

Jackson Heart Study

Manual 2

Cohort Procedures

Exam 3

Version 2.4

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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. Manuals 2, 3 and 4 describe the Cohort Procedures, Blood Pressure and Central Laboratory and Specimen Repository components of the study. Manuals 5 and 6 comprise Electrocardiography and Magnetic Resonance Imaging studies, respectively. Manual 7 comprises Morbidity and Mortality Classification. Manual 8 articulates the quality assurance and quality control activities of the JHS Examination 3 components. Quality assurance includes activities that are designed to assure quality of data, which take place during the collection of data, while quality control relates to efforts during the study to monitor the quality of data. The Data Management System is described in Manual 9.

JHS Study Protocols and Manuals of Operation

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1	General Description and Study Management
2	Cohort Procedures
3	Blood Pressure
4	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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INTRODUCTION

The JHS cohort is comprised of 5301 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, conducting off-site examinations, ongoing contact with the cohort, and participant follow-up and satisfaction.

Chapter 2 provides an overview of the design, logistics, training and quality control.. The training and certification required to administer the forms as well as the quality assurance activities for all interviews are described.

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

Chapter 4 provides the rationale and references for the procedures performed during Exam 3. The training, certification required to perform the procedure, quality assurance and data collection methods are described.

Chapter 5 describes the rationale procedures, training and certification associated with medical data review. Medical data review is conducted with each participant before he/she leaves the Clinic.

Chapter 6 covers the study's referral and review guidelines, including activities associated with reporting results to participants and their 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: "Morbidity and Mortality Classification"..

1.0 RETENTION OF PARTICIPANTS FOR EXAM 3

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 ~ 4-8 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 members 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 3 and 1/2 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 “offices” for 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
 - 3 and 1/2__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.

1.1.2.1 Multiple, ongoing, simultaneous approaches that include multi-media (radio, television , newspaper....)

1.2.2.2 Mailing some item to participants’ homes each month that includes information about the current examination.

1.1.2.3 Mass mailings and follow-up phone call to participants who have missed scheduling their appointments and to participants who have missed keeping scheduled appointments.

1.1.2.4 Targeting “missed appointments” by geographic region and scheduling Community Partnership events in selected regions.

1.1.2.5 Evening phone calls by the Social Worker to reach participants who work during the day to schedule initial appointments or re-schedule missed appointments.

1.1.2.6 Broad dissemination of monthly flyers based on the health focus for the month translated into messages relevant for JHS participants at churches, health fairs, community events and by mail.

1.1.2.7 Follow-up telephone calls by JHS physicians to hard-to-reach participants.

1.1.2.8 Design and broad dissemination of book marks, post cards, mail inserts and mailing labels.... with messages relevant to the current JHS examination.

1.1.2.9 Weekly tracking of clinic appointments.

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, 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 Clinic by phone or web site in advance of receiving a call from JHS.

1.2 Scheduling Clinic Appointment (CLA)

Scheduling Clinic Appointment (CLA)

Note: The Retention Subcommittee is modifying recruitment activities to increase the completion rate for Exam 3. As a result of these modifications, participants may call the clinic or access the website to schedule appointments at times which are outside the exam window. Starting on August 1, 2010 the 3 year exam window will be suspended to allow most participants to schedule appointments at any time. **Participants who received MRI exams during Exam 2 are exempted from this open enrollment period and should not be scheduled before May 1, 2011.** In addition to the procedures currently in place for scheduling clinic appointments (see Manual 2, section 1.2), the following changes in procedure will be made to accommodate scheduling clinic appointments outside of the exam window:

- 1) Data Management will compile a list of participants who are **not** eligible for open scheduling. If there is any doubt about whether the participant is eligible for scheduling an appointment, the staff can consult this list.
- 2) Data Management will **flag** the records of participants who are **not** eligible for open scheduling. Flagging of the records is preferable since it will allow the scheduling system to identify appropriate participants.
- 3) The website will be changed to allow eligible participants to schedule their appointments at any time.
- 4) Clinic staff who schedule appointments will be instructed to schedule appointments when eligible participants call (When in doubt, she should check the list of participants who are not eligible for open scheduling)
- 5) AFU Interviewers will ask all eligible participants to schedule an appointment. (When in doubt, she should check the list of participants who are not eligible for open scheduling)

1.2.1 Eligibility for Exam 3 Scheduling

All participants who completed all or part of the baseline clinic examination (Exam 1) and (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 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 Exams 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 third 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 his/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.jsu.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, Surveillance and 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, Surveillance and 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 and ½ hours)
 - Snack is provided after venipuncture
- 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 Manager Research Clinic 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. Additionally, in-depth interviews regarding the experience of participating in the JHS may be conducted with a designated percentage of the cohort on occasion. Interviewer/recruiters and clinic staff will notify the 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.

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

2.1 Introduction

During the annual follow up interview, cohort members in the relevant Contact Year 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. Two procedures that were conducted in Exam 1 will be conducted again in Exam 3; Ankle-Brachial Blood Pressure and Electrocardiography. 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 2.1 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.

Table 2.1 Core Components of the Exam 3 JHS cohort examination, and location of the procedure / interview in the Manual of Operations		
Exam Component	Description	Manual_section
Anthropometry	Measure height, weight and waist and hip circumference	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	4.1
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.	3.2
Interviews	Collect medical, health, stroke /TIA, and medication/vitamin use, administer psychosocial instruments.	3.0
Venipuncture	Collect by venipuncture blood for fasting glucose and lipids (total cholesterol, Triglycerides, HDL, LDL, VLDL)Hg A1c, C-reactive protein, Urea Nitrogen, Creatinine, insulin, e-selectin and p-selectin.	4.4 & See Manual 4
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.	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.	3.1
Ankle-Brachial Blood Pressure	Assess ankle and arm blood pressure using Doppler.	4.3 & See Manual 3
Sitting Blood Pressure	Assess sitting blood pressure using Omron HEM-907XL	4.2 & See Manual 3
Spot Urine	A midstream, voided urine sample is collected.	M2_4.4 & See Manual 4
Electrocardiography	Obtain a resting 12-lead ECG recording.	4.6 & See Manual 5
Snack	Provide heart healthy snack with no stimulants.	4.7
Magnetic Resonance Imaging (MRI)	Imaging of the heart and aorta that provides the capability to assess cardiac structure and function.	4.9 & See Manual 6

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 2.2 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.

Table 2.2 Components of Annual Follow Up (AFU) and Surveillance in the JHS Exam 3 and their location in the Manuals of Operation		
Component	Description	Manual Section
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	8.0
Annual Follow Up Other 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	8.6 & 8.9
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	9.0 & See Manual 7

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 2.3

Table 2.3 Participant Flow, JHS Exam 3	
Procedures / Workstations	Approximate Time
FIXED SEQUENCE #1¹	
RECEPTION Informed Consent Informed Consent Form Update Contact Information Fasting Status Collect Medications CHANGE OF CLOTHES	20 minutes
ANTHROPOMETRY	6 minutes
BODY COMPOSITION	10minutes
SITTING BLOOD PRESSURE	20 minutes
SPOT URINE	5 minutes
VENIPUNCTURE	5 minutes
SNACK	15 minutes
FLEXIBLE SEQUENCE²	
EKG ABB	40 minutes
STAFF ADMINISTERED QUESTIONNAIRES Medication Survey Health History Medical History Sleep Quality Discrimination Cognitive function Depression Stroke Symptoms	10 minutes 5 minutes 10 minutes 5 minutes 10 minutes 10minutes 10 minutes 5 minutes
Magnetic Resonance Imaging (To be scheduled separately)	

FIXED SEQUENCE #2¹	
DATA INVENTORY (staff activity) CHANGE CLOTHES MEDICAL DATA REVIEW Evaluation	5 minutes 10 minutes
TOTAL TIME	3 and 1/2 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

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 and 1/2 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 2.4. 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 body composition measures, ECG and ABB are scheduled in the non-fixed portion of the exam.

The Participant Itinerary Form (PIN) (Forms Manual) serves as a summary of clinically relevant data. The PIN serves as a summary of procedures and interviews performed during Exam 3 is directly entered into the DMS. The PIN has several purposes: to monitor the amount of time it takes to complete each component of 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.

2.2.3.1 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 Research Clinic, and Research Surveillance and Retention 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 Manager Research Clinic 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 Manager Research Surveillance and Retention and Clinic Liaison are responsible for similarly training new staff. For surveillance staff, the Manager Research Surveillance is responsible, in conjunction with the ARIC Coordinating Center, for training in methods of abstraction and out-of-hospital death interviewing techniques.

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

2.2.3.2 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 Manager Research Clinic (for exam interviews), Manager Research Surveillance and Retention (for annual follow up interviews), Manager Research Surveillance and Retention (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 taped reviews are described below with the appropriate exam component.

Table 2.4 Training and Certification Criteria for JHS Exam 3 Interviews and Procedures				
COMPONENT	CERTIFICATION REQUIREMENT	CERTIFIER OR REVIEWER	RECERTIFICATION REQUIREMENTS	RECERTIFIER OR REVIEWER
AFU (CY 09-12) Annual Follow Up – typically done by telephone	Review of AFU procedures	Manager Research Surveillance and Retention or Interviewer team leader/DMITQA Central Trainer	Annual Rose Questionnaire Exercises Annually, 1 taped participant interview	Manager Research Surveillance and Retention or Interviewer team leader
ANTHROPOMETRY / BODY COMPOSITION Height Weight Waist Hip % Body Fat Fat Mass	Agreement with or within 1cm of trainer	Manager Research Clinic / Clinic Research Coordinator or DMITQA Central Trainer	Biannually (January/July), results sent to Data Management annually Annual recertification for lead technician during annual DMITQA monitoring visit	Manager Research Clinic/Clinic Research Coordinator
Ankle-Brachial Blood Pressure	2 replicate measures Agreement within 4 mmHg on any one reading, (systolic or diastolic) and averages should agree within 3 mmHg.	Manager Research Clinic and Clinic Liaison	Biannually, (January and July) results sent to Data Management annually	Manager Research Clinic and Clinic Liaison
BLOOD PRESSURE, SITTING	2 replicate measures Agreement within 4 mmHg. on any one reading (systolic or diastolic) and averages should agree within 3 mmHg.	Manager Research Clinic and Clinic Liaison	Biannually (January / July), results sent to Data Management annually Annual recertification during annual DMITQA monitoring visit	Manager Research Clinic and Clinic Liaison

Table 2.4 Training and Certification Criteria for JHS Exam 3 Interviews and Procedures				
COMPONENT	CERTIFICATION REQUIREMENT	CERTIFIER OR REVIEWER	RECERTIFICATION REQUIREMENTS	RECERTIFIER OR REVIEWER
Electrocardiography	Three 12-lead resting ECGs	ECG Technician Trainer	Observation quarterly by the most senior certified technician	Most senior certified technician.
CONSENT	Adequate technique on 5 taped consent	Manager Research Clinic/ Clinic Research Coordinator	Biannually (January / July) Methods reviewed annually during DMITQA monitoring visit	Manager Research Clinic and DMITQA monitoring round robin
VENIPUNCTURE	Training by Manager Research Clinic/ lead Lab technician who are certified; 2 acceptable draws/processing	Manager Research Clinic/ Lead Lab technician	Biannually (January / July) Annual DMITQA monitoring visit	Lead Lab Technician or Manager Research Clinic
LETTERS/REPORTS Participant results reports	Accurate letters and reports.	Co-PI/Associate Director Data Acquisition	Methods reviewed annually during DMITQA monitoring visit	Associate Director Data Acquisition and Associate Director Data Management
MEDICATION SURVEY Interview	Adequate technique on 5 taped interview	Manager Research Clinic or lead interviewer	Annually, 1 taped participant interview included in round robin	Manager Research Clinic and DMITQA monitoring round robin
Transcription	80% correct on supervisor review	Manager Research Clinic/Clinic Research Coordinator	Methods reviewed annually during DMITQA monitoring visit	Manager Research Clinic/Clinic Research Coordinator
Coding	80% correct on coding exercises	Same as above	Same as above	Same as above
MEDICAL DATA REVIEW	Accurate interview technique	Manager Research Clinic/Clinic Research Coordinator	Methods reviewed annually during DMITQC monitoring	Manager Research Clinic/Clinic Research Coordinator

Table 2.4 Training and Certification Criteria for JHS Exam 3 Interviews and Procedures				
COMPONENT	CERTIFICATION REQUIREMENT	CERTIFIER OR REVIEWER	RECERTIFICATION REQUIREMENTS	RECERTIFIER OR REVIEWER
MEDICAL HISTORY interview	Adequate technique on 5 taped interviews	Manager Research Clinic or Interviewer team leader	Annually, 1 taped interview included in round robin review	Manager Research Clinic or Interviewer Team Leader
PARTICIPANT SATISFACTION interview	Adequate technique on 5 taped interviews	Manager Research Clinic or Interviewer team leader	Annually, 1 taped interview included in round robin review	Manager Research Clinic or Interviewer Team Leader
PARTICIPANT SAFETY	Local review of safety procedures	Manager Research Clinic or Clinic Research Coordinator	Annual safety review	Manager Research Clinic or Clinic Research Coordinator
RECEPTION interview	Adequate technique on 5 taped interviews	Manager Research Clinic or Interviewer team leader	Annually, 1 taped interview included in round robin review	Manager Research Clinic or Interviewer Team Leader
RESULTS REPORTING	Adequate technique on 5 reports	Chair ,Clinic Operations and Participant Results Subcommittee or Co-PI/Associate Director, Data Acquisitions	Annually review or examples of results reports.	Chair, Clinic Operations and Participant Results Subcommittee or Co-PI/Associate Director Data Acquisition
REFERRALS AND REVIEW GUIDELINES	Adequate technique on 5 referrals	Chair, Clinic Operations and Participant Results Committee or Co-PI/Associate Director, Data Acquisition	Annually, 1 complete review	Chair, Clinic Operations and Participant Results Committee or Co-PI/Associate Director, Data Acquisition
STROKE SYMPTOMS interview	Adequate technique on 5 taped interviews	Manager Research Clinic or Interviewer team leader	Annually, 1 taped interview included in round robin review	Manager Research Clinic or Interviewer Team Leader
SURVEILLANCE	Central and local review of surveillance procedures	Trainers at UNC, Chapel Hill NC and/or Director Surveillance or Manager Research	Exercises annually at University of North Carolina Collaborative Coordinating Center (UNCCC)certification training	Director Surveillance or Manager Research Surveillance and Retention or Records

Table 2.4 Training and Certification Criteria for JHS Exam 3 Interviews and Procedures

COMPONENT	CERTIFICATION REQUIREMENT	CERTIFIER OR REVIEWER	RECERTIFICATION REQUIREMENTS	RECERTIFIER OR REVIEWER
		Surveillance and Retention		Administrator UNCCC

2.4 Quality Assurance

With participant approval, most interviewer-administered forms are taped for quality control. A non-systematic sample of forms is reviewed by the Manager Research Clinic and/or Clinic Liaison monthly. Routine quality assurance is provided through observation by the Manager Research Clinic. 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 Manager Research Clinic 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 staff welcomes the participant to 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, 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 offsite 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), SBP (Sitting Blood Pressure), ABB (Ankle-Brachial Blood Pressure), VEN (Venipuncture Form), HHX (Health History Form), MHX (Medical History 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 are collected and checked for completion. If incomplete, assistance is offered.

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

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

The receptionist informs the participant that s/he will receive the immediately available results of Exam 3 at the conclusion of the exam before the participant leaves the Clinic. Results of all studies done during the visit are reviewed by the JHS clinician after the participant has left the Clinic. These include the anthropometrics, body composition, and blood pressure. Results of other studies done during the visit are reviewed by the JHS clinician when they become available from the Reading Center. 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 3 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. 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 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.

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; and (7) that withdrawing carries no penalties. 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). Time is allowed for the participant 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 Manager Research Clinic or Clinic Liaison is 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 Manager Research Clinic or Clinic Liaison.

3.2.5 Quality Assurance

Routine quality assurance is provided at the Clinic by means of observation by the Manager Research Clinic. 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. 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 he/she 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 Manager Research Clinic 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 digit medication code number is 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 information obtained as part of the 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

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 MacNeilly'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 choices, 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 instructions 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.

3.11.3 Permission to Use

- Williams everyday Discrimination Scale (Public Domain)
- Lifetime Discrimination, Karasek. (Public Domain)
- Perceived Racism Scale, McNeilly Public Domain)

3.12 Personal Data and Socioeconomic Status (PDS)

The Personal Data and Socioeconomic Form (PDS) is the first of several data collection instruments spaced over the baseline Home Induction and Annual Follow-up Interviews. Taken together, the data obtained will allow tracking of the participant's socioeconomic status at different stages of the life course. In the baseline HII, data is obtained on place of birth, marital status, employment or retirement status, first full-time job as well as information on personal and spousal education, income and occupation, and household wealth; job latitudinal satisfaction (adopted from the Karasek), and several measures of thwarted aspirations and relative deprivation. In subsequent annual follow-up interviews additional data is obtained regarding childhood, parental and neighborhood SES factors.

3.12.1 Background, Rationale and Hypotheses

The direct relationship between socioeconomic status (SES) and health is firmly established. This relationship holds for most of the identified risk factors for CVD including smoking, obesity, physical activity, hemostatic factors, diabetes, hypertension as well as access and quality of health care, particularly preventive care. Further, the social class gradient in CVD incidence and survival accounts for much of the black disadvantage (Cooper, 1993; Schoenbaum & Waidmann, 1997). Multiple mechanisms of socio-cultural effects on health and CVD are hypothesized. Included are early life experiences (Elo & Preston, 1992; Smith et al., 1997), disproportionate exposure to ecologic stressors (Harburg, et al., 1973; Karasek, et al., 1981; Markowe, et al., 1985; Meade, et al., 1986), harmful materials or vectors of disease

(Schell, 1997), poor health practices (Adler & Folkman, 1993; Kumanyika, 1987; Lynch, et al., 1996; Sobal & Stankard, 1989; Strogatz, et al., 1991; USDHSS, 1985), and variations in health enhancing personality characteristics (Mirowsky & Ross, 1989; Williams, 1990). The JHS provides opportunity for the additional research needed to understand the ways in which salutogenesis and pathogenesis is shaped by the larger social context.

The comparatively low SES of blacks to whites makes this a plausible explanation for the excess CVD morbidity and mortality in blacks. Clarifying what it is about low SES that influences susceptibility to CVD in black Americans remains one of the most important challenges for health research (James, 1984) and high priority for the JHS. Based on current literature, priority was given to comprehensive measures which: 1) capture the multiple dimensions of individual, family, and neighborhood or community variations of social stratification; 2) address the differential social advantage offered African-Americans by equivalent levels of education, income and occupation; and 3) capture variation in SES over a lifetime, including specific measures of early life SES conditions. Traditional individual measures of income, education and occupation as well as measures of wealth/assets, dominant member approach family/ household social status, and parental occupation/education are included. Direct measures of neighborhood context which may serve as stressors (neighborhood violence and disorder) or buffers (social cohesion and resources) for the development of CVD are also included (Sampson, et al., 1997; Diez-Roux, 1997, 1999). Geo-coded census block information will be appended to each participant record for later determination of neighborhood/community measures; e.g. neighborhood class will be determined by grouping census block-coded occupational and educational data to create a meaningful measure of neighborhood social class according to techniques described by Krieger (Krieger, 1992). Also, specific measures of individual, family/household, and neighborhood/community income, education, occupation, wealth/assets, poverty/deprivation, and socioeconomic/prestige ratings across all three levels and time will be developed from census data. Inclusion of individual and group level measures on the same traits will allow use of contextual regression analysis (Blalock, 1984; Boyd & Iverson, 1979) to determine whether the effects of individual SES are modified by household and neighborhood conditions. These comprehensive measures and analytic approaches during the first five years of the study will assure avoidance of either the individualistic or ecological fallacy in accounting for SES differences in CVD outcome over the course of the JHS.

Measures of early life SES conditions will be sought as indicators of deprived economic status when growing up; for example, parental education and occupation, subjective perceptions of comparative economic position. Class mobility will be assessed by a combination of measures of first job and subjective assessment of social class. Further, global assessments of relative deprivation (Adler, 1993) and thwarted aspirations (Williams, et al., Detroit Area Study) will be obtained.

Hypotheses include:

1. Family/household social status, including wealth, will be related to risk factors, hypertension, subclinical disease and CVD independent of individual level SES.
2. Neighborhood environment will be related to risk factors, hypertension, subclinical disease and CVD independent of individual level SES.
3. The relationship between race and CVD risk factors and outcomes will be modified by all levels of SES.
4. Measures of social status will interact with identified genetic factors to modify the occurrence of subclinical disease and the progression to clinical events.

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3.12.3 Administration

The PDS form is administered to all participants as part of the HII. Detailed instructions for administering each question are provided by the Q x Q instructions. The first question asks about place of birth and then continues with an assessment of participant standing in her/his community. Potentially sensitive questions on personal and household income and wealth conclude the HII. Care must be exercised to administer this section in a nonjudgmental fashion.

3.12.4 Permission to Use:

- Job Stress, Karasek; <http://www.uml.edu/college/she/WE/research/jcg/jcg.htm>

3.13 Tobacco Use (TOB)

The Tobacco Use (TOB) form is administered as part of the HII to document current and past tobacco use. Questions cover all types of tobacco (cigarettes, pipes, cigars, chewing tobacco, and dip / snuff). Additional questions include an estimate of environmental tobacco smoke (ETS) exposure, as well as an assessment of nicotine dependence for cigarette smokers (Fagerström Test for Nicotine Dependence [FTND], items 4 – 9).

3.13.1 Background, Rationale and Hypotheses

Tobacco use has been firmly established as a significant, modifiable risk factor for a wide range of medical disorders. The association between the use of tobacco and the development and severity of coronary heart disease and cerebrovascular disease is well accepted (USDHHS, 1983, 1998a). Evidence attests to its influence on accelerating the progression of atherosclerosis, as well as its role as a proximal cause for significant cardiovascular events, including myocardial infarction and cerebrovascular accidents.

The detrimental effects of tobacco use on the cardiovascular system are associated with both direct and indirect effects of (primarily) nicotine and carbon monoxide, including greater hemodynamic stress, increased output of lipids, catecholamines, fibrinogen and thromboxane, and increased platelet adhesiveness (Bolinder & de Faire, 1995). Smoking has been shown to interact with other cardiovascular risk factors, often yielding synergistic effects on health beyond the additive influence of individual factors (USDHHS, 1983). Finally, considerable evidence exists attesting to the benefits of quitting smoking, with substantial reductions in cardiovascular risk becoming evident once abstinence has been attained

(USDHHS, 1990).

Several studies have previously reported that African-American smokers produce measurably higher levels of cotinine, a primary metabolite of nicotine, than whites (e.g., Wagenknecht, et al., 1990). Cotinine levels are a marker for degree of nicotine dependence. Our own research conducted in Jackson is consistent with these data, demonstrating higher scores on the Fagerström Test for Nicotine Dependence (FTND: Heatherton, Kozlowski, Frecker, & Fagerström, 1991), a well accepted self-report measure of nicotine dependence, for black smokers vs. white smokers (Payne, et al., 1997). Recent evidence suggests that blacks absorb more nicotine from smoking, and that cotinine may be detected in body fluids of black smokers for a longer duration than for white smokers (Caraballo, et al., 1998; Perez-Stable, Herrera, Jacob, & Benowitz, 1998). These findings may provide at least a partial explanation as to why African-American smokers suffer from a disproportionately higher rate of tobacco-related diseases, as well as experience greater difficulty achieving abstinence (Orleans, et al., 1989).

Another recent finding which has important implications for the JHS concerns the role of environmental tobacco smoke (ETS) exposure. Howard, et al. (1998) examined the relationship between cigarette smoking and the progression of atherosclerosis in the ARIC population, as indexed by intimal-medial thickening in the carotid artery. The authors noted a relationship with smoking, but also that ETS exposure was an independent risk factor, as demonstrated by carotid wall changes in individuals who were either past or never smokers. Thus, greater specificity in the degree and nature of ETS exposure seems warranted.

Other lines of research have identified additional issues of interest with respect to the goals of the JHS. For example, a growing literature attests to smokeless tobacco use as a contributor to the development of cardiovascular disease (Bolinder, Ahlborg, & Lindell, 1992; Squires, et al., 1984; USDHHS, 1998a; Westman, 1995). Cigar smoking has increased dramatically since 1993 and, in more recent years, the greatest increase has occurred within the premium cigar market (USDHHS, 1998b). As with many of the previous issues, these issues are understudied, and particularly so for the African-American population.

Finally, other data being collected on participants of the JHS will permit a more in-depth examination of issues related to tobacco use in African-Americans. Several psychosocial factors that are related to tobacco use will be subject to a more intensive investigation. For example, higher levels of distress (depression, anger) and exposure to environmental stressors are related to tobacco use and difficulty in achieving cessation, whereas social support and knowledge of tobacco's detrimental effects on health are associated with a greater likelihood of successful cessation (USDHHS, 1988, 1990, 1998a). This study will provide a unique opportunity to examine the complex interactions among these variables in a large sample of African-Americans.

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3.13.3 Administration

The TOB is administered by a trained interviewer in the participant's home. Detailed instructions for administering each item are provided in the QxQ's. The form systematically gathers information on historical and current use of each form of tobacco. Responses vary from question to question, ranging from open-ended questions that are subsequently recorded or coded, to specific ratings of frequency, amount, etc.

3.13.4 Permission to use:

- Public Domain

3.14 Physical Activity (PAC)

The JHS Physical Activity Survey (PAC) is an interviewer-administered instrument designed to obtain information about respondents' physical activity habits. The survey contains 30 items in 4 sections. The participant responds to a series of 7 questions about usual level of participation in her/his daily routine (active living), 8 questions about occupational activity, and 7 questions about activities in the home, yard, and garden. For the sports/exercise section, respondents are also asked to identify the frequency and duration for the three most frequent sports/exercise activities performed in the past year.

3.14.1 Background, Rationale, and Hypotheses

Physical activity is widely recognized as an important and independent risk factor for many chronic diseases, including CHD, hypertension, and diabetes (Pate, et al., 1995; U. S. Department of Health and Human Services, 1996). The effect of a sedentary lifestyle on CHD is now recognized as almost as great as smoking and hypertension (Kriska & Caspersen, 1997). Epidemiologic surveys consistently show that prevalence of sedentary lifestyles is greater in minority, lower education, and lower income populations (Pate, et al., 1995), although the reasons for the observed differences are not yet understood (King, et al., 1992).

Method of Assessment of Physical Activity and Results to Date from ARIC.

For public health surveys, the most frequent choice for physical activity assessment has been interviews or questionnaires. These are favored because they: 1) do not alter the behavior of the person being surveyed; 2) are practical in terms of cost of administration and participant convenience and, 3) can be adapted to the population being assessed (Kriska & Caspersen, 1997). The physical activity instrument used in the ARIC study was a modified version of a self-report questionnaire developed for a study of Dutch men and women (Baeccke, et al., 1982): the instrument yields 3 scores assessing activity at work, in sport and at leisure. Researchers (Richardson, et al., 1995) reported additional gender-specific reliability and validity data for the ARIC instrument, and concluded the instrument is simple and easy to administer, is reliable and assesses heavy activity quite well. Its weaknesses were the relative inability to accurately assess moderate level activity and the absence of items involving child care and household activity. These weaknesses were shared by most of the instruments available at the time.

Folsom and others (1994) have examined the physical activity data from ARIC in relation to CHD and risk factors. Work physical activity scores from ARIC showed an inverse dose-response relationship with carotid wall thickness in black and white men and women, independent of other risk factors, including body mass index (BMI). In a second study, an association between CHD and the sports and leisure scores was observed in white men and women, but no association was observed in the black participants (Folsom, et al., 1997). In this study, the investigators noted that the black participants had lower levels of activity than whites and fewer (5% vs. 15%) reported any vigorous activity. This restricted range could

have obscured an association between physical activity and CHD. In a more recent study, Pereira, Folsom, et al., (Pereira, Folsom, et al; ARIC manuscript #422), examined physical activity in relation to hypertension. Blacks reported more walking and standing and less sitting at work than did whites, and blacks were less likely to report often or very often playing a sport or exercising during leisure time compared with whites (47% vs. 72%). Neither the sports nor the work index were associated with reduced odds of hypertension in blacks, but the lack of graded inverse association between BMI and waist-hip ratio with physical activity scores once again suggested measurement problems.

The positive features of the ARIC methods for assessing physical activity that have been retained in the JHS instrument include: 1) evidence that it is a valid and reliable measure of vigorous activity; 2) ability to assess activity in different domains (work, sport/leisure); 3) brevity and ease of administration. The ARIC instrument has important limitations and may have not worked as well in blacks as in whites. Fortunately, a modification of the ARIC instrument, known as the Kaiser Physical Activity Survey, has recently been validated in a multi-ethnic sample of women (Sternfeld, et al., 1999; Ainsworth, et al., in press). Sternfeld's (1999) study of the modified ARIC instrument with 2,635 ethnically diverse women ages 20-65 found associations between level of activity and lower BMI, not having young children in the home, social support for exercise, and motivation to exercise, and age, but these demographic and psychosocial correlates of physical activity differed by domain. Ainsworth and others (under review) compared the summary indices from the modified instrument with Caltrac accelerometers and participant physical activity diaries and with fitness and percent body fat measures. One month test-retest reliability correlations were high for all the indices ($r=.79$ to $.91$, $p<.01$). Age-adjusted Spearman rho correlations between the sports/exercise index and the active living index were moderate for VOCpeak ($r=.34$ to $.76$, $p<.01$) and percent body fat ($r=.30$ to $-.59$, $p<.05$). Correlations between similar activities for the instrument and participant's physical activity diaries ranged from $r=.03$ to $.64$. These findings show good reliability and validity for the modified ARIC instrument and that, at least in women, it works well across ethnic groups. Some additional minor modifications were made to adapt a few items for male respondents for the JHS (Personal communication, Barbara Ainsworth, July 31, 1999).

Physical Activity Hypotheses for the JHS

Physical activity will be examined in the JHS in order to examine its impact as an independent heart disease risk factor in male and female African-Americans and to understand its interaction with both established and nontraditional risk factors. Questions of interest include:

1. Is physical activity protective against heart disease and cardiovascular disease in African-Americans? At what levels of intensity and/or energy expenditure can a protective effect be observed?
2. What is the relationship of physical activity to weight and body composition in the adult African-American population?
3. Does physical activity in different settings (occupational, household, leisure/recreational) contribute similarly to protection against heart disease in African-Americans?
4. What sociocultural variables are associated with differing levels of physical activity in the JHS population in different age-sex groups?
5. Can environmental variables such as community crime and violence rates be related to activity levels of men and women at different ages and with varying employment and home/child care responsibilities? Can perceptions of discrimination be related to lower levels of physical activity?
6. What are the most frequent intensities and types of activities in various age-sex subgroups of African-Americans in the JHS?

3.14.2 References

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3.14.3 Administration

The PAC form is administered by trained interviewers as part of the HII in the participant's home. The form contains 30 items and 4 sections, "Active Living," "Occupational Activities," "Home, Family, Yard and Garden," and "Sports and Exercise." Participants are asked to identify the frequency and duration for these activities. Each of these activities is coded based on the effort typically required to perform that type of activity. Detailed instructions for administering each item are found in the QxQ instructions.

3.14.4 Permission to Use:

- Public Domain

3.15 Alcohol and Drug Form (ADR)

The Alcohol and Drug Form (ADR) is a core data collection form administered during the flexible component of the baseline exam to document alcohol and drug abuse. It uses questions from ARIC and several other large epidemiologic studies to provide general information about whether the participant has ever used alcohol and several other substances. Information obtained about alcohol will allow classification of participants into lifetime abstainers, ever users, and users during the past 12 months. It will assess preferred beverage, history of heavy use (yes/no), and provide quantity-frequency information about alcohol intake during the past 12 months. The information about drug use will allow classification into lifetime abstainers, ever users of cocaine or other drugs and provide an estimate of total number of cocaine uses. This form is not designed to be sufficient to allow for assessment of dependence or history of dependence for alcohol or other substances and will not provide lifetime quantitative data about total alcohol or drug exposure.

The sources for each item are shown in Table 15 below.

Table 1. Sources for each item in the Alcohol and Drug Form

ITEM	SOURCE
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Alcohol Item 1	ARIC
Alcohol Item 2	ARIC, 18b. from PHXB
Alcohol Item 3	NHANES3
Alcohol Item 4	ARIC
Alcohol Item 5	NHANES3
Drug Item 6	NHANES3
Drug Item 7	NHANES3
Drug Item 8	NHANES3

3.15.1 Background, Rationale, and Hypotheses

The association of alcohol to CVD risk has been examined in many studies, but some of the findings remain controversial (Hanna, 1997). The lowest CVD death rates appear to occur with light to moderate alcohol intake (about 1 drink per day). Higher death rates are observed in nondrinkers (individuals who have never consumed alcohol as well as those who quit drinking) and individuals consuming more than 2 or 3 drinks per day (Fuchs, et al., 1995; Klatsky, Armstrong, & Friedman, 1992; Klatsky, Armstrong, & Friedman, 1997); Thun, et al., 1997). Plausible mechanisms for the beneficial effects of light to moderate drinking, including increased HDL cholesterol and an antithrombotic effect, have been proposed and are supported by epidemiologic data. Yet many investigators remain concerned about the potential bias (i.e., the confounding of nondrinking controls with people who quit drinking after becoming ill and of subgroups with light-moderate intake with relatively affluent, well-educated adults with healthier lifestyles). Despite all the attention to the “beverage effect” in the popular media, the evidence that wine (and particularly red wine) is more cardioprotective than other beverages is not consistent or strong when total ethanol and other factors are controlled (Klatsky, et al., 1997).

A number of epidemiologic studies have confirmed an association between alcohol and hypertension risk when the level of drinking exceeds 1 or 2 drinks per day. A large prospective study found rates of death from all CVD were 30 to 40 percent lower among men and women reporting at least one drink daily than among nondrinkers, with little relation to amount of alcohol consumed. An earlier study of 72,000 Kaiser Permanente health plan participants which included 30% Blacks found no differences by race in the U-shaped relation of alcohol use to coronary disease (Klatsky, et al., 1992). This group (Klatsky, et al., 1997) also reported on a prospective case-cohort study of risk for CAD hospitalization almost 129,000 members of a northern California health plan; about 20% of the participants were African-American. Each beverage type showed evidence of CAD protection, but these investigators concluded there may be some additional benefits from beer and red or white wine.

About 20 to 30% of cardiomyopathy cases are attributable to chronic alcohol use (Secretary of Health and Human Services, 1994). Cardiac arrhythmias are frequently associated with acute alcohol intoxication and/or prolonged drinking at the level of 6 or more drinks per day (Regan, 1990), and may at least in part explain the increased risk of sudden death associated with heavy drinking. Compared to healthy controls, alcoholic men presenting for outpatient treatment had significantly lower mean ejection fraction, dilation of

the left ventricle, and increased left ventricular mass (Urbano-Masquez, et al., 1989). Cardiac dysfunction has been demonstrated, even in the absence of malnutrition or severe social consequences, in a third of asymptomatic alcoholic men (Regan, 1990).

In comparison to alcohol use, there are as yet few studies of the association between cocaine and other "street" drugs with CVD. Cocaine use is associated with increased acute CVD risk, but limited evidence suggests it may not be an independent predictor of hypertension or renal disease (Braun, et al., 1997; Brecklin, et al., 1998). Illegal drug use may be related to personality characteristics and psychological states which are known to adversely affect CVD risk.

Early Findings from ARIC

Folsom and others (Folsom, et al., 1991) examined ethanol intake in relation to plasma fibrinogen and factor VII in the ARIC cohort. An inverse association of Factor VII with ethanol intake was observed. Patsch, et al., found that alcohol consumption was associated with higher HDL cholesterol levels, with one drink per day associated with HDL increases of approximately 2.5 mg/dl in men and 7.5 mg/dl in women. These associations were essentially unchanged after adjustment for BMI, physical activity, smoking, and age. Demirovic, et al. (1993) reported the overall level of alcohol consumption in ARIC was low, with age-adjusted means for grams of ethanol per week 72.0 for white and 74.3 for nonwhite men and 24.8 for white and 11.2 for nonwhite women. After adjustment for age, artery depth, education, BMI, physical activity, smoking, LDL, and diabetes, the only race-sex group in which an hypothesized relationship between alcohol consumption and carotid wall thickness and distensibility was observed was in white women; however the significance was borderline. Duncan, et al. (1995) examined beverage-specific effects of alcohol on waist to hip ratio in the ARIC cohort. They found a reasonably graded increase in the waist-hip ratio with increased proportion of ethanol intake from beer or liquor (versus wine), which was most pronounced in individuals with BMI < 25. The findings were similar across race-gender categories. The authors noted that very few modifiable factors have been found which impact waist-hip ratio, and suggested that the observed effect may be one of the mechanisms mediating the cardioprotective effect of wine. However, they also acknowledged the likelihood of differences in diet, drinking pattern (e.g., slowly, with meals), and other factors between wine and nonwine drinkers.

Method of Alcohol Use Assessment in ARIC

Information on alcohol use was obtained at each visit by trained interviewers. 10 items queried whether the participant had ever used alcohol; whether s/he currently used alcohol (if not, how much time had elapsed since the most recent use); the current weekly intake of 4 oz. glasses of wine, 12 oz. cans of beer, and/or 1.5 oz shots of liquor in total drinks; and number of days each week when liquor was consumed. This would allow evaluation of effects of 1) total ethanol consumed 2) the pattern of drinking and 3) type of beverage. Several ARIC items have been retained for JHS Alcohol and Drug Form. Drug use was not assessed in ARIC.

Hypotheses include:

1. There will be a J- or U-shaped association of alcohol intake and CVD with abstainers having greater risk than minimal drinkers, and increased risk beginning with the average of 3-5 or more drinks per day.
2. Greater alcohol intake will be associated with other indications of inadequate coping and/or high levels of perceived stress and more dysfunctional psychological status.
3. Association of alcohol intake with CVD will be moderated by type of preferred beverage.
4. A history of heavy drinking during the 12 months preceding the examination (more than 2-3 drinks/day) will be associated with greater CVD risk.
5. Cocaine and other drug use will be associated with increased CVD risk.
Number of times of crack or cocaine use will be associated with demographic and sociocultural CVD risk factors.

3.15.3 References

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3.15.4 Administration

The ADR is administered to all participants during the baseline examination immediately following the food frequency assessment. There are 5 questions about alcohol use, followed by 3 items on drug use. The participant must have sufficient privacy to feel comfortable talking honestly about her/his substance use. Response cards with photographs of commonly used alcoholic beverages and "street" names for drugs will help participants understand the types of substance use we want to know about. Interviewers must be knowledgeable about different quantities and types of alcoholic beverages (for example, a "fifth" of whiskey) to accurately assess amounts reported. It is important not to make assumptions. If the participant says, "one half a beer," ask questions until you are certain of the size of the bottle or can s/he was referring to. Detailed instructions are included in the QxQ instructions following the ADR form in the Forms Appendix.

3.15.5 Permission to use:

- Public Domain

3.16 Hassles and Moods D: Anger (STX)

The Hassles and Moods D: Spielberger Anger Expression Inventory (STX) (see Form Appendix) will assess anger expression using the 16-item anger-in and anger-out subscales of the standardized STX (Spielberger, et al., 1988). Participants are asked to describe her/his reactions when feeling angry, by rating how often they react in the manner described by each item. Each item is rated on a 5-point, Likert-type scale from never (1) to almost always (4). The STX will be administered to all participants in the Take Home Questionnaires following the baseline exam, as one of the measures making up the Hassles and Mood Inventory.

3.16.1 Background, Rationale and Hypotheses

Several negative emotions have been identified as possible risk factors for coronary heart disease (CHD) (Booth-Kewley, et al., 1987). These negative or "coronary-prone" emotions have been found to influence the incidence, symptom expression, morbidity, and mortality associated with CHD.

Chronic anger and hostility have emerged as the primary (toxic) components thought to underlie associations between Type A and CHD. Several epidemiologic studies have found that chronic anger and/or maladaptive anger coping styles are associated with an increased risk of CHD-related morbidity and mortality (Barefoot, et al., 1989; Barefoot, et al., 1983; Barefoot, et al., 1995; Dembroski, et al., 1989; Everson, et al., 1997; Kawachi, et al., 1996; Haynes, et al., 1980). Anger has also been associated with all-cause mortality in a number of studies (Miller, et al., 1996). Anger is not a unitary construct. The measures of anger selected for use in the study assess key components of this multidimensional construct, i.e., cynicism and anger expression.

Hypotheses include:

1. Anger will be associated with an increased risk of hypertension, CHD events, and mortality independent of the contribution of traditional CHD risk factors.
2. The relationship observed between anger, hypertension, and CHD events will be moderated by social support, coping style, SES, and education.

3.16.2 References

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3.16.3 Administration

The STX will be administered to all participants, as a paper-and-pencil questionnaire, as one of the four measures making up the Hassles and Mood Inventory. Following the JHS baseline exam, participants will be provided with the Hassles and Mood Inventory. Participants will be asked to complete the packet of questionnaires at home. Participants will be read a general statement explaining the instructions for completing the packet of questionnaires and briefly explaining the rationale (see Appendix). The completed questionnaire will be picked up from the participant's home by the Sample Coordinator. When picking up the Hassles and Mood Inventory, the Sample Coordinator will check the questionnaires for completeness and will offer assistance to those who may have had difficulty completing the questionnaires. Detailed instructions for the STX are provided in the QXQ instructions (see Forms Appendix).

3.16.4 Data Collection

The STX will be completed on paper, self-administered in the participants' home. When needed, interviewer assistance will be available. Subsequently, the STX data will be entered into the data entry system by clinic staff.

3.16.5 Permission to Use:

- Copyright Psychological Assessment Resources, Inc; 16204 N. Florida Avenue; Lutz, FL 33549 www.parinc.com The Contents of the form may not be used or duplicated without express permission from PAR, Inc.

3.17 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.

3.17.1 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.

3.17.2 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.

3.17.3 Training

None Required.

3.17.4 Certification

None Required.

3.17.5 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.

3.17.6 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.

3.18 Chronic Burden

The Chronic Burden Form (CBF) is a 5-Item assessment of the effects of everyday stress on an individual and his/her family.

3.18.1 Rationale

It is important to understand the chronic problems that may be associated with ethnicity and indicators of social class in order to better understand the psychosocial and biological mechanisms that connect sociodemographic variables and depression, hypertension, metabolic syndrome, and subclinical cardiovascular disease. Chronic ongoing problems are common among middle-aged men and women; acute life events are correlated with social class and to a lesser extent ethnicity. Previous research shows that chronic ongoing problems predict increases in depressive symptoms and that indicators of stress are related to central adiposity. It is hypothesized that African Americans and lower SES CARDIA participants will report more ongoing chronic problems that are very stressful than their counterparts. It is

hypothesized that ongoing chronic problems will predict depressive episodes, and that ongoing chronic problems will predict central adiposity and the other indicators of the metabolic syndrome. (CARDIA Year 15 Protocol Ver. 1 3/22/00)

3.18.2 Administration

3.18.3 Permission to Use:

- Public Domain

The CBF is administered by certified interviewers as a part of the flexible sequence.

3.19 Depressive Symptoms and Dysthymia

The Major Depressive Episode Form (MDE) is an 8-item interview guide that is used to gather data on occurrence, duration, severity and recurrence of depressive episodes.

3.19.1 Rationale

A direct inquiry as to whether an individual has ever had an episode or episodes of depressive symptoms (with duration, severity and recurrence) would be a valuable addition in helping to illuminate the relationships between depression and physical disease onset and course. It is hypothesized that a history of depression will be independently associated with increased coronary calcification. It is also hypothesized that there will be a linear relationship between extent of history of depression (e.g., frequency of recurrence, severity) and increased risk of coronary calcification, hypertension and metabolic syndrome. (CARDIA Year 15 Protocol Ver. 1 3/22/00)

3.19.2 Administration

The MDE is administered by certified interviewers as a part of the flexible sequence.

