

Jackson Heart Study Protocol

Manual 3

Blood Pressure

Visit 3

Version 3.0

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FORWARD

This manual is one of a series of protocols and manuals of operation for the Jackson Heart Study (JHS). The complexity of the JHS requires that a sizeable number of procedures be described, thus this rather extensive list of materials has been organized into the set of manuals listed below. Manual 1 provides the background, organization, and general objectives of the JHS Study. Manuals 2, 3, and 4 describe the operation of the Cohort Procedures, Blood Pressure and Central Laboratory and Specimen Repository Components of the study. Manuals 5 and 6 comprise Electrocardiography and Magnetic Resonance Image studies, respectively. Manual 7 comprises of Morbidity and Mortality Classifications. Manual 8 articulates the quality assurance and control activities of JHS Examination 3 components. Quality control includes activities that are designed to assure quality of data, which take place prior to the collection of data. Quality control relates to efforts during this study to monitor the quality of data. Detailed Manuals of operation for specific procedures, including those for Blood Pressure and Quality Control, make up Manual 4 and 5. The Data Management System is described in Manual 9.

JHS Study Protocols and Manuals of Operation

MANUAL	TITLE
1	General Description and Study Management
2	Cohort Component Procedures
3	Blood Pressure
4	The Central Laboratory and Specimen Repository
5	Electrocardiography
6	Magnetic Resonance Imaging
7	Morbidity and Mortality
8	Quality Control
9	Data Management

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1.0 SITTING BLOOD PRESSURE PROTOCOL

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 Exams 1 and 2 was measured in a resting state, using 2 measurements with a random zero sphygmomanometer. In Exam 2 a blood pressure comparability study comparing BP measurements using the OMRON and the random zero mercury sphygmomanometer was conducted .

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

1.4 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 Exam 3 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 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.*

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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 Participant¹	Explanation to Participant
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 ² or DBP < 80	Recheck in 2 years (no JHS referral)	Your blood pressure is normal

¹ 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). ² Unusually low readings should be evaluated for clinical significance

1.7 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.

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

1.8 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

1.9 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.

1.10 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.

1.11 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

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.

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 4th 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 1. Determination of Cuff Size Based on Arm Circumference

Cuff Size	Arm Circumference	Bladder Size
Small Adult	17-22	Small
Adult	22-32	Medium
Large Adult	32-42	Large
Thigh	42-50	Extra Large

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.

1.12 Procedure

2.5.1 Wrapping the Blood Pressure Cuff around the Arm

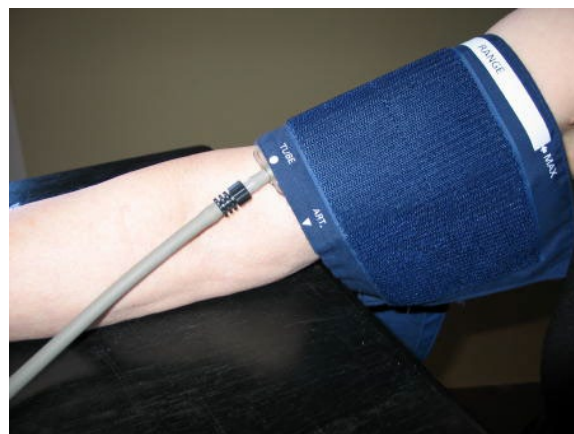
The technician should:

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.



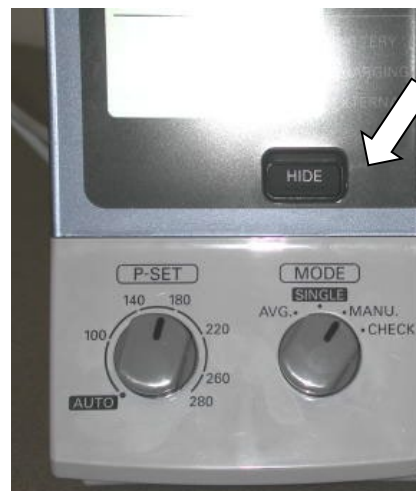
1.12.2 General Guide to Blood Pressure Readings

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.

2.5.4 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 1st (sounds) and 5th (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

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.

1.13 Quality Assurance

1.13.1 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 ± 2 mm Hg of that observed by a trainer)
- Discuss problems and questions with QC officer

1.13.2 Certification Requirements

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

2.0 ANKLE/BRACHIAL SYSTOLIC BLOOD PRESSURE PROTOCOL

2.1 Purpose

The ratio of the ankle blood pressure to the arm blood pressure provides a measure of lower extremity arterial disease (circulation problems). The ankle-arm index (AAI) is reduced to less than 1.0 when there is obstruction to blood flow in the legs. The AAI is a non-invasive measure of atherosclerosis. The AAI is associated with atherosclerotic disease in other vascular beds and predicts cardiovascular mortality.

2.2 Equipment

1. 8 megahertz Doppler pen probe with built-in speakers
2. 9 volt alkaline batteries
3. Doppler conducting jelly
4. Standard mercury column sphygmomanometer: Wall-mounted Baumanometer
5. Calibrated V-Lok BP cuffs in four sizes:
 - 2 large adult cuff
 - 2 small adult cuffs
 - 4 regular adult cuffs
 - 3 thigh cuffs
6. Tissues to remove conducting jelly
7. Black eyeliner pencil

2.3 Exclusions

5. Persons with venous stasis ulceration or other pathology that precludes placing a BP cuff around the ankle (e.g. open wounds).
6. 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.
7. Persons with bilateral amputations of legs.
8. Subjects who fit any of the above categories are recorded as missing data.
9. 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.

2.4 Set-Up Procedure

1. Ask participant to remove shoes and stockings so that the ankles are bare to mid-calf.
2. Participant is positioned on examination in a flat to semi flat position with trunk no more than 45 degrees from surface.
3. Keep participant supine for at least five minutes before measuring BP.
4. Place three BP cuffs on the participant (be sure to check for appropriate cuff size)
 - a) Right arm
 - b) Right ankle
 - c) Left ankle

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 and Ankle Circumference

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

5. Apply ankle cuffs with midpoint of bladder over posterior tibial artery, with lower end of bladder approximately 3 cm above medial malleolus (prominence on medial side of ankle). See Figure 1.

2.5 Procedure

2.5.1 General Guide to Blood Pressure Readings

8. Following any previous inflation, wait at least 30 seconds after cuff has completely deflated.
9. 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.
10. 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.
11. By opening the thumb valve slightly, and maintaining a constant rate of deflation at approximately 2 mmHg per second, allow the cuff to deflate.
12. 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.
13. Deflate the cuff fully by opening the thumb valve.
14. Neatly enter systolic readings in the spaces provided on the form.

2.5.2 Right Arm Systolic Blood Pressure Measurement

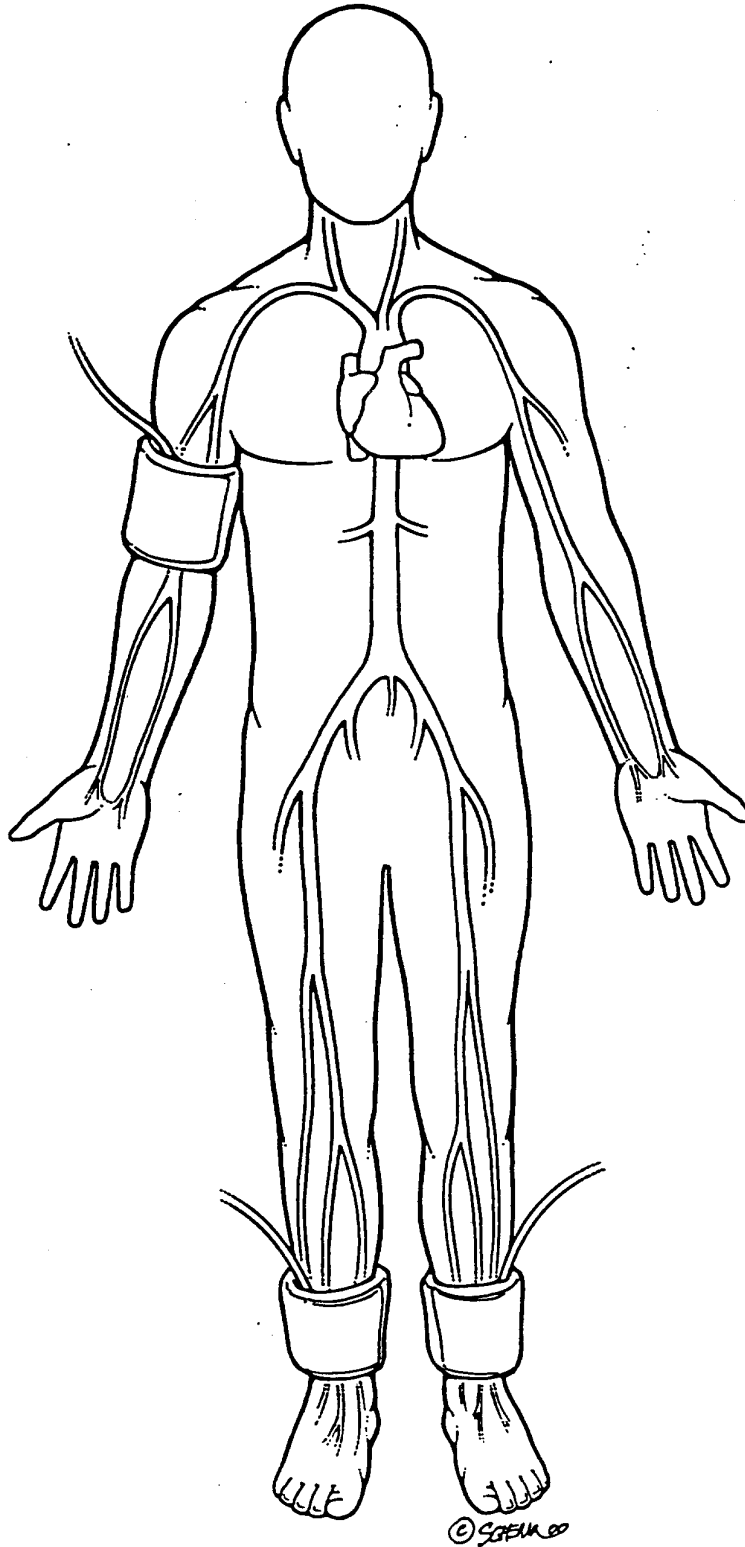
1. Attach right arm cuff tubing to manometer.
2. Apply ultrasound jelly over brachial artery. The brachial artery is located just medial to the center of the cubital fossa.
3. Locate brachial artery using Doppler pen probe.
4. Hold the Doppler Probe absolutely still. It can easily slip off the artery.
5. Measure the systolic blood pressure:
 - a. Inflate cuff quickly to maximal inflation level (30 mmHg above systolic pressure).
 - b. Deflate at 2 mmHg/second, to appearance of systolic pressure.
 - c. Follow down for 10 mmHg. Two subsequent beats should be heard for any valid systolic blood pressure reading.
 - d. Remove Doppler pen probe.
 - e. Deflate cuff quickly and completely.
 - f. Disconnect the right arm cuff from the manometer and connect to the right ankle cuff.
6. Neatly record systolic blood pressure.
7. Disconnect the right arm cuff from manometer.

2.5.3 Right and Left Ankle Systolic Blood Pressure Measurement

1. Connect right ankle cuff to the manometer.
2. Apply ultrasound jelly over posterior tibial artery. This artery is located on the calf and is most easily located at the medial malleolus of the ankle
3. Locate posterior tibial artery using Doppler pen probe.
4. Hold the Doppler probe absolutely still. It can easily slip off the artery.
5. Measure the systolic blood pressure:
 - a. Inflate cuff quickly to maximal inflation level (30 mmHg above systolic pressure).
 - b. Deflate at 2 mmHg/second to appearance of systolic pressure.
 - c. Follow down for 10 mmHg. Two subsequent beats should be heard for any valid systolic blood pressure reading.
 - d. Remove Doppler pen probe.
 - e. Deflate cuff quickly and completely.
6. Neatly record ankle systolic blood pressure.
7. Disconnect right ankle cuff from manometer. Connect left ankle cuff to manometer and repeat procedure.

NOTE: If the posterior tibial pulse cannot be found with palpation or Doppler pen probe, use the dorsalis pedis artery for the measurement. Have another examiner verify the absent posterior tibial pulse.

Figure 1. Right and Left Ankle Cuff Placement



2.5.4 Repeating the Ankle-Arm

Repeat the sequence in reverse order

- a. left ankle
- b. right ankle
- c. right arm

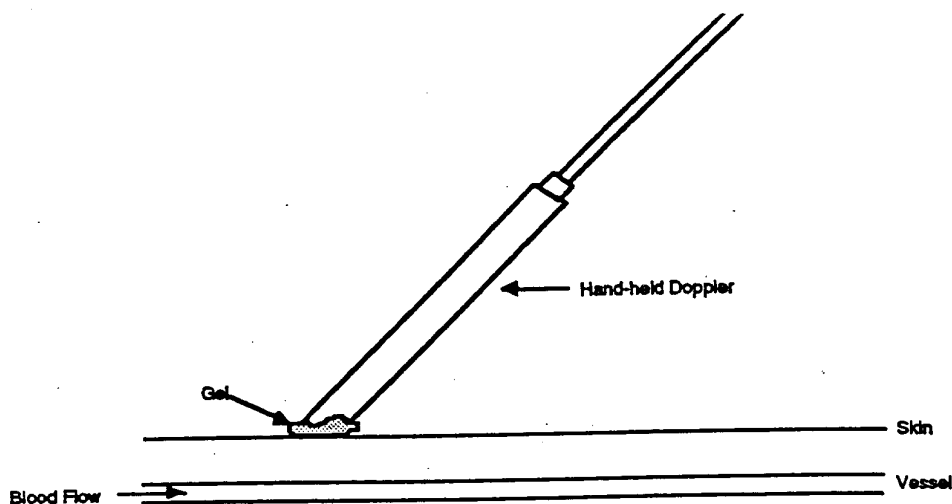
2.6 Tips for Ankle-Arm Measurements

2.6.1 Using the Doppler

Push button in to turn on and gradually turn the volume up. Now place the probe over the artery (brachial or posterior tibial).

The frequency used is 8 Megahertz (vibrations of 8 million times per second). In order to hear the signal above background noise, the instrument must be pushed in toward the artery. Angling the beam upstream improves the signal. For deeper vessels, the unit will have to be tilted back toward perpendicular, but NOTE: the instrument works poorly or not at all if held fully perpendicular to the flow. It must always be angled into and IN LINE with the flow. Please see figure below.

Figure 2. Doppler Probe Position



In some places along the posterior tibial artery, there is anatomical hiding of the vessel by muscle or tendons. Move up or down the vessel a little to find the best signal above background noise.

The purpose of the Doppler is to determine that blood is or is not flowing under the cuff. For correct interpretation, the probe **MUST** be centered directly over the artery and must not be moved while inflating the cuff.

Please note that the Doppler unit turns itself off after 5 minutes automatically. This may occur in the middle of a measurement.

- Mark the location of maximal pulse or Doppler signal on the brachial artery and both posterior and tibial arteries with eyeliner pencil to improve the speed and accuracy of localizing them the second time and to help maintain position.

- Hold the Doppler pen absolutely still while inflating and deflating the cuff; moving a few millimeters will lose the pulse.
- Always use enough jelly to ensure good contact.

2.6.2 Maintenance of Doppler

- KEY POINT: Use only ultrasound gel
- The probe: The probe consists of two crystals; one for transmitting the ultrasound waves and the other for receiving the reflected waves. If either crystal is damaged, the probe will not work properly or will not work at all. The crystals are covered by epoxy resin. This resin is attacked by any gel or liquid containing the chloride ion. Therefore, NEVER use ECG paste or cream as the contact medium between the skin and the crystals. Use AQUASONIC or any gel made for ultrasonic physical therapy equipment. In an emergency use any surgical jelly or lubricant, even Vaseline or mineral oil. Remove the gel after use with a soft tissue. If the probe has dried gel on it, wash it off under running water. Do NOT scrape off the gel because this may damage the epoxy coating. Do NOT autoclave the probe. Gas sterilization is OK.
- KEY POINT: To preserve the battery, turn off the unit immediately after measurements.
- The battery: As the battery runs down, the signal will get weaker to the point where the instrument just doesn't work. Most batteries run down because the instrument has been left turned on. It takes less than a minute to make a blood pressure measurement. Turn the unit off immediately after removing it from the skin. Use an alkaline-type replacement 9-volt transistor radio battery.
- Abnormal Doppler Noise: On occasion there are unusual noises from the Doppler that do not indicate a problem with the Doppler. The normal sound will become obvious with experience in performing this test. Following are some common complaints and their causes.
- Popping noises when the probe is first placed on the skin. Scratchy sound at first. Cause: bubbles in the gel that are moving and/or popping. Also hair movement can cause noise. Remedy: Use a new glob of gel that looks clear, push down enough so hair is immobilized, and just wait a few seconds for things to settle down. If the noise isn't there when the probe is clean (no gel) and suspended in the air, the Doppler and/or probe are probably not at fault.
- Bad static when the dry probe is moved in the air. Cause: a loose connector where the probe connects to the instrument, a broken shield wire in the cable either at the connector or as it comes out of the probe. This can be diagnosed by wiggling the wire or connectors gently. There is NORMALLY some static generated when the cable is flexed, but it isn't severe. Remedy: QC Officer will arrange to replace probe or get connectors fixed.
- High-pitched tone. Cause: radio interference from a mobile service, police station nearby, even another Doppler working nearby. Usually occurs near large open windows, rarely in the center of the building. Remedy: Move to another room.
- Howling noise when the probe with gel on it is held or laid on a table. Cause: acoustic feedback through the probe acting as a microphone. If it doesn't occur without gel on the probe, everything is OK.

2.6.3 Guidelines for Blood Pressure

a. Determining the Maximal Inflation Level (MIL)

Determine the pressure to which to inflate the cuff for the measurement of the systolic blood pressure. This assures that the cuff pressure at the start of the reading exceeds the systolic blood pressure and allows you to hear the first Korotkoff sound. The maximal inflation level (MIL) should be measured specifically for the ankle-arm index measurement, using the Doppler, independently from its measurement for the regular blood pressure measurement. The procedures for determining MIL are as follows:

- Attach the cuff tubing on the arm to the conventional mercury sphygmomanometer.
 - Locate the brachial pulse with the Doppler.
 - Inflate the cuff until the brachial pulse is no longer heard.
 - Deflate the cuff quickly and completely.
 - Inflate the cuff to 30 mmHg above the Doppler systolic pressure for all subsequent readings.
 - Repeat the MIL if the first attempt was unsatisfactory or you have had to readjust the cuff after measuring the MIL. Wait 30 seconds before making a second attempt if the first is unsatisfactory.
 - If the brachial pulse is still heard at a level of 270 mmHg or higher (which means that the MIL is 30 mmHg or higher) repeat the MIL. If the MIL is still 300 mmHg, terminate the blood pressure measurements and write in “300/MIL” on the form. On the Report of Findings, indicate the blood pressure at the level heard. Refer the participant to see their doctor based on the blood pressure taken with a stethoscope. The Doppler will always be higher.
- b. The systolic value is the pressure level at which you hear the first of two or more swishing sounds in the appropriate rhythm. (Note: A single sound heard in isolation [i.e., not in rhythmic sequence] before the first of the rhythmic sounds [systolic] does not alter the interpretation of blood pressure).
- c. Record all readings to the nearest even digit, rounding up (i.e., read any value that appears to fall exactly between the markings on the mercury column to the next higher even marking).
- d. Make readings at the top of the meniscus, or rounded surface of the mercury columns.
- e. When the pressure is released too quickly from a high level, a vacuum is formed above the mercury and the meniscus is distorted. Allow a few moments for it to reappear before reading the manometer or doing a repeat measurement.

2.7 Quality Assurance

2.7.1 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 ± 2 mm Hg of that observed by a trainer)
- Discuss problems and questions with QC officer

2.7.2 Certification Requirements

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

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 ± 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
ALL:		
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	()	()
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)	()	()

	Yes	No
Informs participant of average readings	()	()
OMRON		
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:

Appendix 5 JHS Monthly Log for Sitting Blood Pressure Station

This needs revisions to reflect Omron maintenances

Month _____ Year _____

Weekly Check Procedures:

		Week				
		1	2	3	4	5
1.	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:

Monthly Check Procedures:

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

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

this section needs to be revised to reflect BP observation for OMRON only. There are components that reference random zero techniques.

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:

<i>Omron Technician</i>	
1	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).
2	
3	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 MANUAL .
4	Place the double Y-stethoscope earpieces into ears, holding the bell over participant's artery.
5	Press START on the <i>Omron</i> , cuffs will inflate.
6	Watch the <i>Omron</i> .
7	Listen for the onset of 1 st (sounds) and 5 th (disappearance) Korotkoff phase sounds.
8	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 st reading).
9	

Appendix 9

OmRON®

INSTRUCTION MANUAL

IntelliSense™ Blood Pressure Monitor Model HEM907XL

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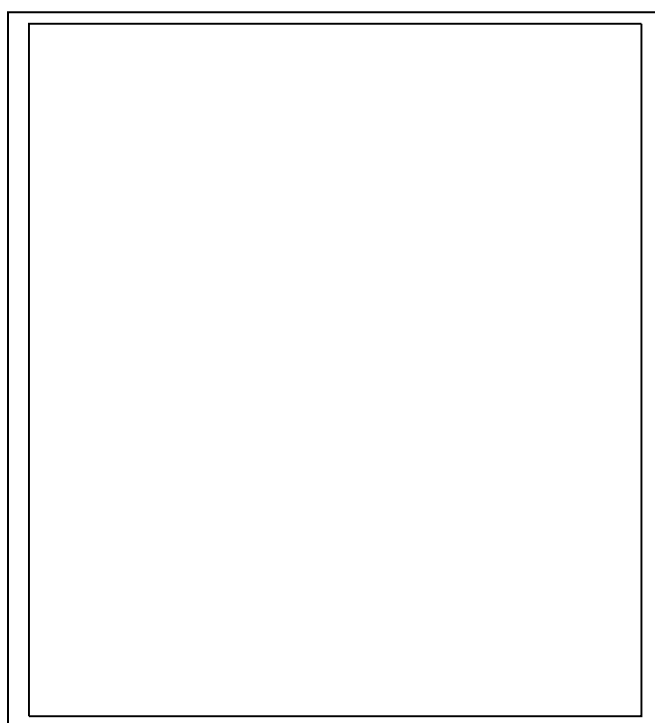
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EXEMPTIONS



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 damage refers to a wide range of damage involving your house, household goods, domestic animals, and pets.


Examples of signs	
	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".

Warning


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

⚠Caution	
<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

⚠Caution	
<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>	
General advice	
<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"> • Do not inflate the cuff without being wrapped over the arm. • Do not use a damaged cuff • Be sure that patients do not touch the Buttons of this unit. <p>After using the unit</p> <ul style="list-style-type: none"> • Do not disinfect this unit by autoclave or gas sterilization (EtO, glutaraldehyde, or high concentration ozone). <p>Do not install or store this unit in the following places.</p> <ul style="list-style-type: none"> • Under the direct sunlight, • Dusty or salty environment • Places having slope, vibration, and/or shock • Storage of chemicals or where combustible gas may be generated, • Under high temperature and high humidity. 	

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 (Err9) 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.

