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BOGALUSA HEART STUDY

POST HIGH SCHOOL STUDY

Z510

1995-1996

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I. INTRODUCTION

The Bogalusa Heart Study has been collecting information on cardiovascular disease risk factor variables in a biracial population since 1972. Although data collection began in children only, the Post High School Studies examine the transition of risk factor variables from childhood into the adult years. Since cardiovascular risk factor variables change over time, documentation during early adulthood is important for later correlation with cardiovascular events as they develop.

The general purpose of the present study is to examine cardiovascular risk factors in young adults 18-38 years of age.

A. Objectives

1. To describe over time the serum lipid levels, blood pressure levels, selected anthropometric measurements, and dietary intake pattern of those young adults who have left Bogalusa High School.
2. To determine if children remain fixed at a given percentile level for selected variables as they enter adulthood.
3. To observe the effects of an altered lifestyle upon the levels of selected risk factor variables.

B. Examination

The fifth risk factor screening survey of the Post High School Cohort began in 1995. This survey is conducted similarly to previous examinations. A small blood sample is obtained for lipid, lipoprotein, and insulin analyses in the Bogalusa Heart Study Office in Bogalusa, LA and sent to New Orleans for analysis on the Bogalusa Heart Study laboratory based in New Orleans, LA. An additional blood sample is taken for SMAC-20, including glucose, to be analyzed by LabCorp, Inc. Urinalysis, height, weight, waist circumference, skinfold measurements, and an electrocardiogram are also obtained. Following a rigid protocol, a series of nine blood pressure readings are taken as well as pulse rate. Information concerning medical and menstrual history is obtained through an interview by trained nurses. In addition, a Health Habits Questionnaire is administered to obtain information on cigarette smoking, alcohol consumption, oral contraceptive use, physical activity, and dietary habits. A letter is sent to the participant three or four weeks later informing the participant of any information potentially raising concern to staff physicians.

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II. SCREENING PROTOCOL

A. Random Assignment of Examiners

1. Examiners are assigned to the different stations in the following order:
   a) venipuncture - 2 examiners (1 centrifuge)
   b) menstrual history and medications - 1 examiner
   c) ECG - 2 examiners
   d) physical examination and ECG assistants – 2 examiners
   e) blood pressure - 3 examiners (2 mercury and 1 automatic)
   f) skinfolds - 1 examiner
   g) height and weight - 1 examiner
   h) urine - 1 examiner
   l) Health Habits Questionnaire - 1 examiner

2. Make a list of all examiners and the various stations. Check off the stations for which each examiner has been trained.

3. List each station on a separate sheet of paper. On each page list the examiners trained for that station in order of their code number.

4. Assign each examiner a random number from a random number table.

5. Assign the correct number of examiners to each station starting with the lowest random number.
6. Once an examiner has been assigned to a station avoid assigning the examiner to another station. If too many examiners have been eliminated from the list of examiners at a particular station then examiners can be assigned to more than one station. Only the examiner assigned to the centrifuge station cannot be assigned to another station.
7. Examiners stay at their assigned station for one week.

B. Venipuncture Protocol

1. General Information

Utilize four trained examiners (RN's) and four trained escorts. Each of the RN's and escorts should have received training in first aid and Cardio-Pulmonary Resuscitation.

Prepare for venipuncture as follows: Obtain data pack and participant from escort. Compare ID label on participant with label on data pack. Check that the color of the adult's wrist band and that of the data pack match. Seat adult on chair NEXT TO THE TABLE TOP with his left (or right -- depending on vein) arm in a comfortable position on the table top. Use cushions and step stools as necessary to adjust adult's position. Reassure

participant. Check the Blind Duplicates Table to determine if the examiner needs to draw blind duplicate samples from the examinee. (See BLIND DUPLICATES PROTOCOL).

Obtain the blood sample as follows: Reassure examinee. Apply tourniquet to the upper arm above the expected puncture site. Ask the examinee to make a tight fist with his hand (on same side blood is drawn). Gently tap antecubital space several times. Stroke veins or inner forearm, wrist to elbow, several times, and prep the skin with alcohol. Place Vacutainer in the Vacutube shield so that the tube label does not face the examiner. (This allows the examiner to observe the blood as it enters the tube). Insert the needles with the tip of the bevel down parallel to the vein in the left arm. Have examinee open fist.
Do NOT TWIST the tube after inserting the needle into the vein. Note: If a problem exists with the veins in the left arm, use the right arm. Make only two attempts. If it is not possible to obtain blood, note this on the inside front cover of the data pack under the

COMMENTS section, and also circle "Not Drawn". It is important to obtain the blood sample; if vein appears difficult after one attempt, please ask designated examiner to draw the blood.

If blood return is slow, use one of the following methods to obtain the blood sample:

(1) With a finger, gently tap the area over the needle several times;

(2) Lift up the tourniquet without releasing it;

(3) Ask the examinee to open and close his appropriate fist several times.

(4) Draw blood to completely fill two 7 ml red top tubes (or four 4 ml red top tubes for those with small veins). Place in rack.

(5) Obtain 2.5 ml lavender top tube and draw blood (tube will only fill halfway). Tube is gently inverted 2-3 times to mix blood with the EDTA.

(6) Obtain the 4.5 ml blue top tube and draw blood to fill completely. Tube is gently inverted 2-3 times to mix blood with the citrate and then placed in rack in ice water bath.

(7) If the adult is a twin, draw a 10 ml yellow top tube.* Gently invert tube 2-3 times to mix blood with ACD. Place tube in rack in a pan of cold water. (If veins are small, obtain 2 red top 4 ml tube and immediately transfer contents into a 10 ml yellow top tube).

(8) If the adult needs to have duplicate samples drawn, do so according to the BLIND DUPLICATE PROTOCOL. Release tourniquet when sufficient blood is obtained. Break the vacuum by pulling back on the collection tube. Do not withdraw the tube completely from the needle. Press the vein just above the needle to stop the blood flow. Remove the needle from the vein. Wipe

venipuncture site with alcohol sponge; apply pressure with dry gauze sponge over puncture site with 2-3 fingers. Elevate the examinee's arm straight above his head. On each tube of blood, place an ID label containing the adult's identification number, last and first name (in that order), the study number and the date. Place plain labels on all tubes except the second red top tube. Labels for the second red top tubes have a red stripe. The red stripe should be near the top of the tube.

NOTE: Write "NONFASTING" on the tube labels if applicable. Place a strip of scotch tape over each label to secure it. Place a Band-aid on the puncture site after the examinee's blood has stopped flowing from the venipuncture site. Record time blood sample was drawn. Complete requested information on SCHEDULE C instructions. On data pack inside front cover record the code number of the examiner who drew the sample and any comments. Needle is discarded into provided heavy plastic container. Escort leads the examinee to table for snack. Return the data pack to the escort. Clean the table top and prepare for the next examinee.

Repeat steps 4-9 for each adult. NOTE: The nurse designated for the Bogalusa lab MUST WRITE the time when the last venipuncture was completed on the Lab Screening List. After the last venipuncture, count all samples, and record number on Form. Clean venipuncture area. Discard pipettes, tubes and other sharp or breakable materials into heavy plastic container provided for needles. Discard paper and other materials into double-lined trash container, which are then put in a large plastic container for transfer. Take full containers to core-lipid laboratory in New Orleans for proper medical waste disposal.

2. Blind Duplicate Protocol

From the screening list, blind duplicates are identified in advance by the New Orleans staff. ID's are ordered as to haphazard sequence of arrival at the Bogalusa Heart Study Office. To each identified screenee assign a name (Last, First) from list of names provided by New Orleans staff. These names are randomly drawn from the New Orleans Telephone Directory. Randomly generated blind duplicate identification numbers can be referenced for each screenee in the master census file.

As those selected screenees come to the venipuncture station, attempt to draw duplicate samples of blood for the designated tube. If successful, on Table 1 write the code number of the examiner drawing the blood under the column labeled YES and next to the name of the appropriate participant. Do this for the serum and the plasma tubes.

Refer to Table 1 under the column headed ID On Tubes, to determine whether I or B appears in line with the participant's name. If a T appears, place the gum-backed label with the true ID of the first tube of blood drawn. If a B appears, place the label with the blind ID on the first tube of blood drawn.

If the true ID was placed on the first tube of blood drawn, place the blind ID on the second tube. Similarly, if the blind ID was placed on the first tube of blood drawn, place the true ID on the second tube.

Follow steps 2-3 for the next tube but refer to the column headed ID on Tubes.
If unsuccessful in drawing blind duplicate samples from the examinee, on the table write the code number of the venipuncture examiner under the column labeled NO and next to the name of the appropriate participant.

Do not be concerned if it is impossible to draw the required duplicates.

Note: The specific scheme for matching the randomly generated true ID numbers to the randomly generated blind duplicate ID numbers is available to selected personnel only.
NOTE- IF ONLY ONE BLOOD SAMPLE CAN BE DRAWN, PLACE THE TRUE ID ON

THIS SAMPLE

1. Enter the date. For example, May 5, 1996 as 05/05/96.

2. For each blind duplicate sample drawn, enter the true ID, true name, blind ID, and blind name under the appropriate column.

3. Under the column headed Duplicate Blood Drawn, write in the code number of the examiner who drew or attempted to draw the blind duplicate sample.

3. PROTOCOL - Blood Centrifugation

a. Preparations

1) Count samples and record numbers on Form B-10. Inspect the specimens for clotting. If clotted, place in refrigerator until ready for centrifugation. If samples have not clotted yet, place under a lighted lamp until clotted. All samples should be clotted approximately 1 - 1-1/2 hours after the time last venipuncture was completed.

2) Obtain printed labels for centrifuged specimen tubes from the office file. Each label has the screenee's name, ID number, the study number, and the date. There are four labels, one plain label which will be used for serum from the first red top tube, one red-striped label and one black-striped label for plasma from the 2nd red top tube and one blue-striped for plasma from the blue top tube. Write "NF" for NON-FASTING on labels when indicated on the lab screening list.

b. Plasma Samples (Blue Top Tube)

1) Use the International Portable Refrigerated Centrifuge (Model PR-2) with a multiple place horizontal head, multiple place trunnion carriers, and shields equipped with insertable rubber cushions; Ohaus Harvard trip balance scale; capillary pipettes; applicator sticks; scotch tape; tube labels from office file; tube racks; laboratory tables; chair for each examiner; timer; trash receptacle; paper towels; pens; 3 ml plastic tubes; the cold box containing the blood samples that are to be centrifuged.

2) Turn on compressor motor. On this centrifuge the compressor comes on when it is plugged in. Adjust temperature to 2-5@C by using temperature control and thermometer. Turn control to Hi for hot and Lo for cold.

3) Prepare for centrifuging in the refrigerated centrifuge as follows: Check that the shields have insert cushions. Balance the Ohaus Harvard trip balance scale according to standard laboratory procedures. Now place one COLD trunnion equipped with multiple shields on each of the two trays of the scale. Remove and discard stoppers. Beginning at the outermost shield, add one tube of blood to each shield of the trunnion. For an odd number of tubes, use a tube of water as a counter-balance to the tube of blood. Balance the shields with tubes by slowly adding drops of water BETWEEN the tube and the shield. Use capillary pipette or squeeze bottle to add these drops of water. Place in centrifuge racks (opposite each other) and repeat for all samples.