3.19.3 Permission to Use:

- Public Domain

3.20 Health Care Continuity and Trust

Health Care Continuity and Trust is a 10 item interview guide that is used to gather data about health care access and utilization.

3.20.1 References

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3.21. Montreal Cognitive Assessment Form Instructions

Montreal Cognitive Assessment (MoCA)

The Montreal Cognitive Assessment (MoCA) was designed as a rapid screening instrument for mild cognitive dysfunction. It assesses different cognitive domains: attention and concentration, executive functions, memory, language, visuoconstructional skills, conceptual thinking, calculation and orientation.

3.21.1 Rationale

There is an increasing body of scientific literature describing various facets of blood pressure and cognitive decline in the elderly; Alzheimer's Disease, Parkinson's Disease and cerebrocortical circulation; cerebral complications of diabetes; type 2 diabetes, cognitive impairment and dementia and cardiovascular risk factors and cognitive decline in middle aged adults. Additionally there is a growing body of scientific literature on anti-hypertensive medications, cognitive function and quality of life, and hypertension control and cognitive function. In a study to evaluate the changes in blood pressure and cognitive decline, 8,058 men and women ages 48-67 were examined on the second and fourth visits in the Atherosclerosis Risks in Communities (ARIC) Study over a 6-year interval. The investigators reported that the results of the study indicated that older subjects with uncontrolled hypertension had a significantly larger mean score decline on selected tests of cognitive function, than normotensive subjects. Since the study was based on simultaneous changes in blood pressure categories and mean cognitive score changes, cause and effect are not distinguishable. The tests of cognitive function used were the Delayed Word Recall, Digit Symbol Subtest and the Word Fluency Test. Hypertension status was classified in five categories; normal, incident, controlled, partially controlled, and uncontrolled. The investigators recommend future studies with a longer follow-up time and a broader spectrum of cognitive testing. (Moraes, Szklo, Knopman and Sato; 2002).

In 2006, The National Institute of Neurological Disorders and Stroke-Canadian Stroke Network Vascular Cognitive Impairment Harmonization Standards were published in *Stroke* (online Aug 17, 2006). The National Institute for Neurological Disorders and Stroke (NINDS) and the Canadian Stroke Network (CSN) convened a cadre of researchers to recommend minimum, common, clinical and research standards for the description and study of vascular cognitive impairment. Vascular Cognitive Impairment (VCI) is defined as cognitive impairment that is caused by or associated with vascular factors. According to the researchers, since vascular risk factors are treatable, it should be possible to prevent, postpone, or mitigate VCI. Progress in VCI research requires first of all satisfactory diagnostic criteria, therefore the initial goal of the researchers' working group was to define a set of data elements to be collected in future studies aimed at more fully defining VCI, understanding its etiology, and identifying targets for treatment. The recommended protocol consisted of selected subsets from the Montreal Cognitive Assessment inclusive of a 5-word immediate and delayed memory test, a 6-item orientation task, a 1-letter phonemic fluency test (Animal Naming), a cube and clock drawing task, a 3-item picture naming task, a short "Trails B" (from the Trail Making test A and B), paradigm and other brief language and abstraction tasks. (Hachinski et al. *Stroke*, AHA, 2006).

It is hypothesized that there is a relationship between prevalent hypertension and cognitive function, and that partially controlled or uncontrolled hypertension is associated with a decline in cognitive function. It is also hypothesized that antihypertensive medications increase cognitive function and subsequent quality

of life and that risk factors for cardiovascular disease are similar to the risk factors for cognitive impairment.

3.21.2 References

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3.21.3 Administration

The Montreal Cognitive Assessment (MoCA) is administered to all participants during Exam 3 clinic visit by a trained and certified interviewer. The MoCA assesses different cognitive domains: attention and concentration, memory, visuoconstructional skills, conceptual thinking skills, calculations, and orientation. Time to administer the MoCA is approximately 15 minutes. The detailed procedure for administering the form is provided in the QXQ instructions in the Forms Appendix.

3.21.4 Permission to Use:

- Public Domain

General Instructions:

The MoCA form is completed during the participant's clinic visit. The interviewer must be certified and should have a working knowledge of the document "General Instructions for Completing Paper Forms" prior to completing this form. ID Number, Contact Year, and Name should be completed as described in this form.

The MoCA is a useful screening tool for the assessment of cognitive skill associated with concentration, memory, visuoconstructional skills, conceptual thinking, calculations and orientation. Time to administer the MoCA is approximately 15 minutes. The total possible score is 30 points; a score of 26 or above is considered normal.

1. Specific Instructions:
 - A. The testing space needs to be free from distractions –no family members present.
 - B. Sit directly across the table, facing the participant.
 - C. Keep your test sheet on a clipboard out of the participant's view-do not show scores.
 - D. Wear stop watch around your neck.
 - E. Have sharpened pencils without erasers.
 - F. Every staff person uses the EXACT same instructions – this is extremely important for test results to be valid.
 - G. Follow scripts on the instruction sheet
 - H. Give one item at a time – For items that require the participant to draw or write, hand them the material they need at that time, not before. Paper and pencil – remove when they finish that item.
 - I. Explain the purpose of the MoCA - Have script available, "As part of this study, we are interested in hoe people's health is related to thinking skills such as memory and

concentration. I have several tasks I'd like you to complete. I will not be allowed to give any additional assistance during the course of these questions."

- J. Please avoid calling this a test!!!!!!
- K. DO NOT HELP with extra explanations.
- L. Answer questions politely without giving help, be kind and respectful.
- M. You may say, "I am sorry, I am not allowed to give any help."
- N. Put the participant at ease – smile begin small talk - "How are you today?" Comment on the weather.
- O. If a person is uncomfortable or nervous, let him/her know this is normal. "Lots of people get a little nervous doing these kinds of tasks, just do the best you can."
- P. If a person asks if they answered correctly - "I am not allowed to tell you if you are right or wrong, you are doing okay."

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 hip 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

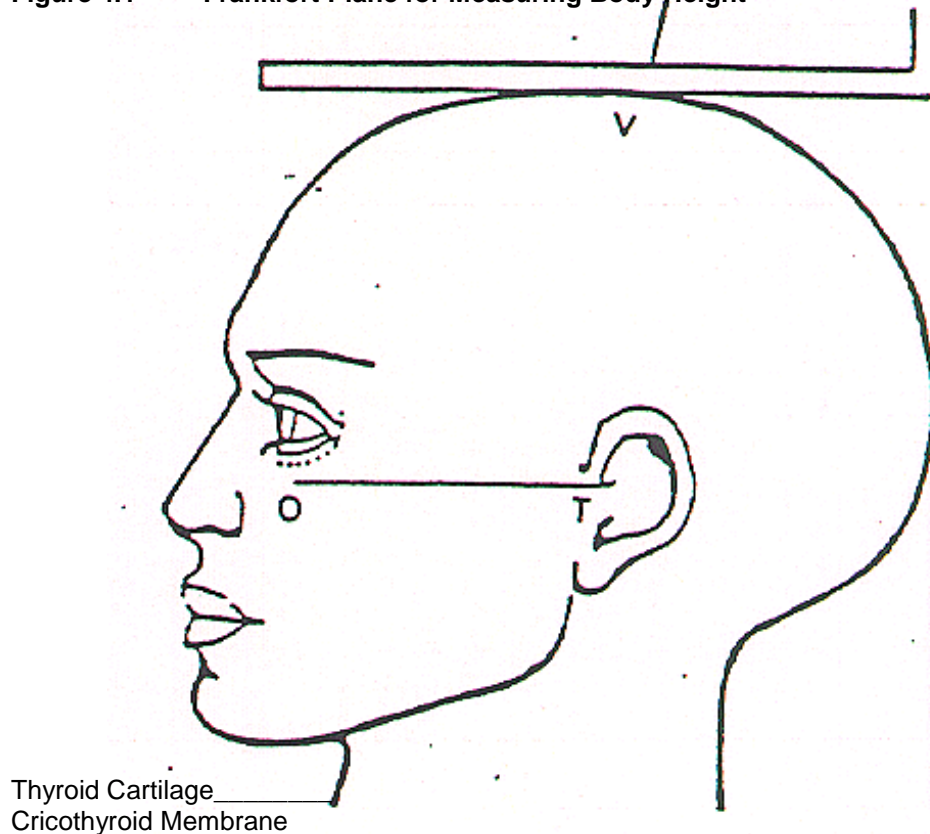
Anthropometry and determination of body composition are performed as part of the fixed sequence #1 before the clinic snack and after the participant has changed into a scrub suit or examination gown and been given the opportunity to empty her/his bladder. All measurements are made with the participant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



ORBITALE: Lower margin of eye socket

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

FRANKFORT PLANE: Orbitale-tragion line horizontal

THYROID CARTILAGE: Firm, cartilaginous prominence on neck

CRICOTHYROID MEMBRANE: Below thyroid cartilage

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

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

Conversion to Metric Measures

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

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

Centimeters	Inches	Centimeters	Inches
122	48.0	165	65.0
123	48.4	166	65.4
124	48.8	167	65.7
125	49.2	168	66.1
126	49.6	169	66.5
127	50.0	170	66.9
128	50.4	171	67.3
129	50.8	172	67.7
130	51.2	173	68.1
131	51.6	174	68.5
132	52.0	175	68.9
133	52.4	176	69.3
134	52.8	177	69.7
135	53.1	178	70.1
136	53.5	179	70.5
137	53.9	180	70.9
138	54.3	181	71.3
139	54.7	182	71.7
140	55.1	183	72.0
141	55.5	184	72.4
142	55.9	185	72.8
143	56.3	186	73.2
144	56.7	187	73.6
145	57.1	188	74.0
146	57.5	189	74.4
147	57.9	190	74.8

148	58.3	191	75.2
149	58.7	192	75.6
150	59.1	193	76.6
151	59.4	194	76.4
152	59.8	195	76.8
153	60.2	196	77.2
154	60.6	197	77.6
155	61.0	198	78.0
156	61.4	199	78.3
157	61.8	200	78.7
158	62.2	201	79.1
159	62.6	202	79.5
160	63.0	203	79.9
161	63.4	204	80.3
162	63.8	205	80.7
163	64.2	206	81.1
164	64.6	207	81.5

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

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

75	165.3	108	238.1
76	167.6	109	240.3
77	168.8	110	242.5
78	172.0	111	244.7
79	174.2	112	246.9
80	176.4	113	249.1

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

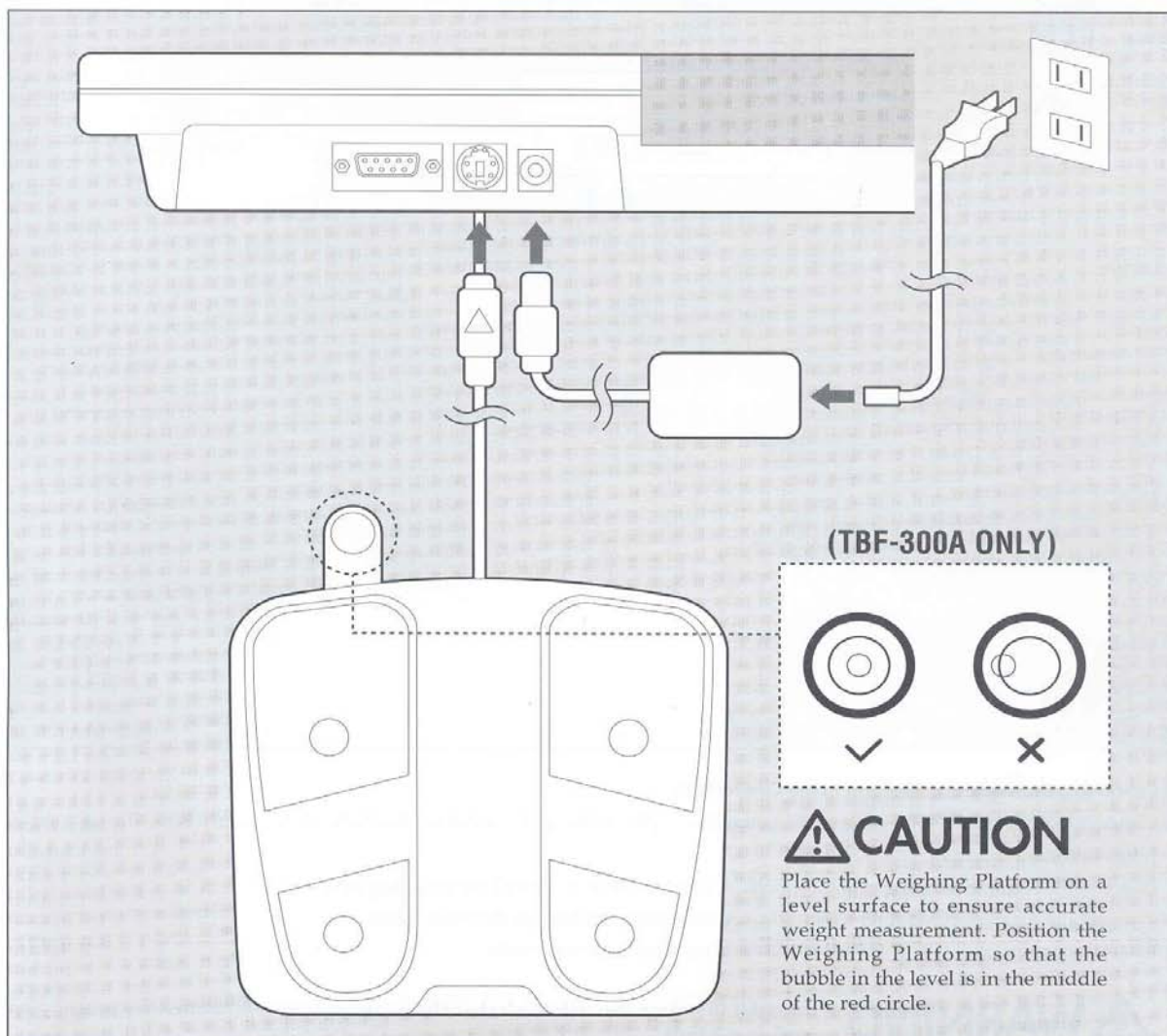
4.1.2.2 Body Weight

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

To maintain accuracy, the scale is zero balanced daily and calibrated with a known weight (50 lbs) every week or whenever the scale is moved. The daily zero balance and the weekly scale calibration are documented on the Anthropometry Equipment Calibration Log (see Appendix). The scale is professionally calibrated and serviced annually. The certified technician follows a checklist for weight measurement (Forms Appendix) which outlines the procedures for checking the equipment and measuring the participant's weight and enters study data on the BCF.

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

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

Figure 4.2 Set Up, Tanita TNF300A Body Composition Analyzer

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,

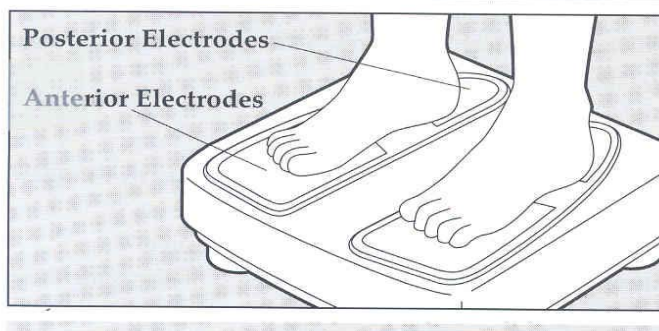
the unit will automatically switch to the measurement section. If further changes are needed, turn off the unit, and repeat the steps for setting number of printouts and language.

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 offsite 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.

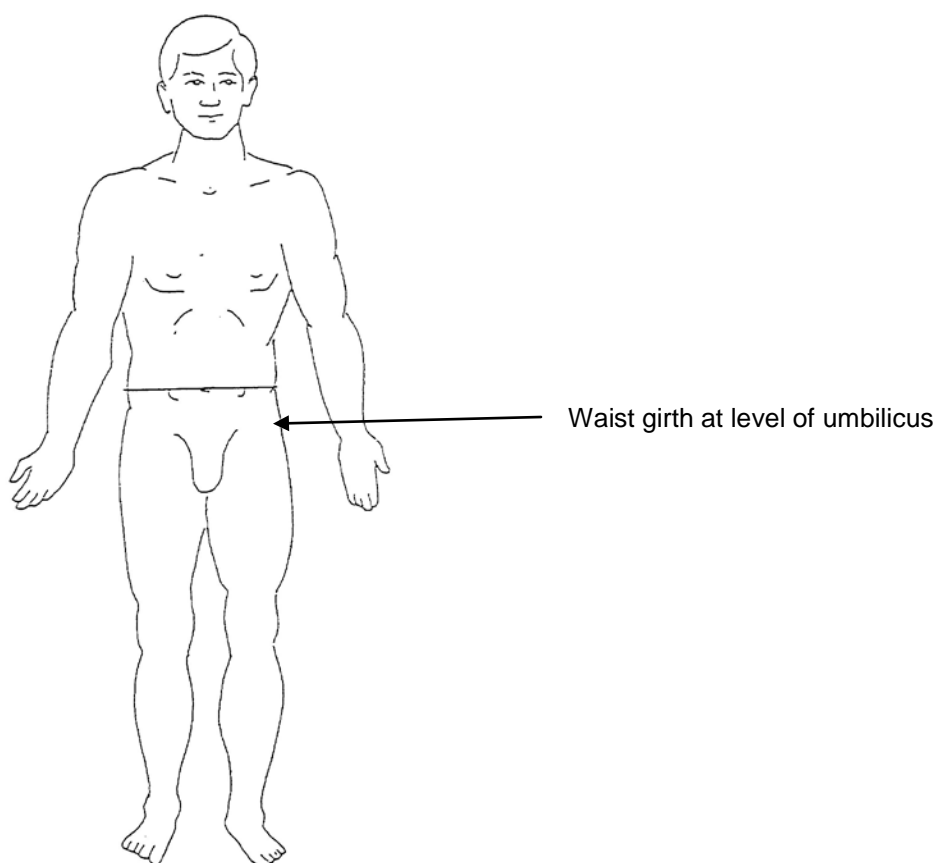
Figure 4.3 Foot Placement for Body Composition Measurement, Tanita TNF 300A Body Composition Analyzer



4.1.2.3 Abdominal (Waist) Girth

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

Figure 4.4 Location of Waist Girth Measurement

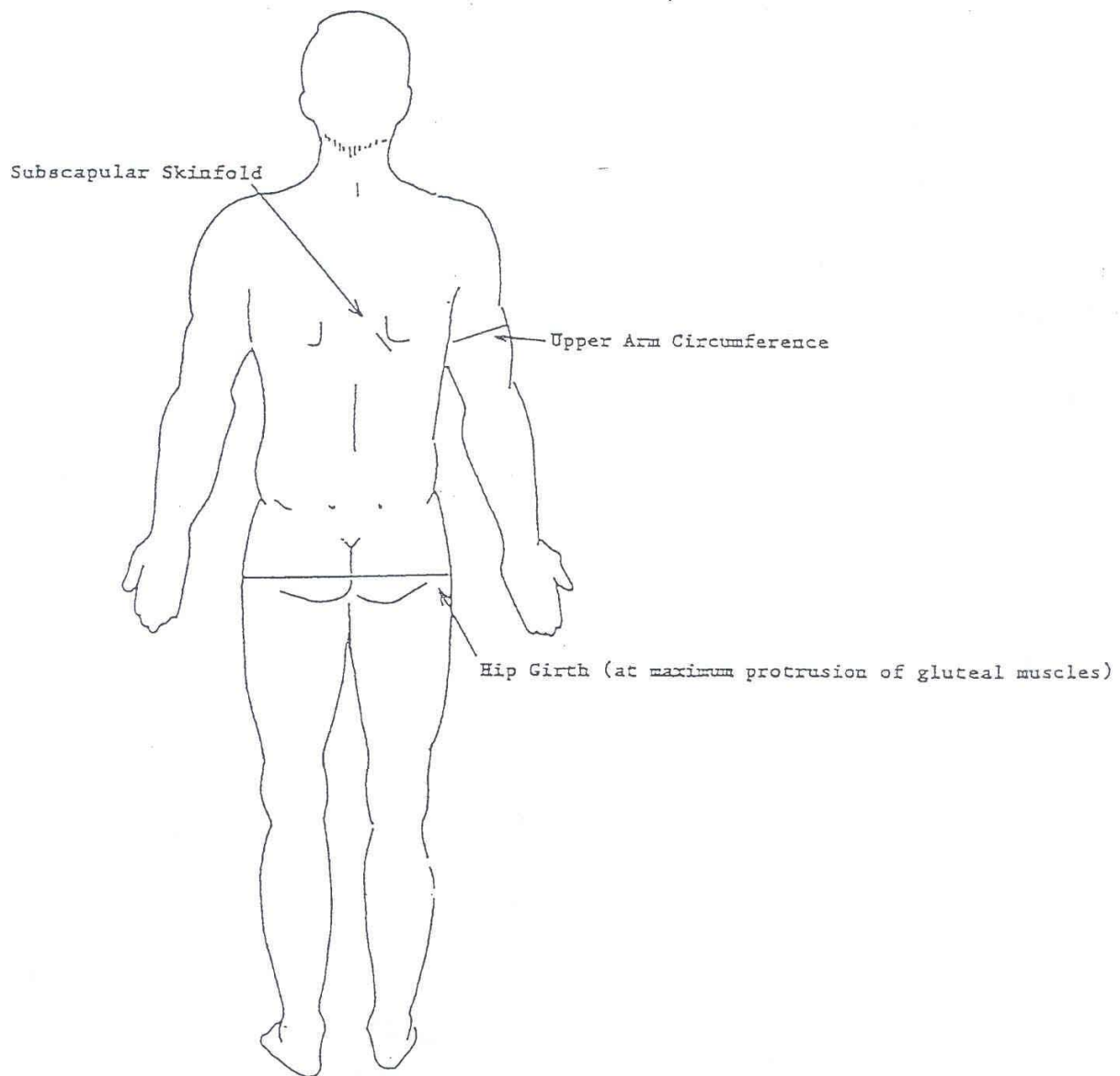


4.1.2.4 Hip Circumference

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

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

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

Table 4.5 Location of Hip and Upper Arm Girth Measurements and Subscapular Skinfold**4.1.2.5 Arm Circumference**

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

marks the posterior tip of the acromion process (shoulder bone). Using a centimeter tape, the technician measures the length of the upper arm between the two marks and marks the midpoint (+).

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

4.1.2.6 Body Fat Percentage and Fat Mass

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

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

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

Figure 4-6 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).

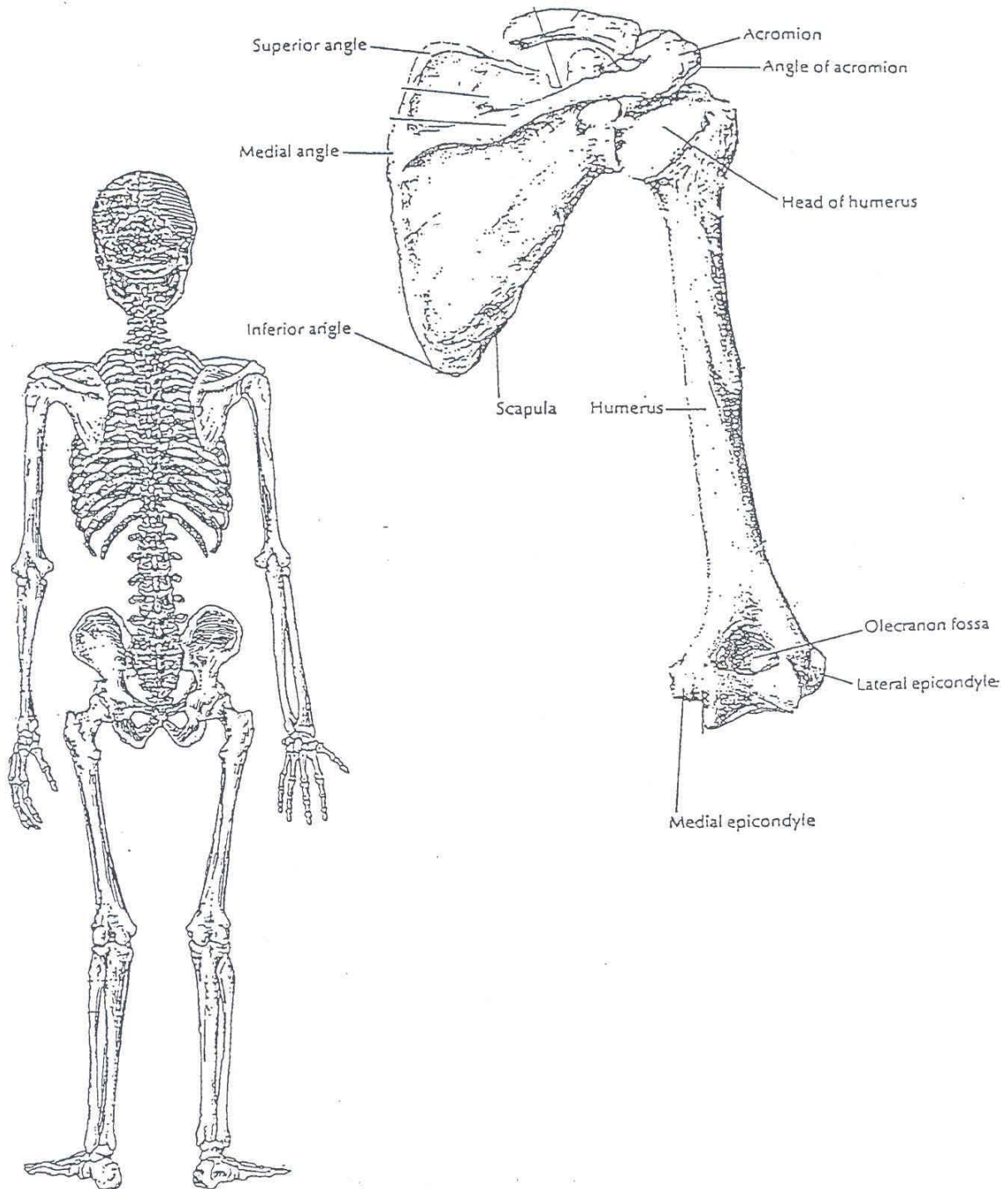
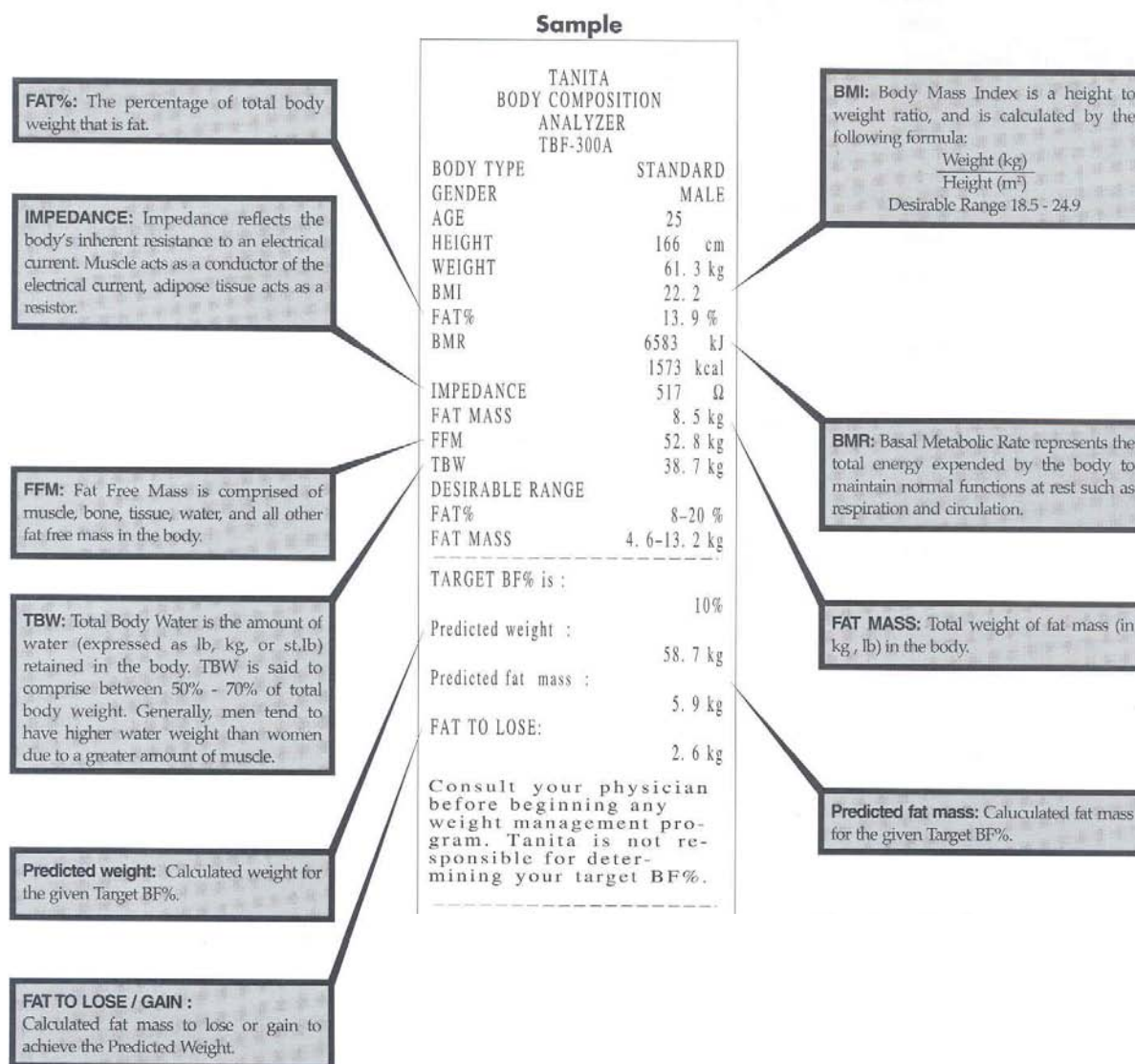
Table 4.6 Bony Landmarks for Anthropometric Measures

Figure 4.7 Sample Tanita TNF 300A Body Composition Print Out



4.1.3 Training

Technicians are trained by the Manager Research Clinic and the Clinic 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 data are 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.

4.2.1 Rationale

As blood pressure rises, so does risk of ischemic heart disease and its complications. The range of normal blood pressure 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. Middle aged persons with a diastolic pressure of 90-104 mmHg (so-called "mild hypertension") have a risk of heart attack that is about 70% 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 pressures. (Exam 1, Manual 1, version 1.0 04/26/2000)

4.2.2 Procedure

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 clinic 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

4.2.3 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.

4.3 Ankle-Brachial Blood Pressure (ABB)

Ankle-Brachial Blood Pressure is performed as part of the flexible sequence #2 during the Exam 3 clinic visit. See Manual 3, Blood Pressure. See Forms Appendix for ABB form and QxQ instructions.

4.3.1 Rationale

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.

4.4 Venipuncture

Blood Samples are obtained via venipuncture for measures of fasting glucose, hemoglobin A1c, lipids, C-reactive protein, urea nitrogen, creatinine, insulin, e-selectin and p-selectin.

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 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. Creatinine is an indicator of kidney function. Insulin is an indicator of insulin resistance which is one of the indicators of diabetes and metabolic syndrome, e-selectin and p-selectin are biomarkers for atherosclerotic plaques.

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.

4.4.3 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.

4.4.3.1 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.

4.4.3.2 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.

4.4.4. Data Collection

4.4.4.1 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.

4.4.4.2 Phlebotomy Room

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

4.4.4.3 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.

4.4.4.4 Obtaining Blood Specimen

See Manual 4 "Central Laboratory and Specimen Repository."

4.5 Spot Urine

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.

4.5.1 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.

4.5.2 Procedures for Collecting the Urine Specimen

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

4.5.2.1 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).

4.5.3 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.

4.5.4 Certification

No certification is required.

4.5.5 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 number of missing specimens are monitored by the Quality Control Subcommittee.

4.5.6 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.

4.6 Electrocardiography

A resting 12-lead electrocardiogram (ECG) will be recorded digitally on all JHS participants.

4.6.1 Rationale

The ECG recording in this 3rd exam visit will document the development of new cardiovascular disease (CVD) including silent myocardial infarction, myocardial ischemia, left ventricular hypertrophy, prolonged QT interval and arrhythmias as well as the development of subclinical ECG findings that are determined to be associated with poor prognosis i.e. the ECG in JHS will be used to detect new (incident) cardiac disease.

4.6.2 Procedures

See Manual 5

4.6.3 Training and Certification

See Manual 5

4.7 Snack

A light snack is scheduled as soon as possible after venipuncture during the flexible sequence for the Exam 3 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 Clinic, but will include heart-healthy alternatives.

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

The purpose of the Magnetic Resonance Imaging (MRI) cardiac imaging, in Exam 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 component of the study.

4.8.1 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

4.8.2 Participant Selection and Scheduling

Two to three JHS participants can receive an MRI per day.

4.8.3 Preparation for the MRI

See Manual 6

4.8.3.1 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.

4.8.3.2 The JHS Clinic staff/Navigator will greet the participant and confirm his/her appointment.

4.8.3.3 The JHS Clinic staff/Navigator will be responsible for explaining and obtaining consent for the MRI examination.

4.8.3.4 The JHS Clinic staff/Navigator will accompany the participant to the waiting area next to the MRI and inform the MRI Technologist.

4.8.4 MRI Procedure and Participant Instructions

4.8.4.1 Radiology staff will register the participant into the PACS system

4.8.4.2 The MRI Technologist will conduct safety screening before the participant enters the MRI environment

4.8.4.2.1 First ask the participant if he/she has ever had an MRI? He/she 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.

4.8.4.3.2 If the participant has not had an MRI before, show him/her the informational brochure with the picture of the machine and talk about the fact that s/he will be inside it for about 45 minutes or so. Mention that it is light inside and that she/he 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.

4.8.4.3.3 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.

4.8.4.3.4 You can use your consent form as a guideline for whether a 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 participant 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 participant. The risk of claustrophobia should also be discussed if the participant has not had an MRI before.

4.8.4.3.5 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

4.8.4.3.6 Items that should be discussed with the MRI technologist (if you have doubt, call the MRI experts before scheduling the participant 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.

4.8.4.3.7 When the participant 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 participant will then have his/her blood pressure measured after resting 5 min. The technologist will go over instructions with the participant and have him/her remove any items that need to be removed before entering the MRI suite.

The participant 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 participant's chest and abdomen. These coils are basically used as antennae to enhance the MRI signal. They look like vests and weigh a couple of pounds each and are buckled into place. The technologist will put headphones on the participant or give him/her earplugs. The participant will also be given a call button to press if s/he needs help during the scan.

4.8.4.3.8 The cardiac MRI process itself should also be discussed with participants whether they have had an MRI before or not. The main thing the participant will be asked to do is to breathe as the technologist instructs and lie as still as possible. The technologist will frequently ask the participant 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 participant will then need to hold his/her breath for between 8 and 20 seconds depending on the sequence being run. There will also be times when the participant will be asked to breathe normally and there may be periods of silence. The technologist will keep the participant informed and ask how s/he is doing over the intercom.

4.8.5 Identification of Alert Findings and Procedure for Reporting Results

4.8.5.1 Wake Forest University Health Systems will perform the interpretation of the Cardiac MRI examinations for clinically significant findings.

4.8.5.2 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.

4.8.5.3 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.

4.8.5.4 UMC will archive a copy of the exam on the UMC Phillips PACS

4.8.5.5 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.

4.8.5.6 If the local radiologist determines that the MR abnormality constitutes an alert (immediate or urgent referral), the local radiologist will instruct the technologist to make and archive a film copy of the MR scan; telephone the JHS PI, and will initiate notification protocol for participant and his./her health care provider.

4.8.5.7 Arrangements for further medical evaluation will be made through discussions involving the participant and health care provider.

4.8.5.8 The alert will be noted on MRI Scan Coding Form Sent to Reading Center.

4.8.5.9 The Reading Center has established the following Alert Status Categories

1. 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

2. Normal
 - a) No clinically significant findings
3. 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.
4. Urgent Referral

Requires direct referral to a hospital or clinic

 - a) Abnormality which requires immediate medical evaluation, typically within on 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.

4.8.5.10 The Reading Center has established the following results categories:

1. No Participant Referral Indicated / Normal
 - a) No clinically significant findings
 - b) Cardiac function parameters: \geq measures beyond 2 standard deviations of normal
2. Abnormal
 - a) Cardiac function parameters: >2 measures beyond 2 standard deviations of normal
 - b) Ascending aortic size ≥ 4.5 cm – 4.9cm
 - c) Pericardial effusion > 4 mm
 - d) Pleural effusion > 1 cm
 - e) Possible mass or tumor
 - f) Any other abnormality deemed by the RC PI as abnormal.
3. Urgent Participant Referral
 - a) Ascending aortic size \geq or $= 5$ cm
 - b) Aortic dissection
 - c) Definite mass or tumor
 - d) Cardiac or pulmonary thrombus
 - e) Any other abnormality deemed by the RC PI as immediate

4.8.5.11 Reading Center Results Reporting Protocol

1. Communication with JHS by RC
 - a) The MR Reading Center will send the participant's MR results data file to the JHS by electronic mail.

- b) The participant's 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.
 - 1) Normal for Age
 - 2) Possible Finding
- c) The Reading Center will in turn send the MR results letter to the JHS by electronic mail.

4.8.5.12 Communication with Reading Center and Data Management Unit

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

4.8.5.13 Clinic Reporting of Results

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 WFU Data Acquisition Center's radiologist.

4.8.5.14

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 for communicating incidental findings to participants and their health care provider (if one was identified)

4.8.6 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 6

4.8.7 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 6.

4.8.8 Quality Assurance

UMMC Radiology department and Wake Forest Reading Center Staff are responsible for quality assurance for the procedure. Please refer to MRI Manual 6.

4.8.9 Data collection

See MRI Manual (Manual # 6) for description of data collection and transfer to JHS.

4.9 Cardiac Magnetic Resonance Imaging with Contrast

The purpose of Cardiac Magnetic Resonance Imaging with contrast is to obtain more detailed MRI pictures of the heart and aorta in 600 African Americans located in the Jackson Mississippi metropolitan area. Data will be gathered regarding left ventricular volumes/mass/ejection fraction, quantitative measures of left ventricular (LV) contraction (tagging), and measures of blood flow (vascular stiffness) and wall thickness in the thoracic aorta. These data will identify individuals with myocardial fibrosis from ischemic (myocardial infarction) and non-ischemic sources. Comparison with other population-based cohort studies such as the Multi-ethnic Study of Atherosclerosis (MESA) will be possible.

4.9.1 Eligibility and Exclusion Criteria

4.9.1.1 The participant must meet the criteria to be eligible for MRI without contrast as determined when Clinic staff and the MRI Technologist complete the JHS MRI Safety Screening Form; this includes all the standard exclusion criteria related to implanted devices and foreign bodies.

4.9.1.2 Additional Exclusion Criteria

Kidney failure

Kidney transplant

Liver failure

Having a known allergy to contrast agents-commonly referred to as "Gadolinium"

4.9.2 Participant Selection and Scheduling

4.9.2.1 One to three participants will be scheduled for MRI each day, Mon-Fri

4.9.2.2 All participants who are scheduled for MRI who meet the inclusion criteria for MRI with contrast will be offered the opportunity by Clinic staff to be scheduled for the MRI with contrast.

4.9.3 MRI with Contrast Procedure and Participant Instructions (See Manual 6, Appendix A)

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 Clinic 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. 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. Participants with elevated blood pressures less than 210/120 mm Hg are referred to their source of medical care at the Medical Data Review following the guidelines shown in Table 5-1.

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.

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

Table 5.1 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 ≥ 260 or	Transportation to emergency care facility. Stop exam and reschedule clinic visit	Your BP is very high.

	DBP \geq 130		
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.

5.2.2 Participant Medical Data Review Exit Interview

Trained staff conducts the medical data review as part of the fixed sequence #2 at the end of the Exam 3 clinic visit to:

- summarize the results of selected measurements obtained during the Exam 3 exams/interviews
- identify potential medical problems
- answer participant questions

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

5.2.3 Clinician Reviews

Clinician reviews of medical data reports are conducted one week after the participant's Exam 3 clinic visit by the Manager Research Clinic, with back up of the Clinic RN and oversight by the Associate Director/co-PI of the Data Acquisition Unit and JHS PI. This step in the Medical Data Review process is to assure that all alerts have been recognized and adequately managed by Clinic staff.

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

5.3 Training

Staff are trained for the data inventory and assembly of study materials for the Medical Data Review, as well as the Medical Data Review tasks by the Manager Research Clinic who is trained to perform the clinician review by the JHS PI or designee.

5.4. Certification

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

5.5 Quality Control

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

6.0 REFERRALS AND REVIEW GUIDELINES

6.1 Rationale

Referrals for follow-up care can be made at the Medical Data Review or in subsequent communications.

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

6.2 Procedures

Referrals are made during the Medical Data Review or upon receipt of the study's clinically relevant data, which follow the criteria listed below. The presence of symptoms will increase level of urgency.

1. Emergency Referral. Transportation to the nearest emergency care facility is provided or an emergency squad is called.

