



DATA COLLECTION MANUAL OF PROCEDURES

April 2, 2011

Body Mass Index (BMI)

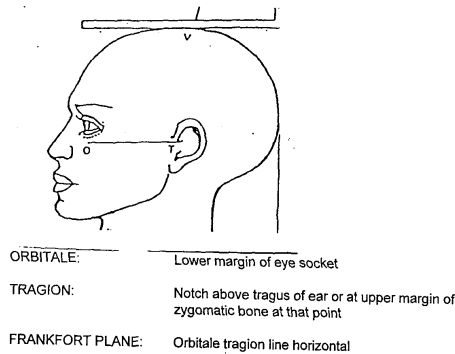
BMI is computed based on measurement of weight and height and represented as kg/m^2 . Procedures for measurement of height and weight are described here.

The following equipment and supplies are needed:

- Shorr Height board
- Tanita TBF-300A Body Composition Analyzer/Scale
- Gulick Tape Measure
- Extra rolls of tape for Tanita
- Plywood squares for Tanita/Seca
- Calculator
- Water soluble colored marker
- T-shirts in various sizes for participants to wear during measurement
- One 5-kg calibration weight for Tanita
- Low footstool
- Basket for emptying pockets and removing hand jewelry (for participants)
- Pens
- Privacy screens
- Appropriate number of data collection forms
- Calibration logs for Tanita scale
- Body Composition script
- Antibacterial wipes for Tanita
- Tape for Tanita explanation sheet
- Baby wipes for participants' feet
- Paper towels
- Pacemaker signs
- Clipboards
- Exam gloves

Height

The subject is to remove shoes for the measurement of height. The subject stands erect on the platform/floor with his/her back parallel to the vertical mounted measure scale, looking straight ahead with his/her head in the Frankfort horizontal plane (the horizontal plane is defined by the lower margin of the bony orbit - the bony socket containing the eye - and the most forward point in the supratragal notch - the notch just above the anterior cartilaginous projections of the external ear). The subject should be instructed to stand as straight as possible with feet flat on the floor. The horizontal measuring block is brought down snugly, but not tightly, on the top of the head. The subject's height is recorded to the nearest 0.1 cm. The subject is asked to step away. The measurer is to raise the measuring block and ask the subject to return and repeat measure. The average of two measurements that differ by ≤ 0.5 cm is used to represent the height. If these criteria are not met a third measurement is to be taken. All three measures are to be entered into the local database. Only the average of the three measures is included in the common database.



Weight (using the Tanita Body Fat Analyzer and Scale)

Clinical sites should maintain records of calibration, with calibration procedures following manufacturer recommendations and the use of known weights. Calibration procedures should be performed every time the scale is moved.

Procedure: Ideally, body weight is measured in the morning after voiding and before breakfast. If this is not possible, efforts should be made to weigh each subject under conditions as similar as possible on all visits (e.g., same time of day, fasting, limited consumption of fluids). Weight to the nearest 0.1 kg and percentage of body fat to the nearest 0.1% will be determined using an electronic scale. Participants will be barefoot and wearing the standard shorts and T-shirt provided by the study. Prior to taking the weight and body fat measurements, ask the participant if he/she has a Pace Maker or other electronic medical device. If the participant does, he/she cannot have his/her body fat measured. Instead, measure the participant's weight using the Weight Only function on the Tanita. The body fat measure will be recorded as 999.9 (reflecting missing data) on the Body Composition Data Collection Form. Make sure you make a note in the Comment section on the body comp form that you used the Weight Only feature of the Tanita to obtain the weight measurement and the reason why no body fat measurement was taken. Before the participant steps on the scale, have him/her wipe his/her feet with a baby wipe in order to get a good measurement.

