diagnoses of all cardiovascular disease (CVD) events including CHD, cerebrovascular accident (CVA) and CHF (**Figures 1-1 and 1-2 detail the processes of surveillance**).

JHS will obtain information pertaining to CVD events from cohort annual follow-up interviews, hospital discharge indexes, and death certificates. Identification and abstraction of CVD event morbidity and mortality data will be carried out by the JHS-Examination Center (EC). The surveillance team at EC will enter event data using automated entry forms (via laptop computer) that are provided by the JHS-Coordinating Center (CC).

Surveillance activities for JHS consist of two essential components which work together to ultimately complete the process of events ascertainment: the annual follow-up (AFU) unit and the medical record abstraction (MRA) unit. The AFU is charged with calls to the cohort members yearly. The call is normally placed between 6 months before the anniversary of the cohort initial clinic examination and not more than 6 months past the anniversary date. JHS started recruitment and Exam 1 in September 2000, hence by the end of recruitment (February 29, 2004) and clinical exam (March 31, 2004), the AFU should be in contact year (CY3) for those recruited into the cohort in September 2000. **The AFU utilizes several forms (First, Second and Third Year Questionnaire [AF1, 2, & 3] Annual Follow-Up Other Form, Annual Follow-up Questionnaire Form and Annual Follow-up Record of Calls) to obtain updated information on cohort health status and events.** The information that is obtained by the AFU unit on cohort hospitalizations and deaths is transmitted to the MRA unit.

The MRA unit has two sub-units that function together to obtain information regarding hospitalizations and in-hospital deaths (via medical record abstraction), and out of hospital deaths (via interview of close relatives, next of kin). A certified abstractor compares the AFU hospitalization reports with the yearly hospital discharge list obtained from area hospitals for quality control (QC) or data checks. The abstractor performs medical record with direct data entry into a laptop computer equipped with Fox-pro® and all JHS abstraction forms. The abstracted information is transmitted to University of North Carolina Coordinating Center (UNCCC) every two weeks. Out of hospital deaths information, including interviews and death certificates, is also transmitted to UNCCC every two weeks.

All event data that is entered into the CC surveillance database will be checked for eligibility based on cohort membership, event timing with respect to the baseline clinic exam and the presence of a valid CVD diagnosis (as defined in the JHS Protocol Manual 10, Section: Cohort Surveillance). All incomplete or ineligible forms will be referred to EC surveillance team for clarification and correction. Other data related to cohort events will include ECG data from hospitalizations, and CT or MRI data from CVA related events. ECG data will be coded and transmitted to the CC through the ECG coding center. Once these data are available then computer generated classification of diagnoses for cohort events will be created using the standard algorithms used in the Atherosclerosis Risk in Communities (ARIC) Study protocols (see ARIC Surveillance Manual of Operation).

After all data quality checks for completeness and eligibility are resolved, the event data will be entered into the second phase of the surveillance data quality process. This second phase includes transmittal of event summary records to Morbidity and Mortality Classification Committee (MMCC) members for independent review of each JHS cohort event according to standard protocols as used in ARIC.

## Event Determination

The MMCC will make final assignment of all diagnostic categories for all cohort events after initial assignment by means of computer algorithm utilized by ARIC. The UNCCC will obtain from JHS-EC copies of hospital discharge summaries for JHS events that need a review. The event summary form (ESF), discharge summary and the management program (MGP)-generated ESF make-up the MMCC review package. The review package is sent to 1 or 2 reviewers based on the event type. Data will be checked for completeness and consistency upon completing the review forms by the MMCC. Incomplete or unresolved (e.g., "dirty") data will be sent back to reviewers for resolution. Final (resolved) data will be entered into the data entry system at UNCCC for event classification. Reviewers' diagnosis results are compared for those that need 2 reviewers. A review package is sent to an adjudicator when two original reviews disagree. Once this review process is complete, the data will be transferred to the closed files.

Potential events will be identified via the hospital discharge lists, AFU procedures and death listing.

## Closure Activities

Each year before closure, the collected hospitalization information at AFU will be compared to the cohort eligibility (CEL) form to identify missed hospitalizations for JHS. For participants that are lost to follow-up, a National Death Index (NDI) search will be activated. JHS will send such AFU data to the UNCCC.

## Data Closure and Data Distribution

Raw data for CHD from the data collection forms (HRA, DTH, CEL, IFI, PHQ, COR, SXI, STR) will be closed in March annually. Raw data, several derived files for event classification results, and one incident CHD file for the complete JHS participants will be distributed in April annually. The first distribution of JHS data will occur ~ April, 2005. Raw data for stroke and CHF will be closed subsequently in April (pending) annually. The distribution of stroke and CHF data will include the raw stroke and CHF abstraction data; the derived stroke and CHF files and the incident stroke and CHF files in May (undetermined) annually. Data and the derived variable dictionary will be sent along with the data distribution.

## Quality Control (QC) Report

Each year in May the UNCCC will generate a set of QC reports for the hospital record abstractions, completeness of event investigation for out-of-hospital deaths, and MMCC reviews for the JHS data. Similar reports for ARIC events would be available at the Jackson ARIC center, for comparison.

## Surveillance Data Management System

The surveillance data management system will be carried out by the UNCCC. Details of this component are provided in the UNC Subcontract technical proposal.

This manual details the procedures for identifying and validating selected events among the JHS cohort. The diagnostic criteria are described in Section 2 and review and classification procedures are described in Section 3. The procedures for obtaining certain indicators of medical care are described Section 4. The procedures for linkage of multiple events are described in Section 5. Sections 6, 7, and 8 describe the surveillance procedures for the identification of CHD, CVA and CHF events respectively. Section 9 describes how the MMCC functions and Section 10 outlines the QC measures used in JHS surveillance.

JHS morbidity and mortality methods evolved from those used for the ARIC Study. ARIC methods have been published (White et al., 1996). Additional information on trends in event rates using surveillance methods has been published (Rosamond et al., 1998). CHD events occurring among cohort participants are ascertained through cohort follow-up. Methods for stroke classification and event rates have also been published (Rosamond et al., 1999).

The JHS cohort is a combined cohort of JHS only and JHS/ARIC joint participants. The JHS cohort also includes an embedded family study cohort. The ARIC cohort at Jackson, MS was available for recruitment into JHS. The recruited ARIC cohort is identified as the JHS/ARIC joint cohort and is a subgroup of JHS. All letters and paper work prepared on behalf of the JHS/ARIC joint cohort will be sent on joint logo (ARIC/JHS) stationary. Letters that require signatures will be jointly signed by both JHS and ARIC Principal Investigators. The data for the JHS/ARIC joint cohort will be collected and processed by ARIC (UNCCC) and released to JHS CC at specified dates.

Figure 1.1

### JHS: CVD Morbidity and Mortality Surveillance

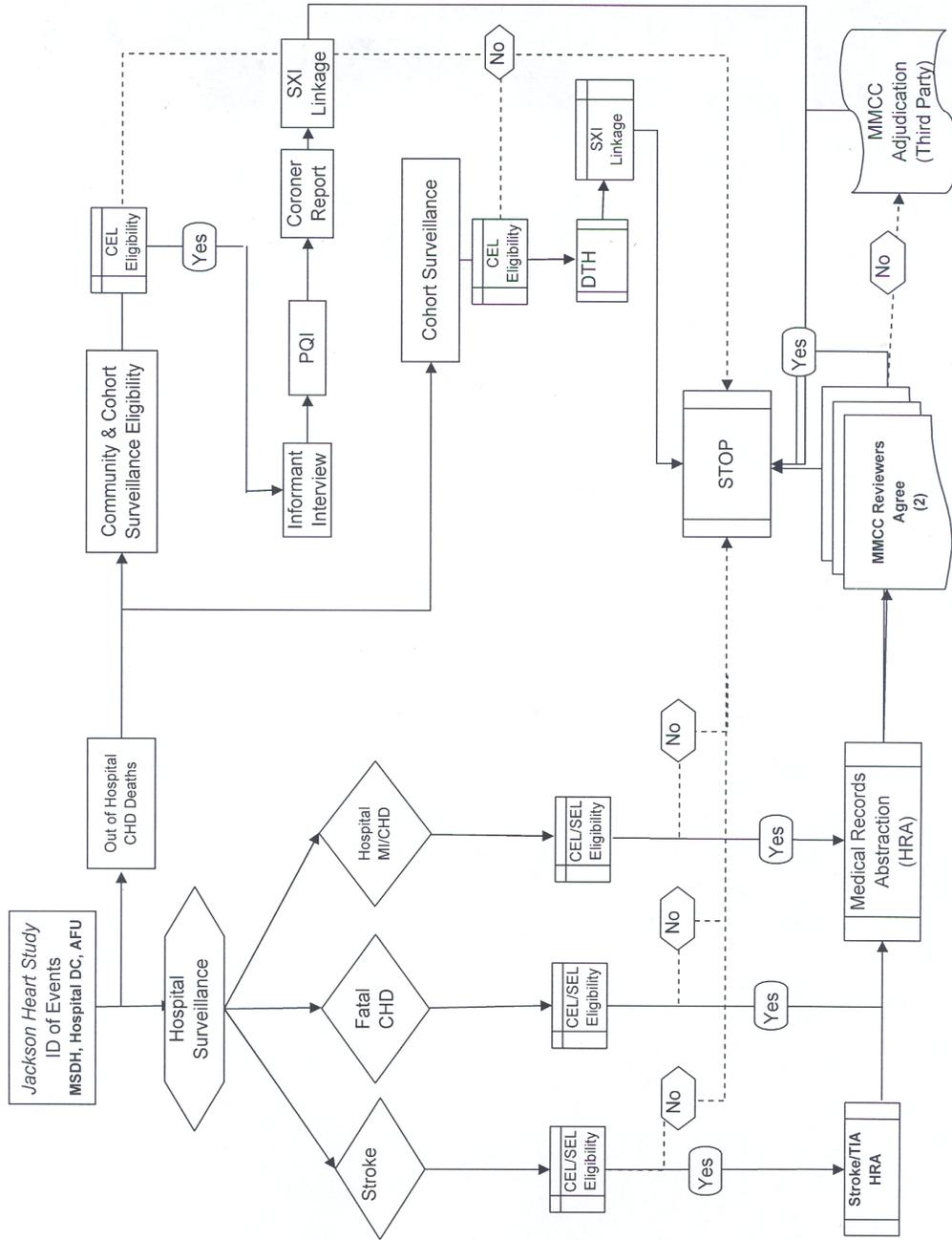
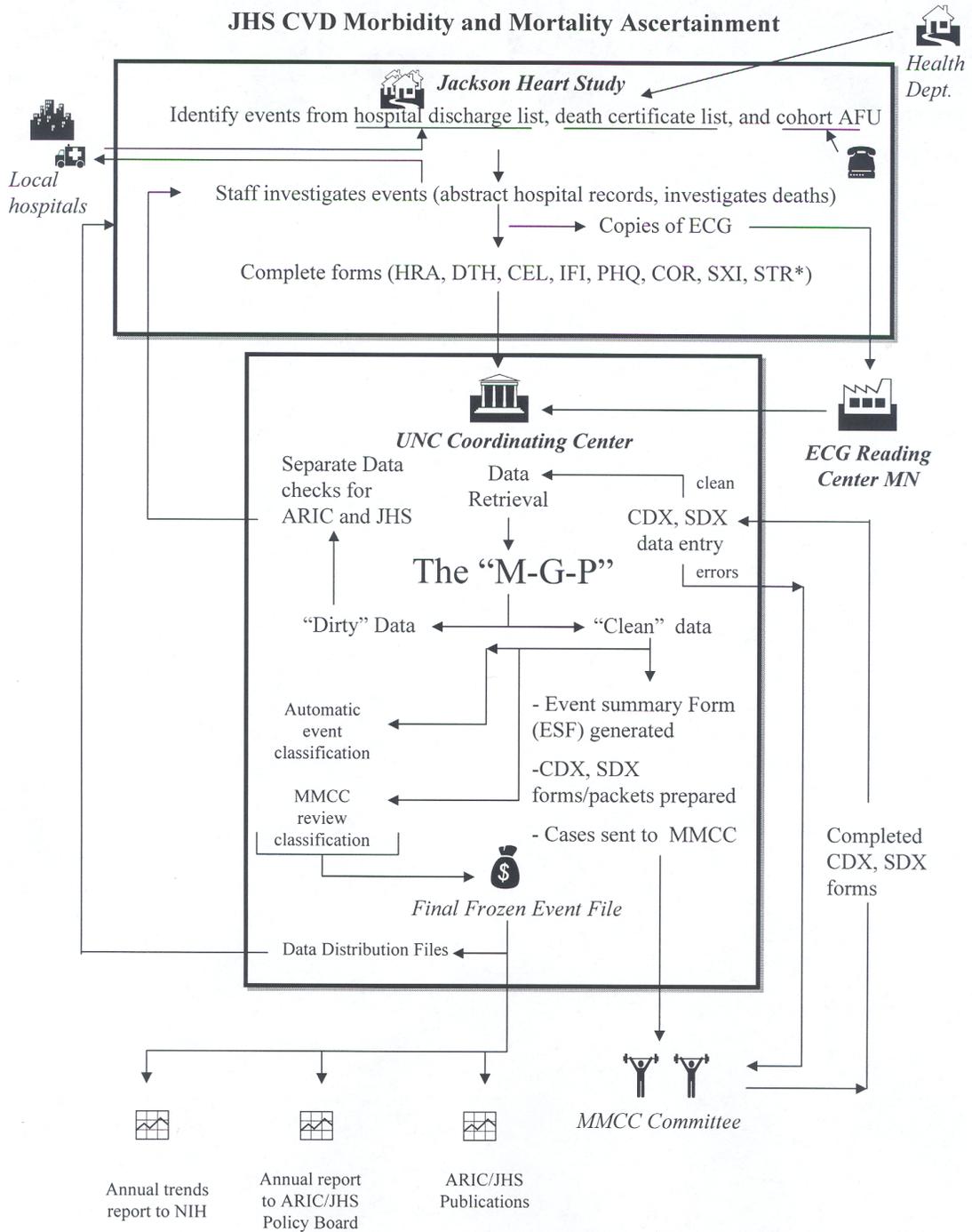


Figure 1.2



## **2.0 DIAGNOSTIC CRITERIA**

### **2.1 Fatal Coronary Heart Disease (CHD)**

#### **2.1.1 Definite Fatal Myocardial Infarction (MI)**

Must meet criteria 1 and 2 below:

1. No known non-atherosclerotic or non-cardiac atherosclerotic process or event that was probably lethal.
2. Definite hospitalized MI within four weeks of death; use criteria in Section 2.2.2 for Definite Hospitalized MI.

#### **2.1.2 Definite Fatal CHD**

Must meet ALL of the following criteria:

1. Lack of sufficient evidence to diagnose Definite Fatal MI according to the criteria given in Section 2.1.1.
2. No known non-atherosclerotic or non-cardiac atherosclerotic process or event that was probably lethal.
3. Presence of one or both of the following findings:
  - a) A history of chest pain within 72 hours of death;
  - b) A history of ever having had chronic ischemic heart disease such as coronary insufficiency or angina pectoris.

#### **2.1.3 Possible Fatal CHD**

Must meet ALL of the following criteria:

1. Lack of sufficient evidence to diagnose Definite Fatal MI or Definite Fatal CHD according to the criteria in Sections 2.1.1 and 2.1.2.
2. No known non-atherosclerotic or non-cardiac atherosclerotic process or event that was probably lethal.
3. Death certificate with consistent underlying cause of death, i.e., ICD10 codes: 410-414, 427.5, 429.2, and 799.

#### **2.1.4 Non-CHD Death**

All deaths that do not meet the above criteria for Definite Fatal MI, Definite Fatal CHD, or Possible Fatal CHD.

#### **2.1.5 Chronology of Death**

The time interval from onset of acute symptoms to time of death is recorded, where possible, for all CHD deaths. For out-of-hospital deaths, their time interval is ascertained by their MMCC reviewer and recorded on the final diagnosis form.

#### **2.1.6 Limitation of Activity**

For out-of-hospital CHD deaths it is noted whether the decedent's activity was limited in the month before death because of sickness or illness.

## **2.2 Hospitalized Myocardial Infarction (MI)**

### **2.2.1 Introduction**

JHS is to establish a well-standardized process for the identification of hospitalized coronary disease of an acute nature. The criteria presented are based on two source documents: the findings of the Community Cardiovascular Cohort Surveillance Program (CCSP) Pilot Study and the results of the Minnesota Heart Survey<sup>1-3</sup>, as well as other surveillance studies. The diagnostic criteria presented here approximate those contained in the above-mentioned documents. The differences in diagnostic criteria are the lack of a duration requirement for cardiac pain, and the use of the more sensitive and specific CK-MB and LDH isoenzymes and inclusion of troponin proteins. The description of diagnostic criteria to follow includes troponins in the category of "cardiac enzymes" even though they are technically structural proteins and not enzymes. The combinations of pain, ECG and enzyme categories required for each diagnosis below are approximately the same as those contained in the above-mentioned documents.

It is recognized that aggressive treatment of early signs and symptoms of acute coronary events, such as coronary artery bypass graft or thrombolytic therapy, may prevent the development of the full diagnostic syndrome. In such cases, it may be difficult to diagnose the event accurately. The use of such modalities is recorded and subject to data analysis, but not employed in the criteria for diagnosis.