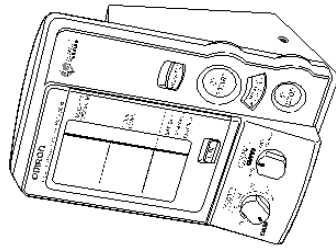


The IntelliSense™ Monitor inflates the cuff to the ideal level with each use. No adjustments are required by the user to select an inflation level. This is especially convenient for hypertensive users and for people with certain arrhythmia or heart disorders, because their blood pressure is likely to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

COMPONENTS OF THE PRODUCT

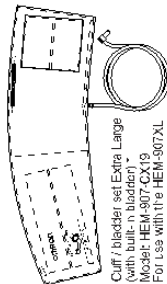
Main unit

IntelliSense™ Blood Pressure Monitor, Model HEM-907XL

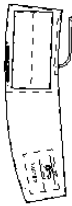


Accessories

(Included and also available separately)



Cuff / bladder set Extra Large with built-in bladder*
Model: HEM-907-CX19
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)

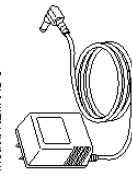


Cuff / bladder set Medium (with built-in bladder)*
Model: HEM-907-CR19
Applicable arm circumference: 9" to 13" (22 to 32 cm)

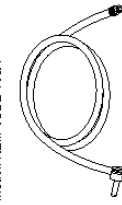


Cuff / bladder set Small (with built-in bladder)*
Model: HEM-907-CS19
Applicable arm circumference: 7" to 9" (17 to 22 cm)

AC adapter
Model: HEM-AC-J

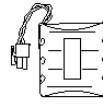


Air tube 1.0 m (33 1/3")*
Model: HEM-TUBE-100X



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

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



Instruction Manual

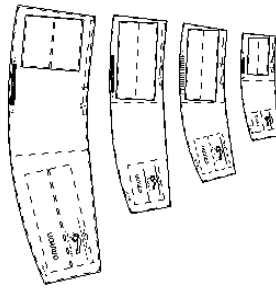


Items identified with an asterisk (*) are consumables and not covered by the guarantee.

COMPONENTS OF THE PRODUCT

Options (no. included)

Cuffs without bladder*



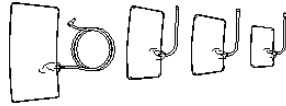
Extra Large Cuff
For use with the HEM-907XL only.
Model: HEM-907-CUFFX

Large Cuff
Model: HEM-907-CUFFL

Medium Cuff
Model: HEM-907-CUFFM

Small Cuff
Model: HEM-907-CUFFS

Bladders*

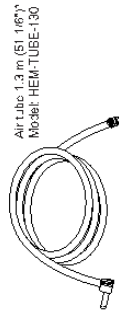


Extra Large Bladder
For use with the HEM-907XL only.
Model: HEM-907-BLDRX

Large Bladder
Model: HEM-907-BLDRL

Medium Bladder
Model: HEM-907-B-DRM

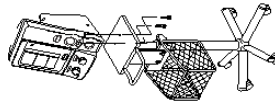
Small Bladder
Model: HEM-907-BLD3S



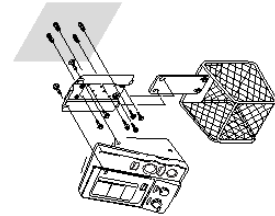
Air tube 1.3 m (55.1")
Model: HEM-TUBE-130

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

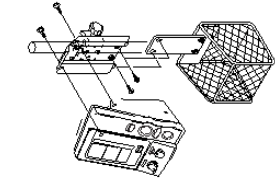
Exclusive Stand
Model: HEM-907-STAND



Wall-hanging kit
Model: HEM-907-WKIT



Pole-mounting kit
Model: HEM-907-PKIT

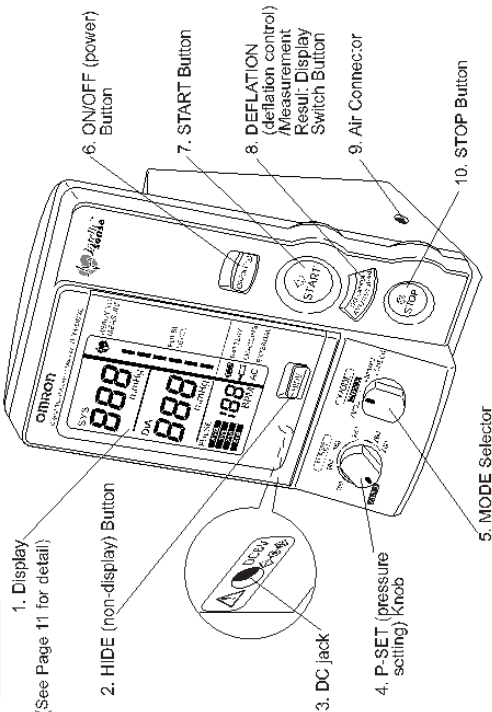


Items identified with an asterisk (*) are consumables and not covered by the guarantee. Accessories and options are subject to change without prior notice.

FEATURES AND FUNCTIONS

Names of the Parts

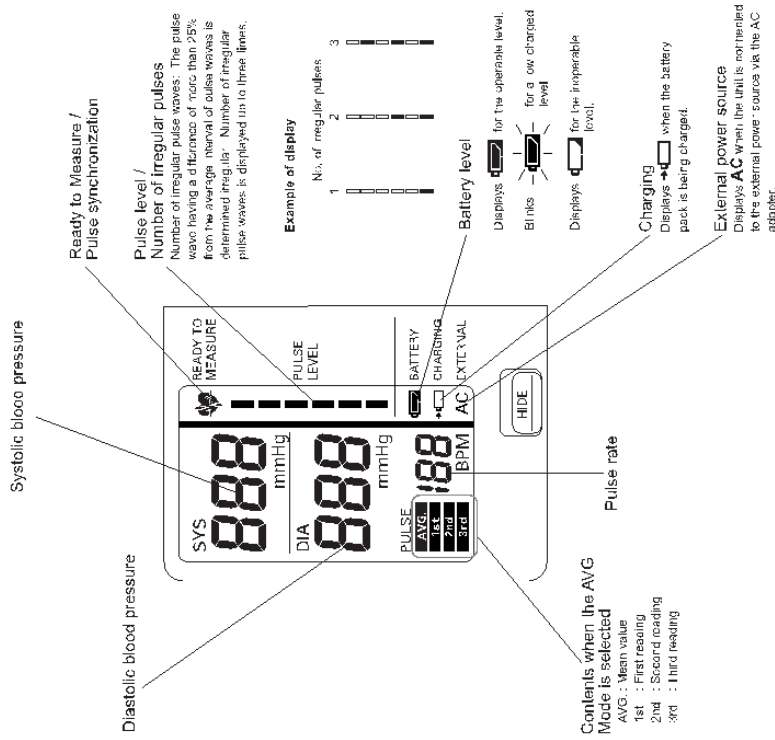
Main unit



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



- Systolic blood pressure**
- Diastolic blood pressure**
- Ready to Measure / Pulse synchronization**
- Pulse level / Number of irregular pulses**
Number of irregular pulse waves. The pulse wave having a difference of more than 25% from the average interval of pulse waves is determined irregular. Number of irregular pulse waves is displayed in to these lines.
- Example of display**
- | No. of irregular pulse | 1 | 2 | 3 |
|------------------------|---|---|---|
| 1 | | | |
| 2 | | | |
| 3 | | | |
- Battery level**
Displays for the operable level.
Blinks for a low charged level.
Displays for the inoperable level.
- Charging**
Displays when the battery pack is being charged.
- External power source**
Displays **AC** when the unit is not inserted to the external power source via the AC adapter.
- Contents when the AVG Mode is selected**
- | | |
|-------|----------------|
| AVG : | Mean value |
| 1st : | First reading |
| 2nd : | Second reading |
| 3rd : | Third reading |
- Pulse rate**

FEATURES AND FUNCTIONS

Functions setting

(1) Inflation level setting P-SET

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).

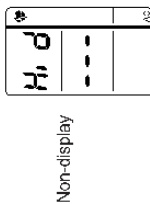
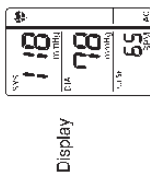
Manual level setting: Inflation level can be set manually between 100 and 280 mmHg. Set the level to 30 to 40 mmHg higher than the expected systolic pressure.

- To set the P-SET to "AUTO", turn the P-SET knob counterclockwise as far as it goes until you can hear a click.
- To set the P-SET to "MANU", turn the P-SET knob clockwise as far as it goes until you can hear a click.
- 20 mmHg. Use the P-SET knob to set the inflation level.
- If the cuff has not been inflated to the necessary level, it may be re-inflated automatically.

(2) Non-display function HIDE

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.

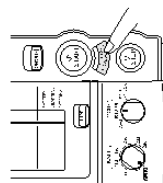
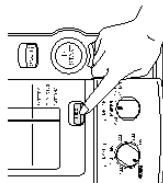
By pushing the HIDE Button, display or non-display of status is switched alternately.



(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 DEFLATION 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	●	●	●	—
Manu display func. set	●	●	●	—
Manu deflation control	—	—	—	●

(4) AVG Function setting

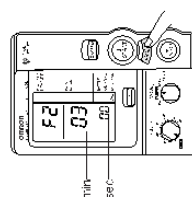
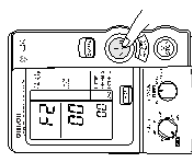
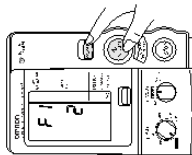
You can set the number of measurements, the waiting time until the 1st measurement, and the measurement interval for the AVG Mode.

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	3 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 an arterial organ. Air embolisms may result.

General advice

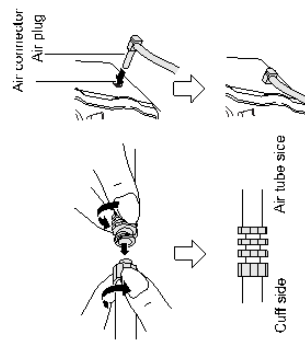
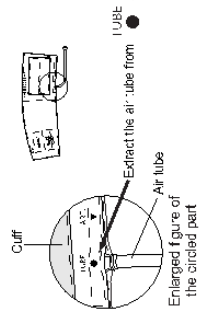
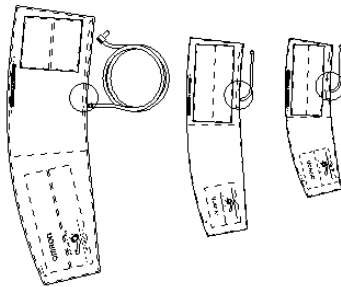
- Do not inflate the cuff without being wrapped over the arm.
- Do not use a damaged cuff.

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.

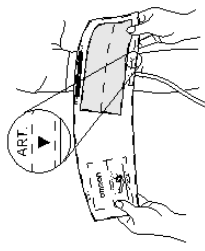
- To use the cuff in small, medium or large size
 - Connect the air tube to the main unit by securing the air plug to the base of the air connector.
 - Securely connect the air tube and the cuff/bladder set by making the luer connection as shown in the Figure on the right.

- 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 plug of the cuff to the air connector securely when connecting to the main unit.

HOW TO APPLY THE CUFF

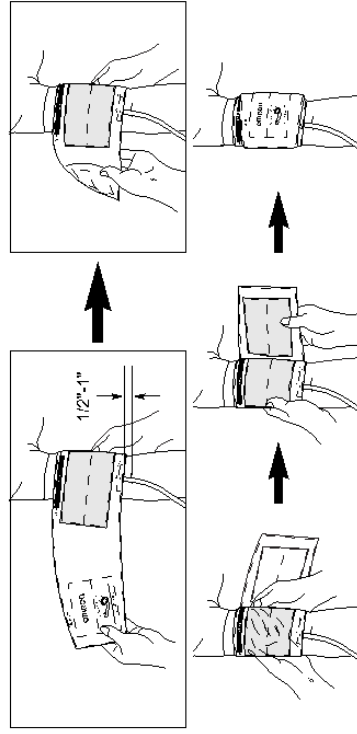
3. Place the right or left hand of the patient with the palm of hand facing upward.

4. Align the Artery Position Mark ^{ART.} 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

Warning	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 touch the AC adapter with wet hands.

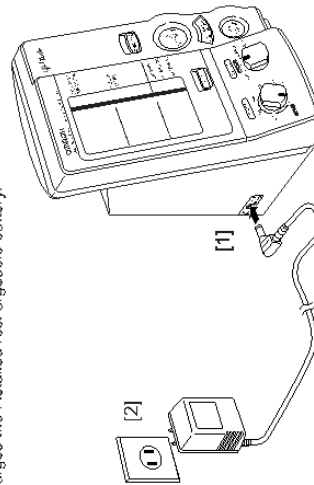
Caution	Be sure to use the AC adapter from the power supply of 110 VAC.
	Do not install or store this unit where it may come in contact with water or liquid medication. This is a Class II device with double insulation. Earth pin is not for protective purposes.

General advice

- 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.

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.

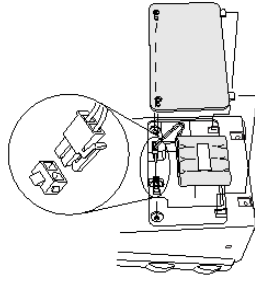


HOW TO USE THE POWER SOURCE

Installation and Replacement of Battery Pack


Warning	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.
	Do not use the battery pack for devices other than for this unit. Do not disassemble the battery pack.

- Remove both screws on the upper portion of the battery cover of this unit, and remove the cover.
- Disconnect the old battery pack from the connector and replace with a new one.
- Install the battery cover and fasten it with both screws. Be careful not to pinch the lead wire.
- 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.

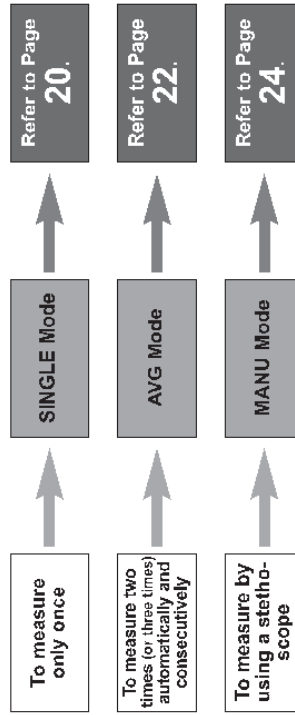
Automatic Power Off

- 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

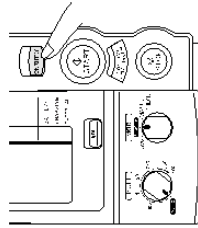
	
Warning	Caution
If cuff inflation does not stop, remove the cuff or pull out the air tubes from the main unit.	Confirm readings with the stethoscope when an irregular pulse wave is displayed or when the measured values are questionable or erratic.
General advice	Do not use a cellular phone near this unit.
• Patients should not touch the unit.	Do not use this unit in a vehicle.

List of Measurement Modes

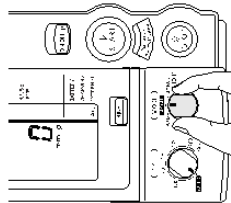


HOW TO MEASURE BLOOD PRESSURE (IN SINGLE MODE)

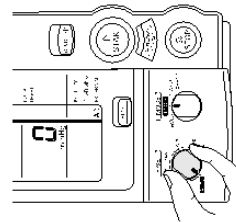
1. Push the ON/OFF (power) Button to turn on the power.



2. Set the MODE Selector to "SINGLE".



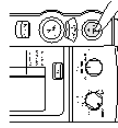
3. Set the P-SET (inflation level) Knob to "AUTO" or to the target pressure value.



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

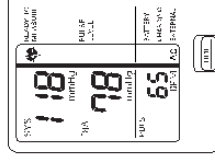
HOW TO MEASURE BLOOD PRESSURE (IN SINGLE MODE)

5. Push the START Button to start the measurement.



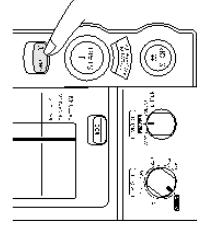
- Do not push the START Button without wrapping the cuff.
- If you want to stop measurement, push the STOP Button. The cuff will rapidly deflate.

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)

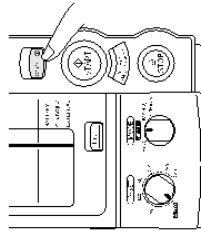
7. Push the ON/OFF (power) Button to turn off the power.



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)

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

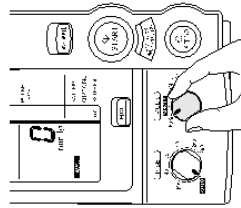


2. Set the MODE Selector to "AVG".

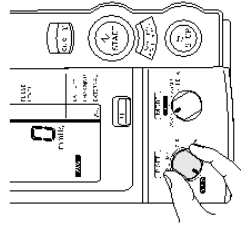
The factory-set values are set as follows:

- 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.)

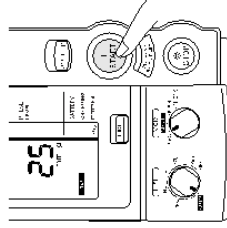
HOW TO MEASURE BLOOD PRESSURE (IN AVERAGE MODE)

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.

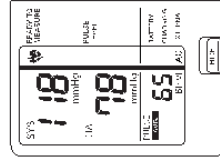
- For setting the number of measurements, the waiting time until the 1st measurement, and the interval, refer to Page 13.
- If you want to stop measurement, push the STOP Button. The unit will rapidly deflate.
- If an error occurs during measurement, the monitor will automatically start measurement again. 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.

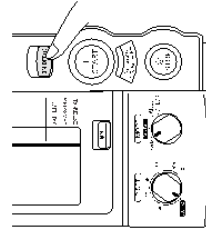
Each time the DEFLATION (deflation control) / Measurement Result Display Switch Button is pushed, the measurement results for each reading and the average value will be displayed.



- 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)

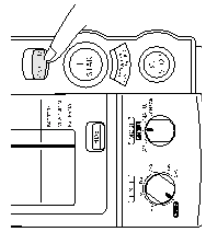
7. Push the ON/OFF (power) Button to turn off the power.

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.

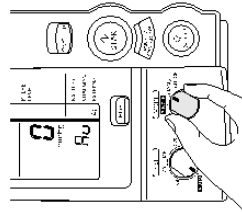


HOW TO MEASURE BLOOD PRESSURE (IN MANUAL MODE)

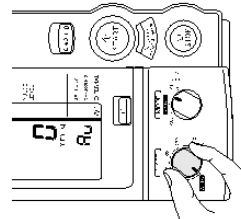
1. Push the ON/OFF (power) Button to turn on the power.



2. Set the MODE Selector to "MANU".



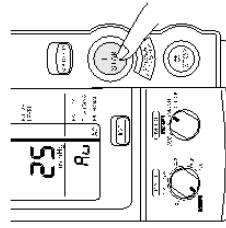
3. Set the P-SET (inflation level setting) Knob to "AUTO", or the target pressure value.



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)

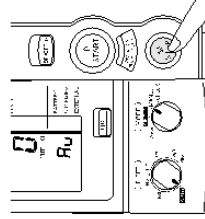
5. Place the stethoscope on the patient's arm.



6. Push the START Button to start the measurement.

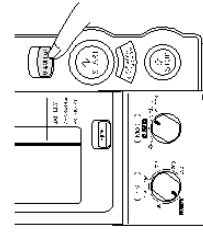
- Do not push the START Button without wrapping the cuff.
- Do not squeeze or press the cuff during the measurement.
- If you want to inflate again after the start of deflation, push the START Button.
- If you want to accelerate deflation after the start of deflation, push the DEFLATION (deflation control) / 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)

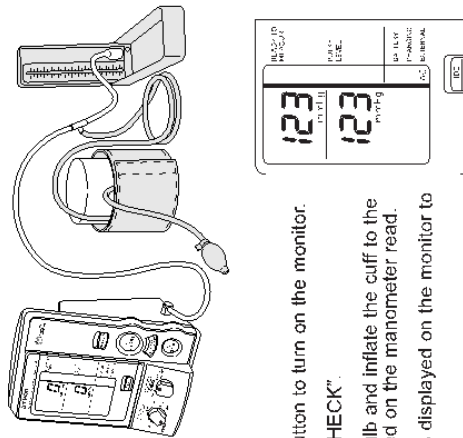
Accuracy of pressure display can be checked in the CHECK Mode.

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.



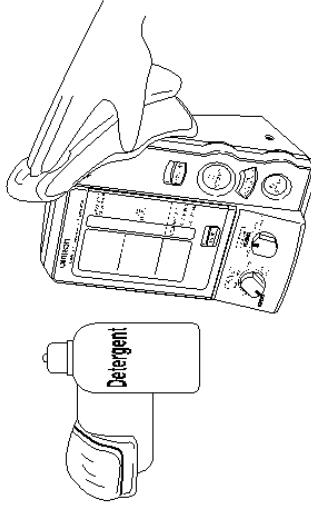
Check result

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

HOW TO CLEAN THE UNIT AFTER USE

⚠ Caution	General advice
<p>When cleaning this unit, unplug the AC adaptor from the electric outlet.</p> <p>After cleaning this unit, dry it well, before plugging the AC adaptor in the electric outlet.</p>	<ul style="list-style-type: none"> 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).

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.



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?	Does the patient have arrhythmia?	Set the P-SET to 30 to 40 mmHg higher than estimated systolic pressure of the patient, then measure.
	Check the patient's condition.	After checking the patient with the stethoscope refer to the "list of error codes". (Refer to Page 28.)
The monitor cannot measure blood pressure.	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.
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?	Are the patient's clothes restricting normal blood flow to the arm?	Remove the clothing and measure again.

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LIST OF ERROR CODES

Error code	Explanation	How to correct
E-1	Inflation error <ul style="list-style-type: none"> When the pressure does not exceed 12 mmHg within the set time after the start of inflation When the inflation does not reach the set cuff pressure within the specified time after the start of inflation 	<ul style="list-style-type: none"> Confirm that the air tube connecting the cuff and the main unit is connected securely. Confirm that the air flow in the air tube connecting the cuff and the main unit isn't being restricted. Confirm that the cuff is wrapped correctly (refer to pages 14 and 15). Check bladder for leaks and, if necessary, replace the bladder with new one (option).
E-2	Deflation error <ul style="list-style-type: none"> When the deflation speed is too fast during the measurement When the deflation speed is too slow during the measurement When the measurement does not finish within the specified time after starting the measurement. 	<ul style="list-style-type: none"> Confirm that air flow in the air tube connecting the cuff and the main unit isn't being restricted.
E-3	Overpressure error <ul style="list-style-type: none"> The cuff pressure exceeded 299 mmHg. 	<ul style="list-style-type: none"> If the measurement is made by setting the P-SET to "AUTO", ask the patient not to move during the inflation. 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. If the measurement is made by manual inflation level setting, set the value to 30 to 40 mmHg higher.
E-4	Insufficient inflation error <ul style="list-style-type: none"> Blood pressure could not be measured due to insufficient inflation level. 	<ul style="list-style-type: none"> Confirm that the cuff is wrapped correctly (refer to pages 14 and 15).
E-5	Indeterminable blood pressure error <ul style="list-style-type: none"> Blood pressure could not be measured even when the cuff pressure reached the specified pressure. 	<ul style="list-style-type: none"> Confirm that the cuff is wrapped correctly (refer to pages 14 and 15).
E-6	Low pulse level error <ul style="list-style-type: none"> Pulse wave was too small. 	<ul style="list-style-type: none"> Confirm that the cuff is wrapped correctly (refer to pages 14 and 15).
E-7	Blood pressure error <ul style="list-style-type: none"> Relationship between systolic and diastolic pressures was abnormal 	<ul style="list-style-type: none"> Ask the patient not to move during the measurement. Check the patient for arrhythmia.
E-8	Pulse rate error <ul style="list-style-type: none"> Pulse rate did not stay within the range of 30 to 199 beats/min. 	
E-9	Device error <ul style="list-style-type: none"> Main unit malfunction. 	<ul style="list-style-type: none"> Contact Omron's repair department toll-free at (1-877-216-1336).

