Chapter 23

New Participant Packet

For LLFS Visit 2, we will extend new participation to members of existing pedigrees who are now interested in participating in the LLFS. These new participants are thought of as a way to keep best relations with currently participating families.

New participants will be found by asking current participants if they have any additional family members that would be willing to participate in LLFS. This will occur either during the telephone call to the current participant to schedule their LLFS Visit 2 or during the annual telephone follow-up, depending on which is more natural for each field center.

Since new participants will not have a baseline visit, it is important to capture information from Visit 1 that we are no longer obtaining at Visit 2. This chapter outlines the exact information from Visit 1 that we feel is necessary to obtain on new participants at Visit 2.

Chapter 2, Re-recruitment. There will be no additional questions about expanding the pedigree, but we will need to add the new participants to the correct place on the existing pedigree. In some cases, these participants may already be on our pedigree, with a study ID number, but did not participate in Visit 1 for various reasons. There will also be no new calculation of the FLoSS score using additional information from these new participants.

Pedigree Updating

During the second in-home visit for LLFS, pedigrees will only be updated/reviewed with new participants. New participants will be placed in the existing LLFS pedigree in a process different from the process of creating the pedigrees which was used in the first in-home visit.

When to update a LLFS pedigree

1. If the participant has Visit 1 data (i.e. enrolled), then no update to pedigree is needed.
2. If this is a new participant (no visit 1 data, new interested family member, new marry-in, etc.) then NEED to check existing LLFS family pedigree/update the pedigree

How to update a LLFS pedigree

When a field center identifies a new participant (NP), that field center needs to alert the DMCC of this new participant and tell the DMCC the pedid of this new participant. The DMCC will then send two files to the field center which will be used to update the existing LLFS pedigree. The first file is the existing pedigree plot for that pedid and the second is the pedigree-specific triplet file (csv file). This excel file will contain columns for pedid, id, dadid, momid, proband (Y/N), deceased (Y/N), sex (1=male, 2=female), twin status (Y/N), adopted (Y/N), and twin relation (M=MZ twin, D=DZ twin). The pedigree plot will include the LLFS ID, first name, last name, and date of birth, for all enumerated members of the pedigree, if this information is known. This plot will also show which family members participated in the first in home visit.

Using these two files, the field center staff must first search to see if the NP name and date of birth are already on the pedigree plot.

1. If the NP name and DOB are on the plot
    a. That family member was also assigned an LLFS ID during visit 1.
    b. Use that LLFS ID for this NP and **DO NOT ASSIGN A NEW LLFS ID**.
2. If the NP name and DOB are NOT on the pedigree plot
    a. UPDATE the triplet file for the family.
    b. First, assign a LLFS ID to the NP from the list of potential NP IDs from DMCC
    c. This will be written in column B of the triplet file, at the bottom after the existing records.
    d. Next, determine the relationship of the NP to the existing pedigree members
        i. New participant, not enumerated in Visit 1
        ii. New marry-in in either generation
        iii. New child of proband generation with only one parent known in pedigree
        iv. New child of proband generation with both parents in pedigree
    e. See directions for each below

NEW PARTICIPANT TRIPLET FILE UPDATE

The following explains how to update the triplet file for a NP. First, assign the NP an LLFS ID from the list of potential NP IDs from the DMCC. Write this LLFS ID in column B of the triplet file, after the existing records. Leave columns C and D (dadid and momid) empty. The proband status (column E) is 0. Data in columns F through J is self-explanatory and needs to be completed.

If the NP and their LLFS spouse have children or the NP is a child of the proband generation, the information for these children will need to be completed as follows:

1. NP marry-in is in offspring generation
    a. Create a 'dummy' child and complete columns A, C, D, E, F, H, I, and J
2. NP marry-in is in the proband generation
    a. Add children to the triplet file in the same way as you added the NP.
3. NP is a child of the proband generation
    a. ONLY ONE PARENT IN EXISTING LLFS PEDIGREE
        i. Create a record for the other parent in the triple file
        ii. Assign another NP LLFS ID (from potential ID list) to this parent and write it in column B
        iii. Complete columns A, E, F, G, H, I, and J for this parent
        iv. Create the record for the new child by assigning the child a NP LLFS ID from the list of potential NP LLFS IDs and write this in column B
        v. Then complete columns A and C through J for the child
    b. BOTH PARENTS IN EXISTING LLFS PEDIGREE
        i. Create the record for the new child by assigning the child a NP LLFS ID from the list of potential NP LLFS IDs and write this in column B
        ii. Then complete columns A and C through J for the child

---

Chapter 3, Interview Guidelines. No additional items to ask new participants.

Chapter 4, Informed Consent. No additional items to ask new participants.

Chapter 5, Appointment Documents. We need to ask new participants to have available a copy of documentation used to verify their age, such as a birth certificate, passport, military record, or marriage license. We will document verification of their reported date of birth using this document.

Chapter 6, Alerts. No additional items to ask new participants.

Chapter 7, Blood Assays. No additional items to ask new participants.

Chapter 8, Blood Pressure, Heart Rate, Weight, Height. In addition to the measurements planned for Visit 2, we will also need to obtain new participants ankle arm index, arm span, sitting height, and knee height. These items were removed for Visit 2 because they should not change over the course of one's adult life and are good indicators of overall height. The specific definitions are:

Ankle Arm Index: Non-invasive measure of atherosclerotic obstruction in the legs; performed while in flat or semi-recumbent position.

Arm Span: Arm span is measured with arms fully extended, distance from longest fingertip to longest fingertip.

Sitting Height: Height with no shoes, sitting on a standard chair.

Knee Height: Knee height is measured on the right leg with the subject in the seated position.

MEASURE: ANKLE-ARM BLOOD PRESSURE

Background and Rationale

The ankle-arm index (AAI) is the ratio of the ankle to arm systolic blood pressure. It is reduced to less than 1.0 when there is obstruction to blood flow in legs. The AAI is a non-invasive measure of atherosclerotic obstruction in the legs and is a general marker of atherosclerotic burden. The degree of sub-clinical and clinical atherosclerosis is hypothesized to be related to the decline in lean mass and increase in abdominal adiposity with age. AAI is associated with atherosclerotic disease in other vascular beds and predicts subsequent mortality and cardiovascular mortality. The impact of sub-clinical cardiovascular disease on loss of bone and muscle mass and subsequent disability is not clear.

Equipment and Supplies

- Handheld 8 megahertz Doppler Probe with Built-in Speaker
- Supply of 9 Volt Alkaline Batteries
- Doppler Conducting Jelly
- Omron HBP-1300 Digital Sphygmomanometers
- Blood Pressure Cuffs (1 large, 1 thigh, 3 adult small, 3 adult regular)
- Black Eyeliner Pencil
- Tissues to Remove Conducting Jelly

Equipment Use

Using the Doppler.