### **2.2.2 Definite Hospitalized MI**

Definite hospitalized MI must meet one or more of the following criteria:

1. Evolving diagnostic ECG pattern (ED1 - ED7, section 2.2.6.2)
2. Diagnostic ECG pattern (D1 or D2, section 2.2.6.4) and abnormal enzymes (Table 2.1);
3. Cardiac pain and abnormal enzymes; (Table 2.1)
  - a) Evolving ST-T pattern (EV1 - EV8, section 2.2.6.3)
  - b) Equivocal ECG pattern (E1 - E4, section 2.2.6.5)

### 2.2.3 Probable Hospitalized MI

Probable hospitalized MI must meet one or more of the following criteria in the absence of sufficient evidence for Definite Hospitalized MI:

1. Cardiac pain and abnormal enzymes OR
2. Cardiac pain and equivocal enzymes and
  - a) Evolving ST-T pattern OR
  - b) Diagnostic ECG pattern OR
3. Abnormal enzymes and evolving ST-T pattern

### 2.2.4 Suspect Hospitalized MI

Suspect hospitalized MI must meet one or more of the following criteria in the absence of sufficient evidence for Definite or Probable Hospitalized MI.

1. Abnormal enzymes OR
2. Cardiac pain and incomplete enzymes and
  - a) Diagnostic ECG pattern OR
  - b) Evolving ST-T pattern OR
3. Cardiac pain and equivocal enzymes OR
4. Equivocal enzymes and
  - a) Diagnostic ECG pattern OR
  - b) Evolving ST-T pattern OR
  - c) Equivocal ECG pattern

The criteria for Definite, Probable, Suspect, and No Hospitalized MI are summarized in Table 2.1.

### 2.2.5 Definition of Cardiac Pain

Pain having both the following characteristics:

1. It occurs anywhere in the anterior chest, left arm or jaw AND
2. Absence of a definite non-cardiac cause of pain. (If there is evidence of a non-cardiac cause, the pain diagnosis is downgraded by computer to "not present".)

Table 2.1. Summary of JHS Diagnostic Criteria for Hospitalized MI

Cardiac Pain	ECG Finding	Enzymes	Diagnosis
Present	Evolving Diagnostic ECG Pattern	Abnormal	Definite MI
		Equivocal	Definite MI
	Incomplete	Definite MI	
	Normal	Definite MI	
	Diagnostic ECG Pattern	Abnormal	Definite MI
	Equivocal	Probable MI	
	Incomplete	Suspect MI	
	Normal	No MI	
	Evolving ST-T Pattern	Abnormal	Definite MI
		Equivocal	Probable MI
		Incomplete	Suspect MI
		Normal	No MI
	Equivocal	Abnormal	Definite MI
		Equivocal	Suspect MI
		Incomplete	No MI
		Normal	No MI
	Absent, Uncodable, or Other	Abnormal	Probable MI
		Equivocal	Suspect MI
		Incomplete	No MI
		Normal	No MI
Not Present, Unknown or Missing	Evolving Diagnostic ECG Pattern	Abnormal	Definite MI
		Equivocal	Definite MI
	Incomplete	Definite MI	
	Normal	Definite MI	
	Diagnostic ECG Pattern	Abnormal	Definite MI
	Equivocal	Suspect MI	
	Incomplete	No MI	
	Normal	No MI	
	Evolving ST-T Pattern	Abnormal	Probable MI
		Equivocal	Suspect MI
		Incomplete	No MI
		Normal	No MI
	Equivocal ECG Pattern	Abnormal	Suspect MI
		Equivocal	Suspect MI
		Incomplete	No MI
		Normal	No MI
	Absent, Uncodable, or other	Abnormal	Suspect MI
		Equivocal	No MI
		Incomplete	No MI
		Normal	No MI

## 2.2.6 Definitions of Electrocardiographic Criteria

The ECG series is assigned the highest category for which all criteria are met, i.e., evolving diagnostic is greater than diagnostic is greater than evolving ST-T patterns is greater than equivocal is greater than other. The ECGs are coded using Minnesota Code.

### 2.2.6.1 Evolving Diagnostic Q Waves

An evolving Diagnostic Q Wave pattern is defined as an evolving pattern on serial ECGs of ECG changes within lead groups, i.e, anterior (V1 - V5); lateral (I, aVL, V6) or inferior (II, III, aVF). Two or more ECG recordings during the hospitalization are needed for this classification.

### 2.2.6.2 Evolving Diagnostic ECG (Judged within lead group)

ED1 through ED7 cannot be assigned if a 7-1-1 code is present. ED2 through ED7 cannot be assigned if a 7-2-1 or 7-4 code is present.

- ED1. If the following condition is met for any lead group, then ED1 is positive. Either no Q-code or a 1-2-6 code in reference ECG followed by a record with a Diagnostic Q-code in the same lead group OR any code 1-3-x or 1-2-8 in reference ECG followed by a record with any code 1-1-x in the same lead group and there is no 7-1-1 code in either ECG, then ED1 is positive.
- ED2. If an Equivocal Q-code in some lead group of reference ECG is followed by a record with a Diagnostic Q-code in the same lead group, AND if there is also a lead group not necessarily the same as for the Q-code change, in which there is no Major ST-segment Depression in reference ECG but followed by a record with a Major ST-segment Depression in that same lead group and there are no 7-1-1, 7-2-1, or 7-4 codes in either ECG, then ED2 is positive.
- ED3. If an Equivocal Q-code in some lead group of reference ECG is followed by a record with a Diagnostic Q-code in the same lead group, AND if there is also a lead group not necessarily the same as for the Q-code change, in which there is no Major T-wave Inversion in reference ECG but followed by a record with a Major T-wave Inversion in the same lead group and there are no 7-1-1, 7-2-1, or 7-4 codes in either ECG, then ED3 is positive.
- ED4. If an Equivocal Q-code in some lead group of reference ECG is followed by a record with a Diagnostic Q-code in the same lead group, AND if there is also a lead group not necessarily the same as for the Q-code change, in which there is no ST-segment Elevation in reference ECG but followed by a record with the ST-segment Elevation in that same lead group and there are not 7-1-1, 7-2-1 or 7-4 codes in either ECG, the ED4 is positive.
- ED5. If there is no Q-code or a 1-2-6 code in some lead group of reference ECG is followed by a record with an Equivocal Q-code in the same lead group, AND if there is also a lead group not necessarily the same as for the Q-code change, in which there is no Major ST-segment Depression in reference ECG but followed by a record with a Major ST-segment Depression in that same lead group and there are not 7-1-1, 7-2-1, or 7-4 codes in either ECG, then ED5 is positive.

- ED6. If there is no Q-code or a 1-2-6 code in some lead group of reference ECG is followed by a record with an Equivocal Q-code in the same lead group, AND if there is also a lead group not necessarily the same as for the Q-code change, in which there is no Major T-wave Inversion in reference ECG but followed by a record with a Major T-wave Inversion in that same lead group and there are no 7-1-1, 7-2-1, or 7-4 codes in either ECG, then ED6 is positive.
- ED7. If there is no Q-code or a 1-2-6 code in some lead group of reference ECG is followed by a record with an Equivocal Q-code in the same lead group, AND if there is also a lead group not necessarily the same as for the Q-code change, in which there is no ST-segment Elevation in reference ECG but followed by a record with an ST-segment Elevation in that same lead group and there are no 7-1-1, 7-2-1, or 7-4 codes in either ECG, then ED7 is positive.

### 2.2.6.3 Evolving ST-T Pattern (Judged within lead group)

This diagnosis cannot be assigned if a 7-1-1 or 7-2-1 or 7-4 code is present.

- EV1 Either 4-0 (no 4-code), 4-4 or 4-3 in reference ECG followed by a record with 4-2 or 4-1-2 or 4-1-1; OR 4-2 in reference ECG followed by a record with 4-1-2; OR 4-2, 4-1-2 or 4-1-1 in reference ECG followed by a record with 4-0, 4-4 or 4-3; OR 4-1-2 in reference ECG followed by a record with 4-2,  
 PLUS  
 no Q-code in both the reference ECG and the follow-up ECG.
- EV2 Either 4-2 or 4-1-2 in reference ECG followed by a record with 4-1-1 OR 4-1-1 in reference ECG followed by a record with 4-2 or 4-1-2 ,  
 PLUS  
 no Q-code in both the reference ECG and the follow-up ECG.
- EV3 Either 5-0, 5-4 or 5-3 in reference ECG followed by a record with 5-2 or 5-1 OR 5-2 or 5-1 in reference ECG followed by a record with 5-0, 5-4 or 5-3,  
 PLUS  
 no Q-code in both the reference ECG and the follow-up ECG.
- EV4 Code 5-2 in reference ECG followed by a record with 5-1 OR 5-1 in reference ECG followed by a record with 5-2,  
 PLUS  
 no Q-code in both the reference ECG and the follow-up ECG.
- EV5 Code 9-0 in reference ECG followed by a record with 9-2 OR 9-2 in reference ECG followed by a record with 9-0,  
 PLUS  
 no Q-code in both the reference ECG and the follow-up ECG.
- EV6 Code 4-1-1 in reference ECG followed by a record with 4-1-1 OR 4-1-1 in reference ECG followed by a record with 4-1-1,  
 PLUS  
 no Q-code in both the reference ECG and the follow-up ECG.
- EV7 Code 5-1 in reference ECG followed by a record with 5-1 OR 5-1 in reference ECG followed by a record with 5-1,  
 PLUS  
 no Q-code in both the reference ECG and the follow-up ECG.
- EV8 Code 5-2 in reference ECG followed by a record with 5-2 OR 5-2 in reference ECG followed by a record with 5-2,  
 PLUS

no Q-code in both the reference ECG and the follow-up ECG.

#### **2.2.6.4 Diagnostic ECG**

- D1 (Diagnostic Q wave)  
An ECG record with any Diagnostic Q-code (Minnesota code 1-1-1 through 1-2-5 plus 1-2-7).
- D2 An ECG record with ST-segment elevation code 9-2 PLUS (T-wave inversion code 5-1 or 5-2 in the absence of 7-2-1 or 7-4).

#### **2.2.6.5 Equivocal ECG**

- E1 (Equivocal Q wave)  
An ECG record with an Equivocal Q-code [(Minnesota code 1-2-8 in the absence of 7-2-1 or 7-3) or (any 1-3 code)].
- E2 An ECG record with ST-segment depression (code 4-1-X or 4-2 or 4-3 in the absence of 7-2-1 or 7-4).
- E3 An ECG record with T-wave inversion (code 5-1 or 5-2 or 5-3 in the absence of 7-2-1 or 7-4).
- E4 An ECG record with ST-segment elevation code 9-2 (in the absence of 7-2-1 or 7-4).

#### **2.2.6.6 Other ECG**

- 01 Reference ECG coded 7-1-1.
- 02 Any ECG coded 7-1-1.
- 03 OTHERWISE Normal ECG(s), defined as 1.0 in "clear" field of all ECGs.
04. Other findings including 1-2-6.

#### **2.2.6.7 Uncodable ECG**

- U1 Technical errors coded 9-8-1 by Minnesota Code.

#### **2.2.6.8 Absent ECG**

- A1 No ECG available for coding.

#### **2.2.6.9 Minnesota Coding Procedures**

The following ECG tracings are identified:

1. The first codable ECG after admission;
2. The last codable ECG recorded before discharge; and
3. The last codable ECG recorded on day 3 (or the first ECG thereafter) following admission or an in-hospital event. Photocopies of the hospital ECGs are sent to the Minnesota Coding Center in Minneapolis for Minnesota Coding, using the Minnesota Coding for hospitalized ECGs. Each ECG is read one time blinded. For cohort, serial change rules are not applied.

#### **2.2.7 Definitions of Cardiac Enzyme Criteria**

All pertinent enzyme results (as defined below) recorded on days 1 through 4 after hospital admission of an in-hospital CHD event are abstracted. Information on non-ischemic cause for elevated enzymes is abstracted exclusively from the discharge summary on the medical chart. For the purposes of this manual, the category of cardiac enzymes includes cardiac troponins, even though troponin is a structural protein of cardiac muscle and not an enzyme.

### 2.2.7.1 Abnormal Cardiac Enzymes

Enzymes are classed as "abnormal" if any enzyme values recorded meet any of the following criteria:

1. a) CK-MB is "present" (if laboratory uses the criterion of "present" or "absent" without reporting a more specific value) or CK-MB is at least twice the upper limits of normal (if the laboratory gives a normal range) or, if no normal range is given, the CK-MB (heart fraction) is greater than or equal to 10% of the total CK value or, if the upper limits of normal is zero and the CK-MB is positive,  
AND
  - b) There is no known non-ischemic cause (cardiac surgery, severe muscle trauma, rhabdomyolysis) for the elevated enzyme value.
- OR
2. a) The ratio LDH1 : LDH2 > 1, or if LDH2 is missing and LDH1 is at least twice the upper limit of normal,  
AND
  - b) There is no evidence of hemolytic disease.
- OR
3. a) Total CK and total LDH are both at least twice the upper limit of normal. (These increases do not have to occur on the same day.)  
AND
  - b) There is no known non-ischemic cause (surgery, severe muscle trauma, rhabdomyolysis) for the elevated enzyme value and no evidence of hemolytic disease.
- OR
4. a) Troponin is "present" (if laboratory uses the criterion of "present" or "absent" without reporting a more specific value) or is at least twice the upper limits of normal,  
AND
  - b) There is no known non-ischemic cause (surgery, severe muscle trauma, rhabdomyolysis) for the elevated enzyme value and no evidence of hemolytic disease.

### 2.2.7.2 Equivocal Cardiac Enzymes

Enzymes are classed as "equivocal" if the criteria for abnormal enzymes are not met and if:

1. Either total CK or total LDH are at least twice the upper limits of normal.  
OR
2. Both total CK and total LDH are between the upper limits of normal and twice the upper limits of normal. (These increases do not have to occur on the same day.)  
OR
3. CK-MB is "weakly present" or between the upper limits of normal and twice the upper limits of normal or  $5\% \leq \text{CK-MB} < 10\%$ .  
OR
4. If LDH1 is present and LDH2 is missing, and LDH1 is between the upper limits of normal and twice the upper limits of normal.  
OR
5. Troponin is "weakly present", or troponin levels are between the upper limits of normal and twice the upper limits of normal.

### 2.2.7.3 Spurious Enzymes

If enzymes met one of the following criteria, the "abnormal" enzymes were considered spurious, and were downgraded to "equivocal".

1. If the first abnormal CK-MB is at or after the date of trauma, cardiac procedure or rhabdomyolysis.
2. If LDH1/LDH2 is abnormal and there is evidence of hemolytic disease.
3. If both total CK and total LDH are abnormal, and there is evidence of hemolytic disease, or the first abnormal total CK/total LDH is at or after the date of trauma, cardiac procedure or rhabdomyolysis.
4. If the first abnormal troponin is at or after the date of trauma, cardiac procedure or rhabdomyolysis.

## 3.0 EVENT CLASSIFICATION-DETERMINING WHICH EVENTS GET MMCC REVIEW

### 3.1 Hospitalized Events

Hospitalized events are classified using a computer algorithm based on criteria given in Section 2.2. Most non-linked hospital events and some linked events have an automatic computer classification for MI. Linked and non-linked hospitalized events that require MMCC review before final hospitalized MI diagnosis (Section 3.1.1) include the following:

- 3.1.1 Hospitalized events (linked to at least one other eligible hospitalization within 28 days or non-linked) if:
  - a) the final computer diagnosis is "Definite MI" but discharge codes from hospitalizations for the event do not include 410 or 411. (Note: Computer "Definite MI" + 410-411 discharge codes lead to automatic classification of Definite MI.)
  - b) the computer diagnosis is "No MI" and hospital discharge ICD9-CM codes from at least one of the hospitalizations for the event include 410. (Note: Computer "No MI" + No 410 discharge code from any hospitalization in the event lead to automatic classification of "No MI.")

This review of linked and non-linked hospitalizations is done, when needed, by one MMCC member for hospitalized MI diagnosis.

- 3.1.2 Special Automatically Classified Cases (No MMCC Review required):
  - a) If no chart can be located for all hospitalizations for the event, an automatic classification of "Unclassifiable" is given.
  - b) No discharge codes for any hospitalizations for the event contains 410-411 codes, there is no mention of acute MI in discharge summary, there is no more than one ECG, and there is no Cardiac Enzyme above the normal limits, an automatic classification of "No MI" is given. (Note: These are the cases that skip out of the HRA form at question 20.)

### 3.2 In-hospital Deaths (MI and Death Classification)

Non-linked in-hospital deaths are reviewed for death diagnosis by two MMCC reviewers (after final MI classification by computer algorithm) and adjudicated by a third reviewer if needed. Linked in-hospital

deaths (including >28 day linked deaths) are reviewed for death and MI if needed by one MMCC reviewer. The following cases, however, need no MMCC review:

- 3.2.1 Those with ICD-10 codes for underlying cause of death and a final computer diagnosis of "Definite MI," and the date of death and date of MI are within 28 days. The corresponding ICD-10 underlying cause of death codes are (I20-25, I46-49, I51.6, R99, J96). (Note: These cases are classified directly as "Definite Fatal MI")
- 3.2.2 Those with ICD-10 codes for underlying cause of death for which the final computer diagnosis of "Definite MI" could not be made according to JHS criteria but who had pain of cardiac origin or a history of MI, angina pectoris, or coronary insufficiency. (Note: These cases are classified directly as "Definite Fatal CHD")
- 3.2.3 Those with ICD-10 codes for underlying cause of death not including for which the diagnosis of a Definite MI could not be made according to JHS Criteria and
  - 1. No pain of cardiac origin, and
  - 2. No history of previous MI, angina pectoris or coronary insufficiency.

(Note: These cases are classified directly as "Non-CHD death")

### 3.3 Out-of-Hospital Deaths

- 3.3.1 All out-of-hospital deaths are reviewed by two members of the MMCC for death diagnosis except those with death certificate ICD-10 codes for underlying cause of death (I20-25, I46-49, I51.6, R99, J96) and a catchment's area hospital admission within 28 days with a final diagnosis of "Definite MI". (Note: Cases are classified as "Definite Fatal MI.")