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CAUTION

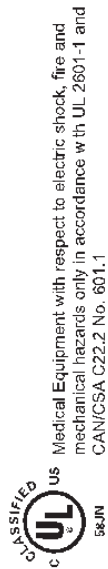
CAUTION: Changes or modifications not expressly approved by Omron Healthcare, Inc. could void the user's authority to operate this product.

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.



FIVE YEAR LIMITED WARRANTY

Your HEM-907X... 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 \$3.20 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

Name:	OMRON Digital Automatic Blood Pressure Monitor
Model:	HEM-907XL
Display:	Digital display
Measurement:	Oscillometric method
Measurement Range:	Pressure: 0 to 299 mmHg Pulse rate: 30 to 199 beats/min
Accuracy:	Pressure: Within ±3 mmHg or 2% Pulse rate: Within ±5% of reading
Inflation:	Automatic inflation with pumping
Deflation:	Automatic deflation by electromagnetic control valve
Air Release:	Automatic rapid air release by electromagnetic control valve
Pressure Detection:	Electrostatic capacity sensor, conductivity sensor, sensor
Power supply:	AC adapter (120 VAC, 60 Hz, 20 VA) or Battery pack (4.8 VDC, 6Wh)
Electric Shock Protection Method:	Class II B type
Operating Temperature and Humidity:	50°F to 70°F (10 to 40°C), 30 to 85% RH, IPX 0 Rating
Weight of Main Unit:	Approx. 32 oz (910 g)
External Dimensions:	Approx. 5 1/2" (W) x 8" (H) x 5 1/8" (D) 139 (W) x 203 (H) x 131 (D) mm
Accessories:	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)
Options:	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"). Stand exclusive for this unit, wall hanging kit, pole mounting kit

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

For Customer Service
Call Toll Free
1-877-216-1336

Manufactured by OMRON

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Vernon Hills, Illinois 60061
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HEM-907XLINST Rev A

Appendix 10 Omron HEM-780 Instruction Manual

Jackson Heart Study Protocol
Manual 4
Central Laboratory and Specimen Repository
Specimen Collection and Processing
Visit 3

Version 1.0
October 14, 2008

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.

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

**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 University of Minnesota Medical Center, Fairview 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.

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 20-30 mL of blood from each participant. Three or four tubes of blood are collected. 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 15 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

Collect 20-30 mL of blood from each participant using three or four Vacutainer tubes. Specimens from these blood collection tubes are used in approximately eleven 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 collection, 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 values can be artifactually decreased.

Tubes #2 is a 10-mL lavender-stoppered tube containing the liquid anticoagulant EDTA. The plasma is used to measure p-selectin and stored for future testing. After each tube is fully filled with blood, invert four times then place into a room temperature rack until centrifugation. *

Tube #3 is a 3 mL lavender stoppered tube containing the anticoagulant EDTA. The whole blood from this tube is used to measure glycosylated hemoglobin. After the tube is filled, invert four times, then

save at refrigerated temperature until shipment to the Central Laboratory. Minimum volume needed in this tube is 1 mL.

*Note: If unable to obtain tube 3, place 1 mL of well mixed WHOLE blood from tube 2 in a 1.5mL microvial and save at refrigerated temperature for the glycated hemoglobin analysis. Record this in section 8 of the venipuncture form.

2.4 Blood Collection Tubes: Labeling and Set-up

Three or tubes are collected in the following sequence:

Tube #1:	9.5-mL red and gray-stoppered tube
Tube #2:	10-mL lavender-stoppered tube (EDTA)
Tube #3:	3-mL lavender-stoppered tube (EDTA)

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 - 1.5-mL polypropylene vials (red top)
- 5 - 1.5-mL polypropylene vials (purple top)
- 5 - 1.5-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: 1.5-mL red top vials (rows A-E)
- Col 2: empty
- Col 3: 1.5-mL purple top vials (rows A-E)

Col 4: empty
Col 5: 1.5-mL clear top vials (rows A-E)
Col 6: empty
Col 7: empty
Col 8: empty
Col 9: empty
Col 10: empty

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 supine (laying) 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 lie supine 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 (#1 through #3) 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 #3, 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. Have the person remain lying down with legs elevated.
2. Take an ampule of smelling salts, crush it, and wave it under the person's nose for a few seconds.
3. Provide the person with a basin if he/she feels nauseous.
4. Have the person stay seated or lying down until he/she feels better.
5. Have someone stay with the person to prevent them from falling and injuring themselves if they should faint.
6. Place a cold wet cloth on the back of the person's neck or on their forehead.
7. 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.
8. 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.

1.1 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. Collect tube #1 (10-mL red and gray top). Place the tube in a rack at room temperature.
2. Collect tube #2 (10-mL lavender top). Invert four times and place in room temperature rack.
3. Collect tube #3 (3 mL lavender top). Invert four times and place in room temperature rack.

2.0 BLOOD AND URINE PROCESSING

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

2.1 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.

2.1.1 Whole blood for glycosylated hemoglobin

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

2.1.2 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.

2.1.3 Urine specimens

1. Thoroughly mix the random urine specimen.
2. Using a plastic transfer pipet, deliver 1.5 mL of urine to each of the five labeled microvials in column 5. **DO NOT OVERFILL THE URINE VIALS.**
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.

2.2 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.

2.3 Stage Two:

Approximately 15 minutes after venipuncture.

2.3.1 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 1.5-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.

2.4 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.

2.5 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.

2.6 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 (minus the urine specimen set aside for local analyses) 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 container should be discarded in accordance with local biosafety guidelines.

3.0 STORAGE AND SHIPPING

3.1 Storage

3.1.1 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 labeled correctly. 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.

3.1.2 Refrigerated Specimens

Maintain a rack for each whole blood or 1.5 mL microvial in the refrigerator until shipment. The whole blood EDTA tube (#3) or microvial may be shipped within 48 hours of collection. .

3.2 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 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.

3.2.1 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 styrofoam box lid. The shipping forms and instructions are shown in Appendix 3.

8. Seal the outer box tightly with strapping tape. Affix UN3373 and UN1845 dry ice labels to outside of box. The UN1845 label must be filled in with the appropriate dry ice weight and addresses.
9. Address the box and contact Federal Express for pickup.
10. If necessary, more than one box may have to be shipped per week.

3.2.2 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 styrofoam box lid. 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.

3.2.3 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) 273-3645 (Julie and Vicky in the lab)
Telephone: (612) 273-3318 (Greg's office)
FAX: (612) 273-3489
Email: jidzore1@fairview.org
grynder1@fairview.org
vmakky1@fairview.org

4.0 QUALITY CONTROL

4.1 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.

4.2 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 3 (glycated hemoglobin); and on Wednesday, draw Tube 2 (special chemistries). The QC urine duplicate can be collected on Thursday or Friday.

4.2.1 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	3	Gly. Hgb	_____
Wednesday	2	Special Chemistry	_____
Thursday or Friday	Urine	Chemistry	_____

4.2.2 Preparation for Drawing and Processing QC Samples

Blood Collection 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.

4.2.3 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 collection 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. Send the urine QC local testing vial as usual.

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.

4.3 Reporting of Results/DNA Amounts

The Central Laboratory has the responsibility for reporting results to the Exam Center as well as the Coordinating Center. All test results are transmitted to the Coordinating Center via FTP. This transmission occurs once per week. In addition, any alert result will be included in a separate manually-transmitted FAX. The following table summarizes the reference ranges and JHS alert ranges for routinely performed tests:

Table 1 JHS Laboratory Reference & Alert Ranges

Analyte	Reference Range	JHS Alert Range
² Glycosylated hemoglobin	4.3 – 6.1%	NA
² C-reactive protein	<0.5 mg/dl	NA
² Glucose	74-106 mg/dL	<60, >200 mg/dL
² Cholesterol	<200 mg/dL*	>360 mg/dL
² Triglyceride	Male: 0 - 250 mg/dL	>1000 mg/dL
	Fem: 0 - 220 mg/dL	>1000 mg/dL
² HDL-Chol.	>35 mg/dL*	<20 mg/dL
² LCL-Chol. (calculated)	<100 mg/dL*	>260 mg/dL
Urea Nitrogen		
Creatinine		
Insulin		
e-selectin		
p-selectin		

*The National Cholesterol Education Program designates these range values as “desirable”.

5.0 TRAINING PROCEDURES

5.1 Technician Training and Evaluation

The technician must study the JHS Specimen Collection and Processing Manual and watch several participant samples being processed. Then the technician may proceed to a mock collection and mock 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):

- Urea Nitrogen (serum)
- 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)
- Creatinine (serum)
- e-selectin (serum)
- insulin (serum)
- p-selectin (plasma)

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
"	GR-454246B	3 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 COLLECTION 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, 1-10 mL lavender top, 1-3 mL lavender top.
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 3 mL lavender-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

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

Jackson Heart Study

Manual 2

Cohort Procedures

Exam 3

Version 2.3

October 17, 2008

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, 3, and 4 describe the operation of the Cohort Procedures, Blood Pressure and Central Laboratory and Specimen Repository Components of the study. Manuals 5 and 6 comprise Electrocardiography and Magnetic Resonance Image studies, respectively. Manual 7 comprises of Morbidity and Mortality Classifications. Manual 8 articulates the quality assurance and control activities of JHS Examination 3 components. Quality control includes activities that are designed to assure quality of data, which take place prior to the collection of data. Quality control relates to efforts during this study to monitor the quality of data. Detailed Manuals of operation for specific procedures, including those for Blood Pressure and Quality Control, make up Manual 4 and 5. The Data Management System is described in Manual 9.

JHS Study Protocols and Manuals of Operation

MANUAL	TITLE
1	General Description and Study Management
2	Cohort Component Procedures
3	Blood Pressure
4	The Central Laboratory and Specimen Repository
5	Electrocardiography
6	Magnetic Resonance Imaging
7	Morbidity and Mortality
8	Quality Control
9	Data Management

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 third 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 third clinical examination (Exam 3) 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 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 forms, the quality assurance activities, and the data collection instruments and procedures.

Chapter 4 provides similar information for the procedures performed during Exam 3.

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

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 Clinic 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 3 (CONTACT YEAR 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. Annual follow up, Clinic, and Community Partnership/Outreach/Translation work collaboratively to bring back a high percentage of the cohort for Exam 3. The retention plan for Exam 3 is designed to maximize the number of participants re-examined ~ 8 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 3. 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 pre-recruitment study (Participant Recruitment Study) and the lessons learned in Exams 1 and 2.

1.1.1. Building on Lessons Learned in previous exams: 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 3 retention activities capitalizing on this lesson include:

- Hosting “family days” in the clinic when we focus scheduling to accommodate entire families or households.
- Including a “family history” format to encourage families to learn and record more about the personal and health histories of their families.

Involving the Council of Elders (with IRB clearance and approval) in contacting participants, discussing the importance of the study and their individual participation and encouraging participants’ continued participation in the study by making an Exam 3 appointment will include:

- A coordinated retention effort from the Council of Elders.
- Identifying a group of young men who might be willing to assist in targeted retention activities with other men.

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 3, 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 by making an Exam 3 appointment.

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.
- 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 no more than 3½ hours, providing advance notification of pending examination schedule and flexible scheduling of examinations.
 - 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 College and Jackson State University 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
 - 3½ hour exam
 - Provide JHS videos, heart health education, and other useful information for use during any potential time in the waiting area or snack area
- 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 Manager Research Clinic..
- 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
- End of clinic "trinkets"
- JHS Newsletter semiannually
- JHS Family Reunion and Birthday Party each September
- Annual Celebration of Life each February
- Community Monitoring Board, held annually in June.
- 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
- Continue innovative "pledge of the investigator" initiated in Exam 1 consent
- Ongoing community workshops and educational offerings, particularly concerning genetics
- Community Monitoring Board
- Ethics Advisory Board

1.1.1.3 Building Community Partnerships

As we have learned from the Participant Recruitment Study and Exams 1 and 2, 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
- 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 Partnership/ Outreach/Translation office will continue a well-articulated public relations and media campaign with targeted television, radio and print activities, when appropriate.

1.1.2 Exam 2 Retention Strategies

The following retention strategies were successfully implemented during Exam 2. Because of their success in facilitating cohort retention, they will also be implemented during Exam 3.

1.1.3 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 Directors’ Council, and the Steering Committee at their regular 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 3 Scheduling

All participants in the ____ who completed all or part of the baseline clinic examination (Exam 1) ND Exam 2 are eligible for continuation in Exam 3 Timing of Exam 3 scheduling is an

approximately equidistant time from the Exam 2 clinic visit.. 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 third 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 for the core exam 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. The MRI, which will be conducted on a subset of the participants, will not be offered to pregnant women.

1.2.1.1 Participant Scheduling List

A designated Data Manager will run a Participant Scheduling List from the program provided by the Data Management, Information Technology, Quality Assessment Unit for that purpose. The Participant Scheduling List orders participants by their expected Exam 3 exam date in keeping with the order of their participation in Exam 2. 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 3 and participant flow is equalized across the three years.

1.2.1.2 Greater than 50 Mile Scheduling List

Also, the Data Management, Information Technology, Quality Assurance Unit has provided a program for identifying persons who have moved > 50 miles from their home address at the time of their last Exam .A designated 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 second and third examinations. 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 February 2009, 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 3. This initial telephone contact will include:

- an introduction and description of Exam 3
- 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 have hi/her exam conducted. 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 JHS 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 him/her.

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/ and select the Participant button. The scheduling system is then selected and s/he follows the instructions for scheduling an appointment.

Other JHS staff may be trained to make clinic appointments, and may do so on an as needed basis in order to reach the monthly target number of appointments required to retain at least 85% of the cohort. All JHS staff who make appointments should follow the protocol for making appointments.

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 Clinic 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 Clinic as possible, determined on an individual basis. However, whenever possible, the interviewer should attempt to schedule the Exam 3 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 Manager Research Retention, in consultation with the Associate Director, Data Acquisitions 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 Manager Research Retention and the Associate Director, Data Acquisitions arrange for participant to return to Clinic 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 WHO ARE EXCLUDED FROM THE EXAM 1 DATA ANALYSIS—See list provided by the Data Management, Information Technology, Quality Assurance Unit 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, attempts 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 3 1/2 hours)
 - Snack is provided after venipuncture to obtain 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 Clinic makes reminder telephone calls to participants three days 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 3. These efforts will include performing an off-site examination with participants who refuse or are unable to travel to the Clinic, 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 Clinic staff will travel to the off site location and complete all Exam 3 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.

In addition to individual off site examinations, on occasion, the Clinic will set up off site examinations in convenient community based locations to accommodate groups of participants who live at a significant distance from the Clinic. 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 3 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 Exam 3 This recognition is a certificate of membership in the JHS cohort that is suitable for framing (see Appendix).

The Annual Follow- Up staff maintain 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/Outreach/Translation 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 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.. Interviewer/recruiters and clinic staff will notify the Data Acquisitions 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 Subcommittees who will advise on strategies to improve study performance.

Exam Component	Description	Manual section
Anthropometry	Measure height, weight and waist and hip circumference.	M2_4.1
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_4.2, 4.3
Informed Consent	Obtain informed consent for core Exam 3 examination including authorization for collection of study data, access to medical records, release of study data, data sharing,	M2_3.2
Interviews	Collect medical, health, stroke /TIA, and ; medication/vitamin use, administer psychosocial instruments	M2_3.0
Venipuncture Laboratories	Collect by venipuncture fasting glucose and lipids (total cholesterol, Triglycerides, HDL, LDL, VLDL) Hg A1c, C-reactive Protein	M2_4.3
Medical Data Review	Ascertain the completeness of the exam and verify abnormal results. 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
Sitting Blood Pressure	Omron HEM-907XL	M2_4.1 M4
Snack	Provide heart healthy snack with no stimulants	M2_4.4
EKG, ABI, MRI		

2.0 EXAM 3 DESIGN, LOGISTICS, TRAINING, AND QUALITY CONTROL

2.1 Introduction

During the annual follow up interview, cohort members in the Contact Year 9 are invited to return for a third clinical examination (Exam 3). 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 Exams 1 and 2, measurements of blood chemistry (glucose, lipids), blood pressure (sitting), body frame / size (anthropometry) are included in Exam 3. 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 reproductive and hormonal 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 3 include 

New interviews in Exam 3 include an assessment of cognitive function, an expansion of sleep quality, and an expansion of health care continuity and trust.

Table 2.2, below, provides a summary of the core components of Exam 3 identifying the activities at each work station and cross referencing each procedure with its respective location in the Manual of Operations. .

Comparability Component	Description	Manual_Section
Blood Pressure	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 3 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 3 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.

Component	Description	Manual_Section
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

Table 2.3 Components of Annual Follow Up (AFU) and Surveillance in the JHS Exam 2 and their location in the Manuals of Operation		
Component	Description	Manual Section
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 third cohort examination for the JHS (Exam 3). 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 third 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 3 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 3. 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 Clinic 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 3. A more detailed rationale is provided for the new components in Exam 3.

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 3 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 3 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 23. The Quality Assurance section (.5) briefly summarizes and /or references the additional quality control activities that are carried out by Clinic personnel and globally by the Data Management, Information Technology and Quality Assurance Unit (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.




Table 2.4 Training and Certification Criteria for JHS Exam 2 Interviews and Procedures				
COMPONENT	CERTIFICATION REQUIREMENT	CERTIFIER OR REVIEWER	RECERTIFICATION REQUIREMENTS	RECERTIFIER OR REVIEWER
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, SITTING 2 replicate measures 	Lead technician (Clinic Manager) certified, all others training by Clinic Manager < 4 mm Hg/reading < 3 mm Hg/average None	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
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
VENIPUNCTURE	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


Table 2.4 Training and Certification Criteria for JHS Exam 2 Interviews and Procedures				
COMPONENT	CERTIFICATION REQUIREMENT	CERTIFIER OR REVIEWER	RECERTIFICATION REQUIREMENTS	RECERTIFIER OR REVIEWER
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
				
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
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

Table 2.4 Training and Certification Criteria for JHS Exam 2 Interviews and Procedures				
COMPONENT	CERTIFICATION REQUIREMENT	CERTIFIER OR REVIEWER	RECERTIFICATION REQUIREMENTS	RECERTIFIER OR REVIEWER
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 and 2 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 Clinic staffing patterns, and unforeseen number of participants who keep scheduled appointments, the configuration of the Clinic 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.

Table 2.5 Participant Flow, JHS Exam 2	
Procedures / Workstations	Approximate Time
FIXED SEQUENCE #1¹	
RECEPTION Informed Consent Informed Consent Form Update Contact Information Fasting Status Collect Medications CHANGE OF CLOTHES	15 minutes
ANTHROPOMETRY BODY COMPOSITION SITTING BLOOD PRESSURE	6 minutes 6 minutes
VENIPUNCTURE	5 minutes
SNACK	8 minutes
FLEXIBLE SEQUENCE²	
EKG	5 minutes
ABI	40 minutes
STAFF ADMINISTERED QUESTIONNAIRES Health History Medical History sleep quality Psychosocial series Cognitive function Health care continuity and trust Stroke Symptoms	20 minutes
FIXED SEQUENCE #2¹	

Table 2.5 Participant Flow, JHS Exam 2	
Procedures / Workstations	Approximate Time
DATA INVENTORY (staff activity) CHANGE CLOTHES MEDICAL DATA REVIEW EVALUATION	5 minutes 10 minutes
TOTAL TIME	2.0 hours

¹Components in the Fixed Sequence #1 and #2 are considered first priority should a participant be unable to complete Exam 3 in one visit

²Components in the Flexible Sequence can be rescheduled for a second visit should the participant be unable to complete Exam 3 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 Clinic physical layout and the scheduling patterns for participants. This approach is intended to minimize participant burden to approximately 3 ½ hours and reduce variability in study measurements.

2.2.2 Fixed Sequences

Exam 3 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 Clinic. The Clinic 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 venipuncture. 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. Venipuncture must be done while the participant is in a fasting state and could affect the participant's blood pressure. Therefore venipuncture is generally performed immediately after anthropometry and sitting blood pressure measures.

Following venipuncture, 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) serves as a summary of procedures and interviews performed during Exam 3 and is directly 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

Prior to beginning Exam 3, the Clinic staff is trained to use a standardized technique for administering all Exam 3 interviews. Central training conducted by the Clinic Liaison in coordination with the managers of the clinic, retention (AFU) and surveillance staffs, includes an overview of the JHS Exam 3 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 Clinic Liaison 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 Retention Manager and Clinic Liaison are responsible for similarly training new staff. For surveillance staff, the Research Surveillance Manager 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, 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 3 interviews and procedures. Interviewers are certified by the Clinic Liaison 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), Retention Manager (for annual follow up interviews), Surveillance Manager (for out-of-hospital death informants' interviews). 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/ and/or Clinic Liaison monthly. Routine quality assurance is provided through observation by the Clinic Manager. Protocol adherence and interviewing techniques are reviewed at least biannually by Data Management, Information Technology, Quality Assurance 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 Clinic Operations Subcommittee. Data quality is monitored by the Quality Control Subcommittee semi-annually.

3.0 INTERVIEWS IN THE JHS EXAM 3 CLINIC VISIT

3.1 Reception

The reception workstation welcomes the participant to the clinic and initiates the exam interviews and clinical measurements at the Clinic. Prior to the participant's arrival, an Exam 3 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 Clinic, but are available for use during the JHS exam), the Participant Itinerary Sheet (PIN), and blank copies of the JHS Exam 3 informed consent form. Folders also contain ALERT/REFERRAL logs for use upon receipt of exam 3 results. 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 3 clinical exam data collection forms. Specifically, the file would include the CON (contact), ICF (Informed Consent Form), FTR (Fasting Tracking), BCF (Body Composition Form), MCA (Montreal Cognitive Assessment, HCT (Health Care Continuity and Trust), SBP (Sitting Blood Pressure), VEN (Venipuncture Form), HHX (Health History Form), MHX (Medical History Form), SLE (Sleep Form) SSF (Stroke Symptoms Form), SUC (Spot Urine Form) (and a blank copy of the medical data review form).

On arriving at the Clinic, the participant is greeted and welcomed. Travel reimbursement and participant payment information is obtained. Health Care Provider Contact forms is 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 immediately available results of Exam 3 at the conclusion of the exam before the participant leaves the Clinic. These include the anthropometrics, body composition, and blood pressure. Results other studies done during the visit are reviewed by the JHS clinician when they become available from the Reading 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 Manager Research Clinic. 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 Manager Research Clinic for quality assurance and standardization.

3.2 Informed Consent

Administration of Informed Consent precedes all other activities at the Clinic. The core content and consent options of the Exam 23 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.

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 3 form. 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 3 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 modify prior consent choices at any time. 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. Also consent is obtained to request a copy of outpatient clinic visits for participants who, through an AFU call, indicate diagnosis and treatment of outpatient heart failure

3.2.2 Administration

The Informed Consent is administered as the first component of the exam as part of the fixed sequence #1. The goals of JHS are reviewed with the participant prior to the administration of any other data collection instrument. Consent to participate in the third 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 Clinic Liaison responsible for providing staff training for new staff.

3.2.4 Certification

Certification requires demonstration of 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 Clinic Liaison.

3.2.5 Quality Assurance

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

3.2.6 Data Collection

Descriptions of the study and the signature pages acknowledging informed consent for Exam 3 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 Clinic 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 third 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 3, 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 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.