- a. Have the Tanita scale set up on a flat and stable surface (on top of plywood square if floor is uneven) so that the bubble in the level on the scale is in the middle of the red circle. Press the [ON/OFF] key to turn on power, 0.0 will appear on the screen.
- b. BEFORE SUBJECT STEPS ON SCALE – Do not stand on weighing platform when entering the following personal data (1-4):
 1. Enter clothing weight to the first decimal place (0.5kgs=Press [0] [.] [5] keys.) (*Note that this will be the same for each participant, since they will all be wearing the standard issue t-shirt and shorts*).
 2. Enter Gender and Body Type (i.e., Standard Male, Standard Female) – Note that we will not use the Athletic body type
 3. Enter Age of subject; any age under 10 begins with a zero (e.g., 7 years old = Press [0] [7], 32 years old= Press [3] [2])
 4. Enter Height using centimeters to the nearest whole number (e.g., 168.4 cm= Press [1] [6] [8])
- c. When the arrow appears next to [STEP ON] on the scale screen (located after the LCD display “8888”), ask subject to step on scale with bare feet placing both heels directly on top of the posterior electrodes while the front part of the foot is in contact with the anterior electrodes. Weight will appear in the upper half of the LCD screen.
- d. After the participant's weight stabilizes, the impedance (body fat) measure is taken. This is denoted by four “bubbles” (o o o o), which appear on the bottom half of the LCD screen. As the measurement is being taken, the bubbles will begin to disappear one by one.
- e. Ask subject to step off the scale when the four bubbles (o o o o) located under the weight have disappeared and the scale emits a short beep. Note: Moving before these signals will interrupt the measurement.

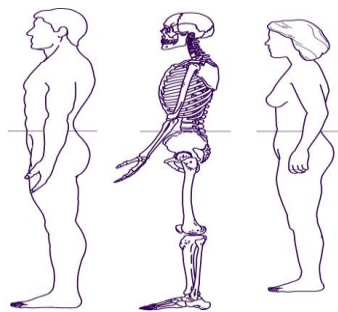
- f. Record body weight and percent body fat on the Body Composition Data Collection Form. Percent body fat will be displayed underneath weight. Note: The Tanita will not measure participants with greater than 75% body fat. The LCD screen will return to the Gender and Body Type within 10 seconds and measurements (trials) can be repeated.
- g. Take two measurements of weight and body fat in a row. Do not take a height measurement in between. If the two measurements of weight differ by greater than 0.2 kg or more or the two measurements of percent body fat differ by greater than 0.5% or more, then both measurements (trials) of weight or percent body fat must be repeated a third time.
- h. Take the first printout from the machine after the participant is measured and tape it to the Tanita explanation sheet. This second copy can be discarded.
- i. When all measurements are completed, turn power off by pressing the [ON/OFF] key.

The average of two measurements that differ by ≤ 0.2 kg is used to represent the weight. If these criteria are not met a third measurement is to be taken. All three measures of weight and body fat are to be entered into the local database. Only the average of the three measures for weight is included in the common database.

Waist Circumference

Ideally, waist circumference would be measured in the morning after voiding and before breakfast. If this is not possible, efforts should be made to measure each subject under conditions as similar as possible on all visits (e.g., same time of day, fasting, limited consumption of fluids). Participants will be wearing the standard shorts and T-shirt provided by the study. Measurement of waist circumference will follow the procedures described in the NHANES III protocol.

- To define the level at which waist circumference is measured, a bony landmark is first located and marked. The subject stands and the examiner, positioned at the right of the subject, palpates the upper hip bone to locate the right iliac crest. Just above the uppermost lateral border of the right iliac crest, a horizontal mark is drawn, then crossed with a vertical mark on the mid-axillary line.
- The measuring tape is placed in a horizontal plane around the abdomen at the level of this marked point on the right side of the trunk. The plane of the tape is parallel to the floor.
- The measurement should be taken at the end of a normal exhalation, with the measurement recorded to the nearest 0.1 cm.
- The average of two measurements that differ by ≤ 1.0 cm is used to represent the waist circumference. If these criteria are not met a third measurement is to be taken. All three measures are to be entered into the local database. Only the average of the three measures is included in the common database.