- Push button in to turn on and gradually turn the volume up. Now place the probe over the artery (brachial or posterior tibial).
- The frequency used is 8 Megahertz (vibrations of 8 million times per second). In order to hear the signal above background noise, the instrument must be pushed in toward the artery. Angling the beam upstream improves the signal. For deeper vessels, the unit will have to be tilted back toward perpendicular, but NOTE: the instrument works poorly or not at all if held fully perpendicular to the flow. It must always be angled into and IN LINE with the flow. Please refer to **Figure 1** on following page.
- In some places along the posterior tibial artery, there is anatomical hiding of the vessel by muscle or tendons. Move up or down the vessel a little to find the best signal above background noise.
- The purpose of the Doppler is to determine that blood is or is not flowing under the cuff. For correct interpretation, the probe MUST be centered directly over the artery and must not be moved while inflating the cuff.
- Please note that the Doppler unit turns itself off after 5 minutes automatically. This may occur in the middle of a measurement.

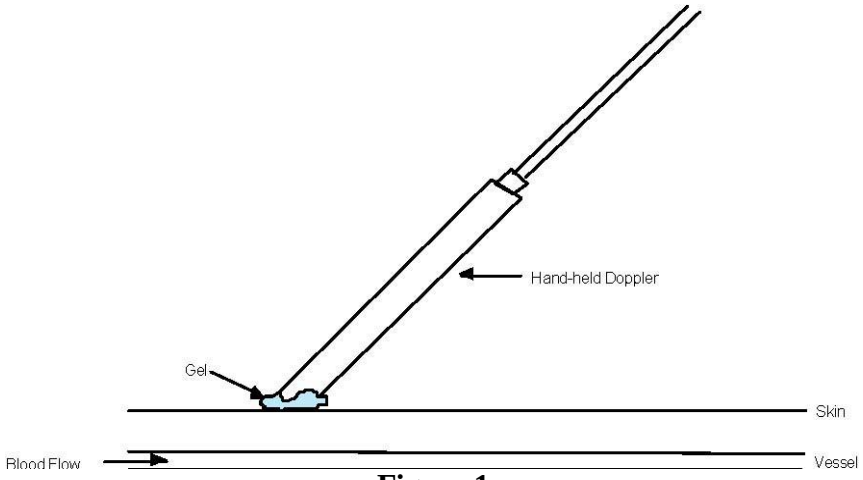

Figure 1

Equipment Maintenance

KEY POINT: Use only ultrasound gel.

The Probe. The probe consists of two crystals; one for transmitting the ultrasound waves and the other for receiving the reflected waves. If either crystal is damaged, the probe will not work properly or will not work at all. The crystals are covered by epoxy resin. This resin is attacked by any gel or liquid containing the chloride ion. Therefore, NEVER use ECG paste or cream as the contact medium between the skin and the crystals. Use AQUASONIC or any gel made for ultrasonic physical therapy equipment. In an emergency use any surgical jelly or lubricant, even Vaseline or mineral oil. Remove the gel after use with a soft tissue. If the probe has dried gel on it, wash it off under running water and dry with a soft tissue. Do NOT scrape off the gel because this may damage the epoxy coating. Do NOT autoclave the probe. Gas sterilization is OK.

KEY POINT: To preserve battery, turn off unit immediately after measurements The battery. As the battery runs down, the signal will get weaker to the point where the instrument just doesn't work. Most batteries run down because the instrument has been left turned on. It takes less than a minute to make a blood pressure measurement. Turn the unit off immediately after removing it from the skin. Use an alkaline-type replacement 9-volt transistor radio battery. Three screws hold the battery in the case. After loosening or removing the screws, gently lift up the back to replace the battery.

Strange Noises from the Doppler. On occasion there are unusual noises from the Doppler that do not indicate a problem with the Doppler. The normal sound will become obvious with experience in performing this test. Following are some common complaints and their causes.

1. Popping noises when the probe is first placed on the skin. Scratchy sound at first.
   Cause: Bubbles in the gel that are moving and/or popping. Also hair movement can cause noise. Remedy: Use a new glob of gel that looks clear, push down enough so hair is immobilized, and just wait a few seconds for things to settle down. If the noise isn't there when the probe is clean (no gel) and suspended in the air, the Doppler and/or probe are probably not at fault.

2. Bad static when the dry probe is moved in the air.
   Cause: a loose connector where the probe connects to the instrument, a broken shield wire in the cable either at the connector or as it comes out of the probe. This can be diagnosed by wiggling the wire or connectors gently. There is NORMALLY some static generated when the cable is flexed, but it isn't severe. Remedy: QC Officer will arrange to replace probe or get connectors fixed.

3. High-pitched tone.
   Cause: radio interference from a mobile service, police station nearby, even another Doppler working nearby. Usually occurs near large open windows, rarely in the center of the building. Remedy: Move to another room.

4. Howling noise when the probe with gel on it is held or laid on a table.
   Cause: acoustic feedback through the probe acting as a microphone. If it doesn't occur without gel on the probe, everything is OK.

Safety Issues and Exclusions

All participants enrolled in LLFS are eligible for ankle-arm index measurement with the following exceptions:

- Persons with open wounds including venous stasis ulcers, rashes, or any open wound
- Persons with bilateral amputations
- Persons unable to lie down at a 45° angle or less.

These are recorded as "missing data." See data entry form.

Some participants will have rigid arteries in the legs and the arteries cannot be occluded before the dial reads 300 mmHg. It is possible to find this in only one leg. This should be recorded as "unable to reach occlusion blood pressure."

Protocol

Clinic Protocol. The participants are being asked to lie flat or semi-recumbent. Flat or semi-recumbent is defined as the trunk being raised no more than 45 degrees from the surface of the examining table. If the participant is unable to lie at 45 degrees or less, they are excluded. Please record this on the form. To facilitate examiner ease in measuring the ankle arm blood pressures, a three wheeled stool is recommended to move from the arm position to the foot position.

Home Visit Protocol. The measurement can be performed in both the home and the clinic using the same protocol. In the home environment the measurement can be performed with the participant lying in a recliner, on their bed, or on the couch. The head can be supported by a pillow in a semi-recumbent position as described above. Two kitchen chairs can be used for examiner ease in moving from the arm position to the foot position. If you are unable to complete the procedure, document this by checking the appropriate reason in Q10g. Note on 3/26/07 a new option of "Unable to follow instructions due to CI (cognitive impairment) was added".

Participant Preparation

- Record the first seated systolic blood pressure measurement from the right arm on the data collection form in Q6a.
- Measure the systolic blood pressure in the left arm using the same protocol as the measurement for the right arm and record in Q6a.
- If the measurements differ by more than 10 mm Hg, use the arm with the highest pressure as the reference arm. Mark the arm used in Q6b.
- Ask the participant to remove their shoes, socks and stockings so that the ankles are bare to mid-calf, if this has not been done already.
- Remove the sleeve of reference arm.
- Lay the participant on the examining table with the reference side toward the observer and the feet at the free end of the table. Keep the participant recumbent or semi-recumbent for at least five minutes before measuring blood pressure.Application of Cuffs:

1. Place three blood pressure cuffs on the participant:
   - Place one cuff on the reference arm. Note: Use the same cuff size that was used for the blood pressure measurement
   - Place one regular adult size cuff on the right ankle
   - Place one regular adult size cuff on the left ankle

2. Apply the ankle cuffs with the midpoint of the bladder over the posterior tibial artery, with the lower end of the bladder approximately 3 cm above the medial malleolus. Rarely, the Velcro will not hold due to the ankles being very thin or large. In these cases use pediatric or large adult cuffs or spiral the cuffs to get a snug fit.