Blood samples via venipuncture 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 venipuncture blood drawing in the fasting state at a later date. The FTR is completed; the non-fasting state and rescheduled date of venipuncture are noted on the Participant Itinerary Form. When the participant returns in the fasting state for venipuncture, the questions concerning fasting status and recent blood donation on the FTR form are updated and the data on the Venipuncture Form (VEN) 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 their 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 venipuncture 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 3 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 3. 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 3.

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 Clinic 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 Clinic 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 ask 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 Clinic Manager and Clinic Liaison. 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 Data Management, Information Technology and Quality Assurance Unit 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 by designated Data Management, Information Technology and Quality Assurance staff 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 Data Management, Information Technology and Quality Assurance Unit for blinded repeat coding at the Clinic.

3.5.5 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 Data Management, Information Technology and Quality Assurance 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 3. It serves to update health information obtained as part of AFU interview and Exam 2 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), , 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.

3.6.2 Administration

The HHX is administered to all participants during the Exam 3 clinic visit by a trained and certified interviewer. The time reference for all health history questions (section B) is since the time of the last clinic visit (Exam 2). 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 3. It serves to update from Examination 2 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 3 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 second JHS examination. Detailed procedures for administering the form are provided in the QxQ instructions immediately following the form in the Forms Appendix.

3.8 Personal and Family History

Personal and Family Health History (PFH)

The Personal and Family Health History (PFH) is intended to gather baseline information on the personal and family health background of each respondent. This form was adapted from the ARIC

Personal History form and additional questions on the health history of full brothers and sisters and

natural children were added to assure that a wide range of essential family health data can be captured. Likewise, this data provides important baseline information for the family component of the JHS.

3.8.1 Background, Rationale, and Hypotheses

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.

3.8.2 Administration

The PFH is administered to all participants by clinic staff during the clinic exam . instructions for administering each question are contained in the QxQ instructions. The initial question requires the respondent to rate her/his health status. Subsequent questions seek specific information on self-reported history of hypertension, hyperlipidemia, heart attack, stroke in related family members – siblings and parents.

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 exams 1 and 2 and is updated during Exam 3. The time frame for this form is since the last JHS exam (Exam 2).

3.9.2 Administration

The SSF is 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 Sleep Questionnaire

The sleep quality questionnaire is administered to obtain information on the participant's self report of his/her quality and quantity of sleep. The instrument was used in MESA Exam 4.

3.10.1 Rationale

Recent studies suggest that disordered breathing during sleep might be related to cardiovascular conditions such as hypertension, heart disease, and stroke.

3.10.2 Administration

This is a **self-administered form** that should take about three minutes to complete. The participant should complete the form privately, in a quiet room, sitting at a table, and with no sense of urgency.

3.11 Discrimination

The Discrimination Form (DIS) is a core data collection form administered during the flexible part of the examination to document racial discrimination experiences. This is a repeat of the instrument administered in the baseline exam. This assessment includes the

participant's attributions, day-to-day experiences, major life events, and coping/responses to racial discrimination. Jackson, et al. (1996) concluded key dimensions include racism as major and minor stressors, perceptions of racism, responses to racism, and indicators of institutional racism. No single instrument assesses the multiple dimensions. A multidimensional measure of racism that captured these key elements has been adapted from the Discrimination Scale (Kreiger, 1990), the Everyday Racial Discrimination Questionnaire (Williams, 1997), and the Perceived Racism Scale (McNeilly, et al., 1996).

3.11.1 Background, Rationale, and Hypotheses

Several studies have found that exposure to racist provocation in the laboratory setting leads to increased cardiovascular and psychological reactivity (Anderson, et al., 1989; Armestead, et al., 1989). There is some evidence from epidemiologic and other studies that perceived discrimination may adversely affect health as well as blood pressure (Dressler, 1990; James, 1984; Thompson, 1996; Williams, 1997; Krieger, 1990; Krieger & Stanley, 1996), while others found no association with hypertension and cardiovascular disease (Broman, 1996). The inclusion of a measure of discrimination in the JHS will allow for further investigation of whether discrimination, as a source of psychosocial stress, contributes (directly or in interaction with other sociocultural measures) to the development of hypertension, CVD and subclinical markers of LVH, carotid wall thickness, etc. If perceived discrimination proves to be related to the development and progression of CVD, it may be relevant to understanding race and SES discrepancies observed.

Development of discrimination measures is in its infancy though a number of measures have been developed over the past several years. In particular, measurement issues have included attention to the acute, every day, and lifetime measures. Both major life domains as well as explicit exemplars (dimensions) have been offered. Three major measures were considered for the JHS: Krieger's questionnaire (used in CARDIA), Williams, et al. (1997) measure of everyday discrimination, and Mac Neilly's (1996) Perceived Racism Scale. By adapting these three measures, JHS captures information on acute, episodic, daily and lifetime discrimination. In addition, because some limited research suggests that coping strategies may modify the relation of discrimination to outcomes, a question on response to discriminatory situations is included.

Hypotheses include:

1. Perceived discrimination is associated with risk factors, sub-clinical and overt cardiovascular disease at baseline.
2. Among persons with similar degrees of sub-clinical and overt disease at baseline, those with higher levels of perceived discrimination will be at greater risk for subsequent CVD events over the course of follow up.
3. Perceived discrimination interacts with SES to modify the effects of other social stressors.

3.11.2. Administration

The DIS is administered by the clinic staff during the flexible component of the exam. Detailed instructions for administering each question are provided in the QxQ Instructions. The first portion of the DIS ascertains information on the participant's day-to-day experiences. The subsequent section gathers information on the participant's lifetime experiences, frequency of those experiences and the last time for the experience. The DIS consists of 20 multiple choice, yes/no, and fill in the blank type questions. The exact wording and order of the questions are followed to ensure standardization. Questions are

skipped only when indicated by the skip pattern instructions. Because of the number of skip pattern instruction in this form, the interviewer needs to memorize the flow of the questions. Items in PARENTHESES, SHADED BOXES and/or CAPITAL BOLD LETTERS are instructions to the interviewer and are not read to the participant. The questions are read clearly using the exact wording on the form. The nature of the discrimination questions may be considered sensitive and care must be taken to ask the questions and to record the responses in a nonjudgmental manner.

3.12 OTHER PSYCHOSOCIAL INSTRUMENTS

3.10 Participant Evaluation of Clinic Visit

The Participant Evaluation of Clinic Visit (PEC) is continued from Exams 1 and 2 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.

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 3 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. The participant is also invited to complete an anonymous evaluation of his/her clinic experience. This information will not be entered into the DMS. The participant is instructed to place his/her hand-written responses in an evaluation box provided in the clinic. 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 3. 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 Manager Research Clinic 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 3 CLINIC VISIT

4.1 Body Composition and Anthropometry (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 the 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 Clinic, 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, 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

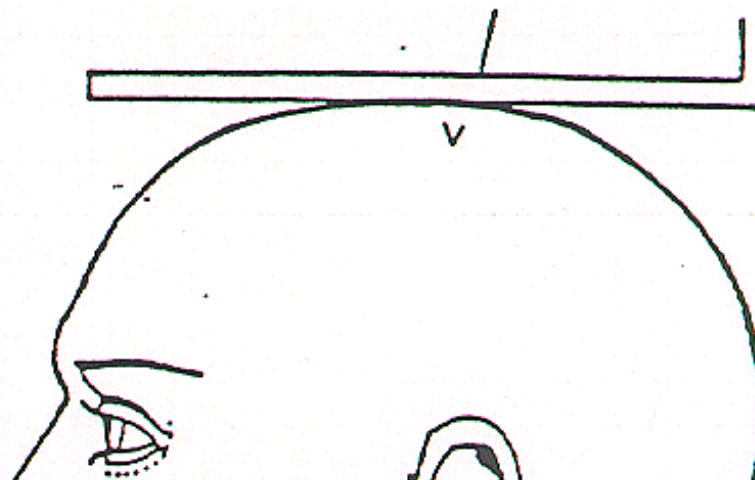
Anthropometry and determination of body composition are performed as part of the fixed sequence #1 before the clinic snack and after the participant has changed into a scrub suit or examination gown and been given the opportunity to empty her/his bladder. All measurements are made with the participant 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



Thyroid Cartilage _____
Cricothyroid Membrane

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

Centimeters	Inches		Centimeters	Inches
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

Kilograms	Pounds		Kilograms	Pounds
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

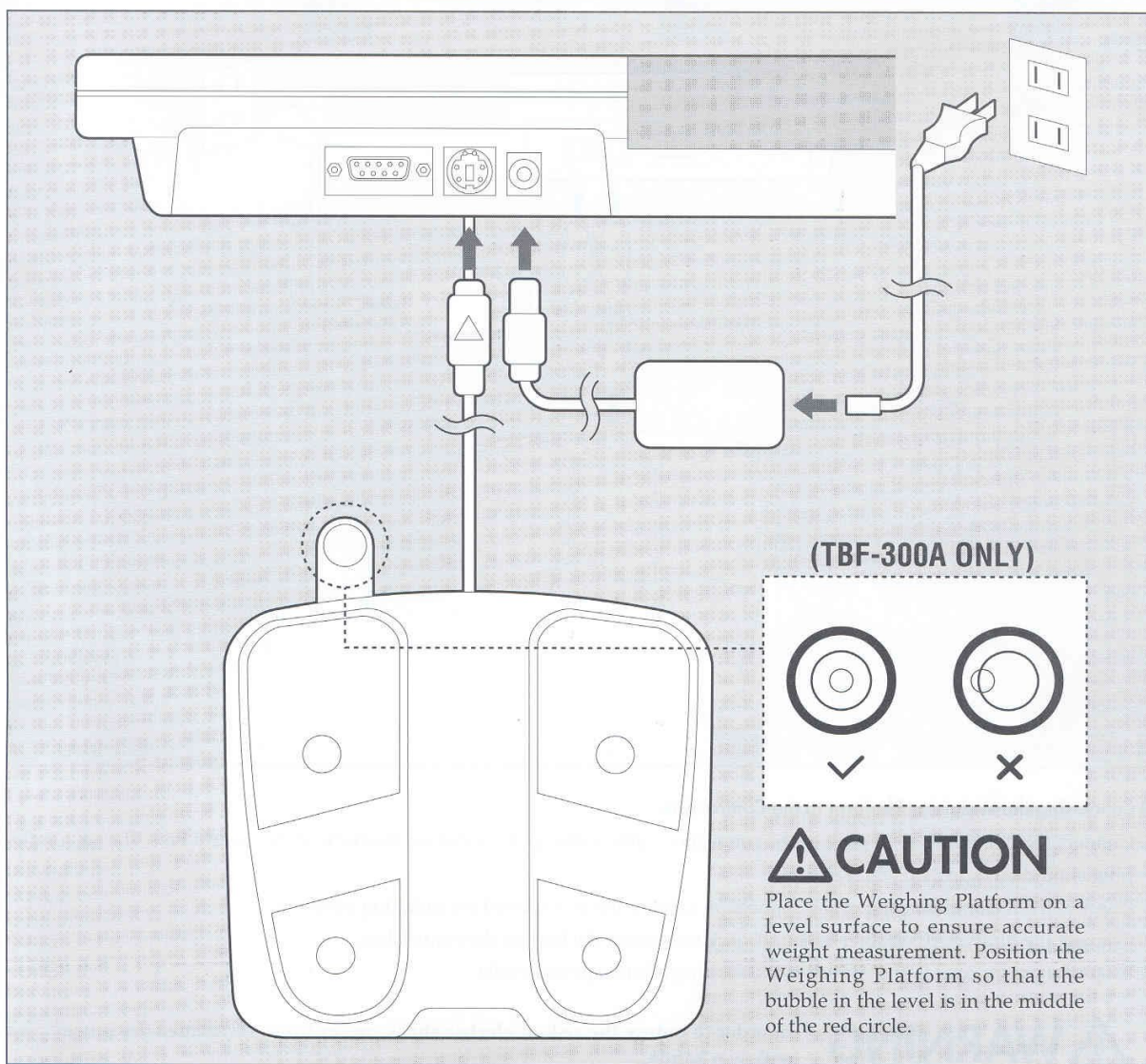
Using the balance beam scale--Before a participant is weighed, the scale is balanced so that the indicator is at zero when no weight is on the scale. The scale must be level and on a firm surface (not a carpet). The participant is instructed to stand in the middle of the platform of the balance scale (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



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)

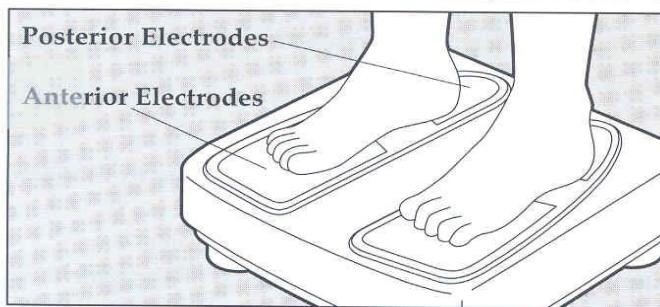
Set the number of printouts and the printing language. Press and hold the [0] key and press the [ON/OFF] key once. Release the [0] key after "Prt-1" is displayed on the screen. Using the number keys, enter '3' to obtain 3 printouts (one for participant, one for provider, one to be filed in participant 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.

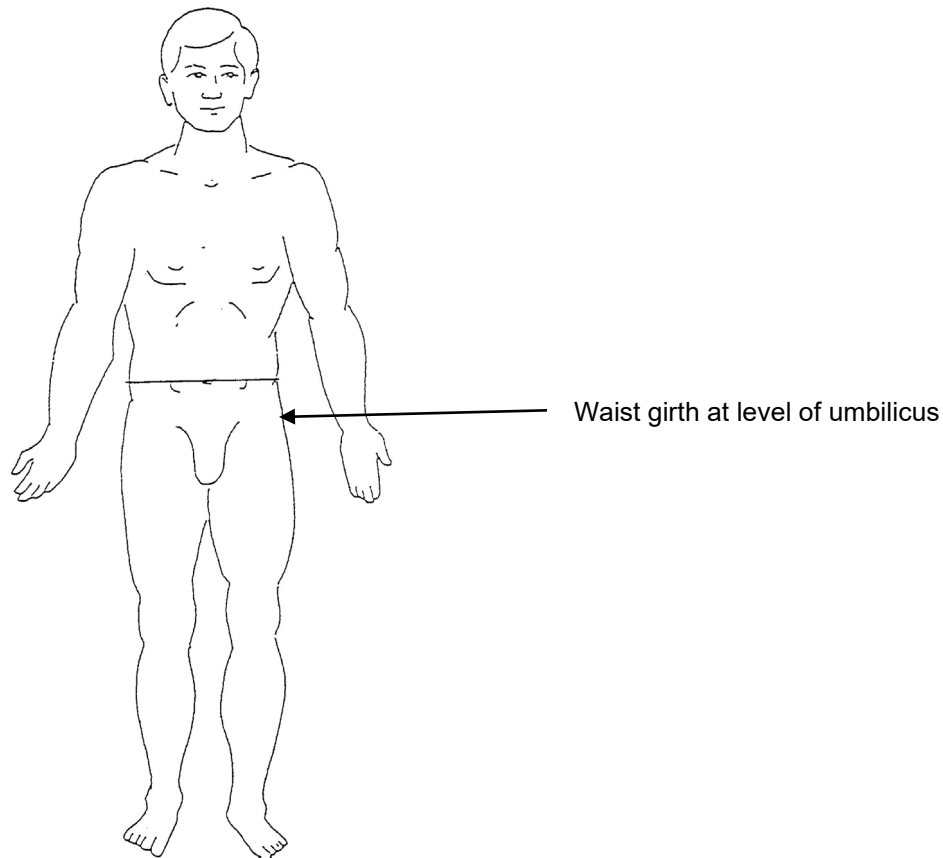
Figure 4.3 **Foot Placement for Body Composition Measurement, Tanita TNF 300A Body Composition Analyzer**



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

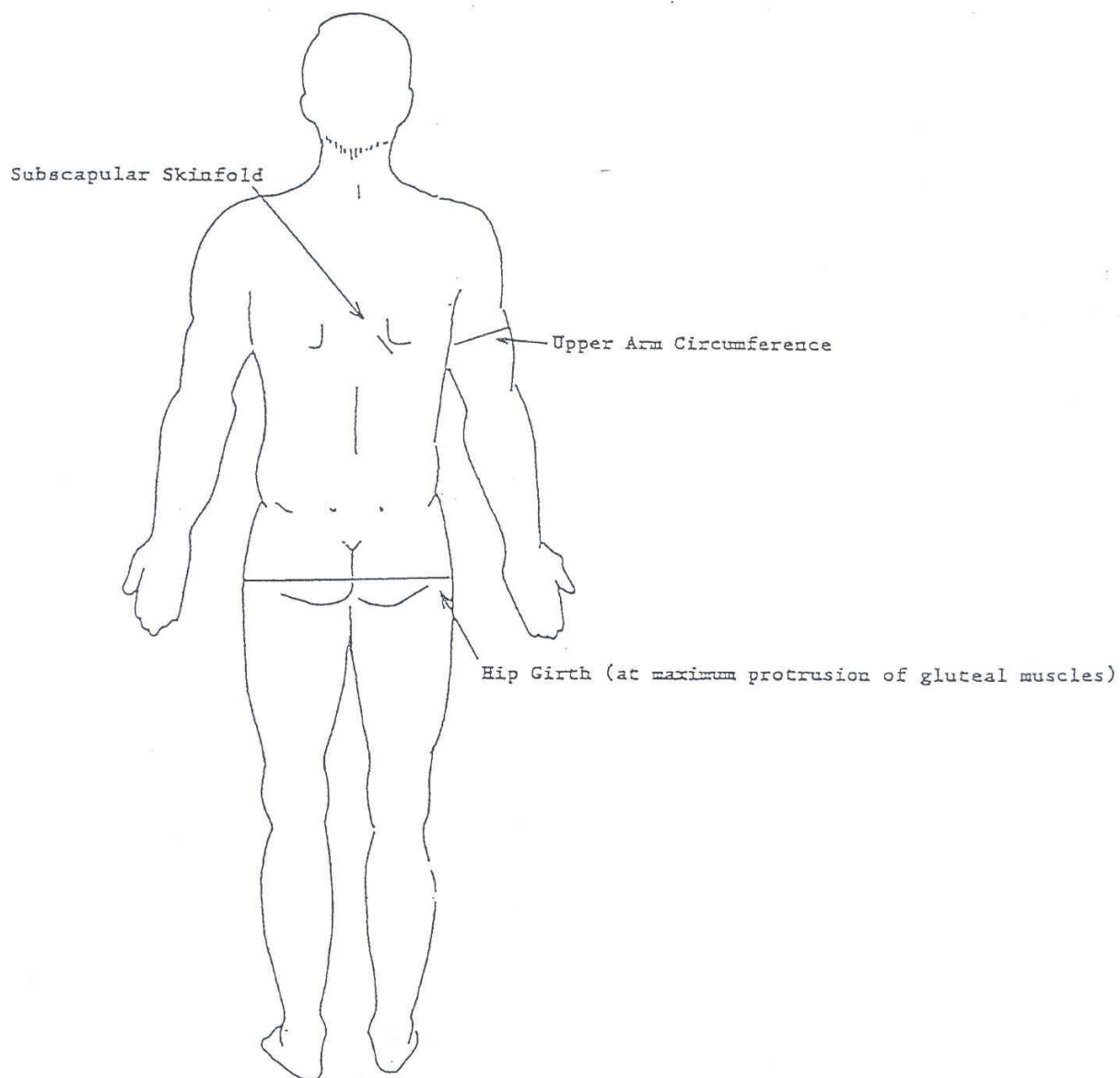
4.1.2.4 Hip Circumference

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 firth 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 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

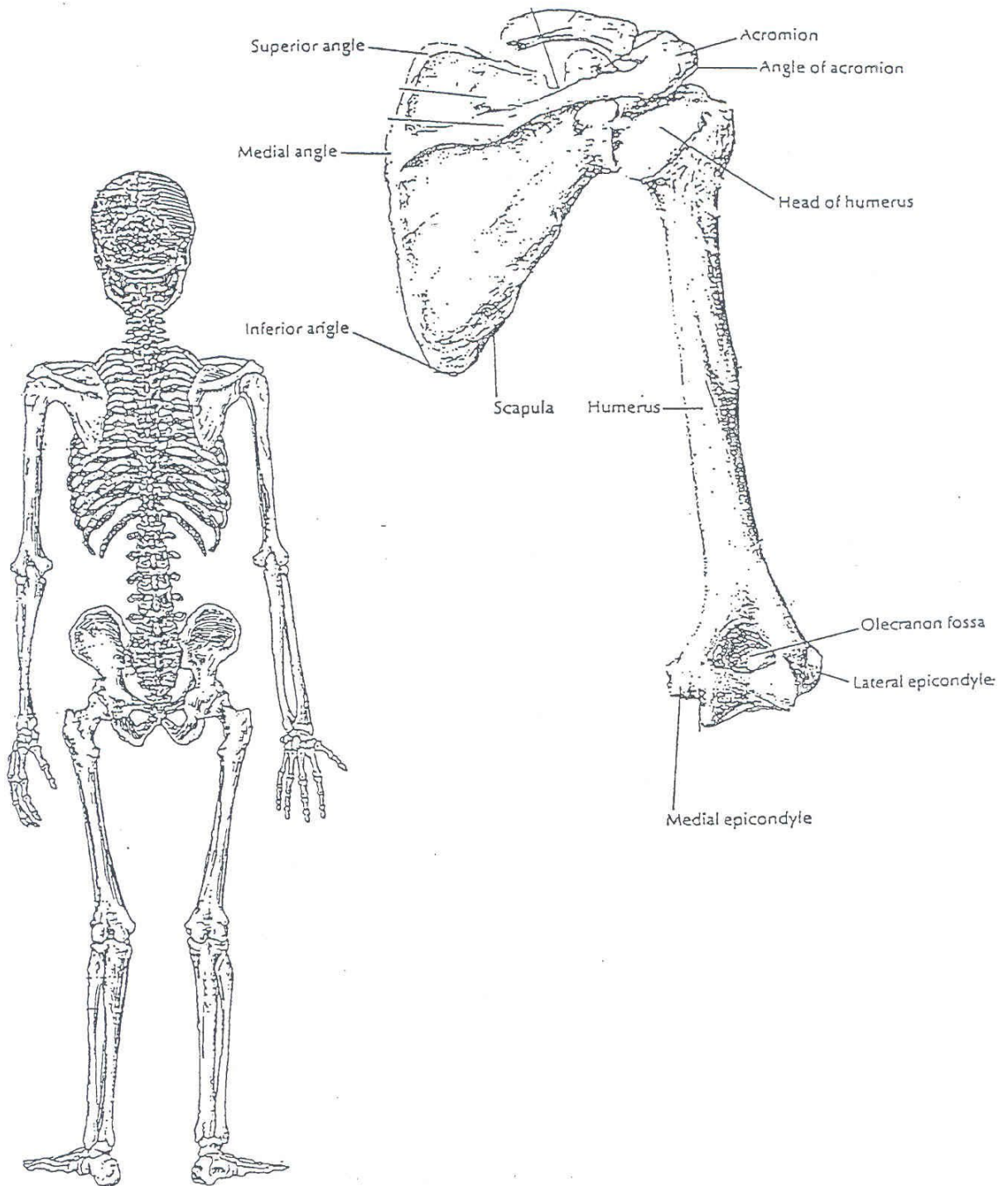
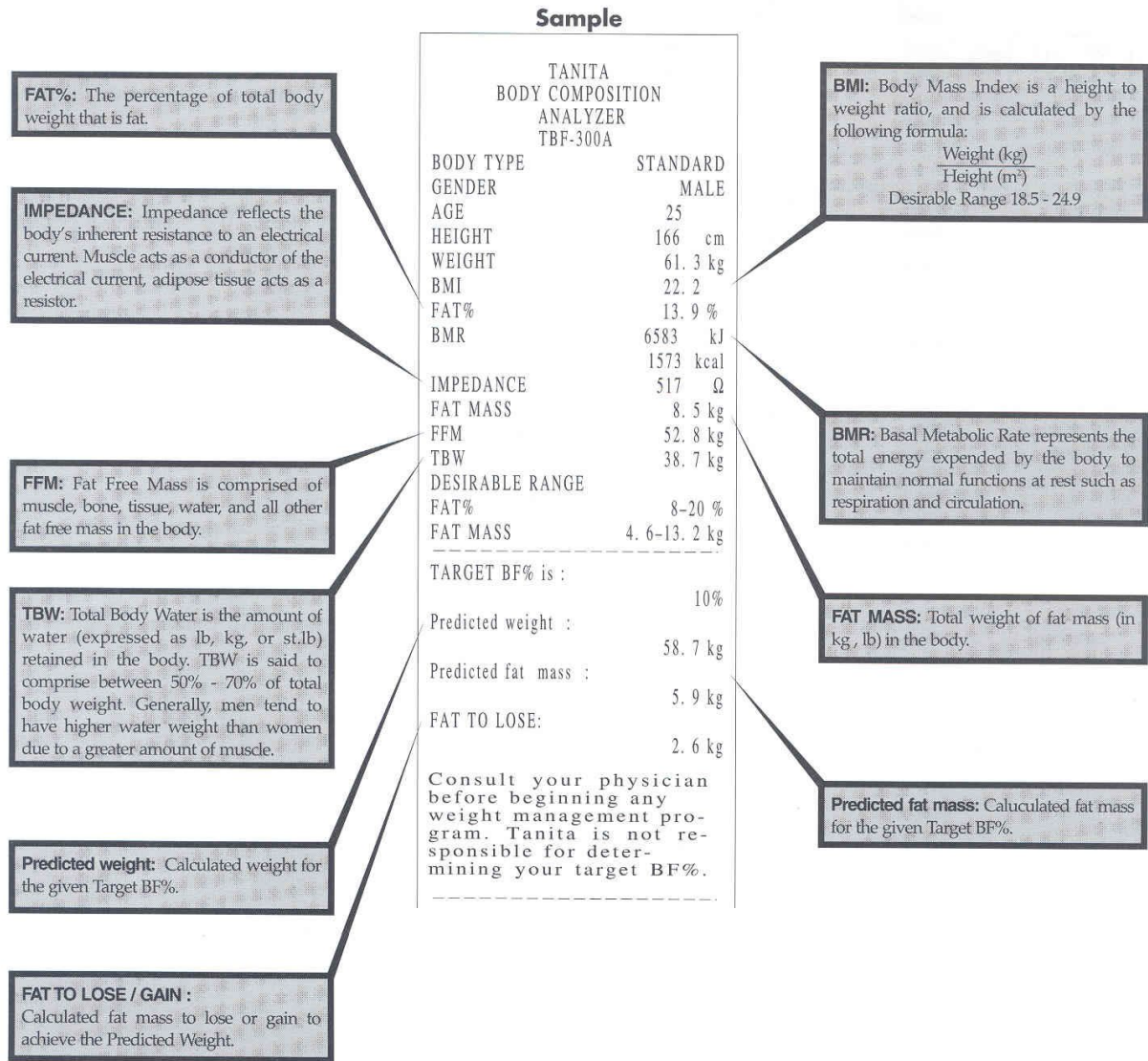


