Attachment 4: Protocols for Home Assessments

- 4a. Height and weight
- 4b. Waist circumference
- 4c. Blood pressure
- 4d. Blood sample (finger stick)

OMB No.:0925-0610
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Attachment 4a

WEIGHT AND HEIGHT PROTOCOL

1.1 Equipment

- Privacy screens
- SECA 882 Scale from SECA Corporation
- 3'x3' plywood boards to place beneath the scale and the stadiometer (if you know that the floor is hard and level where the equipment is located at the school site, you do not need to have this board)
- Carpenters level, at least 3' in length
- Alcohol or Clorox wipes to wipe off scale after each participant
- Baskets or bags for participants' extra clothing and other items
- Stadiometer
- Small stepstool, if needed, because there is the possibility that some staff may be shorter than participating participant are
- 12" ruler
- Comment logs for any necessary private notes about participants measured

1.2 Personnel

- Research assistants trained and certified in measuring height and weight according to study protocol

1.3 Procedures for Weight

1.3.1 Preparation

1. Keep the battery unit unplugged from the scale unless it is being used on a daily basis.
2. The SECA 882 Scale does not give accurate weights above 400 lb (180 kg) maximum according to the manufacturer. Weighing such participants using these scales may damage the scale. Prior to undertaking the screening, check with the school nurse or coach to be certain that there is no participant greater than 400 lb in the school. For participants over 350 lb (160 kg), the SECA 634 Scale must be used to obtained an accurate weight measurement. For other special circumstances, see the section on Special Circumstances below.
3. The scale should be calibrated monthly and checked daily for correct calibration. See the section on Equipment Calibration and Maintenance below for instructions.
4. Move scale CAREFULLY as electronic sensors are easily damaged.
5. Make sure control cable is locked into control box.
6. Place a 3'x3' plywood board beneath the scale prior to leveling unless the floor is hard and level.
7. Adjust scale feet so that (1) scale wheels are off carpet and (2) scale is level (use a carpenter's level to check).
8. Plug the scale in as required.
9. Turn scale on by pressing ON button.
10. If low battery signal appears, change batteries immediately (scale may not be accurate on low batteries).
11. Switch to kilogram display (light above that button will be ON to indicate kg measure).
12. Make sure you have a reading of ZERO before having subject step onto platform. Press Tare/Reweigh if you do not have a zero reading.

1.3.2 Procedure

1. Explain what you are going to do.
2. Ask the participant to remove any excess clothing (sweatshirts, sweaters, or jackets), to remove shoes, and place any items from pockets in baskets provided.
3. If the participant has refused to remove excess clothing, do not take a measurement, and note the refusal on data collection form.
4. Have the participant step up onto the scale, placing feet next to one another over the center of the scale. If the participant's feet are longer than the scale, then heels and balls of feet should be on the scale and toes hanging off front. Make sure body weight is distributed evenly over both feet. Arms should hang freely by the sides of the body, head held up and facing forward.
5. Make sure the subject is not leaning to one side or forward or backward, and that the head is held stationary, looking straight ahead.
6. If the measurement drastically fluctuates, first make sure the participant is still standing in the exact middle of the scale base with feet right next to each other. The further the center of weight is from the exact center of the base, the more likely the scale reading will fluctuate. This is more likely to happen with heavier and/or taller individuals. You may also need to check that the scale is still level.
7. When the readout is stable, record weight on data collection form to the nearest 0.1 kg. The participant may want to know his/her value. DO NOT switch the scale to 'pounds' and re-measure—the opportunity for error due to forgetting to switch back is too great. Either use a calculator to multiply (kg x 2.2 = lb) or refer to a conversion chart (see appendix). Use a low voice that cannot be overheard.
8. Have the participant step off the scale. Repeat procedures in steps 4 through 7 either immediately or after collecting a first height reading.
9. Record second weight on data collection form. If the first two measurements are $\leq \pm$ 0.2 kg of each other, stop and circle both measurements.
10. If the first two measurements are not $\leq \pm$ 0.2 kg of each other, repeat the procedures in steps 4-7, having the participant step off the scale between each measurement until two values are $\leq$ 0.2 kg of each other. Record each measurement on data collection form—space is left for up to 4 measurements, although it is not expected to take that many. Circle the two measurements which are within 0.2 kg of each other and which are to be data entered. If you cannot obtain two measures within 0.2 kg of each other by the third try, check the battery reading on the scale and summon the experienced measurer to conduct the final measure.
11. If the scale registers maximum weight of 400 pounds (180 kg) or a valid weight measurement cannot be made for some other reason, then check the box for item 9 on data collection form if at Baseline Data Collection or check the box for use of the heavy duty scales and measure the subject again on the SECA 634 Scale. If a valid weight cannot be measured on either scale, then check the invalid weight box and make note of the reason why the measurement could not be made. See the section on Invalid or Missing Weight/Height Data Due to Special Circumstances for more details.
12. Either send the participant with the clipboard to the next station, or take participant to next station and give clipboard with forms to study staff there.
13. Take notes on a separate log (not data collection form which the kids will be carrying around) with ID and observations about kids whose weight measures may come under review, for example, 'very tall and skinny boy', 'short stocky girl', 'girl had recent growth spurt in height and has been on diet for weight'.