4) Centrifuge as follows: Place the balances shields in centrifuge racks opposite each other. Close centrifuge lid and secure latch. Set timer on centrifuge for 15 minutes. Slowly accelerate centrifuge until reaching 20 RPM on the gauge dial.

5) While centrifuging is in progress, discard cold bath and assemble the following equipment on the laboratory table: Scotch tape, tube labels with blue stripes, capillary pipettes, 3 ml plastic tube for each sample, rack for tubes, and a container for discarded red cells.

6) Automatic timer will turn centrifuge off after 15 minutes. Do not use fingers to stop the centrifuge. When centrifuge stops spinning, remove the blood sample tubes to an empty tube rack. If there is a delay in processing samples, place specimens in refrigerator to keep sure-seps from melting and contaminating specimens.

7) FIRST LABEL CHECK: Prepare an empty 3 ml plain plastic tube with matching gum label having a blue stripe near the top. Remove the top and place the empty tube in the front rack. Place one sample containing centrifuged blood into the front rack. Compare the labels for duplication of information (i.e., adult's identification number, last and first names, date, and "NF" for non-fasting if appropriate).

8) SECOND LABEL CHECK: Place suction bulb on larger end of a clean capillary pipette. Hold blood sample in hand and squeeze suction bulb to avoid bubbling air through the specimen. Gently suction plasma from above red cells with the pipette. In order not to disturb the red cells allow plasma to remain at least 2 mm above the cell layer. Do not apply excessive force in the suction or allow pipette tip to enter cell layer. **Attempt to collect all plasma that is free of red blood cells**. Place specimen in newly labeled tube by gently placing tip of pipette on inside of the tube and slowly releasing specimen into tube. Remove suction bulb from pipette and discard pipette. Securely replace the clean top previously removed from the tube.

9) THIRD LABEL CHECK: Compare labels on the tubes for duplication of information. Place plasma tube containing the blue-striped label into tube rack. If the child is in the special HDL-DNA marker study, save red cells and replace top, and

return sample to tube rack. If child is not in special HDL study, discard red cells and used tubes. Minimum Plasma = 1-1/2 cc - Less is QNS on B10 form.

10) Repeat steps 7-9 for each centrifuged sample. Count all samples and record number on Form B10. Keep plasma in the refrigerator until it is ready to be shipped to New Orleans.

c) First Serum Sample (First Red Top Tube with No Stripe on Label)

1) Use the International Centrifuge (Cat. No L110) with a multiple place horizontal head, multiple-place trunnion carriers, and shields equipped with insertable rubber cushions; Ohaus Harvard trip balance scale; wood applicator sticks; capillary pipettes; Scotch tape; sure-seps; dates tube labels from office file; tube racks; laboratory tables; chair for each examiner; timer; trash receptacle; paper towels; pens; 3 ml plastic tubes with preservative and antibacterial agent; Cold Pack Box number two containing the blood samples that are to be centrifuged.

2) When ready, remove samples from refrigerator and place on laboratory table. Remove stopper and discard. Take applicator stick and gently circle inside wall of tube to release the blood clot. Discard stick and return sample to rack.

3) Repeat step 2 for each sample of blood.

4) Prepare for centrifuging as follows: Check that the shields have insert cushions. Balance the Ohaus Harvard trip balance scale according to standard laboratory procedures. Now place one trunnion equipped with multiple shields on each of the two trays of the scale. Use like trunnions (e.g., triple rack) on each tray of the scale. Beginning at the outermost shield, add one tube of blood to each shield of the trunnion. For an odd number of tubes, use a tube of water as a counterbalance to the tube of blood. Place sure-seps on each 7 ml tube of blood. (Sure-seps cannot be used for 4 ml tubes). Balance the shields with tubes by slowly adding drops of water BETWEEN the tube and the shield. Use capillary pipette or squeeze bottle to add these drops of water.

5) Centrifuge as follows: Place the balanced shields in centrifuge racks opposite each other. Close centrifuge lid and secure latch. Plug in centrifuge. Turn gauge to number 11 on the gauge dial. Set office timer for 15 minutes.

6) While centrifuging is in progress, assemble the following equipment on laboratory table: Scotch tape, tube labels, capillary pipette, red top serum tube containing the preservative and antibacterial agent for each sample, rack for serum tubes.

7) After timer sounds, turn centrifuge to OFF position. Do not use fingers to stop the centrifuge. When centrifuge stops spinning, remove the blood sample tubes to the tube rack on the table. If there is a delay in processing samples, place specimens in refrigerator to keep sure-seps wax from melting and contaminating specimens.

8) FIRST LABEL CHECK: Prepare a 3 ml plastic tube containing preservative and antibacterial agent with matching gum label (no stripe on label) indicating first serum tube. Remove the top and place the tube in a second empty rack. Compare the two labels for duplication of information (i.e., child's identification number, last and first name, date, and "NF" for non-fasting if appropriate). If sure-seps and 7 ml tube have been used carefully pour serum into the clean, newly labeled tube with preservative and antibacterial agent. If a 4 ml tube has been used, obtain clean pipette and add suction bulb. Gently suction serum from above the clot with pipette, being careful not to disturb clot. Do not apply excessive suction or allow pipette tip to enter clot. Attempt to collect all serum that is free of red blood cells. Place serum in newly labeled tube by gently placing tip of pipette on inside of tube and slowly releasing serum into tube. Remove suction cap from pipette and discard pipette. Securely replace the clean top previously removed from the serum tube.

9) SECOND LABEL CHECK: Place suction bulb on larger end of a clean capillary pipette. Hold blood sample in hand and squeeze suction bulb to avoid bubbling air through the specimen. Gently suction plasma from above red cells with the pipette. In order not to disturb the red cells allow plasma to remain at least 2 mm above the cell layer. Do not apply excessive force in the suction or allow pipette tip to enter cell layer. Attempt to collect all plasma that is free of red blood cells. Place specimen in newly labeled tube by gently placing tip of pipette on inside of the tube and slowly releasing specimen into tube. Remove suction bulb from pipette and discard pipette. Securely replace the clean top previously removed from the tube.

10) THIRD LABEL CHECK: Compare labels on the tubes for duplication of information. Gently invert serum 2 to 3 times to mix with the preservative. If less than 1 ml of serum is extracted, take extra serum from around and under the clot. Place sample aside for re-centrifuging for 5 minutes once all extractions are completed if RBC's are present in sample. Re-extract serum and place in a plain 7 ml red top tube to avoid a double dose of Thimerosal. Use same label on second tube. Place serum tube in tube rack; discard clot and used tube. Minimum Plasma = 1 cc. Less is QNS on B100 form.

11) Repeat steps 8-10 for each centrifuged blood sample. Count serum samples and record on Form B10. Keep serum in refrigerator until it is ready to be shipped to New Orleans.

d) Second Serum Sample (Second Red Top Tube with Red-Striped Label)

1) Remove samples from refrigerator. Remove tubes from rack one at a time. Remove and discard stoppers. Take applicator stick and gently circle inside wall of tube to release the blood clot. Discard stick and return sample to rack. Continue until clots from all samples have been released.

2) Repeat steps 3-10 in part B, with these changes:

(a) Prepare two empty 3 ml plastic tubes, one with red-striped label and the second with a black-striped label.

(b) After centrifugation, using a clean pipette with suction bulb, gently suction serum. Place 2 ml serum in red labeled plastic tube and 1 + ml serum in black labeled plastic tube. Discard blood clots and tubes.

3) Repeat for each centrifuged blood sample. Count serum samples and record on Form B10. Keep serum in refrigerator until it is ready to be shipped to New Orleans.

4) Turn off centrifuge.

e) Daily Log

1) In a daily log, record the following information:
   (a) the number of first serum samples
   (b) the number of plasma samples
   (c) The number of second serum samples
   (d) the number of whole blood samples (green top)
   (e) the number of red cell samples
   (f) the number of twin samples
   (g) the study number
   (h) the date
   (i) the code number of the examiner

2) Remove samples from refrigerator and place in Cold Pack Boxes. Follow the instructions in Part B of the BLOOD TRANSPORTATION PROTOCOL.

3) Clean lab area. Check supplies. Notify designated RN if supplies need to be restocked. This completes the BLOOD CENTRIFUGATION PROTOCOL.

C. PROTOCOL - HEALTH HABITS QUESTIONNAIRE

General

The Health Habits Questionnaire is designed to be a self-administered questionnaire. The questionnaire will be administered to the post high school participants. It contains the following sections:
Additional Demographics - some basic information not collected or updated in the registry information.
Occupational/ Job Data - data on current occupation for those who **are** currently working.
Smoking History Section (Buff Cover) - focuses on each screenee's **cigarette** smoking history.
Alcohol History Section (Pink Cover) - focuses on each screenee's alcohol usage. The screenee should consult the beverage display if needed.
Physical Activity Section (Gold Cover) - contains questions
concerning amount and types of physical activity expended during the week.
Cook-Med1ey Scale - psycho-social questionnaire.

Social Support Sca1e - psycho-social questionnaire aimed at ascertaining degree of social networks and support.

For spouses who will be examined, only the smoking and alcohol questionnaires will be administered.

Questionnaire Administration: Placement in the Screening Flow

HHQ_I: contains demographic (form A), occupational (form B), smoking (form C), alcohol (form D), physical activity (form E), Spielberger (form F), and social support (form G) questionnaires. It is administered immediately after brunch. As young adults complete the brunch, they are requested to take their drink to the questionnaire booth and fill out the forms. The monitor will instruct the participant about filling out the questionnaires. Upon completion of the HHQI they are asked to raise their hands. The questionnaires will be placed into the designated "CONFIDENTIAL" box and participants will proceed to the Interview Station.

Introductory Procedures

The Health Habits Questionnaire is administered by trained Bogalusa Heart Study Staff members who are responsible for maintaining a quiet and confidential atmosphere. As each screenee reaches the questionnaire station, the staff member checks the name on the questionnaire label and on the screenee label, making sure the labels are the same. The staff member hands the screenee the first section of the questionnaire and a sharp pencil and is directed to a confidential booth.

Instructions to the Screenee

Instructions are given individually to each screenee as he/she reaches the Questionnaire Station and is handed the questionnaires. The monitor will briefly go through each questionnaire with the screenee to instruct the screenee about answering the questionnaire. Each screenee is told to read and answer every question to the best of his/her ability but NOT to consult or communicate in any way with other screenees. Each screenee is told to be sure to read the instructions at the beginning of each section of the questionnaire, to raise his/her hand if there is a problem. The screenee is told to raise his or her hand when finished. The monitor will then ask the participant to go through the questionnaire to make sure that everything is filled out as best as possible. The questionnaires are then placed into the designated box. Each screenee is also told to look at the beverage displays should they need to when answering the alcohol section.

Questions during administration

Screenees are instructed to raise their hand if a question arises while answering a questionnaire. The staff member in charge keeps a watchful eye for those questions. Questions should be answered as quietly and quickly as possible and in a nonjudgmental manner. A synonym list **is** provided for the staff member and should be used if a screenee has a problem understanding a word.