Figure 4.7 Sample Tanita TNF 300A Body Composition Print Out



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. Clinic supervisors and technicians are certified after participating in central training by the Manager Research Clinic and Clinic 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/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 by Data Management, Information Technology and Quality Assurance monitors. Deviations from protocol and possible remedial actions are discussed with the Manager Research Clinic and staff at that time. Quality control observations of technicians by an observer are also performed biannually by Clinic 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 Data Management, Information Technology and Quality Assurance Unit for review. Major deviations from the protocol are brought to the attention of the Clinic Operations Subcommittee.

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 Data Management, Information Technology and Quality Assurance Unit biannually.

Digit preference, systematic differences in location statistics, completion of checklists/logs according to schedule are analyzed by the Data Management, Information Technology and Quality Assurance. Important quality assurance/control measures analyzed include training/certification, instrument checks, random repeatability studies and biannual observations of technicians by other technicians and Data Management, Information Technology and Quality Assurance monitors are monitored and reviewed by the Quality Control Subcommittee. 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 3 clinic visit. See Manual 3, Blood Pressure. See Forms Appendix for SBP form and QxQ instructions.


4.2 Electrocardiogram

See Manual __

4.4 Venipuncture

Blood Samples are obtained via venipuncture for measures of fasting glucose, hemoglobin A1c, lipids, C-reactive protein and DNA.

4.4.1 Rationale

Glucose and lipids are well known risk factors for heart disease and their measurement is continued in Exam 3 to provide immediate information to participants regarding their values. Hemoglobin A1c is a well known measure for diabetes control. C-reactive Protein is a measure of non-specific inflammation which is thought to be a CVD risk factor. 

4.4.2 Administration

The FST form is completed by trained and certified technicians during the fixed sequence #1 component of the Exam 3 clinic. The Venipuncture and QxQ instructions for completion are contained in the Forms Appendix.

4.34.3 Training

Certification

4.3.4 Quality Control

In the Clinic, 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 Clinic 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 Clinic.

4.4.5.1 Quality Control Duplicate Blood and Urine Samples

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

To reduce the burden upon JHS participants, no one person is asked to contribute sufficient extra blood to make a complete set of duplicates for all tests. Instead, extra blood is drawn from three participants 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 Clinic 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.

4.3.5.2 Weekly Blood and Urine QC Sample Checklist

The JHS Clinic 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.

4.3.8 Data Collection

4.3.8.1 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.

4.3.8.2 Phlebotomy Room

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

4.3.8.3 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.

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.

4.3.8.4 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 upright 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 hemo concentration 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.

Remove alcohol prep from its sterile package.

Cleanse the vein site with the alcohol prep using a circular motion from the center to the periphery.

Allow the area to dry to prevent possible hemolysis of the specimen and a burning sensation to the patient when the venipuncture is performed.

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.

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.

With the needle bevel upward, enter the vein in a smooth continuous motion.

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.**

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.

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 re-applied during the collection to spare the participant a re-stick, but the tourniquet must not be on for more than two minutes.

Keep a constant, slight forward pressure on the end of the tube. This prevents release of the shutoff valve and stopping of blood flow.

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.

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.

Turn needle slightly or lift the holder in an effort to move the bevel away from the wall of the vein.

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.

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:

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.

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.

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.

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:

Take an ampule of smelling salts, crush it, and wave it under the person's nose for a few seconds.

Provide the person with a basin if he/she feels nauseous.

Have the person stay seated until he/she feels better.

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.

4.3.8.5 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.

4.3.9. BLOOD AND URINE PROCESSING

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

4.3.10 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.

4.3.11 Whole blood for glycosylated hemoglobin

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

4.3.12 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.

4.3.13 Urine specimens

1. Thoroughly mix the random urine specimen.
2. Using a plastic transfer pipette, 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.

4.3.14 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.

4.3.15 Stage Two:

Approximately 15 minutes after venipuncture.

4.3.16 Lavender-stoppered Tube (Tube #2)

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.

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.

Fasten the purple screw caps onto the microvials in column 3, and leave them in the sponge rack.

Re-stopper collection tube #2, and discard it in a biohazard waste bag.

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.

4.3.17. 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.

4.3.18. Final Blood Processing

Remove the red and gray top tube from the centrifuge and place it in the sponge test tube rack.

Remove the stopper from tube #1. Using a plastic transfer pipette, aliquot all of the serum equally into the five tubes in column 1.

Fasten red screw caps on each of these vials.

Replace the stopper on the red and gray-stoppered blood collection tube and discard it in a biohazard waste bag.

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.

4.3.19. Black and blue-stoppered tubes (#4)


This tube is to be shipped to the Central Laboratory without centrifugation.

Shipments of tube #4 must occur daily, and the specimens must be stored at ambient temperature.

Tube #2 (see above) may be shipped within 48 hours of collection.

4.3.20. 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 (minus the urine specimen set aside for local analyses) 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. 

STORAGE AND SHIPPING

Storage

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.

Ambient Specimens

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

Refrigerated Specimens

Refrigerated specimens of whole should be sent to the Central Laboratory (one tube 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.

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 Clinic during a week, two or three weeks of frozen specimens can be combined into one shipment.

Ship CPT specimen 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 air bill. Do not over-estimate the package weight.

Packaging Instructions (frozen specimens)

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

Place a layer of dry ice on the bottom of the styrofoam box.

Put half of the bags of specimens into the styrofoam box on top of the dry ice.

Layer more dry ice on top of and around the sample bags.

Put the remaining specimen bags into the styrofoam box on top of the dry ice.

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.

Place packing material (e.g. bubble wrap) on top of the dry ice to fill the box.

Place the paper shipping forms on top of the packing material. The shipping forms and instructions are shown in Appendix 3.

Seal the outer box tightly with strapping tape. Affix UN3373 label to outside of box.

Address the box and contact Federal Express for pickup.

If necessary, more than one box may have to be shipped per week.

Packaging Instructions (ambient specimens)

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

Close the mailer and place it inside a large zip-seal storage bag. Press the air out of the bag and seal.

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.

Place the paper shipping forms on top of the packing material. The shipping forms and instructions are shown in Appendix 3.

Seal the outer box tightly with strapping tape. Affix UN3373 label to outside of box.

Address the box and contact Federal Express for pickup.

If necessary, more than one box may have to be shipped per day.

Packaging Instructions (refrigerated specimens)

Place refrigerated specimens into a three-tube foam mailer system. Place the mailer in a zip-seal bag.

Press the air out of the bag and seal.

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.

Place the paper shipping forms on top of the packing material. The shipping forms and instructions are shown in Appendix 3.

Seal the box tightly with strapping tape. Affix UN3373 label to outside of box.

Address the box and contact Federal Express for pickup. This shipment occurs on Tuesdays and Thursdays.

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 Clinic 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

Spot Urine

3.5 Microalbuminuria study

A urine sample is collected on all JHS participants at Visit 3 in order to perform assays for microalbuminuria. Procedures for the collection of the urine sample are provided below.

3.5.1 Rationale

A primary focus of Visit 3 is the continuation of the assessment of the risk factors associated with atherosclerosis and other aspects of coronary heart disease and stroke.

3.5.2 Procedures for Collecting the Urine Specimen

A mid-stream urine sample is collected from each participant (preferably) at the beginning of the clinical exam.

3.5.2.1 Participant Instructions

After participants complete the reception work station activities and are taken to change clothes, they are informed about the urine collection by saying something like:

“During your exam, we hope to collect a urine specimen. You may do that as you change clothes for the exam. Or, if you wish to do it later, please notify us when you need to use the bathroom.”

The urine specimen is collected at the exam center whenever the participant needs to void. If the participant has not voided by the time of the exit interview, the participant is asked to void at that time.

When the participant is ready to void, a specimen cup (labeled with his/her ID) and lid and a TIME VOIDED label are provided by the staff member working with the participant at that time. The participant is instructed to

1. void in the cup, filling it if possible, and place the lid securely on top of the container
2. record the time of voiding on the label, and

3. bring the specimen cup back to the staff member, OR
4. place the sample container in a refrigerator designated for urine samples, and report to a staff member that the specimen has been collected, depending on locally approved OSHA regulations.

Bathrooms are equipped with a wall clock and pencils for participants to use in recording the time of voiding on the label. The staff member verifies the participant has written the "time voided" on the label, and assesses the adequacy of the sample for processing. If insufficient, the participant is requested to void again in a clean container prior to leaving the exam center. A note is made on the participant's Itinerary Sheet that a second sample is needed by the JHS staff person who observes the placement of the participant's urine specimen in the refrigerator. A note can also be made on the participant's first sample that a second sample is needed. The optimal time for the collection of the second specimen is after the snack when the participant is changing back into street clothes. The instructions for providing the urine sample are repeated to the participant at that time.

Prior to processing, the laboratory staff records whether a urine sample was obtained and transcribes the collection time of the urine void from the ID label onto each participant's LABORATORY (SUC) form (Appendix 3.6.a).

3.5.3 Training

Training in the provision of instructions to participants for the collection of urine specimens is provided for new staff by a certified laboratory technician, the Manager Research Clinic or designee.

3.5.4 Certification

No certification is required.

3.5.5 Quality Control

Techniques and adherence to protocol are observed by Data Management, Information Technology and Quality Assurance monitors; the quality of the urine specimens and missing are monitored by the Quality Control Subcommittee.

3.5.6 Data Collection

Information on the collection and processing of urine samples is recorded on the paper version of the Laboratory (SUC) form for delayed data entry. When the first urine sample is insufficient for processing, the participant is asked to provide a second sample, which is mixed with the first. The time of the urine sample, however, is recorded on the Laboratory form as the hour and minutes of the last voided specimen. The assessment of volume adequacy for the Laboratory form is made immediately prior to processing.

4.4 Snack

A light snack is scheduled as soon as possible after venipuncture 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.

4.4 Cardiac Magnetic Resonance Imaging (MRI) for Morphologic Structure, Function and Flow Measurements

The purpose of the Magnetic Resonance Imaging (MRI) cardiac imaging, in Exam Cycle 3, is to image the heart and aorta in ~2000 African Americans located in Jackson, Mississippi metropolitan area. The MRI will be done in the UMMC Imaging Center at the Pavilion on the UMMC campus. Selected participants will be eligible to participate in this components of the study.

4.4.4 Rationale

Accurate, noninvasive assessment of even subtle alterations in the cardiac structure and function is crucial to the characterization of subclinical cardiovascular disease. MRI provides the capability to assess cardiac structure and function in asymptomatic individuals with little or no risk. The measurements of JHS participants will include

Structural and functional measures of the heart, including ejection fraction and LV wall thickening

*Sub-clinical atherosclerosis in the aorta (wall thickness)

*Vascular compliance and pulse wave velocity in the aorta

*Regional (intra-myocardial) motion and mechanical strain (Tagging)

The MRI data will provide:

1. The basis for determining how subclinical disease progresses to clinical disease.
2. The relationship of MRI parameters to existing measures to CVD and the predictive value of these measures for progression to clinical events.
3. The refinement of risk stratification algorithms that reliably identify high risk persons for targeted interventions in a cost-effective manner.
4. The assessment of risk estimates in subgroups of participants according to ethnic background/race.

Emerging science on obesity, heart failure, the metabolic syndrome, other studies' experience, and unpublished results make it clear that the JHS MRI exam presents a unique opportunity to address numerous highly relevant CVD issues which are not being addressed in other NHLBI studies or are not powered sufficiently to address the issue in African Americans. We believe that the emerging science on structure (i.e. left ventricular mass) and function of the heart, diabetes, and hypertension justify measuring directly phenotypes related to heart structure and function.

Magnetic resonance imaging is capable of determining soft tissue characteristics of the carotid artery wall, including wall thickness, plaque size, composition and lumen size. The potential for finding abnormalities related to small vessel disease of the heart represents a tremendous opportunity for enhanced understanding of ventricular dysfunction and congestive heart failure. MRI represents a relatively new imaging modality for epidemiologic studies. For established risk factors, MRI offers high degree of reproducibility and the ability to successfully image left ventricular mass on a greater proportion than echocardiography. MRI is also much more sensitive to the presence of disease.

Studies have shown that African Americans have a significantly higher prevalence of LVH compared to whites, regardless of how LVH was defined. A study by Drazner et. al. indicated that: LVH prevalence was 14% in African-American women, 3.4% in white women, 14% in African-American men, and 6% in white men when defined by body surface area. LVH indexed to height revealed a prevalence of 47 percent in African-American women, 22 percent in white women, 25 percent in African-American men, and 8.7 percent in white men. Understanding the effect of hypertension, diabetes and other CVD risk factors on the heart, might explain the racial/ethnic disparity in cardiovascular diseases such as heart failure, valvular heart disease and atrial fibrillation

4.7.2 Participant Selection and Scheduling

9. Two JHS participants can receive an MRI per day.

4.7.3 Preparation for the MRI

1. A JHS Clinic staff/Navigator will be on site at the Pavilion for participant enrollment, screening and to facilitate getting the participant to the MRI suite.
2. The JHS Clinic staff/Navigator will greet the participant and confirm his/her appointment.
3. The JHS Clinic staff/Navigator will be responsible for explaining and obtaining consent for the MRI examination.
4. The JHS Clinic staff/Navigator will accompany the participant to the waiting area next to the MRI and inform the MRI Technologist.

4.7.4 MRI Procedure and Participant Instructions

1. Radiology staff will register the participant into the PACS system
 2. The MRI Technologist will conduct safety screening before the participant enters the MRI environment
1. First ask the participant if he/she has ever had an MRI? They may have already been through this as a patient for a back injury, etc. If so, this scan may be as easy or even easier.

If the subject has not had an MRI before, show them the informational brochure with the picture of the machine and talk about the fact that the subject will be inside it for about 45 minutes or so. Mention that it is light inside and the subject will have a call button to talk to the technologist. The participant will be given ear protection because the machine will make knocking and buzzing noises.

There are no dyes or injections with this study so it's very safe as long as the subject has no exclusions to MRI. You are lucky at Jackson to have an excellent MRI from the participant's point of view because it's relatively short and has more space inside than some other types of MRIs.

2. You can use your consent form as a guideline for whether to person is qualified and willing to undergo the MRI. As you go through the consent, talk about the magnetic nature of the scan and whether the subject has any implanted devices such as an ICD or pacemaker or if the person possibly has imbedded shrapnel or the like, all of which are exclusions. Permanent makeup is another exclusion for undergoing an MRI as a study subject. The risk of claustrophobia should also be discussed if the subject has not had an MRI before.

Below are some objects that may be removed before undergoing MRI:

- a) Hearing aids

- b) Some partial plates or dentures depending on what they are made of (fillings and crowns are not a problem)
- c) Some types of medicine patches
- d) Body piercing jewelry

Items that should be discussed with the MRI technologist (if you have doubt, call the MRI experts before scheduling the subject and check):

- a) Coronary or carotid artery stents (these must be at least 6 weeks old before the MRI is done)
 - b) Implanted devices such as rods, pins, screws, CABG wires etc (chances are these are fine for MRI, but should be noted).
 - c) Filters, coils, shunts and other complex implants should be discussed with the MRI technologist or safety officer.
3. When the subject arrives at the MRI center, the MRI technologist will go over all the above checklist items and more to make sure it's safe for the participant. The subject will then have their blood pressure measured after resting 5 min (hope you guys can do this). The technologist will go over instructions with the subject and have them remove any items that need to be removed before entering the MRI suite. The subject will lie on a table that will move into the machine and the technologist will attach 3 ECG leads to the chest and a pulse monitor to the finger. The technologist will then place the MRI coils on the subject's chest and abdomen. These coils are basically used as antennas to enhance the MRI signal. They look like vests and weigh a couple for pounds each and are buckled into place. The technologist will put headphones on the subject or give them earplugs. The subject will also be given a call button to press if they need help during the scan.
4. The cardiac MRI process itself should also be discussed with the subject whether they have had an MRI before or not. The main thing the subject will be asked to do is to breathe as the technologist instructs and lie as still as possible. The technologist will frequently ask the subject to "take a deep breath in and blow it all the way out, take a deep breath in and hold your breath" (the technologist will say this at a pace of about 8 or so seconds). The subject will then need to hold their breath for between 8 and 20 seconds depending on the sequence being run. There will also be times when the subject will be asked to breathe normally and there may be periods of silence. The technologist will keep the patient informed and ask how they are doing over the intercom.

3.

4.7.5 Identification of Alert Findings and Procedure for Reporting Results

- 1. Wake Forest University Health Systems will perform the interpretation of the Cardiac MRI examinations for clinically significant findings.
- 2. The results of the reading will be transmitted to Dr. Herman Taylor, PI of the Jackson Heart Study with the JHS unique identifier to identify the participant.
- 3. The JHS will then include this information in the results report generated by the JHS Clinic for the JHS participants and their healthcare providers as appropriate.
- 4. UMC will archive a copy of the exam on the UMC Phillips PACS
 - 1. The Reading Center at Wake Forest will perform the ultimate interpretation of the Cardiac MRI examinations for clinically significant findings.

The Data Acquisition MR technologist at UMMC, however, will immediately alert the local radiologist of any potential clinically significant abnormality at the time the JHS participant is being imaged.

- 2. If the local radiologist determines that the MR abnormality

constitutes an alert (immediate or urgent referral), the:

- a) The local radiologist will instruct the technologist to make and archive a film copy of the MR scan.
- b) The local radiologist will telephone the JHS PI, and will initiate notification protocol for participant and his/her health care provider
- c) Arrangements for further medical evaluation will be made through discussions involving the participant and health care provider.
- d) Alert will be noted on MRI Scan Coding Form Sent to Reading Center.

The Reading Center has established the following Alert Status Categories

The MR Reading Center physician will record the participant's alert status in the MR results data file at the time of image interpretation.

- 0 = Normal
- 2 = Abnormal
- 3 = Urgent referral

Normal

- a.) No clinically significant findings

Abnormal

Requires follow-up within one week

- a.) Abnormality which may require medical evaluation as deemed by the participant's physician.
- b.) Findings which either (1) require further medical evaluation, or (2) the participant should be made aware of the findings so they may discuss these findings with a physician.

Urgent Referral

Requires direct referral to a hospital or clinic

- a.) Abnormality which requires immediate medical evaluation, typically within one to several days following the MRI examination.
- b.) Phone call and written report to the Field Center PI or designee
- c.) If the alert had previously been handled at the JHS (see below), then no further action is necessary.
- d.) If the alert had not been triggered at the JHS Reading Center, the Coordinator will contact the JHS PI and the notification protocol will be initiated.

The Reading Center has established the following results categories:

No Participant Referral Indicated / Normal

- 1. No clinically significant findings
- 2. Cardiac function parameters: ≤ 2 measures beyond 2 standard

deviations of normal

Abnormal

1. Cardiac function parameters: >2 measures beyond 2 standard deviations of normal
2. Ascending aortic size ≥ 4.5 cm – 4.9cm
3. Pericardial effusion > 4 mm
4. Pleural effusion > 1 cm
5. Possible mass or tumor
6. Any other abnormality deemed by the RC PI as abnormal.

Urgent Participant Referral

1. Ascending aortic size \geq or = 5 cm
2. Aortic dissection
3. Definite mass or tumor
4. Cardiac or pulmonary thrombus
5. Any other abnormality deemed by the RC PI as immediate

Reading Center Results Reporting Protocol Communication with JHS by RC

1. The MR Reading Center will send the participant's MR results data file to the JHS Coordinating Center by electronic mail.
2. The participants MRI result values derived from the MASS analysis program will be compared to the expected index ranges for gender and indexed values by body surface area to determine the type of letter he/she will receive. There will be two categories of results letters that a participant could receive.
 - a) Normal for Age
 - b) Possible Finding
3. The Coordinating Center will in turn send the MR results letter to the JHS by electronic mail.

Communication with Coordinating Center

1. The JHS Exam Center will review each participant's referral status when the MR results letters are received from the Coordinating Center.
2. Likewise, the JHS Exam Center will receive and review any MR results data files sent as alerts from the Reading Center.