Procedures for Larger Weight Capacity Scales

1. There are multiple stations for taking measurements, each surrounded by privacy screens. All stations have a regular scale. In addition, one station has the heavy duty scale--let's call it station X.
2. The participants are directed to a station in a seemingly 'random' order, but all heavy kids are sent to station X, interspersed with normal kids.
3. All kids at station X are first put on the regular scale and weight is recorded, then on the heavy duty scale and weight is recorded. We explain that we are doing this to compare weights from the two scales as part of our study. For participants weighed at station X, the procedures for the HD scale are identical to the regular scale, that is, continue to have the participant step off the scale and repeat the steps until two measures within 0.2 kg are recorded. Record each measurement on data collection form—space is left for up to 4 measurements, although it is not expected to take that many. Circle the two measurements which are within 0.2 kg of each other and which are to be data entered. If you cannot obtain two measures within 0.2 kg of each other by the third try, check the battery reading on the scale and summon the experienced measurer to conduct the final measure.

1.4 Procedures for Height

1.4.1 Preparation

Stadiometer Set-up

1. Position the base vertically on the floor.
2. Place a 3'x3' plywood board beneath the stadiometer unless the floor is hard and level. Make sure board surface is level using a carpenter's level.
3. Head/foot piece may be secured at any location along stature extension using small wing nut in back of piece.