Timing

No strict time limits are set for any of the sections. If a screenee is unable to complete all sections of the questionnaire because of time constraints, the designated staff member should follow closing procedures according to protocol. The screenee is NOT allowed to return at another time to complete the remaining questionnaires. The screenee is NOT allowed to proceed to the next station unless he/she has finished at the Questionnaire Station; I.e., the screenee cannot be removed from the Questionnaire Station prematurely in order to proceed to other stations. If a screenee is unable to read, he/she should be asked to stop and turn in his/her questionnaire and proceed to the next station. This should be done in an unobtrusive and non-judgmental manner. The monitor should return the questionnaire along with the others for the week.

Closing the Questionnaire

As each screenee completes the Health Habits Questionnaires, the monitor asks the screenee to re-check the questionnaire for completeness. It is then placed into the Confidential Box. The staff member should thank the screenee, re-emphasize the confidentiality of the data and send the screenee to the next station.

Activities of the Field Staff

1. Use the following equipment:
   screening lists
   pencils (sharpened)
   1 to 2 tables
   confidential booths
   beverage displays (beer bottle, wine glass, shot glass, glass and beer can) placed on a table immediately in front of the seating area
   Example posters (Smoking, Type A, Nutrition)
2. Trained Bogalusa Heart Study staff members are designated to administer each questionnaire.
3. The monitor adheres to the following procedures in administering the questionnaire.
   a) The purpose of these questionnaires is to collect important information so that we can find out more about heart disease. It is vital that the monitor establishes a favorable atmosphere, stresses confidentiality, and develops a consistent approach to all individuals.
   b) As each screenee reaches the Questionnaire Station, the monitor checks the name on the questionnaire label and on the screenee label, making sure the labels are the same. The monitor directs the screenee to a confidential booth and gives him the questionnaire and a sharp pencil.
   c) Standard instructions are read to all of the screenees. They are told the following:
   "Thank you for participating in the Bogalusa Heart Study. Your participation is very important. We would like you to answer a few questionnaires. Each questionnaire is self- explanatory, but, if you have any questions, please raise your hand and we will be happy to answer your questions. Remember, all of your answers *to* these questionnaires are confidential. No one but you will know how you responded. Here is the first set of your questionnaires. Please read the

directions and answer all of the questions to the best of your ability."

d) INSTRUCT THE PARTICIPANT ON THE FOLLOWING POINTS:

For the smoking questionnaire, point out on the first page that participants should circle the number that corresponds to their current smoking status. If the participant smokes, they should fill in the corresponding box. Same for former smokers. All participants should fill in the second page as well.

For the physical activity questionnaire, point out that question # 7 should add up to approximately 24 hours. For the last page, if the participant does any activities listed, they should also fill in the amount per session,

OTHER COMMON PROBLEMS SHOULD BE NOTED AND DISCUSSED WITH THE NEW ORLEANS STAFF ON HOW THEY MAY BE HANDLED.

e) Upon completion of the questionnaires the monitor will ask the screenee to please re-check the questionnaires to make sure that they are complete. The questionnaires are placed in the CONFIDENTIAL box and the monitor thanks the screenee and directs her/him to the next station.

Activities of New Orleans Staff

1. Stamp the date(s) of examination on all pages.
2. Code the brand of cigarettes in the Smoking History Section.
3. Place each screenee's questionnaire in card order.
4. Proceed with data entry protocol.

SYNONYM LIST

1) activities - things to do
2) angry - mad
3) argue - disagree, tell somebody they are wrong
4) attitudes - the way you look at things
5) automatically - do something without even thinking about it
6) believe - think, accept
7) blame myself - think it's your fault
8) bored - tired of, not interested
9) bothers - disturbs, upsets, annoys
10) cheerful - happy
11) chew tobacco - chew a "plug;" tobacco you put into your mouth, chew and spit out
12) cigar - a dark brown or black cigarette
13) chosen - selected, picked
14) confidential - private, secret
15) control - power, to be in charge of
16) difficult - hard
17) easy-going - take it easy, laid back, calm
18) education - learning, amount of school
19) effect - work, trouble
20) expect - intend, plan, want
21) fidget - can't sit still
22) the following - what comes next
23) frightened - afraid, scared

24) hard-driving - hard-working, energetic, intense
25) hobbies - things you like to do in your free time
26) imagine - pretend, make-believe
27) immediately - right away, right now
28) important - outstanding
29) independent - on your own, don't need help
30) indicates - shows
31) interest - what I like to do, things I like to do
32) jigger - 1-1/2 ounces of liquor; shot glass
33) leader - head, person in charge
34) member - part
35) nervous - upset
36) obedient - mind, do what you are told
37) occasions - times
38) opinions - how you feel or think about things
39) pep - energy
40) prefer - want most
41) problem - difficulty
42) properly - in the right way, correctly
43) related - has something to do with
44) relaxation - rest, take it easy, playtime
45) remember - think back
46) resist - don't give in
47) responsible - in charge
48) rushed - in a hurry
49) satisfied - pleased
50) self-control - will power, make myself do what I need to do
51) snuff - sniff tobacco powder into your nose
52) solution - answer
53) solve - find answer, work out
54) sometimes - every now and then
55) statement - sentence
56) temper - mood, feeling quick-tempered, get mad easily
57) temptation - things you aren't supposed to do but want to do
58) tend - seem to
59) upset - unhappy
60) usually - most of the time, often, regularly
61) volunteer - offer; do things without getting paid
62) well-behaved - act like I'm supposed to

D. PROTOCOL - INTERVIEW: MENSTRUAL HISTORY

The interview is conducted by trained interviewers who, as professionals, maintain the privacy and confidentiality of the interview responses.

General

A. The interview has several advantages over other methods of data collection.
   1. No reading knowledge is required so it can be used with all segments of the population regardless of education.
   2. Misinterpretations of the questions are minimized since the interviewer can directly respond to points of confusion.

B. The key concept in this brief interview is communication. The interviewer must establish an atmosphere, which will maximize the participation of the respondent. It is very important that the interviewer be an understanding person, capable of accepting what the respondent says without judgment or rejection.

Introductory Procedures

A. Project a friendly personality.
   1. The respondent's first reaction is likely a mixture of curiosity and a desire to be courteous to a stranger — this reaction allows the interviewer time to demonstrate her friendly intentions and to describe the interview in such a. way that the respondent's further interest is stimulated.
   2. Often a smile, a comment about the weather or some other light non-controversial subject is helpful in creating the right atmosphere.

B. State the purpose of the interview.
   1. In your own words, explain that you will be asking some questions about her menstrual history.
   2. All of her answers will be related to heart disease. Some of her answers are necessary for interpreting the results from blood samples.

C. Emphasize the confidential nature of the interview.
   1. The information that is being collected will only be used for heart disease research.
   2. No one will know the answers that are given to the questions other than research staff members.
   3. Once the data are stored in the computer, the respondent's name and address are deleted and the results are filed with a special identification number. Only the New Orleans research staff will know to whom the identification numbers belong.
   4. Girls age 12 or above are interviewed about their menstrual history. This interview should be done without a parent present unless the child requests that a parent be present. Do NOT encourage the presence of a parent, since this will seriously decrease reliability of some answers.

D. Develop a good interviewing relationship.
   1. Create a permissive atmosphere in which the respondents feel completely free to express themselves. The interviewer in no way states her ideas, reactions, or preferences.
   2. Answer questions only if asked. Most people will go through the interview without

asking any questions.

3. Remember that you, as the interviewer, play two roles:
   a. The "technician" who applies standard techniques and uses the same instrument (interview).
   b. The human being who builds up a permissive and warm relationship.
4. Use probing techniques to help obtain complete answers.
   a. Be silent if the respondent has started to answer but appears to have more to say. Some people say "I don't know" in order to gain time to gather their thoughts. Silence and waiting is frequently the best probe for a "don't know.'
   b. Use neutral questions to obtain a clearer and fuller response — "How do you mean?" or "I'm not sure I understand your answer."
   c. If the respondent doesn't understand the question or strays from the subject, repeat the question.

Schedule C Interview

"I would like to talk to you about your menstrual history; this makes a difference in some of the blood tests we do."

A. Have a calendar readily available for reference, if needed.
B. Read each question out loud and record the answers according to Instructions Schedule C.
C. Complete questions 1 through 13.

Closing the Interview

A. Thank the respondent for participating and leave her with a feeling that the interview has been an interesting and worthwhile experience.
B. Reemphasize that all collected data are CONFIDENTIAL.
C. Continue interview with Schedule D according to protocol and instructions for Schedule D.

INSTRUCTIONS (Form) SCHEDULE C - MENSTRUAL HISTORY INTERVIEW

Label

A label with study number, ID number, and name is placed in the space marked "LABEL."

Menstrual History

Q1. Mark the appropriate answer. Explain the term menstrual period if needed. If the answer is [1] "No" stop and go on to Q9 (and Q10 if necessary). Stop at this point and close the interview. If the answer is [3] "Yes" go on to Q2.

Q2. Post Menarcheal Girls Only. Record in numerical form the month and year of the first menstrual period. Probing questions such as "Do you remember what grade you were in when you started having periods?" may help the respondent remember the date. If the date is unknown, code 9999 in the date field.

Q3. Mark the appropriate answer. If the answer is [1] "No" or [9] "Uncertain or Unknown," skip Q4 and go on to Q5. If the answer is [3] "Yes" go on to Q4.

Q4. Record in numerical form the month, day, and year of the first day of the respondent's last period. The first day is defined as the first day of bleeding. If the date is unknown, code 999999 in the date field.

Q5. Mark the appropriate answer. Explain "regulate your period" "hormones" Explain that this does not include "birth control pills." If the answer is [1] "No" or [9] "Uncertain or Unknown," skip Q6 and go on to Q7. If the answer is [3] "Yes" go on to Q6.

Q6. If the answer to Q5 is [3] "Yes," ask the brand name of the hormone. Write the brand name on the line and record the appropriate two digit code number that can be found on the brand name code sheet. If the respondent has trouble identifying the brand, open the pill notebook and have her flip through it. Ask the respondent if she recognizes the pills she is now taking. If she identifies the brand name, record both the brand name and the two digit code number that corresponds with that brand and go on to Q7. If the answer is uncertain or unknown, code 99 in the date field.

Q7. Mark the appropriate answer. If the answer is [1] "No," skip Q8 and go to Q9. If the answer is [3] "Yes," go to Q8.

Q8. Use the same instructions as for Q6.

Q9. Mark the appropriate answer and go on to QIO.

Q10. Mark the appropriate answer and go on to Q1I.

Q11. Mark the appropriate answer. If the answer is [1] "No" or [9] "Uncertain or Unknown," and the answer to Q3 is also "No," flag the datapack for amenorrhea and go on to Q12. If the answer to Q11 is [3] "Yes," close the interview.

Q12. Mark the appropriate answer and go on to Q13.

Q13. Ask the respondent how many months pregnant she is and record the number of months in a 2 digit format: 3 months will be "03". Close the interview.

Interviewer's Code

Write the three-digit identification code of the interviewer in the specified space. Thank the respondent and continue with the next schedule.