This review for death diagnosis is done after final MI classification, in case there is an eligible linked hospital admission within 28 days of death, and is done by two MMCC reviewers, then adjudicated by a third reviewer if there is no agreement between the two reviewers.

- 3.3.2 "Definite" and "Possible" CHD deaths are classified as to time from first symptoms to death.

### 3.4 Case Law Used by MMCC

An important function of the MMCC is to maintain complete records of any clarifications of JHS diagnostic criteria required to reach diagnostic decisions. Such "case law" is systematized for convenient reference purposes and, when appropriate, incorporated into the JHS diagnostic protocol. New case law is developed as a result of discussions with the MMCC and is approved by the Chair of the MMCC before adoption.

The following are general cohort morbidity and mortality rules established as case law.

#### Final Classification Rules

- 1. When the death certificate is the only available document, and the ICD code is compatible with CHD (ICD-10:I20-25, I46, I51.6, R99, J96) then final JHS classification of cause of death is usually "Possible CHD," unless there is (I) a demonstrable coding error, or (II) an explicit non-CHD probable cause of death (such as malignant hypertension with renal failure). Analogously, for other ICD codes the classification of cause of death is usually "Non-CHD".
- 2. The classification "Diagnosis Unclassifiable" will be reserved for cases not meeting JHS criteria for CHD diagnosis, but in whom a specific non-atherosclerotic or non-cardiac atherosclerotic process cannot be identified.

3. In the case of conflicting information, the more inclusive cause of death (e.g., Definite CHD rather than Definite MI) is preferred.
4. Stroke qualifies as a “yes” answer to “a non-atherosclerotic or non-cardiac atherosclerotic process,” if judged to be the probable cause of death.
5. If the decedent was debilitated from a potentially lethal non-atherosclerotic or non-cardiac process and had a related downhill course, with no symptomatic evidence of a recent coronary event, the death is classified a non-CHD.
6. In cases of “Definite” or “Probable MI,” treated or aborted with TPA or similar clot-dissolving therapy, in which the patient dies of a direct complication or adverse effect of this therapy (i.e., hemorrhage), a final death classification of “Definite fatal CHD” should usually be assigned.
7. If a patient having an elective coronary artery by-pass graft (CABG) dies as a complication of surgery, a final death classification of “Definite fatal CHD” should usually be assigned.
8. Generally, “hypertensive heart disease” will not be considered a “non-atherosclerotic cause of death”.

#### Chronology

9. Death is assumed to have occurred at the time the patient stops breathing on his/her own and does not recover.
10. Symptoms are assumed to begin when the patient changes his/her activity. If symptoms come and go, the onset of symptoms is the time when they crescendo, leading to death.
11. In cases where timing of symptoms or death is unknown, the best estimate of the chronology is to be made.
12. Symptoms of CHD leading to a hospital admission for CHD are usually considered to be related to a subsequent death from CHD, which occurs either before discharge or within 28 days of admission, whichever occurs first. Deaths of doubtful chronology admitted for the investigation or treatment of CHD are classified as deaths occurring in > 24 hours if admitted for at least 24 hours.
13. Unknown chronology of death of an institutionalized patient is usually considered to be 24 hours.

#### Evidence

14. The relative credibility of conflicting witnesses is established from all the available evidence, i.e., there is no fixed hierarchy of credibility (such as physician overriding a lay informant). However, as a general rule:
  - (i) A knowledgeable physician takes priority for medical history.
  - (ii) A witness takes priority for events around death and timing of death.
15. A clinical history of atherosclerotic heart disease (ASHD) or CHD counts as evidence of previous manifestations of CHD. If the event under consideration is the first manifestation of CHD, it does not qualify as a “history” of CHD.

16. A history of coronary artery bypass grafting (CABG) or coronary angioplasty at any time prior to death is equivalent to a positive history of CHD.
17. Mention in the chart or documented previous angiographic evidence of CAD is regarded as equivalent to recorded history of CHD when evaluating whether there was a past history of ischemic heart disease. However, evidence of CAD on catheterization at the time of the event under consideration is not a "history of CHD".

The following are case laws developed and approved by the MMCC specifically for use with COHORT Reviews

1. For cohort morbidity and mortality events, autopsy or unequivocal angiographic evidence of old MI or other chronic CHD counts as evidence of a history of CHD.
2. For cohort morbidity and mortality events, autopsy reports may be used to judge cause of death and in most cases take precedence. Autopsy evidence of an acute MI or MI within 4 weeks may be used to answer "Yes" to "Was there a definite MI within 4 weeks of death" Such evidence includes acute coronary arterial thrombosis deemed sufficient to produce acute MI, even in the absence of evidence for acute myocardial tissue necrosis.
3. The diagnosis of "Definite MI" based upon "Evolving Diagnostic" ECG may be downgraded to the algorithm diagnosis which would be obtained if the ECG were "Diagnostic," and the diagnosis of "Probably MI," based upon "Evolving ST-T" ECG may be downgraded to the algorithm diagnosis which would be obtained if the ECG were "Equivocal," but only if:
  - a. the clinical history is compatible with the downgraded diagnosis, and
  - b. "Evolving Diagnostic" or "Evolving ST-T" ECG is suspicious because (1) a non-MI cause of the ECG abnormality is identified, or (2) a hospital ECG interpretation contradicts it.
4. Changes in hospital pain or enzyme classification are permitted only in restricted circumstances based on strong clinical judgment. When a reviewer makes a change in classification, the change should be reflected in the reviewer's answer to Item 7b (physician "preferred diagnosis"), not in the answers to Items 3, 5 or 6.
  - a. The JHS protocol, not individual hospital physician's judgment, determines what exact enzyme level qualified as "elevated."
  - b. Reviewers may downgrade enzyme classification on the basis of an identified non-cardiac or non-ischemic cause, but only if enzymes review has not already occurred.
  - c. Reviewers may downgrade the pain classification on the basis of an identified non-cardiac or non-ischemic cause, but only if pain review has not already occurred.
  - d. Changes in pain or enzyme classification are permitted when the narrative summary clearly contradicts the pain, enzyme, or ECG information abstracted and a JHS abstractor's error appears probable.
  - e. If enzymes have been downgraded from "Abnormal" to "Equivocal" driving the JHS algorithm diagnosis from "Definite MI" to "Suspect MI," or "Probable

MI” to “Suspect MI,” a reviewer who disagrees with the prior downgrading of enzymes should request another review of the decision to downgrade before completing classification of the case. Cases in which there remains continued disagreement as to whether enzymes should be downgraded should be sent for adjudication. The adjudicator in such cases may assign a more likely diagnosis of “Probable MI,” but may not upgrade the diagnosis to “Definite MI.”

- f. An angina equivalent (e.g. pulmonary edema, exhaustion, syncope) may be considered similar to chest pain in recording a “preferred diagnosis.”
5. Upgrading the MI diagnosis in hospital deaths, e.g., from “No MI” to “Suspect” or “Definite MI,” is not permitted on the basis of the judgment that had the patient lived, the enzymes or ECG would have provided sufficient evidence for the upgraded diagnosis.
6. Upgrading the MI diagnosis in cases of delayed hospitalization is not permitted on the basis of the judgment that had the patient been hospitalized earlier the enzymes or ECG would have provided sufficient evidence for the upgraded diagnosis. When the discharge summary clearly indicates a perioperative MI and JHS chest pain are “absent,” a diagnosis of “Probable” (but not “Definite”) “MI,” may be assigned if the algorithm criteria for “probable” or “Definite MI” would have been met had chest pain been “present.”

If a reviewer believes the ECG DX and the discharge summary were so discrepant as to suggest a missing ECG that might change the MI DX, the reviewer should not review the case and notify the CC of the problem. The UNCCC will check at the coding center as to whether the appropriate tracings were in the system. If this were done, and if the tracings were appropriately included and coded, then the procedures should mandate acceptance of the ECG criteria. On the other hand, if a request for a check should reveal missing ECG or a programming error, such could then be corrected as needed.

### **3.5 MMCC Final Diagnosis Forms**

When a member of the MMCC reviews a case, s/he completes a MMCC Final Diagnosis Form CDX (See Appendix VI) and returns it to the Coordinating Center for processing. The CDX form is used for evaluating events among cohort participants.

## **4.0 MEDICAL CARE ASSESSMENT**

Medical care elements which are recorded in cohort members include the participant's access to and use of providers for routine and special care, use of all prescription and over-the-counter medications, records of all hospitalizations for all reasons, records of all cardiovascular procedures and all cardiovascular diagnoses received, and detailed information on hospitalizations for CHD and CVA.

For out-of-hospital deaths, the Physician Questionnaire and Informant Interview Form allow collection of information about physician visits prior to the acute event, utilization of physician and emergency services during the acute event, history of hospital admission within one month prior to death, receipt of cardiopulmonary resuscitation, delay in receiving definitive care, use of nitrates and digitalis shortly before death, and history of CABG. The potential for cardiopulmonary resuscitation is assessed by the information on whether death was witnessed and the location of death.

For events that include abstraction of the full hospital record, additional data on medical care are obtained. These data include information on transportation to the hospital, time of arrival, receipt of cardiopulmonary resuscitation, use of a number of procedures, and medications for treatment of the

cardiovascular event (such as angioplasty and beta blocking agents), and the use of diagnostic procedures (such as cardiac catheterization and echocardiography).

## **5.0 LINKAGE OF MULTIPLE EVENTS**

Since many deaths are listed on both the hospital discharge index and the state death index, survey personnel must compare these lists carefully to avoid duplicating the investigation of in-hospital deaths. If an eligible in-hospital death is found first from the death certificate lists, the case is flagged and it is linked with the hospital chart when that record is found. The linked forms are given the same event ID number. An in-hospital chart is abstracted, and the death certificate obtained as soon as possible. Again, only one event ID number is assigned to these forms.

If an eligible hospital record indicates that a patient was transferred directly from another acute care hospital, or that the patient upon discharge is being transferred directly to another acute care hospital, the record for the other hospitalization is abstracted onto another Hospital Record Abstraction Form (HRA). The two forms initially have different hospitalization ID numbers.

On occasion, it is difficult to differentiate between two or more successive admissions for the same event and two or more different events in the same person. As it is often difficult to make this distinction on the basis of ECG, enzyme or pain characteristics, a simple rule is followed: a CHD death or a hospital admission for MI occurring within 28 days of a previous admission for MI is regarded as the same event, for purposes of calculating rates.

Over the duration of the JHS cohort morbidity and mortality, increasing numbers of cohort members are hospitalized for cardiovascular conditions more than once. Others are hospitalized and subsequently die of CHD. These events can be linked for future use. Sufficient information for correct identification of these patients is collected, where hospitals permit, and matching procedures based on these identification variables are conducted. Patient initials, last name, SSN, sex, race, and date of birth of all JHS cohort morbidity and mortality participants are compared. If the similarity is beyond a threshold level, these cases are sent out to the EC in the form of a data check for investigation. The EC then determines if these events belong to the same participant and records their findings on all Cohort morbidity and mortality Event Inventory/Linkage Summary (SXI) forms for this participant. The Coordinating Center also produces a listing of possible linkages suggested from cohort morbidity and mortality forms. Various forms (HRA, IFI, COR) contain questions as to whether the person had been hospitalized within 4 weeks prior to this event. The EC uses this listing to find linked hospitalizations that have not yet been abstracted. Any positive findings from this investigation are also recorded on the SXI form.

## **6.0 COHORT MORBIDITY AND MORTALITY**

### **6.1 Introduction**

The aim of cohort morbidity and mortality is to identify all hospitalizations for each cohort participant and validate the diagnosis of all potential congestive heart failure (CHF), coronary or cerebral vascular disease events. Ascertainment and validation of all out-of-hospital fatal events that are cardiac related are also completed.

#### **6.1.1 Identification of Events**

In addition to the procedures for identification of potentially eligible events used in ARIC Manual 3, Version 6, cohort morbidity and mortality also uses information obtained from the annual follow-up interviews. When the annual follow-up interview indicates that the participant has either died or been admitted to a hospital (for any reason), the medical record or death certificate is obtained, and information abstracted into a computer data base system. The JHS records the occurrence of all hospitalizations but only investigates selected kinds of medical events for cohort participants. These include: 1) hospitalized MI and stroke, 2) death from CHD, stroke and all-causes, 3) congestive heart failure. The identification and classification of clinical stroke and congestive heart failure events will be covered separately in Section 10 and 11 respectively. This section (section 6) describes the identification, investigation and diagnosis of cardiac related hospitalized and fatal events. JHS also

records the occurrence of a number of non-hospitalized, non-fatal events, events identified through the routine operations of the JHS clinics and annual follow up interviews, such as angina pectoris and peripheral vascular disease, including intermittent claudication. These are generally defined using standard instruments, such as the Rose Questionnaire, and their identification and diagnosis are described elsewhere.

#### **6.1.1.1 Identification of Hospitalized CHD Events**

All hospitalized events occurring in cohort members are identified. Cohort events are deemed eligible based on the following criteria: 1) a valid cohort ID; 2) occurrence must be after the participant's baseline (visit 1) examination; and 3) an eligible CHD discharge code and/or a CHD key word in the discharge summary. Hospital admissions may be identified initially through review of hospital discharge indexes or information elicited during the annual follow-up interview. Hospital chart abstraction is carried out whenever needed to identify MI. All events discharged with specified diagnostic codes are abstracted onto the Hospital Record Abstraction Form (HRA). In order to assure completeness of ascertainment, the discharge summary information is reviewed for events discharged with certain screening codes more remotely related to MI. If an MI is suggested, the chart is abstracted. In addition, all discharge diagnoses for all hospitalizations are recorded.

#### **6.1.1.2 Obtaining Access to Hospital Medical Records**

A critical feature of the process of hospitalized event identification among cohort members is obtaining information from medical records. Hospital cooperation is sought for the cohort morbidity and mortality components of the JHS. The protocol sent to hospital administrators emphasizes the fact that, for cohort members, JHS obtains signed hospital record release forms. On occasion, there may be a need to carry out special negotiations with out-of-area hospitals where cohort member was hospitalized.

A critical feature of cohort morbidity and mortality is obtaining information from medical records. Without complete cooperation of hospitals, the usefulness of event rates in any community is limited. Cooperation is sought through hospital administration, medical records directors, hospital ethics committees, and influential medical staff.

It is sometimes necessary to compromise with the hospital review committees and house staff. Again, the major consideration is confidentiality. Some hospitals will not permit the abstraction of a patient's name. It is important to obtain the name because this is the surest method to reduce redundancy in the records and determine case fatality after discharge. However, less optimal procedures are available. The first is to seek permission to code the name and record addresses, social security numbers, and birth dates. If these are available, the likelihood of redundancy can be reduced by sorting lists of individuals by birth dates or social security numbers."

#### **6.1.1.3 Hospital Discharge Index**

Eligible hospitalized events are identified from the discharge index of each hospital surveyed. Discharge indices are obtained directly from the hospital or from an indexing service.

Using the discharge index for each hospital, all hospitalized events occurring in JHS cohort members are identified. However, only special diagnoses require hospital chart abstraction. Hospital chart abstraction onto the Hospital Record Abstraction Form is carried out for all of the hospitalizations with the following ICD9-CM primary or secondary discharge diagnosis codes:

MI: 402, 410 – 414, 427, 428 and 518.4

A list of diseases included in these ICD9-CM rubrics is presented in Appendix I.

Hospital chart discharge summaries are reviewed for the following screening codes:

Diabetes: 250  
 Diseases of the circulatory system... 390-459  
 Other Dyspnea and respiratory abnormalities 786.02; 786.09

Cardiovascular symptoms: signs and ill-defined conditions:

794.3 (Abnormal function study)  
 798 (Sudden death, cause unknown)  
 799 (other)  
 35.0 35.39; 35.9 – 35.99 Operations on valves and septa of heart  
 36 – 36.3 Operations on vessels of heart  
 37.21 – 37.23 Diagnostic procedures on heart and pericardium  
 37.6 – 37.66 Implantation of heart assist system  
 88.50 – 88.58 Angiocardiology using contrast materials  
 88.72 Diagnostic ultrasound of heart  
 92.05 Cardiovascular and hematopoietic scan and radioisotope  
 Function study

Should any mention of MI on the present admission (or synonyms for these conditions) be uncovered by the review of discharge summaries for the above conditions, hospital chart abstraction onto the Hospital Record Abstraction Form is undertaken.

A number of hospitalized events for cohort members are fatal. Hospital abstracting for these events is the same as for non-fatal events, regardless of whether the ICD-10 code for cause of death from the death certificate satisfies the eligibility criteria for fatal events.

#### **6.1.1.4 Hospitalized Events Occurring Outside the Study Community**

Review of death certificates or annual follow-up interviews may reveal that the cohort member was hospitalized outside the study area. Hospitalization may occur outside the study area for the following reasons:

1. A major hospital catchments area for the region exists outside of the area (e.g., tertiary care hospital referral centers).
2. Residents who work outside of the geographic area may be admitted to an out-of-area hospital if they have an event requiring admission on an emergency basis.
3. A resident may have an event while in transit outside of the geographic area for recreation or social activities.
4. A cohort member may have moved from the study community.

Every effort is made to identify discharge diagnoses for such events and, if applicable, review the hospital chart. In soliciting access to discharge indexes and, occasionally, medical charts, a letter briefly describing the JHS cohort study is sent to the hospital administrator as well as the director of medical records, along with a copy of the JHS hospital record release form, signed by the participant at the time of the first exam. In some situations, it is also useful to send an abbreviated protocol. Additional contacts, including telephone conversations, with the hospital administrator or the head of the proper department (cardiology, neurology, etc.) may be necessary. No major obstacles are expected in obtaining access to medical charts, in view of the consent for such access provided by JHS cohort members. Cohort participants who deny access to medical records are not investigated.