2. Immediate Referral. The participant is urged to see her/his health care provider within one day.

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

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

3. Urgent Referral. The participant is asked to see her/his health care provider in ~~one week~~ one to 4 weeks.

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

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

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

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

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

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

Table 6.1 Medical Care Referral Guidelines			
Referral Classification	Examination Findings	Recommendation to Participant	Explanation to Participant
EMERGENT/ IMMEDIATE (Presence of symptoms will increase level)	Markedly elevated symptomatic HTN SBP \geq 260 210 or DBP \geq 430 120	See health care provider today	Your BP very high
URGENT Referral	*SBP \geq 180-209mm Hg or *DBP \geq 110-119mm Hg	See health care provider within a week	Your BP very is high.
ROUTINE Referral	*SBP 160-179 mm Hg or DBP 100-109 mm Hg *SBP 140-159 mm Hg or DBP 90-99 mm Hg *SBP 120-139 mm Hg or DBP 80-89 mm Hg	See health care provider within one year	Your BP is high Your BP is high Your BP is borderline high
NO Referral	* SBP 130-139mm Hg or DBP 85-89mm Hg *SBP \leq 140mm Hg and DBP \leq 90mm Hg Height, weight	Recheck in one year Recheck in two years None	Confirm only Confirm only Your reading is high normal Report only

*Interview items/measurements require confirmation during Medical Data Review

TABLE 6.2 SUMMARY OF PROCEDURES FOR ROUTINE REPORTING AND IDENTIFICATION, NOTIFICATION, AND DOCUMENTATION OF ALERTS					
Exam	ACTION SEQUENCE FOR ROUTINE RESULT REPORTING	Action Sequence for Identifying Abnormal / Alert Result	ABNORMAL / ALERT VALUE BY CATEGORY OF REFERRAL	ACTION SEQUENCE FOR REPORTING ABNORMAL / ALERT RESULT	ALERT / REFERRAL DOCUMENTATION
BP	BP Technician informs participant of BP ↓ Clinic nurse discusses findings	BP Technician identifies alert value ↓ Notifies Manager Research	Emergent: SBP \geq 210 DBP \geq 120	Stop clinic exam and transport to local ER. Notify participant and HCP by telephone.	Record alert value, referral action, notification method and date of notification on ALT (Alert and Referral Log) at time of

TABLE 6.2 SUMMARY OF PROCEDURES FOR ROUTINE REPORTING AND IDENTIFICATION, NOTIFICATION, AND DOCUMENTATION OF ALERTS					
Exam	ACTION SEQUENCE FOR ROUTINE RESULT REPORTING	Action Sequence for Identifying Abnormal / Alert Result	ABNORMAL / ALERT VALUE BY CATEGORY OF REFERRAL	ACTION SEQUENCE FOR REPORTING ABNORMAL / ALERT RESULT	ALERT / REFERRAL DOCUMENTATION
	<p>and gives instructions for follow up at exit interview.</p> <p>↓</p> <p>Social Work referral to assist with HCP or other identified social needs as indicated.</p> <p>↓</p> <p>Weekly Manager Research Clinic review of <u>all</u> results from preceding week with review of appropriate alert action for previously identified alerts. Any new alerts identified initiate Alert Action sequence for participant and HCP notification.</p> <p>↓</p> <p>Weekly clinician review of <u>abnormal</u> results from preceding week with review of appropriate alert action.</p> <p>↓</p> <p>Comprehensive <u>abnormal</u> results reporting to HCP (if requested) within 2 weeks following clinic visit.</p>	<p>Clinic/Clinic Research Coordinator</p> <p>↓</p> <p>Confirms reading</p> <p>↓</p> <p>Contacts JHS Medical Officer or Clinician on-call</p> <p>↓</p> <p>Initiates Alert Action procedure</p>	<p><u>Immediate:</u> SBP 210-259</p> <p>DBP 120-129</p> <p><u>Urgent:</u> SBP 180-209</p> <p>DBP 110-119</p> <p><u>Routine 1:</u> SBP 160-179</p> <p>DBP 100-109</p> <p><u>Routine 2:</u> SBP 140-159</p> <p>DBP 90-99</p> <p><u>Routine 2:</u> SBP 120-139</p> <p>DBP 80-89</p>	<p>Continue with clinic exam. Notify participant and HCP at exit interview. If no HCP, use Referral Procedure and make appointment for same day.</p> <p>Continue with clinic exam. Notify participant at exit interview and HCP by letter (M2Appendix) for 1-week appointment. If no HCP, use Referral Procedure and make appointment for one week.</p> <p>Continue with clinic exam. Notify participant at exit interview and HCP by letter (M2Appendix) for one-month appointment. If no HCP, use Referral Procedure and make appointment for one month.</p> <p>Continue with clinic exam. Notify participant at exit interview and HCP by letter (M2Appendix) for two-month appointment. If no HCP, use Referral Procedure and make appointment for two month.</p>	<p>action.</p>

TABLE 6.2	SUMMARY OF PROCEDURES FOR ROUTINE REPORTING AND IDENTIFICATION, NOTIFICATION, AND DOCUMENTATION OF ALERTS
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Exam	ACTION SEQUENCE FOR ROUTINE RESULT REPORTING	Action Sequence for Identifying Abnormal / Alert Result	ABNORMAL / ALERT VALUE BY CATEGORY OF REFERRAL	ACTION SEQUENCE FOR REPORTING ABNORMAL / ALERT RESULT	ALERT / REFERRAL DOCUMENTATION
				Continue with clinic exam. Notify participant at exit interview and HCP by letter (M2 Appendix) for one year appointment. If no HCP, use Referral procedure and make appointment for one year.	
Lab	<p>Central Lab notifies Manager, Research Clinic/Clinic Research Coordinator or Lead Lab Tech of alert values Manager Research Clinic/Clinic Research Coordinator notify participant and JHS Medical Officer/Clinician on call</p> <p>↓</p> <p>Monthly Manager Research Clinic review of <u>all</u> results from preceding week with review of appropriate alert action for previously identified alerts. Any new alerts identified initiate Alert Action sequence for participant and HCP notification. Retain paper file of lab results for back up until completion of comprehensive reporting.</p>	<p>Lab Technician identifies alert (Panic) value ↓ Notifies Manager Research Clinic/Clinic Research Coordinator ↓ Reviews reading ↓ Contacts JHS Medical Officer or Clinician on-call ↓ Initiates Alert Action procedure ↓</p>	<p><u>Emergent:</u> None</p> <p><u>Routine:</u> All other abnormal values not classified as alert value</p>	<p>Notify participant and HCP by telephone on day alert received. FAX complete lab results to HCP. If no HCP, use Referral Procedure and make appointment for same day.</p> <p>Notify participant in clinic and HCP by letter (M2Appendix) for 1-week appointment. Enclose copy of alert lab value and complete venipuncture results to HCP. If no HCP, use Referral Procedure and make appointment for one week.</p> <p>Notify participant in clinic and HCP by letter (M2Appendix) for</p>	Record alert value, referral action, notification method and date of notification on ALT (Alert and Referral Log) at time of action.

TABLE 6.2 SUMMARY OF PROCEDURES FOR ROUTINE REPORTING AND IDENTIFICATION, NOTIFICATION, AND DOCUMENTATION OF ALERTS					
Exam	ACTION SEQUENCE FOR ROUTINE RESULT REPORTING	Action Sequence for Identifying Abnormal / Alert Result	ABNORMAL / ALERT VALUE BY CATEGORY OF REFERRAL	ACTION SEQUENCE FOR REPORTING ABNORMAL / ALERT RESULT	ALERT / REFERRAL DOCUMENTATION
	<p>↓</p> <p>Monthly clinician review of routine <u>abnormal</u> results from preceding week with review of appropriate alert action.</p>			<p>1-week appointment. Enclose copy of alert lab value and complete venipuncture results to HCP. If no HCP, use Referral Procedure and make appointment for one week.</p>	

Table 6.3: Venipuncture and Urine Microalbumin Alert Values

Alert Category	Glucose	Lipids	Hemoglobin A1c	Urine Micoalbumin
Emergent		None	None	None
Immediate	Glucose:<45 or >.500	None	>12%	None
Urgent	Glucose: 45-60 or 200-500	Total Chol: >360 HDL: < 20 LDL: > 260 TG: >1000	>10%	>300mcg
Routine:	Any abnormal value not Classified as an alert	Total Chol: >200 -360 HDL: >20 <35 LDL: >100 <260 TG: >200 <1000	>8%	>30 mcg

6.3 RESULTS REPORTING

This activity concludes a process that extends over one month after the participant completes the exam. When all study results are received from the Central Laboratory and by the Data Management Unit, they are summarized for final disposition by Clinic medical staff. Final summaries of the study results are compiled.

As urgent and immediate alert values are returned from the Central Laboratory, the medical staff reviews them and assumes responsibility for referrals.. Routine results may bypass physician review until the final report is generated. The JHS clinician or Manager Research Clinic reviews all letters and reports sent to the participants and her/his health care provider.

6.3.1 Results Reported Only by Request

All other study measurements, i.e. those not routinely reported to participants and/or their health care provider, are considered to be of research value only. If a participant requests them in writing, these values are provided on a case by case basis. See Appendix (Request Form)

On the rare occasion that the Clinic receives a request for a participant's study results from a third party medical care pay or, a results report can be released according to the following steps.

1. A signed statement from the participant authorizing the release of JHS data to anyone other than the participant or her/his identified health care provider is required prior to the release of the study data by the JHS. A copy of the request and the authorization for release of study data is kept in the participant's folder.
2. The report contains only the information that was released to the participant's health care provider (or the participant), i.e., an exact copy of the cover letter and the results report.

3. This information is sent with a cover letter (see Appendix) from the Clinic stating that the JHS does not provide diagnostic services or treatment.
4. The information is sent directly to the third party with an exact copy to the study participant, indicating the date on which the information was sent.

6.3.2 Reporting of Genetic Data

The results of any genetic study will be handled as any other results not routinely reported as they are of research value only (See section 8.5.3).

If, during the course of the JHS, a genetic polymorphism is discovered which has clear clinical relevance and is treatable, information will be released study wide to participants regarding these polymorphisms. A description of the polymorphism, its health risk and treatment will appear in the JHS participant newsletter along with a mechanism to receive more information and a referral for gene testing. The cost of any such referral is the responsibility of the participant.

7.0 Participant Safety

7.1 Rationale

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

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

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

7.2 Procedures

7.2.1 Measures to Protect the Participant

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

- The possibility of hypoglycemia with a 12-hour fast is diminished by routine inquiry about reasons that should exempt the participant from fasting during the scheduling of baseline exam. Other medical conditions or dietary restrictions, which may be incompatible with the snack provided in the clinic, are also ascertained.
- Hematomas or prolonged bleeding may result from venipuncture. These are usually avoided if well-trained technicians follow the procedures for venipuncture. Prior to venipuncture, the participant is asked: "Do you have any bleeding disorders?" If the participant answers affirmatively or is uncertain, s/he is asked about whether s/he has had blood drawn previously

and if so, whether there were any problems such as swelling or continuing to bleed at the venipuncture site. If the answer to this question is “yes,” the Manager is summoned to approve the venipuncture. Occasionally, with any participant, bleeding persists after the venipuncture. If the participant continues to bleed:

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

If the measurements taken have not stopped all bleeding within 30 minutes, and there is no obvious explanation for the prolonged bleeding, a medical referral is made. Also, the participant is instructed to seek medical care promptly if bleeding recurs after leaving the JHS clinic.

Participants may experience dizziness or syncope during the venipuncture. When a participant feels faint or looks faint following venipuncture, follow the rules for a minor emergency, below (section 7.3.2). Additionally,

- Have someone stay with the participant to prevent him/her from falling and injuring himself/herself if s/he should faint
- Place a cold wet cloth on the back of the participant's neck or on his/her forehead
- Once the episode has passed, some fruit juice may be given to the participant in order to counteract any possible hypoglycemia due to his/her pre-clinic visit fast
- If the participant continues to feel sick, take a blood pressure and pulse reading. Contact a medical staff member, who will advise you on further action

7.2.2 Stopping Rules for Interviews and Procedures

Participant safety and comfort during the clinical examination are monitored throughout the clinic visit. Interviewers and technicians observe participants for signs of fatigue or physical and/or emotional discomfort. When any one of these conditions is observed, participants are offered the opportunity to discontinue the interview or procedure, and are given an opportunity to rest before the next procedure. Participants incapable of completing the entire clinical exam are invited to change back into her/his street clothes and participate in the medical data review and reschedule the clinic exam on another day.

For participants with conditions which require emergency and immediate referrals, such as cardiac events, unstable angina, or blood pressure $\geq 210/120$ mm Hg (see Tables 16 and 17), the JHS physician is consulted immediately, the clinic exam is terminated as soon as the condition is observed, and another appointment for the exam is rescheduled as appropriate. For blood pressures requiring referral within one week (SBP 180-209 mm Hg or DBP 110-119 mm Hg; the urgent referral category in Table 20), the JHS physician is also consulted, and the clinic exam is either continued and the participant advised to seek medical care within one week, or the clinic exam is terminated and rescheduled, based on the JHS physician's recommendation. The termination of any interview or procedure is documented on the Participant Itinerary Sheet (PIN).

7.3 Methods for Handling Emergencies

While all life-threatening emergencies (e.g., acute MI) require immediate evaluation of the participant at an acute care facility, some emergency measures may be required in the clinic before departure (e.g., cardiac arrest). In addition, there are minor emergencies (hypotension, fainting, etc.) which may require treatment in the clinic only. Although most emergencies are of the less

severe nature, the Clinic is prepared for both types.

7.3.1 Major Emergencies

In a serious event the primary concern of the Clinic staff is to implement pre-established procedures to get the participant to the nearest medical facility. The JHS clinic is located within a few city blocks of a large, general, and acute-care hospital. A staff person with certification in basic life support is on duty and physically present at every clinic session. Needed life support procedures are continued until emergency care arrives or the participant is transported to a hospital. The Clinic has specific emergency procedures which define:

- Who is in charge during the emergency
- Who is to administer treatment
- Who is to be notified
- What action clinic staff is to take
- Which reports are to be filed

In addition to trained personnel and emergency equipment, the Clinic has posted in a conspicuous place (e.g., the reception area): phone number of police and fire stations, ambulance services, and specific phone numbers or codes to alert medical teams, if applicable.

In each participant's folder, the name and phone number of her/his health care provider or usual source of medical care and the home and work telephone numbers of one or more contact person are available on the CON form. The Clinic is required to have either a physician or a registered nurse on site at all times when participants are interviewed and examined.

All emergency situations are coordinated by the staff person designated, a priori, or by a physician if present. The Clinic has a designated physician on duty for each clinic session. If not physically present in clinic, s/he is within immediate reach by phone or paging system and within a short distance to the clinic. The physician duty roster is posted with the clinic secretaries and in the office of the nurse/clinician so that the name of the responsible physician is readily accessible. However, in no case is emergency referral and/or care deferred while staff is attempting to locate a clinic doctor.

JHS staff is trained to carry out specific responsibilities during an emergency. Retraining is the responsibility of the Clinic following institutional guidelines.

All emergencies, whether serious or minor, are documented. This requires filling out an institutionally-approved form identifying the type of emergency. This is done by the person in charge at the time, and all reports are co-signed by a clinic physician and are filed at the Clinic.

7.3.2 Minor Emergencies

The most common minor emergency is simple syncope (fainting) and near syncope. These events may occur during venipuncture. Many syncopal episodes can be prevented if clinic staff is alert to early signs. In any situation in which syncope is likely, e.g., after the venipuncture, staff verifies that the participant does not look or feel faint. If the participant looks faint or feels faint in the venipuncture area:

1. Have the person remain sitting in the chair or sitting with head between the knees
2. Crush an ampoule of smelling salts and wave it under the participant's nose for a few seconds
3. Provide the participant with a basin and a towel if s/he feels nauseous
4. Have the participant stay in the chair until s/he feels better and her/his color returns

If the participant continues to feel sick, recline the chair, place a cold wet towel on the back of the person's neck, and notify the supervisor. If a participant feels faint, s/he is cautiously lowered to the supine position on the floor and one attendant immediately calls for an in-house nurse/clinician to assist the participant. The remaining attendant raises the participant's legs above the plane of the body to increase venous return. Prior to this, the staff member momentarily palpates for a carotid pulse and checks to be sure the participant is breathing. If life support measures are needed, the procedures outlined in section 7.3.1 are followed.

7.4 Emergency Equipment

A basic first aid kit is maintained at the Clinic. The kit contains a reference guide of its contents, and is checked every year and immediately after each use. The Manager Research Clinic identifies a person responsible for this task.

8.0 FOLLOW UP OF THE JHS COHORT

8.1 Rationale

Annual Follow Up (AFU) interviews are conducted for the purpose of reviewing the health-related developments occurring since the last contact with the JHS. Each follow up is completed by telephone (preferred) or in person (if necessary). The follow up call is preceded by a letter sent by mail about two weeks in advance of the call (Appendix: AFU Contact Letter). Information for this letter is taken from the study data base and is merged into the letter using mail merge procedures.

Each study participant is re-contacted approximately every 12 months on a time schedule based on the date of the baseline clinic examination. This date has been adjusted for Exams 2 and 3 to accommodate an examination of shorter duration (three years) and to equalize the distribution of participants across the three years of the exam cycle. This will mean that some participants will be contacted sooner, while others will be contacted later, than they might otherwise have been with the new time windows.

8.2 Procedures

8.2.1 Training and Certification

AFU interviewers are trained and certified in general interviewing techniques and the administration of all relevant AFU interviews. This requires familiarity with the contents and procedures for administering the forms, assigning contact and appointment status codes on the Record of Calls (ARC) form, scheduling a clinic appointment for Exam 3, verifying contact information on the CON form, and recording any changes in consent restrictions on the Informed Consent Tracking (ICT) form.

Staff is certified in administering all forms and questionnaires after review of a standardized protocol. Satisfactory completion of two annual follow up interviews is necessary for certification on any new form or interview. Recertification is required annually with the recommendation of a periodic refresher course and retraining if quality assurance analysis indicates poor performance or inconsistent results.

8.2.2 Quality Assurance

Individual interviewer performance is reviewed regularly by the Manager Research Surveillance and Retention using a remote listening device that allows her/him to randomly select an interviewer. At least one interview is monitored each quarter.

The Data Management, Information Technology, Quality Assurance Unit conducts regular quality assurance of data from AFU interviews by interviewer code, providing output to the interviewer. In conjunction with the Data Manager, any data discrepancies are addressed. Discrepancies in excess of 5% require review of protocol elements and reanalysis within 6 weeks to assure correction of identified issues.

8.3 Annual Follow Up

8.3.1 Eligibility Requirements for Annual Follow Up Interviews

Participants who completed at least part of the baseline clinic examination are contacted annually. Individuals excluded from annual follow-up (AFU) and subsequent examinations at the beginning of the study are only those enumerated residents who completed the home interview, but did not sign the informed consent form at the baseline exam.

Unless requested otherwise by the participant, or a participant is lost to follow-up, an attempt is made annually to contact all surviving JHS cohort members. This includes participants who have moved away from the community in which they were recruited. Telephone AFU interviews can be conducted anywhere in the continental U.S. Addresses and telephone numbers of cohort members with multiple residences are kept on file to contact participants on their target anniversary date.

8.3.2 Time Window for Annual Contacts between Examinations is calculated by Data Management.

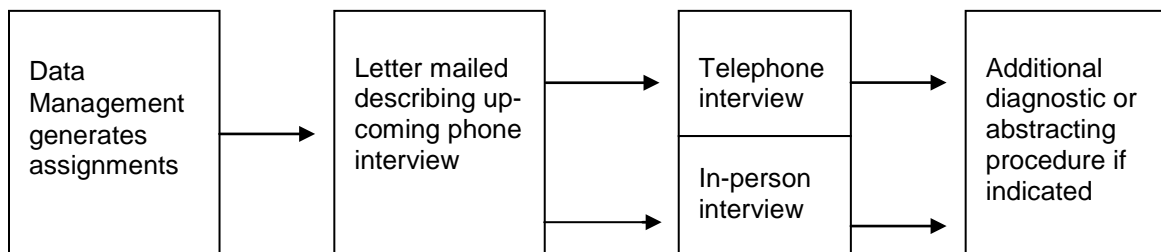
8.3.3. Modified Windows for Exam 2 and 3 Scheduling are designed by Data Management

8.4 Annual Follow-Up Procedures

Annual follow-up of cohort members is used to (1) maintain contact and correct address information on cohort participants, (2) update tracing information on three contact persons, (3) ascertain the participant's vital status (4) document interim medical events/hospitalizations, life events and functional status between the three-year comprehensive examinations, and (5) obtain additional sociocultural information.

There are four primary components to annual follow-up: (1) the generation of scheduling material by the Data Management Unit; (2) the scheduling of the AFU interview by AFU staff; (3) the administration of the AFU interview; (4) the ascertainment of medical information relating to hospitalizations for cardiovascular disease and documentation of fatal events. It is anticipated that the scheduling of a clinical examination every third contact year will occur during the annual follow up call beginning in AFU Year 03 (Contact Year 04). These steps are summarized in Figure 8.1 and described in the following sections.

Figure 8-1. Interim Contact Procedures between Clinical Examinations in the JHS Cohort Study



8.5. Maintaining Contact and Correct Address Information on Participants

8.5.1 Following up on Participants' Returned Mail

- a. All returned mail should be given to the sender.
- b. After the sender documents what specific mailing did not reach the intended participant, the returned mail should be sorted as follows:
 - c. If there is a forwarding address, the mail should be given to the designated staff for entry into the DMS, and, if appropriate, to re-address and re-send the mail to the participant at the new address.
 - d. If there is no forwarding address, it should be given to the designated staff for tracing. The designated tracing staff will enter information from the returned mail into a spread sheet in the following order: Last name; first name; JID#. The spread sheet should be e-mailed to the designated staff who will obtain the participant's "Contact Sheet"
 - e. The tracing staff will read the participant's contact history before attempting to call the participant or his/her listed contacts.
 - f. The tracing staff will attempt to reach the participant by calling the contact persons listed on the "Contact Sheet" in the order listed and when new participant contact information is obtained, she will enter it on the spread sheet, document how the new information was obtained, and e-mail the spread sheet to the designated staff for entry into the DMS, and to the sender, along with the piece of mail that was traced.
 - g. The sender will make the decision to resend the same piece of mail to the new address or, if it is outdated or obsolete, to send any other appropriate mail.
 - h. When a new phone number is obtained, the tracing staff will call the phone number to verify both the phone number and the address. She will enter the new phone number on the spread sheet, verify that the address is correct, or enter a new address if appropriate, document how the information was obtained and e-mail the spread sheet to the designated staff for entry into the DMS and to the sender along with the piece of mail that was traced.
 - i. When attempts to locate the participant via contacts have been exhausted, internet search sites such as zabasearch.com anywho.com and msn.intellius.com and others may be used. The online Social Security Death Index may be used to identify lost participants who are deceased.

8.6 Follow-up on Disconnected and Wrong Phone Numbers

- a. JHS staff who attempt to reach participants via telephone and receive a message of a disconnected or wrong telephone number should follow the appropriate steps to contact the participant.
- b. AFU Staff will follow the “AFU Participant Tracing Instructions”
- c. Other staff sends to the Manager Surveillance/Retention the participant's information such as (Last Name, First Name and JID) for her referral to the appropriate staff.
- d. When AFU staff has exhausted all of the attempts to reach a participant via the listed contact persons, they should refer this record to the Manager Surveillance/Retention for her referral to the appropriate staff
- e. When the participant is reached, the tracing staff will update the participants' address, phone number and contacts and refer the participant to the appropriate Research Interviewer or to the Manager Surveillance/Retention for the next appropriate steps such as conducting the AFU interview, scheduling a call-back time and/or scheduling the Clinic appointment.

8.7 Follow-up on Participants Who are Reported “Deceased”

- a. Participants may be reported deceased from a variety of resources such as obituaries in newspapers, announcement in church, word of mouth etc.
- b. Reports of deceased participants should be referred directly to the Manager Surveillance/Retention who will request that the appropriate AFU staff call to confirm the death and express condolences.
- c. Upon completion of the confirmatory telephone call, the Research Interviewer will enter the code “S” on the ARC indicating “Reported Deceased”
- d. The IT Programmer (Mr. Pramod Anugu) will, on a monthly basis remove from JHS mailing lists persons who are reported deceased.
- e. The JHS Social Worker will request a monthly report of participants reported deceased and will send the JHS “Condolence Card”

8.8 An updated list of participants will be generated, as needed ,by IT for use in addressing mail to the cohort.

8.9 Scheduling Annual Follow Up Interview

The Data Management, Information Technology Quality Assurance Unit initiates the AFU procedures by generating several times a year AFU materials for use in scheduling and conducting the AFU interview. These materials include the Participant Tracing Information Sheet (see Forms Appendix). The list of participants includes the participant name, participant ID, date of baseline exam, and date of Visit 2, sorted in the order requested by the Manager Research Retention. The Participant Contact Information Sheet includes the participant's name, address, telephone number(s); gender, date of birth, state of birth, social security number; employer's name and address; date of baseline exam; and the names, addresses, and telephone numbers of two contact persons, and the primary care provider. The Contact (CON) form lists the current data on file for the names and addresses of the participant and her/his three contact persons.

The scheduling of AFU interviews at the Clinic is done year round and involves identifying the

participants who require scheduling, establishing contact, administering the AFU form, and recording participant-reported medical events to JHS surveillance staff. The procedures for scheduling the exam and event classification are described in sections 1.2 and Manual 7: "Morbidity and Mortality Classification" respectively.

Participants who do not have phones, have trouble communicating by phone, or have special needs are not contacted by telephone but are visited in-person. If these participants can be identified in advance, the letter indicates that an interviewer will visit the home, and AFU interviews take place there.

8.10 Conducting Annual Follow Up Interviews (AFU and AFO)

In Contact Year 06 forward, version "B" the AFU and Version C of the Annual Follow-Up Other (AFO) forms are administered along with AFU Year 1, 2, 3, or AFE supplementary questions for any persons who have not previously completed them. QxQ instructions for the Record of Calls and version "B" of the AFU and version "C" of the AFO forms and prototype scripts for their administration have been prepared for the AFU interview (See Forms Appendix). The interview includes the use of three forms (CON, ARC and AFU) which update address and tracing information of cohort participants (See Forms Appendix); and ascertains their vital status (AFU, section A), death information (AFU, section B); perceptions of general health (AFU, section C); chest pain on effort (AFU, section D); possible infarction (AFU, section E); intermittent claudication (AFU, section F); TIA/stroke (AFU, section D); hospitalizations (AFU, sections H and K); and functional status, weight loss, and life events (AFU, section I) (See Forms Appendix, Annual Follow-up form). The Record of Calls (ARC) is used throughout the contacting process to log each participant's interim and final contact and appointment status (when applicable). At some point after the AFU interview, every participant-reported hospitalization is verified and the discharge diagnoses recorded. Potential cardiovascular events are reviewed further by the abstraction of participants' hospital records to document the presence/absence of JHS Study end point criteria. Detailed information on diagnostic criteria and event determination of the cardiovascular events is provided in Manual 7, Morbidity and Mortality.

The components of the AFU interview are usually done in the following order: (1) completion of the Record of Calls; (2) administration of the AFU questionnaire; (3) documentation of the participant's hospitalizations during the past year - section K of the AFU form; (4) completion of the AFO questionnaire; (5) completion of any incomplete AF1, AF2, AF3, or AFE forms; (6) scheduling of the appointment for Visit 3 exam (Contact Year 10); (7) updating of the contact information (CON form; and, if indicated, updating of the informed consent information (ICT form).

The Record of Calls (ARC form) is used to keep track of attempts to contact a participant. The participant's name, ID, contact year, and contact year date ranges are pre-printed at the top of the form. Space is provided to document contact attempts, pertinent information for future contacts, and the outcome of the contact. There are 27 contact RESULTS CODES. The final result code is circled and entered into the data entry system. The paper copy of the form is kept in the participant's folder to assist in future contacts. The results codes are as follows:

- A Annual Follow-Up Notification Letter Sent – Letter notifying participant that s/he will be contacted by the JHS in the near future for the annual follow-up call.
- B No Action taken – No attempt has yet been made to contact the participant.
- C No Answer – No answer after 10 rings
- D Busy – Busy signal

- E Answering Machine – Message left on answering machine for participant.

- F Privacy Block – Phone with privacy block on all calls

- G Disconnected/Non-Working Number – Recording from phone company or fast busy signal.

- H Recording/ # Change – Recording from phone company of number change. Record new number in notes section and retry.

- I Participant Does Not Live Here/Never Heard Of – Phone answered, name does not reside here or denies knowledge of name.

- J Participant Lived Here, But Moved Permanently – Phone answered, person has moved. New contact information, if available, recorded in notes section and retry.

- K Tracing – Attempts are being made to locate the participant, but so far neither the participant nor a reliable source have been contacted.

- L Physically/Mentally Incompetent – Participant was successfully contacted by phone, letter or in person, but has a physical or mental impediment to communication (e.g. slurred speech, hearing impaired).

- M Language Barrier – Participant was successfully contacted by phone, letter or in person, but interviewer was unable to understand the respondent, or the participant was unable to understand the interviewer.

- N* Contacted, Interview Complete – Participant was successfully contacted by phone or in person and the entire interview, including the questionnaires (AFU, AFO, AF1, 2, or 3) and hospitalization was completed.

- O* Contacted, Interview Partially Complete or Rescheduled – The participant was successfully contacted by phone, letter or in person, but the interview is incomplete or was not done at all. This may be a temporary code if it is possible that the interview may be completed at a later date within the same contact year.

- P* Contacted, Interview Refused – Participant was successfully contacted by phone, letter or in person, but the interview was not done and will not be completed at a later date within the same contact year.

- Q* Reported Alive, Will Continue to Attempt Contact This Year – Reliable information (e.g., from employer, relative, etc.) indicates that the participant is living, but direct contact has not yet been made. It is possible that contact will be made during this

same contact year through further efforts. For example, “temporarily away”, would fit in this category. Record date of return in notes section and retry.

- R* Reported Alive, Contact Not Possible This Year – Reliable information indicates that the participant is living, but direct contact has not yet been made. This code should be used only if repeated contact attempts have been made, or when it has been determined that it is not possible that contact will be made during this same contact year.

- S* Reported Deceased – Reliable information indicates that the participant has died.

- T* Unknown / Lost to AFU – Neither the participant nor another source of information has been contacted in a manner sufficient to provide reliable vital status data during the specified date range.

- U* Does Not Want Any Further Contact – Participant has requested that s/he does not wish to be contacted any more by the JHS. This code alerts staff that no additional contacts should be attempted during the same contact year. Notes should be kept on the ARC to describe the nature of the refusal. The Director of Recruitment determines the type of action to be taken at the following contact anniversary date, e.g., a polite letter, post card or an alternative that is sensitive to any known reasons for this participant’s desire not to be contacted again by the study.

- V Other – Any other results not covered by specified RESULTS CODES.
- W ARIC AFU – This participant has completed the ARIC AFU conducted by ARIC interviewers
- X Exam scheduled --Exam 3 has been successfully scheduled. Enter the date and time in the NOTES boxes.
- Y Clinic Exam not scheduled, pending – Participant is willing to schedule clinic exam, but unable to do so at time of AFU call. Indicate in the NOTES boxes the plans for further contact regarding scheduling.
- Z Clinic Exam not scheduled, refused – Participant indicates that s/he is not willing to schedule Exam 3 visit. This code requires an entry in the NOTES box to indicate whether the refusal is considered to be a “soft” or a “hard” refusal. A “hard” refusal generates mailing of a “refusal” letter to the participant while a “soft” refusal is followed by supervisor contact to attempt to convert the participant to a successful scheduling. Please refer to the section on Off Site Examinations is necessary to retain participation.
- AA* Interview completed by proxy / informant

Codes A-M and V are interim codes. Codes N – T, U, and AA are final codes. See Forms Appendix for detailed instructions for completing the form, and a description of the Results Codes for contacts. It should be noted that these codes are required for all AFU contacts, in contrast to the APPOINTMENT CODES (X-Z) which are only used in the Contact Years in which the participant is scheduled for a clinic visit.

8.11 Annual Follow Up (AFU)

Once contact has been made, the entire AFU interview is administered to surviving participants. When a participant has expired prior to the annual contact, the relevant portions of the AFU form (Sections A, B, H and K) are administered to a member of the participant's household (or a contact person) in order to officially record the death and to obtain the date and location of death and other relevant medical information.

Section A of the AFU form documents the participant's vital status and the date on which the status determination was made. The criteria for establishing participant vital status are defined in the form's instructions. Section B is completed on individuals who have died and records demographic information necessary for obtaining a copy of a death certificate. Sections C-G are administered to all surviving participants and document perceptions of health and interim (since the previous AFU interview) medical events; the majority of the questions were taken from the London School of Hygiene Questionnaire for chest pain on effort, possible infarction, and intermittent claudication. Guidelines for administering this section are provided below, in Section 8.8. Sections H and O on the AFU form are administered to all respondents (participants and proxies) to document overnight hospitalizations in acute or chronic medical care facilities. The surveillance staff is notified of every cohort hospitalization and an event investigation is initiated. Section I is administered only to surviving participants. Section J is administered to all respondents to ascertain any changes in stress, coping and social support and negative emotions of anxiety or depression. Section L is administered to all respondents to ascertain any change in employment status. Table 8.2 summarizes the data collected in each of the versions of the AFU interview since study inception in 2000.

Table 8.3 Summary of Data Collected During Annual Follow-Up (AFU) Interview From JHS Cohort Members

Data Item	JHS/ AFU Form Version		
	A	B	C
DATE OF STATUS DETERMINATION	X	X	X
VITAL STATUS	X	X	X
DEATH INFORMATION			
Date of death	X	X	X
Location of death	X	X	X
COMPARISON OF HEALTH TO OTHERS ONE'S OWN AGE	X	X	X
STROKE/TIA	X	X	X
HOSPITALIZATIONS	X	X	X
FUNCTIONAL STATUS	X	X	X
MARITAL STATUS	X	X	X
RESIDENCE WITHIN ARIC STUDY BOUNDARIES	X	X	X
NURSING HOME ADMISSIONS	X	X	X
HISTORY OF CARDIOVASCULAR AND RELATED DISEASES	X	X	X
DIAGNOSTIC PROCEDURES FOR CVD	X	X	X
INVASIVE PROCEDURES/TREATMENT FOR CVD			X
CURRENT MEDICATIONS FOR HYPERTENSION, HYPERCHOLESTEROLEMIA, DIABETES	X	X	X
REGULAR OR CURRENT USE OF ASPIRIN	X	X	X

Data Item	JHS/ AFU Form Version		
	A	B	C
HISTORY OF HRT USE OR GYNEGOLOGIC SURGERY	X	X	X
CURRENT CIGARETTE SMOKING	X	X	X
CURRENT EMPLOYMENT STATUS	X	X	X

8.12 Administration of London School of Hygiene Questionnaire

The questions in Sections D-F (CHEST PAIN ON EFFORT, POSSIBLE INFARCTION, and INTERMITTENT CLAUDICATION) of the AFU form are based on the London School of Hygiene Questionnaire. The purpose of the London School of Hygiene Questionnaire (generally referred to as the 'Rose Questionnaire') is to standardize the identification of 'angina on effort' as defined by Dr. Geoffrey Rose. It is not the purpose of the questionnaire to arrive at a medical diagnosis. The questionnaire will fail to identify angina pectoris in some participants whose pains are regarded by the physician as genuinely ischemic. It may categorize other cases as pain due to a quite different cause. Any special effort, however, to alter the conduct of the interview in such instances would destroy the basic purpose of the questionnaire technique, which is to insure uniformity in the eliciting of defined symptoms.

Questions must be put to the participant exactly as they are printed: small changes can make unexpectedly large differences in responses. Unequivocal answers must be recorded as such, whether they seem reasonable or not. Supplementary questions (probing) should rarely be used. When they have to be asked, they should depart as little as possible from the wording of the initial question, and must not be such as to suggest any one particular answer to the participant.

If serious doubt arises about the correct interpretation of a particular answer, it is recorded in such a way as to exclude the suspected condition. An example of this type of situation is demonstrated in the following question and hypothetical response.

{Question} "Do you get it when you walk uphill or hurry?"
{Response} "Well, I think I might, but I really can't remember."

This answer is recorded as NO and no probes are employed.

An exception is made to this rule only if a negative response to the lead-in question is an interpretation or denial of a positive response.

{Question} "Have you ever had any pain or discomfort in your chest?"
{Response} "No, only indigestion."

The answer is recorded as YES, because the participant's interpretation of the symptom is disregarded.

A frequently made error in the administration of the Rose Questionnaire is to extrapolate the participant's response to similar, but not defined, situations in the question.

{Question} "Do you get it when you walk uphill or hurry?"
{Response} "Yes, the chest pain occurs when I cut the grass."

The answer to this question is recorded as NO, i.e., a strict interpretation is required. If pain is experienced only during some other form of exertion (e.g., cycling, stair climbing, lawn mowing, etc.) it must always be recorded NO. The response 'NEVER HURRIES OR WALKS UPHILL' can only be coded if the participant specifically denies walking uphill or hurrying.

For the remaining questions, unequivocal answers need not be probed. However, responses qualified by terms describing frequency of events, such as 'occasionally' or 'sometimes' should be probed by a question such as 'Does it happen on most occasions?' Individual QxQ instructions are provided in the Forms Appendix.

8.13 Annual Follow Up Other (AFO)

The AFO form is administered to determine recent medication use related to chest pain or some other heart condition, whether the participant has experienced any of the signs or symptoms of congestive heart failure, had any invasive procedures or diagnostic tests with their associated indication (reasons), update family history, assess the degree of global psychosocial experiences over the previous year, and health care access.

If the additional year questions for Contact year 02, 03, 04, 05 were not administered in the corresponding Annual Follow-Up year 1, 2, 3, or 4 (forms AF1, AF2, AF3, AFE), these forms should be administered during the current Contact year..

8.14 Congestive Heart Failure Questions

Detailed information on congestive heart failure (CHF) symptoms that may have been experienced in the past year, since the last JHS contact, is assessed as part of the AFO form. Participants are asked about possible symptoms of CHF as detailed in the table below. Difficulty breathing or swelling of the feet or ankles are common symptoms that are assessed by a series of questions that request information about shortness of breath when at rest or that awakens the participant at night, needing extra pillows to improve his/her breathing, night time cough, or lower extremity swelling. The items included in this battery were derived from several standardized sources used by Multiethnic Study of Atherosclerosis (MESA), Framingham and Cardiovascular Health Study (CHS) (1-4).

Table 8-4. Congestive Heart Failure Criteria Symptoms List

Paroxysmal nocturnal dyspnea Orthopnea Dyspnea on exertion Shortness of breath (dyspnea at rest) Night Cough Bilateral lower extremity edema

8.14.1 Background, Rationale, and Hypotheses

Congestive heart failure (CHF) is a syndrome that disproportionately affects African Americans (5-6). National Health Surveys were unable to document differences in self-reported heart failure between blacks and whites (7), but there is evidence that African American ancestry is a major risk factor for hypertension and hence congestive heart failure (6). CHF is lethal in African Americans, and contributes significantly to high prevalence of cardiovascular disease morbidity and mortality in African Americans nationally (7-8). African Americans appear to develop asymptomatic left ventricular dysfunctional (ALVD) which is a precursor for the development of symptomatic congestive heart failure (9). It also appears that African American males are at a greater risk of developing ALVD (10). Risk factors for the development of CHF are numerous, but two major ones are hypertension and coronary heart disease (9). Congestive heart failure mortality rate increases with age in African Americans and at every age mortality rates for African Americans exceed rates for the white population (11). CHF may occur earlier in life in African Americans because of the

high prevalence of hypertension in this group (12). National surveys reported that African Americans have higher prevalence and incidence of hypertension and heart failure across every age group when compared to whites (13). Most of these studies also reported that CHF is at least 50% higher in African Americans than in whites. Overall, the heart failure rates are 3 to 7 times higher in African Americans when compared to other ethnic groups nationally.

The management of heart failure is characterized by high rates of hospital admission and readmission. For African Americans the most practiced self-care behavior for heart failure is the use of prescribed medications, with the least practiced behavior of symptom monitoring and management (14) of the contributable risk factors such as coronary heart disease and hypertension. This suggests that African Americans respond more to intervention than prevention and this may account for high readmission rates into hospitals (5). Clinical studies reported higher rate of readmission in elderly African American patients with CHF when compared with whites, but case fatality CHF mortality rates are similar (8).

CHF mortality rates in Mississippi are about 4 to 6 times higher than US National rates for ages 20-64 (15). Finally, the CHF mortality rates in African Americans in Mississippi are increasing, according to the most recent available data (11). Data on incidence and prevalence of CHF in African Americans is limited or unavailable. JHS is all African American study and will be an excellent resource for studying CHF in African Americans. The CHF questions will collect incident data on CHF in cohort participants during the annual follow-up interview. The next phases (II and III) of the JHS will include CHF event ascertainment. This will parallel the current system that is utilized by JHS to identify, classify, review and adjudicate both coronary heart disease (CHD) and stroke.

8.14.2 References

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8.15 Diagnostic Tests / Invasive Procedures Questions

These items are included to assess the type and reasons for any cardiovascular diagnostic tests or procedures the participant may have had in the previous year. They are intended to update and supplement information previously gathered. Of particular note beginning with Contact Year 06, items have been added to assess the participant's awareness of the rationale or indication for each test or procedure conducted. A series of likely clinical indications are included for each relevant test / procedure. Items are based upon standard clinical care practices for cardiovascular disease diagnosis / intervention.

8.15.1 Background, Rationale, and Hypotheses

Capturing these data may be very important. Cardiac catheterizations are done very frequently, and coronary disease is clearly the leading killer of the JHS cohort. But, paradoxically, there are unresolved questions about the high rate of negative catheterizations (i.e., catheterizations that don't lead to definitive interventions like PTCA or surgery) in African American patients (vs the rates of procedures in whites). The whole notion that blacks were somehow "immune" to coronary disease found support in the high frequency of negative catheterizations seen in studies like the National Heart Lung and Blood Institute's CASS Study (which set the standards for bypass surgery that are followed by most surgeons today). An increasing number of cardiac catheterizations are done outside the hospital. Our data may shed some light on this as we collect these data points longitudinally.

8.15.2 References

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8.16 Update Family History Questions

This section of the AFO provides an update on family history items initially obtained in the Home Induction Interview and during Exam 2. The intent is to determine if there have been any deaths or new diagnoses among natural parents, full siblings, or natural children of cohort members since the last JHS contact. The items were modified from those asked in the Personal and Family History (PFH) form, Exam 1. Original items were modified from those used in ARIC. Additional questions were added in the JHS on the health history of full siblings and natural children to assure that a wide range of essential family health data can be captured.

8.16.1 Background, Rationale and Hypotheses

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

8.17 Update Global Psychosocial Questions

Five questions will be used to assess global psychological functioning each year at annual follow-up. Participants will be asked to rate her/his response to each question on a 6-point Likert-type scale. The specific psychological domains assessed include: major stressors, depressed mood, anxiety, coping, and social support.

8.17.1 Background, Rationale and Hypotheses

Epidemiologic and clinical studies have identified a number of psychosocial risk factors that appear to influence the incidence, morbidity, and mortality associated with cardiovascular disorders. Measures of each of these psychosocial domains are assessed at baseline. An annual global assessment will provide valuable information on change over the year's time.

Hypotheses include:

1. Greater global distress will be associated with an increased risk of hypertension and CHD events independent of the contribution of traditional CHD risk factors.
2. The relationship observed between global psychological distress, hypertension, and CHD events will be moderated by global social support, global coping, SES, and education.

8.17.2 Scoring/Coding

Each item is read to the participant and requires a rating on a 6-point Likert-type scale. One score is derived for each of the Psychosocial Annual Follow-up Questions. Each rating scale ranges from 0 (assigned 0 points) to 5 (assigned 5 points).

8.18 Access to Care Questions

Items 11 through 29 were included to supplement the information collected at the baseline and subsequent visits regarding participant access to health care resources. These questions will be provide ongoing information regarding the status of JHS participants in terms of type and stability of health insurance coverage, prevalence of prescription medication insurance coverage, out of pocket expenditures for medications, prevalence of health care access barriers, interactions with health care providers, and satisfaction with health care. These items were derived from items frequently used in population-based surveys such as the Medical Expenditure Panel Survey [1], National Health Interview Survey, Community Tracking Survey [2], which are frequently used to inform policy makers, legislators, and the public regarding health care access and utilization issues in the United States.

8.18.1 Background, Rationale, and Hypotheses

Health insurance status is an important determinant of health care access and satisfaction with health care. Numerous researchers have determined that regardless of race, the lack of health

insurance status is associated with poor health outcomes, decreased use and expenditures for a variety of health services, increased prevalence of experiencing health care access barriers, decreased satisfaction with care, decreased quality of health care, and increased financial burden [3-5].

Simply asking questions regarding current health insurance coverage with each round of data collection does not address the considerable changes in health insurance status that can occur between data collection periods. Health insurance coverage instability can occur when a person gains or loses coverage as well as when the person experiences changes in coverage such as reduced benefits or increased co-payments. Instability in coverage has been associated with the same health care access barriers experienced by persons who are uninsured. Furthermore, asking uninsured persons about the length of time uninsured is important since longer time uninsured is associated with increased financial burden and access barriers [6].

Clearly, a means of measuring health insurance instability is needed to accurately determine the impact of health insurance status on health care access, utilization, and the health of JHS participants. The prevalence of health insurance instability among JHS participants is unknown. Asking annually about current health insurance coverage, the type of coverage, gaps in coverage, and the length of time not covered will provide information about the current health insurance status as well as stability of coverage over time.

Health insurance coverage does not always include coverage for prescription medications. Recent changes in Medicare prescription coverage have sparked interest in examining how elderly Americans cope with prescription medication expenditures. Co-payments and restrictions in coverage influence participants' ability to purchase medications and other health services. Out of pocket expenses for prescription medication affect use of medications and ultimately health. However, not much has been written regarding factors that influence prescription medication use and expenditures for African Americans or non-elderly Americans. Asking questions about the status of insurance coverage for prescription medication and the OOP associated with prescription medication use will allow investigation of factors influencing prescription medication expenses and the affect of these expenses on the lives of JHS participants [7,8].

Few questions were asked at the baseline visit regarding health care access barriers and the use of health services. The AFO delves more deeply into use of primary care services and the existence and nature of health care access barriers experienced by JHS participants. Self report of the number of primary care visits has been shown to be a fairly reliable measure of the level of utilization. In addition to asking about problems getting care the participant is asked about whether he or she/has gone without care, the type of care foregone, and confidence with getting high quality care. The inclusion of these measures of realized health care access will allow analyses of the relationship between primary care use, health insurance status, and health status [8,9].