Resting Seated Blood Pressure

Equipment will be site-specific and will be documented at each site. Every attempt should be made to maintain the same equipment throughout the study to reduce inter-equipment variability. Sites are to maintain service records for equipment.

- Dinamaps (Model 8100)
- Dinamap Operations Manual

- Table/desk
- Towels for participant to lean arm on table and for seat elevation (if needed)
- Chair
- Pens and calculator
- String to determine midline of arm (to measure arm circumference)
- Gulick Measuring Tape to measure participant's arm circumference
- Water soluble colored marker
- Data Collection MOP with Blood Pressure script
- Blood Pressure Data Collection Forms
- Referral letters for participants with high blood pressure
- Set of four blood pressure cuffs. Cuff size will be determined by arm circumference. Each of the following cuff sizes should be available: Small Adult (bright blue), Adult (dark blue), Large Adult (maroon), and Large Adult Long (maroon-long).
- Clipboards

Procedure: It is suggested that seated blood pressure measurements be done at the beginning of a visit, but only after the participant has been sitting quietly in an isolated area for at least five minutes. During this five minute resting period, participants should NOT be engaging in any of the following: reading, filling out forms, talking or crossing their legs or ankles.

Selecting the appropriate cuff size: To select the appropriate cuff size, it is necessary to determine the participant's right arm circumference.

1. The right arm is to be bare with no clothing covering the arm.
2. The participant is to hold the arm at the side of the body with the elbow flexed to 90 degrees (handshake position).
3. On the lateral (outside) aspect of the arm measure the length of the arm from the acromion process (bony extremity that forms the highest point of the shoulder) to the olecranon process (tip of the elbow) and determine the midpoint of this length. Mark this midpoint on the lateral surface of the arm using a cosmetic pencil.
4. With the arm relaxed and the elbow extended and hanging just away from the side of the trunk and the palm facing the thigh, place the tape measure around the arm at the midpoint mark. The tape measure is to be parallel to the floor.
5. The average of two measurements that differ by ≤ 1.0 cm is used to represent the arm circumference. If these criteria are not met a third measurement is to be taken. All three measures are to be entered into the local database. Only the average of the three measures is included in the common database.
6. Using the arm circumference measurement, determine the cuff size according to the chart below:

Arm Circumference	Cuff Size
17.0 to <24.0 cm	Small Adult
24.0 to <33.0 cm	Adult
33.0 to <41.0 cm	Large Adult
≥ 41.0 cm	Thigh or Large Adult Long (If a participant's upper arm circumference would indicate use of the thigh cuff, but the arm is too short for the cuff, or the cuff does not remain secured when inflated, the Large Adult Long arm cuff should be used.)

Taking the seated blood pressure: The subject should be seated with both feet flat on the floor and the right forearm resting on the table. Palpate the antecubital fossa and position the cuff around the arm so that the midpoint of the bladder length is at heart level, and the cuff arrow marked "artery" is aligned with the brachial artery. Cuffs are labeled with range and index lines. The correct cuff has been selected if the index line is within the range as the

cuff is wrapped around the arm. The cuff should be wrapped snugly enough so that no more than one finger-width distance exists between cuff and skin. Have the participant rest for five minutes prior to taking the first measurement. After a minimum of a 30-second wait, obtain a second measurement. Duplicate measurements with systolic blood pressure differing by ≤ 10 mmHg and diastolic blood pressure differing by ≤ 6 mmHg should be obtained. If these criteria are not met a third measurement is to be taken. All three measures are to be entered into the local database. Only the average of the three measures is included in the common database. Please see the appendix for actions to be taken for elevated blood pressure. If the participant has an elevated blood pressure based on the alerts provided, please give him/her a letter and record this information on the two tally forms (so Stacey can provide information to the Data Safety Monitoring Board).