Exam Center Reporting of Results

1. Reporting of results will be made to the JHS participant, referring physician or both in the form of a letter or telephone contact. If necessary, the JHS PI or other clinical staff will consult Data Acquisition Center's radiologist.
5.
 - 5.7.6 Reporting Incidental Findings
 1. A Radiologist at Wake Forest University performs a clinical interpretation of the MRI and informs the Clinic, through a dictated report, of any significant incidental findings.
 2. Clinic staff will enter the incidental findings into the Local Exam Interpretation (LEI) form

3. The Clinic will be responsible to communicating incidental findings to participants and their health care provider (if one was identified)

4.7.7 Training

The UMMC Department of Radiology is responsible for the performance of the MRI examinations, and thus conducts the training for the MRI procedure. Please refer to MRI Manual 9.

4.7.8 Certification

The MRI Reading Center is located at Wake Forest University, and is responsible for the certification of UMMC radiology technicians performing the MRI. Please refer to MRI Manual 9.

4.7.9 Quality assurance

UMMC Radiology department and Wake Forest Reading Center Staff are responsible for quality assurance for the procedure. Please refer to MRI manual 9.

4.7.10 Data collection

See Reading Center Manual for description of data collection and transferal to Coordinating Center.

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 3. At the end of the Clinic 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, 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.

At the Clinic , 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	≥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 ¹	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 ² or DBP < 80	Recheck in 2 years (no JHS referral)	Your blood pressure is normal

¹ 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). ² 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 Clinic 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 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 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.

Jackson Heart Study Protocol

Manual 9

Data Management System

Visit 3

Version 3.0

October 8, 2008

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, 3, and 4 describe the operation of the Cohort Procedures, Blood Pressure and Central Laboratory and Specimen Repository Components of the study. Manuals 5 and 6 comprise Electrocardiography and Magnetic Resonance Image studies, respectively. Manual 7 comprises of Morbidity and Mortality Classifications. Manual 8 articulates the quality assurance and control activities of JHS Examination 3 components. Quality control includes activities that are designed to assure quality of data, which take place prior to the collection of data. Quality control relates to efforts during this study to monitor the quality of data. Detailed Manuals of operation for specific procedures, including those for Blood Pressure and Quality Control, make up Manual 4 and 5. The Data Management System is described in Manual 9.

JHS Study Protocols and Manuals of Operation

MANUAL	TITLE
1	General Description and Study Management
2	Cohort Component Procedures
3	Blood Pressure
4	The Central Laboratory and Specimen Repository
5	Electrocardiography
6	Magnetic Resonance Imaging
7	Morbidity and Mortality
8	Quality Control
9	Data Management

MANUAL 9 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

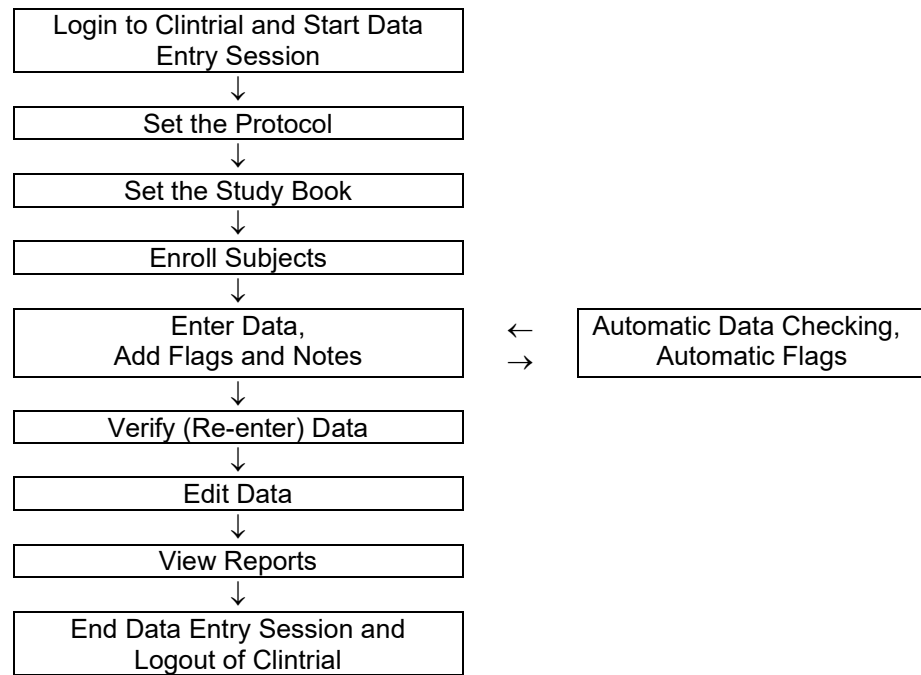
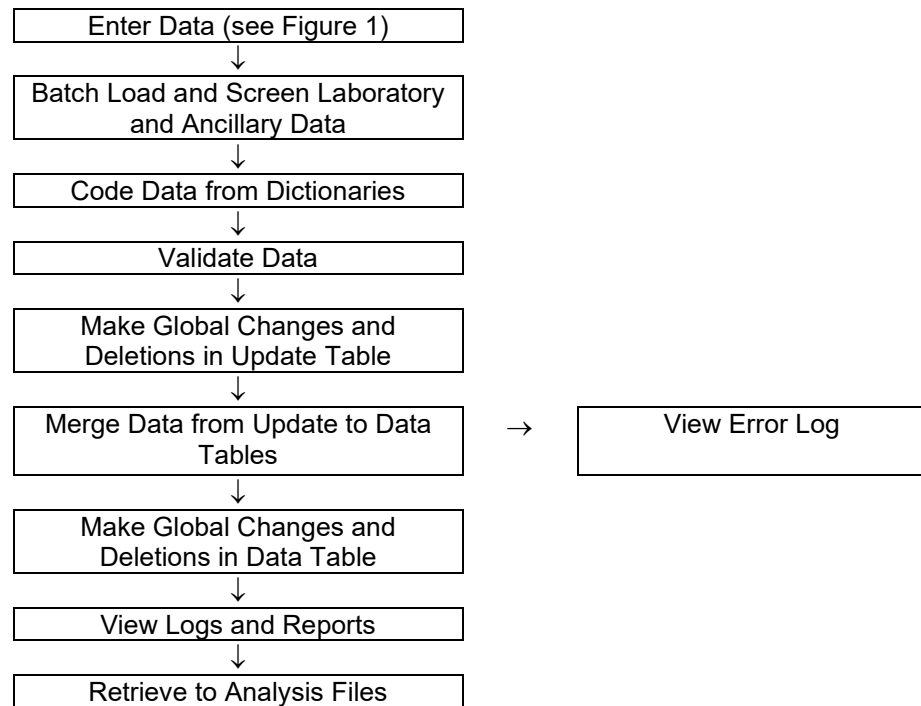


Figure 2 Data Management Workflow



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 4.5 software manuals and from the Clintrial 4.5 Design Training Guide published by Domain Pharma Corporation. Clintrial is a trademark of Domain Pharma Corporation.

The current release of Clintrial 4.5 stores data in an Oracle9i database. Oracle is a registered trademark of Oracle Corporation.

The SAS® System Version 9.1 from SAS Institute Inc. is used in writing the custom reports and for the data retrieval process in the JHS DMS.

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 4.5 > 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. The Family Study Component of this study is organized and the data is stored and processed in Progeny and the Genetic Cluster Server. The surveillance component is also processed outside ClinTrial since abstraction data collected via laptop using database programmed in FoxPro for data abstraction which is processed by the JHS Events Ascertainment Reading Center at University of North Carolina at Chapel Hill.

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:

- **EXAM** (center exam)
- **ANNUAL** (annual follow-up data)

An enrollment study book named **ENROLL** was used in Visit 1 to exclusively enroll study participants.

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_EXAM 3**.
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, **EXAM**.
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)

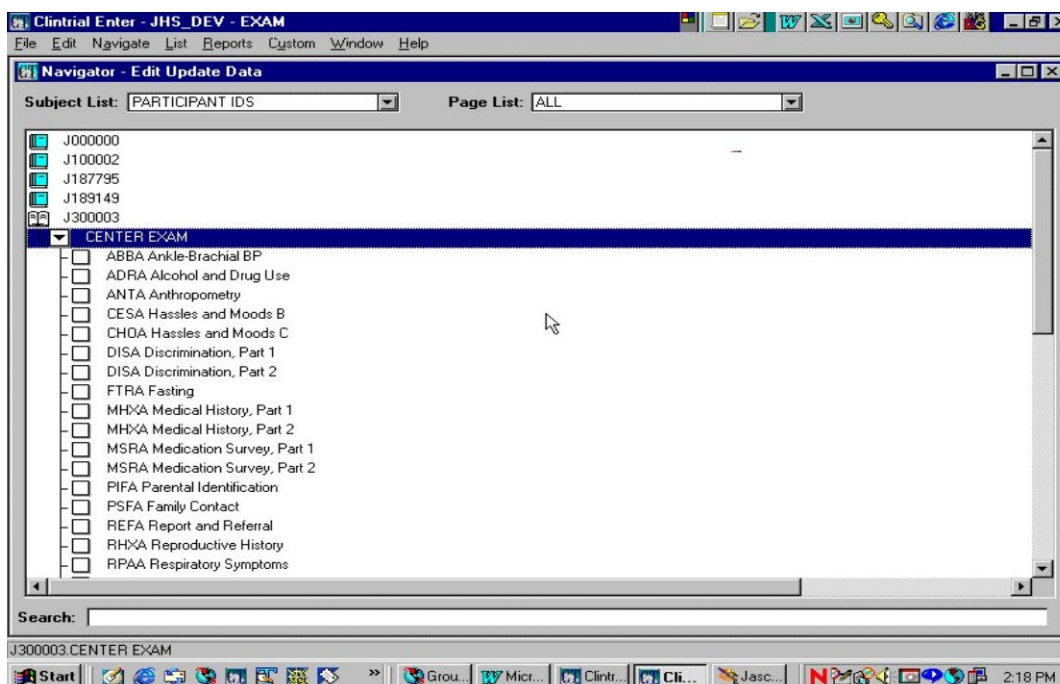


Figure 4 Navigator Menu Commands

Menu command	Description
Go To	Open a form by using the Go To dialog box. Enter ID NUMBER, CONTACT YEAR, and PAGE number.
Go To Selected	Go to the study page highlighted in the Navigator.
Next*	Go to the next study page in the navigation order.
Previous*	Go to the previous study page in the navigation order.
Next Subject	Go to the current study page for the next subject.
Next Page	Go to the next study page for the current subject.
Previous Subject	Go to the current study page for the previous subject.
Previous Page	Go to the previous study page for the current subject.
Navigate by Subject	Set the navigation order to By Subject (list of subjects under each study page).
Navigate by Page	Set the navigation order By Page (list of study pages under each subject).
Expand	Expand the selected Navigator order.
Collapse	Collapse the selected Navigator order.
Sort Subjects	Set the sort order for subjects in Navigator as ascending or descending.
Navigator	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 application window titled "Clintrial Enter - JHS_DEV - EXAM". The main window title is "J300003.CENTER EXAM.FTRA Fasting (UPDATE)". The form contains the following fields:

- ID NUMBER: J300003
- CONTACT YEAR: 1
- PAGE NUMBER: 610
- LAST NAME: ANDERSON
- INITIALS: NC
- PAGE REPEAT: (empty)

Below these fields is the "FTR Fasting Form" section with 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 and several open applications, including "Grou...", "Micr...", "Clintr...", "Cli...", and "Jasc...". The system clock shows 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, Don't Know, Refused, and Missing (Not Applicable). 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. 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)** or the special code for missing data 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
Tab or Enter	Next field.
Shift-Tab or Shift-Enter	Previous field.
Ctrl-Home	First field in page section (a partition of the study page).
Ctrl-End	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
Home	Moves cursor to the beginning of the field.
End	Moves cursor to the end of the field.
Ctrl-Right Arrow	Moves cursor one word to the right.
Ctrl-Left Arrow	Moves cursor one word to the left.
Escape	Restores a non-coded field to its original value.
Shift-Home	Selects text from cursor position to the beginning of the field.
Shift-End	Selects text from cursor position to the end of the field.
Shift-Right Arrow	Selects one character to the right.
Shift-Left Arrow	Selects one character to the left.
Ctrl-Shift-Right Arrow	Selects one word to the right.
Ctrl-Shift-Left Arrow	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 SBPC 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 SBPC 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:

FLAG CATEGORY (AND FLAG NAME)	Action
OVERRIDE	Use when overriding an edit range.
PERMANENTLY_MISSING	Use when a field value or form is permanently missing.
CANT_ENTER	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).
QUERY	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 retention 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.

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

Clintrials 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.

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.

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 9.1 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 9.1 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 9.1 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 which was developed and delivered to the JHSCC by UNC-CSCC has been modified for subsequent JHS examinations beyond VISIT 1.

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 4.5 > 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.

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 9 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. You will then be asked to choose the type of installation, click on "Custom Installation" then click on OK.
9. 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.
10. 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).
11. 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 4.5 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 XP Net8 Easy Config module by selecting the following: **Start > Programs > Oracle for windows > Oracle NET Configuration Assistant.**
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 4.5 > 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 4.5 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 4.5. 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 4.5 and click Add/Remove.
5. The directory C:\CT45 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 XP > Oracle Installer.**
2. Select all Oracle modules (shift-down arrow) in the rightmost column labeled "Products Installed at C:\ORAWIN" 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>
ADMIN	Admin	Non-protocol	DBA System	Full Full
	Design	Non-protocol	Global System	Full Full
	Tools	Non-protocol	SQL	Full
ANALYSIS	Retrieve	Protocol	Merged Library	Read Write
ENTRY	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 (CTSYS) 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 9

Data Management System

Visit 3

Version 3.0

October 8, 2008

For Copies, Please Contact:

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FOREWORD

This manual is one of a series of protocols and manuals of operation for the Jackson Heart Study (JHS). The complexity of the JHS requires that a sizeable number of procedures be described, thus this rather extensive list of materials has been organized into the set of manuals listed below. Manual 1 provides the background, organization, and general objectives of the JHS Study. Manuals 2, 3, and 4 describe the operation of the Cohort Procedures, Blood Pressure and Central Laboratory and Specimen Repository Components of the study. Manuals 5 and 6 comprise Electrocardiography and Magnetic Resonance Image studies, respectively. Manual 7 comprises of Morbidity and Mortality Classifications. Manual 8 articulates the quality assurance and control activities of JHS Examination 3 components. Quality control includes activities that are designed to assure quality of data, which take place prior to the collection of data. Quality control relates to efforts during this study to monitor the quality of data. Detailed Manuals of operation for specific procedures, including those for Blood Pressure and Quality Control, make up Manual 4 and 5. The Data Management System is described in Manual 9.

JHS Study Protocols and Manuals of Operation

MANUAL	TITLE
1	General Description and Study Management
2	Cohort Component Procedures
3	Blood Pressure
4	The Central Laboratory and Specimen Repository
5	Electrocardiography
6	Magnetic Resonance Imaging
7	Morbidity and Mortality
8	Quality Control
9	Data Management

MANUAL 9 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

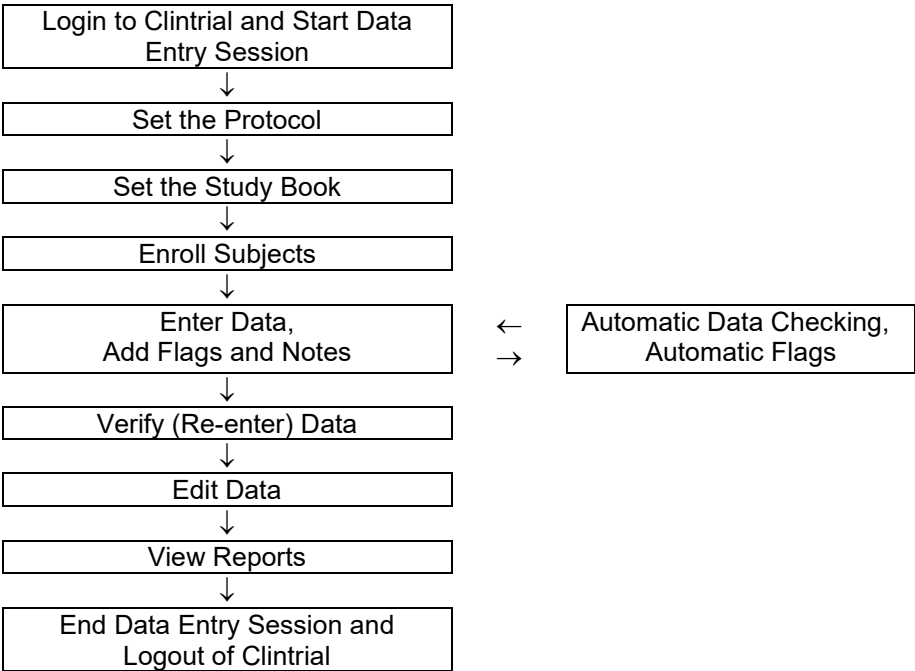
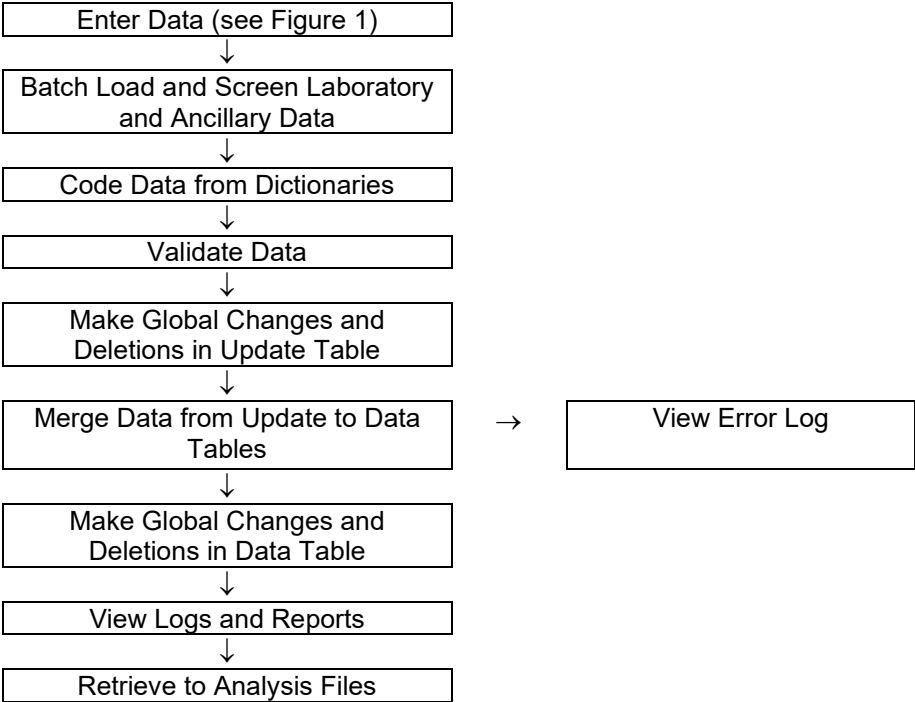


Figure 2 Data Management Workflow



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 4.5 software manuals and from the Clintrial 4.5 Design Training Guide published by Domain Pharma Corporation. Clintrial is a trademark of Domain Pharma Corporation.

The current release of Clintrial 4.5 stores data in an Oracle9i database. Oracle is a registered trademark of Oracle Corporation.

The SAS® System Version 9.1 from SAS Institute Inc. is used in writing the custom reports and for the data retrieval process in the JHS DMS.

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 4.5 > 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. The Family Study Component of this study is organized and the data is stored and processed in Progeny and the Genetic Cluster Server. The surveillance component is also processed outside ClinTrial since abstraction data collected via laptop using database programmed in FoxPro for data abstraction which is processed by the JHS Events Ascertainment Reading Center at University of North Carolina at Chapel Hill.

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:

- **EXAM** (center exam)
- **ANNUAL** (annual follow-up data)

An enrollment study book named **ENROLL** was used in Visit 1 to exclusively enroll study participants.

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_EXAM 3**.
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, **EXAM**.
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)

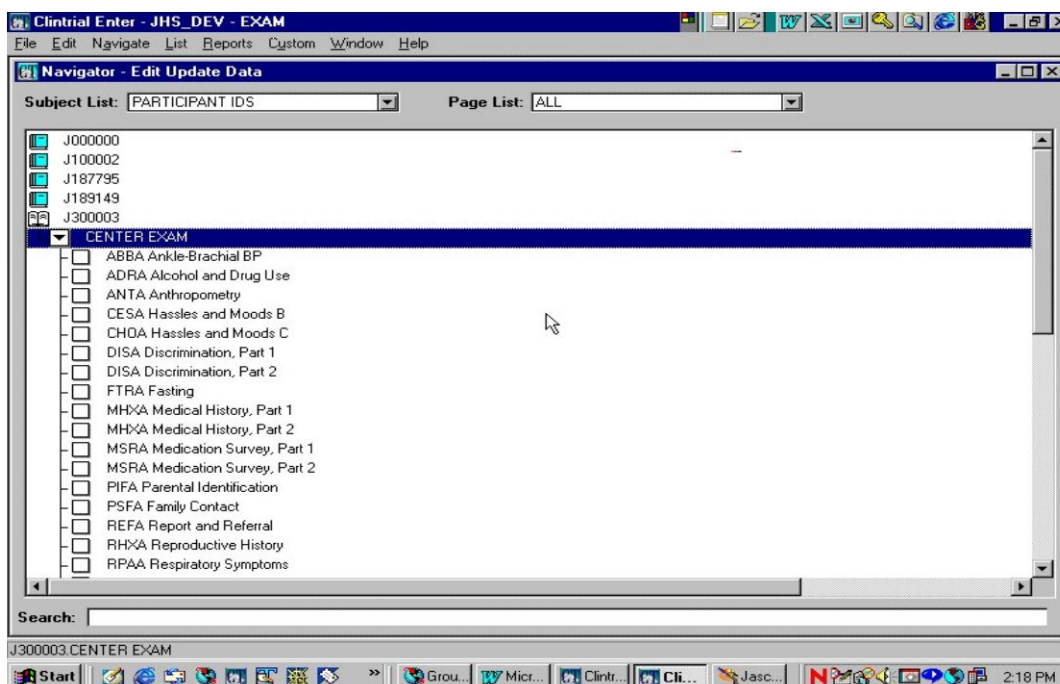


Figure 4 Navigator Menu Commands

Menu command	Description
Go To	Open a form by using the Go To dialog box. Enter ID NUMBER, CONTACT YEAR, and PAGE number.
Go To Selected	Go to the study page highlighted in the Navigator.
Next*	Go to the next study page in the navigation order.
Previous*	Go to the previous study page in the navigation order.
Next Subject	Go to the current study page for the next subject.
Next Page	Go to the next study page for the current subject.
Previous Subject	Go to the current study page for the previous subject.
Previous Page	Go to the previous study page for the current subject.
Navigate by Subject	Set the navigation order to By Subject (list of subjects under each study page).
Navigate by Page	Set the navigation order By Page (list of study pages under each subject).
Expand	Expand the selected Navigator order.
Collapse	Collapse the selected Navigator order.
Sort Subjects	Set the sort order for subjects in Navigator as ascending or descending.
Navigator	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:

<u>Field Type</u>	<u>Data Type</u>	<u>Description and Example</u>
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, Don't Know, Refused, and Missing (Not Applicable). 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. 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)** or the special code for missing data 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
Tab or Enter	Next field.
Shift-Tab or Shift-Enter	Previous field.
Ctrl-Home	First field in page section (a partition of the study page).
Ctrl-End	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
Home	Moves cursor to the beginning of the field.
End	Moves cursor to the end of the field.
Ctrl-Right Arrow	Moves cursor one word to the right.
Ctrl-Left Arrow	Moves cursor one word to the left.
Escape	Restores a non-coded field to its original value.
Shift-Home	Selects text from cursor position to the beginning of the field.
Shift-End	Selects text from cursor position to the end of the field.
Shift-Right Arrow	Selects one character to the right.
Shift-Left Arrow	Selects one character to the left.
Ctrl-Shift-Right Arrow	Selects one word to the right.
Ctrl-Shift-Left Arrow	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 SBPC 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 SBPC 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:

FLAG CATEGORY (AND FLAG NAME)	Action
OVERRIDE	Use when overriding an edit range.
PERMANENTLY_MISSING	Use when a field value or form is permanently missing.
CANT_ENTER	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).
QUERY	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 retention 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.