The relationship of the JHS participant and health care providers is an important aspect of health care access. Being listened to and respected, having things explained, and having the provider spend enough time with a person are important aspects of these relationships which can have an impact on a person's perception of how they are treated by health care professionals as well as trust and satisfaction with health care. These attitudes can also influence JHS participants' willingness to access the health care system [10].

Hypotheses that can be examined with these health care access measures include:

- Health insurance status (including instability in coverage) will be associated with the use of primary care services, prevalence of having unmet health care needs, satisfaction with care, confidence with getting care, prevalence of symptoms indicating angina or heart failure exacerbation, and level of stress and anxiety.

- Prescription medication coverage status will be associated with the use of medications to treat chest pain and heart failure and OOP expenditures for prescription medications.
- Out of pocket expenditures for prescription medications will be associated with use of medications to treat chest pain and heart failure.
- Interactions with health care providers will be associated with use of and satisfaction with health care.

8.18.2 References

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8.19 Updating Contact Information

Tracing information listed on the computer-generated Participant Contact Information Sheet is verified at the conclusion of the AFU form using the CON form (see Forms Appendix). Instructions for administering the form and a prototype script are provided at the end of the annual follow-up instructions. Any changes to tracing information recorded on the paper form during the telephone interview are recorded on the computerized version of the CON form by staff certified in the use of the JHS Data Entry System. Prior to making any changes in the DMS, a hard copy of the current version is printed, dated, and placed in the participant file for future reference.

8.19.1 Tracing Participants Unable to Contact

Participants found to have moved or who are otherwise lost to follow-up are traced using the tracing information obtained at baseline exam, Exam 2, and during subsequent annual follow-up contacts or other local sources of information, such as the telephone directory, city directory, etc. By using the Contact Form, Data Acquisitions Unit staff can call or write to the family members, friends, employers, or physicians the participants identified as contact persons during previous interviews. By using Social Security numbers, periodic searches of the National Death Index are done. Every

attempt is made to schedule and complete an AFU interview for each participant.

9.0 SURVEILLANCE / EVENTS ASCERTAINMENT

See Manual 7, "Morbidity and Mortality" for a complete review of the procedures and protocol associated with cohort surveillance and events ascertainment.

Appendices

APPENDIX 1 RETENTION OF PARTICIPANTS FOR EXAM 3

- Appendix 1.1 Prototype Participant Letter: Cohort Notification of Exam 3
- Appendix 1.2 Prototype Participant Letter: Notification of Upcoming Annual Follow Up Interview and Exam 3 Scheduling Call
- Appendix 1.3 JHS Information / Consent Brochure
- Appendix 1.4 Prototype Participant Letter: Refusal Conversion
- Appendix 1.5 Prototype Employer Letter: Request for Release from Work
- Appendix 1.6 Prototype Employer Letter: Institutional Heads Request for Collaboration with JHS to Release from Work
- Appendix 1.7 Prototype Health Care Provider Letter: Request for Continued Collaboration / Support of JHS Participation
- Appendix 1.8 Certificate of JHS Membership
- Appendix 1.9 Prototype Participant Birthday Card
- Appendix 1.10 Prototype Participant Holiday Card / Calendar
- Appendix 1.11 Prototype Condolences Letter
- Appendix 1.12 Prototype JHS Participant Newsletter
- Appendix 1.13 Prototype Annual Family Reunion and Birthday Celebration
- Appendix 1.14 Prototype JHS Participant Web-based access

APPENDIX 2 EXAM 3 DESIGN, LOGISTICS, TRAINING, AND QUALITY CONTROL

- Appendix 2.1 Standardized Interview Techniques
- Appendix 2.2 Instructions for Completing Paper Forms

APPENDIX 3 INTERVIEWS IN EXAM 3

- Appendix 3.1 Consent Form

APPENDIX 4 PROCEDURES IN EXAM 3

- Appendix 4.1 Tanita TNF 300A Manual
- Appendix 4.2 Anthropometry Equipment Calibration Log
- Appendix 4.3 Checklist for Anthropometry Measurement
- Appendix 4.4 Checklist for Height Measurement
- Appendix 4.5 Checklist for Weight Measurement
- Appendix 4.6 Checklist for Maximal Waist Measurement

- Appendix 4.7 Checklist for Maximal Hip Circumference Measurement
- Appendix 4.8 Report on Use of Observation and Equipment Checklists

APPENDIX 5 MEDICAL DATA REVIEW

Appendix 5.1 Prototype Medical Data Review Print Out and Information Sheet

Appendix 5.2 Tanita Patient Education Handout

APPENDIX 6 REFERRAL AND RESULTS REPORT

Appendix 6.1 Prototype Health Care Provider Results Reporting Letter: Health Care Provider Designated

Appendix 6.2 Prototype Health Care Provider Results Reporting / Referral Letter: No Health Care Provider Designated

Appendix 6.3 JHS Alerts and Referrals Procedures

Appendix 6.4 JHS Resource Manual



APPENDIX 1 RETENTION OF PARTICIPANTS FOR EXAM 3

January 30, 2009

ADDRESS BLOCK

Dear _____

It has been almost a year since the Jackson Heart Study (JHS) conducted your annual follow-up telephone interview. As in the past, a JHS interviewer will be calling to gather information about your health status over the past year. If you have had any hospitalizations or illnesses during the past year, please gather information regarding the date and type of illness or hospitalization so it is available when the JHS interviewer calls.

This year, we are pleased to invite you to your third clinic examination. We will repeat some of the tests you had in exams one and two so that we can note any changes over time. If you weigh less than 350 pounds, are not pregnant, and have not already had your CT (Computed Tomography) scan of your heart and abdomen, you may schedule it while you are here. You will receive a \$25 check or gift such as a coffee mug, in appreciation for your time.

During your Exam 3 visit, we will also tell you about four additional studies that may be offered to you:

- Peripheral Arterial Tonometry, which looks at the health of your blood vessels
- A study that is looking for a relationship between heart disease and hearing loss
- MRI (Magnetic Resonance Imaging) of your heart that will be scheduled at a later date and
- A study where photographs of your eyes will be taken and reviewed by an eye specialist to see if you have any changes caused by diabetes.

<Interviewer's Name>, an interviewer will call you in the near future to conduct your interview and schedule your Exam 3 clinic appointment. The exam will take about 3 and ½ hours. Please have your calendar ready to select a convenient day and time for your visit. You may telephone the JHS office at ### to set an appointment. Your identification number is JID please have it available when you call.

We thank you for your continued participation in the Jackson Heart Study.

Sincerely,

Herman A, Taylor, Jr., MD, MPH, FACC,
Principal Investigator, Jackson Heart Study
Professor of Medicine

**Appendix 1.2 Prototype Participant Letter: Notification of Upcoming Annual Follow Up
Interview and Exam 3 Scheduling Call**

Appendix 1.3 JHS Information Brochure

**Tips for a
Healthy Heart**



- ▼ Keep Blood pressure at or below 120/80.
- ▼ Keep Cholesterol—under 200.
- ▼ Keep Glucose (blood sugar) level less than 126.
- ▼ Exercise at least five days a week.
- ▼ Do NOT smoke—if you do, QUIT.
- ▼ Cut back on your salt intake.

The Jackson Heart Study is supported by the National Institutes of Health contracts provided by the National Heart, Lung and Blood Institute and the National Center on Minority Health and Health Disparities with Jackson State University, Tougaloo College and the University of Mississippi Medical Center.



Jackson Heart Study

350 West Woodrow Wilson Dr., Suite 701
Jackson, MS 39213
Phone: 601-815-5050
www.jsums.edu/~jhs/

**Fight the No. 1 Killer
of African Americans:
HEART DISEASE**



Support the Jackson Heart Study and all African Americans by returning for Examination 3.

You Can Help Change Lives Forever

Cardiovascular disease (also known as heart disease) is the number-one-killer of African Americans. African Americans in Mississippi have higher rates of death from heart disease than any other group. The Jackson Heart Study was developed to help fight this silent killer by examining the factors that influence the development of heart disease. The findings from our study could help significantly impact the heart health of many in our community and throughout the United States. Your continued participation can make a difference.



If you participated in Exam 1 of the Jackson Heart Study,
Contact us TODAY to set up an appointment for EXAM 3.



HEART DISEASE FACTS

Findings from the JHS Baseline Exam (Exam 1)

- ▼ More than 80% of 65+ year old participants have hypertension, and more than 50% of 45-64 year old participants have hypertension. These percentages are greater than national percentages for the same ages.
- ▼ JHS participants showed a greater percentage of being overweight or obese compared to national data in all age groups, and the majority of our study's women in all age groups are obese.
- ▼ Participants who were obese had the highest percentage of high blood pressure.
- ▼ The majority of participants were aware of their high blood pressure and were being treated for it.
- ▼ More than half of all men in the study had a dietary cholesterol greater than 300.
- ▼ Eighty percent of the men in the study consumed a very high sodium diet.
- ▼ The majority of participants exercised less than 3 times a week.

SOME DETAILS

The third examination in the Jackson Heart Study will be conducted from February 2009 through May 2012. Like the first and second exams, it will not cost you anything. This exam will take approximately three and a half hours and will consist of:

- ▼ Blood Pressure Readings
- ▼ EKG (Electrocardiogram) 
- ▼ Height, Weight and Body Composition Measurements
- ▼ Medical History
- ▼ Medication Survey
- ▼ Fasting Glucose (blood sugar), A1c and Lipids (cholesterol) and Creatinine
- ▼ Urine for albumin
- ▼ MRI (Magnetic Resonance Imaging) 
- ▼ Interview Questionnaires
- ▼ Explanation of Test Results

Appendix 1.4 Prototype Participant Letter: Refusal Conversion

[DATE]

[NAME]

[ADDRESS]

[ADDRESS]

Dear [Mr. Ms. Name]

Recently, you indicated that you did not want to participate in the current Jackson Heart Study (JHS) examination. I appreciate all the time you have already given us both on the phone and in the JHS clinic. On behalf of all the JHS staff and investigators, and all the people who benefit from the knowledge gained as a result of your participation thus far, I want to thank you for being a loyal participant. As a member of this ongoing study you contribute valuable information in our search for causes and prevention of heart disease in African Americans, but we know that it is only possible because you have been willing to sacrifice some of your time and tell us about yourself.

Thank you again, and should you reconsider, we would be more than happy to hear from you. If your schedule permits, we can offer to come to your home to conduct the interviews and brief physical examination. This should take no more than 90 minutes of your time, at most.

Again, we are sad to lose you after so many years. If you should change your mind, please call me at 601.979.8719 or access our web-based scheduling system at www.jsums.edu/~jhs/ and sign in with your personal JHS identification number, JXXXXXX. Any time you give us will be of great benefit to the study and the people whose health may be improved as a result of JHS findings.

With best regards,

Herman Taylor MD, MPH

Director and Principal Investigator

Mary Crump RN, MSN

Clinic Manager

Appendix 1.5 Prototype Employer Letter: Request for Release from Work

DATE

EMPLOYER NAME

ADDRESS

Dear Employer:

Your employee, [NAME], is a participant in an important medical research project called the Jackson Heart Study (JHS). This project is sponsored by the National Heart, Lung, and Blood Institute in the Jackson Metropolitan area. It is being conducted by Jackson State University, Tougaloo College and the University of Mississippi Medical Center. The purpose of the study is to better understand characteristics which may predispose African-Americans to heart or blood vessel diseases.

The JHS requires an examination every three to four years to collect medical information. We hope you will allow your employee time off to complete this examination—hopefully without having to take personal or vacation time to do this. Her/his participation is important to the study. If you have any further questions you may call me at [telephone number].

Thank you.

Sincerely,

Herman A. Taylor, Jr. MD, MPH
Principal Investigator

**Appendix 1.6 Prototype Employer Letter: Request for Collaboration with JHS to Release
from Work**

Date

Business Leader/Employer Name
Business Leader/Employer Address

Dear NAME BUSINESS LEADER/EMPLOYER:

I would like to extend my thanks and appreciation for your continued support of the Jackson Heart Study (JHS). As a business leader in Hinds, Madison and/or Rankin Counties, your advocacy in and support of the Study remains critical.

Cardiovascular disease is still the number one killer of African Americans in Mississippi and the nation. The JHS is the first large scale epidemiologic observational study on African Americans and heart disease. Between September 2000 and March 2004, the JHS recruited over 5,300 participants aged 21 and over. Between October 2005 and December 2008, most participants returned for a follow-up examination and related scans. During this time, the business community demonstrated support by allowing potential participants time off without having to use company personal leave or vacation time. A collaborative effort with the business leadership will again allow maximization of our efforts to reach participants. JHS's 3rd exam cycle will occur over a period from February 2009 through May 2012, during which time each participant will undergo a clinical exam. By allowing your employees time off for their exams, once again you are providing support needed to achieve our research goals.

We look forward to your continued support and involvement with the JHS. Should you need to talk with me or require further information, I can be reached at (601) 979-8744. Thank you for your continued support of the JHS.

Regards,

Herman A. Taylor, MD, MPH, FACC
Director/Principal Investigator

**Appendix 1.7 Prototype Health Care Provider Letter: Request for Continued Collaboration /
Support of JHS Participation**

Date

Health Care Provider Name

Health Care Provider Address

Dear NAME HEALTH CARE PROVIDER

I would like to extend my thanks and appreciation for your continued support of the Jackson Heart Study (JHS). As a health care provider in Hinds, Madison and/or Rankin Counties, your advocacy in and support of the Study remain critical.


Cardiovascular disease is still the number one killer of African Americans in Mississippi and the nation. The JHS is the first large scale epidemiologic observational study on African Americans and heart disease. Between September 2000 and March 2004, the JHS recruited over 5,300 participants aged 21 and older. Between October 2005 and December 2008, most participants returned for a follow-up examination and related Computed Tomography (CT) and Magnetic Resonance Imaging (MRI) Scans. During this time, the health care provider community demonstrated support by distributing study information and discussing the importance of research participation with their patients. A collaborative effort with the health care providers will again allow us to continue our efforts to reach participants, as well as allow us to offer health care resources when needs are identified. JHS will begin the 3rd exam cycle in February 2009 and it will continue through May 2012. By continuing to support this important research investigating the high rates of heart disease in our community, you significantly contribute to the cardiovascular health of all African-Americans.

We look forward to your continued support and involvement with the JHS. Should you need to talk with me or require further information, I can be reached at (601) 979-8744. Thank you for your continued support of the JHS.

Regards,

Herman A. Taylor, MD, MPH, FACC
Director/Principal Investigator

Appendix 1.8 Certificate of JHS Membership



Certificate of Membership

has completed Examination Two and is a continuing member of the Jackson Heart Study

Participant

Certified by _____ *on this* _____ *day of* _____

Director, Jackson Heart Study

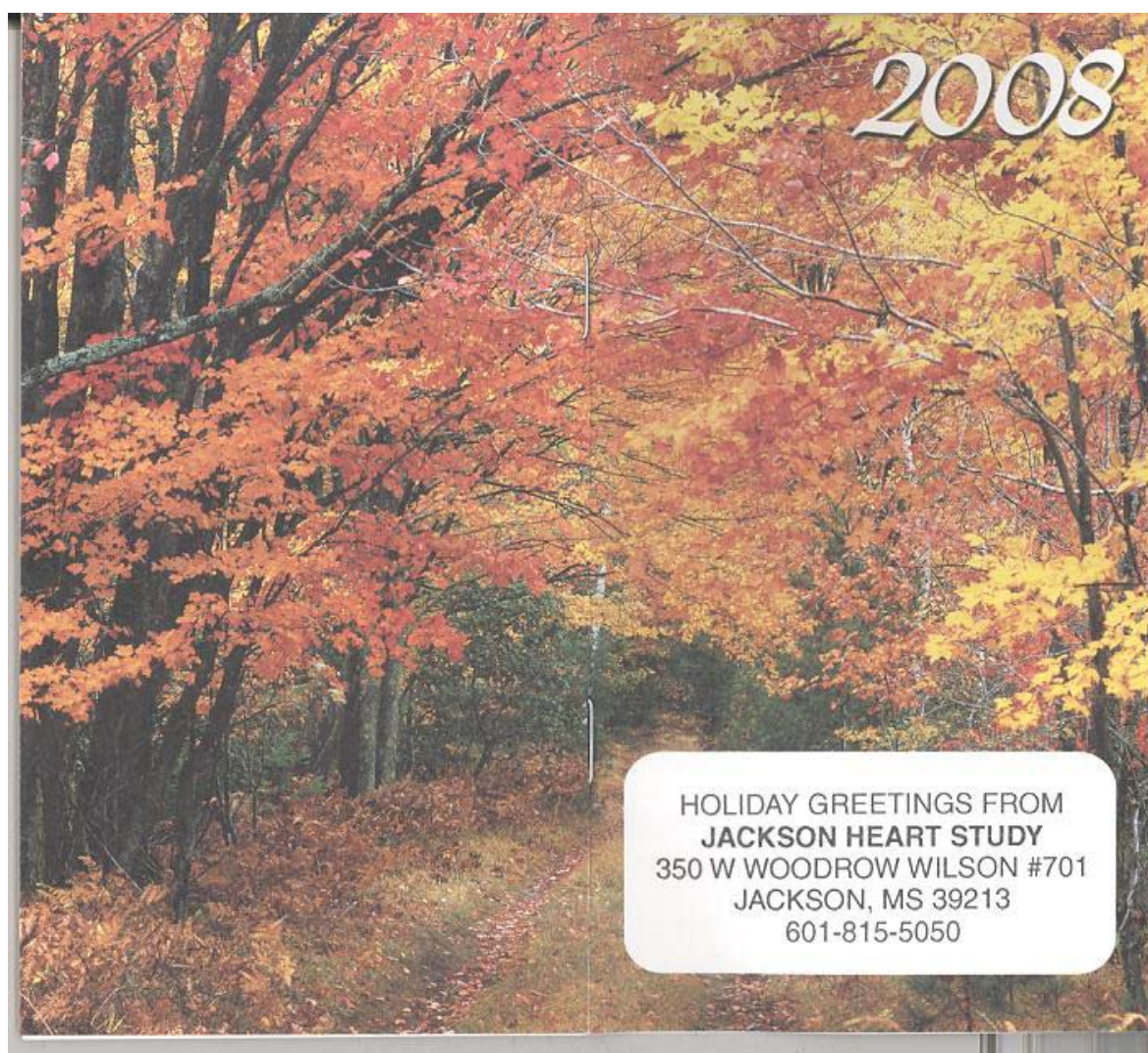
_____ **D A T E**

Appendix 1.9 Prototype Participant Birthday Card



May this day be the beginning
of the best years of your life!

Happy Birthday
from the
Jackson Heart Study

Appendix 1.10 Prototype Participant Holiday Card / Calendar

Appendix 1.11 Prototype Condolences Card

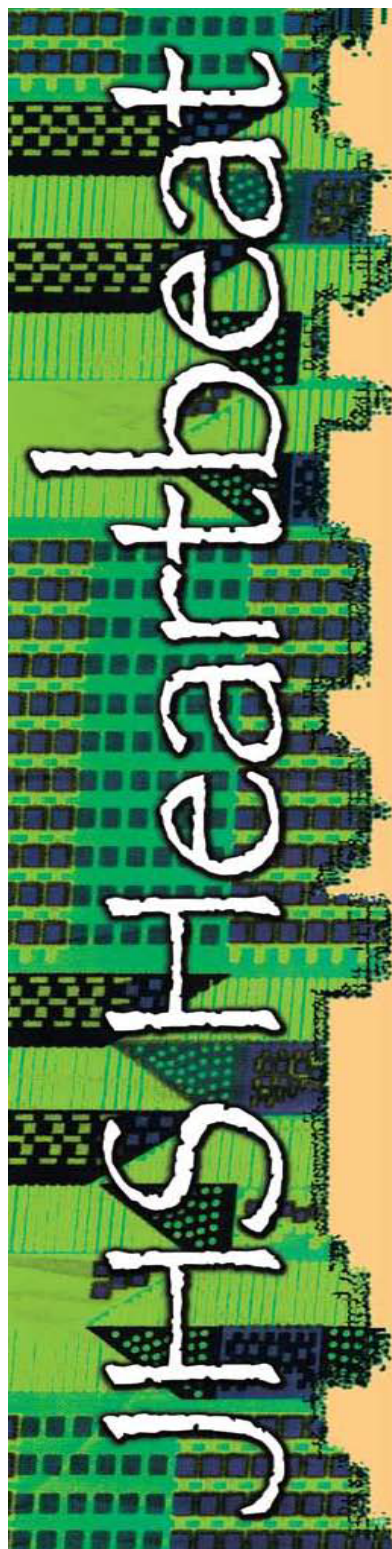


In Sympathy

*Condolences from the
Jackson Heart Study on the loss of your
loved one.*



Appendix 1.12 Prototype JHS Participant Newsletter



Jackson Heart Study Partners Newsletter • Winter 2008–2009



Stroke: The “Not-So-Silent Killer”— Much More Common Than Assumed

(Herman A. Taylor, Jr. MD, MPH)

This issue of our newsletter is dedicated to Stroke. If hypertension is called “the silent killer” then I will call stroke “the not so silent killer”. Stroke is related to hypertension and to cardiovascular diseases which makes it an important part of the Jackson Heart Study (JHS). Since Mississippi is in the stroke belt (along with most of our southern neighbors) and African Americans have a higher incidence of cardiovascular diseases including stroke than Caucasians, we at the JHS are paying as much attention to stroke as to all other major causes of cardiovascular diseases and their risk factors. This article will draw largely on the news from “World Stroke Day, October 29, 2008”.

Stroke is the rapidly developing loss of brain functions due to a disturbance in the blood vessels supplying blood to the brain. This can be due to one of two major causes; an interruption of the blood supply to the brain (Ischemic) or to a rupture of the blood vessels (Hemorrhage). Roughly 80% of all strokes are due to the former. As a result, the affected area of the brain is unable to function leaving an inability to move one or more limbs on one side of the body, inability to formulate speech or inability to see one side of the visual field. A stroke is a medical emergency and can cause permanent neurological damage, complications and death. I am sure you know someone who has had a stroke.

The theme of World Stroke Day 2008 was “Little stroke, big trouble”. The focus on “little” stroke is chosen for good reasons. Subclinical or “silent” strokes occur five times as often as clinically obvious strokes and can affect thinking, mood, and personality. A recent Study by Professor Hachinski at the University of Western Ontario, Canada presented at the World Stroke Congress (WSC) found that about 10 percent of apparently healthy middle-aged participants with no symptoms of stroke were affected by “silent strokes”. Since we live in the USA’s stroke belt where the incidence of stroke, hypertension and cardiovascular disease are much higher than the national average and even more so in the African American population, when we analyze the JHS stroke data, we can expect to find a much higher incidence among our JHS cohort.

The aim of this year’s World Stroke Day as well as this article is to improve awareness of the “preventable catastrophe” stroke presents.

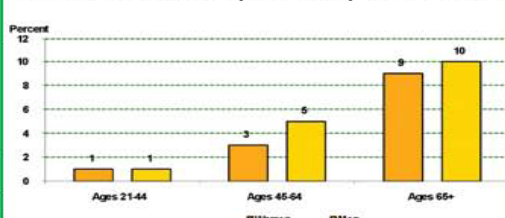
By focusing on subclinical “silent” strokes we wish to emphasize the likelihood that the earlier we intervene the more likely we are to be successful. Subclinical “silent” stroke is a brain injury most commonly caused by a blood clot interrupting blood flow in the brain. It is called silent because like hypertension there may be no observable symptoms. “Silent” strokes are most often detected through brain imaging and several patients who have suffered “silent” strokes who undergo brain imaging tests prove to have neurological and neuropsychological damage. Unlike hypertension where one’s blood pressure can be checked regularly and routinely there are no similarly routine and cost effective way of checking for strokes.

A recent study (JUPITER) which received much publicity at the recent meeting of the American Heart Association suggests that cholesterol drugs (statins) may significantly reduce the risk of stroke and other cardiovascular events in healthy patients. Dr. Phillip Gorelick, Director of the Center for Stroke Research at the University Of Illinois College Of Medicine, in an interview with the National Stroke Association suggested that the JUPITER findings will likely influence short-term treatment guidelines for cardiovascular prevention including stroke. “One must bear in mind that lifestyle modification remains an important aspect of stroke and other cardiovascular disease prevention.”

At the JHS, Stroke Surveillance is a critical part of the study. It will help us better understand and monitor stroke risk factors as well as stroke care, stroke incidence and stroke mortality. It will allow us to develop an overall picture of stroke in the African American community, do time trend analyses, to better explore its distribution, stroke risk and care in this important subpopulation.

Such a surveillance system would also help us to formulate policy decisions concerning programs and research for the African American population. The stroke outcome data obtained through the surveillance will also help to develop a stroke prediction model specific for our African American population which can be used to further educate and inform both our cohort members and the physicians who care for them.

Percent of JHS Participants with previous stroke



Stroke was more prevalent in older than younger or middle-age participants, and more common in men than women.

Source: The Jackson Heart Study Data Book: A Report to the Cohort and Community
NIH Publication No. 08-5948
September 2008

Appendix 1.13 Prototype Annual Family Reunion and Birthday Celebration



You are cordially invited to the
Seventh Annual Jackson Heart Study
Family Reunion
“Your Health and Your Family Tree”

at 10:00 a.m.

on Saturday, September 22, 2007

at the Jackson Medical Mall

UMC Conference Center.
(Livingston Road entrance)



Come and join your fellow participants for food, fun and fellowship.

Let's talk about genetics...the family life line.



"Your Health and Your Family Tree"

September 22, 2007

9:30 a.m. - 10:00 a.m.Registration

Welcome.....Mary Crump
Manager of Clinical Research

Invocation.....Rev. Curtis Page
JHS Council of Elders

Greetings.....Dr. Herman Taylor
Director of JHS

Ms. Cheryl Nelson
National Heart, Lung, and Blood, Institute

JHS Genetics Focus Groups.....Dr. Doris C. Withers
Genomic Education & Outreach Consultant
Medgar Evers College, The City University of New York

Family Health Portraits.....Dr. Evelyn Walker
JHS Field site Director, National Heart, Lung and Blood Institute

Words of Gratitude.....Mary Crump

Refreshments



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JHS Field site Director, National Heart, Lung and Blood Institute

Words of Gratitude.....Mary Crump

Refreshments

Appendix 1.14 Prototype JHS Participant Web-based access



The user can then click "Reschedule" which will cancel the current appointment and will allow him to schedule a new one.



APPENDIX 2 EXAM 3 DESIGN, LOGISTICS, TRAINING, AND QUALITY CONTROL

Appendix 2.1 Standardized Interview Techniques

I. Overview of Interviewing

A. Interviewer bias – includes anything that creates a systematic difference between responses obtained by different interviewers

- 1 Respondent's perception of the interviewer and his/her reaction to that.
- 2 Interviewer's perception of the respondent and his/her reaction to that.

B. Characteristics of a good interview

There is an appropriate atmosphere

- friendly, but businesslike

1. The respondent is at ease
 - female interviewers may be perceived as less threatening
 - ensure confidentiality of participant
 - someone much older than respondent may be viewed as more judgmental
 - space for interviewing is appropriate, quiet, friendly
2. The interviewer obtains the answer to the question that is asked
 - proper use of probes
 - repeats question, rather than interpreting it
3. Clarification is obtained for confusing answers
4. The interviewer gives only neutral responses to the respondent's answers
5. The response is recorded accurately

C. Specific skills required for interviewers

1. Be able to ask questions at the correct pace and in a conversational tone
2. Know the questions and response categories well enough to keep the interview flowing smoothly
3. Know when there are probes that can be used, and know how to use them
4. Be able to think as an interviewer, and put aside other roles (researcher, and health care provider, etc.) for the time being
5. Be able to maintain a positive attitude about the interview so that respondent feels that the interview is important
6. Be able to keep some level of control over the interview process, e.g. by rewarding the respondent for answering questions, and not for other behavior

7. Neat, pleasant, professional dress; not too timid, not too aggressive

II. Administration of Interviewing

B. Administration of work

1. Supervisor
 - a. One supervisor for each ten interviewers
 - b. Importance of prompt review of work, and quick feedback
 - c. Face-to-face conference with each interviewer once a week
2. Other considerations
 - a. Good pay and working conditions help keep up morale
3. Tracking procedures
 - a. Response rate, overall and by interviewer
 - b. Reasons for non-response
 - c. Length of interview, overall and by interviewer

B. Interviewer training

1. Must cover all aspects of the interview
 - a. Introducing yourself
 - b. Handling people who are reluctant
 - c. Following instructions for administration of interview form
 - d. Obtaining consent
 - e. Answering consent
 - f. Obtaining privacy for the interview
 - g. Setting respondent at ease
 - h. Administering the interview
 - i. Ending the interview
 - j. Importance of role playing, using both standard and problematic situations
 - k. Discuss problems that arose

C. Quality control of field work

1. Observation
 - a. Supervisor going with interviewer
 - b. Tape recording
 - c. Monitoring telephone interview
2. Editing
 - a. Field editing
 - b. Editing by supervisor – edit first few interviews, if no problems then only need edit a 000000sample of remaining interviews
3. Validation
 - a. That interview was done – by re-interview, telephone call, or sending a letter

D. Ways to reduce the standard errors from interview effects by 10% for at least the one-third of items most affected by interviewers (Source: Fowler FJ, Mangione TW)

1. Increase effective sample size by about 20% (if simple random sample)
2. If interviewers receive less than 1 day of basic training, increase by a day or two
3. Tape all or a sample of interviews; review one a week per interviewer, provide feedback
4. Rewrite questions to reduce the need for probing and make administration and reading of questions easier
5. Reduce the number of interviews per interviewer by 20% by using 20% more interviewers

Reference

Fowler FJ, Mangione TW. Reducing Interviewer effects on health survey data – Executive Summary. Center for Survey Research – Univ. of Massachusetts/Boston. Report No. NCHSR 86-8. U.S. Department of Health and Human Services.

E. **Standardized Interviewing Techniques**

The Jackson Heart Study is a single site study being conducted in the Jackson Mississippi area, with African-American persons aged 35-84. The aim is to produce a study that represents 6,500 people throughout the Jackson area in Madison, Rankin and Hinds counties.

In order to produce valid and reliable data, the study designers must pay attention to the training and the methods in which the data are collected. Thus, a standardized approach to interviewing and the training of interviewers is necessary. The study is standardized through the use of scripts in training, centralized training of supervisors, setting of qualifications for supervisors, reviewing of data that is collected, listening to tapes that are produced at interviews, and finally observing the interviewer in the field.

Scripts are used to teach you techniques in probing as well to determine how well you are following skip patterns in the forms and adhering to the various aspects of protocol. Scripts are specifically used in the Rose Questionnaire. All of your interviews will be taped and you will gain knowledge about how to do this talking with experienced interviewers who are systematically reviewed by your supervisor to determine that you are asking the questions as written and are not leading the study respondent or providing answers for them. You will occasionally be observed through monitoring visits.

The study is further standardized in centralizing training for supervisors and where possible for the interviewers. The study initially will train local interviewer supervisors who will be responsible for training on site as the need for new personnel is required.

1. **Dealing with the Sample Population**

The sample members for Jackson Heart Study will include a variety of persons who, generally, will have characteristics similar to those encountered with any household survey. Some of the situations you may encounter at the household, along with suggestions for dealing with them appropriately, follow:

1. Fear of Being Victimized – Some of your respondents may refuse to participate in a survey because they are afraid of being victimized in some way. It is your responsibility to assure the sample member of the legitimacy of your call/visit and intentions and to make the respondent feel secure. Your identification badge and letter will aid you in reassuring the respondent.
2. Handicaps – If a sample member seems to have a handicap that will interfere with proper completion of the interview, would cause undue stress for the sample member, or prevent the sample member from completing the clinic/examination, do not attempt to complete the interview with her/him. Determine if there is a person available who is knowledgeable about the sample member's health and tactfully obtain information which will help determine if the sample member should be excluded from the study. If such a person does not exist, thank the sample member for his/her time and terminate the interview. Code the result appropriately and provide explanatory notes so that your supervisor can evaluate the case.
3. Difficulty Understanding Questions – Some of your respondents may have difficulty in comprehending the questions slowly and allow the respondent adequate time to respond. Repeat the question, if necessary. (Unless specifically allowed by the specifications, do not define and explain, which may result in obtaining a biased response.)
4. Tendency to Stray from the Topic – Some respondents will welcome the opportunity to talk with someone who is neutral about their health problems. Attempts to explain their

problems or vent their feelings may cause them to stray from the questions being asked. You must be careful to control the interview situation, while not alienating the respondent.

5. Tendency to Respond in a Socially Desirable Manner – Some of the respondents will rely on you to help with a response or offer responses that they think are what you or the government would like to hear rather than expressing their knowledge or opinion about a given subject. Keep in mind that we are trying to gather objective data on the sample members' health. Reassure sample members that there are no right or wrong answers to the questions and encourage them to respond according to their experience and knowledge.

2. Interviewing Guidelines

The survey response rate and the quality of the data collected depend on how well you handle various interview situations. Every interview situation will be different, and it is impossible to enumerate every possible situation that you might encounter and suggest ways for handling those situations. There are, however, some basic guidelines presented in this section that, if followed, will assist in obtaining a sample member's participation in the survey and obtain accurate data.

3. Contacting the Respondent

- **Official Notification:** Jackson Heart Study staff will have notified appropriate law enforcement personnel, post offices and community leaders of the study. If interviewer/recruiters are questioned in the field, show their ID badge (which should always be worn in the field) and other identifying information.
- **Leaving Messages:** Interviewer/recruiters will leave door hangers along with business cards. This will provide an opportunity for someone in the household to directly contact the Interviewer/recruiter or Jackson Heart Study staff to schedule an appointment.
- **Interviewing People You Know:** Interviewer/recruiters are not allowed to conduct interviews with friends, relatives or acquaintances. If the Interviewer/recruiter discovers that the respondent is someone s/he knows, inform her/him of the Jackson Heart Study policy and record on HEF form. Jackson Heart Study wants to be able to ensure confidentiality to all respondents and to maintain a professional relationship in the interview setting.
- **Your Introduction:** Initial contacts with sample members will be made in person (or by the printed Jackson Heart Study door hanger). When you meet with a sample member, read the introduction as it is printed. The focus of the introduction is to identify the Interviewer/recruiter, the organization you represent and the purpose of your visit. Attitude: Approach each respondent with a positive, self-assured and matter-of-fact manner. Friendliness, not familiarity, is an asset.

4. Obtaining Participation

You will be provided with the following materials to motivate sample members to participate in the study:

- Introductory letter,
- Study brochure, and

- Copies of local newspaper clippings and endorsements.

You may, however, encounter questions about the survey or objections to participation. A list of possible questions and suggested answers appear below.

5. Commonly Asked Questions

- A. **“Will I have to take any drugs and/or medications?”** Explain to the respondent that there will be no drugs or medication administered during the clinic visit -- only related tests, such as EKG, Lab test, Physical Examination.
- B. **“How often and how long are the clinic visits?”** Explain clinic visits are (1) once every three years, (2) clinic visit will last approx. 2-4 hours.
- C. **“What type of tests will be administered?”** Name all tests that will be administered.
- D. **“Will transportation be provided?”** Transportation will be provided as needed.
- E. **“Are child accommodations provided?”** Yes.
- F. **“How do I know you and the survey are legitimate?”** Repeat your introduction and give the respondent the introductory letter and brochure. Suggest that the respondent call the number on the brochure for information and verification. Also point out that the local health officials are aware of the survey and show the sample member local newspaper clippings and endorsements. Above all else, always wear your picture ID badge in the field and have it visible.
- G. **“What’s this survey about?”** Explain that we are interviewing approximately 5,000 participants in the Jackson Heart Study who live in 3 counties in the state of Mississippi, Hinds, Madison and Rankin, to collect data about their health. The data collected will help the National Institutes of Health, and local area health professionals to understand better, the factors associated with heart disease.
- H. **“I don’t want to buy anything!”** “We are not selling anything. We are doing an important research study for the National Heart, Lung and Blood Institute.”
- I. **“Why interview me?”** “Researchers used scientific sampling procedures to select a random sample of the people in your community. It is important that you participate because we can’t replace you with someone else if you don’t.”
- J. **“Who’s paying for this study?”** The National Heart, Lung and Blood Institute is sponsoring the study.
- K. **“I’m too busy”** “Then let’s make an appointment for some other time that is more convenient for you. We can make the appointment now.” Note: If the participant does not make an appointment then and request for you to call back, tell them you can call back tomorrow morning, afternoon, or evening. “Which would you prefer?”
- L. **“My answers won’t be of any help.”** Explain that there are no right or wrong answers and their opinions and experiences will be helpful to the study.
- M. **“I don’t want everybody to know my personal information.”** Advise that “Your answers will be kept fully confidential. The information that you give us will be analyzed statistically, and there will be no way that your name will be connected with

your answers. Your name, address, and phone number will be separated from your answers, and all identifying information will be destroyed when the study results are reported. Your answers will not be given to your doctor or anyone else responsible for your health care without your permission and will not, in any way, affect the care you receive from them."

- N. **"I can't help you because I never had heart problems."** Explain that you still need to talk to them about their health and that the study is based on selecting people from the general population, most of whom will not have heart problems. Also, explain that if a question is asked for which they don't know the answer, they can simply say "don't know" and you will move on to the next applicable question.
- O. **"Will this affect my medical care?"** Assure the sample member that participation in this study will not affect any medical care s/he now receives or might receive in the future. Also, explain that participation in the survey is voluntary and that all data collected will be kept fully confidential.
- P. **"My doctor may not want me to be in the study."** Inform the sample member that area physicians are in support of Jackson Heart Study and show her/him copies of local endorsements. Suggest that the sample member complete the home interview, and if s/he still feels uncomfortable about the clinic examination, s/he may contact his/her physician to discuss the study.
- Q. **"What do I get out of the study?"** "There are several things that you will get from the study. You will receive free of charge a medical examination and a free home blood pressure cuff with instructions on its use. You may find out that you have a medical condition you have been unaware of and you will be able to get treatment from your personal physician for it earlier. You will also have an opportunity to participate in one of the most important health studies ever conducted. *Legacy of Health.*"
- R. **"How long will this take?"** The telephone call today will take about 15-20 minutes, depending on your answers. Let me start and I'll move through the interview as quickly as I can" (Immediately ask the first question).
- S. **Request for information that you are unable to provide.** If you are unable to answer a sample member's question about the study, advise her/him that you will talk to your supervisor to get the needed information, and that you will be back in touch in a day or so. Then talk to your supervisor as soon as possible.
- T. **"What will the clinic visit involve?"** If this question is asked during annual follow up call, provide the respondent with a brief explanation, such as: "The clinic visit will involve a physical examination by highly trained clinic staff using modern equipment and an interview." If this question is asked later during the visit, interviewer/recruiters will review the Jackson Heart Study brochure with the respondent. The Jackson Heart Study brochure will consist of the clinic scheduled activities and a brief description of the major tests that will be conducted at the clinic.
- U. **"Will I get results of my test?"** "Any abnormal findings will be made known to you, as well as either complete results or a summary of results of important tests. For example, we will provide the actual blood pressure values, blood cholesterol and fasting blood sugar results, and many more. Your lab results will be given to your primary physician also."
- V. **"Where did you get my name or why have you come to my house."** You are already identified as a participant in the JHS and came to the clinic approximately 4 years ago.

- W. **“I would like to participate but I can’t take that much time off work.”** Tell the respondent that the Jackson Heart Study project has received extensive community support and that Jackson Heart Study staff will be happy to send a letter to the employer requesting time off (see attached letter). Be sure to note that the respondent has requested this letter and inform your supervisor as soon as possible.
- X. **“I heard you can get AIDS from blood tests.”** Explain that the clinic uses only sealed, disposable needles. The needles will not be “shared”; therefore there is not a known risk for AIDS from blood drawing.
- Y. **“I don’t like the idea of blood tests.”** “I don’t like to have my blood drawn. The clinic staff is very well trained and performs blood drawings with a minimum of discomfort. The blood tests are one of the most important parts of the Jackson Heart Study and are needed to compare with your other study results.”
- Z. **“I just told you the answer to that question.”** “I’m sorry I repeated the question. I don’t want to rely on my memory to record your information correctly.” Note that this can be avoided if you realize the respondent has answered the question by a lead-in such as “I know this sounds repetitive but could you tell me...” or “You may have told me this before but just to make sure I have it right...”

The important point to remember when answering questions or overcoming objections is to try not to alienate the respondent. If you feel that you are unsuccessful in countering the respondent’s objections, politely thank her/him for his/her time and terminate the interview. Try to “leave the door open” for someone else to talk to the sample member and encourage her/him to participate.

6. Conducting the Interview

The interviewer must help the respondent to feel at ease and comfortable with the interview. During the initial contact and throughout the interview, you should:

- Maintain a positive attitude.
- Repeat that any information the respondent gives you will be kept confidential if s/he appears to be apprehensive about providing information,
- Maintain control of the interview.
- Assume a nonjudgmental, noncommittal, neutral approach to the respondent and the subject matter, so that the sample member will feel comfortable answering the questions truthfully.

The process of asking the questions, probing, and recording responses correctly is crucial to obtaining usable, high-quality data. The standard practices listed below must be followed.

7. Asking the Questions

- Ask the questions using the exact words printed in the questionnaire.
- Ask the questions in the exact sequence in which they appear or as instructed. Whenever you are not to ask questions in sequence, a skip instruction will appear beside the

response categories for the question asked. (Skip routing instructions are discussed in more detail later in this chapter.)

- Ask every question specified even when a respondent has seemingly provided the answer to the question when another question was asked. The answer received in the context of one question may not be the same answer that will be received when the other question is asked.
- If the answer to a question indicates that the respondent did not understand the intent of the question, repeat the question.
- Read the questions at a moderate speed, preferably at a pace of about two words per second.
- Avoid suggesting answers to the respondent. As noted elsewhere in this manual, the sample members may rely on you to help with an answer to a question. As the interviewer, your job is to ask the questions, make sure the respondent understands the questions, and then record his/her responses. Do not assist the respondent in selecting responses.
- Read transition statements just as they are printed in the questionnaire. Transition statements are designed to inform the respondent of the nature of a question or a series of questions, to define a word, or to describe what is being asked for in the question.
- Sensitive questions should be asked in a neutral manner, which should not differ from the normal professional flow of the interview. The respondent may be more comfortable if you avoid eye contact when asking sensitive questions.
- Read questions in a natural tone, following the punctuation in the question. Only emphasize words that are underlined or appear in bold. When response categories are to be read, put a brief pause between the options so the participant knows what the choices are.
- Do not show the questionnaire to the respondent. You do not want the respondent to see the questions and response categories of the questionnaire. For this reason, you will want to arrange the seating so that you are sitting across from the respondent. When it is appropriate for the respondent to see the response categories to a question, the questionnaire will instruct you to guide the respondent to look at a designated RESPONSE CARD.

8. Probing

You will be required at times to probe to obtain a more complete or more specific answer from a respondent. Chapters 3 and 4 provide explanation of the questions you will ask. When you know the objective of a question, you will be able to judge whether a response is adequate or inadequate. In order to elicit complete, adequate answers, you often will need to use an appropriate neutral or non-directive probe. The important thing to remember when probing is that you must not suggest answers or lead the respondent. General rules for probing follow.

- Use neutral questions or statements to encourage a respondent to elaborate on an inadequate response. Examples of neutral probes are “What do you mean?”, “How do you mean?”, “Tell me what you have in mind.”, “Tell me more about...”.