### **6.1.1.5 Range of Facilities Covered for Hospitalized Events**

Events occurring to cohort members in acute care hospitals are investigated, regardless of where the hospital is located. Events in other institutions providing medical care (such as nursing homes, rehabilitation hospitals, long-term chronic disease hospitals and psychiatric hospitals) are not investigated. Cohort events in hospitals in the study community are identified by review of the discharge indexes from these hospitals and by the annual follow-up interview. The annual follow-up interview also allows identification of events occurring in or leading to admission to acute care hospitals out of the study community. Events in out-of-area hospitals will generally have to be investigated by requesting a complete copy of the medical record to be mailed to the EC.

### **6.1.2 Identification of Deaths**

#### **6.1.2.1 Death Certificates**

JHS obtains a monthly printout from the state department of health of deaths in the community, from which cohort deaths are identified. Deaths occurring in cohort members are also identified if the member has moved out of the study community. Methods include systematic review of death certificates, annual follow-up interview, hospital chart review, use of obituary notices and other means. The corresponding death certificate is located and abstracted onto the JHS Death Certificate Form (DTH). ICD10 codes for both the underlying and contributory causes of death are recorded for all deaths.

#### **6.1.2.2 Deaths Occurring Outside the Study Area**

Deaths outside of the study area but within the state are included on State Health Department monthly printouts, but some delay between the death and death registration is expected. The delay for out-of-state deaths is even greater, and they may appear only on final death files at the State Health Department. If the death certificate file is reviewed for the JHS prior to receipt of the out-of-area certificates, a subsequent review is undertaken to identify these deaths. If the location of an out-of-area death is learned through the annual interview with a participant's proxy, a copy of the death certificate can be obtained directly.

Deaths occurring outside the study community are also identified through the National Death Index and, by monitoring of obituaries.

#### **6.1.2.3 Identification of Deaths Requiring Special Investigation**

Deaths in cohort members that occurs out-of-hospital (as defined in Section 6.2.1.2) require a special investigation to determine whether or not they died of CHD if their death certificates have any of the following ICD10 codes for the underlying cause:

E10-E14, I10-I11, I20-I25, I46-I51, I70-I9(except I97.2), J81, J96, R96, R98 and R99.

For a listing of disease categories see Appendix I.

Deaths in hospitalized cohort members which occur before an ECG or a complete set of enzymes is obtained also require special investigation, if the death certificate has one of the death certificate codes as shown.

The special investigation required for these deaths is described in Section 6.2.1.2.

## **6.2 Event Investigation**

For the hospitalized event of MI, investigation entails review of the hospital record. Investigation of the fatal events occurring in cohort members includes review of the death certificate and hospital record where available (Section 6.1).

### **6.2.1 Procedures for Fatal CHD**

The Death Certificate (DTH) Form is completed for all eligible fatal events. A worksheet and the Surveillance Event Inventory/Linkage Summary (SXI) Form are used to monitor selection and completion of investigation forms. One or more of the following data forms may be completed: Hospital Record Abstraction (HRA) Form, Stroke (STR) Form, Informant Interview (IFI) Form, Physician Questionnaire (PHQ), and the Coroner/Medical Examiner Report (COR) Form. Autopsy reports for cohort members are copied.

For out-of-hospital deaths and some inadequately diagnosed in-hospital events, investigations include physician questionnaires, interviews with next-of-kin and collection of other information (see below).

### **6.2.2 Out-of-Hospital CHD Deaths**

CHD deaths occurring outside of regular acute care hospitals are categorized as "out-of-hospital CHD deaths". This includes deaths in nursing homes and other chronic care facilities. It also includes persons dead on arrival at acute care hospitals, dying in outpatient departments or emergency rooms, or admitted without vital signs. For purposes of defining out-of-hospital death, "no vital signs" means no pulse rate or no systolic blood pressure. A person admitted on a respirator who never had a pulse rate or a systolic blood pressure off the respirator is also considered an out-of-hospital death.

For out-of-hospital deaths information is sought from the decedent's family and physician(s) within 6 months after death. The family member is contacted for an interview, and the physician is sent a questionnaire. Whenever possible, the informant is the spouse or another family member of the decedent. Also, the informant may be someone else who witnessed the death. Some death certificates contain the names of the spouse and a witness.

If neither an Informant Interview (IFI) nor a Physician Questionnaire (PHQ) form can be completed, then the Hospital Discharge Indices from eligible hospitals are checked for the period covering 28 days before death. If an ICD code eligible hospitalization is found, a HRA is abstracted, regardless of discharge day.

### **6.2.3 Procedures for Fatal Events**

The Cohort Eligibility Form (CEL) and the DTH Form are completed for all fatal events occurring in cohort members. One or more of the following forms may also have to be completed: 1) Hospital Record Abstraction Form (HRA), 2) Informant Interview Form (IFI), 3) Physician Questionnaire (PHQ), and 4) Coroner/Medical Examiner Report Form (COR) and their supplements.

The DTH Form is completed and submitted to the Coordinating Center prior to or concurrent with submission of other forms. Occasionally it is necessary to obtain certificates for deaths occurring out-of-state to study area residents by writing to the state in which the death occurred.

A proportion of fatal events (in-hospital or out-of-hospital) are coroner or medical examiner's cases. This means that the county coroner or state medical examiner has performed an investigation of the circumstances of death in order to ascertain whether the causes were natural. In this case, the coroner/medical examiner signs the death certificate. In general, the coroner/medical examiner takes cases of unexpected death where no physician was in attendance during the 24 hours prior to death. During this investigation, the coroner/medical examiner may or may not order an autopsy. Any death where a legal question is likely to arise (e.g., after surgery, during an automobile accident, etc.) will

probably be a coroner/medical examiner case. If a death is certified by a coroner/medical examiner, the Coroner/Medical Examiner Form is completed and submitted to the Coordinating Center. If an autopsy is performed, a copy of that report is sent to the Coordinating Center.

Specific procedures for investigating in-hospital and out-of-hospital deaths and requirements for completion of the other forms listed above are given in the next two sections.

### **6.2.1.1 In-Hospital Deaths**

In-hospital deaths may be identified initially from death certificates or hospital discharge indexes. Hospital records for these events are abstracted if eligible as hospitalized events according to the rules. The Death Certificate Form is also completed and sent to the Coordinating Center for all deaths.

If the in-hospital death is initially identified from the hospital discharge index, the death certificate printout must be crosschecked to avoid duplication. If the in-hospital death is initially identified from the death index, the hospital discharge index must be crosschecked. Occasionally the hospital lies outside the catchment's area for the JHS community. In this case, this fact is noted on the Death Certificate Form and an attempt is made to find and, if eligible, abstract the hospital record.

Cohort members who die in the emergency room, are pronounced dead on arrival at the hospital, or are admitted without vital signs are reclassified as out-of-hospital deaths. Only the administrative data of the Hospitalized Event Form are recorded for patients without vital signs. If the death is first identified from the death index and if the death certificate indicates "dead on arrival," an attempt is made to find the hospital record in order to verify this information.

If the hospital record indicates that the cohort member has been transferred directly from another acute care hospital or is transferring directly to another such hospital, the record for the other hospitalization is found and reviewed.

### **6.2.1.2 Out-of-Hospital Deaths**

Out-of-hospital deaths with one of the eligibility codes given in Section 6.1.2.3 require a special investigation into the cause of death. For this purpose out-of-hospital death is defined to include:

1. Deaths occurring outside of regular acute care hospitals.
2. Deaths occurring in hospital emergency rooms or outpatient departments.
3. Persons who were either dead on arrival or were admitted without vital signs. For purposes of defining out-of-hospital death "no vital signs" means no pulse rate and systolic blood pressure (or admitted on a respirator with no pulse rate or systolic blood pressure at any time off the respirator).

When the special investigation for out-of-hospital deaths is required, the information from the decedent's family and physician must be obtained within 6 months after death if feasible. The former is contacted for an interview, the latter by questionnaire. Often the informant is the spouse or other family member of the decedent. On other occasions the informant is someone else who witnessed the death or someone whose name is mentioned on the death certificate.

First an attempt is made to contact and interview the spouse or a first-degree relative (i.e., son, daughter, or sibling) of the decedent, or someone else who lived with the decedent. If another person witnessed the death, this person is interviewed as well. Using the information provided by the participant at the time of the clinic interview, the informant's telephone number can be identified, and a "Format 1" letter sent (Appendix II). If a number cannot be found when reviewing information in the clinic interview, a reverse ("criss-cross") directory is used. If the informant's telephone number is still unavailable, a "Format 2" letter is sent asking the informant to provide a telephone number on the enclosed, self-addressed stamped post card. A copy of the participant's consent form is attached to the letter to the informant. These letters are sent with both the interviewer and the EC Principal

Investigator's signatures. After enough time elapses for the "Format 1" letter to arrive, or after receiving the reply post card to the "Format 2" letter, the interview is conducted using the Informant Interview Form. This interview may be conducted over the telephone, or if necessary, in person. If no reply is received, a "Format 4" letter is sent to next-door neighbors (identified by the reverse telephone directory) to request information on the whereabouts of the potential informant. A "Format 4" letter is also sent to the neighbor(s) when an informant's telephone number is initially available, but attempts at telephone contacts are unsuccessful. If no reply is received from the neighbor(s), no further effort is needed.

When the death is witnessed by someone other than a member of the decedent's family, both the family member whose name was given by the participant, and the witness recorded on the death certificate are interviewed. In such a case, the information from both interviews is recorded on separate Informant Interview Forms. Up to three (the three most complete) Informant Interview Forms may be completed for a given event.

Information is sought from physicians by sending the Physician Questionnaire. From both the clinic and informant interviews an attempt is made to identify the physician(s) who attended the decedent during the four weeks period prior to death. One questionnaire is sent to the physician who signed the death certificate. Another questionnaire is sent to the physician (if any, and if different from the first) who saw the patient for heart disease during the 28 days prior to death. Release-of-Information Forms signed by the deceased cohort participant are attached to these letters. If there is no response after four weeks of the initial mailing to the physician, a follow-up letter and another copy of the Physician Questionnaire are sent. If there is no response after eight weeks of the initial mailing, the physician is contacted by telephone. Up to two (the two most complete) Physician Questionnaires may be completed for a given event.

If the decedent died in a nursing home, personnel are asked to complete a Physician Questionnaire based on the nursing home record. JHS/ARIC may offer to assist with abstraction if this would be helpful.

A Release of Information Form may be needed.

If information provided by the informants or physicians indicates that a person who died out-of-hospital was hospitalized within 28 days prior to death for MI or heart surgery, an attempt is made to ascertain the discharge diagnoses and, if applicable, review and abstract the hospital record. Requests to hospitals include copies of the JHS/ARIC release forms.

### **6.2.1.3 Procedures for Hospitalized Events**

For hospitalized events with one of the discharge diagnosis codes for MI (402,410-414, 427, 428, 518.4), the Cohort Eligibility Form is completed. For a possible MI, the Hospital Record Abstraction Form is used for hospital record abstraction. For the special case of MI, for events with discharge codes other than ICD9 410 or 411, if the patient was discharged alive with no ECGs taken and no cardiac enzymes measured, only the administrative information on the Hospital Record Abstraction Form is completed.

For certain ICD9 procedure and diagnosis codes (35-39, 88.5, 88.72, 92.05, 250, 390-459, 786.02, 786.09, 794.3, 798, 799), which refer to conditions, more remotely related to MI, the medical record is obtained and its discharge summary reviewed. Any evidence in the discharge summary of the occurrence of MI requires the use of the Hospital Record Abstraction Form.

For all remaining ICD9 codes, the discharge lists are perused and only the discharge diagnoses recorded. These latter codes do not lead to hospital abstraction.

Abstracting of cardiac enzyme levels and ranges, copying of ECGs and treatment of transfer status follow guidelines specified for ARIC in Manual 3, Version 6.

### 6.2.1.4 Summary of Cohort Investigations

Event Type	CEL	DTH	PH Q	IFI	FORM COR	HRA (Full)	HRA (Part)	SXI*
Out-of-Hospital Death (CHD eligible)	Y	Y	Y	Y	Y			Y
Hospital Death (no vital signs at arrival, CHD eligible)	Y	Y	Y	Y	Y*		Y	Y
Hospital Death (vital signs at arrival, CHD eligible)	Y	Y			Y*	Y		Y
Hospitalized Case (discharged alive, CHD eligible)	Y					Y		Y
Hospitalized Case (not CHD eligible)	Y							
Death (not CHD eligible)	Y	Y						Y

\* If a death is certified by a coroner/medical examiner, the Coroner/Medical Examiner Form is completed and submitted to the Coordinating Center. If an autopsy is performed, a copy of that report is sent to the Coordinating Center.

### 6.2.1.5 Summary of CHD Event Investigations

The following scheme summarizes the forms completed for eligible events:

1. Out-of-hospital CHD death (died in outpatient department, includes DOA, ER admitted without vital signs)
  - a) Death Certificate (DTH) Form.
  - b) Up to two Physician Questionnaires (PHQ) and three Informant Interview (IFI) Forms.
  - c) Coroner Form on all coroner/medical examiner's (COR) cases and Hospital Record Abstraction (HRA) Form on cases admitted to a catchment's area hospital in past 28 days with heart conditions meeting JHS screening codes regardless of day of discharge.
2. \*Hospital CHD deaths, no vital signs in-hospital
  - a) DTH.
  - b) First part of HRA.
  - c) PHQ, IFI, COR.
3. \*Hospital CHD death, vital signs sometime in hospital
  - a) DTH, HRA (full).
4. \*Hospitalized CHD case, discharged alive
  - a) HRA (full).

\*If a patient also transferred to or from a catchment's area hospital, complete an additional Hospital Record Abstraction form.

### 6.3 Diagnostic Criteria

Events occurring among cohort participants receive a computer derived diagnosis classification into fatal diagnostic categories (definite fatal myocardial infarction, definite fatal CHD, possible fatal CHD, non-CHD death) and MI categories (definite, probable, suspect, and no). However, for cohort events, the final diagnosis classification is determined by MMCC review. The only exceptions are those outlined in Section 6.4.1.1.

#### 6.3.1 Hospitalized Myocardial Infarction (MI)

As described in Section 6.1.1, all hospitalized events occurring in cohort members are identified; detailed chart abstraction is carried out only when acute MI is suspected. In addition, hospitalization for mild and chronic manifestations of ischemic heart disease, such as angina pectoris and congestive heart failure. (So-called silent infarctions are not identified from the hospital records, but from ECG changes occurring to cohort members between their baseline and follow-up examinations.) Both Q-wave (transmural) and non-Q-wave (non-transmural) infarctions are sought in all hospital records abstracted.

It is recognized that aggressive treatment of signs and symptoms of impending myocardial infarction, such as angioplasty, CABG or thrombolytic therapy, may prevent the development of the full diagnostic syndrome. In such cases, it may be difficult to diagnose the event accurately. The use of such modalities are recorded and subject to data analysis, but are not employed in the criteria for diagnosis. A computer derived diagnostic classification is created for all eligible cohort events. These categories (definite MI, probable MI, suspect MI and No MI) follow the same criteria outlined in the cohort morbidity and mortality section 2.2.2 to 2.2.4.

##### 6.3.1.1 Definition of Cardiac Pain

1. Pain occurring anywhere in the anterior chest, left arm or jaw, and
2. Absence of a definite non-cardiac cause of chest pain.

##### 6.3.1.2 Definitions of Electrocardiographic Criteria:

The ECG series is assigned the highest category for which criteria are met, i.e., evolving diagnostic ECG patterns are higher than diagnostic ECG patterns, which are higher than evolving ST-T patterns, which are higher than equivocal ECG patterns, which are higher than other, which are higher than uncodable.

To fit an evolving ECG Pattern (Evolving Diagnostic and Evolving ST-T) two or more recordings are needed. Changes must occur within lead groups, i.e., lateral (I, aVL, V6), inferior (II, III, aVF), or anterior (V1-V5) and be confirmed for all codes by Serial ECG comparison.

##### Example

Reference ECG codes: 1-3-4 4-0 5-0 9-0  
 Follow-up ECG codes: 1-2-4 4-0 5-2 9-0

To be considered Evolving Diagnostic (pattern ED3) both the 1-2-4 and the 5-2 must be determined to be Significant Increase by Serial Change rules. If the 1-2-4 change is not Significant Increase and the 5-2 change is Significant Increase, then the change would fit Evolving ST-T (pattern EV3). If the 5-2 change is not Significant Increase, then pattern would

be Diagnostic ECG (pattern D1) because of the 1-2-4, regardless of whether or not the 1-2-4 change is Significant Increase.

#### Minnesota Coding Procedures

The following ECG tracings are identified:

1. The first codable ECG after admission;
2. The last codable ECG recorded before discharge; and
3. The last codable ECG recorded on day 3 (or the first ECG thereafter) following admission or an in-hospital event.

Photocopies of the cohort hospital ECGs are sent to the Minnesota Coding Center in Minneapolis for Minnesota Coding, using the Cohort Hospital ECG Form (ECG) shown in Appendix P of Manual 5. ECGs are read three times, blinded; the final codes are adjudicated by a senior coder. Minnesota Code criteria are in Appendix E of Manual 5.

The data from the ECG form is entered and a determination is made at the Coordinating Center by computer algorithm as to whether or not the Minnesota Code change criteria are met. A list of those IDs that fit the change criteria (i.e., any pattern ED1 through ED7 or EV1 through EV5, defined above) is sent to the ECG Coding Center. ECGs for these IDs are examined side by side for Serial ECG change.