Dinamap Blood Pressure Machine Operation Instructions

1. Turn the Dinamap power switch on the front panel "ON".
2. The monitor will display zeros in all windows.
3. The green light below the Manual Mode will be on. The Dinamap is always preset for manual determinations. Once you are ready to measure blood pressure, you will press the AUTO Mode to change to automatic blood pressure determinations. The green light above the AUTO switch will now turn on. Always position the cuff on the subject and be prepared to begin readings before changing to AUTO Mode. Changing to AUTO Mode will cause inflation to begin automatically and possible damage to the cuff.
4. ALARM LIMITS should be OFF.
5. While the cuff is inflating in the AUTO Mode, set the CYCLE time for 1 minute by pressing the SET switch until the number "1" appears in the window. This sets the readings at one minute intervals and allows the readings to continue automatically.
6. The "Cuff light" will blink while a reading is in progress.
7. When the number of desired readings (2, possibly 3) are completed for the subject in the AUTO Mode, press Manual to stop. This will save the prior readings and stop automatic determinations.
8. Pressing CANCEL at any time will stop a determination and display the previous set of readings.
9. The Dinamap stores up to 99 minutes of data, for a maximum of 100 readings. Pressing the PRIOR DATA switch repeatedly will display prior readings. The elapsed time since each determination will also appear in the CYCLE time window. Turning the Dinamap OFF will erase all prior readings.
10. For Trouble-Shooting, please refer to the Dinamap Operations Manual.

Data Management Note: For the physical measures, the information that will be sent to the RCU is calculated measures for the following:

1. Height (to the nearest 0.1 cm): ___ . ___ cm
2. Weight (to the nearest 0.1 kg): ___ . ___ kg
3. Arm circumference (to the nearest 0.1 cm): ___ . ___ cm
4. Waist circumference (to the nearest 0.1 cm): ___ . ___ cm
5. Resting systolic blood pressure: ___ mmHg
6. Resting diastolic blood pressure: ___ mmHg
7. Resting pulse/heart rate: ___ beats/min

Psychosocial Survey

The survey consists of two parts, the EARLY common element questions and the CHOICES-specific questions, and will be completed by all participants at the clinic visit.

Frequently Asked Questions (FAQs)

Following the pilot of the EARLY common element questions and the CHOICES-specific questions, we created an FAQ document, which is listed here. If any participant has a question on one of the items on the survey or needs

clarification, please refer to this document. If the item is not specified in this document, please tell the participant to re-read the question and then to answer it as best they can.

Question 5: What is the highest grade in school you finished?

- What about if I am currently in college?
 - Response: If currently in college, mark “High School” because he/she has not yet finished college.

Question 11: How many adults (age 18 or older) live in your home? (Be sure to count yourself).

- Do you mean my current home or my family home?
 - Response: Where you currently live.

Question 14: How difficult is it for you to live on your total household income right now?

- What does total household income mean?
 - Response: Total household income means the income available to you in the house where you currently live. This may include your own income plus income from a partner or roommate with whom you share expenses.

Question 28: Over the past week, how many times did you eat the following meals that were prepared in your home or in the place where you live? (Fill in the number of days for each meal.)

- Does the dorm cafeteria count?
 - Response: Yes, it counts because it is a ‘place where you live’.

Question 43a-g: In a typical week, how many times do you...?

- How do I respond to these questions?
 - Response: Please mark one option for each row, being careful not to double-count any eating occasion.

Question 50: Do you have access to a bathroom scale at home?

- How about if I weigh myself at the gym or some other place?
 - Response: Only answer YES if you have a scale at home.

- Does home refer to where I live now or my permanent home?
 - Response: Home refers to where you currently live.

- Does the scale need to be in the bathroom?
 - Response: No, it does not necessarily have to be IN the bathroom.

Questions 116-136: Opinions on Healthy Weight

- How do I answer the questions in this section that ask about work if I do not work but am a full-time student?
 - Response: These questions should be answered for work OR school.

Questions 137-151: Coping Strategies

- What is a ‘medium amount’?
 - Response: A medium amount is more than a little but less than a lot (note: a little and a lot are based on participants’ interpretation)

Question 152: What is the main type of housing in your neighborhood (where you currently reside most days of the week)?