Detailed Measurement Procedures

Determining the Maximal Inflation Level (MIL). The maximal inflation level will be automatically determined by the HBP-1300 manometer for each extremity.

- If the MIL is 300 mmHg, terminate the blood pressure measurements and select "Unable to Occlude" on the form. On the Report of Findings, indicate the blood pressure at the level heard. Refer the participant to see their doctor based on the seated blood pressure taken with HBP-1300 monitor. The Doppler will always be higher.

Performing the Measurement:

1. Reference Arm Systolic Blood Pressure Measurement
   - Position yourself next to the participant's reference arm
   - Attach the cuff tubing to the monitor
   - Turn on the HBP-1300 monitor
   - Locate the brachial artery by palpation
   - Apply ultrasound gel to the Doppler
   - Place the Doppler on participant's reference arm and locate brachial artery
   - Measure the systolic blood pressure using the Doppler:
   - Press the start button on the HBP-1300 to inflate the cuff
   - The HBP-1300 will deflate at 4 mmHg per second
   - Note the numeric systolic value on the monitor as the audible blood flow returns
   - Press the stop button 10 mmHg below the appearance of systolic pressure
   - Deflate the cuff quickly and completely
   - Record systolic blood pressure in space provided for brachial (arm) on form in Q7a.

2. Right Ankle Systolic Blood Pressure Measurement
   - Position yourself next to the participant's right ankle
   - Attach the cuff tubing to the monitor
   - Locate the posterior tibial artery by palpation. If the posterior tibial pulse is difficult to locate, the dorsalis pedis pulse (located on the top, center of the foot) may be used; however this should be documented.
   - Apply more ultrasound gel to the Doppler
   - Measure the systolic blood pressure using the Doppler (same as above)
   - Record the systolic value from the first reading in the space provided for right posterior tibial on the form in Q7b.

3. Left Ankle Systolic Blood Pressure Measurement
   - Position yourself next to the participant's left ankle
   - Attach the cuff tubing to the monitor
   - Repeat systolic blood pressure measurement as for right leg
   - Record the systolic value from the first reading in the spaces provided for left posterior tibial on the form om Q7c.

4. Repeating the Ankle-Arm
   - Repeat the sequence in the reverse order:
     - left ankle (Record in Q8a)
     - right ankle (Record in Q8b)
     - reference arm (Record in Q8c)
   - Review the form for completeness
   - Remove cuffs and conducting jelly

Tips for the Ankle-Arm Measurements:

- Mark the location of maximal pulse or Doppler signal on the brachial artery and both posterior and tibial arteries with an eyeliner pencil to improve the speed and accuracy of localizing them the second time and to help maintain position.
- Hold the Doppler pen absolutely still while inflating and deflating the cuff; moving a few millimeters will lose the pulse.
- Always use enough jelly to ensure good contact.
- The systolic value is the pressure level at which you hear the first of two or more swishing sounds in the appropriate rhythm. (Note: A single sound heard in isolation [i.e., not in rhythmic sequence] before the first of the rhythmic sounds [systolic] does not alter the interpretation of blood pressure).

Calculation of Ankle-Arm Blood Pressure Ratio. The ankle-arm blood pressure ratio is calculated in the manner described below. The fields for calculating these measures in the home/clinic are Questions 10b-10f.

Q10b. The average brachial systolic blood pressure is determined
(Brachial Measurement #1 + Brachial Measurement #2)/ 2

Q10c. The average right posterior tibial systolic blood pressure is determined
(Right Posterior Tibial Measurement #1 + Right Posterior Tibial Measurement #2) / 2

Q10d. The average left posterior tibial systolic blood pressure is determined
(Left Posterior Tibial Measurement #1 + Left Posterior Tibial Measurement #2) / 2

Q10e. Ankle-Arm Blood Pressure Ratio for Right Side:
Measurement 1 = (average right posterior tibial / average brachial)

Q10f. Ankle-Arm Blood Pressure Ratio for Left Side:
Measurement 2 = (average left posterior tibial / average brachial)

Results. This is a screening test for atherosclerotic obstruction in the lower legs. Participants will receive a report (at the discretion of each field center) of the ankle-arm index in each leg after these results have been hand-entered on the Ankle-arm Blood Pressure Results form which includes the information described below:

The ankle-arm blood pressure index is the ratio of the ankle to the arm blood pressure. It is a screening test for peripheral arterial disease. A low ratio may mean that there is an obstruction or blockage.

Left leg	Right leg
Normal	Normal greater than 0.9
Low	Low 0.9 or less

Contact the Pittsburgh Field Center for a sample participant results letter.

Staff Alert. An extremely low AAI could indicate severely restricted blood flow to the leg, however, a clinical intervention to restore flow would only be done if there were severe symptoms (i.e., severe pain at rest, or ulceration or gangrene). The staff is not expected to be able to diagnose these conditions but should encourage participants who ask them about any symptoms to consult their physician.

Quality Assurance

Training Requirements. Staff performing the ankle-arm index measurements should be research technicians or clinicians previously trained in taking research blood pressure measurements. In addition, training should include:

- Read and study manual
- Attend LLFS training session on techniques (or observe administration by experienced examiner)
- Practice on volunteers
- Compare measurements with those made by experienced colleagues (Goal: Obtain measurements within ± 2 mm Hg of that observed by a trainer)
- Discuss problems and questions with local expert or QC officer

QC Reports. Monthly reports of the distribution of final digits for each technician will be reviewed by the QC Officer. Trends toward digit preference will be discussed with the technician without revealing which digit and retraining/re-certification may be required.

References:

1. Newman AB; Siscovick DS; ManolioTA; Plak J; Fried LP; Borhani NO; Wolfson SK. Ankle-arm index as a marker of atherosclerosis in the Cardiovascular Health Study. Cardiovascular Health Study (CHS) Collaborative Research Group. Circulation, 1993 Sep, 88(3):837-45.
2. Newman AB, Shemanski L, Manolio TA, Cushman M, Mittelmark M, Polak JF, Powe NR, Siscovick D. Ankle-arm index as a predictor of cardiovascular disease and mortality in the Cardiovascular Health Study. The Cardiovascular Health Study Group. Arterioscler Thromb Vasc Biol. 1999;19:538-45.
3. Newman AB, Arnold AM, Naydeck BL, Fried LP, Burke GL, Enright P, Gottdiener J, Hirsch C, O'Leary D, Tracy R; Cardiovascular Health Study Research Group. Successful aging": effect of subclinical cardiovascular disease. Arch Intern Med. 2003;163:2315-22.
4. Newman AB, Fitzpatrick AL, Lopez O, Jackson S, Lyketsos C, Jagust W, Ives D, DeKosky ST, Kuller LH. Dementia and Alzheimer's disease incidence in relationship to cardiovascular disease in the Cardiovascular Health Study cohort. JAGS. 2005;53:1101-1107.