CODE NUMBER
ORAL CONTRACEPTIVE BRAND NAMES

19	Brevicon (21 or 28)
16	Clomiod - deleting
26	Demulen 1/35 (21 or 28)
30	Demulen 1/50 (21 or 28)
31	Enovid 5 mg
32	Enovid 10 mg
33	Enovid-E
34	Loestrin 1/20 (21 or FE)
35	Loestrin 1.5/30 (21 or FE)
02	Lo/Ovral
36	Micronor
03	Modicon (21 or 28)
13	Nordette (21 or 28)
04	Norinyl 1+35 (21 or 28)
05	Norinyl 1+50 (21 or 28)
06	Norinyl 1+80 (21 or 28)
09	Ortho-Novum 1/50 (21 or 28)
40	Ortho-Novum 1/80 (21 or 28)
25	Ortho-Novum 7/7/7 (21 or 28)
23	Ortho-Novum 10/11 (21 or 28)
08	Ortho-Novum 2 mg
10	Ovcon-35
15	Ovcon-50
11	Ovral
41	Ovrette
12	Ovulen (21 or 28)
42	Tri-Norinyl (21 or 28)
43	Triphasil (21 or 28)
44	Tri-Levlen (28)
99	Woman takes oral contraceptives but cannot figure out which one.

37 Norinyl 2 mg
07 Norlestrin 1/50 (21, 28 or FE)
38 Norlestrin 2.5/50 (21, 28 or FE)
39 Nor-Q.D.
17 Ortho-Novum 1/35 (21 or 28)

E. PROTOCOL – INTERVIEW: MEDICATION

The interview is conducted by trained interviewers who, as professionals, maintain the privacy and confidentiality of the interview responses.

General

A. The interview has several advantages over other methods of data collection.
   1. No reading knowledge is required so it can be used with all segments of the population regardless of education.
   2. Misinterpretations of the questions are minimized since the interviewer can directly respond to points of confusion.

B. The key concept in this brief interview is communication. The interviewer must establish an atmosphere, which will maximize the participation of the respondent. It is very important that the interviewer be an understanding person, capable of accepting what the respondent says without judgment or rejection.

Introductory Procedures

A. Project a friendly personality.
   1. The respondent's first reaction is likely a mixture of curiosity and a desire to be courteous to a stranger — this reaction allows the interviewer time to demonstrate her friendly intentions and to describe the interview in such a. way that the respondent's further interest is stimulated.
   2. Often a smile, a comment about the weather or some other light non-controversial subject is helpful in creating the right atmosphere.

B. State the purpose of the interview.
   1. In your own words, explain that you will be asking them some questions about their medication history.
   2. All of their answers will be related to heart disease. Some of their answers are necessary for interpreting the results from their blood samples.

C. Emphasize the confidential nature of the interview.
   1. The information that is being collected will only be used for heart disease research.
   2. No one will know the answers that are given to the questions other than research staff members.
   3. Once the data are stored in the computer, the respondent's name and address are deleted and the results are filed with a special identification number. Only the New Orleans research staff will know to whom the identification numbers belong.

D. Develop a good interviewing relationship.

1. Create a permissive atmosphere in which the respondents feel completely free to express themselves. The interviewer in no way states her ideas, reactions, or preferences.
2. Answer questions only if asked. Most people will go through the interview without asking any questions.
3. Remember that you, as the interviewer, play two roles:
   a. The "technician" who applies standard techniques and uses the same instrument (interview).
   b. The human being who builds up a permissive and warm relationship.
4. Use probing techniques to help obtain complete answers.
   a. Be silent if the respondent has started to answer but appears to have more to say. Some people say "I don't know" in order to gain time to gather their thoughts. Silence and waiting is frequently the best probe for a "don't know.'
   b. Use neutral questions to obtain a clearer and fuller response — "How do you mean?" or "I'm not sure I understand your answer."
   c. If the respondent doesn't understand the question or strays from the subject, repeat the question.

Schedule D Interview

"I would like to ask you some brief questions about medications and your medical history."

A. Read each question out loud and record the answers according to Instructions Schedule D.
B. Complete questions 1 through 15.

Closing the Interview

A. Thank the respondent for participating and leave her with a feeling that the interview has been an interesting and worthwhile experience.
B. Reemphasize that all collected data are CONFIDENTIAL.
C. Continue interview with Schedule D according to protocol and instructions for Schedule D.

INSTRUCTIONS (Form) SCHEDULE D INTERVIEW

Schedule D is completed by Bogalusa field staff at the time the interview is being conducted.

Medication/Medical History

Q1. Mark the appropriate answer. If the answer is [1] "No," or [9] "Uncertain or Unknown," skip Q2 and go on to Q3. If the answer is [3] "Yes," go on to Q2.
Q2. Mark the appropriate answer.
Q3. Mark the appropriate answer. If the answer is [3] "Yes," go on to Q4. NOTE: This question does not include birth control pills or insulin.
Q4. Write the hormone(s) the respondent is taking in the space provided.
Q5. Mark the appropriate answer. If [3] "Yes," go on to Q6.

Q6. Mark the appropriate answer. If the answer to "Other treatment, what kind?" is [3] "Yes," write what kind in the space provided. Be sure to mark either [1] "No" or [3] "Yes" for each of the six treatments indicated.

Q7. Mark the appropriate answer. If [3] "Yes," go on to Q8.

Q8. Mark the appropriate answer.

Q9. Mark the appropriate answer. If the answer is [3] "Yes," go on to Q10.

Q10. Write the name of the medication(s) taken in space provided.

Q11. Mark the appropriate answers. Be sure to mark either [1] "No," [3] "Yes," or [9] "Unknown" for each of the three medications indicated. Examples of androgens or anabolic agents commonly used by football players, weight lifters, body builders, etc., are DURABOLIN, ANADROL, WINSTROL, HISTERONE, AND TESTOSTERONE.

Q12. Mark the appropriate answer. If [3] "Yes," go on to Q13.

Q13. Ask the respondent what kind of serious illness he/she has had during the past year and write the response in the space provided.

Q14. Mark the appropriate answer.

Q15. Mark the appropriate answer. Close the interview.

I

Interviewer's Code

Write the three-digit identification code of the interviewer in the specified space. Thank the respondent and send them on to the next station.

CODE NUMBERS
OTHER HORMONES*

01	Pregesterone
02	Premarin
03	Prednisone
04	Depo-Estradiol
05	Ogen
06	Estradiol Valerate - 10 mg
07	Depo-Testosterone
08	Anabolic steroids (Anavar, Teslac, Winstrol)
09	Clomid
10	Decadron
11	Depo-Medrol
12	Depo-Provera
13	Micronor
14	Nor QD
15	Ovrette
16	Provera
99	Unknown or Uncertain

*Does not include insulin or birth control.

CODE NUMBERS
SERIOUS ILLNESS

01	Heart and Blood Vessels
02	High Blood Pressure

03 Kidney or Bladder
04 Gynecological (other than pregnancy)
05 Complications of Pregnancy
06 Infectious Disease
07 Lung Problems
08 Chronic Disease (other than above)
09 Orthopedic Injuries or Surgery
10 Ulcer
11 Diabetes
12 Gunshot or Knife Wounds
13 Mental Illness or Depression
14 Other Surgery
15 Accidents
16 Migraine Headaches
17 Seizures
18 Tumors, Cancer
99 Other (please flag)

F. PROTOCOL - ANTHROPOMETRICS

1. Height (Schedule E)
   - Use the Stadiometer portable height measure.
   - A trained examiner takes this measurement.
   - Ready the height measure by placing the instrument on a flat surface. Holding the base plate in this position, pull the sliding head plate so that there is enough room for a subject to stand on the base plate but under the white blade.
   - Have the subject stand erect facing forward with his heels, buttocks, and head firmly against the back of the Stadiometer. The subject's knees are locked, his chin is parallel to the floor, his eyes are looking forward and his hands are at his sides. The subject is barefoot or in stocking feet and must have hairstyle which does not interfere with the taking of the height measurement--e.g., no top knot.
   - Take the height measurement as follows: With the subject standing in the position described in step 6, slowly lower the sliding head plate so that it rests firmly on the center and top of the subject's head, compressing his hair.
   - Read the number at the top of the sliding head plate at the point where the metal rim of the plate slides along the scale. The observer's eyes are level with the red line to prevent paralax in reading the measurement.
   - Read the measurement to the nearest millimeter. Have the subject step away. Record the reading on Schedule C under HEIGHT in a four-digit format. For example, record a reading of 95.5 cm as 0 9 5 . 5.
   - Repeat the measurement as above a second time and record next to “Second Reading”.
2. WEIGHT (Schedule E)

Use the Detecto-Doctor's scale. Scale must be placed on a hard, level surface.

A trained examiner takes this measurement.

Have examinee stand still in the center of the scale with his arms hanging loosely at his sides. The subject is barefoot or in stocking feet.

Take weight measurement as follows: Stand on the opposite side of the scale and face the young adult. Set the balance indicators at the zero readings. Move the indicator that is closer to you to the left, placing the indicator in EACH 20 KILOGRAM NOTCH, until the balancing plate falls to the down position. Then move this indicator to the right by ONE 20 kilogram notch. The balancing plate now rests in the up position. If the balancing plate does not rest in the up position, return to step 3. If the bar does rest in the up position, adjust the indicator which is farther from you until the entire plate oscillates freely and is perfectly level, the black arrow on the left of the plate being level with the top of the white arrow in the balance plate housing.

Read the measurement on the lower beam to the nearest 20 kilograms; read the measurement on the farther indicator to the nearest 0.25 kilograms. Record these readings on Schedule E under WEIGHT to the left of First Reading in a five-digit format, rounding to the nearest even tenth of a kilogram unless the tenth kilogram position is .5. For example, record a reading of 41.25 kg as 4 0 + 0 1 . 2. In this format the number in the tenth kilogram position will be 0, 2, 5 or 8.

Ask the subject to step from the scale; return the indicators to zero reading. Plate now oscillates freely. This completes a weight measurement.

Repeat steps 3-6 but record next to "Second Reading."

3. Subscapular Skinfold (Schedule F)

All skinfold measurements are made by trained examiners using the Lange Skinfold Calipers (Cambridge Scientific Industries, Inc.). The examinee wears street clothing.

a. Have the subject stand with his back to the examiner.

b. Circle the proper entry in schedule F indicating which side was measured (the right side is preferable whenever possible).

c. With thumb and forefinger, pick up through the slit in the gown a skinfold immediately below the inferior angle of the right scapular in line with the natural cleavage lines of the skin (an approximate 45 degree angle with the long axis of the body).

d. Using the large calipers, measure the thickness of the skinfold one cm. below where the hand is holding the skinfold. Record the measurement on Schedule F (to the measurement on Schedule F (to the nearest millimeter) to the left of "First Reading" under "SUBSCAPULAR."

e. Repeat steps c & d but record next "Second Reading" under "SUBSCAPULAR."

f. Repeat steps c & d but record next to "Third Reading" under "SUBSCAPULAR"

4. Triceps Skinfold (Schedule F)
   a. The point of measurement is the cross at the midpoint on the backside of the right upper arm (preferably right arm) and circle the proper entry on Schedule F indicating which side was measured.
   b. Have the participant stand with his arm hanging loosely at his side and his right hand cupped in his left hand with the palm up and slightly closed (not a tight fist). With the thumb and forefinger of the left hand, grasp a skinfold parallel to the long axis of the right arm over the triceps muscle (back of arm, not side) and one centimeter below the midpoint mark. Feel the skinfold slide free of muscle. Compress the skinfold with your thumb and forefinger. Place the caliper prongs just above your fingers, at the point where the pen-marked lines intersect. At this point, the calipers are perpendicular to the arm length. Allow the pointer to stabilize. Read the measurement, remove the calipers, and record the measurement on Schedule F (to the nearest millimeter) to the left of "First Reading" under "TRICEPS."
   c. Repeat step b but record next to "Second Reading" under "TRICEPS."
   d. Repeat step b but record next to "Third Reading" under "TRICEPS."
   e. Check that three entries are made on Schedule F for triceps skinfold measurements.