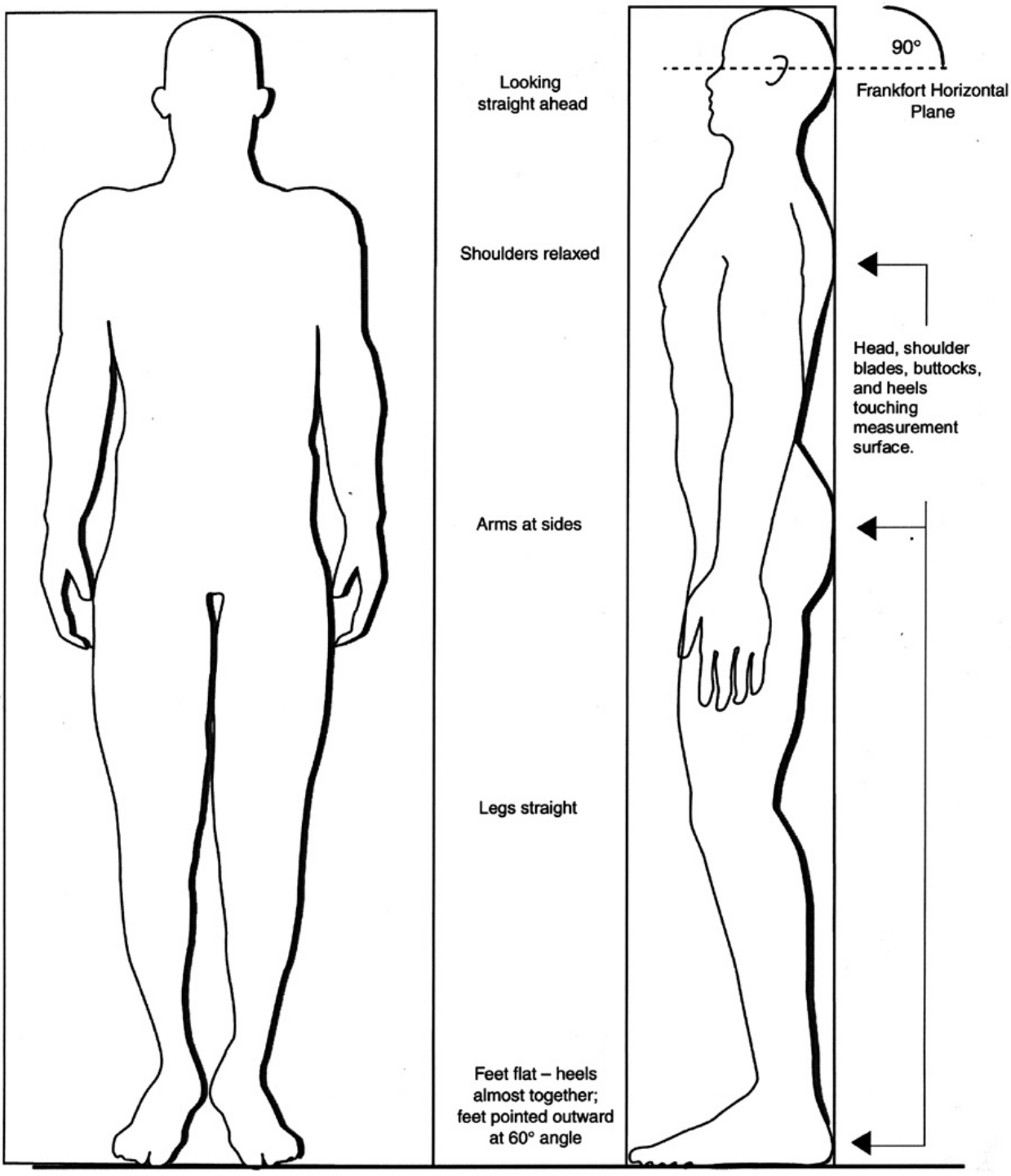
Precautions

1. When possible, locate unit in a corner so that the chance of someone walking into the unit from either side is minimized. However, be sure that there is sufficient space for a participant to stand comfortably upright without touching the lateral walls (at least 2 feet away from the lateral wall should be sufficient for even the largest participant).
2. Do not leave participants unattended around unit in vertical configuration with stature extension in place.

1.4.2 Procedure

1. Introduce yourself and explain what you are going to do.
2. Ask the participant to sit and remove shoes. Participant may keep on socks or hose.
3. If the participant refuses to comply with procedures, then he/she is not measured and no height is recorded on data collection form. Indicate that a valid measurement is not available and make note of the reason why a valid measurement is not available.
4. Refer to the diagram below (from National Health and Nutritional Examination Survey Anthropometry Procedures Manual, 2002). Have the participant stand erect with the mid-axillary line perpendicular to the floor, weight distributed evenly on both feet, arms hanging freely by the sides of the body with the palms facing the thighs.

Attachment 4a



5. Ask the participant to place ankles or knees together, whichever come together first. If the participant has knock-knees, the feet are separated so that the medial borders of the knees are in contact but not overlapping.
6. The scapula and buttocks are in contact with the vertical board if possible, or whichever part of the body touches the board first.