MEASURE: ARM SPAN

Arm Span: Record the arm span in Question 12a after measurement by the following procedure:

Locate a wall in the home that can be used to measure the participant's arm span. The easiest would be a corner in the room. With the participant standing with their back to the wall, ask him/her to reach out with the arm fully until the longest fingertip touches the corner of the wall at shoulder height. Ask the participant to stretch out their other arm fully. Place a piece of painter's tape approximately at shoulder height and approximately at finger tips.

> Script: *In this test I will measure the length of your arm span from fingertip to fingertip. Please stand with your back to the wall and fully extend your right/left arm at shoulder height, just until your fingertip touches the corner of the wall. Now extend your other arm also at shoulder height. I will place a piece of tape at the outstretched fingertip and mark the tape.*

A carpenter's square or other straight edge will be used to determine the length to measure. Holding the square perpendicular to the wall at the longest fingertip, mark the tape where the square crosses the tape. Ask the participant to step away from the wall. Using a measuring tape, measure the distance between the 2 marks, on the tape, to the nearest 0.1 centimeter, rounding down.

If a corner is not available, measure against an open piece of wall. It should be wide enough to allow the participant to stretch out his/her arms fully. Ask the participant to stand with his/her back against the wall. Ask the participant to stretch out their right arm fully. Place a piece of painter's tape approximately at shoulder height and approximately at finger tips. Repeat for the left arm. The participant is asked to step away from the wall. Using a measuring tape, measure the distance between the two marks, on the tape, to the nearest 0.1 centimeter, rounding down.

Important Note: If the participant is unable to stand, the measurement can be done in a seated position. Also, if the participant cannot fully extend both arms at shoulder height, do not measure arm span. Full extension means that both arms are extended to a 90° angle from the trunk. If participant is unable to complete arm span, mark the form with a "N" for not applicable, subject is unable to perform the procedure.

However, if the participant is unable to complete the procedure because they were unable to sufficiently follow instructions to complete the measurement, then enter "U" for measurement 1 (Q11a) and then proceed to Q13a.

Height as Young Adult: The participant is asked to report in Question 12b their height as a young adult, that is, during their mid-twenties. This height may or may not be different than present height. Record the response given in feet and inches (or cm for the Danish cohort).

MEASURE: SITTING HEIGHT

Sitting Height: Record the sitting height in Questions 13a-13h after measurement by the following procedure outlined below. If participant is unable to complete sitting height, mark the form with a "N" for not applicable, subject is unable to perform the procedure. However, if the participant is unable to complete the procedure because they were unable to sufficiently follow instructions to complete the measurement, then enter "U" for measurement 1 (Q13a) and then proceed to Q14a.

Home Visit Protocol: Follow the procedures above for standing height. Positioning for this measure can be found in #1 below.

Clinic Protocol:

1. Have the participant sit on the seat with the legs hanging unsupported over the edge and with the hands resting on the thighs in a cross-handed position. If the feet are touching the floor, weight should be on the buttocks and not the feet. If the participant is uncomfortable in this position, i.e. feels that they are slipping forward, they can rest their feet on the rungs of the seat, again, with their weight on the buttocks and not on the feet. The knees should be directed straight ahead, and the back of the knees should be near the edge of the seat but not in contact with it. The muscles of the thighs and buttocks should be relaxed.

   Script: *"Please sit on this seat with your knees facing forward. Place your hands on your thighs in a cross-handed position. Sit up as straight as possible with your*

buttocks and back touching the backboard. (Optional: Do not support your body weight on your feet. All your weight should be on the buttocks.) Relax the muscles of your legs and buttocks."

2. Ask the participant to sit as erect as possible with the buttocks, spine, and back of the head against the wall.
3. The participant should face straight ahead with their head in the Frankfort position (see **Figure 2**).
4. Place the horizontal bar firmly on the top of the head. (Place a weight, of about 0.5 kg, on the headboard. This weight presses down on the hair, thus flattening any hairstyle and overcomes the natural friction of the machine so that any upward or downward movement during the measurement is recorded on the counter).
5. Have the participant breathe in deeply; Script: *"Take a deep breathe in"*
6. Record the reading in mm on the stadiometer just before the participant exhales; Script: *"Breathe out"*
7. The participant should step away from the stadiometer, and the procedure should be repeated for the second measurement. If the two measurements differ by ≥ 0.4 cm, two additional measurements should be taken.
8. Deviations/exceptions to standard positioning:
   For participants with extremely kyphotic (stooped) posture, it may not be possible to obtain contact between the headboard and scalp when the participant's buttocks are against the wall-plate. In this case, measure sitting height with the participant sitting sideways (side of arm against the wall-plate) and positioned so the headboard contacts the scalp. Record that the participant was measured in the sideways position on the scoring form so that follow-up measurements will be made in the same position.

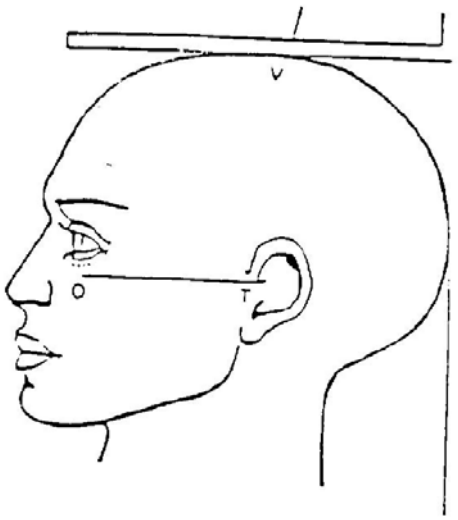

Figure 2

MEASURE: KNEE HEIGHT

Knee Height: Loss of height occurs frequently in the elderly. Knee height is independent of age among adults and does not appear to decrease over time (Chumlea, 1985).

Record the knee height in Questions 14a-14c after measurement by the following procedure outlined below.

If participant is unable to complete knee height, mark the form with a "N" for not applicable, subject is unable to perform the procedure. However, if the participant is unable to complete the procedure because they were unable to sufficiently follow instructions to complete the measurement, then enter "U" for measurement 1 (Q14b) and then proceed to Q15.

1. Knee height is measured on the right leg, using a sliding broad-blade caliper, with the subject in the seated position (see **Figure 3**) (Chumlea, 1985). The patient's shoes and socks are removed, and pants rolled up past the knee.