Skinfold Caliper Adjustment Protocol

a. Once a month, test the accuracy of the Lange Calipers.
b. Use the gage block set (manufactured by L.S. Starrett Company, Athol, Massachusetts) with individual blocks measuring 5, 11 and 20 mm.
c. Measure each gage block with the Lange Caliper.
d. If the Lange Caliper scale reads 0.5 mm or more different from the actual measurement indicated on the gage block, the caliper should be readjusted.
e. For readjustment, notify the Bogalusa Heart Study Coordinator and send the Lange Caliper to:
Cambridge Scientific Industries, Inc.
Cambridge, Massachusetts
Specify in an accompanying letter the size of the gage block and the inaccurate caliper reading.

PROTOCOL - WAIST AND HIP MEASUREMENTS

WAIST CIRCUMFERENCE (SCHEDULE F)

The subject stands with feet together in a straight upright position with the arms abducted coronally at approximately a 30 ^{o} angle. A non-stretchable metal or plastic tape measure is used.

1. Description of Measurement

The circumference of the waist is at a level mid-way between the inferior border of the rib cage and the superior border of the iliac crests.

2. Method of Measurement

Place the measuring tape around the abdomen of the subject at a level mid-way between the inferior border of the rib cage and the superior border of the iliac crests. Making sure the tape is horizontal, reduce its diameter so that it touches the entire circumference of the abdomen but does not compress the tissue. With the subject's abdomen relaxed, locate the point on the tape where the zero endpoint aligns with the other end of the loop. Record that number in a four-digit format (XXX.X) to the nearest 1/10th centimeter on Schedule F - next to FIRST READING.
Repeat measurements and record next to SECOND READING.
Repeat measurements and record next to THIRD READING.

HIP CIRCUMFERENCE (SCHEDULE F)

1. Description of Measurement

The circumference of the hip is at the level of the greater trochanter.

2. Method of Measurement

Approaching from behind, palpate with each index finger the right and left trochanters of the femur. Slight movement of the leg will help feel the bony trochanter. If the subject is obese this especially requires moving each leg in turn so the examiner may locate the trochanter. At the level of the trochanter, horizontally encircle the hips with the tape measure. Reduce the diameter of the thus formed loop so that it touches the entire circumference of the hips but does not compress them. Locate the point at which the zero end of the measure aligns with the other end of the loop and record that number in a four-digit format (XXX.X) to the nearest 1/10th centimeter on Schedule F - next to FIRST READING.
Repeat measurement and record next to SECOND READING.
Repeat measurement and record next to THIRD READING.

G. PROTOCOL - RIGHT UPPER ARM LENGTH AND CIRCUMFERENCE (Schedule H)
All right upper arm length measurements are made by trained examiners using the GPM (Swiss made) anthropometric caliper while all right upper arm circumference measurements are made by trained examiners using a woven linen centimeter tape measure.

Right Upper Arm Length

1. The examinee stands with arms hanging loosely at his sides and with his right upper arm bare. While the participant's right upper arm remains against his body, lift his right forearm until his elbow makes a 90 degree angle.
2. While the participant's right arm is in position, place the metal tip of the anthropometric caliper at the top of the bony prominence in the shoulder (the acromion). Hold the caliper in place with one hand and with the other hand, guide the bottom tip of the caliper over the bony prominence of the elbow (the olecranon).
3. Slide the two caliper tips together gently but firmly. Read the measurement in the small window at the bottom slide bar of the caliper. Immediately record the measurement to the nearest 1/10th centimeter on each of the three copies of Schedule H next to the RIGHT UPPER ARM LENGTH.
4. Read the "midpoint chart" to determine the midpoint reading on the anthropometric caliper scale.
5. Using the caliper as a guide, mark a cross with a felt-tip pen of a clearly visible color at the midpoint on the back side of the upper arm. Make sure that this cross is made along the two midpoint planes parallel and perpendicular to the longitudinal axis of the right upper arm.
6. This completes the RIGHT UPPER ARM LENGTH measurement. The subject can now rest his arm. Note - If the measurement(s) cannot be taken on the examinee's right are (e.g., are in cast, an arm deformity, etc.), take the readings on the left arm but not this fact on each of the three copies of Schedule H next to ARM USED.

Right Upper Arm Circumference

1. The examinee stands with arm hanging loosely at his sides and with his right upper arm bare.
2. Place the tape measure on the examinee's right upper arm at the midpoint as marked during the right upper arm length measurement, so that it forms a circle, which touches but does not compress the right upper arm. Read the measurement and immediately record it to the nearest 1/10 centimeter on each of the three copies of Schedule H next to RIGHT UPPER ARM CIRCUMFERENCE.
3. This completes the Right Upper Arm Circumference measurement.

CUFF SELECTION (Schedule H)

1. Measure the right upper arm length and the right upper arm circumference according to the Right Upper Arm Length and Circumference Protocol.

2. Determine in Table 1 which circumference column contains the measured value of the circumference. Read down this column until it intersects the row containing the measured value of the length. Notice the one letter (T, M, A, L, or P), which appears at the area of intersection in Table 1 below.

TABLE 1
Permissible Cuff Size by Right Upper Arm Circumference and Length (in cm) for Use with the Mercury Sphygmomanometer

	Arm Circumference		
Length	26.4-	26.5 – 29.4	29.5+
21.4 -	T	T	M
21.5 – 27.4	M	M	A
27.5 – 31.4	M	A	A
31.5 +	M	A	L

3. On the four copies of Schedule H, next to CUFF SIZE SELECTED, circle the one letter determined in step 2.

4. Make sure that the size marked on the cuff is correct as indicated in Table 2. Notice that the dimensions refer to the bag (or bladder) within the cuff.

TABLE 2
Description of Cuffs Used with the Mercury Sphygmomanometer and Automatic Blood Pressure Measuring Instruments

Cuff	Instrument Baum (Mercury)	Dinamap (Automatic) [Selected Screenings]	Dimensions of Bag (cm)
T*	X		7.00 x 21.59
M	X		9.52 x 21.59
A	X		12.06 x 22.22
L**	X		15.2 x 33
P (hard)		X	
X (soft)		X	

*An "M" cuff modified by A.W. Voors

**Length may be slightly larger depending on the manufacturer of the "L" cuff.

5. This completes the Cuff Selection Protocol.

H. PROTOCOL- MERCURY SPHYGMOMANOMETER BLOOD PRESSURE (Schedule H)

All blood pressure measurements are made by trained examiners using the Baum mercury sphygmomanometer.

1. Use the correct sized cuff, one stethoscope with comfortable ear pieces, one desk lamp, one table, two chairs, seat cushions, and wooden blocks. Place the sphygmomanometer so that the mercury column faces the examiner with the meniscus of the mercury column at the general eye level of the examiner in order to avoid parallax. Arrange the desk lamp so that it lights the mercury column and numbers.
2. Seat the participant comfortably with his right upper arm exposed. -- The subject's forearm is supported on the table and is approximately at .the~ level of his heart. Use seat cushions for elevation if needed.
3. Note the designated CUFF SIZE SELECTION on Schedule H. The examiner circles the letter of the CUFF SIZE USED on Schedule H.
4. Take the blood pressure readings as follows*: Completely deflate the blood pressure cuff. Place the cuff firmly and <u>smoothly</u> around the examinee's right upper arm, with the lower margin approximately two centimeters above the antecubital space. With the inflatable rubber bag resting over the brachial artery, place the cuff tubing parallel to the brachial: artery with the center of the bag over the artery. Palpate the brachial artery. Close the screw valve and inflate the cuff until the radial pulse disappears. Disappearance of the radial pulse by palpation gives an estimate of the systolic blood pressure, i.e., the minimum pressure above which the examiner elevates the mercury level in subsequent measurements. Completely deflate the cuff. Apply the stethoscope bell (diaphragm) to the antecubital space over the brachial artery. Apply the stethoscope head firmly, but with as little pressure as possible and- with no air space between the skin and the stethoscope. The stethoscope head does not touch the clothing, cuff, or tubing. Holding the stethoscope in place, close the screw valve and raise the cuff pressure 20 to 30 mm Hg above the pressure at which the radial pulse disappeared. Adroitly release and close the screw valve allowing the pressure to fall at the rate of 2 to 5 mm Hg per second (release slower or faster as needed with pulse-rate to match Korotkoff sounds with falling mercury column).

   <u>IMPORTANT</u>: Auscultatory gap occasionally results in erroneously low systolic readings. Exclude this event by palpating for disappearance of the radial pulse.

   * Reference: Recommendations for Human Blood Pressure Determination by Sphygmomanometer, American Heart Association (1967)
5. Observe the Korotkoff sounds. Phase I of the Korotkoff sounds occurs as the FIRST APPEARANCE of the faint, clear pulse sound which gradually increases in intensity. Record this <u>FIRST</u> <u>AUDIBLE</u> <u>SOUND</u> as the systolic pressure. This sound becomes louder with a tapping noise proceeding through Phases II and III; the sounds are clearest and loudest in Phase-III. Phase IV occurs as the distinct abrupt change of quality evidenced by

the MUFFLING of the pulse sounds so that a soft, blowing is heard. Record this MUFFLING as Phase IV. This muffling sound ultimately disappears completely. The COMPLETE DISAPPEARANCE of the Korotkoff sounds, at the first point at which the pulse sounds disappear, is Phase V. Record the COMPLETE DISAPPEARANCE of the Korotkoff sounds as Phase V. Excessive stethoscope pressure may cause sounds to persist to 0 mm Hg (occasional exception, i.e., in aortic insufficiency). If sounds persist to 0 mm Hg, reduce the pressure on the stethoscope head over the brachial artery and repeat steps 5-6.

7. On the first measurement, record each of Phases I, IV, and V to the nearest even mm of Hg as a three-digit number on Schedule H, e.g., 0 9 2 / 0 7 2 - 0 6 8. IMPORTANT: If either Phase I or Phase IV is not detected, repeat steps 5-6. When a repeat reading is necessary at any point in determining Phases I, IV, or V, completely deflate the cuff, raise the arm and have the subject quickly make a fist and stretch his fingers 10 times before repeating steps 5 and 6. If Phase V is detected at 0, record this measurement as 000. Completely deflate the cuff. If difficulty arises in obtaining the blood pressure or if the examinee complains of arm pain, elevate the right arm and then return his/her arm to the original position.
8. Allow approximately 10-30 seconds for resting between blood pressure readings.
9. Repeat steps 5-7, but record next to SECOND READING.
10. Repeat steps 5-7, but record next to THIRD READING.
11. After recording three readings remove the cuff.
12. Designate on Schedule H which arm was used for the measurement (prefer right arm)
13. Record the examiner's code.
14. Direct the participant to the next station.
15. If the ears become tender, indicate to the Community Coordinator that another examiner is needed to operate this station.

PROTOCOL - PULSE RATE (Schedule H)

Each participant will have two radial pulse readings made by trained examiners.

1. The screenee should be seated and calm.
2. The right arm should be comfortably supported and examiner should then locate the radial pulse at the right wrist.
3. Count the pulse for 30 seconds and record this number on Schedule H-3 (Pulse Rate) in the space provided under FIRST READING.
4. After a 10 second wait, repeat the pulse count for another 30 second period and record this in the space provided under SECOND READING.