- The silent probe, which is pausing or hesitating to indicate to the respondent that you need more or better information, is a good probe to use after you have determined the respondent's response pattern.
- Clarification probes should be used when the response is unclear, ambiguous or contradictory. Be careful not to appear to challenge the respondent when clarifying a statement and always use a neutral probe.
- Repeat the question if the respondent misunderstood or misinterpreted the question. After hearing the question the second time, the respondent will likely understand what information is expected.
- Unless you have been provided with a response code of "Don't know", the "I don't know" response almost always requires a probe since this response can mean one of several things:
 - The respondent doesn't understand the question and says "Don't know" to avoid saying s/he doesn't understand;
 - The respondent is thinking the question over and says "Don't know" to fill the silence and gain time to think;
 - The respondent may be trying to evade the issue because s/he feels uninformed, is afraid of giving a wrong answer or the question seems too personal; or, the respondent may really not know.

Some of the questions in the Jackson Heart Study ask about recall of events over time. You may assist the respondent without violating probing rules by working with her/him on math or pinpointing dates or events (such as age a parent was diagnosed with a specific disease). Another way to help pinpoint more accurate information is to ask respondent to think about time of year or season when an event occurred.

9. Recording Responses

Most of the questions in the Jackson Heart Study instruments have precoded responses. There are a few questions, however, that are open-ended – that is, you must write in a response to the question. Some questions have pre-coded responses as well as an "Other (Specify)" category. If the respondent's answer does not fit into a pre-coded answer, you must specify the response. The recording practices below must be followed at all times to assure that the response recorded accurately reflects the respondents' answers and to assure that questionnaire data can be converted to machine-readable form. Detailed Instructions for Completing Paper Forms may be found in Appendix 10.

10. Instrument Conventions

Certain conventions are used consistently in the Jackson Heart Study instruments. Familiarity with these conventions will help you use the instruments with ease and confidence.

11. Instructions to the Interviewer

Your instructions are always in CAPITAL LETTERS, and they are not to be read to the respondent. Often, your instructions are also in brackets. For example:

37.	Have you ever smoked a pipe regularly?		
	[CODE "NO" IF LESS THAN 12 OZ. IN A		
	LIFETIME]	Yes	1
		<div style="border: 1px solid black; padding: 2px; display: inline-block;">Go to Item 44</div> —	
		No	2

Instructions to interviewers may also appear in boxes. Boxed material in capital letters are interviewer instructions. Other statements which are in boxes but are not capitalized are to be read to the respondent. An example of each type of boxed statement appears below.

Did your natural father ever have or does he now have any of the following diseases? [READ EACH RESPONSE CATEGORY]

26a.	Cancer?	Yes	1
		No	2
		Don't know	7
26b.	Diabetes? (sugar in the blood)	Yes	1
		No	2
		Don't know	7
26c.	High blood pressure or hypertension (high blood)?	Yes	1
		No	2
		Don't know	7
26d.	Stroke?	Yes	1
		No	2

	Don't know	7
26e. Heart attack?	Yes	1
	No	2
	Don't know	7

If "No" or "Don't Know", Go to Item 28
--

I would like to ask you a few questions about your parents' health.

The first box consists of an interviewer instruction; the second of a lead-in statement which is to be read to the respondent.

12. Questions

Questions are printed in upper and lower case type. Answer choices and codes are printed below the question. Answer choices are never read to the respondent unless they are included in the body of the question or unless you are instructed to do so. In Example 1 below, the answer choices are not read to the respondent; In Examples 2 and 3, they are read because they are included in the question or because you are instructed to do so.

EXAMPLE 1

14. What was the cause of your natural mother's death?	Cancer	1
	Heart attack	2
	Stroke	3
	Other (Specify)	4
	Don't Know	7
Specify: _____		

EXAMPLE 2

1. Compared to other people your age, would

you say that your health is excellent, good, fair, or poor?	Excellent	1
	Good	2
	Fair	3
	Poor	4

EXAMPLE 3

36. (Do/did) you inhale the cigarette smoke? [READ RESPONSE CATEGORIES]	Not at all	1
	Slightly	2
	Moderately	3
	Deeply	4

13. Alternate Wording

Where you must choose the correct wording for a question, a choice of words or phrases is given in parentheses. The choice you make depends upon previous answers from that respondent. For example:

57. What (is/was) your (current/most recent)
occupation? [IF MORE THAN ONE JOB,
RECORD OCCUPATION FOR JOB FOR
MOST HOURS WORKED PER WEEK.]

For currently employed respondents you would read "What is your current occupation?"
For unemployed respondents, you would read, "What was your most recent occupation?"

14. Word Insertion

Many questions in the Jackson Heart Study survey instruments contain capitalized words or phrases within brackets. For these questions, you must insert the appropriate name, date, place, etc., as required by the questions. For example:

[IF YES TO ANY DISEASES IN QUESTION 26, ASK FOR EACH DISEASE.] How old was he when he was first told he had [NAME OF DISEASE]? [ENTER "99" FOR "DON'T KNOW"; "98" FOR AGES 98 AND OLDER.]

Age

27a. Cancer:

--	--

27b. Diabetes:

--	--

27c. High Blood
Pressure:

--	--

27d. Stroke:

--	--

27e. Heart attack:

--	--

53. How long have you lived in
[NAME OF COMMUNITY]?

--	--

YEARS

In the first example, you would insert the name of each disease specified in the preceding question. In the second example, you would read the name of your study community, e.g. Mississippi.

15. Skip Instructions

Skip instructions direct you to the next applicable question or item in the instrument. As with other interviewer instructions, they are in capital letters and appear with arrows, brackets, or as a lead-in to a specific question. Since skip instructions are crucial to the accurate administration of the questionnaire, see example below.

EXAMPLE 1

12. Have you ever taken birth control pills
to prevent pregnancy?.....Yes 1

Go to Item 17 — No 2

13. At what age did you start taking birth control pills for the first time?

--	--

age

14. Are you currently taking birth control pills?.....Yes 1

No 2

Go to Item 16

15. At what age did you stop taking birth control pills?

--	--

age

16. For how many years altogether have you used birth control pills?

--	--

Years

C. HORMONE USE

17. Have you ever taken female hormone pills, skin patches, shots,
or implants, including birth control pills for reasons other than
preventing pregnancy?.....Yes 1

Go to Item 30 — No 2

Don't Know 7

Appendix 2.2 Instructions for Completing Paper Forms

I. Instructions for Completing Paper Forms General

A. Background

The Jackson Heart (JHS) Study utilizes computer-assisted direct data entry as its primary mode of data collection. Nevertheless, the existence of paper forms is necessary for situations in which direct data entry is not possible. In such instances, data is collected on paper forms and then entered on the computer at some later time. The purpose of this document is to provide instructions for completing these paper forms. It should be read carefully prior to working with any forms. Specific sets of instructions associated with each form (QxQ's) should then be read for those forms that are of interest.

B. Form Structure

Most of the paper forms in JHS are designed to correspond exactly to the computer screens used for data entry. However, the quantity of text showing on one paper page will not usually match the quantity of text on a screen. For example, the first page of a form may show items 1 to 10, while the first screen of the form may show items 1 to 8.

Most forms are structured as follows:

First page:

- a. Form Title
- b. "Header" Information
 1. Participant's ID Number
 2. Contact Year
 3. Form Code (preassigned 3-letter code)
 4. Version (1-letter code and date)
 5. Participant's Last Name and Initials
- c. Summarized Instructions
- d. First Screen of the Form

Following pages:

- a. Form Title, Code, and Version
- b. Successive Screens

C. General Instructions for Completing and Correcting Items on the Forms

All items fall into two main categories: (1) fill in the boxes, and (2) multiple choice. Techniques for completing each of these types of items, as well as making corrections, are described below. A general rule is to record information only in the spaces provided (except for some error corrections).

1. Fill In The Boxes: Recording Information

When alphabetic information is required, print the response beginning in the leftmost box using capital letters. Punctuation may be included.

Example: If the participant's last name were O'Reilly, it should be entered as follows:

LAST NAME:

O	'	R	E	I	L	L	Y				
---	---	---	---	---	---	---	---	--	--	--	--

If the response contains more characters than there are boxes, beginning with the first character enter as many characters as there are boxes.

Example: If the subject's last name were Hobgoodnotting, it should be entered as follows:

LAST NAME:

H	O	B	G	O	O	D	N	O	T	T	I
---	---	---	---	---	---	---	---	---	---	---	---

Whenever numerical responses are required, enter the number so that the last digit appears in the rightmost box. Enter leading zeroes where necessary to fill all boxes. (This does not apply to the address section or to any item which combines alphabetic and numeric information. Such items should be treated as alphabetic.)

Example: If the participant's diastolic blood pressure was 96, it should be coded as:

Diastolic:

0	9	6
---	---	---

In some cases, numeric fields have a pre-printed number of decimal places. Also, it is possible that the QxQ instructions will specify the number of decimal places to be recorded. Instructions on how to round values to the expected number of decimal places are found in the QxQ instructions. When necessary, enter trailing zeros to fill the requested number of places to the right of the decimal point. Leading zeros may be needed so that all boxes to the left of the decimal are also filled.

Example with trailing zero: If the participant takes twelve vitamins per day, it should be recorded as:

Number per day:

1	2	0
---	---	---

Example with leading zero: If the participant takes two and one-half vitamins per day, it should be recorded as:

Number per day:

0	2	.	5
---	---	---	---

In most cases when dates are recorded, slashes ("/") are used as the separator characters for month, day, and year. These are usually pre-printed in the response field. The format to be used to record dates is indicated under the boxes. If not, the QxQ instructions will indicate which format and separator to use. JHS uses the U.S. order for recording dates (month/day/year). The QxQ instructions may also contain information on how to handle partial dates. When necessary, use leading zeros within each date unit (month or day or year) so that each box is filled.

Example: Data collected on April 3, 2000 would be recorded as:

Date of data collection:

0	4
---	---

m m

0	3
---	---

d d

0	0
---	---

y y

JHS usually records time using a 12-hour clock, with AM or PM indicated separately. In most cases, colons (":") are used as the separator character for hours and minutes, and are typically pre-printed in the response field. The format to be used is indicated under the boxes. If not, the QxQ instructions will indicate which format and separator to use. When necessary, use leading zeros within each time unit (hour or minute) so that each box is filled. Note that midnight is recorded as 12:00 AM, and noon is recorded as 12:00 PM.

Example: A time of fasting determination of 8:05 in the morning is recorded as:

a. Time of fasting determination:

0	8
---	---

 :

0	5
---	---

h h m m

b. AM.....A

PM.....P

2. Fill In The Boxes: Correcting Mistakes

If a number or letter is entered incorrectly, mark through the incorrect entry with an "X". Code the correct entry clearly above the original incorrect entry.

Example: If the participant's systolic blood pressure was actually 130, but was incorrectly entered:

Systolic:

1	3	9
---	---	---

The correction would look like:

Systolic:

1	3	9
---	---	---

If a mistake is made, corrected, and then it is discovered that the correction is incorrect, make a second correction as shown below:

Systolic:

1	3	9
---	---	---

3. Fill In The Boxes: Unknown Or Inapplicable Information

If an item of this type (either alphabetic or numeric) *does not apply* to the subject being interviewed, leave it **blank**. For example, if the participant does not have an "other" phone number, that item is left blank. Similarly, if the form provides spaces for three measurements, but only two are taken, the third space is left blank.

If the item *does apply*, but the response is unknown, mark through the box(es) with two horizontal lines.

Example: The question "How old were you when you had your first heart attack?" is asked, but the participant does not recall how old s/he was. The question *does apply* because it has been established that the participant has had a heart attack, but the *answer to this question is not known*. In this case, the response would look like:

How old were you when you had
your first heart attack?

--	--

4. Multiple Choice: Recording Information

In this type of question several alternatives are given for the answer, each having a corresponding letter. When it is decided which alternative is most appropriate, circle the corresponding letter in the space provided. Always circle one letter only.

Example: If the participant indicates that they have never had chest pain or discomfort, the response would look like:

Have you ever had any pain or discomfort in your chest?	Yes	1
	No	2

5. Multiple Choice: Correcting Mistakes

If a response is coded incorrectly, mark through the incorrectly coded response with an "X" and circle the correct response.

Example 1: The actual response is No, but Y was circled incorrectly. The correction looks like:

Yes	1
No	2

Example 2: If a mistake is made, corrected, and then it is discovered that the correction is incorrect, make a second correction as shown below:

Yes	1
No	2

6. Completing "Header" Information

The following guidelines should be observed in filling out the "header" information located at the top of the first page on all forms:

ID NUMBER: Write in the participant's 7-digit ID. The first box contains the letter J, followed by the 6-digit numeric portion of the ID number.

Example: ID NUMBER:

J	9	9	9	9	9	9
---	---	---	---	---	---	---

CONTACT YEAR: Fill in the appropriate contact year for the form. Use leading zeroes. Note: This item may be pre-coded on some forms.

LAST NAME: Code the response beginning in the leftmost box using capital letters. If the name contains more letters than there are boxes, beginning with the first letter enter as many letters as there are boxes. Punctuation (e.g., apostrophes and hyphens) and blanks may be entered as part of the last name. Follow the guidelines and examples given above for alphabetic "fill in the boxes" items.

INITIALS: Record the participant's first initial in the first box and middle initial in the second box. If a female participant is married and uses a "maiden" name (father's surname) as a middle name, use that initial as the second initial. Otherwise, if the participant has more than one middle name, record only the first initial and the second initial. If there is no middle name, record the first initial in the first box and leave the second box blank.

Example 1: A participant's first initial is K, but he has no middle name. The entry would be as follows:

INITIALS:

K	
---	--

Example 2: If the participant's full name is John Oscar Van Camp, Jr., and the participant specifies that his last name is "Van Camp", it should be entered as:

LAST NAME:

V	A	N		C	A	M	P				
---	---	---	--	---	---	---	---	--	--	--	--

 INITIALS:

J	O
---	---

7. Skip Patterns ("Go to" Boxes)

Skip patterns occur in many multiple choice type items. Here, if a certain response is selected, it is necessary to skip over one or more items to the next applicable item. This is indicated by an arrow from the response which necessitates a skip to a box containing a "go to" statement. If that response is selected, the next item to be asked is the one indicated in the box. If the other response is selected, always proceed to the next item unless otherwise directed. The box will also indicate the screen containing the "go to" item if that item is not on the current screen.

Example: 7. Since we last contacted you, have you had any pain or discomfort in your chest?

Yes	1	
No	2	Go to Item 20. Screen 5

In this case, if the response is "No", skip to Item 20 on screen 5. If the response is "Yes", proceed to the next question, Item 8.

Occasionally, a skip pattern will occur in a fill-in type item. In those instances, specific instructions are provided on the form. Again, if the skip criteria are not satisfied, continue with the next item.

A few items will trigger a skip regardless of the response. For these, follow the instructions on the form.

II. General Instructions: Completing Computer Data entry Screen

SEE MANUAL 6, DATA MANAGEMENT

III. Instructions for Recording Responses that Do Not Match Precoded Response Categories

Most of the questions in the JHS instruments have precoded responses. There are a few questions, however, that are open-ended that is, you must write in a response to the question. Some questions have precoded responses as well as an "Other (SPECIFY)" category. If the respondent's answer does not fit into a precoded answer, you must specify the response. The recording practices below must be followed at all times to assure that the response recorded accurately reflects the respondent's answers and to assure that questionnaire data can be converted to machine-readable form.

- You must listen to what the respondent says and record the appropriate answer if the response satisfies the objective of the question.
- In recording answers to open-ended questions or "Other (SPECIFY)" categories, print the response verbatim.
- Record the response immediately after it is given.
- Use a black ball point pen provided by the Clinic.
- Record in the white space below the questions any responses that "don't quite fit" in one of the response categories. Your notes will help the analysts in understanding points of confusion, difficulty, etc.
- Print or write legibly.
- If a respondent refused to answer a question, write "refused" in the left margin beside the question.
- A single answer choice code must be circled in each question to represent the respondent's answer. The only deviation from this rule is for disease questions which are subdivided into several diseases and an answer code is to be circled for each disease listed.

APPENDIX 3 INTERVIEWS IN EXAM 3



Appendix 3.1 Consent Form

Title of Investigation:

The Jackson Heart Study

Principal Investigator:

Herman A. Taylor, MD, MPH

Introduction: as one of more than 5,000 persons who were recruited and took part in exam 1 and 2 of the Jackson Heart Study (JHS), you are being invited to continue your participation in this study by taking part in exam 3. Please feel free to ask us about any information in this document or about anything we tell you that you do not understand.

Purpose: The Jackson Heart Study is a medical research study designed to identify the risk factors and causes of high blood pressure, heart or other cardiovascular disease, obesity, diabetes, kidney disease, and/or lung disease in African Americans. It is conducted by Jackson State University, Tougaloo College, and the university of Mississippi Medical Center, and sponsored by the National Heart, Lung, And Blood Institute (NHLBI), the National Center on Minority Health and Health Disparities (NCMHD), and the National Institute of Biomedical Imaging and Bioengineering (NIBIB).

Procedures: If you agree to take part in Exam 3 you will come to the clinic for the exam. If you are unable to come to the clinic we will make a home visit or meet you at another location that is convenient for you. This exam will take no more than 3 ½ hours of your time. During the exam the following will be done.

- An **interview** with questions about your health, health care, lifestyle and family medical history. To assure all the questions are asked in the same way of everyone, some interviews may be tape-recorded.
- An **examination** to measure your blood pressure, height, weight, waist and hip size, and body composition using a special scale.
- **Laboratory tests** will include urine and blood tests to see how well your kidneys are working and blood tests to check your cholesterol (lipids and blood fats) and sugar levels. About four tablespoons of blood will be drawn from your arm for these blood tests.
- **EKG** (electrocardiogram) will measure the electrical activity of your heart by attaching electrodes (band-aid like stick-ons) to your chest.
- **ABI** (ankle brachial index) monitors, which are small electrical devices that use sound waves, will be placed on your ankles against the skin to measure the pressure in your legs.

MRI (Magnetic Resonance Imaging)

Participants who agree will also come back to have an MRI done, which will take about 45 minutes. The MRI will be done at the University of Mississippi Medical Center Pavilion, which is located near the main hospital; and will be sent to Wake Forest University for review. To see if you qualify to have the MRI we will ask you some questions about your medical history. If you have metal clips or fragments in your body, have a pace maker, artificial heart valve, ear implant or spinal cord stimulator or if you are pregnant or might be pregnant you will not be able to have the MRI.

Before the MRI begins EKG wires will be placed on your chest with a cool gel to help the pads stick; a rubber pad that looks like a large vest will be put over your chest and abdomen with a couple of straps; a clip will be placed on your finger to monitor the oxygen level in your blood; and we will give you head phones to cover your ears and help drown out the noise that the machine makes. You will lie flat on the MRI table, which glides into the chamber. The MRI will take many pictures of the heart from different angles, which will give us information about how your heart looks and works.

Results Reporting

With your permission, any abnormal test results will be sent to your health care provider. If you do not have one, or are unable to afford such care, we will help you locate affordable health care by providing a list of people we can refer you to for such care. Results of your MRI will be sent to us from Wake Forest University and someone from the Jackson Heart Study Clinic will send you a letter describing any abnormal findings. A copy of the MRI may also be given to your primary care doctor if requested.

Annual Follow-Up and Records Review

- After the examination we will contact you once each year to ask about your health during that year. If you were hospitalized for heart disease or related diseases we will also ask you to sign a medical records release, which will allow us to get copies of the hospital and doctor's medical records. In the event of your death, information will be sought from your relatives or other informants including coroner's reports and information from the state health department. In all these instances, your social security number may be used to confirm your identity and assure that the correct records are reviewed.

Risks:

All of the procedures included in this study are a part of standard health care and are considered safe. A skilled technician will draw your blood. No materials will be injected into your body. The risks of the MRI scan to an unborn child are unknown, pregnant women may not take part in this part of the research study. Pregnancy tests will be done on all women of child-bearing potential before beginning this phase of the study.

- The risk of the MRI exam includes feeling uncomfortable in tight places.
- The risk of drawing blood includes pain, bruising, bleeding, infection, or feeling faint.
- The risk of taking blood pressure measurements includes some discomfort from the temporary tightness of the cuff when it is inflated or annoyance due to repeated blood pressure measurements.
- Some of the interview questions may cause you to be embarrassed or become anxious.

Benefits: You may or may not receive a direct benefit from being in this study. You will be given a summary report of all of your results from this examination, including your blood pressure, blood cholesterol, blood sugar, kidney function, Body Mass Index, and body composition, urine protein level. We encourage you to share your summary results report with your health care provider and, with your permission, abnormal results will be sent to her/him. If you do not have regular health care, or are unable to afford such care, the JHS will assist you in locating affordable health care. All study participants will also receive a regular newsletter updating them on the overall findings of the JHS. We hope to learn information that will help others in the future.

Alternatives: You may decide not to take part in the clinical examination. Even if you decide not to take part in the examination, you may continue as a JHS participant by responding to annual follow up calls, and by participating in any future JHS clinical examinations.

Costs: There will be no costs to you for participating in this study. The JHS will be responsible for the cost of all study procedures including the urine test for pregnancy. If you need care for some problem identified with the MRI Scan, you will be responsible for the costs of that care.

Research-related injury: In case of injury or illness resulting from your participation in this study, medical treatment is available to you at the University of Mississippi Medical Center. You will be charged the usual and customary charges for any such treatment you receive.

Compensation: You will receive your choice of a \$25.00 check or gifts with an approximate value of \$25.00 (coffee mugs or other similar items) in appreciation for completing Exam 3. If you have the MRI done you will receive an additional \$25.00 check for the extra time involved.

If you need transportation to or from the clinic the JHS will provide a taxi service. If you use your own transportation to get to the clinic JHS will reimburse you for the mileage from your home address to the JHS, up to \$20.00. You will have to provide documentation of the mileage. Child care, if needed, will be provided at the JHS clinic.

Participation is voluntary: Your participation in the JHS is completely voluntary and you are free to withdraw your consent and to stop taking part at any time, without affecting any future relationship for you or your relatives with the JHS, Jackson State University, Tougaloo College, the University of Mississippi Medical Center, or the Jackson Medical Mall. You may decide not to answer any question or complete any examination.

Withdrawal: You may choose to stop your participation in this study and withdraw at any time. If you decide to withdraw, the information already collected about you may still be used in this study unless you request that your records, and test results obtained from this exam or prior exams be removed from study files. You may also request that your DNA and blood samples and cell lines be destroyed or that all identifiers be removed (including code numbers) from such samples. Your decision to stop your participation will have no affect on the quality of your medical care.

New Information: You will be told of any information we learn during your participation in this study that may affect your willingness to participate.

Confidentiality: The confidentiality of your information is a top priority for the JHS. Every effort will be made to keep the information we learn about you private. All information collected during this research--including interviews, laboratory data, or examination findings--will be kept confidential and results will not be disclosed to anyone without your permission except as described below. Information may be released to other researchers for scientific purposes, but only after removing your name and all other personal identifiers. Research may be done for conditions not directly related to the heart and blood vessels. Researchers from private companies, under conditions of data confidentiality specified by the JHS and the Institutional Review Boards reviewing the JHS, may have access to your information or samples, in a way that cannot identify you. Please note that neither the JHS investigators, nor you, nor your family would benefit financially from this.

Study records may be reviewed by the Food and Drug Administration (FDA), the Office for Human Research Protections (OHRP), and the Institutional Review Boards (IRB) of the University of Mississippi Medical Center, Jackson State University, and Tougaloo College and Office of Integrity and Compliance of the University of Mississippi Medical Center. Study data may be submitted to regulatory agencies in other countries but you will not be identified. If the National Heart, Lung, and Blood Institute or the National Center on

Minority Health and Health Disparities shares this information with others, the information is no longer covered by the federal privacy regulations. To help insure your privacy, a Certificate of Confidentiality has been obtained from the National Heart, Lung, and Blood Institute for this study. This Certificate is intended to help protect against the involuntary release of information collected during this study. The researchers can make disclosures of information only in very special cases (for example, if they think that a participant or someone else is in serious danger of harm).

Protected Health Information: Protected Health Information is any personal health information through which you can be identified. The protected health information collected in this study includes your name, date of birth, and social security number. A decision to participate in this research means that you agree to the use of your health information for the study described in this form. This information will not be released beyond the purposes of conducting this study. The information collected for this study will be kept indefinitely. While this study is ongoing, you may not have access to the research information beyond the summary report of your clinic examination results. This summary report may be released to your health care provider only upon your special request to do so.

Your information will be grouped with that of all other persons taking part in the JHS and will be used only for statistical analysis to further medical knowledge without disclosing your personal identity. When results of this study are published, presented at medical or research meetings, or to the Jackson community, only group findings will be presented.

Additional Studies: You may be invited to take part in other studies conducted by JHS or other investigators outside the regularly scheduled JHS exam cycle.

Questions: Any questions about the study, the specific interviews, examinations, laboratory tests, or record reviews, or any questions about the findings of the study can be answered by the Director of the Jackson Heart Study, Dr. Herman A. Taylor. He can be reached at the Jackson Medical Mall offices of the Jackson Heart Study, 350 W. Woodrow Wilson Drive, Suite 701, Jackson, MS 39213, (601) 815-5050. A pager number is provided through the voice mail for after hours and on weekends.

This research study has been reviewed by the Institutional Review Boards (IRBs) of Jackson State University, Tougaloo College, and The University of Mississippi Medical Center. Any questions about your rights as a research participant can be addressed to one of the following persons:

Richard Ogletree Pharm.D.
Chair, IRB
Univ. of MS Medical Ctr
2500 North State Street
Jackson, MS 39216-4505
(601) 984-2815

Sophia Leggett, Ph.D
Chair, IRB
Jackson State University
1400 J.R. Lynch Street
Jackson, MS 39217
(601) 979-2931

Madhu Singh, Ph.D.
Chair, IRB
Tougaloo College
500 West County Line Rd
Jackson, MS 39174
(601) 977-7737



STATEMENT OF PARTICIPATION

I have been told about this study and the possible risks and benefits. My participation is voluntary and I may withdraw at any time without any penalty or loss of benefits to which I am entitled, including medical care at the University of Mississippi Medical Center.

By signing this form I am not giving up any legal rights I may have.

For Exam 3, I VOLUNTARILY agree to any of the following conditions marked with an X or √ in the “Yes” column.

Yes No

- | | | |
|--------------------------|--------------------------|--|
| <input type="checkbox"/> | <input type="checkbox"/> | I give my permission for JHS investigators to review a copy of my medical records. This includes any clinic records that might be requested if, during one of my annual follow-up calls, I indicate that I have been seen by a provider for possible congestive heart failure. |
| <input type="checkbox"/> | <input type="checkbox"/> | I would like to receive JHS results from the clinic examinations. |
| <input type="checkbox"/> | <input type="checkbox"/> | I give permission for JHS to provide my health care provider with my examination results, if they are outside the normal range. |
| <input type="checkbox"/> | <input type="checkbox"/> | I agree to have my study data or samples released to researchers from for-profit organizations who wish to develop diagnostic laboratory tests, medications or other therapies that could benefit many people. (Note: Neither you nor your heirs will benefit financially from this, and your blood samples, blood cells, or DNA will not be sold to anyone for profit.) |
| <input type="checkbox"/> | <input type="checkbox"/> | I agree to participate in the MRI Scan portion of the Jackson Heart Study to look at the shape of my heart and how it works. |
| <input type="checkbox"/> | <input type="checkbox"/> | I agree to the use of my study data, including imaging scans, interview data and examination results by scientists for future research studies related to blood pressure, heart or blood vessel disease, obesity, diabetes, kidney disease and risk factors for these diseases. |

- ☐ ☐ I agree to the use of my study data, including imaging scans, interview data and examination results for future other research by scientists studying diseases not directly related to heart disease risk factors and related disease.
- ☐ ☐ You may store and use left-over samples of my **blood and urine** for future research studies related to blood pressure, heart or blood vessel disease, obesity, diabetes, kidney disease, or lung disease, and risk factors for these diseases.

By signing this form I am not giving up any legal rights I may have.

Name of Participant Date

Signature of Participant Date

Participant's legally authorized representative (when applicable) Date

Relationship to Participant Date

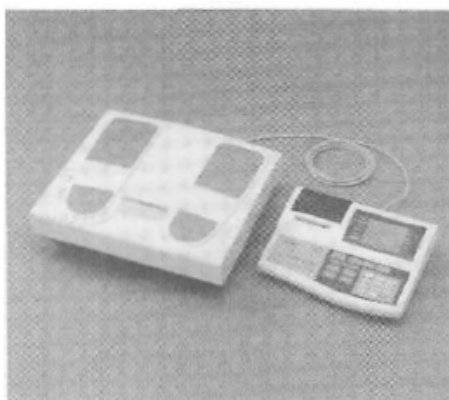
Name of Person Obtaining Informed Consent (please print name) Date

I acknowledge that the participant identified above has been entered into this study, with properly obtained informed consent. I pledge that I will maintain the highest standards of scientific conduct in carrying out this research to protect this participant from harm. I promise to assure that all participant information is used **ONLY** for the purposes expressly granted in this consent. Further, I will maintain confidentiality of all participant research information in keeping with the law and federal regulations.

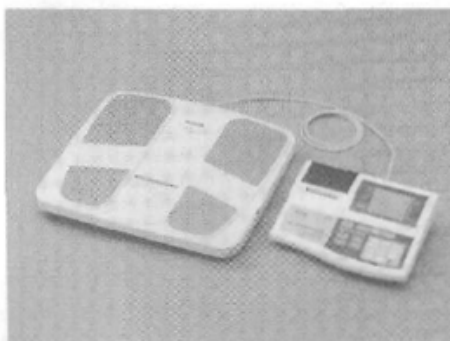
Signature of Principal Investigator, Herman A. Taylor, Jr. MD, MPH Date

APPENDIX 4 PROCEDURES IN EXAM 3

Appendix 4.1 Tanita TNF 300A Manual

**TANITA****BODY COMPOSITION ANALYZER
GOAL SETTER****TBF-300A** **TBF-300 / 310 / 410****INSTRUCTION MANUAL**

<TBF-300/TBF-300A>



<TBF-310>



<TBF-410>



Please read this Instruction Manual carefully and keep it handy for future reference.

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2. Specifications

MODEL		TBF-300A	TBF-300	TBF-310
Impedance Measurement	Measurement System	Tetrapolar Bioelectrical Impedance Analysis		
	Measurement Frequency	50kHz		
	Measurement Current	500 μ A		
	Electrode Material	Pressure Contact Stainless Steel Foot Pads		
	Measurement Style	Between Both Feet		
	Measurement Range	150 ~ 900 Ω		
Weight Measurement	Measurement System	Strain Gauge Load Cell		
	Maximum / Minimum Capacity / Graduation	200kg / 0.1kg 440lb / 0.2lb		270kg / 0.2kg 600lb / 0.5lb
Input Items	Clothes Weight	0~200kg / 0.1kg increments 0~440lb / 0.2lb increments		0~270kg / 0.2kg increments 0~600lb / 0.5lb increments
	Gender	Male / Female		
	Body Type	Standard / Athletic		
	Age	7 ~ 99 years old / 1year increments		
	Height	90 ~ 249cm / 1cm increments 3ft ~ 7ft 11.5in / 0.5in increments		
	Target Body Fat %	4 ~ 55%		
Output Items	Display	Target Body Fat %	4 ~ 55%	
		Weight	0 ~ 200kg / 0.1kg increments 0 ~ 440lb / 0.2lb increments	0 ~ 270kg / 0.2kg increments 0 ~ 600lb / 0.5lb increments
		Gender	Male / Female	
		Age	7~99 years old / 1year increments	
		Height	90 ~ 249cm / 1cm increments 3ft ~ 7ft 11.5in / 0.5in increments	
		Body Type	Standard / Athletic	
		Height	90 ~ 249cm / 1cm increments	
		FAT%	1 ~ 75% / 0.1% increments	
	Print out	Body Type	Standard / Athletic	
		Gender	Male / Female	
		Age	7 ~ 99 years old / 1year increments	
		Height	90 ~ 249cm / 1cm increments 3ft ~ 7ft 11.5in / 0.5in increments	
		Weight	2 ~ 200kg / 0.1kg increments 4.4 ~ 440lb / 0.2lb increments	4 ~ 270kg / 0.2kg increments 10 ~ 600lb / 0.5lb increments
		BMI	0.1 increments	
		BMR	1kJ increments / 1kcal increments	
		Impedance	150 ~ 900 Ω / 1 Ω increments	
		FAT%	1 ~ 75% / 0.1% increments	
		Fat Mass FFM TBW	0.1kg / 0.2lb increments	0.2kg / 0.5lb increments
		Others	Wrestler section information Desirable Range for FAT% and FM (Standard and 20~79 years old ONLY)	
	Display		3 Rows, 5Digits LCD	
	Cable Length Between Weighing Platform and Control Box		2m / 6ft6.5in (Remote Type)	
	Output Data Interface		RS-232C (D-sub 9 pins Male Connector)	
	Power Source		AC Adapter (included) Center Minus	
	Rated Power		DC5V 3.5A	
	Power Consumption		17.5W	
	Temperature Range of usage		0 ~ 35°C / 32 ~ 95°F	
Weight of Equipment	Weighing Platform		7.0kg / 15.4lb	5.4kg / 11.9lb
	Control Box		1.0kg / 2.2lb	

MODEL		TBF-410
Impedance Measurement	Measurement System	Tetrapolar Bioelectrical Impedance Analysis
	Measurement Frequency	50kHz
	Measurement Current	500 μ A
	Electrode Material	Pressure Contact Stainless Steel Foot Pads
	Measurement Style	Between Both Feet
Weight Measurement	Measurement Range	150 ~ 900 Ω
	Measurement System	Strain Gauge Load Cell
	Maximum / Minimum Capacity / Graduation	200kg / 0.1kg 440lb / 0.2lb
Input Items	Clothes Weight	0 ~ 200kg / 0.1kg increments 0 ~ 440lb / 0.2lb increments
	Gender	Male / Female
	Body Type	Standard / Athletic
	Age	7 ~ 99 years old / 1year increments
	Height	90 ~ 249cm / 1cm increments 3ft ~ 7ft 11.5in / 0.5in increments
Output Items	Target Body Fat %	4 ~ 55%
	Target Body Fat %	4 ~ 55%
	Weight	0 ~ 200kg / 0.1kg increments 0 ~ 440lb / 0.2lb increments
	Gender	Male / Female
	Age	7~99 years old / 1year increments
	Height	90 ~ 249cm / 1cm increments 3ft ~ 7ft 11.5in / 0.5in increments
	Body Type	Standard / Athletic
	Height	90 ~ 249cm / 1cm increments
	FAT%	1 ~ 75% / 0.1% increments
	Body Type	Standard / Athletic
	Gender	Male / Female
	Age	7~99 years old / 1year increments
	Height	90 ~ 249cm / 1cm increments 3ft ~ 7ft 11.5in / 0.5in increments
	Weight	2 ~ 200kg / 0.1kg increments 4.4 ~ 440lb / 0.2lb increments
	BMI	0.1 increments
	BMR	1kj increments / 1kcal increments
	Impedance	150 ~ 900 Ω / 1 Ω increments
	FAT%	1 ~ 75% / 0.1% increments
	Fat Mass	0.1kg / 0.2lb increments
	FFM	
	TBW	
	Others	Desirable Range for FAT% and FM (Standard and 20 ~ 79 years old ONLY)
Display		3 Rows, 5Digits LCD
Output Data Interface		RS-232C (D-sub 9 pins Male Connector)
Power Source		AC Adapter (included) Center Minus
Rated Power		DC5V 3.5A
Power Consumption		17.5W
Temperature Range of usage		0 ~ 35°C / 32 ~ 95°F
Weight of Equipment		11.0kg / 24.2lb

3. Important Notes for Users

GB

■ Caution Symbols

Thank you for purchasing this precision crafted Tanita product. This product is intended for use with the assistance of a health care or fitness professional. For optimum performance and safety, please familiarize yourself with the **Caution Symbols** below. These symbols are designed to alert the user to potential hazards when using this equipment. Ignoring these **Caution Symbols** may result in serious injury, or damage to the product.

Please be sure to review before proceeding with the INSTRUCTION MANUAL.



WARNING

This symbol indicates the possibility of serious injury if the product is mishandled or instructions are ignored.



WARNING

This symbol indicates the possibility of **ELECTRICAL SHOCK**. Please pay special attention to sections which bear this mark.



CAUTION

This symbol indicates the possibility of physical injury or equipment damage if instructions are ignored.



This symbol indicates general precautions that should be taken when using this product.



WARNING

• Individuals with a Pacemaker or Other Internal Medical Devices

Because Tanita's Body Composition Analyzers send a weak electrical current through the body, **Individuals Who Have a Pacemaker or Other Internal Electrical Medical Devices Should Not Use This Product**. The weak electrical signal may cause such internal devices to malfunction.

• Cross Contamination

The Body Composition Analyzer should be used with bare feet. Please be sure to clean the weighing platform with appropriate disinfectant after each use. **Never pour any liquid directly on the weighing platform**, as it may leak and cause internal damage that could cause the product to malfunction. Use a soft cloth and appropriate disinfectant or mild cleaners to wipe off weighing platform. Do not wipe the weighing platform with strong chemicals.

• Please consult your Physician before beginning any weight management program and for help in establishing your target body fat percent. Tanita Corporation is not responsible for establishing individualized target body fat percent values.

• The minimum percent body fat values used to calculate the Minimum Wrestling Weight (in wrestler mode) are derived from the 1996 American College of Sports Medicine (ACSM) Position Stand "Weight Loss in Wrestlers", that has been adopted by the National Collegiate Athletic Association (NCAA) in their 1998 Weight Management Guidelines. TANITA Corporation is not responsible for establishing these minimum requirements, nor for any future changes to the current standards. Tanita is providing information only, and does not recommend the application of the guidelines for any given individual. State wrestling associations may have standards and guidelines that differ from the NCAA. (TBF-300A)

• To reduce the risk of fire hazards or equipment damage, use only the original AC adapter provided by TANITA.



WARNING

• Inserting and Removing the Power Cord

To reduce the risk of electric shock or product damage, never insert or remove the power cord with wet hands.

• To avoid a fire hazard, make sure the wall outlet is functioning properly; avoid using multiple outlet extension cords.



CAUTION

• To reduce the chance of inaccurate measurement, be sure to place the weighing platform on a flat and stable surface.

• To reduce risk of injury or equipment malfunction, always step on the weighing platform slowly.

• When handling printer unit, avoid any sharp edges.



Maintenance

In order to insure optimum performance of this Body Composition Scale, please observe the following instructions:

- Unplug the unit from the wall outlet when it will not be in use for long periods of time.
- Always turn the equipment off before unplugging from a wall outlet.
- Never disassemble the equipment. Always call the nearest Tanita dealer or branch office for instruction.
- In order to reduce the risk of a short circuit, please keep any liquid or metal objects (paper clips, etc.) away from the printer.
- Do not drop the unit, and avoid locations with constant vibration.
- Avoid placing the weighing platform or display in direct sunlight, or too close to a heating unit.
- Avoid rapid temperature fluctuations.
- Excessive humidity may damage the equipment.
- When transferred to any location where there is a difference of more than 20°C (40°F), wait 2 hours before using.



General Instructions for Accurate Measurement

The body composition analyzer is designed for standard and athletic individuals. However, certain individuals may not receive accurate results, as they fall outside the population for which Tanita equations were developed.

- Because this body composition analyzer uses a minor electric current to measure impedance (electrical resistance), best results will be observed when measurement is taken in bare feet.
- Poor contact between the feet and electrodes may produce an error message. Heels should be placed directly on top of the posterior electrodes, while the front part of the foot needs to be in contact with the anterior electrodes. Also, make sure the soles of the feet are free of excess dirt, as this may act as a barrier to the mild current.
- If there are calluses on the soles of the feet, or an individual is wearing thin nylons, accurate measurement may still be possible. Place 0.5cc of saline or water in the center of each electrode. This will act as a conductive material, and may allow the current to pass freely through a thin barrier.
- Keep the electrodes clean by wiping them with disinfectant.
- Fluctuations in hydration status may affect body composition results.
- Wrestlers should confirm proper hydration (i.e. urine specific gravity (USG) testing) before assessing body fat percent and weight. Severe dehydration will skew the Body Fat Percent reading.

• Interpretation of Results

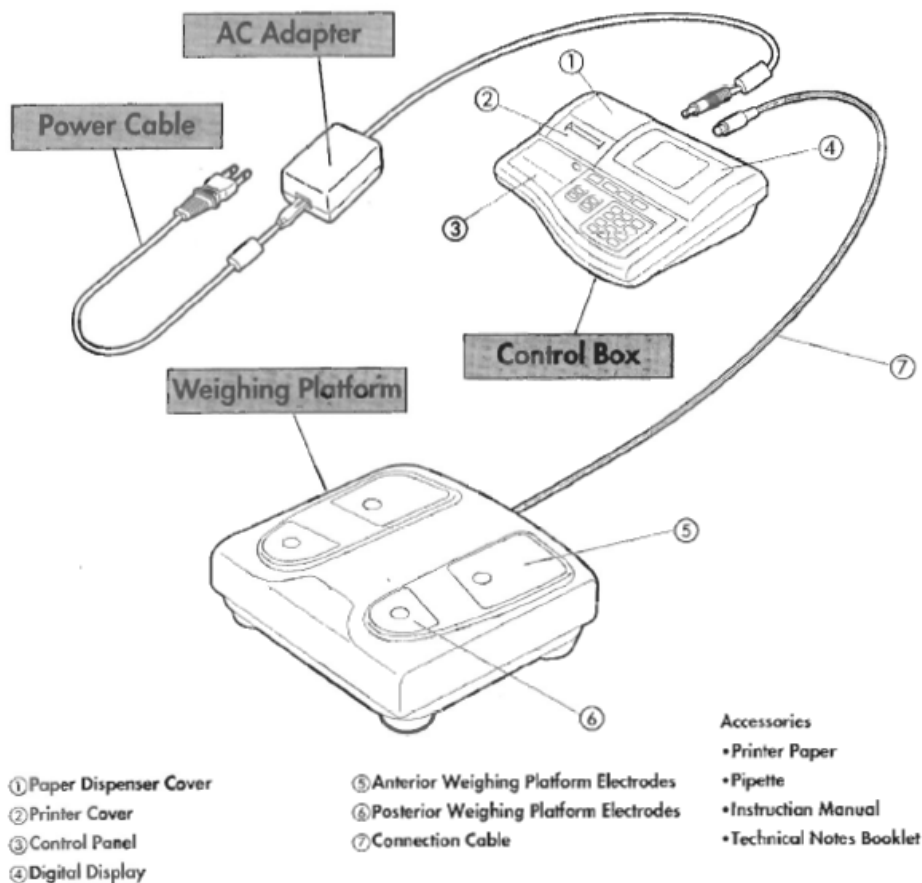
The data provided by this machine, as well as any supplementary information such as diet or exercise programs based on this data, should be interpreted by a licensed professional.

For more information regarding Accurate Measurement, please refer to the **Technical Notes** booklet.