   Script: *Please remove your shoes and socks from your right foot and roll up your pant leg past your knee. In this test, we will measure the length of your leg from heel to knee. Place the heel of your right foot on this measuring caliper and this other arm will rest on your knee.*
2. To obtain the measurement, the participant sits on a chair/examination table with both dangling. The participant may require the assistance of the examiner to help him onto the table.
3. The examiner places the fixed blade of the large sliding caliper under the heel of the right leg just below the lateral malleolus of the fibula. **Please Note:** If the participant has had a knee replacement on the right knee, the measurement may be taken on that leg as long as the participant can bend the replaced knee to a 90 degree angle. If the participant is unable, the left leg will be used to measure knee height. If the participant is unable to bend either knee, this measurement will not be taken.
4. From a squatting position, the examiner raises the leg so that the knee and ankle are both at a 90 degree angle (see **Figure 3**). This is best accomplished by resting the participant's foot in the palm of the examiner's hand.
5. The moveable blade of the caliper is placed on the anterior surface of the right thigh, above the condyles of the femur at the edge of the patella.
6. The shaft of the caliper is held parallel to the shaft of the tibia so that the shaft of the caliper passes over the lateral malleolus of the fibula and just posterior to the head of the fibula. Pressure is applied to compress the tissue.
7. The recorder checks the positioning of the leg and the caliper. Knee height is recorded to the nearest 0.1 cm. Measurements to the nearest 0.1 cm are obtained and then repeated.

Figure 3

Reference: Chumlea WC, Roche AF, Steinbaugh ML. Estimating stature from knee height for persons 60 to 90 years of age. J Am Geriatr Soc 1985; 33: 116-20.

Chapter 9, Socio-Demographic Information. The majority of this form was changed for LLFS Visit 2 because the questions asked in Visit 1 should not change between visits. Thus, new participants will receive both the Visit 1 SDI form, as described below, and the new form associated with the SDI chapter for Visit 2.

ADMINISTRATION

There are two versions of this questionnaire – one for U.S. participants and another for the Danish cohort. This interview is designed to be administered by an interviewer; however, when necessary, it may also be mailed and self-administered. At the top of the form there is a box "For Internal Use Only" in which to check the way in which the interview was completed. It is important that this box be completed accurately by study personnel.

METHODS

Participant is to answer each question by following skip patterns specified in the questionnaire. For questions requesting "Year or Age", participant can provide either response. The participant should be instructed to provide whichever – year or age – he or she is most likely to remember accurately.

Enter the information as provided by participant.

Question 1 – Date of Birth: Four digits should be used for year of birth. The first three letters of the month should be entered. If applicable, leading zeros should be entered for day. For example, the date of birth for a person born on January 5, 1915 would be formatted as:
DAY: 05 Month: JAN Year: 1915

Question 2 – Source of Birth Date: Select only one box for birth date source. If participant has a birth certificate in his/her possession, birth certificate should be marked. In the absence of a birth certificate, mark the item that participant most commonly uses when s/he needs to provide a proof of age. If the participant uses a source not listed as one of the choices on the questionnaire, write this source in block letters on the line provided next to "other (Please Specify)".

Question 2a – Birth Date Verification: This question requests that the birth date source mentioned above be used to verify the participant's birth date. Select either "yes" or "no" to indicate whether the birth date was confirmed or matched by viewing the source document. If the birth date is not verified, select "no" and state the reason on the line provided.

Questions 3a and 3b – Birth Place: Follow skip patterns as specified in the questionnaire. Write down the names of places on the lines provided. Participant should answer any or all information that s/he recalls.

Questions 4a and 4b – Birth Place-International: Participant is asked to provide the name of the country where s/he was born, if not born in the US. Write down the year when participant came to the US using 4 digits (1915) on the line provided. If participant is unable to remember the year, ask for his/her age at the time when s/he arrived in the US. If applicable, leading zero should be entered for age (e.g., if participant was 7 years old when he or she came to the U.S. write 07).

Question 5 – Childhood Residence: Participant is asked to provide the name of city/town, county, state and country where s/he lived the majority of his/her childhood before age 16. Write down the names of places in block letters on the lines provided.

Questions 7, 8 and 9 – Gender, Hispanic Origin and Race/Ethnicity: These items are *self-assigned.* For Question 9, race, ask participant to choose all that apply. If participant's *self-identified* race is not among the categories listed, mark "other" and ask participant to specify the *self-identified* other race. Write this other race in block letters on the line provided. Show the respondent the card so that s/he can see the choices provided.

Question 10 – Educational Attainment of Participant: Participant is asked to choose the category corresponding to the highest degree or level of education s/he has **completed**. Do not select the choice unless the person has completed that level of education. For example, if the participant has completed half of 5th grade, select 4 grade. Only one response should be marked. Show the respondent the card so that s/he can see the choices provided. If the participant has had vocational training, check the box for vocation training and jot down the number of years of vocational training s/he had on the line provided.

Question 11a – Participant's Occupation: Question 11a asks about participant's **main** occupation during most of his/her life. If participant worked on a farm or a family business, specify whether this work was paid or unpaid. If participant never worked, check the box provided for "never worked" and skip to Question 12a. Ask participant to provide this information as briefly as possible. Write down participant's response in block letters. ***Please***

Note: If the participant is currently working, be sure that the occupation jotted down here represents the role s/he played in his/her ***main occupation***, which may not necessarily be related to the type of work s/he is currently performing especially if the participant is working part-time or on a 'side job'. The participant should be encouraged to report only one occupation which should be his/her primary occupation for most of his/her life. However, if the participant insists that he/she had more than one **main** occupation, list all and include them on separate lines or clearly separate them with " ;".

Question 11b – Number of Subordinates: Participant is asked to provide the number of subordinates s/he had when s/he **stopped** working from his/her main occupation. We are defining 'subordinates' as those employees who had a lower rank than the participant and who reported to him/her as their supervisor. If participant had more than 1,000 subordinates, write "999". If the person does not know, write don't know. **Please Note:** If the participant is still working at his/her **main** occupation, you may enter the current number of subordinates. If the participant is currently unemployed or working in a job outside of his/her main occupation (i.e. part-time, 'side job', etc.) or has retired, enter the number of subordinates the participant had when s/he stopped working from his/her **main** occupation.

SPOUSE/PARTNER

Questions 13-14: This set of questions pertains to the spouse/partner to whom the participant has been married or lived with the longest.

Question 13 – **Educational Attainment of Participant's Spouse/Partner:** Participant is asked to choose the category corresponding to the highest degree or level of education his/her spouse/partner has **completed**. Do not select the category unless the participant's spouse/partner has completed that educational level. For example, if the spouse/partner has completed half of 5th grade, select 4th grade. Only one response should be marked. If participant has been married or lived with a partner more than once, the question should be answered for the spouse/partner to whom s/he was married or lived with for the longest time. Show the respondent the card so that s/he can see the choices provided.

Question 14a – Occupation of Participant's Spouse/Partner: **Question 14a** asks about the main occupation of participant's spouse/partner during most of the spouse's/partner's working life. If the participant has been married or lived with a partner more than once, the question should be answered for the spouse/partner to whom s/he was married or lived with for the longest time. Ask the participant to provide this information as briefly as possible. Write down the participant's response in block letters. If a participant's spouse/partner never worked, check the box next to "never worked" and skip to Question 15a. **Please Note:** If the participant's spouse/partner is currently working, be sure that the occupation written down here represents the role s/he played in his/her ***main occupation***, which may not necessarily be related to the type of work s/he is currently performing especially if the participant's spouse/partner is working part-time or on a 'side job'. The participant should be encouraged to report only one occupation which should be his/her spouse's/partner's primary occupation for most of his/her life. However, if the participant insists that the spouse/partner had more than one **main** occupation, list all list all and include them on separate lines or clearly separate them with " ;".