- How do I answer for just a regular house?
 - Response: Choose detached single-family housing.

Question 153: Many shops, stores, markets or other places to buy things are within easy walking distance of my home.

- These things are in within walking distance, but I would not walk because of safety concerns. How should I answer?
 - Response: Answer this question with the distance of places in mind, not the feasibility of walking. Other items in this series of questions ask about feasibility and comfort issues.

Question 158: The crime rate in my neighborhood makes it unsafe to go on walks at night.

- How do you answer if part of your neighborhood is safe but the other part is not?
 - Response: Give your overall impression of the safety of your neighborhood.

Question 159: How many motor vehicles in working order (e.g., cars, trucks, motorcycles) are there at your household/where you live?

- Do you mean my permanent residence or where I live now?
 - Response: Answer for where you currently live.
- How do I answer if one of the vehicles is my roommate's and I don't have access to it?
 - Response: Answer only for those vehicles to which you have access.

Paffenbarger

The Paffenbarger Questionnaire (Questions 71 – 76) is a physical activity questionnaire looking specifically at activity over the “past week”. The questionnaire asks about flights of stairs climbed, number of days and amount of time spent brisk walking for exercise or transportation and other sport, fitness or recreational activities.

It is important to make sure that all questions (intended to be answered) are completed. The questionnaire has a specific method of scoring and all questions must be answered to do so correctly.

GPAQ

The GPAQ is the Global Physical Activity Questionnaire (Questions 77 – 98). The questionnaire is looking at moderate-intensity and vigorous-intensity activities as well as sedentary behavior. The questionnaire is divided into five sections: Activity at Work/School, Household Activity, Travel To and From Places, Recreational Activity, and Sedentary Behavior. Within each section, the questionnaire asks if moderate and vigorous-intensity activities occurred and if so, how many days and how much time is spent doing the activities, on average.

The GPAQ, like the Paffenbarger, has a specific method of scoring, so it is important that each question be answered (as long as the participant is willing to do so). Additionally, this questionnaire has many skip patterns, so it is very easy to accidentally skip a question – be alert to this when checking the survey once the participant is finished.

CES-D Depression Scale

We are required to alert the Data Safety Monitoring Board if any participant's score on the CES-D depression scale (question 102 items a-j) is ≥ 13 . Because we will need to impute data for any missing values in order to calculate this score for each participant, it is VERY important to check with the participant if any of these items are left blank when they turn in their survey. Stacey Moe will be responsible for handling all of the calculations and referrals, but data collectors will be responsible for ensuring we have as complete data as possible.

ASA24 (Online dietary recall)

Participants will complete two 24-hour recalls within a four-week window of their baseline and 24-month measurement visit. Both a weekend day (defined as Saturday and Sunday only) and weekday will be included.

APPENDICES

BODY COMPOSITION MEASUREMENT SCRIPT
MEDICAL EVENTS FORM AND MEDICATION TRACKING FORM ADMINISTRATION SCRIPT

“I am going to take your height, weight, and body fat measurements. Each of these measurements will be done twice in a row (height, height; weight/body fat, weight/body fat).”

HEIGHT MEASUREMENT

“Please step back into the height board until some part of your body (heels, upper back, buttocks) touches the board and bring your feet together until your ankles or knees touch, whichever touch first. Stand straight up against the board. Your arms should be straight down at your sides, palms facing in.”

- Check that they are properly aligned, both from front and from left side.

“Now, I am going to position your head.”

- Position head so an imaginary horizontal line can be drawn between the bottom of eye socket and the opening of the ear – Frankfort Plane.

“Please don’t move your head until we finish. Now, hold your head still, keep your feet flat, and take a deep breath and hold it; stand up tall.”

- Verify body is properly aligned and head position did not shift with deep breath. Move the headboard onto the head with sufficient pressure to compress hair.
- Record the height on the form.

TANITA WEIGHT AND BODY FAT MEASUREMENT

“Now I will take your weight. Do you have a Pacemaker or any other electronic medical device?”