PROTOCOL - PULSE METRIC VASCULAR COMPLIANCE

PULSE METRIC TECHNICAL SUPPORT: (619) 546-0270

PURPOSE: This equipment consists of a Blood Pressure cuff attached to a Computer. It takes a blood pressure by the oscillometric method similar to an automatic blood pressure machine like a Dynamap. The data are stored in the computer and will be sent to the engineers at PulseMetric for analysis of vascular compliance (stiffness of vessels).

DATA COLLECTION:

1) Turn on computer and monitor. The C prompt will appear after a few seconds (this looks like c>).
2) The Dynapulse 2000A Main Menu screen will appear. “1. BLOOD PRESSURE MEASUREMENT & ANALYSIS” will be highlighted white. Press Enter to accept.
3) The Patient screen will appear. Use the up arrow to highlight “PATIENT” yellow and press Enter.
4) Hit F1=(Create/Search) and a box Will appear to enter ID#.
5) Enter 5 digit BHS ID# and Enter.
6) A box will appear to enter subject LAST NAME, FIRST NAME. Enter this information and hit Enter.
7) Back at the Patient screen use the down arrow to highlight “TEST MEASURE” and press Enter. A picture similar to a mercury sphygmomanometer will appear. You are now ready to collect data.
8) Select correct BP cuff according to BHS protocol as for sphygmomanometer BP. Place cuff on subject’s arm with arrow lined up over approximate location of brachial artery. The available sizes are Large Adult, Adult, Child.
9) “START” will be highlighted yellow. Press Enter to begin first ‘test’ BP measurement. Tell subject to relax.
10) If error message appears “INCREASE RANGE” the subject’s blood pressure falls outside of the preset limits of 180/50 mmHg. The message will then disappear and the sphygmomanometer screen will again be displayed. Use the down arrow to highlight yellow “ADJUST RANGE” and Enter.
11) To the top, right of the screen the word “FROM” will be highlighted yellow. Press Enter.
12) Use up or down arrows to highlight yellow the desired maximal BP as indicated by the Adjust Range error message and press Enter. The message “HIC~H RANGE EXCEEDING ___ SELECTED. ARE YOU SURE (Y/N)?” will appear. Press the letter Y.
13) If the lower limit for the diastolic BP is Ok (no error message regarding DBP appeared), use down arrow to highlight yellow the word “ESC” and press Enter
14) If the lower limit for DBP needs to be changed, use the down arrow to highlight yellow the word “TO” and Enter.
15) Use up or down arrows to highlight yellow the desired minimal DBP as indicated by the Adjust Range error message and press Enter.
16) Then, use down arrow to highlight yellow the word “ESC” and press Enter.

17) Use the up arrow to highlight yellow the word “START” and press Enter to begin the test measurement.
18) After the first test BP is taken, the ‘Heart Beat Pressure Wave’ display will appear. Note Measurement Time. This is the number of seconds read to the far right hand side on the top of the Heart Beat Pressure Wave display. This should be between 20 and 35 seconds. Record in datapack. If measurement time is correct, continue with protocol starting at number 24 below.
20) If Measurement Time Is <20 or >35 seconds, be sure that Test Measurement Is still highlighted yellow and press Enter.
21) Adjust white air flow control valve in appropriate direction:
    a) If >35 seconds, move valve 1/8-1/4 turn in “fast/shorter” direction (down).
    b) If <20 seconds, move valve 1/8-1/4 turn in “slow/longer” direction (up).
22) Start should still be highlighted yellow. Press Enter to begin second ‘test’ BP measurement. Note Measurement Time. Record in datapack. If measurement time is between 20 and 35 seconds, continue with protocol starting at number 24 below.
23) If measurement time is still not between 20 and 35 seconds, adjust air flow control valve as in number 13 and perform third test measurement. Record in datapack. If measurement time is correct, continue with protocol starting at number 24 below. If measurement time is still not correct after third test measurement. Thank subject for participation and conclude the study.
24) Once measurement time is between 20 and 35 seconds, use Down Arrow to highlight yellow “Auto Measure” and press Enter. (It should be noted that none of the ‘test measurements’ are stored in the computer.
25) “Go” will be highlighted yellow. Have subject raise arm and squeeze fist a few times. Then, tell subject to relax and press Enter to begin measurement. Three BP measurements will be performed and saved in the computer automatically, one minute apart. Have subject raise arm and squeeze fist between measures as per usual protocol. Watch the clock counting down the seconds between measurements so you can Instruct subject to relax as it nears 0 seconds and is about to begin the next BP measurement.
26) At the conclusion of each of the three BP measurements, note the following results and record in the datapack: SYSTOLIC BP, DIASTOLIC BP, MEAN BP, TIME RECORDED.
27) At the conclusion of the third measurement, disconnect subject. If screen does not automatically flip back to patient screen, use the up arrow to highlight yellow the word Patient and press Enter. You are now ready to enter data on the next patient. Go back to number 5.
28) At the conclusion of screening, from the patient information screen, use down arrow to highlight “Quit” yellow and Enter.
29) The message “Do you really want to quit? (y/n)” appears. Hit the letter Y.
30) From the main menu, use the down arrow to highlight “3. Exit to DOS” white and Enter.
31) The message “Do you really want to quit? Type “y” or “n” appears. Type the letter Y.
32) You will now be back at the ‘c prompt’ (c:\>). Turn off the computer and monitor.

MANAGEMENT UTILITIES (PulseMetric):

Management utilities menu can be accessed from main menu by highlighting white "2. MANAGEMENT UTILITIES" and pressing Enter. The following eight choices are available:

1) CHANGE CONFIGURATION: This Is used to change the configuration Including COM port (now 4), printer, type monitor, etc.
2) CHANGE TIME & DATE: This Is used to change time and date if the CMOS (internal hard drive brain) goes down.
3) CHANGE DEFAULT DIRECTORY; This is used to change the directory where the data will be stored automatically. The default setting is a directory called "C:\dpdata."
4) DEFAULT INSTITUTIONAL INFO: This is used to change the name/address of the institution where studies are performed.
5) CHECK CALIBRATION: This is only used by the manufacturer for calibration by connection to a mercury sphygmomanometer.
6) MAKE BACKUP COPIES: This is used to copy flies from the hard drive to a floppy. Highlight all desired files and enter to copy.
7) CHECK DYNAPULSEICARDIOCOM1PORT: This gives you the COM & IRQ settings.
8) RETURN TO MAIN MENU.

I. PROTOCOL - URINE COLLECTION (Schedule G)

1. A trained examiner sends the screenee to the bathroom with a urine cup. The cup has a marked level indicating how much urine will be collected.
2. The examiner instructs the screenee to begin urinating and after urination has begun, to use the container to collect a mid-stream urine sample (about 1 oz or 30 ml).
3. The screenee is also instructed to place a paper cover on the cup and return it to the examiner. Subject's name is written on the cover to identify the sample.
4. A Bogalusa staff nurse transfers 5 ml of urine into a small plastic screw top with a Pasteur pipette.
5. The tube is identified with a label containing the study number (C410) and the screenee's ID printed on it. NOTE: The label is yellow-striped.
6. Add one drop of 5% sodium azide to each tube as a preservative.
7. Securely tighten screw top and chill sample at 1-5@C until ready for shipping (DO NOT FREEZE).
8. See Transportation Protocol for shipping instruction.
9. A trained technician then performs a dip stick test using the remaining urine.
10. Dip reagent end of test strip in fresh, well-mixed urine and remove immediately.
11. While removing test strip, run the edge of the strip against the rim of the urine container to remove excess urine.
12. Compare the reagent side of test areas with corresponding color charts at the times specified on the LABSTIX bottle, recording the results on the Schedule F.

13. Complete the items, COLOR, APPEARANCE, and DEBRIS on the bottom of Schedule F by circling the response that most closely describes the urine sample.

14. Discard remaining urine.

J. PROTOCOL - ECG

A. ECG Recording

1. The MacPC is always left connected to power module and turned on during screening. If turned off, it may lose the ECGs stored in memory. If left on and unused for a while, the screen will go blank to save power. Press the stop key. This key is third from the top on the extreme right hand side. It has a circle with a triangle inside of it. The message "Automatic time out. Continue?" Press the number under "YES." At the conclusion of the screening day, the ECG machine should be turned off and the Power Module should be turned on (to recharge overnight). The power module should be placed away from the patient leadwires (higher or lower shelf for instance) td avoid line frequency noise.

2. Attach electrodes to subject. (See Part B, "Application of Electrodes.")

3. Program the patient information.

   a. From Main Menu press the number 1 at top left of keyboard. Then press the Enter key which is a long key with an arrow pointing down with a left turn. You are, at the main menu when the top line says "Task", bottom line starts out "PatInfo." If the Main Menu is not already displayed, then press stop key.

   b. From Patient Last Name: Type last name and Enter. If the screen says "New Pt?" Select YES and Enter.

   c. From Patient First Name: Type first name and Enter.
   d. From Patient ID: Type ID# and Enter.
   e. From Referred By: Type BHS and Enter.
   f. From Location Number: Type 57 and Enter.
   g. From Room Number: Type ECG Recorder's Code and Enter
   h. From Pt >1 year of age: YES will already be displayed so just need to press Enter.
   i. From Age: Type Age in Years and Enter.
   i. From Height: Enter E measurement in iron as recorded on the ECG worksheet and Enter (See Part B, "Application of Electrodes.") NOTE: E point is measured in cm, therefore, it must be multiplied by ten before entered here. i.e.: 15cm = 150 mm).
   j. From Weight: Enter V6 measurement (in mm as above) as recorded on the ECG worksheet and Enter.
   k. From Sex: Press the number 2 for MALE or press the number 4 for

Female and Enter.

m. From Race: Make no entry, just press Enter.

n. From Medications: Make no entry, just press Enter. The Main Menu will reappear.

4. Record the 12 lead ECG.

a. Press the Record button on the top right hand corner of the MacPC. It is labeled 12. The words **Acquiring Data** will appear.

b. If the message “Bad lead V” or “Bad limb __” appears, correct the problem and then press the record button again. Alternatively, you may press the Record button a second time and the message “override” appears in the bottom right hand corner. If the ECG obtained with this method is unacceptable, check leads and re-record. Staple all ECGs obtained together and put in datapack. Copy only the ‘good’ one. The others will be deleted as described below, prior to transmission.

c. If after pressing the record button, the message “Press record to override gain decrease” appears, quickly press the record button to ensure that the ECG will be recorded on full standard.

d. After the ECG is recorded, the message **ECG Acquisition Complete** will appear, then **Analyzing ECG** then **printing reports.** The ECG will be printed.

e. After the ECG has printed, **Processing ECG for Storage** will appear then **ECG Storage Complete** Type Any Key to Continue will appear: If there is inadequate memory for storage a message to this effect will appear (“Insufficient memory, Delete ECG or continue”) and you will be given the option to delete an ECG or continue. If there is an ECG made in error that can be deleted, follow the directions for deletion and the newly performed ECG will then be saved. If no ECGs can be deleted, you must transmit saved ECGs (which will thereby erase them) and then REPEAT THE ECG being performed. If you choose to continue, NO ECGs will be saved.

f. Press any key to return to the Main Menu.

g. Disconnect the leads from the subject and wipe off the electrode jelly.

h. Have ECG assistant mark time ECG recorded on ECG worksheet.

i. Make a Xerox copy of the ECG (only the ‘good’ one if multiple ECG’s done) and place a copy in the “Transmitted ECG’s” envelope. Deliver to Dr. Urbina once a week. Place the original in the datapack.