Question 14b – Number of Subordinates of participant's spouse/partner: Participant is asked to provide the number of subordinates his/her spouse/partner had when the spouse/partner **stopped** working. We are defining 'subordinates' as those employees who had a lower rank than the participant's spouse/partner and who reported to him/her as their supervisor. If participant's spouse/partner had more than 1,000 subordinates, write "999". If the respondent does not know, write don't know.
Please Note: If the participant's spouse/partner is still working at his/her main occupation, you may enter the current number of subordinates. If the participant's spouse/partner is currently unemployed or working in a job outside of his/her main occupation (i.e. part-time, 'side job', etc.) or has retired, enter the number of subordinates the participant had when s/he stopped working from his/her main occupation.

Question 15a – Highest Annual Combined Household Income: This question asks about the highest annual combined household income participant and anyone in his/her family attained when participant and/or his/her spouse/partner were working. Participant should include income from all sources such as wages, salaries, self-employment, governmental sources, help from relatives, rent from properties, interest, dividends, and any other income sources. Only one answer should be marked. Since this is a sensitive question, use the income response form to elicit the response. Participants tend to feel more comfortable when asked to point to their income level on the response form rather than to verbally state their response to this particular question. **If the participant was/is living with someone with whom they did NOT or don't share their income, the participant should report his/her income only, i.e., not the combined income with his/her living partner. If the incomes of the spouse/partner were/are pooled, then the combined income should be reported. Please note that, for those who have had a change in marital status, the *highest annual income* when working may not necessarily be the income they earned when together.**
If the participant earned more while living and working on his/her own than s/he did when living with a spouse/partner, the highest income should be reported.

Question 15b – Time Estimate of Earned Income: The participant is asked to provide a time interval for when this highest level of annual combined household income was earned. If the participant is unable to provide the time interval in the format of a range between the two years in which this income was earned (i.e. "Year 1910-Year 1925"), s/he may provide the age range s/he was during the time this income was earned (i.e. "Age 35-50).

Question 15c – Dependents on Income: Question 15c asks about the **maximum** number of **household** members, **including participant**, who depended on this income**.** Provide the maximum number of household members on the line provided. If applicable, leading zeros should be entered.

Question 15d – Rate of Difficulty: Question 15d asks the participants to rate the level of difficulty they and their family experienced when paying for the very basics during most of their life. Read the 5 choices out loud (with the exception of 'don't know' or 'refused') and ask the participants to select the one best choice. Mark only one response.

Questions 16a-16b – Housing Ownership and Value: These questions ask about ownership and financial value of participant's principal place of residence. Follow skip patterns as specified in the questionnaire. Mark only one answer per question. For Q16b, ask the participant to point to the correct choice on the response form.

Questions 17 - Financial Assets: This question asks about the value of any financial assets participant may have. Assets refer to bank accounts, retirement accounts, investments, such as stocks and bonds, and other financial assets. Only one answer per question should be marked. Ask the participant to point to the correct choice on the response form.

Note: Questions 15d through 16a will be asked of the Danish cohort.

Documents Referred to in this Chapter:

- Socio-demographic Information Data Collection Form – United States
- Socio-demographic Information Data Collection Form

Chapter 10, Physical Function and Activity. New participants in Visit 2 will need to answer questions 13a, 13b, 14a, and 14b from Visit 1 Panel 3 ADLs. These four questions ask about a participant's physical activity and exercise habits when they were about 50 years old. Since these are questions of a historical nature that should not change from the first time they were asked, they are omitted during the administration of Panel 3 during Visit 2 for returning participants.

Chapter 11, Cognitive Assessment. Vegetable fluency was removed for Visit 2, however it will not be asked of new participants because it cognitive data collected is similar to the other tests and we have an expanded battery of cognitive test for Visit 2.

Chapter 12, Medical Personal History. For new participants, the time frame reference for the questions in Panel 4 (Visit 1) needs to be changed from 'since we last contacted you' to 'EVER'. Additionally, the basic historical smoking questions from Visit 1 were added back into Panel 4 (Visit 2) for new participants.

Panel 5 (Visit 2) for new participants, the time reference for the questions will be changed from 'since we last talked to you' to either 'EVER' or 'within the last year' on Panel 5 Medical History. Additionally, we should ask what their usual weight at about age 50 (Question 7 on Panel 5 from Visit 1).

Chapter 13, Performance Measures. No additional items to ask new participants.

Chapter 14, Spirometry. No additional items to ask new participants.

Chapter 15, Carotid Ultrasound. No additional items to ask new participants, as this is new to all participants.

Chapter 16, Medication Inventory. No additional items to ask new participants.

Chapter 17, Long Distance Visits. No additional items to ask new participants. Based on geography, there may be some discussion amongst the field centers as to which field center a new participant should belong to however this does not affect what forms are given to the new participant.

Chapter 18, Participant Follow-up. Participant follow-up will be the same in new and returning participants. However over the course of follow-up for Visit 1, returning participants were administered the health habits questionnaire, the NEO, and the expanded NEO, all from Visit 1 or Visit 1 annual follow-up. Therefore new participants will be given the health habits questionnaire and the expanded NEO, detailed below.

Administration of the Health Habits Questionnaire:
Phase III annual follow-up will commence upon Institution Review Board Approval from each Field Center sometime in the fall of 2011. Phase III will include the addition of a Health Habits Questionnaire (Panel 19-II) that specifically asks information about historical physical activity and sleep habits. All participants due for annual follow-up (both short and expanded) will be asked to complete this questionnaire via telephone interview or via self-administered by mail as additional part of the annual follow-up. This questionnaire is to be completed only once for each participant that is followed up in the 1 year period from the start of this data collection.
Detailed Q-by-Q:

Questions 1-4 Historical Physical Activity:
These pertain to assessing historical physical activity levels during teenage years, around age 25, age 50 and over the past month. Please read the 5 response options and ask the participant to choose the option that is most suitable. Encourage them to make their best guess, but if they are unable to provide an answer mark "Don't Know". For those that have no reached age 50, the appropriate answer for Question 3 is "Not Applicable". Note that the terms exercise and physical activity can be used interchangeably for these questions. Examples of light activities for response Option 2 or 3 include dusting, doing dishes, leisurely walk, watering plants. Options 4 and 5 are for moderate intensity activities such as a brisk walk, bowling, golf, vacuuming, washing car. Response answer #6 should be marked when participants state that they are performing high intensity activities such as jogging, running, hiking, biking, swimming laps, racquet sports, aerobic machines or dancing, Zumba, shoveling snow, gardening (planting, weeding). If a participant answers that they do not sweat, then ask them to rate their intensity level for their activities as low, moderate or high intensity.