7. Verify position on the right side of the body. If the heels, buttocks, scapula, and posterior aspect of the head cannot be placed in one vertical place while maintaining a reasonable natural stance, position the participant so that only the buttocks and heels or the head are in contact with the vertical board. If the participant's buttocks are large enough that sliding the heels all the way to board back causes irregular or very unnatural posture, allow participant to stand with feet under hips.
8. Ask for permission to touch the participant, and, if given, position the participant's head in the Frankfort horizontal plane. In this position an imaginary line parallel to the floor can be drawn from the bottom of the eye socket (orbital margin) to the external opening of the ear (external auditory canal) – which is also equivalent to drawing a line from the corner of the eye where the upper and lower lid meet to the top of where the ear attaches to the head. If necessary, ask the participant's permission to reposition head. Reposition by gently placing one hand under the chin and the other on top of the head and tilt the head up or down until proper alignment is achieved with eyes looking straight ahead. If the participant does not give permission, then use verbal instructions for the participant to position head.
9. Ask the participant to inhale deeply and maintain a fully erect position without altering the load on the heels. Holding a deep breath makes the individual stand up straighter and taller, and allows for a more stable and reliable reading. If the participant is breathing heavily enough to cause oscillations in the level, you must wait until the participant settles down or ask the participant to exhale and hold his/her breath.
10. Position the headboard firmly on top of the head with sufficient pressure to compress the hair to the scalp (see notes below regarding interfering hair styles).
11. Some participants have hairstyles that may interfere with measurement of height. In this circumstance there are two possible ways to deal with this, dependent on the preference of the participant.
    a. If the participant gives permission and the hairstyle is easy to modify, then make the modification (e.g., remove ponytails on top of head).
    b. If a hairstyle is not easy to undo (or the participant refuses to undo it), leave the hair as is and obtain the height as described (net height). Then ask the participant to be seated and using a small clear ruler measure the distance from the scalp to the top of the hairstyle (interference height). Note the interference height (in cm) in the margin of the form and subtract this value from the net height to get the actual height recorded.
12. Get eye-level with the headboard—stand on a stool or bend down as necessary.
13. Read from the side of stadiometer to the nearest 0.1 centimeter. Use the SIDE measuring scale, not the front scale, so you are better able to judge the participant's posture.
14. Record height (to scalp, not to top of hair) on data collection form.
15. Have the participant step off the stadiometer. Repeat procedures in steps 4 through 13 either immediately or after collecting a weight reading.
16. Record second height on the data collection form. If the first two measurements are $\leq \pm$ 1.0 cm of each other, stop and circle both measurements on Form ST3.
17. If the first two measurements are not $\leq \pm$ 1.0 cm of each other, repeat the procedures in steps 4-13, having the participant step off the stadiometer between each measurement until two values are $\leq \pm$ 1.0 cm of each other. Record each measurement on the data collection form—space is left for up to 4 measurements, although it is not expected to take that many. Circle the two measurements which are within 1.0 cm of each other and which are to be data entered. If you cannot obtain two measures within 1.0 cm of each other by the third try, summon the experienced measurer to conduct the final measure.

18. Height is measured and recorded once. The participant may want to know his/her value. Read off the 'feet-inches' side of the stadiometer or use a calculator to multiply (cm x .3937 = in) or refer to a conversion chart (see appendix). Use a low voice that cannot be overheard.
19. Either send the participant with the clipboard to the next station, or take participant to next station and give clipboard with forms to study staff there.
20. Take notes on a separate log (not on data collection form which the kids will be carrying around) with ID and observations about kids whose height measures may come under review, for example, 'very tall and skinny boy', 'short stocky girl', 'girl had recent growth spurt in height and has been on diet for weight'.

1.5 Invalid or Missing Weight/Height Data Due to Special Circumstances

There are going to be cases of participants coming to health screening from whom we cannot get a reliable or valid height or weight:

- They may have a permanent condition such as using a wheelchair, using leg braces, twisted spine, etc.
- They may have a temporary condition such as a cast or other substantial wrap around an injury or are verifiably pregnant.
- They may refuse to be measured or take off heavy layers of clothing or jewelry.
- They may weigh more than the maximum capacity of the scale.

Other situations may arise that cause us to be unable to provide legitimate height and weight measurements. We do not want to exclude any participant from participating, but we do not want to use invalid data.

- If the participant has a temporary condition, such as a cast or wrap around an injury, try to make arrangements on a case-by-case basis to get height and weight under fasting conditions at a later date when the injury has healed.
- If the participant uses a wheelchair or is otherwise permanently unable to provide height and weight measures, study staff needs to judge whether to explain to the participant that we won't need to measure height and weight or whether to proceed with the measurement procedures in order to maintain good relations. If recorded, check the flag(s) to indicate not to use the height and/or weight.

Attachment 4b.

WAIST CIRCUMFERENCE PROTOCOL

1.1 Equipment

- Privacy screens
- Waist measuring tapes (G-tape) with tension device
- Colored small adhesive dots or water-based color marker
- Alcohol wipes (to clean the skin if using water-based color marker)
- Large binder clips or elastic bands for holding participants' shirts above the waist