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.

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.

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 9.1 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 9.1 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 9.1 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 which was developed and delivered to the JHSCC by UNC-CSCC has been modified for subsequent JHS examinations beyond VISIT 1.

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 4.5 > 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.

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 9 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. You will then be asked to choose the type of installation, click on "Custom Installation" then click on OK.
9. 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.
10. 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).
11. 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 4.5 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 XP Net8 Easy Config module by selecting the following: **Start > Programs > Oracle for windows > Oracle NET Configuration Assistant.**
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 4.5 > 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 4.5 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 4.5. 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 4.5 and click Add/Remove.
5. The directory C:\CT45 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 XP > Oracle Installer.**
2. Select all Oracle modules (shift-down arrow) in the rightmost column labeled "Products Installed at C:\ORAWIN" 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_RECLEN	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>
ADMIN	Admin	Non-protocol	DBA System	Full Full
	Design	Non-protocol	Global System	Full Full
	Tools	Non-protocol	SQL	Full
ANALYSIS	Retrieve	Protocol	Merged Library	Read Write
ENTRY	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 6

Magnetic Resonance Imaging

Visit 3

Version 1.0

October 15, 2008

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FOREWORD

This manual is one of a series of protocols and manuals of operation for the Jackson Heart Study (JHS). The complexity of the JHS requires that a sizeable number of procedures be described, thus this rather extensive list of materials has been organized into the set of manuals listed below. Manual 1 provides the background, organization, and general objectives of the JHS Study. Manuals 2, 3, and 4 describe the operation of the Cohort Procedures, Blood Pressure and Central Laboratory and Specimen Repository Components of the study. Manuals 5 and 6 comprise Electrocardiography and Magnetic Resonance Image studies, respectively. Manual 7 comprises Morbidity and Mortality Classifications. Manual 8 articulates the quality assurance and control activities of JHS Examination 3 components. Quality control includes activities that are designed to assure quality of data, which take place prior to the collection of data. Quality control relates to efforts during this study to monitor the quality of data. Detailed Manuals of operation for specific procedures, including those for Blood Pressure and Quality Control, make up Manual 4 and 5. The Data Management System is described in Manual 9.

JHS Study Protocols and Manuals of Operation

MANUAL	TITLE
1	General Description and Study Management
2	Cohort Component Procedures
3	Blood Pressure
4	The Central Laboratory and Specimen Repository
5	Electrocardiography
6	Magnetic Resonance Imaging
7	Morbidity and Mortality
8	Quality Control
9	Data Management

Cardiac MRI Protocol Draft

Patient preparation (Page 2):

1. Blood Pressure
2. Patient setup

Brief scan overview:

1. Localizers (Scan 1-6)
2. Baseline white blood function (EF, morphometry- PIE software)
 - a. Four chamber (Scan 7)
 - b. Two chamber (Scan 8)
 - c. Three chamber (Scan 9)
 - d. Short axis stack (extend through atria) (Scan 10)
3. Short axis tagging – base, mid, apex with paired vertical and horizontal tags (results in 6 series- Intramyocardial strain use HARP software)
 - a. Base – horz & vertical (Scan 11 & 12)
 - b. Mid – horz & vert (Scan 13 & 14)
 - c. Apex –horz and vert (Scan 15 & 16)
4. Aorta Measurements
 - a. LAO Phase contrast (Scan 17)
 - b. Dark blood T2 aortic arch (Scan 18)
 - c. AX phase contrast aortic arch (Scan 19)
 - d. TRUFI abd aorta localizer (Scan 20)
 - e. Dark blood T2 aorta @ diaphragm (Scan 21)
 - f. AX phase contrast @ diaphragm (Scan 22)
 - g. Dark blood T2 aorta below renals (Scan 23)
 - h. AX phase contrast below renals (Scan 24)
 - i. Dark blood T2 aorta above bifurcation (Scan 25)
 - j. AX phase contrast above bifurcation (Scan 26)

Patient Preparation

1. Blood Pressure (measured after sitting 5 min).
2. Patient Setup for Cardiac scan
 - a. Place the three ECG leads on chest for Siemens Cardiac gating per training.
 - b. Attach PG sensor to finger.
 - c. Place headphones.
 - d. Place the two body matrix coils: one on chest, other on abdomen.
 - e. Instruct patient in proper breathing for scan: breathe in, breathe out, breathe in and hold it (not too deep).

Scan 1: 3-plane localizer Chest

Coil	Body Matrix
Plane	3-planes
FOV	400 mm
Slice thickness	7 mm
Spacing	
Averages	1
Matrix	240 x 384
Phase FOV	
Bandwidth	1130
TR	230
TE	1.1
Flip angle	65
Gating	cardiac
Sequence Variant	Tfi2dl_72
Sequence name	LOC_Trufi_MULTI Chest

Instructions: You should get a total of 11 images (1-3 sagittal, 4-6 coronal & 7-11 axial)

Scan 2: 3-plane localizer Abdomen

Coil	Body Matrix
Plane	3-planes
FOV	400 mm
Slice thickness	7 mm
Spacing	
Averages	1
Matrix	240 x 384
Phase FOV	
Bandwidth	1130
TR	230
TE	1.1
Flip angle	65
Gating	cardiac
Sequence Variant	Tfi2dl_72
Sequence name	LOC_Trufi_MULTIAbdomen

Instructions: You should get a total of 11 images (1-3 sagittal, 4-6 coronal & 7-11 axial)

Scan 3: localizer 2-Chamber (vertical long axis)

Coil	Body Matrix
Plane	oblique
FOV	400 mm
Slice thickness	7 mm
Spacing	
Averages	1
Matrix	144 x 192
Phase FOV	
Bandwidth	1130
TR	260
TE	1.1
Flip angle	65
Gating	
Sequence Name	LOC_Trufi_2CH

Instructions: 1 slice localizer plotted from the prior localizer which shows the left atrium and left ventricle.

Scan 4: localizer Short Axis (10 slices, base to apex)

Coil	Body Matrix
Plane	oblique
FOV	400 mm
Slice thickness	7 mm
Spacing	
Averages	1
Matrix	144 x 192
Phase FOV	
Bandwidth	1130
TR	260
TE	1.1
Flip angle	65
Gating	
Sequence Name	LOC_Trufi_SAX

Instructions: 10 slice localizer plotted from the 2 chamber localizer which shows the left atrium and left ventricle (only 4 of 10 shown below).

Scan 5: localizer 4-Chamber

Coil	Body Matrix
Plane	oblique
FOV	400 mm
Slice thickness	7 mm
Spacing	
Averages	1
Matrix	144 x 192
Phase FOV	
Bandwidth	1130
TR	260
TE	1.1
Flip angle	65
Gating	
Sequence Name	LOC_Trufi_4CH

Instructions: 1 slice localizer plotted from the prior short axis localizer.

Scan 6: localizer 3-Chamber

Coil	Body Matrix
Plane	oblique
FOV	400 mm
Slice thickness	7 mm
Spacing	
Averages	1
Matrix	144 x 192
Phase FOV	
Bandwidth	1130
TR	260
TE	1.1
Flip angle	65
Gating	
Sequence Name	LOC_Trufi_3CH_LOC

Instructions: 1 slice localizer plotted from the prior short axis localizer showing the left atrium, left ventricle and aortic root.

Scan 7: Cine 4 Chamber

Coil	Body Matrix
Plane	Oblique
FOV	400 mm
Slice thickness	7 mm
Spacing	20% 1.4 mm
Averages	1
Matrix	156 x 192
Phase FOV	81.3%
Bandwidth	930
TR	37.38
TE	1.13
Flip angle	82
Gating	cardiac
Option	
Sequence Variant	Tfi2d1_14
Sequence Name	Trufi_4CH_CINE

Instructions: 4 chamber CINE images (“true fisp” or trufi), one level, with ~ 25 images showing a beating heart.

Scan 8: Cine 2 Chamber

Coil	Body Matrix
Plane	Oblique
FOV	400 mm
Slice thickness	7 mm
Spacing	20% 1.4 mm
Averages	1
Matrix	156 x 192
Phase FOV	81.3%
Bandwidth	930
TR	37.38
TE	1.13
Flip angle	82
Gating	cardiac
Option	
Sequence Variant	Tfi2d1_14
Sequence Name	Trufi_2CH_CINE

Instructions: 2 chamber CINE images (“true fisp” or trufi), one level, with ~ 25 images showing a beating heart.

Scan 9: Cine 3 Chamber

Coil	Body Matrix
Plane	Oblique
FOV	400 mm
Slice thickness	7 mm
Spacing	20% 1.4 mm
Averages	1
Matrix	156 x 192
Phase FOV	81.3%
Bandwidth	930
TR	37.38
TE	1.13
Flip angle	82
Gating	cardiac
Option	
Sequence Variant	Tfi2d1_14
Sequence Name	Trufi_3CH_CINE

Instructions: 3 chamber CINE images (“true fisp” or trufi), one level, with ~ 25 images showing a beating heart.

Scan 10: Cine Short Axis Stack – Entire LV

Coil	Body Matrix
Plane	Oblique (short Axis)
FOV	400 mm
Slice thickness	8 mm
Spacing	25% 2 mm
Averages	1
Matrix	109 x 192
Phase FOV	81.3%
Bandwidth	930
TR	45.54
TE	1.07
Flip angle	78
Gating	cardiac
Option	Concatenations = 12
Sequence Variant	Tfi2d1_18
Sequence Name	Trufi_SAX_Stack

Instructions: 2 chamber CINE images (“true fisp” or trufi), five levels from the apex of the LV through the left atrium(apex, mid, base, LA-Ao, LA posterior), resulting ~ 275 images (11 series of ~25 images each) showing a beating heart.

Scan 11 & 12: Tagging Cine Short Axis Base of LV

Coil	Body Matrix
Plane	Oblique (short Axis, Base of LV)
FOV	400 mm
Slice thickness	8 mm
Spacing	25% 2 mm
Averages	1
Matrix	192 x 256
Phase FOV	75%
Bandwidth	170
TR	60
TE	4
Flip angle	12
Gating	ECG trigger (prospective)
Segments	7
Option	
Sequence Variant	FI2d1r5
Sequence Name	TAG_Grid_Base_SAX of LV

Instructions: Short axis tagging image through the base of the Left ventricle. Be sure that the tag lines are clearly visible throughout the cardiac cycle, if not repeat.

Scan 13 & 14: Tagging Cine Short Axis Mid Cavity of left Ventricle

Coil	Body Matrix
Plane	Oblique (short Axis, Mid cavity of LV)
FOV	400 mm
Slice thickness	8 mm
Spacing	25% 2 mm
Averages	1
Matrix	144 x 256
Phase FOV	75%
Bandwidth	170
TR	41.1
TE	3.75
Flip angle	78
Gating	ECG trigger (prospective)
Option	
Sequence Variant	FI2d1r5
Sequence Name	TAG_Grid_Mid_SAX of LV

Instructions: Short axis tagging image through the Mid (Papillary muscle level) of the Left ventricle. Be sure that the tag lines are clearly visible throughout the cardiac cycle, if not repeat.

Scan 15 & 16:**Tagging Cine Short Axis Apex**

Coil	Body Matrix
Plane	Oblique (short Axis, Apex of LV)
FOV	400 mm
Slice thickness	8 mm
Spacing	25% 2 mm
Averages	1
Matrix	144 x 256
Phase FOV	75%
Bandwidth	170
TR	41.1
TE	3.75
Flip angle	78
Gating	ECG trigger (prospective)
Option	
Sequence Variant	FI2d1r5
Sequence Name	TAG_Grid_Apex_SAX of LV

Instructions: Short axis tagging image through the apical region of the Left ventricle. Be sure the tag lines are clearly visible throughout the cardiac cycle, if not repeat.

Scan 17: Phase contrast LAO Thoracic Aorta

Coil	Body Matrix
Plane	Oblique
FOV	460 mm
Slice thickness	8 mm
Spacing	0
Averages	1
Matrix	128 x 128
Phase FOV	100%
Bandwidth	387
TR	80.65
TE	3.45
Flip angle	15
Gating	Peripheral gating (PG)
Option	
Sequence Variant	FI2d1_6
Sequence Name	PC LAO Thoracic Aorta & PC LAO Thoracic Aorta_P

Instructions: This will be a CINE image of the “Candy-cane” view of the thoracic aorta plotted from the prior axial image. Two series of ~30 images will be generated (magnitude and velocity).

Scan 18: Dark Blood T2 Fatsat Thoracic Aorta

Coil	Body Matrix
Plane	Axial
FOV	300 mm
Slice thickness	6 mm
Spacing	0
Averages	1
Matrix	320 x 320
Phase FOV	80% (Phase encode A-P)
Bandwidth	179
TR	800
TE	89
Flip angle	180
Gating	cardiac
Option	Fat sat
Sequence Variant	Tse2d1_11
Sequence Name	DBT2 FS Ax DESC_AO-diaphragm

Instructions: plotted from the 3 plane localizer of the chest at the level of the right pulmonary artery.

Scan 19: Phase contrast Axial Thoracic Aorta

Coil	Body Matrix
Plane	Axial
FOV	360 mm
Slice thickness	8 mm
Spacing	0
Averages	1
Matrix	108 x 192
Phase FOV	75%
Bandwidth	389
TR	76.55
TE	3.14
Flip angle	15
Gating	ECG trigger, prospective
Option	
Sequence Variant	flfqshph
Sequence Name	PC AX Thoracic Aorta & PC AX Thoracic Aorta_P

Instructions: This will be at the same axial level through the ascending and descending aorta as the dark blood T2 images. CINE phase contrast images throughout the cardiac cycle will generate two series of ~30 images will be generated (magnitude and velocity).

Scan 20: TRUFI abd aorta localizer

Coil	Body Matrix
Plane	Coronal
FOV	440 mm
Slice thickness	7 mm
Spacing	0
Averages	1
Matrix	256 x 166
Phase FOV	81%
Bandwidth	977
TR	2.62
TE	1.11
Flip angle	70
Gating	nongated
Option	
Sequence Variant	tfi 2d1
Sequence Name	LOC_ABD_Aorta_trufi

Instructions: This will be a CINE image of the of the abdominal aorta plotted from localizers to include the aorta from the diaphragm through the aortic bifurcation. Typically you should oblique the image based on the sagittal image to center the abdominal aorta in the slice plane. Two series of ~30 images will be generated (magnitude and velocity).

Scan 21: Dark Blood T2 Fatsat Abdominal Aorta - diaphragm

Coil	Body Matrix
Plane	Axial
FOV	200 mm
Slice thickness	5 mm
Spacing	0
Averages	4
Matrix	320 x 320
Phase FOV	80% (Phase encode A-P)
Bandwidth	179
TR	800
TE	26
Flip angle	180
Gating	cardiac
Option	SPAIR Fat sat
Sequence Variant	Tse2d1_17
Sequence Name	DB T2 FS AX DESC_AO-diaphr

Instructions: Plotted at the diaphragm on the aorta localizer of the abdomen. **NOTE:** Non-breathheld.

Scan 22: Phase contrast Axial Abdominal Aorta - diaphragm

Coil	Body Matrix
Plane	Axial
FOV	360 mm
Slice thickness	4 mm
Spacing	0
Averages	1
Matrix	108 x 192
Phase FOV	75%
Bandwidth	389
TR	76.55
TE	3.14
Flip angle	15
Gating	ECG trigger, prospective
Option	
Sequence Variant	flfqshph
Sequence Name	PC AX DESC_AO-diaphragm & PC AX DESC_AO-diaphragm_P

Instructions: Plotted at the diaphragm, the same as the previous T2 scan. CINE phase contrast images throughout the cardiac cycle will generate two series of ~30 images will be generated (magnitude and velocity) for each location.

Scan 23: Dark Blood T2 Fatsat Abdominal Aorta - renals

Coil	Body Matrix
Plane	Axial
FOV	200 mm
Slice thickness	5 mm
Spacing	0
Averages	4
Matrix	320 x 320
Phase FOV	80% (Phase encode A-P)
Bandwidth	179
TR	800
TE	26
Flip angle	180
Gating	cardiac
Option	SPAIR Fat sat
Sequence Variant	Tse2d1_17
Sequence Name	DB T2 FS AX ABD AOR-renals

Instructions: Plotted 2cm below the renal arteries on the abdominal aorta localizer. **NOTE:** Non-breathheld.

Scan 24: Phase contrast Axial Abdominal Aorta - renals

Coil	Body Matrix
Plane	Axial
FOV	360 mm
Slice thickness	4 mm
Spacing	0
Averages	1
Matrix	108 x 192
Phase FOV	75%
Bandwidth	389
TR	76.55
TE	3.14
Flip angle	15
Gating	ECG trigger, prospective
Option	
Sequence Variant	flfqshph
Sequence Name	PC AX DESC_AO-Renals & PC AX DESC_AO-Renals_P

Instructions: Plotted 2cm below renals, the same as the previous T2 scan. CINE phase contrast images throughout the cardiac cycle will generate two series of ~30 images will be generated (magnitude and velocity) for each location.

Scan 25: Dark Blood T2 Fatsat Abdominal Aorta - bifurcation

Coil	Body Matrix
Plane	Axial
FOV	200 mm
Slice thickness	5 mm
Spacing	0
Averages	4
Matrix	320 x 320
Phase FOV	80% (Phase encode A-P)
Bandwidth	179
TR	800
TE	26
Flip angle	180
Gating	cardiac
Option	SPAIR Fat sat
Sequence Variant	Tse2d1_17
Sequence Name	DB T2 FS AX ABD Aorta-Bifu

Instructions: Plotted 2cm above the aortic bifurcation.

NOTE: Non-breathheld.

Scan 26: Phase contrast Axial Abdominal Aorta - bifurcation

Coil	Body Matrix
Plane	Axial
FOV	360 mm
Slice thickness	4 mm
Spacing	0
Averages	1
Matrix	108 x 192
Phase FOV	75%
Bandwidth	389
TR	76.55
TE	3.14
Flip angle	15
Gating	ECG trigger, prospective
Option	
Sequence Variant	flfqshph
Sequence Name	PC AX ABD Aorta-bifurcati & PC AX ABD Aorta-bifurcati_P

Instructions: Plotted 2cm above aortic bifurcation, the same as the previous T2 scan. CINE phase contrast images throughout the cardiac cycle will generate two series of ~30 images will be generated (magnitude and velocity) for each location.

***** End of Document*****

Jackson Heart Study Protocol

Manual 8

Quality Control

Visit 3

Version 1

October 10, 2008

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FOREWORD

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JHS Study Protocols and Manuals of Operation

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1	General Description and Study Management
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6	Magnetic Resonance Imaging
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8	Quality Control
9	Data Management

Manual 8 Quality Control

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1.0 INTRODUCTION

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

- 1) Detailed protocol development. A clear description of the study design, training, certification, and the various data collection activities provides the blueprint for the study. Each protocol is a written reference for staff and researchers. Procedures for handling the routine, as well as the exceptional, are given. Those protocols constitute the JHS Manuals of Operation.
- 2) Training and updating training. Training is the transfer of the study plans in the protocol to the research staff. The process has resulted in clarification and revision of the protocol. Special materials for this purpose have been developed for the Jackson Heart Study (JHS) and are the basis for continuing education during the study. Continued investment in quality data during the study is made by periodic refresher training sessions, which review the protocol and update personnel on any changes which have occurred.
- 3) Certification. Criteria to examine the adequacy of an individual's training have been established. Individuals meeting these criteria are qualified to execute a protocol or a segment of it. Certification and periodic re-certification indicate that an acceptable performance standard has been mastered or an adequate knowledge of material has been achieved. The Coordinating Center (CC) monitors the study to ensure that staff performs only those functions for which they are certified and that re-certification activities are implemented as planned and as scheduled.

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

- 1) Observation monitoring. Over-the-shoulder observations of staff by supervisors or those who wrote the protocols identify techniques that need improvement and points where the protocol is not understood or not being followed. Also, periodic monitoring visits are made to the Examination Center (EC) by Coordinating Center (CC) staff to observe actual clinic activities. Detailed checklists are used to assess strict adherence to protocol. Immediate feedback is given, and general recommendations for improvements are sent to the Steering Committee for action.
- 2) Interview monitoring Another form of observation in the JHS study takes place with the interview portion of the protocol. A supervisor reviews the tapes on a random basis, reviewing at least one of each type per month. The supervisor checks for adherence to protocol and for accuracy of recorded responses. The director of retention conducts weekly over-the-shoulder observation of recruiters in the field. Two recruiters are randomly selected for each week. In addition to field observation of the recruiters, the director for retention conducts weekly phone calls to a random subset of participants to obtain feedback on their recruitment experience. The subset of participants chosen is from the pool of participants interviewed by the recruiters who are not chosen for field observation that week. The data collection instruments for field observation and phone calls to participants are in Appendix II.
- 3) Quantitative monitoring. Random repeated measurement by the same and by different technicians are used as quality control tools. There are two important benefits from random repeat measurements. First, randomly re-doing a fraction of an individual's work is likely to stimulate a better overall quality of data. Second, the duplicate determinations provide

measurements of data quality. At the time of reporting the results of the study, it is important to establish that the "error" in the data is not so large as to threaten the validity of conclusions. Actual study data are useful to monitor quality of performance. Mean and standard deviations of study variables, by technician, are monitored for differences among technicians or trends over time. Digit preference in anthropometry or blood pressure measurement is monitored with study data.

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

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

1.1 Monitoring of Data Quality and Implementing Corrective Action

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

- The role of the JHS CC in quality assurance and control is described later in this manual. More specifically, as the repository for JHS Study data, the CC is responsible for preparation and dissemination of QC reports. These reports, consisting of tabulated data and summary statistics, identify specific QC problems. The JHS CC, via its CC-EC liaison, maintains contact with the EC to confirm that it has been notified of a problem and that corrective action has been implemented. The CC maintains central logs of data quality problem and solutions. The CC conducts periodic EC monitoring during which CC staff participate in and observe a routine JHS clinic visit. In response to requests from the SQA, the CC replicates pertinent sections of quality control reports prepared by reading centers/laboratories. Some external quality control programs for the reading centers/laboratories are administered by the CC and reported to the SQA.

The distribution of the QC reports and the designation of persons or groups responsible for responding to the reports and implementing corrective action are described below. The EC and/or reading centers are given the responsibility of reading, implementing corrective action, and responding to the reports in their respective area. Monitoring reports for protocol deviations, recurrent problems, or temporal trends is the responsibility of the SQA. Immediate QC problem sent to the appropriate centers including the EC directly for correction with a record kept by the reading center/laboratory/CC. The distribution of periodic reports described latter in this manual is as follows:

- 1) QC reports on technician-specific performance are sent quickly to the EC principal investigators, and the SQA within a week of generating the report.
- 2) Summary QC reports without technician-specific data are sent to the Steering Committee through the SQA. The following centers and committees have responsibility for responding to the reports as follows:

- a) EC Co-PI, study coordinators, local certifiers/trainers. Review each QC and monitoring report, including those with technician-specific quality; identify a solution to each problem; implement corrective action; report corrective action to CC monitor.
- b) Principal Investigators of laboratories and reading centers directors. Review each QC and monitoring report for their laboratory/center; identify a solution to each problem; implement corrective action; report corrective action to SQA.
- c) Statistics and Quality Assurance Subcommittee (SQA). Review each QC and monitoring report with attention to deviation from protocol, recurrent technician or field center problems and temporal trends; direct exam center, recruiting and interviewing staff/reading center/laboratory attention to problem and recommend additional corrective action if they persist; monitor the implementation of corrective action; contact and coordinate study agencies and investigators to review data quality problem and solutions; prepare summary reports and recommendations for the Steering Committee.
- d) Steering Committee. Review QC summary reports; monitor data quality trends; direct the QC in areas needing special attention; responsible for changes in protocol.