Reference for Historical Physical Activity Questionnaire:
Von Bonsdorff MB, Rantanen T, Leinonen R, Kujala UM, Tormakangas T, Manty Mi, Heikkinen E. Physical activity history and end-of-life hospital and long term care. J of Gerontol A Biol Sci Med Sci 2009; 64A:778-784.

Questions 5 – 23J Sleep Habit Questionnaire:
Please see next page for detailed Q-by-Q from the Sleep Heart Health Study Manual of Procedures. Note that the SHHS does not specify a time period, just states "usually". So, in order to maintain the
integrity of the established questionnaire, the wording will be maintained and we will not define a time period.

Reference for Sleep Heart Health Sleep Habits Questionnaire: http://www.jhucct.com/shhs/

Sleep Habits and Lifestyle Questionnaire (SH) Form

Question by Question Specifications

Section A: Sleep

1. How much sleep do you usually get at night (or in your main sleep period) on weekdays or workdays?

2. How much sleep do you usually get at night (or in your main sleep period) on weekends or your non-workdays?
   Clarification for questions 1 and 2:
   - If an individual has a job, they should report the usual amount of sleep they get on their work days for question 1 and for their non-work days for question 2.
   - If an individual does not work, then the individual should report the usual time for weekdays (Monday through Friday) for question 1 and the usual time for weekends (Saturday and Sunday) for question 2.

3. How long does it usually take you to fall asleep at bedtime?
   - If a range is given, take the midpoint. If midpoint is a fraction of a minute, the midpoint should be rounded up to nearest minute.
     Example: 10-20 minutes should be written as 15 minutes
     10-15 minutes should be written as 13 minutes
   - If two times are given, a usual time and a special circumstances time, code the usual time
     Example: "Usually it takes 10 minutes but if my spouse is snoring it takes 30 minutes." Code as 10 minutes.

4. During a usual week, how many times do you nap for 5 minutes or more?
    - If a range is given, take the midpoint. If midpoint is a fraction, round to nearest integer value.
      Example: 6 or 7 naps should be coded as 7 (6.5 rounded up to 7)
      10 to 12 naps should be coded as 11 naps
    - If respondent describes napping pattern in words, convert to an integer value, if possible.
      Example: "I usually fall asleep in front of the TV after dinner." Code as 7 naps per week.
    - If response is "None", SKIP to item 8.
    - If response, is "1 or more times", complete item 4a.

4a. Number of times during a usual week that you nap for 5 minutes or more:
    - Enter number of naps.

5. Do you try to "make time" in your schedule for a regular nap or "siesta" in the afternoon? (check one)
    - Check only one response.
    - If response is "Never or rarely", SKIP to item 8.

6. When you do nap in the afternoon, how long do you sleep?
    - Enter hours and minutes.
    - There is a space for comments.
    - What are your reasons for regular napping in the afternoon?
    - All that apply are checked and others left blank.

7. Please indicate how often you experience each of the following. (check one box for each in items a through j)
    - If someone writes in a comment such as "Not Applicable", code for the response "Never".
    - If two boxes have been marked and it is not clear which is the intended single response, code the value marked that is closest to the response "Rarely".

Section B: Snoring and Breathing

Questions 9 through 15 are about snoring and breathing during sleep. To answer these questions, participants should consider both what others have told them and what they know about themselves.

8. Have you ever snored (now or at any time in the past)?
   Clarification:
    - "Ever" refers to 1 or more times at any time in the past, regardless of whether it was recent.
    - If answer is "Yes", then participant should have answers coded for questions 10 - 13.
    - If answer is "No" or "Don't Know", then participant should have skipped out of questions 10 - 13, however:
    - If "Don't Know" responses are given for any of questions 10 - 12, or a response of "No" is given for question 13, enter data as given on the form.

- If a valid response is given for <u>any</u> of questions 10 through 13, then the "No," "Don't Know," or missing response on question 9 is to be changed to a "Yes" on the questionnaire and entered into the database as "Yes." Valid responses are defined as
  Q10: values 0 to 4; Q11: values 1 to 4; Q12: 1 to 3, and Q13: only the value of 1.

- If answer is missing, and a valid response is given for <u>any</u> of questions 10 through 13, then the missing response on question 9 is to be changed to a "Yes" on the questionnaire and entered into the database as "Yes."

9. How often do you snore? (check one)
   Clarification:
   - "How often" refers to the number of nights per week that any snoring is thought to occur. (Not how many times per night or how much of the night).
   - If "Do not snore any more" is checked, SKIP to item 13.
   - If two boxes have been marked and it is not clear which is the intended single response, code the value marked that is closest to "Rarely".
10. How loud is your snoring? (check one)
    - If two boxes have been marked and it is not clear which is the intended single response, code the value marked that is closest to "Only slightly louder than normal breathing".
11. Has your snoring been: (check one) Clarification:
    - In comparison to a few years ago, do you think you now snore more, less or about the same?
    - If two boxes have been marked, treat as missing data.
12. Have you ever had somnoplasty, laser treatment, or surgery as treatment for your snoring?
    Clarification:
    - Has a physician ever used a laser to tighten your throat tissue ("LAUP"), or have you ever had tissue in your throat or airway removed by cutting, specifically to reduce your snoring?
13. Are there times when you stop breathing during your sleep?
    Clarification:
    - Are there times when it seems like you are holding your breath or have a pause in your breathing, or have an "apnea" for about 10 seconds or so?
    - If "No" or "Don't know" is checked, SKIP to item 16.
14. How often do you have times when you stop breathing during your sleep?
    Clarification:
    - How often do you have times when it seems like you are holding your breath or have a pause in your breathing, or have an "apnea" for about 10 seconds or so?
    - If two boxes have been marked and it is not clear which is the intended single response, code the value marked that is closest to "Rarely".
15. During the past year, how often have one or more members of your household been in or near the room where you have slept?
    Clarification:
    - Close enough to hear whether or not participant snores
16. Have you ever been told by a doctor that have a sleep disorder (other than sleep apnea)?
    - Check "Yes" or "No"
    - If response is "No", SKIP to item 19.
17. What other sleep disorder? (check all that apply)
    - Check all that apply.
    - If response is "Other", enter other sleep disorder in space provided.

Section C: Sleepiness

19. What is the chance that you would doze off or fall asleep (not just "feel tired") in each of the following situations? (*Check one box for each situation. If you are never or rarely in the situation, please give your <u>best guess</u> for what would happen*.)
    Clarification:
    - If the participant never does the activity in the question, prompt "Try to imagine (activity) .... what do you think the chance of dozing or falling asleep would be on a usual day if you did (activity)?
    - If someone writes in a comment such as "Not Applicable" treat as missing data.
    - If two boxes have been marked and it is not clear which is the intended single response, code the value marked that is closest "No Chance".