- If yes, DO NOT use the body fat measurement function of the Tanita. Use the Weight Only function instead. This will also mean that no body fat measurement will be taken.
- If no, continue with script.

“Please take off your socks and shoes. We need bare feet with this scale. Also, I am going to give you a wipe to wipe off the bottoms of your feet. This helps give us a good reading.”

- Weight: turn the power on by pressing the [ON/OFF] key. When it shows zero (0.0), enter clothes weight (0.5kg), gender and body type, age, and height). When arrow appears next to [Step on], say:

“Please step onto the scale so that the backs of each of your feet are on one of the back circles/electrodes and so the fronts of your feet cover these front circles/electrodes. Make sure your weight is balanced between your two feet. Keep your hands at your sides and look straight ahead. The scale will send a gentle current through the soles of your feet to measure your body composition. Most people can’t even feel the current. Please do not move until I tell you that the measurement is finished.”

- Record weight after it stabilizes.
- Record body weight and body fat.
- When four bubbles have disappeared and scale emits a beep, say:

“Okay, you may step off the scale.”

“This printout is for you to take home. I’m going to tape it to this explanation sheet, which I will give back to you at the end of the visit. This sheet explains what the Tanita machine is telling us.”

- Tape first print out to explanation sheet and discard the second printout.
- Look at participant BMI on print out to re-assess eligibility for the study. If the Tanita was not used, determine BMI based on height and weight using the BMI table.

WAIST CIRCUMFERENCE MEASUREMENT

“We are almost done with the body composition, but now I am going to measure your waist circumference. To do that, I need to find the upper edge of your hipbone. It can sometimes be difficult to find, so please let me know if I am palpating your skin too hard. Once I have found it, I am going to make a mark on your hip so I know where to put the tape measure.”

- Mark right hipbone (iliac crest) with water soluble marker.

“Now I am going to put this tape measure around you so that I can get the circumference of your waist. Please look straight ahead and keep your arms at your sides unless I ask you to raise them so I can get a better look to make sure my tape measure is in the right place.”

“Right before I take the measure, I am going to ask you to breathe in (inhale) and then breathe out (exhale) and I am going to take 2, possibly 3 measurements.”

Body Composition Data Collection Form

1. Height (cm)

a. Measure 1

b. Measure 2

c. Mean Value of Measures 1 & 2

|_|_|_| . |_|

|_|_|_| . |_|

|_|_|_| . |_|

Repeat a third measure if difference is > 0.5 cm

d. Measure 3 (if needed)

e. New Mean Value of Measures 1, 2 & 3

|_|_|_| . |_|

|_|_|_| . |_|

2. Weight (kg)

a. Measure 1

b. Measure 2

c. Mean Value of Measures 1 & 2

|_|_|_| . |_|

|_|_|_| . |_|

|_|_|_| . |_|

Repeat a third measure if difference is > 0.2 kg

d. Measure 3 (if needed)

e. New Mean Value of Measures 1, 2 & 3

|_|_|_| . |_|

|_|_|_| . |_|

3. Tanita – Body Fat (%)

a. Measure 1

b. Measure 2

c. Mean Value of Measures 1 & 2

|_|_|_| . |_|

|_|_|_| . |_|

|_|_|_| . |_|

Repeat a third measure if difference is > 0.5%

d. Measure 3 (if needed)

e. New Mean Value of Measures 1, 2 & 3

|_|_|_| . |_|

|_|_|_| . |_|

4. Waist Circumference (cm)

Tape Measure Used: _____

a. Measure 1

b. Measure 2

c. Mean Value of Measures 1 & 2

|_|_|_| . |_|

|_|_|_| . |_|

|_|_|_| . |_|

Repeat a third measure if difference is > 1.0 cm

d. Measure 3 (if needed)

e. New Mean Value of Measures 1, 2 & 3

|_|_|_| . |_|

|_|_|_| . |_|

5. Notes _____

UNDERSTANDING YOUR PRINT OUT

IMPEDANCE

Impedance is the body's resistance to electrical current and is used to calculate fat %.