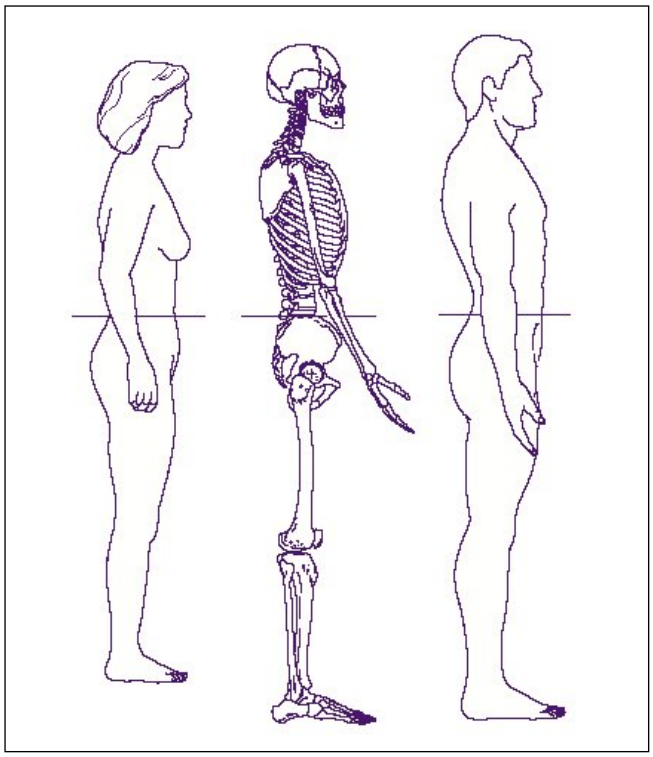
1.2 Personnel

- Health researchers trained and certified in measuring waist circumference according to study protocol (NOTE: It helps to have 2 people perform this measurement—one to hold the tape in place and one to record)

1.3 Procedures

1. Explain what you are going to do. NOTE that females are permitted to measure girls and either males or females are permitted to measure boys unless the participant objects. It is preferable to have more than one staff person working behind the screen so that the participant is not left alone with an adult.
2. Ask permission to touch the participant. If the participant refuses, do not take the measurement. If the participant either refuses or the measurement can't be taken for some reason, note the reason on the data collection form.
3. Have participant stand in normal posture, breathing regularly. The measurement is made at a normal minimal respiration.
4. Ask the participant to push down elastic waist or unzip jeans/pants if needed so the crests of the ilium (hip bone) are exposed. Ask the participant to tuck shirttail under the armpits and then drop arms to sides. If the participant refuses to alter clothing, do not complete the measurement.
5. To define the level at which waist circumference is measured, a bony landmark is first located and marked. (NOTE: Be careful not to poke or scrape the participant with your fingernails.) Position at the right side of the subject and palpate the upper crest of the hipbone to locate the right iliac crest (see figure below from NHLBI Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults: the Evidence Reported, page 59). Place a small adhesive dot (or mark with a colored water-based marker) at the point where the uppermost lateral border of the right iliac crest meets the mid-axillary line which is an imaginary vertical line from armpit. The iliac crest can be marked on both sides of the body in order to line up the measuring tape.

Attachment 4b.



6. Standing in front of the participant's right side, wrap the measuring tape in a horizontal plane around the abdomen at the level of the colored dot/mark on the right side of the trunk. This horizontal plane is parallel to the floor.
7. The bottom of measuring tape should be at level of dot/mark for measurement purposes. Ensure that the tape is wrapped parallel to the ground and front and back are at same level. The tape should be snug but not compressing the skin.
8. While holding the tape with one hand and the body of the tensioning device with the other, pull the tensioning device until red mark can be seen emerging from the end of the tensioning device. Do not pull on the end of the tape that does not have the tensioning device.
9. Read the scale adjacent to the end of the measuring tape and measure to nearest 0.1 centimeter.
10. Record first waist circumference on the data collection form.
11. Remove tape and repeat procedures in steps 5-9.
12. Record second waist circumference on the data collection form. If the first two measurements are $\leq \pm$ 1 cm of each other, stop and circle both measurements on the form.
13. If the first two measurements are not $\leq \pm$ 1 cm of each other, repeat the procedures in steps 5-9, removing the tape between each measurement until two values are $\leq \pm$ 1 cm of each other. Record each measurement on the data collection form—space is left for up to 5 measurements, although it is not expected to take that many. Circle the two measurements which are within 1 cm of each other and which are to be data entered.
14. Remove the adhesive dot or wipe marker spot with an alcohol wipe from the participant's skin and ask the participant to return clothing to normal.