Simultaneous ECG comparison is performed on the final Minnesota codes using the first codable ECG of the hospitalization as the reference. Serial ECG changes are determined three times, blinded. Serial change categories are 1) significant increase, 2) decrease (4-, 5-, and 9-2 codes, but not for Q-codes), 3) no change (this implies no increase for Q-codes) or 4) technical problem. The final categories are adjudicated by a senior coder and added to the EKG Form.

As an example, the JHS protocol defines a new Minnesota code 1-2-7 as a potential ischemic event. Persons with this severity of ECG change will have simultaneous ECG comparison. The ECG comparison procedure (for this case) requires a  $\geq 1$  mm R-wave amplitude decrease between corresponding leads of the reference and comparison ECGs. The criteria for 1-2-7 are QS patterns in V1, V2 and V3. If the reference ECG has R-waves that are  $\geq 1$  mm tall in V1 or V2 or V3, when comparing these ECGs side by side, and the R-waves in the reference ECG appear to decrease the appropriate amount (at least 1 mm), then a "significant increase" is noted on the Appendix O form. If the reference ECG has R-waves  $< 1$  mm tall, it cannot fulfill the change criteria and no change (or no increase) is noted.

#### 6.4 Event Determination

Final assignment of diagnostic categories for all cohort events of interest in the JHS is made by the MMCC, after initial assignment to diagnostic categories is carried out by computer algorithm. The final classification of a cohort event is that preferred by the MMCC review process. This section describes the procedures by which these determinations are made.

Computer-generated summaries of all relevant coded information from the data collection forms are provided to the MMCC in summary form (Event Summary Form (ESF)) for review. In addition, the MMCC considers remarks by family interviewers, hospital record abstractors, or clinic examiners or other uncoded information recorded on the data collection forms. These are recorded in the form of note logs in the database and made available for use by the committee. All cohort events (with some exception noted below) are reviewed by two members of the MMCC. The final diagnosis decision made by the MMCC reviewer is recorded on the CDX form.

For types of events which often are not classifiable by computer algorithm, e.g., out-of-hospital deaths, the diagnostic criteria given in Section 3.3 may not be specific enough to permit unequivocal classification of each event by the MMCC. If the MMCC discovers a rule which helps standardize this process, it either 1) makes a recommendation to the JHS Steering Committee for further specification of the JHS diagnostic criteria or 2) records the rule as a part of the "case law" for its own use in classifying similar events.

In addition to diagnosing all cohort clinical events, the MMCC provides other information about these events. Examples include clinical judgments required prior to making diagnoses and resolution of conflicting evidence regarding the time interval between onset of symptoms and death. These are discussed in the appropriate sections below.

#### **6.4.1 Diagnosis of Coronary Heart Disease**

##### **6.4.1.1 Hospitalized MI**

The following cohort cases are automatically classified (do not require MMCC review). These account for 10-15% of the total number of cohort events.

1. The computer assigns a diagnosis to cohort events that skip out of the HRA form and no 410-discharge code is present. These events are automatically classified as NO\_MI by the JHS diagnostic algorithm.
2. The computer also assigns a final diagnosis of NO\_MI for cohort events with no 410 codes, no pain, normal or incomplete enzymes, and ECG finding that is absent, uncodable, or other.

All non-linked, non-fatal hospitalized CHD events where discharge codes do not include 410, chest pain is absent or present, enzymes are normal or incomplete, and ECG findings are equivocal, absent, or uncodable will automatically be assigned a final diagnosis of NO\_MI by the computer.

All non-linked, non-fatal cohort cases that are not automatically classified by the computer will only be reviewed by one MMCC reviewer (instead of 2) and the computer. A second MMCC reviewer will adjudicate disagreements between the reviewer and the computer.

All other events including linked non-fatal hospitalizations, fatal hospitalization (linked and non-linked), and out-of-hospital death (linked and non-linked) are reviewed by two MMCC reviewers and an adjudicator if necessary. The only exception is for linked greater than 28-day deaths. These special reviews are sent to one MMCC reviewer with no adjudications.

##### **6.4.1.2 CHD Death**

Narratives recorded by family interviewers and other uncoded information is important in diagnosing deaths that occurred out-of-hospital. For many out-of-hospital events, the MMCC must resolve conflicting information collected from several informants. In-hospital deaths meeting the criteria for "Definite MI" require MMCC review for a possible Non-CHD cause of death before being classified as "Definite Fatal MI".

A computer diagnosis of "Definite Fatal MI", "Definite Fatal CHD" or "Non-CHD Death" is provided for those events for which all the necessary coded information is available and unequivocal. Except for a sample of unequivocal computer diagnosed Non-CHD Deaths, all cohort deaths require MMCC review and classification.

All out-of-hospital deaths classified as "Definite Fatal CHD" or "Possible Fatal CHD" requires an MMCC determination of the interval between the onset of symptoms and death. Differences between reviewers in time interval are not adjudicated.

#### **6.4.2 Event Summary Forms (ESF)**

Event summary forms for cohorts include information that is taken from various cohort forms (AFU and clinic visit forms). The information includes visit exam reports, annual follow-up information, previous cohort diagnosis for MI, and previous diagnosis for stroke. Autopsy reports, if available, can also be included for cohorts. For cohorts, it is the reviewer's decision whether to downgrade the "spurious" enzymes. The reviewer is given the downgraded enzyme values, original enzyme values, and 2 pages of additional enzyme data.

#### **6.4.3 Additional Cohort Forms**

The Cohort Eligibility Form (CEL) is used to determine if a cohort event is eligible for cohort morbidity and mortality. Data from the CEL is run through various data and code checks against other cohort morbidity and mortality forms such as the DTH and HRA. The Annual Follow Up Form (AFU) data pertaining to Rose angina are printed out on the cohort ESF and is also used to locate any possibly missing cohort events that are cohort morbidity and mortality eligible.

### **6.5 Diagnosis of Prevalent MI at Baseline and Interim MI Between Clinic Visits**

#### **6.5.1 Procedures**

##### **6.5.1.1 Minnesota Coding**

Cohort 12-lead ECGs will be taken during EC visits. One ECG is taken at the baseline exam and a second ECG is taken at the follow-up exam three years later.

Abnormal ECGs and a 10% selection of normal ECGs will be transmitted from the Epicare Computer Center to the Minnesota Coding Center in Minneapolis. These ECGs will be coded visually by the Minnesota Code. ECGs are read three times, blinded; the final codes are adjudicated by a senior coder.

##### **6.5.1.2 Adjudication**

The visual Minnesota Codes will be sent to the Coordinating Center for comparison with the computer-generated codes. Adjudication between the visual code and the computer code will be performed by two electro cardiographers only on ECGs that have a discrepancy involving any Q-code, or any 4-2, 4-1-2, 4-1-1, 5-2, 5-1 or 9-2. The Coordinating Center determines the IDs that have any of these discrepancies and will send a report form to the Minnesota Coding Center listing the ID, acrostic, date and time of ECG, the visual codes and the computer codes. These ECGs are examined and the adjudicated codes are recorded on the report form, which is returned to the Coordinating Center.

##### **6.5.1.3 Serial ECG Coding**

The CC adds the adjudicated codes to the database as the definitive Minnesota Codes for the ID involved.

When two ECGs from different EC visits are available, a determination is made at the Coordinating Center as to whether or not Minnesota Code change criteria are met. A list of those IDs that fit the change criteria (i.e. any pattern ED1 through ED7) is sent to the ECG Coding Center. ECGs for these IDs are examined side by side for Serial ECG change.

Simultaneous ECG comparison is based on the final Minnesota Codes. Serial ECG changes (significant increase, no increase or technical problem) are determined three times; the final categories are adjudicated by a senior coder and added to the Appendix O form. The simultaneous ECG evaluation procedure uses the ECG of the first clinic visit as the reference ECG for comparison.

JHS requires Minnesota Code change plus agreement by simultaneous ECG comparison before declaring the ECG pattern change meets JHS criteria for an interim MI.

### **6.5.2 Definitions**

A determination that a JHS participant has had an MI, either prior to the initial clinic visit or between visits, can be made on ECG evidence alone, using the following criteria:

#### **6.5.2.1 Prevalent MI at Baseline**

Baseline ECG (initial cohort visit) coded:

- a) Any 1-1-X code
- OR
- b) Any 1-2-X and 4-1-1 or 4-1-2 or 4-2 or 5-1 or 5-2

#### **6.5.2.2 Interim MI between Cohort Visits**

This is an Evolving Diagnostic ECG Pattern (ED1 through ED7) between the baseline ECG (initial cohort visit) and an ECG from a later cohort visit. An “unrecognized MI” or “silent MI” can be said to have occurred in the interval between visits if such ECG evidence of MI was found and there was no clinically recognized MI event picked up by the hospitals during follow-up. More information on the determination of unrecognized MI can be found in Borland, 2002.

## 7.0 COHORT MORBIDITY AND MORTALITY FOR STROKE

### 7.1 Introduction

Potential clinical stroke events are identified and then validated for cohort participants. The procedure for identification, investigation, and classification of these events is outlined below. More information on the stroke classification system can be found in Rosamond, 1999.

### 7.2 Identification of Stroke Events

There are two ways of identifying cohort stroke events. The abstractors review the CEL forms; identify those cohorts with a stroke code listed on their hospital discharge form and/or one of the following keywords listed in their discharge summary or mentioned during the admission: stroke, TIA, cerebrovascular disease, cerebral hemorrhage, cerebral infarction, subarachnoid hemorrhage, cerebral embolus, paralysis, aphasia, diplopia, lacunar (syndrome infarction), dysarthria, cerebral angiography, carotid endarterectomy, CT/MRI scan showing cerebrovascular findings, or Neuro ICU care. Death certificates listings are also reviewed for the presence of an underlying cause of death suggestive of stroke (ICD10 code: I60-69). Stroke deaths without additional hospitalization data will not be investigated. Classification of non-linked stroke deaths (not linked to a hospitalization within 28 days) is classified on the basis of underlying cause of death code.

### 7.3 Investigation

If a cohort event meets the above criteria, a specially trained abstractor then reviews these records and completes the Stroke Form (STR, Appendix VI). Approximately every month, these data are sent to the Coordinating Center and run through a series of data check programs.

### 7.4 Diagnosis

All potential stroke hospitalizations are automatically assigned a stroke diagnosis by the computerized stroke algorithm (Appendix III). The computerized stroke algorithm classifies stroke events based on the data from the STR form and the DTH form if the event is a death. The possible computer stroke classifications are as follows: definite or probable subarachnoid hemorrhage (SAH); definite or probable brain hemorrhage (IPH); definite or probable brain infarction, thrombotic (TIB); definite or probable brain infarction, non-carotid embolic (EIB); possible stroke of undetermined type; undocumented fatal stroke; out of hospital death stroke; or no stroke. Undocumented fatal strokes and out of hospital death strokes do not require a STR form. In the rare case where a stroke event meets the criteria for two different diagnoses, the following hierarchy is used:

Definite IPH  
 Definite SAH  
 Definite EIB  
 Definite TIB  
 Probable IPH  
 Probable SAH  
 Probable EIB  
 Probable TIB  
 Possible stroke of undetermined type

A Stroke Event Summary Form (S-ESF) is produced for each stroke event that include information on number of major/minor symptoms, procedures, discharge diagnosis codes, and the computer classification of the event. The S-ESF and all hospital materials for the stroke event are sent to one member of the Stroke-Mortality and Morbidity Classification Committee (S-MMCC) for classification. The S-MMCC reviewer fills out a Stroke Final Diagnosis Form (SDX). The S-MMCC reviewer can either cite exclusionary conditions such as major head trauma, neoplasm, CNS infection, etc., or classify the stroke event in one of the following categories: definite or probable subarachnoid hemorrhage (SAH); definite or probable brain hemorrhage (IPH); definite or probable brain infarction,

thrombotic (TIB); definite or probable brain infarction, non-carotid embolic (EIB); possible stroke of undetermined type; or other (no stroke) if no exclusionary conditions were met. Event summary forms (S-ESF) are not produced for the following three event types: 1) Events where the STR form indicates that neurological symptoms did not last more than 24 hours or there were no new neurological symptoms prior to or during the hospital admission; 2) Out of hospital stroke deaths not linked to a hospitalization; or 3) hospitalized events with no medical chart available. These events are automatically classified without physician review as “no stroke”.

## **7.5 Classification**

The one S-MMCC reviewer and the computer algorithm determine final classification of stroke events. If there are discrepancies between these two sources, the final event classification is determined by a second reviewer (stroke –adjudicator). An event is considered classified if one of the following situations occurs:

1. If the reviewer has not cited any exclusionary conditions and the computer algorithm diagnosis agrees with the reviewer's diagnosis, the event is classified as such.
2. If the reviewer does cite exclusionary conditions and the computer algorithm diagnosis is no stroke, the event is classified as no stroke.

If the S-MMCC reviewer and the computer algorithm disagree, the adjudicator's classification is taken as the final classification.

**Table 7.1. Matching ICD-9 with ICD-10 for Underlying Cause of Death Codes related to STROKE**

<b>ICD-9 Code</b>	<b>ICD-9 Classification</b>	<b>ICD-10 Code</b>	<b>ICD-10 Classification</b>
430	Subarachnoid hemorrhage	I60	Subarachnoid hemorrhage
431	Intracerebral hemorrhage	I61	Intracerebral hemorrhage
432	Other intracerebral hemorrhage	I62	Other nontraumatic intracranial hemorrhage
433	Occlusion of precerebral arteries	I63	Cerebral infarction
434	Occlusion of cerebral arteries	I63	Cerebral infarction
		I65	Occlusion of precerebral arteries not resulting in infarction
		I66	Occlusion and stenosis of cerebral arteries not resulting in infarction
435	Transient ischemic attack	G45	Transient cerebral ischemic attacks and related syndromes (Not relevant death classification. Do not include in algorithm)
436	Acute, ill-defined CVD	n/a	n/a
437	Other ill-defined CVD	I64	Stroke, not specified as hemorrhage or infarction
		I67	Other CVD
438	Late effects of CVD	I69	Sequel of CVD

**Important Notes:**

I63 includes occlusion and stenosis of cerebral and precerebral arteries resulting in infarction.

I65 includes embolism and narrowing not resulting in infarction

Excluded is ICD-10 code I68, cerebrovascular disease in diseases classified elsewhere (cerebral amyloid angiopathy, cerebral arteritis in infectious and parasitic diseases)

Comparability ratio for ICD-9 cerebrovascular disease 430-434, 436-438 and ICD-10 I60-I69 reported to be 1.04

## 8.0 COHORT MORBIDITY AND MORTALITY FOR CONGESTIVE HEART FAILURE

The CHF working group at the JHS has developed a definition for CHF and both inpatient and outpatient CHF criteria based on the modification of those used by Multiethnic Study of Atherosclerosis (MESA), Framingham and Cardiovascular Health Study (CHS) (patient symptoms, physician physical findings, and diagnostic procedures). Inpatient CHF criteria will be included in the Hospital Record Abstraction (HRA) Form as an addendum, and outpatient CHF criteria will be developed for the Outpatient Record Abstraction Form. The current HRA form captures CHF discharge codes, but no further information is abstracted. The addendum HRA form will allow detailed HRA abstraction that will parallel that for CHD cases. The Cohort Eligibility form (form CEL) will be adjusted to accommodate abstraction of records that meet the CHF criteria and definition for both inpatient and outpatient cohort participants.

The CHF working group also developed CHF questions that are being administered to cohort members during the AFU interview. Specific questions are available at (cite website & JHS forms manual here). The CHF questions are already part of the expanded informant interview form that is now completed for out-of-hospital deaths.

The protocol for identifying and classifying heart failure events among cohort participants has been developed and will be re-evaluated after the first 6 months and modifications made as appropriate. The definition for CHF adopted by the JHS is:

- a constellation of various symptoms and physical signs that occur in a participant whose cardiac output cannot match metabolic need despite adequate filling pressure as a result of various disease processes.

CHF identification will follow the usual routines of reviewing the hospital discharge list and death certificate keywords and ICD9-10 codes suggestive of CHF. A summary of the preliminary approach to heart failure classification is provided below.

### 8.1 Inpatient

#### 8.1.1. Introduction

#### 8.1.2. Identification of CHF Events

**Definition:** Congestive Heart Failure is defined as a constellation of various symptoms and physical signs that occur in a participant whose cardiac output cannot match metabolic need despite adequate filling pressure as a result of various disease processes.

Hospitalizations. Trained and certified CHF abstractors review the Cohort Eligibility (CEL) forms and identify participants with (1) a discharge diagnosis of ICD9 code 428 and/or underlying cause of death I50, and (2) radiographic findings consistent with CHF or increased venous pressure >16, or dilated ventricle/left ventricular function <40% by echo/MUGA scan, or (3) autopsy finding of pulmonary edema / CHF.

In- or Out-of-Hospital Deaths. Death certificates are reviewed for underlying secondary or tertiary or higher cause of death that is suggestive of CHF (ICD9 code 428 or ICD10 code I50).

Review and Classification. Any CHF event that meets the above criteria is reviewed by a trained CHF abstractor who completes a CHF abstraction form. The abstracted data is transmitted to UNC-CSCC and run through a series of data check programs. All CHF hospitalizations are automatically assigned a CHF diagnosis by the computerized CHF algorithm which depends on abstracted data on the CHF and the death form (DTH) if the event is a death. The computerized CHF classifications include (1) Definite CHF, (2) Probable CHF, or (3) No CHF in accordance with inpatient or outpatient location using the following criteria:

- Inpatient Definite CHF. Criteria for Definite CHF in an inpatient setting include: (1) a discharge diagnosis of ICD9 code 428 and/or underlying cause of death I50, and (2)

radiographic findings consistent with CHF or increased venous pressure >16, or dilated ventricle/left ventricular ejection fraction < 40% by echo/MUGA/MRI scan, or (3) autopsy finding of pulmonary edema / CHF.