NEW FIVE-FACTOR INVENTORY (PANEL 11B-II)

The complete five-factor inventory (60 questions) will be administered for the expanded telephone follow-up. We have added the domains of Extraversion, Agreeableness, and Openness to Experience to those of Conscientiousness and Neuroticism which were collected during the enrollment in-person or telephone examination. If the participant is hard of hearing and cannot complete this form via telephone, it can be mailed. If the form is mailed, please be cognizant of the study data collection windows so that every effort is for this form to be completed and returned to the field center within the data collection window. If that is not possible, it is better to have complete data returned late, than no data at all. As of October 6, 2010, the NEO is not to be administered if it has already been completed with a previous annual follow-up.

Methods: This questionnaire should be administered to the participant or their designated family reporter/proxy. When this form is administered to the study participant, the following script is used:

> ***<u>Interviewer Script:</u>*** *"Now I'm going to read some statements. Listen carefully. For each statement, choose the response on this card that best represents your opinion. Choose strongly disagree (1) if the statement is definitely false for you, choose Disagree (2) if the statement is mostly false, choose Neutral (3) if you can't decide, choose Agree (4) if the statement is mostly true , and choose Strongly agree (5) if the statement is mostly true for you. For example, if statement was "I laugh easily", and this was definitely true for you, you would say "strongly agree" (or choose Category 5).*

<u>Important Scoring Note:</u> If the respondent answers "I don't know", this is marked as "neutral". When this questionnaire is administered to a designated family reporter/proxy it may be sometimes difficult to administer this questionnaire to them. In such instances, please make every effort to put them at ease and that they are being ask these questions based on their knowledge of this person, their characteristics, etc. They should not be worried about their answers, there is no right or wrong answers, we are just asking for their perception of the person.

The following script should be used to introduce the questionnaire to DFR/proxy's:

Interviewer Script: *"Now I'm going to read some statements. Listen Carefully. For each statement, choose the response that best represents your opinion regarding* [insert Name Here]. *For each statement, choose the response on this card that best represents your opinion. Choose strongly disagree (1) if the statement is definitely false for you, choose Disagree (2) if the statement is mostly false, choose Neutral (3) if you can't decide, choose Agree (4) if the statement is mostly true , and choose Strongly agree (5) if the statement is mostly true for you. For example, if statement was "I laugh easily", and this was definitely true for you, you would say "strongly agree" (or choose Category 5)."*

Important Scoring Note: If you receive 10 "I don't know" (i.e., neutral) responses in a row, you can stop administering the questionnaire. The remainder of the questions should be marked as "R" in the DES.

Alternate Phrasing of Unfamiliar Words: If the participant is not familiar with a word used in a statement, you may give them a synonym for the unfamiliar word. These substitutions should only be used if the participant says they do not understand the word or phrase. Suggested substitutions are listed question-by-question below.

Bolded text is modification to original item:

1. None needed
2. None needed
3. I don't like to waste **or spend too much time** daydreaming, **or thinking or dreaming about things during the day.**
4. I try to be courteous **or polite** to everyone I meet.
5. I try to keep my belongings **and things** clean and neat.
6. I often feel inferior **or not as good as / less important than** others.
7. None needed
8. None needed
9. I often get into arguments with my family and [coworkers] **classmates**.
10. I'm pretty good about pacing myself **or giving myself enough time (taking the right amount of time)** so as to get things done on time.
11. When I am under a great deal of stress, sometimes I feel like I'm going to pieces **or I'm going to fall apart.**
12. I don't consider myself especially "light hearted" **or easy going, relaxed**.
13. I am interested by the patterns I find in art and nature; **I am interested in art and nature**.
14. Some people feel that I am selfish and egotistical; **that I only care about myself or spend a lot of time thinking about myself.**
15. I am not a very methodical **or planful, orderly person**.
16. I rarely **(hardly ever)** feel lonely or blue.
17. None needed
18. I believe letting children hear controversial speakers **with whom many people disagree** can only confuse and mislead them.
19. I would rather cooperate **or work together** with others than compete with them.
20. I try to perform all the tasks assigned to me conscientiously **or carefully; mindfully**.
21. I often fell tense or jittery; **nervous, shaky**.
22. None needed

23. Poetry has little or no effect on me; **poetry doesn't do much for me.**
24. I tend to be cynical and skeptical of others' intentions; **I think other people have bad intentions, I don't trust people.**
25. I have a clear set of goals **or things I want to do**, and I work toward them in an orderly fashion **(a certain order)**.
26. Sometimes I feel completely worthless **or of no use or value**.
27. None needed
28. None needed
29. I believe that most people will take advantage of you, **or use you for their benefit**, if you let them.
30. I waste a lot of time (**spend too much time**) before settling down to work.
31. I rarely (**hardly ever**) feel fearful or anxious **or afraid**.
32. None needed
33. I seldom **(don't often)** notice the moods or feelings that different environments produce; **in other words, I don't often notice the moods or feelings different places have or notice feeling different in different places.**None needed
34. I work hard to accomplish my goals; **to finish the things I want to do.**
35. None needed
36. I am a cheerful, high spirited **or happy** person.
37. I believe we should look to our religious authorities **(leaders)** for decisions on moral issues **or to help us with problems about what is right and wrong.**
38. Some people think of me as cold and calculating **or unemotional and sneaky**.
39. When I make a commitment, I can always be counted on to follow through; **When I say I'll do something, I do it.**
40. None needed
41. I am not a cheerful optimist; **I am not a happy person who is hopeful about the future**.
42. Sometimes when I am reading poetry or looking at a work of art, I feel a chill or a wave of excitement; **I get excited**.
43. I'm hard-headed and tough-minded **or stubborn** in my attitudes; **in other words, I don't change my mind easily.**
44. Sometimes I am not as dependable or reliable **(or trustworthy)** as I should be.
45. I am seldom **(not often)** sad or depressed.
46. My life is fast-paced **or busy; in my life, a lot happens all the time.**
47. I have little interest in speculating on the nature of the universe or human condition; **in other words, I am not really interested in trying to figure out the meaning of things or people.**
48. I generally try to be thoughtful and considerate **and kind**.
49. I am a productive **or hard working** person who always gets the job done.
50. I often feel helpless **(powerless)** and want someone else to solve my problems.
51. None needed
52. I have a lot of intellectual curiosity; **I am curious about learning.**
53. None needed
54. I never seem to be able to get organized; **to get my things in an orderly, neat way.**
55. At times I have been so ashamed **or feel so bad about myself that** I just want to hide.
56. None needed
57. I often enjoy playing with theories and abstract ideas; **I often enjoy playing with ideas and guesses about the meaning of things and I enjoy trying to figure out things.**
58. If necessary, I am willing to manipulate, **trick or use people** to get what I want.
59. None needed

Alternative phrasings adapted from Markey PM, Markey CN, Tinsley BJ, Ericksen AJ. A preliminary validation of preadolescents' self-reports using the Five-Factor Model of personality JOURNAL OF RESEARCH IN PERSONALITY 36 (2): 173-181 APR 2002.

Chapter 19, Data Management. No additional items to ask new participants. Logistically, data from each participant is entered into the same REDCap project, and the skip logic is determined based on the question new or returning participant for Visit 2.

Chapter 20, Quality Control. No additional items to ask new participants.