BLOOD PRESSURE[1]

1.1 Equipment

- Omron HEM-907 or HEM-907XL blood pressure machines
- Cuffs in small, medium, large, and extra-large sizes
- Tape measure (and an extra for back-up)
- Laminated cuff size chart
- List from Omron IntelliSense™ Blood Pressure Monitor manual for error codes and other problems and their possible solutions
- Extra batteries for BP machine

1.2 Personnel

- Health Researchers trained and certified in taking blood pressure according to study protocol

1.3 Procedures

1. To set up the Omron HEM-907 or HEM-907XL blood pressure machine, see the Users Manual. Set the machine to **AVG** function of F1 (number of measurements) = 3 times, F2 (waiting time until the start of 1st measurement) = 5 minute initial wait time, F3
2. Explain what you are going to do and how the machine works.
3. Ask participant to remove outer layers of clothing if necessary.
4. Direct the child to take a seat.
5. Blood pressure is normally measured on the right arm. If there is a mechanical obstruction or problem with the right arm, then the left arm may be used. If for some reason the blood pressure cannot be measured on either arm, make a note on data collection form.
6. Measure upper arm circumference on bare skin approximately half-way between the shoulder and the elbow using a tape measure.
7. Choose appropriate cuff size using the chart:

Blood Pressure Machine and Cuff Size Chart	
upper arm circumference	cuff size
17-22 cm (7-9 in)	Small
22-32 cm (9-13 in)	Medium
32-42 cm (13-17 in)	Large
42-50 cm (17-20 in)	extra-large

8. If the participant is between sizes, choose the larger size. Check cuff size used on data collection form.
9. Palpate the brachial artery. Place cuff with **ART** marking on brachial artery.
10. Wrap the cuff snuggly using both hands and securely fasten it with the Velcro™ tape. The white triangle marked “INDEX” should meet up with the white bar marked “RANGE,” between “MIN” and “MAX.” At this time, the lower edge of the cuff must be placed 1/2 ” to 1” above the inner side of the elbow joint.
11. Rest the participant’s arm on table (or other appropriate surface) so that the cuff is at about his/her heart level. The inside of the forearm should be facing upwards.

[1] Adapted from the HEALTHY Study

12. Connect the cuff to the blood pressure machine's air tube. Make sure it is a tight connection.
13. Remind the participant to sit upright with both feet flat on the floor and to remain still for 5 minutes. Sometimes it is helpful to tell the participant to pick something to look at for the entire time you are taking the measurement. This keeps the participant from moving and causing extraneous noises during measurement.
14. Check that the **MODE** selector is set on **AVG** and **PSET** is set on **AUTO**.
15. Press **START** to begin the 5-minute timer and measurement procedure.
16. If the participant moves excessively during the 5-minute rest time, the timer must be reset. Do this by pushing the **STOP** button. Then reset the timer by pushing the **START** button again.
17. At the end of the 5-minute waiting period, the BP machine automatically begins to inflate the cuff to take the first blood pressure measurement. The cuff squeezes briefly and the participant should continue to remain still and quiet. Then the cuff begins to slowly deflate as it takes their first blood pressure measurement. Record on data collection form.
18. After the cuff completely deflates, the machine automatically times a 1-minute interval and inflates again for their second blood pressure measurement. Record on data collection form. Remind the participant to remain still and quiet.
19. Again the machine will repeat the 1-minute timer and take the third and final blood pressure measurement. Record on data collection form. Remind the participant to remain seated until you can check the blood pressure readings and remove the blood pressure cuff from the arm.
20. At the end of the 3 blood pressure measurements, the machine displays the average values. Press the **DEFLATION/Avg/1st/2nd/3rd** button to view the first blood pressure measurements. Check these against your recorded numbers. Press the **DEFLATION** button again and the 2nd blood pressure measurement appears. Again, check these values against your recorded numbers. Press the **DEFLATION** button one last time to check the third blood pressure measurement values.
21. Monitor values as they are collected.
    a. In general, after the 3 machine readings have been made, if any 2 of the 3 systolic measures OR any 2 of the 3 diastolic measures differ by > 20 mm Hg, then redo the entire BP measurement procedures (5-1-1) and record those values on the data collection form.
    b. If the values are not > 20 mm Hg apart but do seem suspicious or indicate machine malfunction, also re-do the entire BP measurement procedures and record them on data collection form.
    c. Use the comments section to make note of these situations, and to record manual measurements if taken. Always make sure the cuff on firmly and securely before starting.