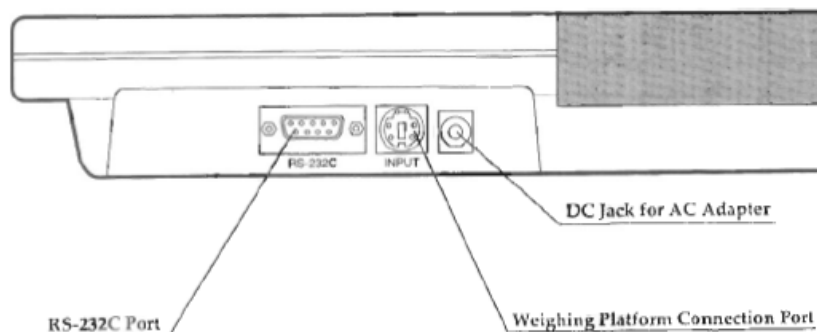
4. Components

GB

■ Overview (TBF-300/TBF-300A)

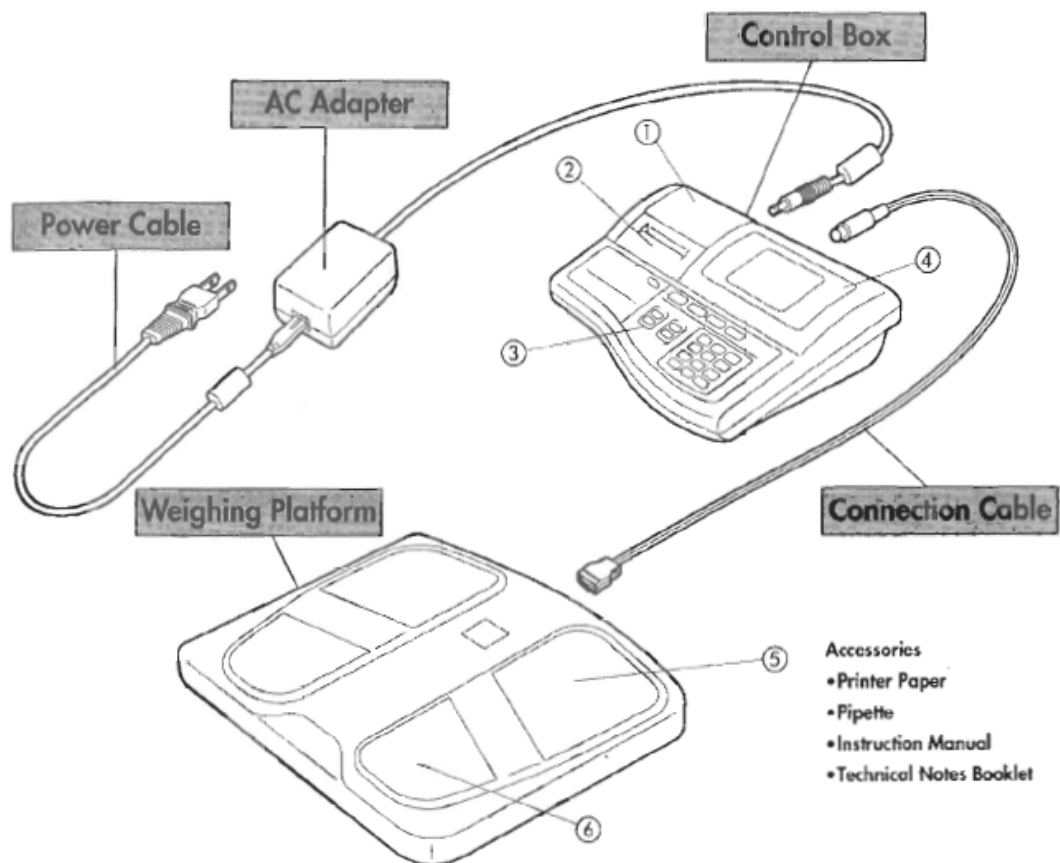


■ Rear View of Control Panel (TBF-300/TBF-300A)



Overview (TBF-310)

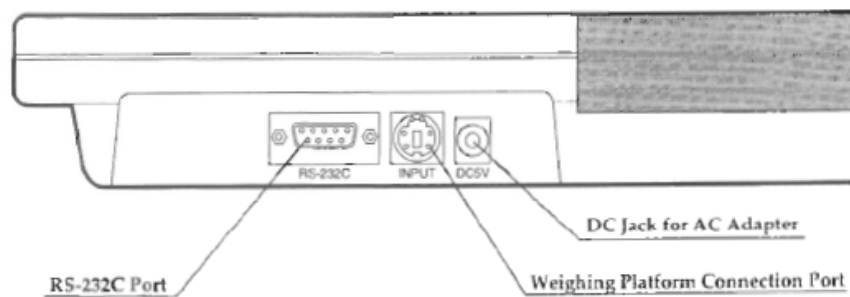
GB



- ① Paper Dispenser Cover
- ② Printer Cover
- ③ Control Panel

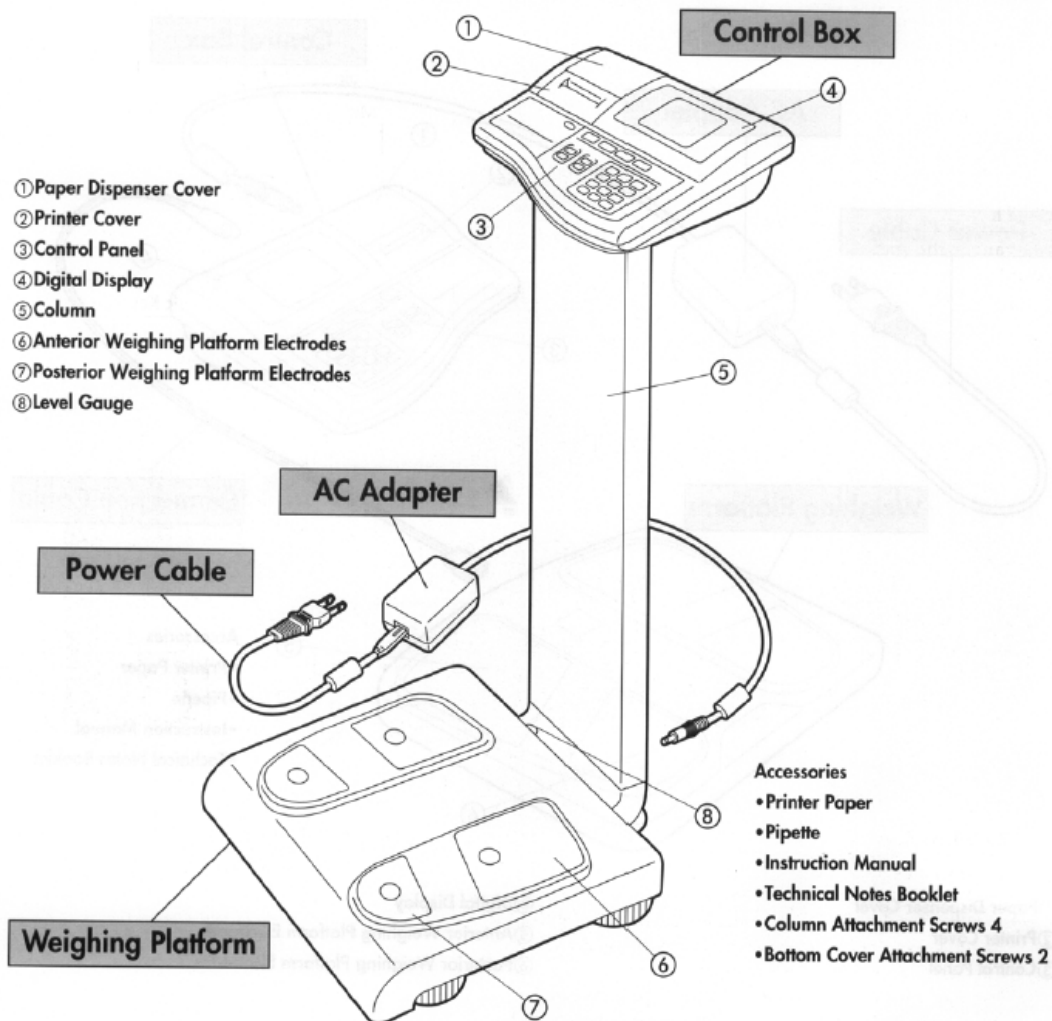
- ④ Digital Display
- ⑤ Anterior Weighing Platform Electrodes
- ⑥ Posterior Weighing Platform Electrodes

Rear View of Control Panel (TBF-310)

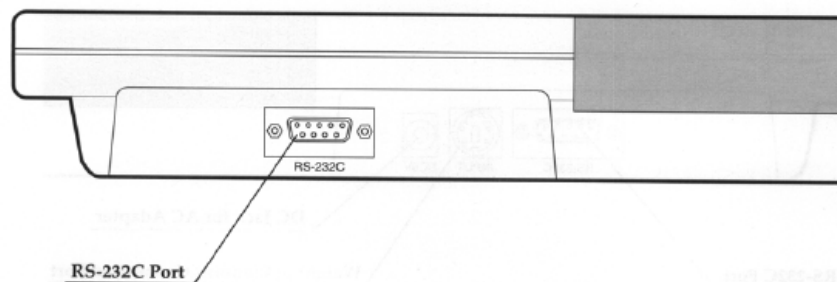




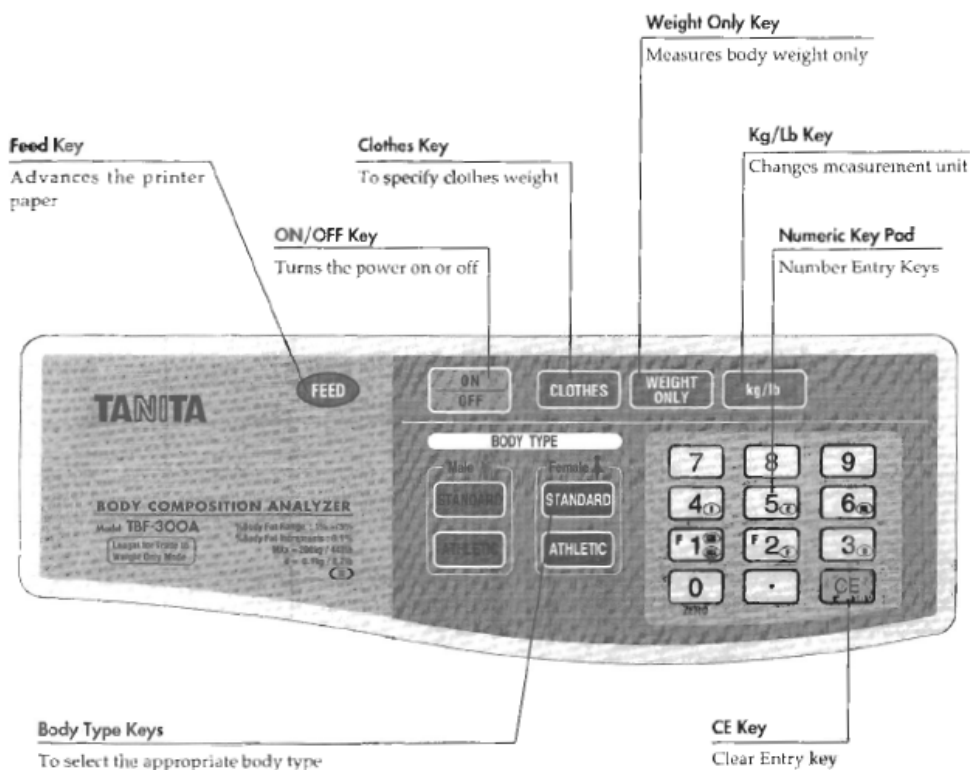
Overview (TBF-410)



Rear View of Control Panel (TBF-410)



Control Panel Functions



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 require the Athlete mode.

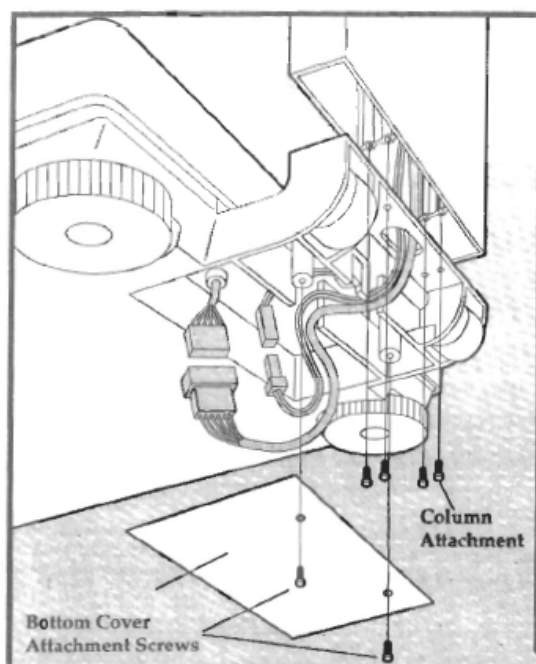
Please see **Technical Notes** booklet for further explanation.

***NOTE FOR TBF-300A USERS:** The TBF-300A is specially designed so that individuals age 16 or more may select the "Athletic Mode" when the Wrestler function is activated (See P.19).

5. Assembly Instructions

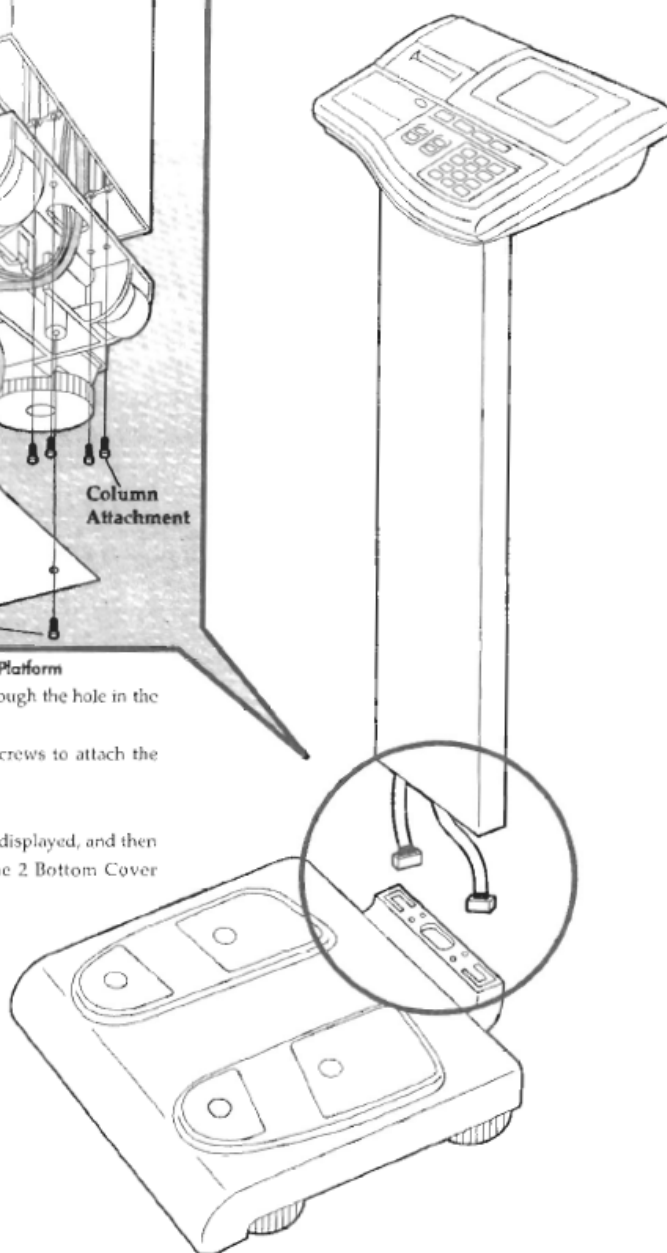
GB

■ TBF-410



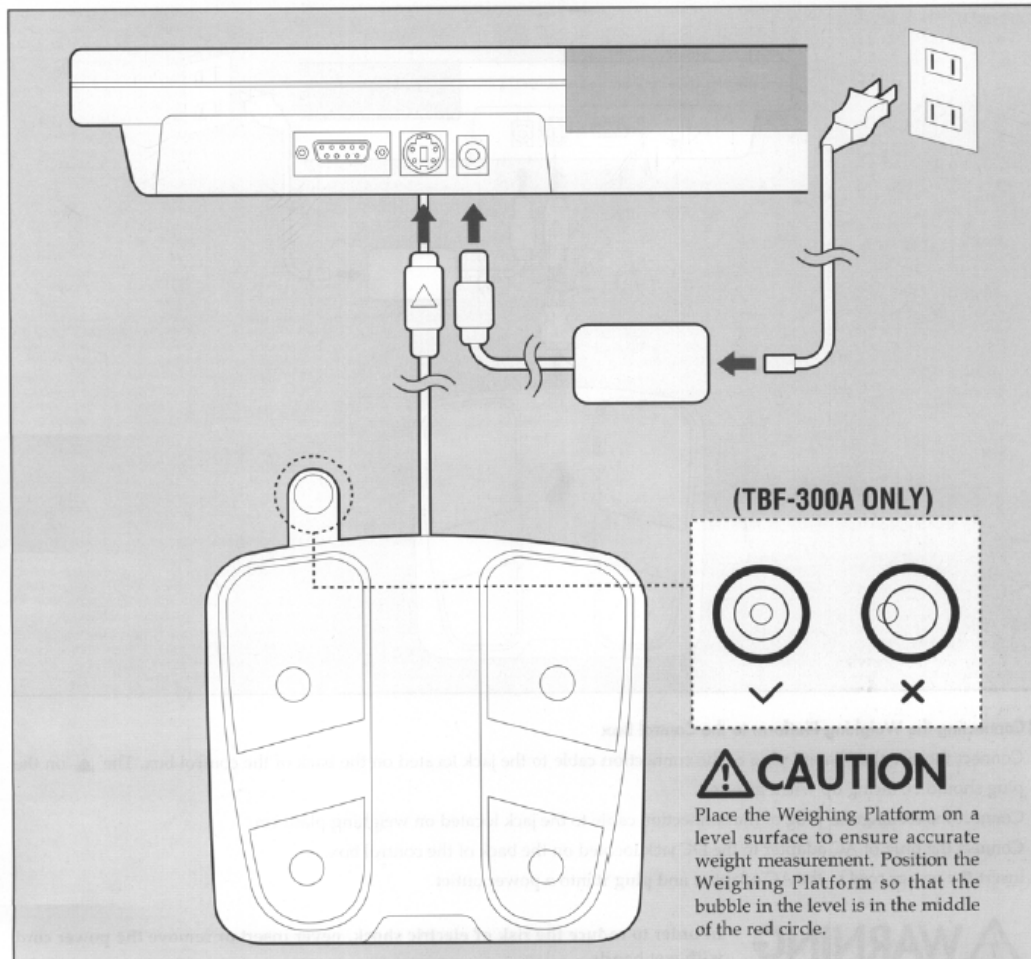
■ Attaching the Column to the Weighing Platform

- ① Feed the 2 cords from the column through the hole in the weighing platform.
- ② Screw in the 4 column attachment screws to attach the column to the weighing platform.
- ③ Remove Bottom Cover.
- ④ Insert the 2 cords from the column as displayed, and then replace the Bottom Cover using the 2 Bottom Cover Attachment Screws. When replacing the bottom cover, please put the cords in the appropriate location so they will not be squeezed between the cover and the weighing platform. This may damage the cords.



6. Set Up

■ TBF-300/TBF-300A



■ Connecting the Weighing Platform to the Control Box

1. 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.
2. Connect the plug of AC adapter to the DC jack located on the back of the control box.
3. Insert the power cord to the AC adapter, and plug it into a power outlet.



WARNING

- In order to reduce the risk of electric shock, never insert or remove the power cord with wet hands.

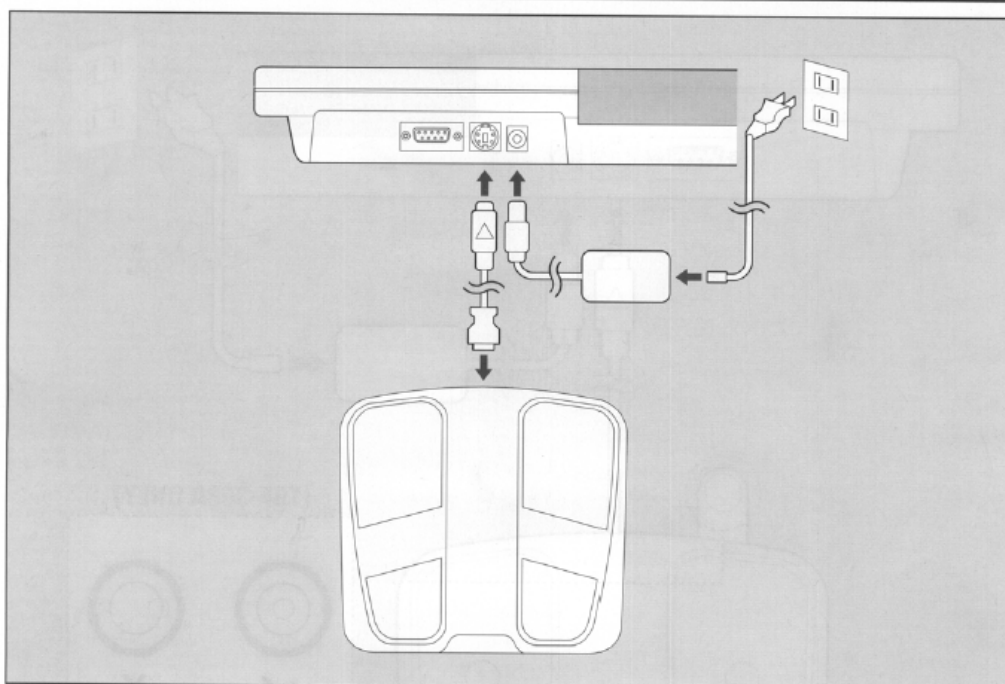


CAUTION

- Use only the Tanita AC adapter provided with the unit.
- Put the weighing platform on a flat, level surface.



■ TBF-310



■ Connecting the Weighing Platform to the Control Box

1. Connect the circular shaped plug of the connection cable to the jack located on the back of the control box. The ▲ on the plug should be facing up when inserted.
2. Connect the rectangular plug of the connection cable to the jack located on weighing platform.
3. Connect the plug of AC adapter to the DC jack located on the back of the control box.
4. Insert the power cord to the AC adapter, and plug it into a power outlet.



WARNING

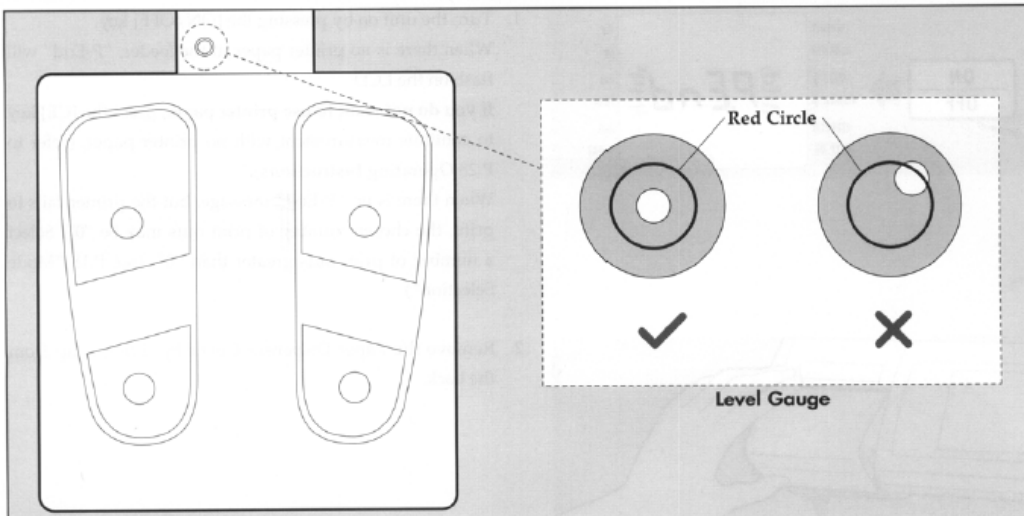
- In order to reduce the risk of electric shock, never insert or remove the power cord with wet hands.



CAUTION

- Use only the Tanita AC adapter provided with the unit.
- Put the weighing platform on a flat, level surface.

■ TBF-410



■ Leveling the Weighing Platform

- For optimum accuracy, place the unit on a flat and level surface.
- Check the level gauge to make sure the air bubble is in the center of the red circle.
- The weighing platform has adjustable feet to ensure a level and stable weighing surface. If the air bubble is not in the center of the red circle, it can be centered by turning the feet.

■ Plugging in the Unit

1. Connect the plug of AC adapter to the DC jack located on the back of the weighing platform.
2. Insert the power cord to the AC adapter, and plug it into a power outlet.



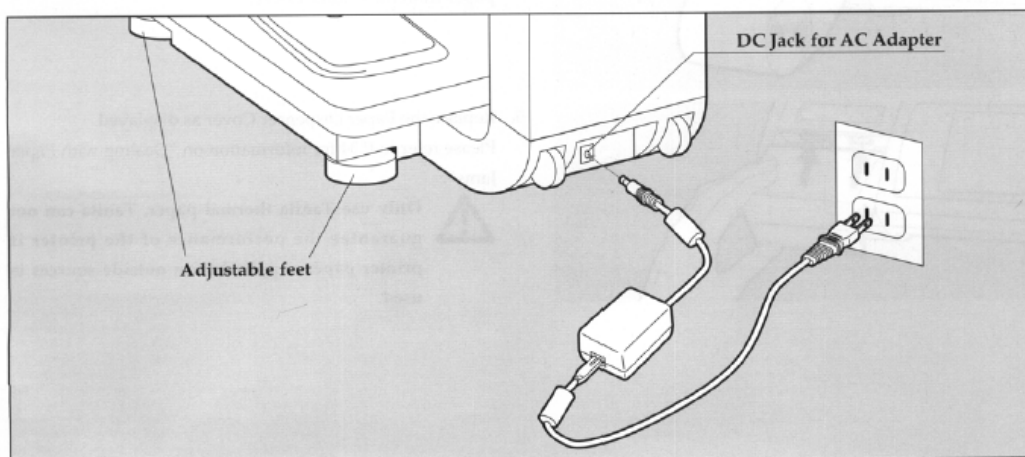
WARNING

- In order to reduce the risk of electric shock, never insert or remove the power cord with wet hands.



CAUTION

- Use only the Tanita AC adapter provided with the unit.
- Put the weighing platform on a flat, level surface.



7. Loading Printer Paper



Please change printer paper when red lines appear along the sides.

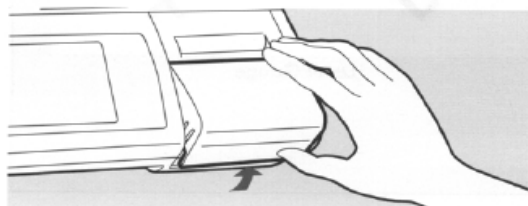


1. Turn the unit on by pressing the [ON/OFF] key.

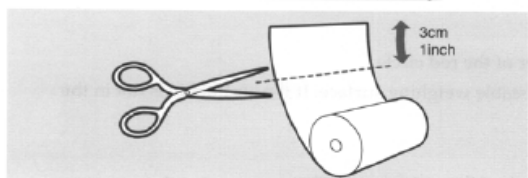
When there is no printer paper in the feeder, "P-End" will flash on the LCD.

If you **do not want to use printer paper**, press the [CE] key to continue measurement with no printer paper. (refer to P.28 **Operating Instructions**).

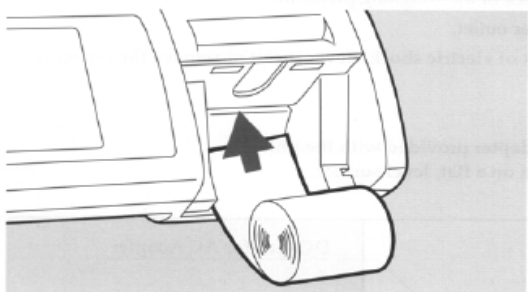
When there is no "P-End" message, but the printer fails to print, the chosen number of print outs may be "0". Select a number of print outs greater than "0". (see P.18 "Mode Selection")



2. Remove the Paper Dispenser Cover by lifting it up from the back.



3. In a straight line, cut approximately 1 inch (3cm) off of the paper roll, this will ensure smooth feeding.



4. Insert the printer paper in the holder as displayed. Be sure to feed the printer paper straight into the automatic feeder. As the front edge of the printer paper enters the appropriate slot, it will automatically feed. Once the printer paper feeds, it will exit the printer paper feed slot located on the printer cover, and be cut. Remove printer paper from the Printer Cover.



5. Replace the Paper Dispenser Cover as displayed. Please refer to P.34 for information on "Dealing with Paper Jams".



Only use Tanita thermal paper. Tanita can not guarantee the performance of the printer if printer paper supplied from outside sources is used.

8. Mode Selection



Please determine which functions (modes) you would like to activate on your new TBF unit. Your selection will be recorded automatically. If there is no need to make a change, the machine may be started by simply pressing the [ON/OFF] key.



Please read the page that corresponds to the model which you have purchased.

■ TBF-300A : P.19

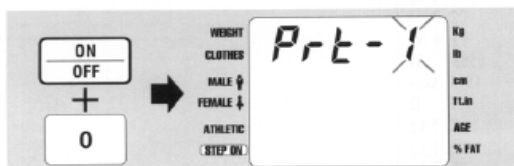
■ TBF-300/ TBF-310/ TBF-410 : P.25

TBF-300A

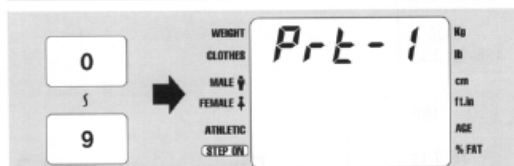
For the TBF-300A: A. Setting the Number of Print Outs and Printing Language
B. Setting the Mode
C. Setting the Original Mode

A. Setting the Number of Print Outs and Printing Language

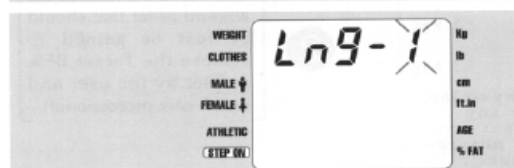
Select the number of print outs (0 ~ 9) and the printing language (English or Spanish).



1. 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.



2. Select the desired number of print outs.
Using the number keys, enter the quantity of print outs desired. As many as nine are possible.
[1] ~ [9] : Quantity of print outs
[0] : No print out



3. Language Selection



If "0" has been selected for the number of print outs in Step 2 above, it will not be possible to preset this item.

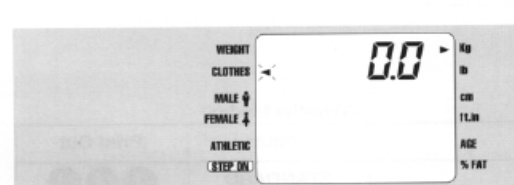
The LCD will automatically advance to the Language Selection Screen. The current language selection will be displayed as a numerical value.

Example: (LNG-1) denotes English as the selected language.

Select a preferred language by pressing the corresponding number on the key pad.

[1] : English

[5] : Spanish



4. When input has been completed, the unit will automatically switch to the measurement screen.
If further change to the functions is desired, please turn off the unit, and refer to steps 1 to 4 above.



The unit will start up with this setting the next time it is used.



Sample

1 This section prints the both the body type and body composition data of the current user. In Wrestler Mode, "Athletic" can be selected only for individuals aged 16 or more. If you enter 15 years of age or less, calculation will automatically be performed for a "standard" body type.

TANITA
BODY COMPOSITION
ANALYZER
TBF-300A

BODY TYPE	STANDARD
GENDER	MALE
AGE	25
HEIGHT	166 cm
WEIGHT	61.3 kg
BMI	22.2
FAT%	13.9 %
BMR	6583 kJ
	1573 kcal
IMPEDANCE	517 Ω
FAT MASS	8.5 kg
FFM	52.8 kg
TBW	38.7 kg
DESIRABLE RANGE	
FAT%	8-20 %
FAT MASS	4.6-13.2 kg

TARGET BF% is : 10%

Predicted weight : 58.7 kg

Predicted fat mass : 5.9 kg

FAT TO LOSE: 2.6 kg

Consult your physician before beginning any weight management program. Tanita is not responsible for determining your target BF%.

Wrestler Mode

Min WEIGHT at 7% BF is 56.8 kg

FAT MASS 4.0 kg

FFM 52.8 kg

Min Weight is calculated as per state association guidelines.

2 This section calculates the amount of fat that should be lost or gained to achieve the Target BF% (preset by the user and health care professional).

3 This section automatically calculates the Minimum Wrestling Weight (MWW) using the methodology adopted in the 1998 NCAA Weight Management Guidelines. (See P.23, 29) (TBF-300A ONLY!)

<Goal Setter Mode>

	Input	Print Out
ON	STANDARD	1 2
	ATHLETIC	1 2
	TARGET BF 00%	1
OFF	STANDARD	1
	ATHLETIC	1

<Wrestler Mode>

	Input	Print Out
ON	STANDARD	1 2 3
	ATHLETIC	1 2 3
	TARGET BF 00%	1 3
OFF	STANDARD	1 2
	ATHLETIC	1 2
	TARGET BF 00%	1

B. Setting the Mode

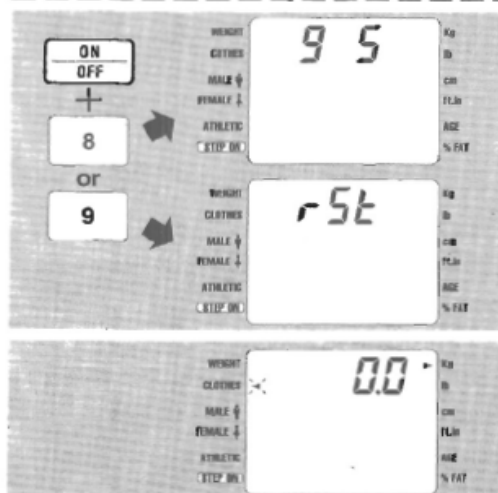
Select the mode according to the items you wish to output.

<HINT!>

If you want to output ①②③ in the print out sample on P.20 : Select the Wrestler Mode.

If you want to output ①② :

: Select the Goal Setter Mode.



1. Turn on the power while pressing the [8] key or the [9] key.

[ON/OFF]+[8] : Start up in Goal Setter Mode

[ON/OFF]+[9] : Start up in Wrestler Mode



If "0" has been selected for the number of print outs in P.19 "A. Setting the Number of Print Outs and Printing Language", it will not be possible to preset this item.

2. When input has been completed, the unit will automatically switch to the measurement screen.



• The unit will start up with this setting the next time it is used.



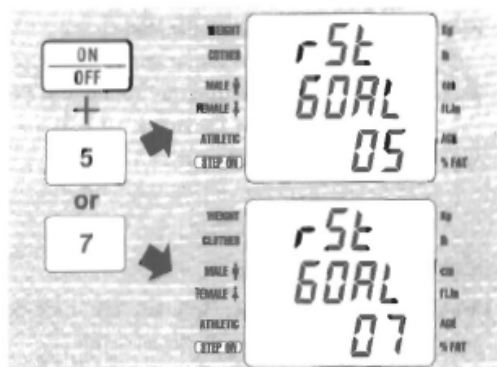
Wrestler Mode: Setting the Minimum Body Fat Percent (TBF-300A ONLY)

When the "Wrestler Mode" is activated, the TBF-300A automatically calculates the Minimum Wrestling Weight at a predetermined minimum body fat percent. The 1996 ACSM Position Stand "Weight Loss in Wrestlers" as adopted by the NCAA recommends the following MINIMUM body fat percents as follows:

5% for Collegiate Athletes

7% for High School Athletes

<To set the Minimum Body Fat Percent>



1. Turn on the power while pressing the [5] key or the [7] key. Depending on the key pressed, '05' or '07' will be displayed at the bottom of the screen.

[5] : Sets the Minimum BF% to the automatic calculation value of 5% (Collegiate level) in Wrestler mode

[7] : Sets the Minimum BF% to the automatic calculation value of 7% (High School level) in Wrestler mode

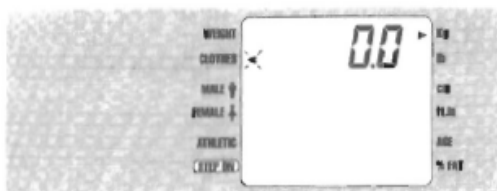


• If the number of print outs is set to "0", this item cannot be preset.

• If the Wrestler Mode is not turned ON, this item cannot be preset. Please read "C. Setting the Original Mode" on P.24.

• The target BF% value is completely separate from the Minimum Wrestling Weight (Min WEIGHT) calculations.

For example: The target BF% value may be entered as 15%, even though the Min WEIGHT is calculated at a predetermined minimum body fat of 5 or 7%.



2. When input has been completed, the unit will automatically continue to the measurement screen.

Wrestler Mode: Setting the Minimum Weight Guideline

Minimum Wrestling Weight is calculated according to the methodology adopted by the NCAA (1998 Guidelines). The calculations are as follows:

$$\text{Body Fat Percent (BF\%)} = (4.57 / \text{Body Density} - 4.142) \times 100 \text{ (Brozek equation)}$$

$$\text{Fat weight (FW)} = \text{Body Weight (BW)} \times \text{BF\%} / 100$$

$$\text{Fat free Weight (FFW)} = \text{BW} - \text{FW}$$

$$\text{Minimum Wrestling Weight (MWW)**} = \text{FFW} / \text{Predetermined Minimum BF\%*}$$

* If the predetermined minimum BF% is 7% : $\text{MWW} = \text{FFW} / 0.93$

* If the predetermined minimum BF% is 5% : $\text{MWW} = \text{FFW} / 0.95$

** MWW appears as "Min WEIGHT" on the printout.

CAUTION

- The minimum percent body fat values used to calculate the Minimum Wrestling Weight (MWW) are derived from the 1996 American College of Sports Medicine (ACSM) Position Stand "Weight Loss in Wrestlers", that has been adopted by the National Collegiate Athletic Association (NCAA) in their 1998 Weight Management Guidelines. Tanita Corporation is not responsible for establishing these minimum requirements and guidelines, nor for any future changes to the current standards. Tanita is providing information only, and does NOT recommend the application of the guidelines for any given individual. State wrestling associations may have standards that differ from the NCAA.
- The Minimum Wrestling Weight as calculated with the minimum body fat percent is the *MINIMUM* weight at which an athlete may be allowed to compete. The *MINIMUM* body fat percent and resulting *MINIMUM* wrestling weight may NOT be the optimal body fat or weight for a given individual athlete. Attempting to achieve these *MINIMUM* standards does NOT necessarily impact the athlete's performance, and may be unhealthy for given individuals.
- If it is necessary to set the Minimum BF% to a value other than 5% or 7%, please contact our customer service department.

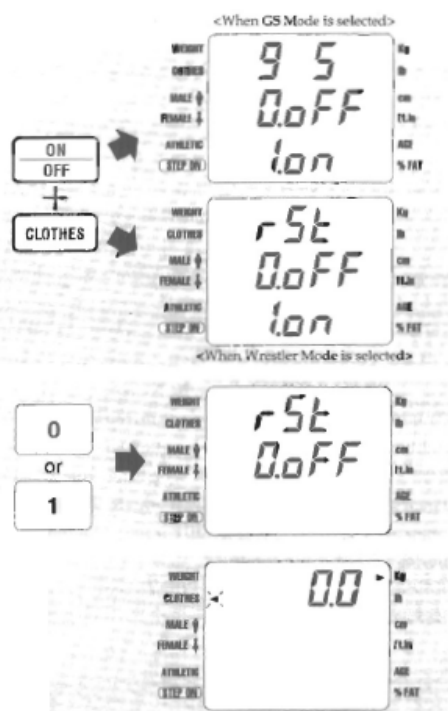
GB

C. Setting the Original Mode

This process is used to inactivate the Goal Setter function (Target BF% section of printout) and the Wrestler Mode (Section ③: Minimum Wrestling Weight of the printout). (See P.20. for sample printout.)

<HINT!>

If Goal Setter Mode or Wrestler Mode is on when using "B. Setting the Mode", there is no need to change this setting. (It will automatically come on.)



1. Turn on the power while pressing the [CLOTHES] key.

[0] : Mode is deactivated

[1] : Mode is activated



If "0" has been selected for the number of print outs in P.19 "A. Setting the Number of Print Outs and Printing Language", it will not be possible to preset this item.

2. When input has been completed, the unit will automatically switch to the measurement screen.



- The unit will start up with this setting the next time it is used.
- In standard use, if the Target BF% is not input, please select [gs 0.off].

This is the end of the section pertaining to the TBF-300A settings.

Please proceed to P.28 "9. Operating Instructions".

TBF-300 / TBF-310 / TBF-410

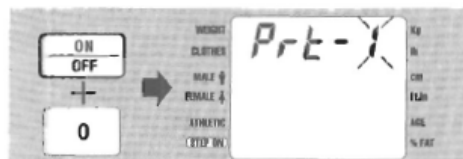
For the TBF-310 / TBF-410

A. Setting the Number of Print Outs and Printing Language; and

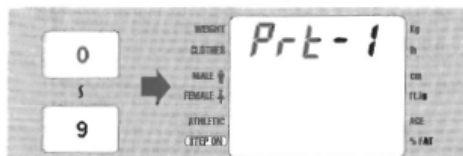
B. Setting the Original Mode

A. Setting the Number of Print Outs and Printing Language

Select the number of print outs (0 – 9) and the printing language (English, French, German, Italian, Spanish, and Dutch).



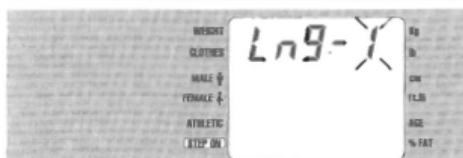
1. Press and hold the [0] key, and press the [ON/OFF] key once. Release the [0] key after "Prt-1" is displayed on the screen.



2. Select the desired number of print outs.
Using the number keys, enter the quantity of print outs desired. As many as nine are possible.

[1] ~ [9] : Quantity of print outs

[0] : No print out



3. Language Selection



If "0" has been selected for the number of print outs in Step 2 above, it will not be possible to preset this item.

The LCD will automatically advance to the Language Selection Screen. The current language selection will be displayed as a numerical value.

Example: (LNG-1) denotes English as the selected language.

Select a preferred language by pressing the corresponding number on the key pad.

[1] : English

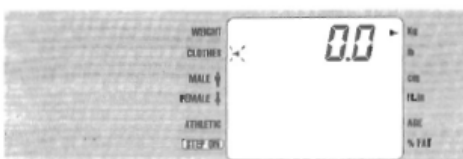
[2] : French

[3] : German

[4] : Italian

[5] : Spanish

[6] : Dutch



4. When input has been completed, the unit will automatically switch to the measurement screen.

If further change to the functions is desired, please turn off the unit, and refer to steps 1 to 4 above.



The unit will start up with this setting the next time it is used.

(GB)

Sample

1 [This section prints the both the body type and body composition data of the current user.]

TANITA
BODY COMPOSITION
ANALYZER
TBF-300

BODY TYPE	STANDARD
GENDER	MALE
AGE	25
HEIGHT	166 cm
WEIGHT	61.0 kg
BMI	22.1
BMR	6566 kJ
	1569 kcal
IMPEDANCE	527 Ω
FAT%	14.1 %
FAT MASS	8.6 kg
FFM	52.4 kg
TBW	38.4 kg
DESIRABLE RANGE	
FAT%	8-20 %
FAT MASS	4.6-13.1 kg
TARGET BF% is :	
	10%
Predicted weight :	58.2 kg
Predicted fat mass :	5.8 kg
FAT TO LOSE:	2.8 kg
Consult your physician before beginning any weight management program. Tanita is not responsible for determining your target BF%.	

2

[This section calculates the amount of fat that should be lost or gained to achieve the Target BF% (preset by the user and health care professional).]

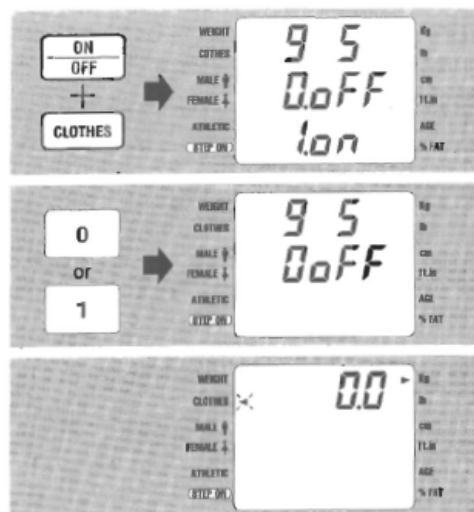
Goal Setter Mode	Input	Print Out
ON	STANDARD	1 2
	ATHLETIC	1 2
	TARGET BF 00%	1
OFF	STANDARD	1
	ATHLETIC	1

B. Setting the Original Mode

This process is used to select activation or deactivation of the Target BF% function (See the sample printout on P.26).