FAT MASS

Fat mass is the total weight of fat in the body.

FFM

Fat free mass (FFM) is the weight of muscle, bone, tissue (skin, organs) and water – the body's weight without fat.

TBW

Total body water (TBW) is the amount of water in the body. TBW is between 50%-70% of total body weight. Men tend to have higher water weight than women because men often have more muscle.

BMI

Body Mass Index (BMI) is a number calculated with a person's weight and height. BMI is used to measure body fatness.

FAT %

The percentage of total body weight that is fat.

BMR

Basal Metabolic Rate (BMR) represents the calories (kcal) the body burns just to function normally at rest (breath, circulate blood) without exercising.

CONVERSION RATES

Weight

1 kg = 2.2 pounds

___ kg x 2.2 = _____ pounds

Height

2.54 cm = 1 inch

___ cm / 2.54 = _____ inches

OTHER GOOD RESOURCES

BMI:

BMI numbers mean different things for kids and adults, learn more at: <http://www.cdc.gov/nccdphp/dnpa/bmi/index.htm>.

Nutrition and Physical Activity:

Families can enjoy a healthy lifestyle together. For fun family activities about healthy eating, physical activity and alternatives to sedentary activity check out: <http://www.nhlbi.nih.gov/health/public/heart/obesity/wecan/index.htm>.

If you are interested in learning more about the impact of how you move and what you eat on good health, look at:

<http://www.cdc.gov/nccdphp/dnpa/>.

* Please consult your physician before beginning any weight management program. *

BLOOD PRESSURE ADMINISTRATION SCRIPT
MEDICAL EVENTS FORM & MEDICATION TRACKING FORM ADMINISTRATION
SCRIPT

“To determine the appropriate cuff size for you, I need to measure the circumference of your arm. In order to that, I am going to first measure the length of your upper arm so that I can find the midpoint of your arm and then I’m going to put this measuring tape around your arm, which will give me the circumference. I will do this twice, possibly three times.”

- Measure participant’s arm and determine cuff size

“You can take a seat here. Please place your right forearm on the towel on the table, and please keep your feet flat on the floor.” [If the participant’s upper arm is not at heart level, have him/her sit on towels or elevate his/her arm using towels.]

“Before I put the cuff on, I’m going to touch your arm to find the right spot to place the cuff.”

- Palpate the brachial artery
- Squeeze the air from the cuff before you put it on the participant

“Now, I’m going to put the cuff on your arm. Please sit quietly, do not cross your legs, and do not move your arm with the cuff on it.”

- Place the cuff firmly and smoothly around the participant’s arm

“The cuff will pump up fairly tightly for a few seconds each minute for the next two or three minutes, but it is NOT painful. Sometimes I have to take a third reading, but it’s not a big deal – it has to do with the machine, not you.”

“I’m going to take the two blood pressure measurements now. Remember, the cuff will tighten up for a few seconds but it will not hurt.”

- When the participant is relaxed and ready, turn the Dinamap on and follow the instructions for taking BP measurements.
- Record the Dinamap BP machine number, the date and staff ID on the BP data collection form

“The measurement will begin in a couple of seconds.”

- After the first blood pressure measurement, ask the participant to:

“Please raise your arm with the cuff above your head and hold it upright for 2 seconds, open and close your fist three times. Now, place your forearm back on the towel on the table and relax. The next blood pressure measurement will begin in a few moments.”

- Repeat the above after each measurement is taken. Do not forget to record readings on the BP data collection form.
- When both (or all three) measurements are complete, press MANUAL to stop the Dinamap BP machine.
- Check prior data for all measurements and verify that you recorded the correct numbers on the BP data collection form. When all measurements are correct, press OFF on the Dinamap BP machine.
- Remove the cuff from the participant’s arm.

MEDICAL EVENTS AND MEDICATION TRACKING FORMS

“Okay, we are finished with the blood pressure measurement. Now I just have a few safety questions to ask you.”