Attachment 4d

BLOOD COLLECTION PROTOCOL

Materials Needed

- A disposable lancet device. Blade depth: 2.0mm; blade width: 1.5mm retractable sharps to reduce the possibility of inadvertent needle stick;
- A microcontainer that hold 200 – 500 uL whole blood.with K2 EDTA additive
- Capillary tubes kits
- A dropper-like apparatus that holds the capillary tube for sample collection and releases it into the microtainer;
- Alcohol swabs. If a surgical or other disinfectant soap is used, alcohol swabs can be eliminated;
- Sterile cotton balls or gauze pads;
- Examination gloves;
- Adhesive bandages;
- Trash bags suitable for medical waste and containers for sharps. Bags containing medical waste should be clearly identified as such;
- Storage and mailing containers (provided by the Boston Children's Hospital central lab). Since specimens require shipment, follow the FedEx or other appropriate regulations for the transport of body fluids;

There will be a label placed upon the microtainer which will note the subject's study ID#, and date of collection.

Overview of Procedures

The procedure for (centralized) capillary sample collection involves the following:

1. Prepare supplies by getting a capillary tube, microtainer, and dropper device from kit.
2. Place the capillary tube into the tweezer-like end of the dropper device.
3. Clean the finger with an alcohol pad
4. Allow finger to dry in order to avoid stinging related to fingerstick puncture with alcohol on the tip of the finger
5. Ready the disposable lancet.
6. Prick the fingerstick and wipe off the first drop of blood with a gauze pad

7. Lightly squeeze the finger to allow a second drop to form and apply any end of the micro liter capillary tube tip to the drop. The blood will enter the tube by capillary action.
8. Open the microtainer and release the capillary tube into the microtainer.
9. Close the microtainer top and gently shake
10. Apply label to the microtainers.
11. Refrigerate the microtainer prior to mailing to the central laboratory
12. Mail the samples within 5 days of collection to the Boston Children's Hospital laboratory by overnight mail delivery, preferably with morning delivery, as noted on the lab form
13. Include a cool pack in the sample box in order to ensure stability of the sample during the mailing procedure
14. Mailings should be done Monday through Thursday only and NOT before any legal holiday.
15. Sample labels and packing slips denoting the date and the subject number will be provided by the home office.

Step-By Step Procedures

Prepare the Participant's Finger

1) Select examination gloves. If necessary, rinse them to remove powder.
2) Wash the participant's hands thoroughly with soap and warm water, and then dry them with an appropriate towel (NOT NEEDED IF THE ALCOHOL PAD IS USED).
3) Make sure the hand and finger are warm to the touch. If not, rub gentle, ask participant to swing arm around, run in warm water again, whatever is necessary to promote blood flow.
4) Grasp the finger that has been selected for puncture between your thumb and index finger with the palm of the participant's hand facing up.
5) If not done during washing (see preceding notes), massage the fleshy portion of the finger gently.
6) Clean the ball or pad of the finger to be punctured with the alcohol swab. Dry the fingertip using the sterile gauze or cotton ball.

Puncture the Finger and Form Drops of Blood

1) Grasp the finger and quickly puncture it with a sterile lancet in a position slightly lateral to the center of the fingertip.
2) Wipe off the first droplet of blood with a sterile gauze or cotton ball.
3) If blood flow is inadequate, the lancet may not have been held sufficiently close to the finger so the procedure will need to be repeated with a new lancet. Try to gently message the proximal portion of the finger and then press firmly on the distal joint of the finger.
4) A tiny drop of blood should form at the puncture site.
5) Do not let the blood run down the finger or onto the fingernail.

Fill the Collection Container

1) Continuing to grasp the finger, touch the tip of the collection capillary tube to the beaded drop of blood.
2) Draw the blood into the capillary tube.
3) When the tube is full, place it in the microtainer provided.
4) When possible, repeat steps 1 through 3 to fill a second capillary tube.
5) Mildly agitate the specimens.
6) Check that the container is properly labeled, and place it in an appropriate storage area.
7) Stop the bleeding, and cover the finger with an adhesive bandage. Bleeding should stop quickly. If bleeding is slow to stop, apply pressure to the puncture site with a sterile gauze or a cotton ball.
8) Place collected and labeled blood samples back into a Styrofoam rack (to provide stability during shipment). When packaging samples, please wrap the tubes with absorbent material (i.e., blue hospital pads or newspaper) and secure with tape.
9) Samples, either in microtainers or tubes, should be placed in leak-proof container (“zip-lock” type bag) and then stored with cool gel-pack – NO ICE. The sample should not freeze. Samples can be refrigerated until time of mailing when they are then placed in the Styrofoam mailing kits.
10) Check with your shipping vendor for specifications and limitations.
11) Specify overnight mail with first morning delivery. Shipments can only be sent Monday-Thursday and NOT before any holiday or weekend.