SCHEDULE OF QUALITY ASSURANCE AND QUALITY CONTROL ACTIVITIES

Table 1: Schedule of Quality Assurance Activities

Procedure	Quality Assurance or Quality Control	Monitoring Methods	Responsible	Reporting ? Frequency	Written Report to CC & SSQC
AFU Interviews	QA QC	Weekly Monitoring – observation (5% of interviews)	Director of Retention	Monthly	Yes
Data:					
Data	QC (Data Entry)	Completeness & integrity of data	CC	Weekly	No
	QA (Transmittal)	Completeness & integrity of data	CC	Monthly	No
Cohort Procedure:					
Interviewer-administrated forms for re-certification	QA	Content analysis of taped interviews; and by observation.	Clinic Manager & CC/EC Liaison	Yearly	No
Clinic	QA (Procedures)	Observation	Clinic Manager	<u>Weekly</u>	No
	QC (Interviews)	Monitoring - Observation	Clinic Manager	<u>Weekly</u>	No
Protocol adherence & interviewing techniques	QA	Monitoring of examinations	CC	Quarterly Semi-annually	Yes
Measuring Tapes	QA: Equipment Validation	Checked for damage	Clinic Staff	Weekly	No
Scales	QA: Equipment Validation	Zero balanced/calibrated	Clinic Staff	Daily/weekly	No
Sitting Blood Pressure	QA: Equipment Maintenance	Recording of all checks, problems and maintenance	Clinic Staff	Daily	No
	QC	Adjusted means of BP data Re-certification of technicians	CC	Quarterly Semi-annually	Yes
Omaron BP Machines Tanita 300A	QA Equipment Maintenance	<ul style="list-style-type: none"> ➤ P-Set ➤ inspection ➤ Standardization of manometer 	Clinic Staff	<ul style="list-style-type: none"> ➤ Weekly ➤ Monthly 	<ul style="list-style-type: none"> ➤ No ➤ No
Medical data review	QA	Done in accordance to JHS Protocol	Clinic Manager	Quarterly	No
Referrals & results reporting	QA	Done in accordance to JHS Protocol	Clinic Manager	Quarterly	No
Exam Center Refrigerator / Freezer	QA Equipment Maintenance	Check Freezer Temp, refrigerator & centrifuge(s)	Clinic Manager	Quarterly (should be more frequent??)	Yes

Blood Analysis Lab	QC	Condition of arrival Analytes Means & SDs; check extreme values with lab	Lab & CC	Monthly	Yes
MRI	QC	Range Checks, Descriptive statistics & Trend Analysis	Lab & CC	Monthly	Yes

2.0 OPERATION OF QUALITY ASSURANCE AND QUALITY CONTROL ACTIVITIES

2.1 Quality Assurance Monitoring Process for Retention

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

In order to monitor 5% of the average number of annual follow-up interviews completed, two Research Interviewers per week will be randomly selected by the CC. Observations will be done by the Director of Retention to determine if research protocols are being followed. A checklist will be used to determine satisfactory performance (Appendix). Random selection will be done on a rotating cycle to monitor all Research Interviewers in an ongoing manner. Protocol adherence and interviewing techniques are reviewed at least biannually by the CC/EC Liaison. Deviations from protocols and possible remedial actions are discussed with the Director of Retention and the staff at that time. Major deviations are brought to the attention of the Retention and Events Monitoring Subcommittees and the EC Co-PI. Data quality is monitored by the SQA quarterly.

2.2 Interviews Exam 3 Visit

With participant approval, most how many, what proportion? interviewer-administered forms are taped for quality control. A non-systematic sample of forms is reviewed by the Clinic Manager and/or Clinic Liaison monthly. Routine quality assurance is provided through observation by the Clinic Manager. Protocol adherence, and interviewing techniques are reviewed at least biannually by Clinic Liaison. Deviations from protocols and possible remedial actions are discussed with the Clinic Manager and staff at that time. Major deviations are brought to the attention of the JHS Clinic Operations Committee and the EC Co-PI. Data quality is monitored by the SQA quarterly.

The Exam Center Co-PI is responsible for ensuring that the medical data review, referrals and reporting of results are done according to procedures in the JHS protocol. The CC/EC liaison will be responsible for conducting a random exit interview with participants related to medical data review and referrals. In terms of reports, the CC will perform a bimonthly analysis to determine which participants have or have not received their clinic results. A written report will be submitted to the SQA subcommittee.

2.3 Quality Assurance for Cohort Procedures

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

On a monthly basis, two staff members are selected randomly on a rotating cycle for observations (by whom? The EC/CC liaison person? Is there any written log kept of these observations?) to determine quality assurance protocol. The staff person will be observed on two areas of clinic exam components to determine satisfactory performance. The EC/CC liaison will monitor clinic operations using designated evaluation tools in (Appendix). Review of tape interviews will be done biannually or on as needed basis and outcome of the evaluation will be utilization in the certification of technicians. Monthly, the EC/CC liaison will conduct QA checks on equipment maintenance logs for blood pressure, body composition and lipid and glucose testing. Weekly, QA monitors involve overall operation of the clinic. The various cohort procedures will be assessed for a given clinic staff by the Clinic Manager or a designated evaluator on the specific time frame in Table 1 of the manual. The corresponding instrument for each procedure is provided in Appendix – Evaluation/Certification/Site Visit Checklist. Deviations from protocols and possible remedial actions are discussed with the Clinic Manager and staff at that time. Major deviations are brought to the attention of the JHS Clinic Operations Committee and the EC Co-PI. Data quality is monitored by the Quality Control Committee quarterly.

3.0 DESCRIPTION OF THE QC SYSTEM FOR REPEATED MEASUREMENTS

In several areas, repeated measurements during a clinic examination are taken for quality control purposes and are recorded on study forms separate from the participant's original forms. These forms are designated as belonging to phantom participants. The phantom participants are approximately 10% of assigned study IDs for venipuncture. The 10% of the total sample of 5,000 participants (excluding deceased participants) translated to 500 participants. The sampling of these 500 participants is weighted heavily in the earlier phase of the Exam 3 clinic visits and reduced over time once sufficient data has been collected, analyzed and reviewed. Details of sample size and the methodology for carrying out repeated measures for all replicate procedures are given below. The EC with the assistance of the CC creates phantom participant folders when needed, and initializes a phantom participant diskette. As a safeguard against gathering unnecessary data on the phantom participant forms, only a subset of the usual study forms is included for QC repeated studies. The data collected on the phantom form is later keyed into ClinTrial. Repeat measurements are then entered by the technician making the measurements, entering the phantom forms just as regular study data, as explained below, and the folders are processed as regular study data. There is one extra form in the QC phantom participant's folder, the JHS QC Phantom Participant and Non- Participant ID Form (PNP: Exam 3 Forms Manual), which is used to match the phantom ID to the IDs of the JHS participants contributing repeat measurements. This form is also used to record IDs used for data collected on persons who are not JHS study participants (e.g., monitors from the CC.) This form is sent to the CC with a copy kept in the phantom participant's folder. As a further backup, the QC phantom ID is entered on a form in the associated JHS participant's folder, as explained below.

The procedures for using the QC phantom participant folders are:

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

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

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

- 1) The research nurse assigns a JHS cohort ID at the start of their visit.
- 2) As soon as the ID is assigned, a label for that ID is placed in the box marked "Phantom Participant ID Number" on the QC Phantom Participant and Non-Participant ID Form, and "N", for "An ID Used for a Non- Participant" is circled.
- 3) Also as soon as the ID is assigned, the person making the assignment records the date and their own ID number in the spaces provided.

- 4) The same week the non-participant is seen, the QC Phantom and Non-Participant ID Form will be photocopied. The copy is retained at the EC, and the original is sent to the JHS CC

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

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

3.1 Replicate Clinic Procedures

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

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

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

Task (Activities)

Target Sample (including sample size)

Selection and Assignment Study units

3.1.1 Study Plan – Body Composition and Sitting Blood Pressures (*Sitting & Ankle-Brachial*)

- **Task (Activities)** – The following measures listed under selected measures will be repeated on a random selection of JHS participants. Fifty percent of the replicate study participants will have their repeated measures conducted by the same technician and the other 50% by a randomly selected technician. The Clinic Manager (or designate) will be given random selection schemes. One scheme will assist the Clinic Manager (or designate) in identifying the randomly selected participant for a given clinic day and whether or not the second measurement will be done by the same technician or by a different technician. The second will assist the Clinic Manager (or designate) to randomly select a second technician for repeated measurement.
- **Target Sample** The target sample size was arrived using data from JHS participants who had clinic visit between September 2000 and September 2001. In addition to setting the significance level (α) at 5% and a power greater than 90%, it was assumed that the mean difference of these measures for each pair would not exceed 5%. For body composition measures the sample sizes ranged from 140 to 200 for each of the measures. The sample sizes for the sitting blood pressures ranged from 150 to 200. Over sampling will accommodate refusals and gather enough data at the onset to ensure an adequate sample size to detect data problems at the onset and thus correcting any identified issues.
- **Selection & Assignment Study units** – Study subjects will be pre-selected at random prior to their clinic visit. The goal is to select the 360 subjects over 36 months (144 weeks) after the start date. An average of 2.5 (\cong 3) subjects per week will need to be assigned for repeated measures. Hence, three JHS participants are randomly assigned to participate in repeated measures for any of selected body composition or blood pressure replicate measures; there will be a resultant sample size of 432 – over sampling of 20%. Hence if a randomly selected participant refuses to participate, there will be no need to replace that individual. This based on the assumption that the refusal rate will be below 20%.

Selected Measures –

Procedures	Measures (Variables)
Body Composition	Height (BCFB8), Weight (BCFB 9), Girth-Waist (BCFB 5), Hip Girth (BCFB6) & Body Fat % (BCFB15)
Sitting Blood	Heart Rate (SBPC8), First Systolic BP (SBPB13), First Diastolic BP

Pressure	(SBPB14), , Second Systolic BP (SBPB16), Second Diastolic BP (SBPB17) & Second zero reading (SBPB18).
Ankle-Brachial Blood Pressure	Max. Inflation level (ABBB6), Brachial (ABBB7), Right posterior tibia (ABBB8), Left posterior tibia (ABBB9), Left posterior tibia (ABBB10), Right posterior tibia (ABBB11) & Brachial (ABBB12)

3.1.2 Study Plan – Electrocardiography:

- **Task (Activities)** – The replicate study in this case with utilize repeating scans for a random subset of JHS participants. This will not be done routinely but once a year as part of re-certification of ECG technicians. Each technician will have to complete 5 QC scans as part of the re-certification process. Individuals selected for the scan will be done at random. In addition to these yearly QC scans; ECG scans sent in from hospitals (as part of surveillance) can also be evaluated for QC. There will no re-reads of blinded images because all ECG scans are machine-read.
Target Sample – The sample size will be 60 participants for the entire recruitment period. This translates to 20 participants per year (5 participants per technician per year).
- **Selection & Assignment Study units -**
The CC, working in conjunction with the EC and the ECG Reading Center, will design a randomization scheme to carry out this aspect of the ECG replicate study. The study will be designed such that the scans will address inter- and intra-reliability.

3.1.3 Study Plan – Magnetic Resonance Imaging (MRI):

- Task (Activities)** – Given the time requirement and radiation exposure of this procedure, participants will not be re-scanned as part of the replicate studies. However, replicate studies will be conducted by re-reads of blinded MRI scans. .
Target Sample – The sample size will 10% of the total scans (n=2500), which is 250 re-reads.
Selection & Assignment Study units - The CC, working in conjunction with the MRI Reading Center, will design a randomization scheme to carry out this aspect of the MRI replicate study. The study will be designed such that the scans will address inter- and intra-reliability.

3.1.4 Study Plan – Venipuncture and Urine:

- **Task (Activities)** –Replicate QC blood-drawing tubes will be assigned to each of three phantom participants per week(?). The blood draws are on three different participants whose clinic visits are on the same day. The urine collection will be on a fourth person other than the three individuals that had blood drawn. The clinic manger (or designate) will be given random selection scheme. For a given clinic day, the scheme will assist the clinic manager (or designate) in identifying the randomly selected participant and with blood tubes need to be drawn. The scheme will also be used to randomly select a participant for repeated urine collection.
-
- **Target Sample** – The target sample for this replicate study will JHS participant. The total sample size for this study is 250 (5% of the total cohort of 5000).
- **Selection & Assignment Study units** – Study subjects will be pre-selected at random prior to their clinic visit. The goal is to select the 250 subjects over 36 months (144 weeks) after the start date. An average of 1.8 (\cong 2) subjects per week will need to be assigned for repeated measures.

Hence, three JHS participants are randomly assigned to participate in repeated measures for additional blood draw; there will be a resultant sample size of 288 – over sampling of 9%. If a randomly selected participant refuses to participate, there will be no need to replace that individual.

Selected Measures –

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

3.1.3 Schematic of Repeated Measures per Week

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

Table 2: Assignment of Repeated Procedure to Participants per Week

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

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

Table 3: Numbering and Description of Repeated Clinic Procedures

Procedure Number	Description
1	Height & Weight
2	Girth: Waist & Hip
3	Body Fat %
4	Heart Rate & 1 st & 2 nd Sitting BP
5	Max Inflation, 1 st & 2 nd Ankle-Brachial BP
6	Venipuncture
7	Urine

4.0 ANALYSIS OF STUDY DATA FOR QUALITY CONTROL PURPOSES

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

- 1) Status of the variables for each participant record (no problem, skipped due to skip rule, problem with the entry).

- 2) Frequencies for categorical variables, or means, standard deviations and selected percentiles for continuous variables.
- 3) Digit preference analysis for blood pressure and anthropometry measures (and others?)
- 4) Quality control charts or plots.
- 5) Univariate and comparative analysis of current data and previous finger stick data on a monthly basis.

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

Summary statistics by technician (monthly) or by period of observation (quarterly) are generally not sufficient for quality control purposes, due to the large amount of explained variation in a small amount of data. For example, the means of weight measurements made by two technicians may differ simply because of age or sex differences between the two groups examined. In order to adjust for such known sources of variation, the CC periodically examines selected items of study data in terms of age- and sex-adjusted means by technicians. In addition to looking at differences among technicians within the EC in a given reporting period, the CC also looks at trends in adjusted means and in variability after adjustment, over time. Relatively sudden shifts in the mean for a given technician or increases in measurement variability after adjustment may indicate that changes in measurement technique have occurred which should be examined. Similar analyses of trends in the study data's summary statistics monitor laboratory data for signs of measurement drift or reduced measurement precision. Certain measurements, which involve a degree of subjective judgment by technicians, such as blood pressure or anthropometry data, are commonly subject to digit preference. The CC periodically analyzes such data for digit preference, by technician. Technicians will be provided feedback on their performance of quality data collection. A sample report is provided in the Appendix.

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

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

5.0 QUALITY CONTROL REPORTS FOR THE COHORT COMPONENT

A large number of reports are generated by QC work. In order to spread out the workload and the distribution of the reports, a schedule for the Cohort Component reports has been developed.

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

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

- 1) Certification
 - a. Number of technicians certified by area
 - b. Number of studies performed in past month, by area, and technician
 - c. As in (b.), for the past two months. This report documents which technicians are not performing enough studies to maintain certification.
***Note:** In addition to the bimonthly reports, semi-annual reports are also produced to account for revisions generated by the bimonthly reports.*
- 2) Body Composition
 - a. Digit preference (quarterly)
 - b. Repeated measures (semi-annually)
 - c. Adjusted means by technician (quarterly)
- 3) Sitting Blood Pressure
 - a. Digit preference (quarterly)
 - b. Adjusted means by technician (quarterly)
 - c. Analysis of serial measures (three repeat measurements within a sitting) (every four months)
 - d. Cuff size checks (every four months)
- 4) Laboratory (lipids, hemostasis, clinical chemistries, hematology)
 - a. Repeated measures (monthly)
 - b. Condition of sample on arrival (monthly)
 - c. Analysis of QC samples from frozen storage (semi-annually)
 - d. Internal QC results (quarterly)
 - e. External QC results (frequency varies)
- 5) Venipuncture

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

For repeated measures technicians who consistently (2 consecutive analysis) have clinical and/or statistical significant difference in the repeated measures will receive written communication of the significant differences in the repeated measures of the specific measurements. If these differences persist for a given technician then the SSQC will recommend that the technician be subject to retraining of that (those) procedures.

6.0 SPECIAL STATISTICAL ANALYSES IN QUALITY CONTROL REPORTS

6.1 Monitoring for Digit Preference

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

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

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

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

This score can be shown to have values between 0 and 100 (It is 0 when all observed digit frequencies ($O_i; i=1,2, \dots, k$) are N/k and is 100 when all observed frequencies are all in one cell). Using the cut off point used by ARIC; a $DPS \geq 20$ is the threshold for marked digit preferences. A technician is judged to show "strong evidence of digit preference" if all of the following are true: (1) $N \geq$ minimum N required (25 for blood pressure and 50 for anthropometry); (2) the p -value for χ^2 statistic is < 0.05 ; and (3) the digit preference score (DPS) is greater than or equal to 20. The Table below illustrates a technician specific report as is pertains to digit preference.

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

Technician Code =

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

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

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

6.1.1 Replicate Data Analysis

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

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

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

R is useful for overall assessment of the reliability of the measurement method. For routine monitoring of the data collection process, the standard deviation σ_e is most closely watched. In monitoring laboratory data, σ_e for each assay is compared with the target standard deviation (S.D.), which the laboratory has set based on analyses of internal quality control pools. Blind replicate estimates of the laboratory S.D., which are more than twice the target S.D. are considered cause for concern.

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

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

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

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

7.0 QUALITY CONTROL ANALYSES ON THE VARIOUS CLINIC PROCEDURES/MEASURES

7.1 Venipuncture and Equipment Records

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

- Daily checks of the back-up generator to the freezer.
- Daily logs of lab equipment will be sent to the CC for review and analysis.
- The monthly Quality Control Checklists should be kept in a permanent file in the Exam Center.

7.2 Sitting Blood Pressure

7.2.1 Quality Control

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

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

7.2.2 Technician Training and Quality Control

Blood pressure technicians are trained by the certified trainer, Clinic Manager or their designee prior to start of Exam 3. New technicians hired after the start of the study are trained locally by the EC Co-PI or a designated "Blood Pressure Supervisor". Recertification occurs every six months. Prior to certification, each technician is required to have a clinical hearing test.

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

7.2.3 Equipment Maintenance

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

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

8.0 SPECIMEN REPOSITORY QA ACTIVITIES

8.1 *Quality Control Duplicate Blood and Urine Samples*

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

To reduce the burden upon JHS participants, no one person is asked to contribute sufficient extra blood to make a complete set of duplicates for all tests. Instead, extra blood is drawn from five participants (per week?_ and sent out under the same [? Don't each of the duplicates get a different,not same phantom ID? This is unclear] QC ID number. For data analysis, results on each laboratory measurement are matched to the appropriate participant results.

8.1.1 *Weekly Blood and Urine QC Sample Checklist*

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

8.1.2 *Preparation for Drawing and Processing QC Samples*

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

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

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

8.1.3 *Collecting and Processing QC Blood and Urine*

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

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

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

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

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

8.2 Maintain Plasma Repository

The JHS Specimen Repository Center shall provide facilities and equipment to receive, store, aliquot, and distribute plasma from JHS participants. The facilities must provide aseptic and/or sterile conditions as appropriate (Biosafety Level 2 Containment). The specimens shall be maintained by the contractor in

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

8.3 Preparing Aliquots from Selected Specimens

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

8.4 Prepare and Ship Panels of Aliquots or Specimens

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

APPENDICES

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

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

Week: _____

AFU Interviewers	Participant	Phone #	Comments
207			<input type="checkbox"/> Prepared <input type="checkbox"/> Knowledgeable <input type="checkbox"/> Professional behavior
208			<input type="checkbox"/> Prepared <input type="checkbox"/> Knowledgeable <input type="checkbox"/> Professional behavior
209			<input type="checkbox"/> Prepared <input type="checkbox"/> Knowledgeable <input type="checkbox"/> Professional behavior
262			<input type="checkbox"/> Prepared <input type="checkbox"/> Knowledgeable <input type="checkbox"/> Professional behavior

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

Appendix II: JHS Quality Control Phantom Participant ID Form

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

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

Jackson Heart Study Annual Schedule of Staff Certification, Criteria

Technician ID No. _____

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

Jackson Heart Study Exam Center Quality Control Weekly Checklist

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

Appendix IV: Evaluation/Certification/Site Visit Checklist

JHS Data Management Certification / Site Visit Checklist

DATE:
Mo Day Year

Manager Trainee Name/ID:

Data Manager Name/ID:

Purpose of Evaluation:

Certification

Site Visit

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

Preparation:

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

Comments: _____

Corrective action taken: _____

Supervisor / Site Visitor Signature _____

JHS Interviewer-Administered Questionnaire Supervisor / Site Visit Checklist

DATE:
 Mo Day Year

Interviewer Name/ID:

CC Clinic Liaison Name/ID:

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

Health History Medications Medical History
 Renal Disease Respiratory Symptoms Stroke Symptoms

Purpose of Evaluation:

Certification Supervisor QC Check Site Visit

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

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

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

Comments: _____

Corrective action taken: -----

Evaluator Signature: _____

JHS Self-Administered Questionnaire Supervisor / Site Visit Checklist

Date:
 Mo Day Year

Interviewer Name/ID:

Supervisor Name/ID:

Interview/form reviewed:

Informed Consent

Purpose of Evaluation:

Certification: Supervisor QC Check: Site Visit:

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

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

Answers participant's questions and concerns.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Speaks slowly and distinctly reading the script of the instructions to the participants at neutral (but expressive) and even pace.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Reads script of instructions as written.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Completes the editing process and reviews forms.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
General Overall Rating	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Comments: _____

Corrective action taken: _____

Supervisor / Site Visitor Signature _____

JHS Anthropometric Certification / Supervisor / Site Visit Checklist

DATE:
 Mo Day Year

Technician
Name/ID:

Supervisor
Name/ID:

Measurements:

Weight

Height

Waist

Purpose of Evaluation:

Certification

Supervisor QC Check

Site Visit

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

Weight Measurements:

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

Height Measurements:

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

Girth-Waist Measurements:

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

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

Girth Hip Measurements:

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

Comments: _____

Corrective action taken: _____

Supervisor / Site Visitor Signature _____

JHS Sitting Blood Pressure Certification / Supervisor / Site Visit Checklist

DATE:
Mo Day Year

Technician
Name/ID:

Supervisor
Name/ID:

Purpose of Evaluation:

Certification

Supervisor QC Check

Site Visit

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

Throughout Exam:

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

Comments: _____

Corrective action taken: _____

Supervisor / Site Visitor Signature _____

JHS Venipuncture Certification / Supervisor / Site Visit Checklist

DATE:
mo day year

Technician ID/Name:

Supervisor Name/ID:

Purpose of Evaluation:

Certification *Supervisor QC Check* *Site Visit*

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

Venipuncture:

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

Handling of filled draw tubes:

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

Comments: _____

Corrective action taken: _____

Supervisor / Site Visitor Signature _____