<HINT!>

When the unit is shipped from the factory, it set to [0.off].



1. Turn on the power while pressing the [CLOTHES] key.

[0] : Mode is deactivated

[1] : Mode is activated



If "0" has been selected for the number of print outs in P.25 "A. Setting the Number of Print Outs and Printing Language", it will not be possible to preset this item.

2. When input has been completed, the unit will automatically switch to the measurement screen.



The unit will start up with this setting the next time it is used.

This is the end of the section pertaining to settings.

Please proceed to P.28 "9. Operating Instructions".

9. Operating Instructions

GB

■ Body Composition Analysis

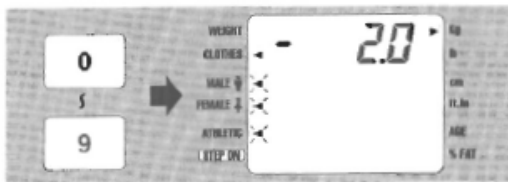


Do Not Step On The Weighing Platform Until All Data Has Been Entered, And The Flashing Arrow Appears Next To [STEP ON].



1. Press the [ON/OFF] key to turn on the Power

After a momentary automatic display check, 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 data entry, mistakes may be corrected by pressing the [CE] key. Follow the flashing arrow on the LCD for proper sequence.



2. Enter Clothes Weight

This function will automatically subtract the chosen amount of clothes weight.

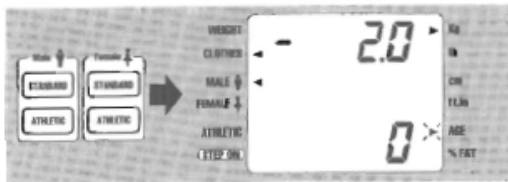
Enter Clothes Weight to the first decimal place, or the flashing arrow will not advance.

Example: 2.0kg = Press the [2] [.] [0] keys

4.0lb = Press the [4] [.] [0] keys

Clothes weight can be entered by 0.1kg / 0.2lb increments (TBF-310: 0.2kg / 0.5lb increments).

The flashing arrow will now appear next to the MALE icon, FEMALE icon, and ATHLETIC on the LCD.



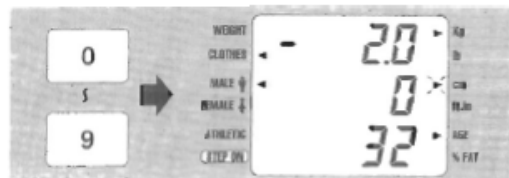
3. Enter Gender and Body Type

Select from one of four body types: Standard Male, Standard Female, Athletic Male, Athletic Female. The Athletic Key should be selected for individuals aged 17 or more 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 require the Athlete mode.

Please see **Technical Notes** booklet for further explanation

* When selecting Wrestler Mode on the TBF-300A, "Athlete" can be selected for individuals aged 16 or more. If you enter 15 years of age or less, calculation will automatically be performed for a "Standard" body type.



4. Enter Age

Enter age of the subject using two digits. For children under ten years old, first enter [0].

Example: 32 years old = Press the [3] [2] keys

9 years old = Press the [0] [9] keys

Age range is from 7 to 99 years old.

After age is entered, the arrow will automatically advance to [HEIGHT] on the LCD.



5. Enter Height

Using Centimeters, measurement is made to the First Whole Number.

Example: 172 cm = Press the [1] [7] [2] keys.

Using Feet and Inches, measurement is made to the First Decimal Place by 0.5 inch increments.

Example: 5 ft 7.5 in = Press the [5] [7] [.] [5] keys.

6 ft 0 in = Press the [6] [0] [.] [0] keys.

The range for height is from 90cm (3'0") to 249cm (7'11.5").

When using the lb. mode, height will automatically round up or down to the nearest 0.5 in or whole number.



6. Setting Target Body Fat Percent

After entering the height, [GOAL] will automatically flash on the screen. Using the numeric key pad, enter the desired target Body Fat %.

Example: 16% = Press the [1] [6] keys.

9% = Press the [0] [9] keys.

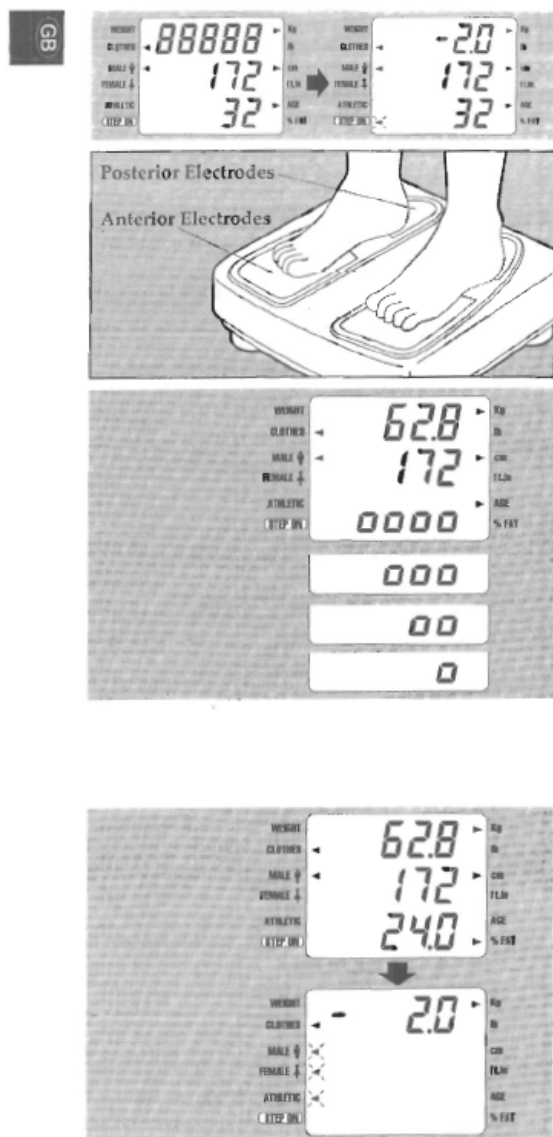


Note for wrestlers (if Wrestler Mode is selected and Wrestler Mode is ON in the case of the TBF-300A): The target body fat percent value is completely separate from the Minimum Wrestling Weight (Min WEIGHT) calculations. For example: The target BF % value may be entered as 15%, even though the Min WEIGHT is calculated at a predetermined minimum body fat of 5% or 7%. See P.22/23 for more information and precautions.

* If "0" print out is chosen, the "Target Body Fat %" screens will not appear on the display.

⚠ WARNING

- Consult your physician before beginning any weight management program and to establish appropriate individualized body fat percent targets. Tanita Corporation is not responsible for establishing appropriate Target Body Fat Percent values for any given individual.
- Please see technical notes for more information regarding Desirable Body Fat Percent Ranges. Note that while certain types of athletes may attempt to achieve and maintain single digit body fat percents to potentially affect their athletic performance, this is not advisable for the average individual attempting reasonable weight / fat loss. There are specific health risks associated with low body fat percents, especially for women and children. Consult your Physician regarding reasonable fat / weight loss goals.



Mistakes may be corrected by pressing the [CE] key. Pressing this key repeatedly will also allow the user to correct previously entered information.

7. STEP ON:

The flashing arrow will appear next to STEP ON after the LCD display "88888".

8. Taking Measurement:

Step on the weighing platform in bare feet. Make sure heels are placed on the posterior electrodes, and the front part of the feet are in contact with the anterior electrodes.

9. Weight is displayed on the upper portion of the LCD.

10. Impedance Measurement:

After weight stabilizes, impedance measurement is taken. This is denoted by four "bubbles" 0000 which appear on the bottom half of the LCD. As the measurement is being taken, the bubbles will begin to disappear one by one.



Do not step off from the weighing platform until the final bubble has disappeared, and the display emits a short beep.

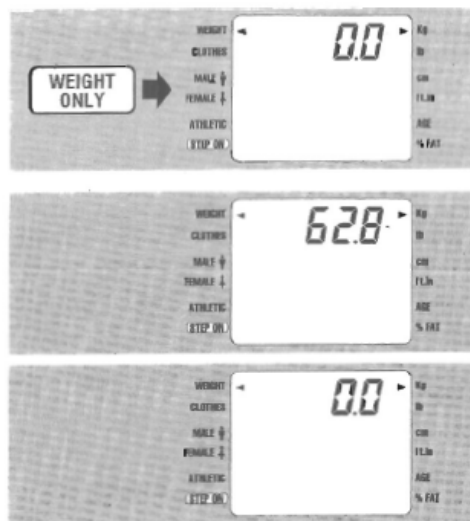
11. Measurement is Now Complete

Weight and percent body fat will be displayed on the LCD, and detailed results will automatically print out. The LCD will return to the Gender and Body Type screen (Step 3) in about 10 seconds, which allows for convenient screening.

Please refer to P.32 for an explanation of the printout, or Technical Notes booklet for more details.

12. If all measuring is complete, press the [ON/OFF] key to turn off the power.

WEIGHT ONLY FUNCTION



1. After turning on the unit, press the [WEIGHT ONLY] key.

After a momentary display check, "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.

2. Weight Measurement

Step on the weighing platform. Weight will be displayed on the LCD.

3. When measuring is complete, press the [ON/OFF] key to turn off the power.



• No printer is available when measuring weight only.

• If body composition analysis is desired, turn the unit off and then on, using the [ON/OFF] key.

Important Note: There is no automatic weight lock function.

GB

10. Explanation of The Print Out

GB

Sample

TANITA BODY COMPOSITION ANALYZER TBF-300A	
BODY TYPE	STANDARD
GENDER	MALE
AGE	25
HEIGHT	166 cm
WEIGHT	61.3 kg
BMI	22.2
FAT%	13.9 %
BMR	6583 kJ
	1573 kcal
IMPEDANCE	517 Ω
FAT MASS	8.5 kg
FFM	52.8 kg
TBW	38.7 kg
DESIRABLE RANGE	
FAT%	8-20 %
FAT MASS	4.6-13.2 kg
TARGET BF% is :	10%
Predicted weight :	58.7 kg
Predicted fat mass :	5.9 kg
FAT TO LOSE:	2.6 kg
Consult your physician before beginning any weight management program. Tanita is not responsible for determining your target BF%.	
Wrestler Mode	
Min WEIGHT at 7% BF is	56.8 kg
FAT MASS	4.0 kg
FFM	52.8 kg
Min Weight is calculated as per state association guidelines.	

FAT%: The percentage of total body weight that is fat.

IMPEDANCE: Impedance reflects the body's inherent resistance to an electrical current. Muscle acts as a conductor of the electrical current, adipose tissue acts as a resistor.

FFM: Fat Free Mass is comprised of muscle, bone, tissue, water, and all other fat free mass in the body.

TBW: Total Body Water is the amount of water (expressed as lb, kg, or st.lb) retained in the body. TBW is said to comprise between 50% - 70% of total body weight. Generally, men tend to have higher water weight than women due to a greater amount of muscle.

Predicted weight: Calculated weight for the given Target BF%.

FAT TO LOSE / GAIN : Calculated fat mass to lose or gain to achieve the Predicted Weight.

BMI: Body Mass Index is a height to weight ratio, and is calculated by the following formula:

$$\text{BMI} = \frac{\text{Weight (kg)}}{\text{Height (m)}^2}$$
 Desirable Range 18.5 - 24.9

BMR: Basal Metabolic Rate represents the total energy expended by the body to maintain normal functions at rest such as respiration and circulation.

FAT MASS: total weight of fat mass (in kg, lb) in the body.

Predicted fat mass: Calculated fat mass for the given Target BF%.

Wrestler Mode: This section automatically calculates the Minimum Wrestling Weight (MWW) using the methodology adopted in the 1998 NCAA Weight Management Guidelines. (see P.23, 29) (TBF-300A ONLY)

NOTE : Please refer to Technical Notes booklet for further explanation.



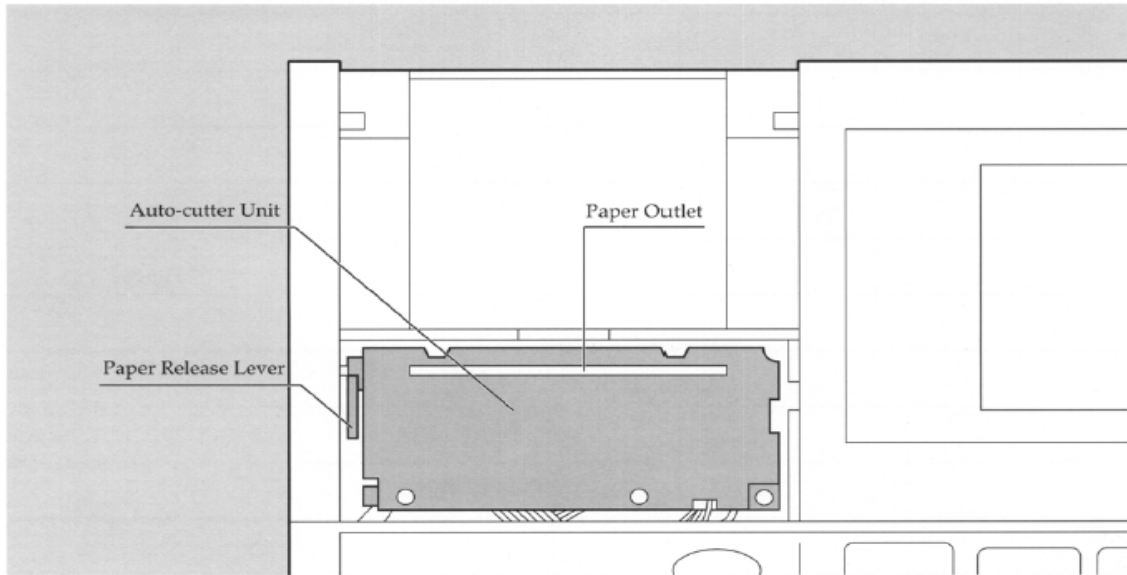
Please consult your physician before beginning any weight management program. Tanita is not responsible for determining Target BF%.



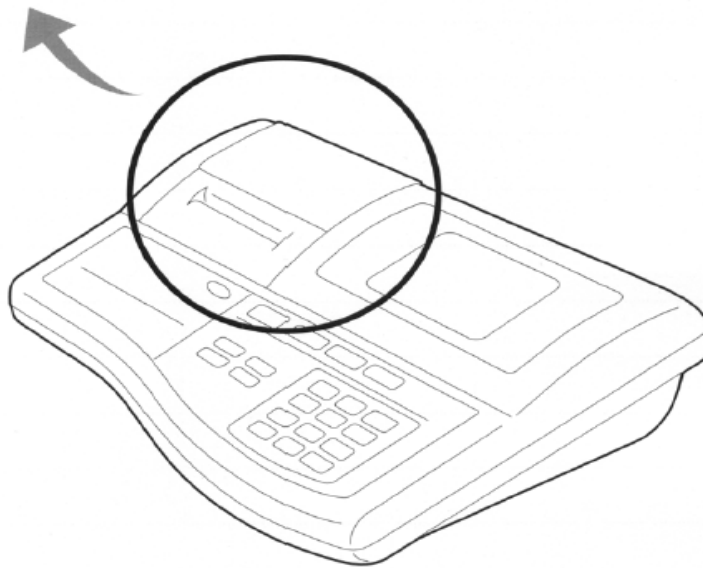
11. Dealing with Paper Jams



Names of Printer Unit Parts



* The above diagram shows the Control Box without the Printer Dispenser Cover and the Printer Cover, overhead view.

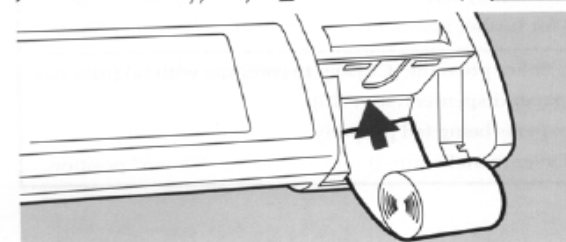
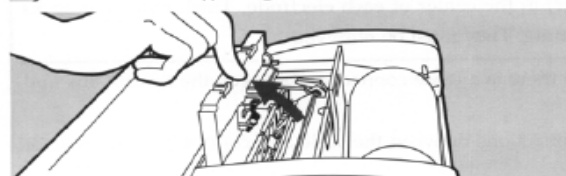
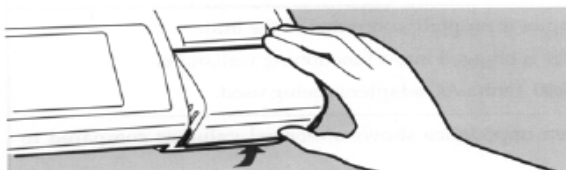


CAUTION

When handling the printer unit, please avoid any sharp edges.



Please follow these instructions to clear any paper jams from the printer assembly:



1. Remove the Paper Dispenser Cover by lifting up from the back side.

2. Remove the Printer Cover as displayed. Apply light pressure with one finger to the printer cover and lift up as displayed.

3. Raise the Auto-cutter Unit as displayed. Using the pointer finger, gently lift one end of the Auto-cutter Unit, it will remain upright until returned to the normal horizontal position.



• Do not attempt to remove the Auto-cutter Unit.

4. Lift the small black lever located on the left side of the Auto-cutter Unit. This will facilitate the clearing of any paper jams that may have occurred. The roll of printer paper must be removed at this time. Carefully search for and clear any scraps of paper from the printer assembly, as this may cause jamming in the future.

5. Be sure to return the Paper Release Lever to its proper position. Next, carefully move the Auto-cutter Unit to its proper position.

IMPORTANT NOTE: Failure to return the Paper Release Lever to its proper position will result in continuous feeding of the printer paper. If this occurs, turn off the unit by pressing the [ON/OFF] key, and follow steps 1 to 5 above.

6. Replace the Printer Cover by gently pressing in on the side tabs of the cover as it slides into position.

7. After completing steps 1 to 5, printer paper can be reloaded. See **Loading Printer Paper** on P.16 for details. Replace the Paper Dispenser Cover.



Listed below are common problems and simple solutions.
Please refer to the Technical Notes Booklet for answers to questions regarding accuracy.

Problem	Solution
The Unit Does Not Turn On when the [ON/OFF] key is pressed	<ul style="list-style-type: none"> • Confirm that the AC adapter is properly connected to the unit. • Make sure the AC adapter is plugged into a functioning wall outlet • Make sure only the original Tanita AC adapter is being used.
"E-01" is displayed	<ul style="list-style-type: none"> • E - 01 is displayed when impedance shows abnormal value as compared to height and weight. • Do not step off the weighing platform until all of the bubbles disappear, and the control box emits a short beep. • Please make sure the subject measures in bare feet, and that the feet are in contact with the electrodes. • If the individual is wearing thin nylons or has thick calluses, place 0.5cc of conductant (saline, water) in the center of each electrode. Thick nylons or socks will produce an E-01 reading. They must be removed.
"E-11" is displayed	<ul style="list-style-type: none"> • E - 11 is displayed when there is a loose connection between the control box and the weighing platform. • Confirm that none of connections between the scale and control box are loose or unplugged. • There may be excessive vibration which will disturb the measurement process.
"E-12/13/14" are displayed	<ul style="list-style-type: none"> • E-12/13/14 are shown when an internal malfunction has occurred. Please call your nearest Tanita office or dealer.
"E-16" is displayed	<ul style="list-style-type: none"> • Make sure the subject was measured with bare feet, and the feet were in contact with the electrodes. If the subject is wearing thin nylons or has thick calluses, place 0.5cc of conductant (saline, water) in the center of each electrode. • Do not step off the weighing platform until all of the "bubbles" disappear, and the control box emits a small beep.
No Print Out	<ul style="list-style-type: none"> • Confirm the number of print outs chosen is more than "0". (see P.19 or P.25) • Confirm that the correct brand of printer paper is being used. • Confirm that the printer paper is being fed in the proper direction. Printer paper will only make an impression on one specially treated side. • Confirm that the printer is not jammed. (See P.34)
Section 2 of the print out is missing	<ul style="list-style-type: none"> • The Target Section (Section 2) will not print out if the selected Target Body Fat % is [0]. Select a Target Body Fat % value between 4% ~ 55% to activate the print out.
Section 3 of the print out is missing (TBF-300A)	<ul style="list-style-type: none"> • The "Wrestler Section" (Section 3) will not print out if the "Wrestler Mode" is deactivated. See P.21 ~ 23 for further instructions on activating "Wrestler Mode".
"P-End" is displayed	<ul style="list-style-type: none"> • Printer paper has run out. Either press the [CE] key to continue with no print out, or put another roll in the paper dispenser. (see P.16). • Confirm that the printer paper is being fed properly. • Check the Paper Release Lever to make sure it is in the correct "Down" position.

Problem	Solution
---- is Displayed	<ul style="list-style-type: none"> The maximum weight capacity has been exceeded.
uuuu is Displayed	<ul style="list-style-type: none"> Do not stand on the weighing platform while entering personal data. Stand on the weighing platform only after the flashing arrow appears next to "Step On".
[FEED] key is Not Functioning	<ul style="list-style-type: none"> Confirm the number of print outs chosen is more than "0". Confirm that there is no paper jam in the printer. <p>[FEED] key is inoperative in the "Weight Only" function. Use "Body Composition Measurement" if a printout is desired.</p>



Note

13.RS-232C Interface Instruction



This Instruction is for RS-232 interface connecting the TBF to a Personal Computer (PC) or Printer.



RS-232C interface is data **OUTPUT ONLY!**

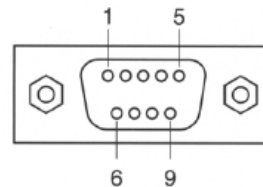
The Body Composition Scale is not capable of receiving instructions from a PC.

■ Specifications

Communication Standard	EIA RS-232C Compatible
Communication Method	Asynchronous
Baud Rate	2400bps
Data Length	7bits
Parity	EVEN
Stop Bit	1bit

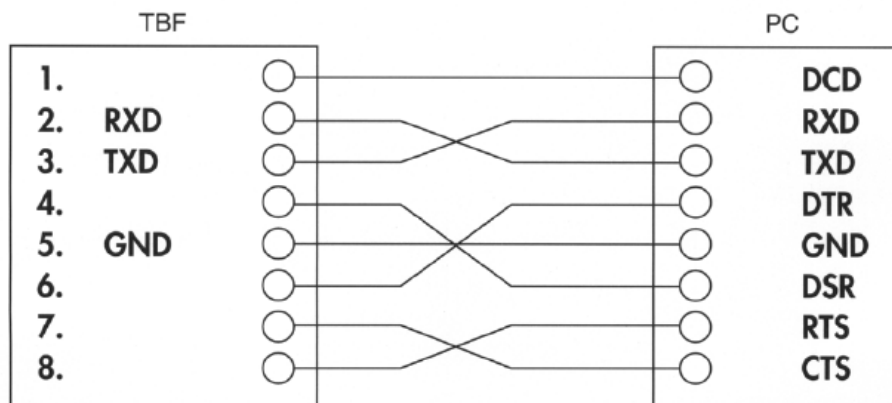
■ Signal Names and Connections

Terminal Number	Signal Name
1	*1
2	RXD
3	TXD
4	*1
5	GND
6	*1
7	*2
8	*2
9	No Connection



*1: Pin No.1,4 and 6 are internal connection.

*2: Pin No.7 and 8 are internal connection.



Note

- A Reverse Cable must be used to connect to a PC.
- A Modem Cable can not be used.

■ Transmission data

GB



Note

The receiving PC or Printer must be ready to accept output data immediately after measurement is complete.

Output Data

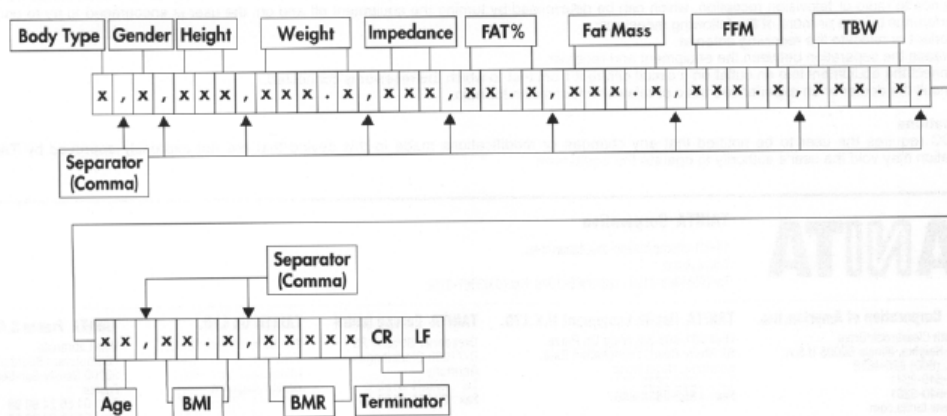
	kg mode	lb mode	Byte Length
Body Type	0:Standard or 2:Athletic	0:Standard or 2:Athletic	1
Gender	1:Male or 2:Female	1:Male or 2:Female	1
Height	xxx (cm)	xxx.x (inch)	2 ~ 5
Weight	xxx.x (kg)	xxx.x (lb)	3 ~ 5
Impedance	xxx (Ω)	xxx (Ω)	3
Fat %	xx.x (%)	xx.x (%)	3 ~ 4
Fat Mass	xxx.x (kg)	xxx.x (lb)	3 ~ 5
FFM	xxx.x (kg)	xxx.x (lb)	3 ~ 5
TBW	xxx.x (kg)	xxx.x (lb)	3 ~ 5
Age	xx	xx	1 ~ 2
BMI	xx.x	xx.x	3 ~ 4
BMR	xxxxx (kJ)	xxxxx (kJ)	3 ~ 5



- When measurement is taken in kg, the data will automatically be transmitted in cm and kg.
- When measurement is taken in lb, the data will automatically be transmitted in inch and lb.
- When using [Weight Only] mode, data can not be transferred via the RS-232C port.
- BMR Conversion Formula : 1kcal = 4.184kJ

Output Data format

- Data is comma delimited.
- Terminal data are CR (ASCII format : 0DH), LF (ASCII format : 0AH)
- Target Body Fat % data, and "Wrestler Mode" data can not be sent via the RS-232 port.
- Measurement data will be sent in the following format:



- b. Height above floor (to nearest cm) on _____
height rule of the 30 cm mark of the
tape when the zero mark of the tape
is aligned with the 150 cm mark of the
height rule

Note: If this measure is outside the 119.5-120.5 cm range,
the tape should be replaced.

- c. Height above floor (to nearest cm) on _____
height rule of the 100 cm mark of the
tape, with the tape aligned as above.

Note: If this measure is outside the 49.5-50.5 cm
Range, the tape should be replaced.

- d. Tape replaced (Y or N) _____ Date replaced _____
Time replaced _____

Technician doing weekly check:

ID# _____ Signature _____ Date _____

Appendix 4.3 Checklist for Anthropometry Measurement

CHECKLISTS FOR ANTHROPOMETRY MEASUREMENTS

Date of Visit: _____

Technician: _____ I.D. # _____

Supervisor: _____ I.D. # _____

This booklet contains a checklist for each anthropometry measurement and equipment calibration. The purpose of these checklists is to help train technicians to take uniform and accurate measurements using calibrated measuring equipment. Each checklist leads you through a series of steps to obtain and to record a measurement. All measurements are done on the right side, unless the limb is missing, atrophied or injured.

	<u>Item</u>	<u>Yes</u>	<u>No</u>
A.	Anthropometry is done BEFORE the Snack.	_____	_____
B.	Prepare participant for anthropometry: (May be done by the receptionist or technician).	_____	_____
1)	If the participant is wearing any nylon hose other than knee highs, the participant is instructed to remove hose.	_____	_____
2)	Participant is wearing light-weight, non-constricting underwear.	_____	_____
3)	Participant is wearing scrub suit.	_____	_____
4)	Participant has removed shoes.	_____	_____
5)	Participant has emptied bladder.	_____	_____

Appendix 4.4 Checklist for Height Measurement

CHECKLIST FOR HEIGHT MEASUREMENT

<u>ITEM</u>	<u>YES</u>	<u>NO</u>
1. Participant is prepared.	_____	_____
2. Procedure is explained to participant.	_____	_____
3. Participant's spine and heels are placed against the wall.	_____	_____
4. Participant's eye to ear plane is horizontal (i.e., Frankfurt plane).	_____	_____
5. Measurement is taken with triangle or measuring block.	_____	_____
6. Recording is completed.	_____	_____
7. Data are recorded accurately to the nearest centimeter, rounding down.	_____	_____

Technician: ____ cm

Supervisor: ____ cm

8. Other: _____

Comments:

Appendix 4.5 Checklist for Weight Measurement**CHECKLIST FOR WEIGHT MEASUREMENT**

<u>ITEM</u>	<u>YES</u>	<u>NO</u>
A. PROCEDURE		
1. Participant prepared and procedure explained	_____	_____
2. Position of participant on center of scale	_____	_____
3. Balance achieved	_____	_____
4. Recordings completed	_____	_____
5. Data recorded accurately to the pound, rounding down	_____	_____
Technician: ___ ___ ___ lbs		
Supervisor: ___ ___ ___ lbs		
6. Other _____	_____	_____

Comments:

Appendix 4.6 Checklist for Maximal Waist Measurement

CHECKLIST FOR MAXIMAL WAIST MEASUREMENT

<u>ITEM</u>	<u>YES</u>	<u>NO</u>
1. Subject stands erect, yet relaxed, with weight equally distributed on both feet.	_____	_____
2. Measuring tape is placed around subject's waist at the level of the umbilicus (navel).	_____	_____
3. Recorder or another observer verifies horizontal position of tape, both front and back of the subject, or uses mirror to check tape.	_____	_____
4. Subject takes a normal breath and <u>gently</u> exhales holding breathe in in a <u>relaxed</u> manner at the end of exhalation.	_____	_____
5. Tape is horizontal and snug, but not tight enough to compress tissue. (Invert tape, <u>if needed</u> , to insure reading edge of tape is snug to skin for measurement).	_____	_____
6. Reading is recorded to the nearest centimeter, rounding down, at point of <u>relaxed</u> and exhalation.	_____	_____

Technician: ____ ____ ____ cm

Supervisor: ____ ____ ____ cm

Comments:

Appendix 4.7 Checklist for Maximal Hip Circumference Measurement

CHECKLIST FOR MAXIMAL HIP CIRCUMFERENCE MEASUREMENT

<u>ITEM</u>	<u>YES</u>	<u>NO</u>
1. Subject stands erect, yet relaxed, with weight equally distributed on both feet and feet together.	_____	_____
2. Measuring tape is placed horizontally and level around the subject's gluteal muscles (hips) at the level of maximal protrusion of the gluteal muscles. Verify this position by passing the Tape above and below the observed maximum.	_____	_____
3. Recorder or another observer verifies horizontal position of tape, both front and back of the subject, or uses a mirror to check tape.	_____	_____
4. Tape is horizontal and snug, but not tight enough to <u>compress</u> tissue. (Invert tape, <u>if needed</u> , to insure reading the edge of tape is snug to the skin for measurement.	_____	_____
5. The measurement is made at the participant's side.	_____	_____
6. Tape is read to the centimeter, rounding down.	_____	_____

Technician: _____ cm

Supervisor: _____ cm

Comments: _____

Appendix 4.8 Report on Use of Observation and Equipment Checklists

REPORT OF USE OF OBSERVATION AND EQUIPMENT CHECKLISTS

DATE: ____/____/____ (Month/Day/Year)

Biannually: ____ January ____ July (20____)

This form should be completed biannually and sent to the Coordinating Center (by the end of January and July).

<u>Form Type</u>	<u>Observer ID</u>	<u>Observed ID</u>	<u>Date (MM/DD/YY)</u>
Anthropometry	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
BP Observation	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____

REPORT ON USE OF OBSERVATION AND EQUIPMENT CHECKLISTS (Cont'd)

<u>Form Type</u>	<u>Observer ID</u>	<u>Observed ID</u>	<u>Date (MM/DD/YY)</u>
BP Tape Test	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
BP Double Stethoscoping	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
Venipuncture	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____

REPORT ON USE OF OBSERVATION AND EQUIPMENT CHECKLISTS (cont'd)

**Tanita
Bioimpedance
Monitor**

_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

Electrocardiography

Ankle-Brachial Blood Pressure

REPORT ON USE OF OBSERVATION AND EQUIPMENT CHECKLISTS (cont'd)

Individual checklist for equipment should be filled weekly or monthly, according to the requirement of the checklist, and kept in the Field Center.

Key: N = Expected total number of checks needed:

n = Number of checks done:

% = % of checks done.

Checklist	Frequency	N	n	%
<hr/>				
Anthropometry Equipment Calibration Log				
(1) Scale Read Zero	Daily			
(2) Weight Scales	Weekly			
(3) Height Rule	Weekly			
(4) Measuring Tape	Weekly			
Sitting Blood Pressure				
Monthly Log for BP Station	Weekly			
	Monthly			
		Appendix 4.2	Anthropometry	
<hr/>				
Equipment Calibration Log				

APPENDIX 5 MEDICAL DATA REVIEW

Appendix 5.1 Prototype Medical Data Review Print Out and Information Sheet**MEDICAL DATA REVIEW REPORT FOR EXAM 3**

1. Name (CONA 1, 3, 4, 2):
2. JHS ID (CON)
3. Birth date (ELGA 5a):
4. Exam date
5. Physician name (CONA 34B,A):
6. Age in years (FTRA1, ELGA5A):
7. Height in feet & inches (ANTA/B1):
8. Weight in pounds (ANTA/B2):
9. BMI (BCF 8)
10. % Body Fat (BCF 12)
11. Avg. Sitting BP (SBPB 22, 23)
12. Taking antihypertensives (MSRA30a)

Possible Angina

- | | | | |
|-----|---|-----|----|
| 13 | Ever had chest pain (MSR B8) | Yes | No |
| 14 | HTN diagnosis (HHX 8A) | Yes | No |
| 15. | Diabetes diagnosis (HHX 12a) | Yes | No |
| 16. | High Cholesterol diagnosis (HHX 9a) | Yes | No |
| 17. | Pain more frequent past 2 months (MHX B 20) | Yes | No |
| 18. | Pain more severe past 2 months (MHX B22) | Yes | N |

Possible Congestive Heart Failure:

- | | | | |
|-----|--|-----|----|
| 19. | Slept on 2+ pillows to breathe (MHX B47) | Yes | No |
| 20. | Awakened by breathing trouble (MHX B48) | Yes | No |
| 21. | Had swelling of feet or ankles (MHX B49) | Yes | No |
| 22. | Decreased swelling overnight (MHX B50) | Yes | No |

Recognized TIA or stroke

- | | | | |
|-----|------------------------------------|-----|----|
| 23. | Stroke diagnosis (SSF B1) | Yes | No |
| 24. | Date of first stroke (DDFB 2A, 2B) | | |
| 25. | Leg pain with walking (MHX B37) | Yes | No |

Cardiovascular surgery

23.	Heart or arterial surgery (MHX B51)	Yes	No
24.	Coronary bypass (MHX B 52 A)	Yes	No
25.	Other heart procedure (MHX B52 B1)	Yes	No
26.	Other revascularization (MHX B52 E1)	Yes	No
27.	Specify (MHX B42 E2)	Yes	No
28.	Other Heart, neck or leg (MHX B52 F)	Yes	No
29.	Balloon angioplasty (MHX B53)	Yes	No
30.	Coronary angioplasty (MHX B54 A)	Yes	No
31.	Neck angioplasty (MHX B54 A)	Yes	No
32.	Lower extremity angioplasty (MHX B54 C)	Yes	No

Catheterization

33.	Heart catheterization (MHX B55 A)	Yes	No
34.	Carotid artery catheterization (MHX B55 B)	Yes	No
35.	Other arterial catheterization (MHX B55 C1)	Yes	No
36.	Specify (MHX B55 C2)		

Diagnostic procedures

37.	Echocardiogram (MHX B56 A)	Yes	No
38.	ECG (MHX B56 B)	Yes	No
39.	Treadmill or stress test (MHX B56 C)	Yes	No
40.	MRI of Brain (MHX B56 D)	Yes	No

Laboratory Values

41.	Glucose (FST A5)
42.	Cholesterol (FST A6)
43.	Triglycerides (FST A7)
44.	HDL (FST A8)
45.	LDL (FST A9)
46.	VLDL (FST A10)

Administrative

47. Code of person Completing

--	--	--

48. Date of Medical Review

		/			/				
M	M		D	D		Y	Y	Y	Y


52. Code of clinician Reviewer:

--	--	--

53. Date of review by clinician:

		/			/				
M	M		D	D		Y	Y	Y	Y

Appendix 5.2 Tanita Patient Education Handout



Eat healthily, exercise regularly and monitor your body composition

Initial Measurement: _____

Target Weight: _____

Target % Body Fat: _____

Target Date: _____

% Body Fat _____

% _____

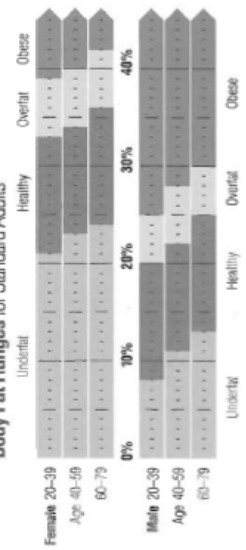
Personal Progress Chart

Week	Date	Time	Weight	% Body Fat

Personal Notes

How much body fat is healthy?

Body Fat Ranges for Standard Adults^{1,2}



¹Based on NHANES BMI Guidelines. ²Wahlehy et al. Am J Clin Nutr 2000; 72:694-701.
 To determine the percentage of body fat that is appropriate for your body, consult your physician.

Tanita Corporation of America, 2625 S. Clearbrook Drive, Arlington Heights, IL 60005
 847-640-9241 • Fax 847-640-7978 • E-mail: prosales@tanita.com • www.tanita.com
 For additional kits call: 1-877-6-TANITA (1-877-682-6482)

A step toward better health

Understanding your body composition readings

This analysis includes a number of measurements providing an in-depth look at your body composition. You and your health professional can use this analysis to assess your current health, and to develop a fitness and nutrition program that, over time, will maximize your health.

Body Mass Index (BMI)

BMI is a standard height to weight ratio useful for classifying risks associated with weight gain. The World Health Organization (WHO) classification has been developed using the following grading system that links increases in BMI to increased health risks.

Body Mass Index	WHO Classification
<18.5	Underweight
18.5 - 24.9	Healthy weight
25.0 - 29.9	Overweight
30+	Obese

Fat %

Body fat is vital to daily body functions. It cushions joints, protects organs, helps regulate body temperature, and stores vitamins. However, serious health risks are associated with both too much, and too little body fat. Compare your results to your "Desirable Range" on the bottom of the print out, or on the reverse side of this sheet. By design, women's bodies require a higher percentage of body fat to be healthy.

BMR

Basal Metabolic Rate reflects the amount of calories used by the body to maintain normal functions when at rest. Daily activities and exercise increase BMR by approximately 15%. BMR helps you establish just how many calories your body needs in a day to achieve proper energy balance.

Impedance

Measured in Ohms (Ω), the Impedance value reflects the strength and speed of an electrical signal traveling through the body. Muscle is the signal's highway, and fat mass is like a traffic jam. More muscle means it's easier for the signal to pass through your body, resulting in a lower impedance value and % of body fat. Consistent conditions and stable hydration status are not only healthy, but will also yield consistent results.

Fat Mass

The body needs fat, but it is important to keep your fat within the recommended range. Compare your personal result to your "Desirable Range" at the bottom of the print out, and focus specifically on fat mass when dieting or exercising.

FFM

Fat Free Mass is everything in the body that is not fat; muscle, water, bone, connective tissue, etc. Muscle acts as the body's natural "fat-burning engine," therefore it is important to maintain or even gain healthy muscle mass when exercising or dieting.

TBW

Reflects Total Body Water. It is important to ensure your body is not dehydrated, especially when exercising or dieting. Enter your TBW below, and compare your hydration level to recommended ranges.*

$$\frac{\text{TBW}}{\text{Weight}} \times 100 = \text{Estimated Hydration Level \%}$$

Note: Individuals who are severely dehydrated may receive an inaccurate measurement.

Female: 45-60%
Male: 50-65%

* Based on Tanita's current research.

Desirable Ranges

Everybody needs fat. These healthy ranges display how much you should have in terms of % and weight. Research shows that individuals with appropriate amounts of fat are less likely to develop obesity-related health conditions.

Target Body Fat %

Set a realistic goal for body fat %. Tanita then calculates the approximate amount of fat mass, not just overall weight, but specifically fat mass that needs to be lost in order to achieve the pre-selected target. Always try to maintain FFM when dieting.

Note: The Target Feature is an estimation only. Please consult a health professional before you undertake any weight management program.

YOUR ANALYSIS

PLACE ANALYSIS HERE
USING STICKER

APPENDIX 6 REFERRAL AND RESULTS REPORT

**Appendix 6.1 Prototype Health Care Provider Results Reporting Letter: Health Care
Provider Designated**

DATE

Provider's name

Provider's address:

Dear Provider Name:

Your patient, PATIENT'S NAME, is a participant in the Jackson Heart Study and was seen at our Clinic on VISIT DATE. During the course of our evaluation, the following abnormality was identified. We believe that this requires your attention.

ABNORMAL RESULT: [LIST RESULT]

The Jackson Heart Study routinely offers to send all clinically relevant data to the participant's health care provider. PATIENT'S NAME has requested that we send the result to you, and we have also provided a report to her/him.

The Jackson Heart Study procedures are designed exclusively for epidemiological research. Our study procedures do not substitute for a clinical examination. The study does not provide any diagnosis or medical treatment. We have recommended to Mr./Mrs./Ms. PATIENT'S NAME that s/he contact you to determine how to follow up on these results.

Should you have any questions, please feel free to contact us at 601-815-5050.

Sincerely,

Mary E. Crump RN, MSN
Clinic Manager

Appendix 6.2 Prototype Health Care Provider Results Reporting/ Referral Letter: No Health Care Provider Designated

DATE

Provider's name

Provider's address:

Dear Provider Name:

Thank you for agreeing to see, PARTICIPANT'S NAME, a participant in the Jackson Heart Study who was seen at our Clinic on VISIT DATE. PARTICIPANT'S NAME does not have a regular health care provider. During the course of our evaluation, the following abnormality was identified. We believe that this requires your attention.

ABNORMAL RESULT: [LIST RESULT]

PATIENT'S NAME has requested that we send the result to you, and we have also provided a report to her/him.

The Jackson Heart Study procedures are designed exclusively for epidemiological research. Our study procedures do not substitute for a clinical examination. The study does not provide any diagnosis or medical treatment. We have recommended to Mr./Mrs./Ms. PATIENT'S NAME that s/he contact you to determine how to follow up on these results.

Should you have any questions, please feel free to contact us at 601-815-5050.

Sincerely,

Mary E. Crump RN, MSN
Clinic Manager

Appendix 6.3 Participant: Referral post Clinic Visit Without Designated Health Care Provider

Date

Participant's name
Participant's address

Dear Mr./Mrs./Ms. _____:

Since your examination at the Jackson Heart Study Clinic on VISIT DATE we have obtained some results of your studies. Your results revealed a finding that should be discussed with your health care provider. A report of the finding is enclosed.

Because the Jackson Heart Study does not provide any clinical diagnosis or treatment, we offer to send all relevant information to participants' usual source of medical care. During your visit you did not designate a health care provider. If you do not have a personal health care provider, and would like assistance in finding one, please call the Jackson Heart Study office at (601) 815-5050 for provider referral information.

Should you have any questions, please feel free to contact us at (601) 815-5050. A final report with results of your additional tests will be forwarded when available.

Sincerely,

MD
Enclosure

Appendix 6.4 Participant: Referral Post Clinic Visit with Health Care Provider
Designated

Date

Participant's name
Participant's address

Dear Mr./Mrs./Ms. _____:

We would like to thank you for your visit to the Jackson Heart Study Clinic on VISIT DATE. Since your examination, we have obtained some results of your studies. In order for all Jackson Heart Study participants to get the best medical care, we would like to let you know that your exam results revealed a finding that should be discussed with your health care provider. A report of the finding is enclosed.