- Inpatient Probable CHF. Criteria for Probable CHF in the inpatient setting include: (1) a discharge diagnosis ICD9 code of 428 and/or underlying cause of death 150, and (2) any three findings from the CHF criteria list.

### 8.1.33 Classification of CHF Events (Inpatient)

#### CHF Criteria (Inpatient):

##### **Definite**

Discharge Diagnosis of 428 and/or underlying cause of death I50

AND

Radiographic findings consistent with CHF or increased venous pressure >16 or Dilated ventricle/left ventricular function <40% by echo/MUGA scan

OR

Autopsy finding of pulmonary edema/CHF

##### **Probable**

Discharge Diagnosis of 428 and/or underlying cause of death 150

AND

Any 3 findings from CHF criteria (list below)

Paroxysmal nocturnal dyspnea

Orthopnea

Distended neck veins/jugular venous distention

Dyspnea on exertion

Shortness of breath (dyspnea at rest)

Night Cough

S3

Rales

Hepatojugular reflux

Hepatomegaly

Bilateral lower extremity edema

Tachycardia (120+)

Decrease in vital capacity by 1/3

## 8.2 Outpatient

### 8.2.1. Introduction

### 8.2.2. Identification of CHF Events

Definition: Congestive Heart Failure is defined as a constellation of various symptoms and physical signs that occur in a participant whose cardiac output cannot match metabolic need despite adequate filling pressure as a result of various disease processes.

### 8.2.3 Classification of CHF Events

Any JHS participant that routinely visits a health care provider on an outpatient basis with problems related to CHF will be identified during the usual AFU. The information which includes the location of outpatient clinics and treating provider's name will be transmitted to the trained and certified CHF

medical record abstractors. The abstractor reviews the Cohort Eligibility (CEL) forms and identify participants with (1) a discharge diagnosis of ICD9 code 428 and/or underlying cause of death I50, and (2) radiographic findings consistent with CHF or increased venous pressure >16, or dilated ventricle/left ventricular ejection fraction < 40% by echo/MUGA/MRI scan, or (3) autopsy finding of pulmonary edema / CHF.

**Review and Classification.** Any CHF event that meets the above criteria is reviewed by trained CHF abstractor who completes a congestive heart failure abstraction form. The abstracted data is transmitted to UNC-CSCC and run through a series of data check programs. All CHF hospitalizations are automatically assigned a CHF diagnosis by the computerized CHF algorithm which depends on abstracted data on the CHF and the death form (DTH) if the event is a death. The computerized CHF classifications include (1) Definite CHF, (2) Probable CHF, or (3) No CHF using the following criteria:

- **Outpatient Definite CHF.** Criteria for Definite CHF in an outpatient setting include: (1) outpatient diagnosis of ICD 428 and/or underlying cause of death I50 (out of hospital), and (2) outpatient diagnosis of ICD 428 and Chest X-Ray (CXR) findings consistent with pleural effusion/pulmonary edema/ cephalization of vessels/ cardiomegaly (1 and 2), or (3) outpatient diagnosis of ICD 428 and echo consistent with dilated ventricle/left ventricular ejection fraction < 40% (1 and 3), or (4) outpatient diagnosis of ICD 428 and any 3 findings from CHF criteria within two weeks of outpatient visit (1 and 4)
- **Outpatient Probable CHF.** Criteria for Probable CHF in the outpatient setting include: (1) outpatient diagnosis of ICD 9 code 428 and/or underlying cause of death I50, or (2) ICD 9 code 425.4 or 518.4 with one or two of the CHF symptoms, and (3) at least one but less than three findings from the CHF criteria

For both Inpatient and Outpatient, the CHF Event summary forms (CHF-ESF) and all hospital materials for the CHF event are sent to one member of the CHF-Mortality and Morbidity Classification Committee (CHF-MMCC) for classification. The trained CHF-MMCC reviewer with medical expertise in CHF assigns a final diagnosis of CHF. The one CHF-MMCC reviewer and the computer algorithm determine final classification of CHF events. If there are discrepancies between these two sources, the final event classification is determined by a second reviewer (CHF adjudicator).

### **Classification of CHF Events (Outpatient)**

#### **CHF Criteria (Outpatient):**

##### **Definite:**

- (1) Outpatient diagnosis of ICD 428 and/or underlying cause of death 150 (out of hospital)  
AND  
(2) Outpatient diagnosis of ICD 428 and CXR findings consistent with pleural effusion/pulmonary edema/cephalization of vessels/cardiomegaly (1 and 2)  
OR  
(3) Outpatient diagnosis of ICD 428 and echo consistent with dilated ventricle/left ventricular function < 40% (1 and 3)  
OR  
(4) Outpatient diagnosis of ICD 428 and any 3 findings from CHF criteria within 2 weeks of our patient visit (1 and 4)

Paroxysmal nocturnal dyspnea  
Orthopnea  
Distended neck veins/jugular venous distention  
Dyspnea on exertion  
Shortness of breath (dyspnea at rest)  
Night Cough  
S3  
Rales

Hepatojugular reflux  
 Hepatomegaly  
 Bilateral lower edema  
 Tachycardia (120+)  
 Decrease in vital capacity by 1/3

### **Probable**

Outpatient diagnosis of ICD 428 and/or underlying cause of death 150  
 OR  
 ICD 425.4 or ICD 518.4 with 1 or 2 of the symptoms listed below  
 AND  
 At least 1 but less than 3 findings from CHF criteria (list below):

Paroxysmal nocturnal dyspnea  
 Orthopnea  
 Distended neck veins/jugular venous distention  
 Dyspnea on exertion  
 Shortness of breath (Dyspnea at rest)  
 Night Cough  
 S3  
 Rales  
 Hepatojugular reflux  
 Hepatomegaly  
 Bilateral lower extremity edema  
 Tachycardia (120+)  
 Decrease in vital capacity by /3

Unvalidated (underlying cause of death fatal heart failure-out-of hospital)

## **9.0 PROCEDURES FOR PREPARING MORBIDITY AND MORTALITY CLASSIFICATION COMMITTEE (MMCC)**

### **9.1 CHD Reviews Specific to Cohort morbidity and mortality**

The JHSCC generates the MMCC Event Summary Forms (ESFs) in the Data Management Program (MGP) as well as AFUs. The steps taken at JHS in processing MMCC materials are to:

- A. Separate and Organize ID Listings and Event Summary Forms (ESFs):** Job 20: Each Cohort AFU, usually one page, must be placed first when all the materials are collated with the ESFs of that event. Job 16: Linked Non-Fatal Hospitalizations (NFH-L), In-Hospital Deaths (IHD), and Linked In-Hospital Deaths (IHD-L). Job 17: Non-Linked Non-Fatal Hospitalizations (NFH). Job 18: Out-of Hospital Deaths (OHD). Job 19: Linked Out-of-Hospital Deaths (OHD-L). The number of events in Jobs 16, 17, 18, and 19 are recorded in a table, "Current Status of JHS Cohort morbidity and mortality Reviews", for monitoring purposes.
- B. Collect All Needed ID Medical Records:** Procedures for obtaining materials are the same as for Community Events. There will be no materials at the EC for Job 18.
- C. Collate and Copy Materials for Each Event for Review:** The pages of all events to be reviewed must have the AFU sheet(s) first with the EFSs next; linked events follow, in reverse chronological order. Job 17 must be copied once. Unless events go to special view, Jobs 16, 18, and 19 need to be copied twice. The original set is

placed in the event folder behind the medical record. The medical records, received in duplicate from the EC, are copied once for Job 16, 18, and 19. The AFUs and ESFs are stapled to the event for review and the linked events are stapled with the ESFs and record; OHD events have none, as will others, and are stapled together. Each event is clipped together with a prepared CDX Form on top.

- D. Prepare the Events for Reviewers:** The IDs to be sent to a reviewer are tracked by Batch Number from the MGP, Sequence Number for the Reviewer, and Dates for the steps in the process are recorded for Jobs 16, 17, 18, and 19.
1. **Non-fatal Hospitalizations (NFH):** (Job 17) The Cohort morbidity and mortality CDX Form is prepared for a single reviewer using the Sequence Number X1 and Parts A and B of the Form with the Type of Review in Question 1.b. as "O" and the Code Number of the intended reviewer. (Prior to 1995 two reviewers diagnosed the non-linked NFH events.)
  2. **Linked Non-fatal Hospitalizations (NFH-L) and In-hospital Deaths, Non-linked and Linked (IHD and IHD-L):** (Job 16) The CDX Form is usually prepared for two reviewers using Sequence Numbers X1 and X2 with the Type of Review in Question 1.b. as "O" and the Code Numbers of the intended reviewers. The events that are NFH-L require Parts A and B completed and IHD and IHD-L require Parts A, B, and C completed by both reviewers.
  3. **Special Linked Non-fatal Hospitalizations (NFH-L) and In-hospital Deaths, Non-linked and Linked (IHD and IHD-L):** (Job 16) The Sequence Number is listed on the ESF for the event with X5, as spanning >28 days. The CDX Form is prepared for a special reviewer with the Type of Review in Question 1.b. as "G" and the Code Number of the special reviewer. The events that are NFH-L require Parts A and B completed and IHD and IHD-L require Parts A, B, and C completed.
  4. **Non-linked Out-of-hospital Deaths (OHD):** (Job 18) Two CDX Forms are prepared.
  5. **Linked Out-of-hospital Deaths (OHD-L):** (Job 19) The CDX Form is usually prepared for two reviewers using Sequence Numbers X1 and X2 with the Type of Review in Question 1.b. as "O" and the Code Numbers of the intended reviewers. These Cohort events require Parts A, B, and C to be completed by both reviewers. Rarely is there a special review generated for an event with Sequence X5, spanning >28 days; the CDX Form prepared for the special reviewer has the Type of Review in Question 1.b. as "G".

## 9.2 Adjudication of CHD Reviews

In Cohort morbidity and mortality, adjudication is necessary when the preferred classification (CDX Questions 7B, 14B) or the algorithm classification (Questions 6, 13), if there is no preferred classification, disagrees between two reviewers. For Non-fatal Hospitalizations in Job 17, if the one reviewer disagrees with the JHS algorithm (Question 7.a. is "No"), then adjudication is necessary for Question 7.b. Special reviews (Sequences X4 and X5) do not require adjudication. Adjudication is required only for the most current data if there were data changes initiating a new review.

Copy the completed CDX Forms that were returned by the original reviewers and the ESFs with the medical records that were sent to the original reviewers. The CDX Forms are prepared for the adjudicator using Sequence Number X3, as "Adjudication", with Type of Review marked in Question 1.b. as "A". These events require the same Parts completed as the original review and

have the same IDs and Batch Number as the original reviews. Clip the adjudicator's new CDX Form on top of the packet of each event to adjudicate. Community events for adjudication are tracked by Batch Number from the MGP, Sequence Number for the Reviewer, and Dates for the steps in the process are recorded. Follow the same procedures for shipping the adjudications as those for original reviews.

### 9.3 Monitoring Return of CDX Forms

Reviewers who do not meet expected deadlines are reminded. If forms are found to be incomplete, they are returned to the reviewer prior to data entry. The DES and MGP also check for incompleteness of forms with inconsistent answers; forms with these problems are returned to the original reviewers for resolution.

### 9.4 Monitoring Consistencies of New Reviewers

When new reviewers have been certified and are ready to begin reviewing cases, the number of CHD events is kept low; the type of reviews best suited to them are OHD, then IHD, and later linked events. As original reviewers, they are paired with experienced reviewers. Feedback to the new reviewers on the cases needing adjudication is helpful. A new reviewer, still requiring training, can be given the same set of events to review as two original reviewers with Sequence Numbers 0X or 1X, which are checked by hand, until the accuracy on the CDX Forms is acceptable for events to be entered into the DES.

### 9.5 Filing and Storing Completed CHD Reviews in Event\_ID Labelled Folders

Verified CDX Forms are placed in the front of the Event\_ID folder and filed in numeric order in secured CSCC file cabinets; any linked IDs are filed independently in numeric order at the same time.

Folders with CHD events *over 5 years old*, as determined from the MGP, can be removed from the secured JHS CHD file cabinets to secured off-site storage.

### 9.6 Stroke Reviews Specific to Cohort morbidity and mortality

All eligible Cohort events (those that have charts and neurological signs and symptoms) are reviewed for a stroke classification. The Stroke Data Management Program (MGP) generates the MMCC Event Summary Forms (ESFs) and lists for both original reviews and required adjudications for the classification of stroke.

The procedures taken at CSCC in processing Stroke MMCC reviews is similar, but less complicated than CHD reviews. The steps are to:

- A. Organize ID Listings and Collect ID Medical Records:** Upon notification that the Stroke MGP is ready, print out the 3 listings of Job 06. The stroke records are prepared and shipped by a special abstractor on a regular basis. If an event has not yet been sent to CSCC when the Stroke MGP generates a case for review, then it must be requested. ID-labeled file folders to contain the records sent must be prepared at CSCC; they are stored in file cabinets separately from the CHD records.
- B. Copy Medical Records and Sorted EFSs:** Both the original review and adjudication are sent to one reviewer; one set of materials is copied for each event. The ESFs are stapled to the specific record. The packets are prepared similarly to reviews for CHD events: each SDX Form is clipped to the packet of the EFS sheet(s) stapled to the record of the event.

- C. Prepare the Events for Reviewers:** Each 7-digit Event\_ID is written in the set of boxes on the Stroke SDX Form. The original review is prepared for a single reviewer using the Sequence Number X1, the Batch Number from the MGP, the Type of Review in Question 1.b. as “O”, and the Code Number of the intended reviewer. The SDX Form for the adjudicator is prepared with Sequence Number X3, the Batch Number from the MGP, the Type of Review in Question 1.b. as “A” and the Code Number of the intended reviewer. The IDs sent to a reviewer are tracked by Batch Number from the MGP, Sequence Number for the Reviewer, and Dates for the steps in the process are recorded for the reviews. The packet shipped, usually by Federal Express, contains a memo describing the cases, a copy of the log sheet, and the sets of reviews in numerical order. The memo states the date that the reviews are expected to be returned to CSCC, usually a period of 3 to 4 weeks, and requests that the reviewer notify CSCC if the reviewer will be unable to complete reviews for an extended time in the future.
- D. Adjudicate Stroke Events:** Adjudication is required if the original reviewer disagrees with the computer diagnosis (variable called “COMPDIAG”, listed on the sheet “Listing of ESF for Original Review). When the original reviewer’s SDX Forms are returned and checked for completeness, the diagnosis should be compared with the “COMPDIAG”; if there is a disagreement, then the event can be sent for adjudication prior to the next stroke retrieval. The event for adjudication is sent to the stroke adjudicator with sequence number X3.
- E. Monitor Return of Stroke Reviews:** As reviewers return their SDX Forms, they are checked for completeness and then entered into the data entry system (DES) and stamped “keyed”. Each form is “verified” by a second individual entering the same data. The number of stroke cases under original review and adjudication are recorded in a table, “Current Status of JHS Cohort morbidity and mortality Reviews”.
- F. File and Store Completed Stroke Reviews in Event-ID Labelled Folders:** Verified SDX Forms are placed in the front of the Event\_ID folder and filed in numeric order in designated secure Stroke file cabinets at CSCC.

### 9.7 Summary of the JHS MMCC Processing Procedures\*

COHORT CHD: COMPLETION OF CDX FORM (Job 16-20)						
Type	MGP Job #	Seq #	MI DX <sup>a</sup> (part B)	Death DX <sup>a</sup> (part C)	Reviewer	Items to check for Adjudications <sup>b</sup>
NH <sup>a</sup> , Unlinked, >=1995 <sup>c</sup>	17,20	*1*	Yes	No	Anyone	Q7a
NH <sup>a</sup> , Linked	16,20	*1, *2	Yes	No	Anyone	Q7b vs Q7b if both Q7b not blank Q7b vs Q6 if one Q7b is blank Q6 vs Q6 if both Q7b are blank
IHD <sup>a</sup> , Linked & Unlinked	16,20	*1, *2	Yes	Yes	Anyone	<u>MI:</u> Q7b vs Q7b if both Q7b not blank Q7b vs Q6 if one Q7b is blank Q6 vs Q6 if both Q7b are blank <u>Death:</u> Q14b vs Q14b if both Q14b not blank Q14b vs Q13 if one Q14b is



adjudication).

- Cohort with 2 reviews: compare preferred DX between reviewers. That is, compare Q7b vs Q7b if both Q7b are not blank, Q7b vs Q6 if one Q7b is blank, Q6 vs Q6 if both Q7b are blank, Similarly for Death Dx (Q13 & Q14b)

NOTE: the comparison listed above is under the assumption that the CDX form is complete (no incomplete items), and Q6(determined by Q3-Q5. See Table 2 in the next page) and Q13 (determined by Q8-12 of the CDX form) are answered correctly. If Q6 and/or Q13 are answered incorrectly, data checks will be generated and the review is considered incomplete.

- Reviews with sequence numbers \*3, \*4 or \*5 do not require adjudication.
  - Cases needing adjudication should be processed right after receiving the reviews from reviewers.  
MGP Job 05 (cohort morbidity and mortality) check the cases still needing adjudication.
- c) In ARIC before 1995, Unlinked Non-fatal Hospitalizations in cohort morbidity and mortality were reviewed by 2 reviewers with sequence number \*1 & \*2.
- d) MGP job 04.OUT is to be sent to Folsom for > 28 days linkage review. Feedback will be passed to the Statistician for the next MGP.
- e) MI diagnosis for unlinked Non-fatal Hospitalizations and linked out-of-hospital deaths are automatically classified by computers.
- f) Linked IHD cases: if MI is computer-classified, but not death, will require 2 reviewers (unless it's >28 death event). If both MI & Death require a manual review, a special review with seq # \*4 will be assigned.
- g) MI diagnosis for linked out-of-hospital deaths is mostly automatically classified by computers. However, a portion of events which linked to >=2 hospitalizations require 2 reviews.