5. Keep a record of number of ECG’s recorded.

a. When 10 ECG’s have been recorded. STOP. Transmit ECG’s to EPICARE CENTER (see 6. below). Then recording of ECG’s can be resumed. ECG’s will be erased if recorded over. Do not transmit until 10 ECG’s have been recorded (this may be every day or every other day).

b. If you do not remember how many ECG’s have been stored a summary can be performed or you can count how many Xeroxed ECG’s you have. Get to the Main Menu by pressing the Stop button.

c. From Main Menu: Press Shift Key and number 1 (Fl) to enter the "Tasks" functions.

d. From System Functions: Press the number 1 (Fl) "Storage."

e. From Storage Functions: Press the number 5 (F3) "Summary." A message will appear listing the number of ECGs stored in the upper left hand corner. Alternately, you can press the number 3 (F2) "Directory." The message **Printing Directory** will be displayed temporarily while the directory is being printed.

f. Type any Key to continue.

6. Delete unwanted ECG's.

a. From Main Menu: Press Shift Key and number 1 (Fl) to enter the "Tasks" functions.

b. From System Functions: Press the number 1 (Fl). "Storage."

c. From Storage Functions: Press the number 3 (F2) "Directory." The message **Printing Directory** will be displayed temporarily while the directory is being printed. Then the Storage Functions menu will be displayed again.

d. Compare Directory to ECG's performed to determine which ECG's to delete. If multiple ECG's were performed on one subject, note the time on the ECG strip of the study to be deleted.

e. From Storage Functions: Press the number 7 "Delete." Information on the first ECG in storage will appear. Press the number underneath the word "Expand."

f. Hit the number 9 "Continue."

g. Additional information on this ECG will be displayed including the time the ECG was recorded.

h. If this ECG is to be retained (saved) press the number 3 "Save." If this ECG is to be deleted, press the number under the word "Delete."

i. Repeat for each ECG in storage. When you have gone through all the ECG's, a message will appear "Delete (number) ECG's?" Press the number under the "Yes" if you are sure. If you believe an error has been made, press the number under the "No" to repeat the deletion process. Then press the "Enter" key.

j. The Storage Function menu will be displayed. From Storage Functions: Press the number 3 (F2) "Directory." The message **Printing Directory** will be displayed temporarily while the directory is being printed. Then the Storage Functions menu will be displayed again.

k. Proceed with transmission (or acquisition of more data).

7. Transmit ECG's to EPICAPE CENTER.

a. Connect the telephone cord from a telephone wall jack to the back panel jack on the MacPC. It is the only jack on the back of the machine that will take a phone cord.

b. From Main Menu: Press Shift Key and number 1 (Fl) 'to enter the "Tasks" functions:

c. From System Functions: Press the number 1 (Fl) “Storage.”
d. From Storage Functions: Press the number 3 (F2) “Directory.” The message **Printing Directory** will be displayed temporarily while the directory is being printed. Then the Storage Functions menu will be displayed again.
e. After the directory is printed, from Storage Functions:
f. Press the number 9 (F5) “More.”
g. From the second screen labeled Storage Functions:
Press the number 1 (Fl) “Transmit.”
h. From Transmission type: Press the number 1 (Fl) “Phone.”
i. From Phone Number: Type in the phone number 9107160837 and Enter.
j. Next, patient data on each stored ECG will be displayed. To transmit all stored ECG’s, press the number 7 (F4) “Yes,” to select all ECG’s for transmission.
l. The messages **Batch Transmission** “Waiting for dial tone” will appear, then “Dialing 9107160837,” then “Waiting for an Answer Tone,” then “9999ID# NAME.”
m. After the last ECG has been transmitted, a message indicating the number of ECG’s transmitted vs. the number you selected to transmit will be displayed (they should be equal). i.e. “10 of 10 transmitted.” Type any key to continue.
n. From Transmission type: Press the Stop button to return to the Main Menu.
o. Write on the directory that all the ECG’s were transmitted, initial, date and time and place the directory in an enveloped labeled “Transmitted ECG’s.” Deliver to Dr. Urbina once a week. Place the original in the datapack.

8. Paper Replacement
a. Press down on the paper lid release button which is the long black button in the middle of the MacPC, immediately to the right of where the paper comes out.
b. Lift the paper lid.
c. Remove the paper roller from the writer and place a new roll of paper on it.
d. Insert the paper roller ends into the slots provided, ensuring that the grid side of the paper is exposed and the paper feeds counterclockwise on the roller.
e. Press down on the paper lid until it snaps closed.
f. Store the thermal paper in a <u>Cool, Dark Location</u>.

B. <u>Application of Electrodes</u>

1. Prepping the Subject:
a. Subject should be undressed with a gown on. Women may leave their bra on loosely, however, application may be easier with bra removed.
b. Ask patient to lie down on the exam table. Obese subjects may be sitting for

electrode application if necessary. Place the Acquisition Module face up and right side up on their stomach being so that the letters LA are pointed towards the left arm and PA towards the right arm. If subject is sitting, have them hold Acquisition Module next to their abdomen in the position described above.

c. Observe the chest and determine approximate locations for electrodes. Never overlap electrodes. Do not move breast tissue, place electrodes in the locations indicated below, directly on breast tissue. However, if V4 location is on nipple, may move electrode slightly to one side to avoid irritating sensitive tissue. Subjects with large amounts of body hair in the area intended for electrode placement may have poor quality ECGs because coarse hair may interfere with electrode adhesion. If this occurs, gently hold the electrodes in place during recording of the ECG. Submit the best ECG obtained. Do not attempt to shave the individual. Do make a notation on the ECG “poor quality: excess body hair.”

d. Limb Lead Placement:

i) Place the sticky side of an electrode pad on a clean, dry, relatively hairless area on each limb.

ii) Connect the appropriate lead (LA,LL,RA,RL) to the electrode pad on that limb using the alligator clip. The leg leads should be placed on the inside of the calf, about halfway between the ankle and knee. The arm leads should be on the inner aspect of the arm above the wrist.

iii) If a limb or part of a limb is missing, apply to the upper arm, shoulder, thigh or hip.

e. Chest Lead Placement using the HEARTSQUARE:

i) Palpate the Sternal Angle. This is the bump formed by the junction of the Manubrium (top of sternum) and the main body of the Sternum. It is usually three finger breadths below the Supra Sternal Notch (see figure).

ii) Locate the Second Intercostal Space. This can be found by palpating the space below the sternal angle.

iii) March your fingers down each interspace until the Fourth Intercostal Space is located.

iv) Place the electrode for lead V1 in the fourth intercostal space to the right of the sternum. It should <u>not be on the sternum</u>.

v) Place the electrode for lead V2 in the fourth intercostal space to the left of the sternum. It should <u>not be on the sternum</u>.

vi) March your fingers down to the next space, the Fifth Intercostal Space.

vii) Place a small X with a magic marker at the center of the sternum at the level of the fifth intercostal space. This is the E position.

viii) Locate the Mid Axillary Line: Have the subject raise their arm. Observe the anterior and posterior axillary folds. Place a small vertical line at approximately the level of the E position and exactly half way in between the axillary folds at the mid axillary line.

ix) Place the Heartsquare firmly on the lower sternum at the B position. Verify that the E and V6 arms of the Heartsquare are exactly

horizontal.

x) Make a small horizontal mark intersecting the line drawn at the mid axillary line to mark the location for V6.

xi) Slide the V6 arm of the square so that the V6 arrow is pointing directly at the cross completed in step (x) above.

xii) Determine the V6 measurement to the nearest 0.5 cm from the Heartsquare by reading the number off of the V6 arm where it intersects the E arm. Give the V6 measurement to ECG assistant to record on ECG worksheet.

xiii) Determine the E measurement to the nearest 0.5cm by reading the number off of the E arm at the E position. Give B measurement to ECG assistant to record on ECG worksheet.

xiv) Identify the same number as the E measurement along the V6 arm and follow the corresponding 450 line to the chest. Place a small mark on the chest to indicate the position for V4.

xv) Remove the Heartsquare and place electrode pads on the V6 and V4 locations.

xvi) Place a pad on a line connecting V2 and V4 and exactly equidistant between them for the V3 lead.

xvii) Place a pad exactly equidistant between V4 and V6 on the same horizontal level (5th intercostals space) for the V5 lead.

xviii) Finish attaching the appropriate leads to the ECG pads using the alligator clips.

f. Subject Associated Problems:

i) Obesity may result in low voltage signals, difficulty in electrode placement or perspiration causing lead slippage. Observe tissue folds, place electrodes on top of folds, not in skin creases.

ii) Large breasted subjects may result in difficulty in lead placement, perspiration. A bra should be worn during the recording. Avoid overlapping the bra material on the electrode. DO NOT ATTEMPT TO MOVE THE BREAST. PLACE LEADS ON THE BREAST AT THE LOCATIONS SPECIFIED ABOVE. May place lead to one side if it falls on sensitive nipple tissue.

iii) Heavy perspiration may result in loss of electrodes and artifact may occur. Use alcohol or acetone to clean and degrease the skin. Let sites dry completely before electrodes are placed.

C. Maintenance

1. Cleaning

a. The MacPC may be cleaned with a soft cloth and a solution of mild dishwashing detergent diluted in water (1 part soap to 10 parts water). UNPLUG THE MACHINE BEFORE CLEANING. Do not get water in open vents, plugs, jacks or the keyboard. Wipe dry thoroughly.

b. The Heart Square should be cleaned between subjects

with the same dilute dish detergent solution.

2. Battery Maintenance
    a. Battery maintenance is TO BE PERFORMED ON THE FIRST DAY OF EVERY MONTH. This will prolong the life of the battery.
    b. Turn the MacPC off by pressing the On/Off button in the bottom right hand corner of the machine. It is the rectangular button with the black circle/white circle on it.
    c. Next, hold down both the letters D and B at the same time and press the On/Off key.
    d. The message "Battery Deep Cycle, Press any key to continue" will be displayed. Press any key.
    e. The message "Battery is ##50, Press On/Off to Stop" will appear. In a few hours when the LCL goes blank, the battery will be completely drained. If you must quit the procedure prior to completion, press the On/Off button.
    f. Recharge the unit for 14 hours by leaving it plugged in and of f and leaving the power module on.
    g. Write your initials and the date performed in the "Battery Maintenance Chart."

K. PROTOCOL - PHYSICAL EXAMINATION (Optional)

GENERAL INSTRUCTIONS

Physical Setting

The examining team maintains a quiet, cheerful atmosphere. The physician and the nurse wear ordinary street clothing (no uniforms or white coats).

Condition of Adult

The adult wears an examination gown, underpants, and socks.

Nurse's Responsibilities

The nurse receives and relaxes the adult, maintains a cheerful attitude, and records the information required on Physical Examination Schedule pages 1-5 and Schedule H: History and Physical Examination Checklist.