As you requested, we have sent a copy of these results to PROVIDER'S NAME. We suggest that you contact her/him as indicated on the enclosed results report to determine how to follow-up on these results.

Should you have any questions, please feel free to contact us at (601) 815-5050. A report of your additional test results will be sent when available.

Sincerely,

MD
Enclosure

Appendix 6.5 Health Care Provider: Referral Post Clinic Visit

Date

Provider's name
Provider's address

Dear PROVIDER'S NAME:

We saw your patient, PROVIDER'S NAME, in the Jackson Heart Study Clinic on VISIT DATE. Since that exam we have obtained some results that revealed a finding that we think requires your attention. A report of the finding(s) is enclosed.

The Jackson Heart Study does not provide diagnosis, medical advice, or treatment. We have recommended to Mr./Mrs./Ms. PATIENT'S NAME that s/he contact you to determine how to follow-up on these results.

Should you have any questions, please feel free to contact us at (601) 815-5050. A final report of additional results will be sent when available.

Sincerely,

MD
Enclosure

Appendix 6.6 JHS Alerts and Referrals Procedures

CLINIC PROCEDURES –EXAM 3 MEDICAL DATA REVIEW AND RESULTS/ALERTS REPORTING

I. Overview

The purpose of medical data review and results/alerts reporting is to provide timely information regarding the results of the JHS clinic examination to participants and, if requested or indicated, their health care provider (HCP). Additionally, medical data review is conducted to identify and provide timely notification of any alert findings that require emergent, immediate or urgent attention by a HCP. This process is a major component of assuring participant safety.

Results that are immediately available during the clinic examination (blood pressure, anthropometrics, and body fat,) are reviewed with the participant at the end of the clinic visit during the exit interview. Any abnormal or alert values will result in an appropriate level referral based on the categorization of findings as emergent, immediate, urgent or routine as identified in Manual 2: Cohort Procedures. Participants without a HCP, but needing referral, will be assisted in that process.

The Medical Data Review and Results/Alerts Reporting Form (ALT) are used to track all results reporting activities.

Table 6.2 provides a summary of procedures for routine results reporting and identification, notification and documentation of alerts. Each column of this summary table is reviewed below.

II. Medical Data Review: Action Sequence for Routine Results Reporting

This section details the action sequence for routine results reporting for each examination component reportable to participants and their HCP (if requested) presented in Table 6.2, column 2. As the same series of steps is listed for each component in the table, this section provides a common overview of the entire process applicable to all procedures.

A medical data review is conducted in several steps for each participant. The first step occurs during the clinic visit at the time of the exit interview. The next step occurs during a weekly review as the Clinic Manager performs quality control to assure that all abnormal results were properly handled. Results of the medical data review process are documented on the ALT and maintained in the Data Management System (DMS).

A. End-of-Clinic Medical Data Review

The end-of-clinic medical data review serves to summarize the results of selected measurements obtained during the baseline exams/interviews, identify potential medical problems and answer participant questions. It is important to note that the intent of this review is to provide factual information about results, identify abnormalities and recommend referral as needed, while avoiding medical advice about prognosis, prevention or therapy. All such medical advice is in the purview of the participant's HCP and is not within the scope of the JHS.

1. Medical Data Review print out

The Medical Data Review (MDR) print out is generated at the end of the clinic visit (Appendix). This print out contains relevant participant personal (birth date, age) and medical history (taking hypertensive medications, history of hypertension, diabetes, elevated cholesterol, stroke, chest pain, coronary bypass surgery, balloon angioplasty or

cardiac catheterization, undergoing dialysis, menstrual bleeding); indication of identified HCP as well as values from the clinic examination (height, weight, sitting blood pressure).

2. Manager Research Clinic/Clinic RN review

Using the information contained in the MDR print out, the Manager Research Clinic or RN conducts an exit interview with the participant at the conclusion of the clinic examination visit. During this exit interview, all known findings from the clinic exam/questionnaires are reviewed with the participant to confirm selected positive symptoms reported during the interviews/exam and to determine if these appear to warrant immediate (same day), urgent (same week) or routine medical follow-up. Specifically, the Manager Research Clinic or RN reviews anthropometrics, blood pressure, and body fat. . The information on the MDR print out provides background information to assist the nurse in determining the urgency of any abnormalities. For example, should the participant have an elevated blood pressure, the Manager Research Clinic or RN will determine from the print out and confirm with the participant that s/he takes blood pressure medication. Ascertaining whether medications have been taken that day, if the participant knows her/his normal blood pressure reading, and the last time s/he was seen by a HCP will be instrumental in subsequent follow-up actions. Guidelines for abnormal and alert referrals are summarized in Table 1 and detailed below.

A printed summary of the exam results that are immediately available from the Clintrial DMS is completed during the end-of-clinic medical data review and given to the participant. This includes BP, height, weight and calculated body mass index and body fat.. In addition, the participant receives a copy of her/his Tanita Bioimpedance monitor print out and a summary health education handout that explains these findings. Any remaining participant questions are answered during this interview.

At the conclusion of the end-of-clinic medical data review, the participant is directed to the Social Worker who conducts the Participant Evaluation of Clinic Visit on as many participants as possible during each clinic day. When it is not possible for the Social Worker to conduct the evaluation interview, participants will be asked to complete the evaluation on their own.

In the event the participant has social service needs, does not have a HCP and either needs alert / routine referral or requests assistance with locating health care, the Social Worker is consulted to assist with the referral process.

B. Daily and Weekly Review

Designated lead technicians conduct a daily review of examination results to detect and initiate action on alert findings. The Manager Research Clinic conducts a weekly review of all available examination results for participants completing clinic examinations during the preceding week. The purpose of this examination is to assure that all alerts have been identified and handled according to the results and alerts reporting protocol. Information needed to complete this weekly review includes 1) appointment listing for previous week, 2) a copy of the MDR and ALT completed at the time of the Exam 3 visit. A notation of review is indicated in the upper right or left hand corner of the result report.

1. Appointment listing

The Data Manager prints a query report from the Participant Itinerary Form for the specified week. This report includes all participants who have completed all or part of a clinic examination during the specified time frame. Specific exam components not completed or refused by each participant are identified in this report.

The Manager Research Clinic uses this report to assure that the reports provided for weekly review are complete.

2. Compilation of reports

The Clinic Receptionist creates a Results Reporting file with name and J number for each participant at the time of clinic file generation on the morning of the clinic visit. This file is placed in alphabetical order by day of the week in the Weekly Review filing space in the JHS file storage room. The MDR Report and the ALT printout are placed in the individual participant Result Reporting file.

3. Notation of review

a. Daily review. All abnormal values are recorded on the ALT form by the lead technician at the time of the daily review and entered in the Medical Data Review and Alerts/Referral Log (ALT) in the DMS (see section D1, below).

b. Weekly review. The Manager Research Clinic affixes a check (✓) followed by her/his initials, the date of review and an indication of the level of reporting to each report reviewed. For normal values, no further annotation is included. For abnormal values, results that require routine reporting are indicated by the letters RR; those requiring alert reporting are indicated by the letters AR.

The Manager Research Clinic affixes a check (✓) followed by her/his initials beside each name on the weekly appointment list that accompanies the weekly compiled results. The placement of initials indicates completion of the weekly medical data review. Using this checklist, the Clinic Receptionist enters confirmation of completion of the weekly medical review in the Medical Data Review and Alerts/Referral Log in the DMS (see section D2, below).

C. Comprehensive Results Report

A comprehensive report of participant examination results is generated by the Data Management Information Technology Quality Assurance Unit and delivered to the Clinic at the time of the exit interview (Medical Data Review printout). In addition to the reportable examination findings, this report includes information necessary for completing the review process, e.g. participant name, J number, gender, HCP status, and whether or not s/he is taking medications for hypertension.

Also, a final packet, including an appropriate cover letter for the participant's HCP, two copies of the results report, an explanations booklet, and a risk factor analysis is generated for distribution to each participant.

A dual process of clinic staff and Manager Research Clinic review of all results reporting letters and results is completed to assure accuracy prior to mailing. Designated clinic staff review the comprehensive results reports generated each week to assure accuracy and subsequently complete the documentation process using the ALT form (see Forms Manual and QxQs for each form). A final quality control review is conducted by the Manager Research Clinic prior to mailing any abnormal results to the participant's designated HCP (with permission of participant).

For participants who request that abnormal results be mailed to their health care provider, the Clinic will mail a complete set of findings to the designated HCP within approximately two weeks of the clinic visit date.

1. Distributing reports

- a. Initial review. Designated clinic staff review letters and reports for 8-10 participants each week to assure accuracy and to complete the ALT forms for each participant.
- b. Quality review. The Manager Research Clinic completes a final quality control review of each participant report packet to assure that the information matches the actual results for each participant and that the correct information is attached to each letter for each participant.
- c. Participant reports. The Clinic Receptionist makes a duplicate copy of the complete participant report (letter, results report, explanations) for both the participant and HCP. The copy is filed in the participant's JHS file.

D. Annotating Routine Medical Data Review

Any abnormal result found at any stage of the medical data review process (end-of-clinic, daily review, weekly review, comprehensive review) is annotated on the Alert and Routine Referral Log (ALT) and entered into the DMS. Likewise, the confirmation of completion of each of the weekly review and comprehensive results reporting procedures is annotated in the Medical Data Review printout and maintained in the participant paper record.

1. ALT form

The Alert and Routine Referral Log (ALT) form is used to record all abnormal findings and subsequent referral action for any reportable result from the clinic examination. The form includes space for recording information on abnormalities in blood pressure, body fat, body mass index, blood glucose and lipids, CT Scan and MRI Scan. For each exam component, space is provided to record the date the abnormal finding was received, the alert item/value, the date of referral action, the JHS code of the person completing the review, the type of referral action taken, the referral source and the method of notifying both the participant and her/his HCP. Specific instructions for completing the ALT form are included in the Forms Manual for Manual 2.

The paper version of the ALT is maintained in the participant's file.

The Data Manager queries the Alerts Reporting Crystal Reports provided by the Data Management Information Technology Quality Assurance Unit to generate a monthly report of Alert and Referral actions on a designated date each month. This report is transmitted electronically to the Manager Research Clinic, the Chair of the Clinic Operations Subcommittee, and the Associate Director of the Data Acquisitions Unit for inclusion in the agendas of appropriate committee meetings (e.g. Clinic Operations, Directors' Council and Steering Committee).

III. Medical Data Review: Action Sequence for Identifying and Reporting Abnormal Results

This section details the action sequence for identifying (Table 6.2, column 3), reporting (Table 6.2, Column 5) and documenting (Table 6.2, column 6) abnormal results for each examination component reported to JHS participants and their health care providers (HCP) (See Manual 2 v2.3, section 6: Results and Alerts Reporting). Table 6.1, column 4 summarizes the range and categorization of abnormal values for quick reference. Definitions for each of the identified alerts categories: Emergent, Immediate, Urgent and Routine, are provided.

A. Definitions of Results Categories

1. Alerts are those results that require participant notification and referral to HCP within a time period prior to the usual results reporting schedule (within 2 weeks after the clinic examination). There are three categories of alert referrals:
 - a. Emergent referrals are those immediate or urgent clinical findings identified during the clinic examinations that are accompanied by life-threatening (e.g. hemodynamic instability) findings. In all such instances, the clinic examination is stopped and the participant is transported to the nearest Emergency facility. Emergency procedures are outlined in Section 7 of Manual 2 v2.3, Cohort Procedures. Chapter 4 of the Clinic Procedure Manual outlines the protocol for handling emergencies, including those that do not fall in any of the alert categories.
 - b. Immediate referral is made for specified abnormal findings that require immediate (same day) attention. When identified during the clinic examination or exit interview, the participant must be notified and notification of her/his HCP is initiated before the participant leaves the clinic. Contact is made with a selected HCP if the participant does not have an established provider.
 - c. Urgent referrals are made for specified abnormal findings identified during the clinic exam. They require participant notification and HCP referral within one week.
2. Routine referral occurs for those abnormalities that are unlikely to result in an adverse affect within several weeks of the clinic examination. These results are reported routinely with comprehensive reporting of results to participants in clinic and HCP (if requested).

B. Identifying and Reporting Clinic Alerts

1. Blood Pressure

The technician completing the BP measurement during the clinic examination identifies abnormalities in blood pressure and notifies the Clinic RN or Manager Research Clinic S/He repeats the BP reading to confirm the abnormality and identifies the alert category. The nurse assesses the participant's clinical status.

BP alert values in accordance with Joint National Commission VII guidelines are summarized below:

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.

If the alert value is determined to be Emergent or Immediate, the JHS Medical Officer or Clinician on call is notified immediately (prior to participant leaving the clinic). S/He reviews and confirms this level of alert finding and provides instructions to initiate participant and HCP notifications according to protocol definitions (described above) including any further recommendations.

Participant notification of BP value occurs at the time of measurement and is discussed and explained at the medical data review conducted at the end of the clinic visit. If the alert is Emergent, the participant is transported to the nearest emergency facility and her/his HCP is notified by telephone. If the alert is Immediate the participant's HCP is notified by telephone at the time of the medical data review at the completion of the clinic visit. If the alert is Urgent, an alert letter (M2A6.1-6.2) is sent to the HCP. If the alert is Routine level 1 or 2, a letter is sent to the HCP (M2A6.1-6.2) recommending a one or two month appointment, respectively.

If the participant does not have a HCP, the Social Worker is consulted and a referral process is initiated.

C. Generating Alerts Reports

Alert values for reportable clinic examination findings are identified and addressed in the clinic at the time of the exam. The weekly medical data review also serves to identify any alert values that may not have been identified in earlier reviews. As described above, technicians conducting each element of the clinic examination identify alerts and notify the Clinic RN or Manager Research Clinic. The JHS Medical Officer or Clinician on call reviews alerts with the clinic nurse and directs alerts actions. Participant and HCP telephone calls are initiated by the Clinic RN with directions to the Clinic Receptionist to provide appropriate reports via Fax to the HCP. The Clinic Receptionist generates participant and HCP alert letters and examination results. The Manager Research Clinic reviews all alert letters and accompanying results for accuracy prior to mailing.

1. Compiling information

Information for alerts reports is compiled by the appropriate technician as described above and delivered to the Clinic RN or Manager Research Clinic for review and confirmation of alert category.

2. Categorizing alert values

The lead technician or Clinic RN,, or Manager Research Clinic, in consultation with the JHS Medical Officer or Clinician on call, categorizes the alert value(s) following identified protocol for each exam component (see above). The Manager Research Clinic or RN initiates the process of participant and HCP notification, making telephone calls and directing distribution of Fax reports to the identified HCP for Emergent or Immediate alerts. The lead technician or nurse notifies the Clinic Receptionist of the alert categorization.

3. Generating cover letters and results report

The Clinic Receptionist will generate the appropriate alert letter as specified above for each exam component requested by the lead technician, RN, or Manager Research Clinic. Once the letter and copy of result report are generated, the Clinic Receptionist delivers it to the Manager Research Clinic for review prior to mailing and documentation in the Medical Data Review and Alerts Referral/Reporting Log (ALT) in the DMS (see section D2, below).

4. Distributing reports

The Manager Research Clinic reviews each participant / HCP letter and enclosed results report for accuracy prior to mailing. This quality control review is conducted to assure that the information matches the actual results for each participant and that the correct information is attached to each letter for each participant. Following this review, the letter is returned to the Clinic Receptionist for mailing.

Prior to mailing the alert results report, the Clinic Receptionist makes a duplicate copy of the complete mailing (letter, results report, explanations) to both the participant and HCP. The copy is filed in the participant JHS file.

D. Documenting Clinic Alerts and Referrals

Any abnormal result found at any stage of the medical data review process (end-of-clinic, weekly review, comprehensive review) is annotated on the Alert and Routine Referral Log (ALT) and entered into the DMS.

1. ALT form

The Alert and Routine Referral Log (ALT) form is used to record all abnormal findings and subsequent referral action for any reportable result from the clinic examination. The form includes space for recording information on abnormalities in blood pressure, body mass index, body fat, blood glucose and lipids. For each exam component, space is provided to record the date the abnormal finding was received, the alert item/value, the date of referral action, the JHS code of the person completing the review, the type of referral action taken, the referral source and the method of notifying both the participant and her/his HCP. Specific instructions for completing the ALT form are included in the Forms Manual for Manual 2.

The paper version of the ALT is maintained in the participant's file.

The Data Manager queries the Alerts Reporting Crystal Reports provided by the Data Management Information Technology Quality Assurance Unit to generate a monthly report of Alert and Referral actions on a designated date each month. This report is transmitted electronically to the Manager Research Clinic, the Chair of the Clinic Operations Subcommittee, and the Associate Director of the Data Acquisitions Unit for inclusion on the agenda of appropriate committee meetings (e.g. Clinic Operations, Directors' Council, and Steering Committee).

Appendix 6.7 JHS Resource Manual

Jackson Heart Study

Resource Guide



WELLNESS



- How to stay well in Mississippi
- Things you can do for yourself and others
- Where to find help in your community

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To Find the Subject You Want

- Look through the list on page 4-5
- For general topics see page 2

To Find Community Services

Local Phone Numbers for Community Services Agencies are listed at the back of the Guide.

For Community Services that are not listed in this guide, please look in the table of contents in the Yellow Pages of the phone book under Social Services.

Local numbers for many types of Services are in the Government Pages or White Pages in your phone book.

Free Statewide Phone Numbers

- Toll-free (800) numbers are included in the back of this Guide.

You are welcome to contact the Jackson Heart Study Social Worker to assist you in obtaining other information or needed services. You can reach her by calling 601-815-5050.

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Basic Needs



Basic Needs

Everyone has basic needs, like food, clothing and a safe place to live. Without them, you can't survive. Yet sometimes these needs can be hard to meet.



This chapter contains ideas about things you can do for yourself and where to find help in your community.



Food

Emergency Food is available from community pantries, community centers, senior meal programs and churches.

Government Food Programs, such as Food Stamps, School Breakfast and Lunch Programs, and the Women, Infants, and Children Program (WIC) are other resources for the low-income.

Things You Can Do

- Look for places with low prices
- Find out about local community food programs.
- Cut out coupons from the newspapers.
- Add more whole grains and beans to your diet
- Eat a wide variety of foods each week.
- Eat fresh fruits and vegetables each day
- Eat less fat, avoid fried foods and pastries
- Eat nourishing soups.

Where To Find Help

Local Phone Numbers

City of Jackson Senior Services	(601) 960-0454
New Dimension Food Pantry	(601) 969-9856
DHS (Food Stamp Office)	(601) 362-9892
WIC office	(601) 364-2666
Meals n Wheels	(601) 960-0346



Housing

Good housing can be expensive. Many people are homeless, or just one paycheck away from it. There are not many resources, but low-income housing is available for senior citizens and the disabled.



There are also agencies that help with utility bills.



Things You Can Do

Looking for a home to Rent

You cannot legally be turned down for housing because of race or a disability. For advice, call the Fair Housing Authority.

Neighborhood Problems

Streetlights out? Too Noisy? Talk to neighbors, or call the City of Jackson.

Homeless

In the Jackson area there are emergency shelters for the homeless. Some shelters offer counseling and other services.

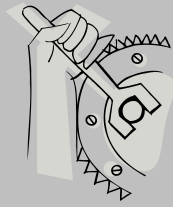


Where To Find Help

Local Phone Numbers

Human and Cultural Services	(601) 960-0335
Jackson Housing Authority	(601) 362-0885
Regional Housing Authority	(601) 373-7040
Hinds Co. Human Resources (Homeless Support Services)	(601) 354-3857
Veterans Homeless Services	(601) 362-4471





Work

A job with fair pay is a basic need. Unemployment offices help people find jobs, and get benefits.

Things You Can Do

- Attend adult education classes to complete a GED program
- Take classes at a community college or university.
- Job training programs, such as Job Corps.
- Temp agencies can help; look in the Yellow Pages
- Veterans can get special help.
- Stay healthy at work by taking regular breaks.
- Report discrimination to the Equal Employment Opportunity Commission (EEOC).
- Report dangers at work to management or the Occupational Safety and Health Organization (OSHA).
- If you are injured at work, discuss with management how to apply for worker's compensation benefits.

Where To Find Help

Local Phone Numbers

JPS Adult Education	(601) 987-3695
EEOC	800-669-4000
Vet Center	(601) 965-5727
WINN Job Center	(601) 321-7931
Unemployment Insurance Office	(601) 321-7937
OSHA	(601) 965-4606



Medical Care

Do you need to see a doctor or some other kind of health care provider? Do you know where to go? Medical care can be very expensive. If you do not have health insurance or money to pay for medical care, you can get low-cost treatment at the community clinic or a hospital. The JHS Social Worker can also help you. **See page 29**



Medicare covers seniors and people with disabilities.

Medicaid covers certain individuals and families with low incomes and resources who need help paying for medical care.

Things You Can Do To Find Medical Care

Community clinics serve almost anyone, even if you have no insurance and do not qualify for Medicare and Medicaid. Private clinics serve people who can pay or have insurance.

Medicare pays medical costs for some people over 65, and some people with disabilities. You can buy “Medigap” insurance to cover costs not covered by Medicare. Sometimes you get Medicare automatically; other times you have to apply.

Children’s Health Insurance Program (CHIP) provides free medical and dental check –ups for children from low-income families.

Private Health Insurance

Insurance is expensive and you usually have to pay part of the treatment cost. There are agencies that assist county residents who are uninsured or underinsured. **See page 29**

Where To Find Help

Local Phone Numbers

Medicaid

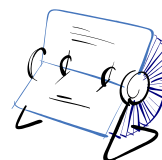
Medicare

Medicaid (CHIP)

(601) 961-4361

(601) 965-6273

866-635-1347



Staying Well

We can prevent a lot of illness and suffering by learning to take better care of ourselves and each other.

Think about your life and the people you live and work with. What are some changes that you would like to make?

This chapter offers helpful information about diet, exercise, drugs, physical disability, mental health problems, violence and dying.

Some problems we can solve alone, if we take the time to make a change. For other problems, we need help from a friend, a family member, professional, or a small support group.



Stress

Are You Stressed?

The signs vary.

Are you:

- ❖ Moody or depressed?
- ❖ Getting aches and pains?
- ❖ Having problems eating?
- ❖ Not sleeping well?
- ❖ Eating too much?
- ❖ Drinking or smoking a lot?
- ❖ Getting violent?



Life can be demanding!

Family, work, commuting to work and money issues can add to the stresses of daily life, and can cause a non-stop kind of stress that wears you down

Times of major change are the hardest, like divorce, or losing your job, or the death of someone you love. Even happy changes, like the birth of a baby can be stressful.

Stress may mean you need to make some changes. Ignoring the signs can lead to bigger problems, even serious illness. Think about what stresses you. Find ways to make a change. Help yourself feel better. Changing the way you live can be very difficult. It takes hard work and patience. You may need help. Talk to friends and family. If you can't cope, there are counselors and others in your community who can help.

Coping With Stress

Things You Can Do To Prevent Stress

Think about what stresses you:

- Learn your signs of stress. When they appear:
- Take a break
- Talk to a friend
- Make a change you think could help you
- Learn about deep relaxation
- Avoid debt. Don't buy what you can't pay for.
- Stand up for yourself
- Find time for yourself every day
- Take up a hobby
- Try to keep a sense of humor



Resist Illness: Adopt a Healthy Lifestyle

- Nutritious Meals eaten slowly can be calming.
- Exercise can give you some relief from stress.
- Drugs and alcohol can make things worse.
- Make sure to get enough sleep.

Trouble Coping Alone? Get Help.

- For help solving a family problem — seek counseling
- Need a professional therapist? Call a mental health clinic.
- Very depressed, even suicidal? Call Contact Crisis Line.

Where To Find Help

Local Numbers

The Crisis Line
Summit Counseling
Central Mississippi Medical Center

(601) 713-4357
(601) 949-1949
(601) 376-2600



Healthy Eating For Cardiovascular Health

Eating well may help prevent serious illnesses like diabetes, cancer and heart disease. The kind of foods you choose, and how much of them you eat are both important. Most experts agree that we should eat more whole grains, vegetables and fruit and less fat, sugar and salt.

Enjoying your food is important, but remember:

- Eat only when you are hungry
- Choose a place where you can eat in peace
- Stop when you feel full.

Steaming, stir- frying, baking and micro waving meats and vegetables are healthier than deep- frying.

Add pepper, lemon juice, or other spices rather than lots of salt. Mrs. Dash's is a healthy alternative to salt.

It is important to remember these food safety tips

- Meat, milk and eggs should be kept in a cold place.
- Always rinse fruits and vegetable before use.



Eating Well

Things You Can Do

- Eat a Variety of Foods
- Use whole grain breads and cereals
- Try to eat five servings of vegetables and fruits daily
- Select low-fat or non-fat dairy products
- Trim the fat from beef and pork
- Skin chicken and turkey to reduce their fat content
- Drink water or fruit juice instead of sodas, coffee and alcohol
- Check food labels for fat, fiber, sugar and salt content.



Cooking

- Cut down on deep-fat frying, try stir-frying, baking or broiling
- Use vegetable oil, like corn, canola or olive
- Use less salt; too much can raise your blood pressure
- Wash fresh fruits and vegetables to remove chemicals
- Cook and eat with family or friends

Eating Problems

Many people eat too much because they are bored, lonely, or depressed, or they are addicted to certain foods. Others eat only small meals or make themselves throw up their food. These habits can be dangerous and hard to change. Join a support group like Overeaters Anonymous.



Exercise

no matter how old you are, exercise and relaxation can help you stay well, look good and live longer.

Some kinds of exercise make you flexible. Some make you strong. Others give you stamina. You need all three.

Regular exercise is best – several days a week, if you can, there are many ways: swimming, gardening, walking, jogging—each helps the body in different ways. Some people join a group; others exercise alone.

Relaxing is also important. Read. Sing. Walk the dog. Play music. Write a letter. Get together with friends. Even making a small change in your daily routine can be relaxing. It's never too late to start.



Exercise and Relaxation

Things You Can Do

Exercise Regularly

- Make exercise a regular part of your life
- Check with your health care provider about safe exercises
- Start slowly; forcing your body could cause an injury
- Exercise should be fun, so enjoy yourself
- Exercise for 20-30 minutes, at least three times a week
- Try different kinds of exercise
- Instead of elevators, use the stairs



Take Time to Relax

- Find a quiet safe spot to sit or lie down
- A few deep breaths can help release tension
- Take a leisurely walk. Or talk to a friend
- Ten minutes of exercise can also ease tension
- Relax with music, movies, reading, or by playing with a pet
- Take a hot shower or bath
- Soak your feet in warm water
- Take at least one day of rest every week



Other Places to Go

- Classes at a YMCA or health club
- A local library museum, or community center
- A park, beach, swimming pool or recreation center

Where To Find Help

Local Numbers

YMCA (601) 948-3091
 Baptist Healthplex (601) 925-7900
 Parks & Recreation Office (601) 960-0471



Mental Health

Many people experience severe mental distress at some point in their lives. It may last only a few days or weeks; it may be there most or all the time. It can make you feel very alone.

The signs vary. You could feel:

- overwhelmed or confused
- frightened or angry
- worthless or depressed
- others do not understand you
- everyone is against you
- you cannot take care of yourself
- you are going to hurt yourself, or someone else.

Get help ignoring the signs, or denying there is a problem, can make matters worse.

For serious mental illness, try to find a mental health specialist. Public mental health programs offer some services and referrals, but treatment is not always easy to get. Family and friends may also be able to help. Self-help groups, counselors and clergy offer important kinds of guidance and support.

Where To Find Help

Local Phone Numbers

Central MS Medical Center
 St. Dominic Behavioral Health
 Brentwood Behavioral Healthcare
 MS State Hospital
 Region 8 Mental Health Center
 Region 9 Mental Health Center

(601) 376-2600
 (601) 200-3090
 (601) 936-2024
 (601) 351-8000
 (601) 859-8371
 (601) 321-2400



Mental Distress

Things You Can Do

Do You Have a Mental Health Problem?

- Learn to recognize the signs that you are becoming sick
- Keep a journal: write down your symptoms and feelings
- Tell friends your trouble signs; let them warn you.
- A support group may help. **See page 34**
- Be hopeful; don't be ashamed.
- You are entitled to respect like everyone else.

Finding Help in a Crisis

Call a mental health center. In a serious emergency, Call 9-1-1

Spending Time With People in Distress?

- Be patient. Recovery takes time.
- Be sensitive. Treat the person with respect.
- Take care of yourself too; take time away.
- Encourage the person to continue treatment of some kind.
- If the treatment is not helping, try to find an alternative.
- Be understanding; invite them to do things with you.
- Encourage the person to be independent.

Treatment

The main treatments are counseling and medication. Both can help people to lead a normal life, though drugs may have unwanted side effects. Most insurance plans don't cover all the costs of treatment for mental health problems—so make sure to check your coverage.

Disability

There are many kinds of disabilities, and many causes. Some of us are born with them. Others are disabled by illness or injury. Physical disabilities limit the full use of your body, while people with developmental disabilities, may be mentally challenged or have problems communicating.

Being disabled does not mean the person is sick or helpless. People with disabilities can be as healthy and capable as anyone else. Many organizations offer services ranging from job training and housing to transportation and sports.

Things You Can Do

Disability Services

Independent Living Centers help with counseling, job training, housing, benefits counseling, peer support, living skills classes and legal advice.

Other Services and Benefits

- For medical help, call the health department. **See page 30**
- To find out if you are eligible for S.S. I. assistance, call the Social Security Administration office.
- For self-help groups. **See page 34**



Where To Find Help

Local Phone Numbers

Social Security Administration
Vocational Rehabilitation

(601) 965-5377
(601) 853-5100



Alcohol and Drug

Many people use some kind of drug. It could be tobacco or alcohol, a prescribed medicine or an illegal drug. Regular use of many kinds of drugs can lead to addiction.

The first step towards healing is to admit that you have a problem and need to make a change. Then you need to find help. Ask a health care provider or counselor who knows about addiction. Drug treatment programs offer chances to start living without alcohol or drug; support groups can help you stay off them.



Things You Can Do

For help with a Drug Problem

- Realize that you are not alone
- There are many people like you.
- Find out about support groups. **See page 32.**
- Seek counseling or a drug treatment program
- Be patient. Recovery takes time.

Tobacco is also a health hazard. Quitting is hard, but not impossible.



Where To Find Help

Local Phone Numbers

ACT Tobacco Center	(601) 815-1181
Baptist Behavioral Health Services	(601) 968-1102
Brentwood Behavioral Health	(601) 936-2024
St. Dominic Chemical Dependency Treatment Center	(601) 200-3090



Violence and Abuse

There are many types of violence and abuse. They include:

- Domestic violence
- Child abuse
- Neighborhood Violence
- Abuse in a Nursing Home or at Work

Things You Can Do

If you are attacked

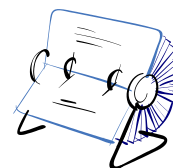
- Go to a safe place
- Call 9-1-1.
- For a place to stay, call an emergency shelter.
- For general help, find a counselor
- To report child abuse or elder abuse, contact the Department of

Where To Find Help

Local Phone Numbers

(DHS) Child Abuse Hotline

(601) 359-4991



Growing Older

Care For the Elderly

Growing older can bring happiness and satisfaction, but can also be difficult. You may be living alone, just when you are having trouble taking care of yourself. You may have health or money problems. There are many Community Services that the elderly may need at this time in their lives. They range from medical care, prescription assistance, financial planning, legal services, and other senior services. The Aging and Adult Services agency can assist seniors



Things You Can Do

- Work to maintain a healthy lifestyle, by eating right and staying active.
- Get financial advice. Try to save money.
- Contact the local senior service agency for help with resources, such as food, clothing, shelter, utilities, etc.
- To get help applying for Social Security, Medicare or Medicaid.
- To get help paying for prescriptions.
- To get information about home care, senior housing, and live- in facilities, such as personal care homes or nursing homes.
- Protect Your Wishes about medical care.
- Have a 'Durable Power of Attorney for Health Care'
- Have a will stating where you want your property to go.

Where To Find Help

Local Phone Numbers

Deliver Me (Senior Support Services)	(601) 354-4646
Social Security Administration	(601) 965-5377
City of Jackson Senior Services	(601) 960-0454
Medicaid	(601) 961-4361
Medicare	(601) 965-6273
Aging and Adult Services	(601) 359-4929



JHS Network Providers

The JHS Network Providers are a group of health care providers who have agreed to see Jackson Heart Study participants who do not have a regular source of health care and need treatment for abnormal JHS examination results. The JHS Social Worker can assist you to select a provider and to obtain affordable health care. This list is constantly updated, so make sure to contact the JHS Social Worker for assistance in obtaining a referral.

Internal Medicine

Arhin Akwasi, M.D.	500 W. County Line Rd. Tougaloo, MS 39174 (601) 957-6776
Natalie Brookins- Reddix, M. D.	5903 Ridgewood Rd. Suite 310 Jackson, MS 39211 (601) 899-3310
Zina Lee, M.D.	5429 Robinson Rd Ext. Jackson, MS 39204 (601) 914-0163
Maurice McShan, M.D.	5908 Ridgewood Rd. Jackson, MS 39211 (601) 899-3310
Denzel Robertson, M. D.	1134 Winter St. Jackson, MS 39204 (601) 948-5572
Adesola Shekoni, M.D.	5160 Galaxie Drive Jackson, MS 39206 (601) 713-0890
Nurudeen Shekoni, M.D.	5160 Galaxie Drive Jackson, MS 39206 (601) 713-0890
Robert Smith, M.D.	1134 Winter St. Jackson, MS 39204 (601) 948-5572

Rosie Walker- McNair, M.D.

1600 N. State St.
Suite #301
Jackson, MS 39202
(601) 352-3440

Indira Veerisetty, M.D.

12 Professional Pkwy
Ridgeland, MS 39157
(601) 856-2460

Family Practice

Hursie Davis-Sullivan, M.D.

1814 Hospital Drive
Jackson, MS 39204
(601) 373-2940

Shunda Garner, M.D.

187 Doctor's Drive
Pearl, MS 39208
(601) 939-8921

Don Gibson, M.D.

811 Hwy 49 S.
Richland, MS 39218
(601) 932-5060

Wesley Granger, M.D.

12 Professional Pkwy
Ridgeland, MS 39157
(601) 856-2460

Samuel Okoye, M.D.

4304 Hwy. 80 W.
Jackson, MS 39209
(601) 922-4722

Joyce Olutade, M.D.

1815 Hospital Drive
Jackson, MS 39204
(601) 815-5700

Andrea Phillips, M.D.	909 Westland Service Drive Jackson, MS 39202 (601) 948-8501
Earnest Rankin, M. D.	2570 Bailey Ave. Suite F Jackson, MS 39213 (601) 366-1693
David D. Richardson, M.D.	1551 E. County Line Rd. Jackson, MS 39211 (601) 957-2273
Selika Sweet, M.D.	4635 Hwy 80 E Pearl, MS 39208 (601) 936-3833
Cassandra Thomas, M.D.	514C E. Woodrow Wilson Jackson, MS 39216 (601) 981-7198

General Practice

Oliver Cunnigen, M.D.	1134 Winter St. Jackson, MS 39204 (601) 948-5572
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Specialty Clinics

Cardiology

Myrna Alexander, M.D.	971 Lakeland Dr., Suite 850 Jackson, MS 39216 (601) 981-8543
Tellis Ellis, M.D.	971 Lakeland Dr., Suite 850 Jackson, Ms 39216 (601) 981-8543
Richard Rayford, M.D.	971 Lakeland Dr., Suite 850 Jackson, Ms 39216 (601) 981-8543

Malcolm Taylor, M.D.

971 Lakeland Dr., Suite 850
Jackson, MS 39216
(601) 981-8543

Gastroenterology

Mark Wilson, M.D.

1421 North State St. Ste. 203
Jackson, MS 39202
(601) 355-1234

Nephrology

Gary Davis, M.D.

5903 Ridgewood Rd, Ste 340
Jackson, MS 39211
(601) 899-3340

Hollye Johnson, M.D.

5903 Ridgewood Rd, Ste.340
Jackson, MS 39211
(601) 899-3340

Tunde Olutade, M.D.

5903 Ridgewood Rd, Ste 340
Jackson, MS 39211
(601) 899-3340

Podiatry

Willie James Lewis, DPM

128 Poindexter St.
Jackson, MS 39203
(601) 355-0026

Robert Woodruff, DPM

3855 Azalea Drive
Jackson, MS 39206
(601) 366-7063

Pulmonary

Obie McNair, M.D.

1134 Winter St.
Jackson, MS 39204
(601) 948-5572

Joyce Wade, M.D.

1151 N. State St. #301
Jackson, MS 39202
(601) 352-0041

Urology

Ronald Davis, M.D.

971 Lakeland Drive, Ste. 315
Jackson, MS 39216
(601) 982-0982

Lionel Frasier, M.D.

971 Lakeland Drive, Ste. 315
Jackson, MS 39216
(601) 982-0982

Felix Gordon, M. D.

971 Lakeland Drive, Ste. 315
Jackson, MS 39216
(601) 982-0982

Community Healthcare Resources

Resources in Hinds County for the Uninsured

Health Care Referrals for uninsured/underinsured participants, who are residents of Hinds County, are made to the Hinds County Health Alliance (HCHA). The HCHA located at the Jackson Medical Mall, is a nonprofit organization that assists Hinds county residents obtain health care. The Hinds County Health Alliance coordinates care services that include: 1) primary care at a discounted cost, 2) prescription drug assistance, 3) transportation assistance, and 4) case management. The address and phone number is:

Hinds County Health Alliance

350 W. Woodrow Wilson, Suite 615
Jackson, MS 39213
(601) 362-3010

Jackson Hinds Comprehensive Health Center

3502 W. Northside Drive
Jackson, MS 39213
(601) 362-5321

UMC Adult Medicine Clinic

Jackson Medical Mall
350 W. Woodrow Wilson Blvd.
Jackson, MS 39213
(601) 815-1420

Hinds County Health Department

350 W. Woodrow Wilson Drive, Suite 411-A
Jackson, MS 39213
(601) 364-2666

Healthcare Resources in Madison County for the Uninsured

Health Care Referrals for uninsured/ under-insured participants who are residents of Madison County are made to G.A. Carmichael Clinic located in Canton. The type of assistance offered includes: medical, dental and eye exams, pharmacy, lab work, WIC, diabetic foot care, immunization, medical screening, and transportation. The address and phone number is:

G.A. Carmichael Clinic

1668 Peace St.
Canton, MS 39046
(601) 859-5213

Madison County Health Department

317 N. Union Street
Canton, MS 39046
(601) 859-3316

*Healthcare Resources in Rankin County for the Uninsured***Family Health Care Clinic**

4635 E Hwy 80
Pearl, MS 39208
(601) 933-2500

Family Health Care Clinic

1551 W. Government St.
Brandon, MS 39042
(601) 825-3163

Rankin County Health Department

100 Tamberlin St.
Brandon, MS 39042
(601) 825-2141

HEALTH ASSOCIATIONS

Alzheimer's Association
601-987-0020

American Cancer Society
601-362-8874

American Diabetes Association
888-342-2383

American Heart Association
601-321-1200

American Lung Association
601-362-5453

American Parkinson's Disease Association
800-223-2732

American Red Cross
601-353-5442

Arthritis Foundation, MS Chapter
601-853-7556

Diabetes Foundation of MS, Inc.
601-957-7878

Epilepsy Foundation of MS
601-936-5222

Lupus Foundation of America
601-366-5655

Muscular Dystrophy Association
601-420-2027

Community Support Services

Catholic Charities 601-355-8634
Mon. – Fri. 8:30 a.m. – 5:00 p.m.
Services include: homemaker and
caregiver services.

Department of Human Services
601-362-9892
477 Medgar Evers Blvd.
Jackson, MS 39213
Services provided: public assistance

Clinton Community Christian Corporation

601-924-9436
Services Provided: Group Meals, Home
Delivered Meals, Transportation
Meal Site: 2001 Northside Dr., Clinton

Deliver Me Senior Support Services

601-354-4646
Services Provided: Financial Assistance for
medicine, eyeglasses, food, etc.

Madison County Meals on Wheels

601-859-5747
Service provided: Meal delivery to seniors

HOSPITALS

Hinds County

Baptist Medical Center
1225 North State St.
Jackson, MS 39202-2002
601-968-1000

St. Dominic
969 Lakeland Drive
Jackson, MS 39216
601-200-2000

Central MS Medical Center
1850 Chadwick Drive
Jackson, MS 39204
601-376-1000

University Medical Center
2500 N. State Street
Jackson, MS 39216
601-984-1000

River Oaks Hospital
1030 River Oaks Drive
Jackson, MS 39208
601-932-1030

Women's Hospital At River Oaks
1026 Flowood Drive
Jackson, MS 39232
601-932-1000

Madison County

Madison County Medical Center
Hwy 16 East
Canton, MS 39046
601-898-4049

Rankin County

Rankin Medical Center
350 Crossgates Blvd.
Brandon, MS 39042
601-825-2811

SUPPORT GROUPS

Alzheimer's Support Groups

University Medical Center Alzheimer's Support Group
601-815-2808

VA Hospital Alzheimer's Support Group
601-362-4471 ext. 11038

Cancer Support Groups

Cancer Masters First Baptist Church
601-949-1949 or 601-939-7251

Central MS Medical Center
601-376-1172

C.O.P.E (Cancer Outreach Provides Empathy)
Methodist Medical Center
601-376-1163

MS Baptist Medical Center Support Groups
601-973-1583

St. Dominic Cancer Support Group
601-200-3070

Caregiver Support Groups

Baptist Adult Day Care
601-956-7794

St. Dominic Caregivers Support Group
601-200-6768

Grief Support Groups

Bereavement Education/ Support Group
Hospice Ministries 601-989-1053

Healing Hearts
First Baptist Church 601-949-1907

St. Dominic Behavioral Health Services
601-200-3110

Literacy Support Groups

Jackson Program For Adult Readers
601-987-3695

Reading Help Program K-12
601-981-359-3778

Stroke Support Groups

Stroke Support Group
Methodist Rehabilitation Center
601-981-2611

Self Help Groups

Alcoholics Anonymous
(601- 982-0081

Overeaters Anonymous
601- 957-0321

Narcotics Anonymous
601- 949-9499

Prescription Resource Information

The Medicare Discount Card (1-800-633-4227) is only one of a number of programs available to help Medicare beneficiaries receive discounts on the price of their prescription drugs. Other Drug Discount Cards may be used as well.

Some of the other Discount Drug Cards are:

- | | |
|--|----------------|
| ● Share Card (Pfizer) | 1-800-717-6005 |
| ● Lilly Answers Card (Lilly) | 1-877-795-4559 |
| ● Care Card (Novartis) | 1-866-974-2273 |
| ● Orange Card (GlaxoSmithKline) | 1-888-672-6436 |
| ● The Merck Assistance Program | 1-800-727-5400 |
| ● The Nordisk Patient Assistance Program | 1-800-727-6500 |
| ● Bayer Patient Assistance Program | 1-800-998-9180 |

Discount Drug Cards to help the uninsured/underinsured are:

- Partnership for Prescription Assistance 1-888-477-2669
- Together RX Access Program 1-800-444-4106
- My Free Medicines 1-800-620-7620

In addition, there are some web sites dedicated to helping patients in getting the medicines they need. Some of those web sites are:

- www.pparx.org
- www.HelpingPatients.org
- www.rxassist.org
- www.rxhope.com
- www.benefitscheckuprx.org
- www.needymeds.com
- www.Qdrug.com
- www.themedicineprogram.com
- www.resourcesforseniors.com/prescript.html
- www.myfreemedicine.com
- www.together-rx.com

JHS participants can work with their health care provider and local pharmacies to determine which discount drug card best suits their needs.

Acknowledgements

This Wellness Guide was adapted from the Wellness Guide Project, School of Public Health, University of California at Berkeley, Berkeley, California.