### 9.8 Procedures for Hospital Records Sent to the Coordinating Center

For the following type of events, EC should deliver the duplicated material to the CC on a regular basis (without CC's request):

- All hospitalized cohorts that are non-skip-outs
- All who transferred with ICD-9 code 410 or 411 or ICD-10 code I20-24
- All deaths in Cohort

For each of these events, a manila right tab file folder is prepared with the event ID label affixed to the top with the added notation if the patient is a Cohort. Included in the file folder is one of the following, ranked in priority:

- Discharge summary
- Progress note of last physician and cardiac consultation
- Progress note of last physician and history and physical

Each page should have the ID label affixed (over the patient's name) and all caregivers' and patient's names *blinded with a black china marker*. These materials are duplicated and placed in the folder behind the completed "Checklist for Hospital Event Materials." Note that death certificates are no longer sent because the DTH form has been entered into the data entry system.

When a significant number of medical records have been prepared, they are put in numeric order and shipped to CC with JHS SHIPPING FORM and a DUPLICATED MATERIALS FOR MMCC SHIPPING INVENTORY sheet (see Appendix V. Duplicate Materials Shipping Forms) with places to fix event ID labels.

If CC requires hospital records for materials not sent for a particular patient's event, such as cases of hospitalizations to determine possible linkages, these are also prepared and sent in a similar fashion.

## **10.0 QUALITY CONTROL**

Each year, the CC generates a set of Cohort morbidity and mortality QC report. In addition, central training for abstractors and MMCC reviewers are held once every 1-3 years to assure data quality.

### **10.1 Quality Control for Medical Record Abstractions**

In JHS Cohort morbidity and mortality, hospital medical records for cohort participants with discharge ICD-9 code 410 or 411 are re-abstracted; 12 per abstractor per calendar year and event year. Each year, items in the re-abstracted HRA were compared to their original abstraction to compute the percentage of disagreement.

### **10.2 Quality Control for the Out-of-hospital Death Investigation**

For OHD events, information from informants, patient's physicians and coroner/medical examiner need to be abstracted. Up to 3 Informant interviews (IFI) and 2 physician questionnaires (PHQ) may be collected. Each year, the percentage of completeness of the abstractions for OHD is computed.

### **10.3 Quality Control for the MMCC Reviews**

Linked or fatal events require either 1 review by a special reviewer or 2 original reviews to determine their MI and/or fatal CHD classification. For events reviewed by 2 original reviewers, if their MI classification and/or death classification disagreed, that event was sent to an adjudicator for adjudication.

### **10.4 Summary of the Annual Cohort morbidity and mortality QC Report**

Each year, the CC generates a QC report includes the following items:

- HRA QC
  - disagreement rates in repeat abstraction, by year and center;
  - % of missing data or unknown responses for HRA items, by year and center
  - % of missing charts, % of MI/death unclassifiable events, by year and center
- Completeness of event investigation for OHD
- MMCC QC
  - disagreement rates for MI/Death classification between 2 original reviewers, by year
  - % of original reviews disagreed with Adjudicators for MI classification, by reviewers
  - % of original reviews disagreed with Adjudicators for Death classification, by reviewers
  - % of dirty data (inconsistent answers among Q3-Q6) for MI classification, by year & reviewers
  - % of dirty data (inconsistent answers among Q8-Q13) for Death classification, by year & reviewers

## **10.5 Certification Procedures**

### **10.5.1 Certification for Medical Records Abstraction**

Medical record abstractors are re-certified every three years during a central (face to face) training session. Generally, these training sessions are conducted over a period of 2 days. The agenda of the training sessions include detail discussions of changes or updates to the data entry systems, updates to question by question instructions for each data collection form, review of ongoing quality control reports. A key feature of the training is the re-certification process. As a part of that process, each abstractor receives a packet of 4 medical records. Each abstractor completes a full hospital record abstraction (HRA) for each record and sends it in electronic form to the CC. Answers from each abstractor for every item on the HRA form are compared and a printout generated. This is reviewed in detail during the training session, with discussion lead by the senior abstractor supervisor. Discrepancies between reviewers on any items are discussed in detail. Items with significant disagreement are identified and the appropriate sections of the question-by-question

instructions and protocols discussed. In addition, each center prepares and presents four cases for review and discussion by the group. An abstractor must successfully complete these exercises in order to be re-certified. The senior abstractor supervisor in consultation with the Chair of the Events Monitoring Committee makes the decision of re-certification.

### **10.5.2 Certification for Informants Interview**

Staffs responsible for conducting informant interviews are also re-certified every three years at the central training. During the training session, the protocol and question-by-question instructions for completing the informant interview form (IFI) are reviewed in detail. A main focus of the informant interview re-certification is review of the informant narrative. Examples (n=40) of informant narratives from all EC are read out loud during the session and critiqued by the interviewers and the supervisors. Successful completion of these exercises is required to be re-certified as an informant interviewer.

### **10.5.3 Certification for MMCC review**

On an approximate annual basis the MMCC meets either in person or by conference call to conduct its training sessions. Topics for discussion during these training sessions include update on changes in ICD coding rules, innovations in diagnostic testing (e.g. incorporation of cardiac troponins), review of quality control data, update on form changes, group discussion of informant interviews and detailed discussion of changes to case law. A main feature of the training session is the re-certification process. As a part of recertification, a standard set of cases (a variety of types including linked and non-linked nonfatal hospitalizations, in-hospital deaths, out of hospital deaths) from cohort morbidity and mortality are distributed to all members prior to the meeting. Committee members are asked to complete the appropriate CDX form as they normally would do and send them to the coordinating center. The data from the CDX forms are summarized in table form and distributed for discussion during the re-certification process. Each case is reviewed in detail with special discussion among the group on any disagreement in diagnosis. This session is lead by the chair of the MMCC. In addition, special cases selected by the chair of the MMCC are presented and discussed in detail. Successful completion of these exercises, as determined by the chair of the MMCC is required for individuals to be re-certified.

## **11.0 CONFIDENTIALITY**

Several procedures are in place to protect the security of the personal identifying information obtained from medical records. Personal identifiers (name, social security number, date of birth, gender, and race) are abstracted from the medical record for the purpose of linkage to the National Death Index. The social security number is used to identify participants when confirming hospitalizations. The participant is notified of such use upon receipt and signing of the Examination Center Consent Form. This information is used to determine vital status of Cohort participants who are lost to follow-up. For cohort morbidity and mortality cases, personal identifiers are used to determine long-term case-fatality of validated myocardial infarction events by either linkage with death certificate data provided by the state health departments or with the National Death Index. Except for the purposes of this linkage, all personal identifiers are removed from distributed datasets. Raw data files residing at the CC are password protected. Personal identifiers are "blacked out" on any paper copy of medical records sent to the CC and these copies are stored in locked secure rooms. Study personnel involved in medical record abstraction and handling of these data have been trained on the protection of human subjects in research.

## **12.0 REFERENCES**

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## Appendix I. ICD10 Codes for Identifying Cohort Morbidity and Mortality Events

### ICD10 Codes for the Identification of Fatal CHD

(January 1, 1999 and beyond)

<u>Code</u>	<u>Title</u>
E10-14	Diabetes Mellitus
I10	Essential Hypertension
I11	Hypertensive Heart Disease
I20	Unstable Angina, angina pectoris
I21-23	Acute Myocardial Infarction
I24	Other Acute IHD
I25	Chronic IHD (including old MI)
I46	Cardiac Arrest
I47	Paroxysmal Tachycardia
I48	Atrial Fibrillation
I49	Other cardiac arrhythmias
I50	Heart Failure
I51	Ill-defined heart disease
I70	Atherosclerosis
I97(not I97.2)	Post procedural disorder of circulatory system
J81	Pulmonary Edema
J96	Respiratory Failure
R96	Other Sudden Death
R98	Unattended Death
R99	Other ill-defined cause

**I.2 ICD9 Codes for the Identification of Hospitalized Myocardial Infarction**

<u>Code</u>	<u>Title</u>
402	Hypertensive Heart Disease
410	Acute Myocardial Infarction
411	Other Acute and Sub-acute Ischemic Heart Disease
412	Old Myocardial Infarction
413	Angina Pectoris
414	Other Chronic Ischemic Heart Disease
427	Cardiac Dysrhythmias
428	Heart Failure
518.4	Acute Edema of Lung, Unspecified

**Appendix II. Form Letters****Format 1-A Sample Letter to Informant: Known Telephone Number**

DATE

NAME  
ADDRESS

Dear [Name, Next of Kin]:

I am writing to ask for your help on behalf of the National Heart, Lung and Blood Institute's ARIC/Jackson Heart Study. The study is designed to measure the rates of heart disease in the Hinds, Rankin and Madison counties. Your name is listed on the death certificate of [NAME, JHS DECEASED PARTICIPANT] who passed away on [DATE]. In a few days a member of my staff will be calling to explain further about the project and seek your permission to ask a few medical questions. Of course, your participation is entirely voluntary.

The information we need will be used for statistical purposes only, and will remain **strictly** confidential. It will contribute to our efforts to better understand heart disease and prevent its occurrence in the future. Thank you very much in advance for your help in this important study.

Sincerely,

Herman A. Taylor Jr., M.D., MPH, FACC,  
Principal Investigator, Jackson Heart Study

HAT/tdc

**Appendix II. Form Letters**

**Format 2: Sample Letter to Informant: Unknown Telephone Number**

DATE

NAME

ADDRESS

Dear NAME:

I am writing to ask for your help on behalf of the National Heart, Lung and Blood Institute's Jackson Heart Study. This study is designed to measure the rates of heart disease in the Hinds, Rankin and Madison counties. Your name is listed on the death certificate of [MR / MRS NAME JHS DECEASED PARTICIPANT] who passed away on [DATE]. We would like to explain more about the project and to ask a few medical questions, but have been unable to find your telephone number.

Could you take a few minutes to fill out and mail the enclosed form so we may get in touch with you? The information we will be calling about will be used for statistical purposes only and will remain **strictly** confidential. It will contribute to our efforts to better understand heart disease and prevent its occurrence in the future. Of course, your assistance in our research is entirely voluntary.

If you have any questions or would like to give us this information over the telephone, please call us at (601)-368-4623. Thank you very much in advance for your cooperation and help in this important study.

Sincerely,

Herman A. Taylor Jr., M.D., MPH, FACC  
Jackson Heart Study Principal Investigator

HAT/tdc  
Enclosure

**Format 3: Sample letter Next of Kin**

DATE

NAME, NEXT OF KIN  
ADDRESS

Dear NAME, NEXT OF KIN

I am writing in follow-up to the telephone interview regarding **NAME OF DECEASED JHS PARTICIPANT**. Thank you for your time. The information you provided has been extremely valuable to the Jackson Heart Study.

As we discussed, you will find enclosed an information release form for NAME, HEALTH CARE PROVIDER. Please sign it and return it to us in the enclosed stamped envelope. Again, thank you very much for your time.

Sincerely,

Tammy Coker  
Jackson Heart Study, Interviewer, Researcher

Enclosure

**Format 4: Reply Postcard From Informant With Telephone Number**

FORMS SHOULD BE RETURN-ADDRESSED TO JACKSON HEART STUDY AND STAMPED.

Dear (Name of Cohort morbidity and mortality Supervisor):

I will be able to help with the Jackson Heart Study.

I do have a telephone number which is ( ) \_\_\_\_\_. The best times to reach me are \_\_\_\_\_ or \_\_\_\_\_.

An alternative telephone number is: ( ) \_\_\_\_\_. The best times to reach me at this number are \_\_\_\_\_ or \_\_\_\_\_.

I do not have a telephone number, but I agree to be interviewed in person, and will be calling your staff to set up a time and a place for the interview.

Sincerely,

Print Name of Informant

**Format 5: Sample Letter to a Neighbor RE: Location of Informant**

DATE

NAME, NEIGHBOR OF JHS PARTICIPANT

ADDRESS

Dear NAME:

I am writing to ask for your help on behalf of the National Heart, Lung, and Blood Institute's Jackson Heart Study. This important study is designed to measure the rates of heart disease in the Hinds, Rankin and Madison counties. As you may know, [JHS DECEASED PARTICIPANT NAME], passed away on [DATE OF DEATH]. As part of the study, we are systematically attempting to contact a next-of-kin or another person who lived with [MR / MRS NAME OF DECEASED JHS PARTICIPANT], in order to obtain some medical information that would help us to find out whether [he/she] died from a heart attack. Since we have not been able to locate such a person and since you were [MR / MRS NAME OF DECEASED JHS PARTICIPANT] neighbor, we believe that you may be able to help us.

Could you take a few moments to fill out and mail the enclosed form? The information we wish to obtain from a next-of-kin or another person who lived with [MR / MRS NAME OF DECEASED JHS PARTICIPANT] will be used for research purposes only, and will remain strictly confidential. It will contribute to our efforts to better understand heart disease and prevent its occurrence in the future. Of course, your assistance in our research is entirely voluntary. If you have any questions, please feel free to call me collect at (601) 368-4623 or our local Surveillance Supervisor, Michelle Richard, at (601) 815-5065.

Thank you very much in advance for your help in this important study.

Sincerely,

Herman A. Taylor Jr., M.D., MPH, FACC  
Jackson Heart Study Principal Investigator

HAT/tdc

**Format 6: Sample Letter Death Certificate/Medical Examiner**

DATE

NAME, CERTIFIER / MD DEATH CERTIFICATE SIGNATOR WHEN NO MEDICAL EXAMINER  
ADDRESS

**RE: NAME (JHS PARTICIPANT)**  
**Date of Birth: DOB**

Dear [NAME CERTIFIER / MD DEATH CERTIFICATE SIGNATOR WHEN NO MEDICAL  
EXAMINER]:

I am writing on behalf of the Jackson Heart Study, a National Heart Lung and Blood Institute epidemiologic study conducted by the University of Mississippi Medical Center, Jackson State University and Tougaloo College. The study is assessing incidence of myocardial infarctions and coronary death in Hinds, Rankin and Madison counties. We need some information concerning [NAME OF DECEASED JHS PARTICIPANT] whose death certificate you signed on [DATE] this information is needed to supplement the death certificate in assigning a cause of death. Could you or a member of your staff take a few moments to provide the answers to the questions on the enclosed form from your records and return it in the self addressed, stamped envelope?

This information will be used for statistical purposes only, and will remain **strictly** confidential. If you have any questions, please feel free to contact me at (601)-368-4623. Thank you very much in advance for your kind assistance and consideration of this request.

Sincerely,

Herman A. Taylor Jr., M.D., MPH, FACC  
Jackson Heart Study Principle Investigator

HAT/tc

Enclosure

**Format 7: Reply Form on the Location of Informant**

POSTCARD SHOULD BE RETURN-ADDRESSED TO JACKSON HEART STUDY AND STAMPED.

Dear (Name of Cohort morbidity and mortality Supervisor):

The following individual(s) was (were) living with (name of decedent) at the time of his/her death:

Name	Relationship to Deceased	Present Address	Present Telephone Number
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

I do not have any information on persons who were living with (name of the decedent) at the time of his/her death.

Sincerely,

\_\_\_\_\_  
(Print Name of Neighbor)

**Format 8: Informant Release of Information Form: Nursing Home**

I hereby authorize and request \_\_\_\_\_ to furnish to the Jackson Heart Study the medical records on (name of the decedent). These records will be reviewed only for research purposes and none of the information will be released to any individual other than the research team. Any costs for reproduction of records will be covered by the study.

Date: \_\_\_\_\_ Signed: \_\_\_\_\_  
\_\_\_\_\_

(Relationship to the Deceased)

\_\_\_\_\_  
  
\_\_\_\_\_

Witness:

**Format 9: Letter to Physician Signing Death Certificate**

DATE

NAME, DEATH CERTIFIER/ MEDICAL EXAMINER / CORONER  
ADDRESSRE: **Name: [NAME JHS DECEASED PARTICIPANT]****Date of Birth: [DOB]**

Dear NAME DEATH CERTIFIER / MEDICAL EXAMINER / CORONER:

I am writing on behalf of the Jackson Heart Study, a National Heart Lung and Blood Institute epidemiologic study conducted by the University of Mississippi Medical Center, Jackson State University and Tougaloo College. The study is assessing incidence of myocardial infarctions and coronary death in Hinds, Rankin and Madison counties. We need some information concerning [NAME, JHS DECEASED PARTICIPANT] whose death certificate you signed on [DATE] this information is needed to supplement the death certificate in assigning a cause of death. Could you or a member of your staff take a few moments and enclose a copy of the Medical Examiners report from your records and return it in the self addressed stamped envelope.

This information will be used for statistical purposes only, and will remain **strictly** confidential. If you have any questions, please feel free to contact me at (601)-368-4623. Thank you very much in advance for your kind assistance and consideration of this request.

Sincerely,

Herman A. Taylor Jr., M.D., MPH, FACC  
Jackson Heart StudyHAT/tc  
Enclosure

**Format 10: Informant Release of Information: Physician**

Health Care Provider(s): **NAME**

The above named physician(s) have my permission to release medical information to the Jackson Heart Study. This information will be used for statistical purposes only and will remain strictly confidential.

Decedent's Name: **NAME OF JHS PARTICIPANT**

My Name: \_\_\_\_\_

Address: \_\_\_\_\_

Relationship to Decedent: \_\_\_\_\_

Date: \_\_\_\_\_ Signed : \_\_\_\_\_

Witness: \_\_\_\_\_

**Format 11: Informant Release of Information: Out-of-Area Hospital**

TO:

(Name of Hospital)

The above named hospital has my permission to release medical information to the Jackson Heart Study. This information will be used for statistical purposes only, and will remain strictly confidential.