Examiner's Responsibilities

1. The examiner examines the adult carefully, following the Physical Examination Protocol.
2. The examiner reports his/her findings to the nurse who records them in the datapack.
3. The examiner determines if there are any significant findings on the physical exam requiring medical follow-up. If so, the chart is tagged and these findings can be discussed with the subject during checkout consultation if deemed serious and important. Ultimately, all such abnormalities will be included in the follow-up letter to the subject and their physician.

NURSE OR EXAMINER'S ASSISTANT

1. Use an examination table equipped with both a bottom sheet or paper

cover and a top sheet to cover the subject; use a small stool or stepladder to assist the adult in climbing onto the table.

2. Prepare the adult for examination as follows: Obtain the datapack from the examinee's escort. When the adult enters the examination room, close the door or curtain over the door and relax him with a few cheerful words. Introduce him to the examiner (physician, medical student, or physician's assistant). Check that the color of yarn on the adult's wrist and that of the datapack match. Instruct the adult to face the nurse and to sit in the middle of the examination table with his legs hanging over the side of the table. Place the top sheet on his lap so that it covers his knees and upper legs.
3. During the examination, proceed as follows: Scan the History Form for any abnormalities and inform the examiner of them. Record on the Physical Examination Form all information determined by the examiner. Assist the examiner in having adult change position. When the adult is supine, loosen his gown straps and cover him with the top sheet. When the adult is supine, loosen his gown straps and cover him with the top sheet. When the examiner begins the examination of the abdomen, gently roll the examination gown up to the shoulders and pull the top sheet to the neck.
4. Attempt to observe the organ systems being examined and recall subject matter on the examination forms as needed to assist examiner. DO NOT HESITATE TO REMIND EXAMINER OF OBSERVATIONS NOT COMPLETED. On the LEFT side of the Physical Examination schedule circle the appropriate column to indicate if organ being examined is normal (NOR), suspicious (SUS), abnormal (ABN) , unknown (UNK); or if a specific physical finding is not present (NO), present (YES) or unknown (UNK) . On the RIGHT side of the Physical Examination schedule circle the appropriate column to indicate if all of the entire organ system being examined is normal (NOR) . If any part is suspicious (SUS), abnormal (ABN), or unknown (UNK) then the appropriate selection should be circled. If there is an abnormal (ABN), and a suspicious (SUS) or unknown (UNK) then abnormal (ABN) should be circled.
5. When the examiner completes the examination, pull down the gown, retie the straps, and help the adult from the table.
6. Check that all items of Physical Examination Schedule pages 1 - 5, and Schedule H: History and Physical Examination checklist are completed before the adult leaves the room. The Physical Examination section of Schedule H should be

filled out by copying responses ("NOR,SUS,ABN,UNK") EXACTLY AS THEY ARE CODED ON THE Physical Examination Schedule pages 1-5.

7. Enter both the physician's and nurse's examiner code numbers on the inside front cover of the datapack.
8. Remind the examiner to note any abnormalities or observations needing further study. IT IS THE RESPONSIBILITY OF THE PHYSICIAN TO DETERMINE IF CHART SHOULD BE TAGGED FOR PHYSICAL EXAM ABNORMALITIES.
9. If the examiner observes abnormalities, both he/she and the nurse or examiner's assistant proceed as follows:
   A) Make no statement to alarm or even to alert the adult.
   B) Always be reassuring. Further studies handle such problems after proper notification.
   C) Help control conversation in all areas of the MRU/office as well as in the examining rooms.
   D) Act in a professional manner; be sympathetic, pleasant and stern when necessary.
10. Escort the adult to the examination room door; hand the datapack to the waiting escort. Instruct the escort to accompany the adult to the next station. This completes the Physical examination Protocol.

EXAMINER

General Instructions

The object of the physical examination is to provide a health service to the subject while making observations for the research program. Carefully examine the subject for physical signs of any active disease warranting further examination, study or treatment by a physician. Refer the subject to the private physician they designate or to the Washington-St. Tammany Charity Hospital (or other resource service with which the Bogalusa Heart Study field staff can act in assistance). Treatment forms no part of the program unless requested by the adult's physician. If requested, consultations and aid to the practicing physicians will be available in any manner that Bogalusa Heart Study field staff can provide. The Bogalusa Heart Study does not intend to interfere with the practice of medicine in the community or with the personal physician. The program is research-oriented with service offered for the adult's benefit. The examination should be brief, but thorough. Conversation in the presence of the adult is considerate, discreet, professional, light when possible and stern when needed.

Note on Schedule H - History and Physical Examination Checklist, near the bottom are the words: "Tag Chart for End of Day Review." IT IS THE RESPONSIBILITY OF THE PHYSICIAN TO DETERMINE IF CHART SHOULD BE TAGGED FOR PHYSICAL EXAM ABNORMALITIES. Such tagging of the data pack signifies the examiner feels it is necessary to

promptly notify the adult and his/her personal physician of a significant, previously unknown abnormality or worsening of a known condition that requires medical follow-up. Make a note (or have the RN or physician assistant make a note) near these words detailing type of abnormality for which the chart is being tagged and check the upper left-hand corner of the front of the datapack folder next to the word 'Physical.' Unless he deems it ABSOLUTELY NECESSARY, the examiner does NOT ALERT THE ADULT to any abnormalities and such notification should be done in a confidential manner during the check—out consultation with only the physician and subject present. When dental abnormalities are noted, charts are only tagged if judged to be severe. Charts are not tagged for obesity.

Specific Instructions - History

1. Ask subject if they have a past history of any significant medical illnesses. Instruct RN to mark appropriate response on Schedule H - History and Physical Examination Checklist. The physician must use discretion (and medical expertise) to decide what constitutes a 'significant' illness. This would include illnesses requiring hospitalization, emergency room visit, prolonged therapy or were of a chronic nature. Examples would be: pneumonia (either treated as inpatient or outpatient), hypertension, arthritis, surgery. Illnesses, not usually regarded as 'significant' would be coded as 'No.' Examples would include: the flu (unless hospitalized), colds, ear aches, sprained ankle etc.

   If the physician is uncertain whether stated illness qualifies as 'significant' or not, code number 9 'UNKNOWN' and have RN write name of illness above the words 'SIGNIFICANT PAST HISTORY OF DISEASE.
2. Ask the subject if they are currently taking any drugs. Instruct RN to mark appropriate response on Schedule H — History and Physical Examination Checklist. This includes prescription, non-prescription and illicit drugs.
3. Ask the subject if they are currently on any special diet. This includes diets prescribed by a physician or initiated without a physician's guidance.

*****Feel free to write in any clarifications next to the item.**

This will assist staff in New Orleans in deciding appropriate answer to keypunch.

Specific Instructions - Physical Exam

1. Use an examination table equipped with both a bottom sheet or paper cover and a top sheet to cover the subject; a stethoscope,

otoscope, flashlight (have extra fully-charged batteries readily available)

2. During the physical examination proceed as follows:

A) Head: Examine the skull for symmetry, bossing, and abnormal ridges.

B) Examine the hair and scalp for texture, alopecia, or active dermatological lesions.

C) Skin: Specifically inspect the skin for xanthomas, impetigo, active

D) staphylococcal infections, rashes or excoriations. Record presence or absence of acne by grading 1=none; up to grade S=severe (see Acne Grade Protocol). Look for vitamin A deficiencies, eczema, allergic reactions and significant scars.

C)Eyes: Examine the eyes for any abnormalities of the lids, palpebral and bulbar conjunctive, cornea, sclera and pupils. Note specifically the presence of xanthelasma. Note if strabismus present.

D)Ears: Examine ears for congenital abnormality or active disease, infectious or otherwise, involving the external ear, external auditory canal, or tympanic membrane.

E) Nose: Inspect nose for coryza, epistaxis, or evidence of upper respiratory infection.

F) Mouth and Throat: Examine mouth and throat for evidence of congenital anomalies or presence of active disease, infectious or otherwise (i.e. tonsillitis, pharyngitis, mouth ulcers, etc.). Inspect lips for cheilosis and tongue for lesions and evidence of thiamine deficiency.

G) Dental: Make a specific note regarding tooth decay. Note caries as absent, minimum, moderate or severe. To reduce time spent tagging charts, for ZS10, charts are not tagged for dental caries except for severe abnormalities (at the discretion of the examiner)

H) Neck: Inspect neck for muscle injury (torticollis) and flex it to test for rigidity. Palpate for masses, thyroid enlargement, thyroid nodules, or other abnormalities. Note the nodes: post- and anterior—cervical and submental. Auscultate for carotid bruits bilaterally.

I) Chest and Lungs: Inspect chest and rib cage for deformities of scapulae or clavicles, for pigeon breast, and for pectus excavatum. Note whether beading of the ribs or flaring of rib cage is present. Briefly examine lung fields and perform limited auscultation for rhonchi, rales, or rubs. If rales are heard, note this fact and describe them in the comments sections. Active disease such as asthma or bronchopneumonia is to be noted.

J) Abdomen: Palpate abdomen for organ enlargement, specifically of the liver, spleen, or kidneys. Make note of abnormal

masses or bruit. Note scars or presence of hernias. Palpate for femoral pulses and inguinal nodes.

K) Heart: Palpate precordium for presence of thrills and location of point of maximal impulse. Estimate cardiac size by percussion and palpation. Palpate for axillary and epitrochlear nodes. Perform auscultation over mitral, tricuspid, pulmonic and aortic areas and along right and left sternal borders. Note rhythm. Note any murmur by location and timing in the cardiac cycle. Note intensity, transmission and quality. Record any comments that might aid in diagnosis. Note femoral pulses as palpated under abdomen.

L) Nodes: Note any abnormality of lymph nodes as palpated in examinations above.

M) Extremities and Posture (Spine): Inspect posture and note if it is abnormal. Examine extremities for symmetry, positional orthopedic variations, clubbing of fingers and other lesions. Inspect palms noting abnormalities and note the symmetry of radial pulses.

N) Subjective Nutritional Appraisal: Make a subjective appraisal of nutritional status and have nurse record as normal, underweight, or 5, 10 or >20% over ideal body weight. To reduce time spent tagging charts, for ZS10, charts are not tagged for obesity except for severe abnormalities (at the discretion of the examiner)

PROTOCOL FOR ACNE GRADE (From Studies of School Children)**

**Pillsbury DM, Shelley B, & Kilgman AM - Dermatology, pp.807—810.

Grade 1: No acne

Grade 2: Sparse to profuse comedones with little or no inflammatory reaction.

Grade 3: Acne consisting of comedones and superficial pustular and inflammatory lesions at the follicular orifice. This process is ordinarily confined to the face. It does not produce significant scarring unless lesions are excoriated. Complete and spontaneous remissions ordinarily seen within one or two years.

Grade 4: Acne characterized by comedones, small pustules, and tendency to deeper inflamed lesions. These inflammatory nodules are not definitely related to follicular pore and apparently result from rupture of the sebaceous duct, with extrusion of sebum into skin tissue, and from inflammation caused by chemical and bacterial factors. The inflammatory lesions tend to be confined to face, neck, tops of shoulders and presternal regions.

Grade 5: Extensive secondarily infected cystic acne (acne conglobata). The face and neck may be severely involved, with extensive lesions on upper trunk. Some extension up into the scalp on the posterior neck may be noted. Coalescence of lesions occurs, with production of bogy canalized sinuses. The resulting scarring may be markedly distorting, with cork-like bands and hypertrophic ridges.