- Administer the Medical Events Form and Medication Tracking Form. If measurement rooms are small, the form needs to be completed quietly and confidentially with the staff member pointing to items and the participant nodding “yes” or “no”.

Participant ID: _____	BP Machine #: _____
Date: __ _ / __ _ / __ _	Staff ID: __ _ _

Blood Pressure Data Collection Form

1. Arm Circumference (cm)

Measure 1	Measure 2	Mean Value of Measures 1 & 2
_ _ _ . _	_ _ _ . _	_ _ _ . _

Repeat a third measure if difference is > 1.0 cm

Measure 3 (if needed)	New Mean Value of Measures 1, 2 & 3
_ _ _ . _	_ _ _ . _

2. Cuff Size Used:

- 1 Small Adult
- 2 Adult
- 3 Large Adult
- 4 Large Adult Long

Arm Circumference	Cuff Size
17.0 to < 24.0 cm	Small Adult
24.0 to < 33.0 cm	Adult
33.0 to < 41.0 cm	Large Adult
≥ 41.0 cm	Large Adult Long

3. Mean Arterial Pressure (mmHg)	4. Pulse Rate (per min)	5. Systolic Pressure (mmHg)	6. Diastolic Pressure (mmHg)
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a. Measure 1: (Taken after 5 min of rest)

_ _ _	_ _ _	_ _ _	/ _ _ _
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b. Measure 2:

_ _ _	_ _ _	_ _ _	/ _ _ _
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c. Mean Value of Measures 1 & 2:

_ _ _	_ _ _
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Repeat a third measure if the first two measures differ by > 10 mmHg systolic and > 6 mmHg diastolic.

d. Measure 3: (If needed)

_ _ _	_ _ _	_ _ _	/ _ _ _
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e. Mean Value of Measures 1, 2 & 3: (If needed)

_ _ _	_ _ _
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* Note: The participant will be EXCLUDED from the CHOICES study if the systolic BP is ≥ 160 mmHg **OR** the diastolic BP is ≥ 100 mmHg.

Comments:

This table shows blood pressure alert values and the corresponding advice and action. If the systolic and diastolic blood pressure values meet different criteria, use the higher of the two. Any action in response to a blood pressure alert should occur during the measurement visit at which the blood pressure alert occurred, meaning a letter should be sent home with the participant when they leave their measurement visit.

<i>Alert</i>	<i>Advice to participant or action by study staff</i>	<i>Deadline for giving advice or taking action</i>
Blood pressure (average BP at any measurement visit)		
SBP \geq 180 mmHg OR DBP \geq 110 mmHg	Participant should be advised to see a health care provider within 1 week.	24 hours
SBP 160-179 mmHg OR DBP 100-109 mmHg	Participant should be advised to see a health care provider within 1 month.	1 week
SBP 140-159 mmHg OR DBP 90-99 mmHg	Participant should be advised to see a health care provider within 3 months.	1 month
SBP < 90 mmHg	Staff should ask participant, "Are you feeling dizzy or lightheaded?" If yes, participant should be counseled to see a health care provider within 1 month.	At study visit

High Blood Pressure Letter

Date: _____

Dear _____:

As you know, we measured your blood pressure during your clinic visit for the CHOICES study. We noted that your blood pressure was _____, which is higher than the expected blood pressure for young adults.

We feel it is important that you follow up with your health provider for another blood pressure reading in the next _____.

If you have any questions, please contact Stacey Moe, the CHOICES study Project Coordinator, at 612-626-8607.

Sincerely,

The CHOICES study staff

Blood Pressure Alerts – Tally Chart

	Number of alerts	Date Letter Given (tally only if NOT given at clinic visit)
SBP \geq 180 OR DBP \geq 110 mmHg		
SBP 160-179 OR DBP 100-109 mmHg		
SBP 140-159 OR DBP 90-99 mmHg		
SBP < 90 mmHg		
Total Blood Pressure Alerts		