Decedent's Name:

My Name:

Address:

Relationship to Decedent:

Date: \_\_\_\_\_ Signed: \_\_\_\_\_

Relationship to Decedent:

\_\_\_\_\_

Witness:

\_\_\_\_\_

**Appendix II. ARIC/Jackson Heart Study Cohort**

**Format 1-A Sample Letter to Informant: Known Telephone Number**

DATE

NAME  
ADDRESS

Dear [Name, Next of Kin]:

I am writing to ask for your help on behalf of the National Heart, Lung and Blood Institute's ARIC/Jackson Heart Study. The study is designed to measure the rates of heart disease in the Hinds, Rankin and Madison counties. Your name is listed on the death certificate of [NAME, JHS DECEASED PARTICIPANT] who passed away on [DATE]. In a few days a member of my staff will be calling to explain further about the project and seek your permission to ask a few medical questions. Of course, your participation is entirely voluntary.

The information we need will be used for statistical purposes only, and will remain **strictly** confidential. It will contribute to our efforts to better understand heart disease and prevent its occurrence in the future. Thank you very much in advance for your help in this important study.

Sincerely,

Herman A. Taylor Jr., M.D., MPH, FACC,  
Principal Investigator, Jackson Heart Study

Thomas Mosley, Ph.D  
Atherosclerosis Risk in Community Study,  
Principal Investigator

HAT/TM/tc

**Appendix II ARIC/Jackson Heart Study Cohort****Format 2-A: Sample Letter to Informant: Unknown Telephone Number**

DATE

NAME  
ADDRESS

Dear NAME:

I am writing to ask for your help on behalf of the National Heart, Lung and Blood Institute's ARIC/Jackson Heart Study. This study is designed to measure the rates of heart disease in the Hinds, Rankin and Madison counties. Your name is listed on the death certificate of [MR / MRS NAME JHS DECEASED PARTICIPANT] who passed away on [DATE]. We would like to explain more about the project and to ask a few medical questions, but have been unable to find your telephone number.

Could you take a few minutes to fill out and mail the enclosed form so we may get in touch with you? The information we will be calling about will be used for statistical purposes only and will remain **strictly** confidential. It will contribute to our efforts to better understand heart disease and prevent its occurrence in the future. Of course, your assistance in our research is entirely voluntary.

If you have any questions or would like to give us this information over the telephone, please call us at (601)-368-4623. Thank you very much in advance for your cooperation and help in this important study.

Sincerely,

Herman A. Taylor Jr., M.D., MPH, FACC  
Principal Investigator, Jackson Heart StudyThomas Mosley, PhD  
Atherosclerosis Risk in Community,  
Principal InvestigatorHAT/TM/tc  
Enclosure

**Appendix II ARIC/Jackson Heart Study Cohort**

**Format 5-A: Sample Letter to a Neighbor RE: Location of Informant**

DATE

NAME, NEIGHBOR OF JHS PARTICIPANT

ADDRESS

Dear NAME:

I am writing to ask for your help on behalf of the National Heart, Lung, and Blood Institute's ARIC/Jackson Heart Study. This important study is designed to measure the rates of heart disease in the Hinds, Rankin and Madison counties. As you may know, [JHS DECEASED PARTICIPANT NAME], passed away on [DATE OF DEATH]. As part of the study, we are systematically attempting to contact a next-of-kin or another person who lived with [MR / MRS NAME OF DECEASED JHS PARTICIPANT], in order to obtain some medical information that would help us to find out whether [he/she] died from a heart attack. Since we have not been able to locate such a person and since you were [MR / MRS NAME OF DECEASED JHS PARTICIPANT] neighbor, we believe that you may be able to help us.

Could you take a few moments to fill out and mail the enclosed form? The information we wish to obtain from a next-of-kin or another person who lived with [MR / MRS NAME OF DECEASED JHS PARTICIPANT] will be used for research purposes only, and will remain strictly confidential. It will contribute to our efforts to better understand heart disease and prevent its occurrence in the future. Of course, your assistance in our research is entirely voluntary. If you have any questions, please feel free to call me collect at (601) 368-4623 or our local Surveillance Supervisor, Michelle Richard, at (601) 815-5065.

Thank you very much in advance for your help in this important study.

Sincerely,

Herman A. Taylor Jr., M.D., MPH, FACC  
Principal Investigator, Jackson Heart Study

Thomas Mosley, PhD  
Atherosclerosis Risk in Community,  
Principal Investigator

Tom Mosley  
ARIC Principal Investigator

HAT/TM/tc

**Appendix II ARIC/Jackson Heart Study Cohort****Format 6: Sample Letter Death Certificate/Medical Examiner**

DATE

NAME, CERTIFIER / MD DEATH CERTIFICATE SIGNATOR WHEN NO MEDICAL EXAMINER  
ADDRESS**RE: NAME (JHS PARTICIPANT)**  
**Date of Birth: DOB**Dear [NAME CERTIFIER / MD DEATH CERTIFICATE SIGNATOR WHEN NO MEDICAL  
EXAMINER]:

I am writing on behalf of the Jackson Heart Study and Atherosclerosis Risk in Community, a National Heart Lung and Blood Institute epidemiologic study conducted by the University of Mississippi Medical Center, Jackson State University and Tougaloo College. The study is assessing incidence of myocardial infarctions and coronary death in Hinds, Rankin and Madison counties. We need some information concerning [NAME OF DECEASED JHS PARTICIPANT] whose death certificate you signed on [DATE] this information is needed to supplement the death certificate in assigning a cause of death. Could you or a member of your staff take a few moments to provide the answers to the questions on the enclosed form from your records and return it in the self addressed, stamped envelope?

This information will be used for statistical purposes only, and will remain **strictly** confidential. If you have any questions, please feel free to contact me at (601)-368-4623. Thank you very much in advance for your kind assistance and consideration of this request.

Sincerely,

Herman A. Taylor Jr., M.D., MPH, FACC  
Principal Investigator, Jackson Heart StudyThomas Mosley, PhD  
Atherosclerosis Risk in Community,  
Principal Investigator

HAT/TM/tc

Enclosure

**Appendix II ARIC/Jackson Heart Study Cohort**

**Format 9-A: Letter to Physician Signing Death Certificate**

DATE

NAME, DEATH CERTIFIER/ MEDICAL EXAMINER / CORONER  
ADDRESS

RE: **Name: [NAME JHS DECEASED PARTICIPANT]**

**Date of Birth: [DOB]**

Dear NAME DEATH CERTIFIER / MEDICAL EXAMINER / CORONER:

I am writing on behalf of the Jackson Heart Study, and Atherosclerosis Risk in Community, a National Heart Lung and Blood Institute epidemiologic study conducted by the University of Mississippi Medical Center, Jackson State University and Tougaloo College. The study is assessing incidence of myocardial infarctions and coronary death in Hinds, Rankin and Madison counties. We need some information concerning [NAME, JHS DECEASED PARTICIPANT] whose death certificate you signed on [DATE] this information is needed to supplement the death certificate in assigning a cause of death. Could you or a member of your staff take a few moments and enclose a copy of the Medical Examiners report from your records and return it in the self addressed stamped envelope.

This information will be used for statistical purposes only, and will remain **strictly** confidential. If you have any questions, please feel free to contact me at (601)-368-4623. Thank you very much in advance for your kind assistance and consideration of this request.

Sincerely,

Herman A. Taylor Jr., M.D., MPH, FACC  
Principal Investigator, Jackson Heart Study

Thomas Mosley, PhD  
Atherosclerosis Risk in Community,  
Principal Investigator

HAT/TM/tc  
Enclosure

**Appendix II ARIC/Jackson Heart Study Cohort**

**Format 10: Informant Release of Information: Physician**

Health Care Provider(s): **NAME**

The above named physician(s) have my permission to release medical information to the Jackson Heart Study. This information will be used for statistical purposes only and will remain strictly confidential.

Decedent's Name: NAME OF ARIC/JHS PARTICIPANT

My Name: \_\_\_\_\_

Address: \_\_\_\_\_

Relationship to Decedent: \_\_\_\_\_

Date: \_\_\_\_\_ Signed : \_\_\_\_\_

Witness: \_\_\_\_\_

## **Appendix III. Computerized Stroke Classification Algorithm**

### **I. Subarachnoid Hemorrhage (SAH)**

#### JHS Definition of Definite SAH:

Evidence in the patient's clinical record of sudden or rapid onset of neurologic symptoms lasting for more than 24 hours or leading to death, plus must meet the criteria specified under at least one of the four below:

1. Meets criteria (a) and (b) below:
  - a. Angiographic identification of a saccular aneurysm as the source of bleeding (e.g. demonstration of a clot adjacent to aneurysm or reduced caliber of otherwise normal vessels) AND
  - b. Bloody (not traumatic) tap or xanthochromic spinal fluid, OR
2. Demonstration by CT or MRI of a blood clot in Fissure of Sylvius, between the frontal lobes, in basal cisterns or within a ventricle with no associated intraparenchymal hematoma, OR
3. Demonstration at surgery of bleeding saccular aneurysm, OR
4. Demonstration at autopsy of recent bleeding of a saccular aneurysm

#### JHS Definition of Probable SAH:

Evidence in the patient's clinical record of sudden or rapid onset of neurologic symptoms lasting for more than 24 hours or leading to death, plus must meet either criterion (1) or criteria (2) and (3) below:

1.
  - a. Angiographic identification of a saccular aneurysm as the source of bleeding (e.g. demonstration of a clot adjacent to aneurysm or reduced caliber of otherwise normal vessels) AND
  - b. Spinal tap was either not done or was traumatic, or missing, OR
2. One or more of the following symptoms or signs occurred within minutes or a few hours after onset:
  - a. Severe headache at onset, or severe headache when first conscious after hospital admission;
  - b. Depression of state of consciousness;
  - c. Evidence of meningeal irritation;
  - d. Retinal (subhyaloid) hemorrhages; AND
3. Bloody (not traumatic) tap or xanthochromic spinal fluid.

### **II. Brain Hemorrhage (IPH)**

#### JHS Definition of Definite IPH:

Evidence in the patient's clinical record of sudden or rapid onset of neurologic symptoms lasting for more than 24 hours or leading to death, plus must meet the criteria specified under at least one of the three below:

1. Demonstration of definite intracerebral hematoma by CT or MRI, e.g. an area of increased density, such as seen with blood, OR
2. Demonstration at autopsy or surgery of intracerebral hemorrhage, OR
3. Evidence in the patient's clinical record that meet criteria (a), (b), (c), and (d) below:
  - a. One major or two minor neurological signs or symptoms from the following list that lasted at least 24 hours or until the patient died:
    - Major:
      - hemiparesis involving two or more body parts
      - homonymous hemianopia
      - aphasia
    - Minor:
      - diplopia
      - vertigo or gait disturbance
      - dysarthria or dysphagia or dysphonia
      - unilateral numbness involving two or more body parts, AND
  - b. Bloody (not traumatic tap) or xanthochromic spinal fluid, AND
  - c. Cerebral angiography demonstrates an avascular mass effect and no evidence of aneurysm or arteriovenous malformation, AND
  - d. No CT / MRI was performed or the CT / MRI was technically inadequate.

JHS Definition of Probable IPH: Evidence in the patient's clinical record of sudden or rapid onset of neurologic symptoms lasting for more than 24 hours or leading to death, plus must meet all the criteria below:

1. One major or two minor neurological signs or symptoms listed above under definite #3 that lasted at least 24 hours or until the patient died, AND
2. Decreased level of consciousness or coma that lasted at least 24 hours or until the patient died, AND
3. Bloody (not traumatic tap) or xanthochromic spinal fluid, AND
3. No CT / MRI was performed or the CT / MRI was technically inadequate.

### **III. Thrombotic Brain Infarction (TIB)**

JHS Definition of Definite TIB:

Evidence in the patient's clinical record of sudden or rapid onset of neurologic symptoms lasting for more than 24 hours or leading to death, plus must meet the criteria specified under at least one of the two below:

1. Demonstration at autopsy of nonhemorrhagic infarct in brain, OR
2. Evidence in the patient's clinical record that meet criteria (a) and (b) below:
  - a. One major or two minor neurological signs or symptoms from the following list that lasted at least 24 hours or until the patient died:
    - Major:
      - hemiparesis involving two or more body parts
      - homonymous hemianopia
      - aphasia
    - Minor:
      - diplopia
      - vertigo or gait disturbance
      - dysarthria or dysphagia or dysphonia
      - unilateral numbness involving two or more body parts, AND
  - b. CT or MRI shows  infarct  or an area of decreased density which may indicate edema or ischemia, with no evidence of hemorrhage.

JHS Definition of Probable TIB:

Evidence in the patient's clinical record of sudden or rapid onset of neurologic symptoms lasting for more than 24 hours or leading to death, plus must meet all the criteria below:

1. One major or two minor neurological signs or symptoms listed above under definite #2a that lasted at least 24 hours or until the patient died, AND
2. Demonstration of negative or nonspecific findings and no evidence of hemorrhage by CT or MRI performed in the first 48 hours after the onset of symptoms or signs, AND
3. A spinal tap was either not done, or was a traumatic tap, or yielded clear, colorless spinal fluid.

#### **IV. Noncarotid Embolic Brain Infarction (EIB)**

##### **JHS Definition of Definite EIB:**

Evidence in the patient's clinical record of sudden or rapid onset of neurologic symptoms lasting for more than 24 hours or leading to death, plus must meet the criteria specified under at least one of the two below:

1. Demonstration at autopsy of:
  - a. An infarcted area (bland or hemorrhagic) in the brain, AND
  - b. A source of emboli in a vessel of any organ, or an embolus in the brain, OR
2. Evidence in the patient's clinical record that meet criteria (a), (b), and (c) below:
  - a. One major or two minor neurological signs or symptoms from the following list that lasted at least 24 hours or until the patient died:
    - Major:
      - hemiparesis involving two or more body parts
      - homonymous hemianopia
      - aphasia
    - Minor:
      - diplopia
      - vertigo or gait disturbance
      - dysarthria or dysphagia or dysphonia
      - unilateral numbness involving two or more body parts, AND
  - b. Establishment of a likely source for cerebral embolus, e.g.: valvular heart disease (including prosthetic heart valve), atrial fibrillation or flutter, MI, cardiac or arterial operation or procedure, cardiac myxoma, bacterial endocarditis, AND
  - c. CT or MRI shows an area of decreased density which may indicate edema or ischemia, with no evidence of hemorrhage

##### **JHS Definition of Probable EIB:**

Evidence in the patient's clinical record of sudden or rapid onset of neurologic symptoms lasting for more than 24 hours or leading to death, plus must meet all the criteria below:

1. One major or two minor neurological signs or symptoms listed above under definite #2a that lasted at least 24 hours or until the patient died, AND
2. An identifiable source for the cerebral embolus as specified in definite #2b, AND
3. Demonstration of negative or nonspecific findings and no evidence of hemorrhage by CT or MRI performed in the first 48 hours after the onset of symptoms or signs, AND
4. A spinal tap was either not done, or was a traumatic tap, or yielded clear, colorless spinal fluid.

## **V. Possible Stroke of Undetermined Type**

### JHS Definition:

Evidence in the patient's clinical record of sudden or rapid onset of neurologic symptoms lasting for more than 24 hours or leading to death, plus one major or two minor neurological signs listed below:

#### Major:

- hemiparesis involving two or more body parts
- homonymous hemianopia
- aphasia

#### Minor:

- diplopia
- vertigo or gait disturbance
- dysarthria or dysphagia or dysphonia
- unilateral numbness involving two or more body parts
- severe headache at onset or severe headache when first conscious after hospital admit
- depression of state of consciousness
- evidence of meningeal irritation
- retinal (subhyaloid) hemorrhages
- palsy of the iii cranial nerve, AND

Clinical history, signs, symptoms, and findings from diagnostic tests and / or autopsy are not sufficient to meet the criteria for classifying the case as a "definite" or "probable" case of one of the four specific diagnostic categories of stroke.

**Appendix IV. ECG Shipping Form**

**JHS  
ECG Shipping Form**

To: Sean Thomas  
ECG Coding Center  
University of Minnesota  
Division of Epidemiology  
Suite 300  
1300 South Second St  
Minneapolis, MN 55454-1015

From: JHS Examination Center \_\_\_\_\_ Date: \_\_\_\_\_ Time: \_\_\_\_\_

JHS Batch Number A R \_\_\_\_\_

Reporting Period:

Starting Date:

Ending Date:

Total Number of Specimens Enclosed:

Number of Contents Pages Attached:

Other remarks concerning shipment contents:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Initials \_\_\_\_\_

\*\*\*\*\*

Arrive at Laboratory

Date: \_\_\_\_\_ Time: \_\_\_\_\_

Contents on condition of total shipment on arrival

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Initials \_\_\_\_\_

**Appendix V. Duplicate Materials Shipping Forms**

**JHS SHIPPING FORM  
DUPLICATED MATERIALS FOR MMCC REVIEWERS**

TO: Central Receiving  
Climmon Walker

FROM:

DATE:

BATCH NUMBER:

REMARKS: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**INITIALS:**

**JHS COHORT MORBIDITY AND MORTALITY SHIPPING INVENTORY  
DUPLICATED MATERIALS FOR MMCC REVIEWERS**

**CENTER** \_\_\_\_ **BATCH** \_\_\_\_ **DATE** \_\_\_\_\_ **TYPE** \_\_\_\_\_

Event ID #	Event ID #
1.	16.
2.	17.
3.	18.
4.	19.
5.	20.
6.	21.
7.	22.
8.	23.
9.	24.
10.	25.
11.	26.
12.	27.
13.	28.
14.	29.
15.	30.

**REMARKS:** \_\_\_\_\_