

**DISC 2006**  
**Manual of Operations**  
**Anthropometry**

A. Anthropometry Supplies

- Stadiometer
- Beam balance or electronic scale
- Gulik II anthropometric measuring tape
- Eyeline pencil, washable marker or pen

B. General Information

1. Height and waist circumference should be measured to the last completed 0.1 cm (i.e., rounded down).
2. Weight should be measured to the last completed 0.1 kg.
3. All measurements will be taken twice. A third measurement will be taken if the first two values differ by more than the acceptable amount specified for that measurement.
4. For both height and waist circumference, if the results of the first two measurements differ by more than 0.5 cm, a third measurement is required. For weight, if the results of the first two measurements differ by more than 0.2 kg, a third measurement is required.
5. Order of measurements: First height; first weight; second height; second weight; third height (if necessary); third weight (if necessary); first waist circumference; second waist circumference; third waist circumference (if necessary)

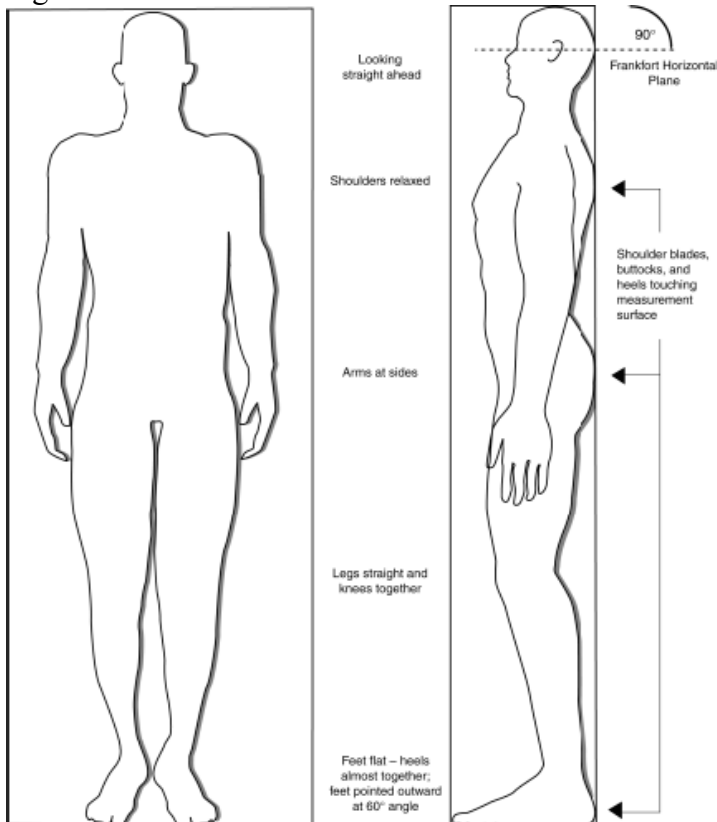
C. Measuring Height

1. Ask the participant to remove any hair ornaments, jewelry, buns, braids, or corn rolls from the top of the head so that an accurate measurement can be obtained. If this is not possible, compress the hair while taking the measurement and make a note on the participant's form.
2. Height should be measured in bare or stocking feet.
3. Have the participant stand on the floor with the heels of both feet together and the toes pointed slightly outward at approximately a 60° angle. Make sure the body weight is evenly distributed and both feet are flat on the floor.
4. Check the position of the heels, the buttocks, shoulder blades, and the back of the head for contact with the vertical backboard (see figure 1). Depending on the overall body conformation of the individual, all points may not touch. In such a

case, make sure the participant's trunk is vertical above the waist, and the arms and shoulders are relaxed.

5. Be sure the participant does not adopt an unnaturally braced posture by standing "at attention", as this alters the alignment of the spine. The participant's shoulders should be slightly rounded.
6. Be sure the head is in the Frankfort horizontal plane. The head is in the Frankfort horizontal plane when the line from the ear canal to the lower border of the orbit of the eye is parallel to the floor and perpendicular to the vertical backboard. If the participant doesn't assume this posture naturally, position the head gently with both hands cupping the chin.
7. Ask the participant to take a deep breath and hold it.
8. Gently holding the head in place, position the headboard firmly on top of the head with sufficient pressure to compress the hair.
9. Be certain to read the stadiometer at eye level to prevent parallax error. If necessary, stand on a stool.
10. Record the participant's height to the last completed 0.1 cm.

Figure 1



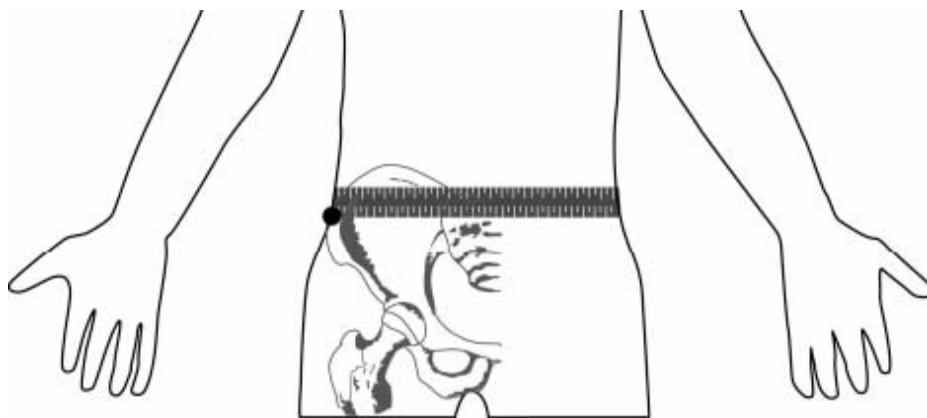
#### D. Weight

1. Weight should be measured while the participant is wearing a hospital gown and has removed any accessories and shoes.
2. Check to be sure the scale is properly zeroed before proceeding.
3. Participants may be sensitive about their balance, so be sure to help each participant on and off the scale.
4. Make sure each participant is centered on the scale, standing still, with both feet fully on the scale.
5. Because some participants may be sensitive about their weight, it is best not to read the measurement aloud.
6. Record the participant's weight to the last completed 0.1 kg.

#### E. Waist circumference

1. Begin by locating the iliac crest on one side of the participant's waist (see figure 2). Draw a horizontal line just above the uppermost lateral border of the right ilium and then cross the line to indicate the midaxillary line of the body. Repeat on the participant's other side.
2. Be sure the participant is standing with a relaxed natural posture, feet close together, shoulders slightly rounded.
3. Standing on the participant's right side, place the measuring tape around the trunk in a horizontal plane at the level marked on the right side of the trunk (see figure 2). Use a mirror or work with a partner standing on the far side of the participant to ensure correct horizontal alignment of the tape.

Figure 2



4. Hold the zero end of the measuring tape below the measurement value.
5. The tape should make contact with the skin of the participant around the entire waist, but should not compress the skin.
6. Record the participant's waist circumference to the last completed 0.1 cm.

#### F. Training

1. To be certified, each technician who will be performing anthropometric measurements must complete the following:
  - a. Read Manual of Operations chapter on anthropometry.
  - b. Watch the video of the anthropometry section of the DISC '06 training session.
  - c. Complete the anthropometry measures for 3 adult volunteers, following usual study procedures (each measurement for each participant should be taken at least twice, with a third measurement taken if necessary). These same volunteers should also be measured by a previously certified technician. The results obtained by the trainee must be within the specified range of the results obtained by the certified technician. For the first technician certified, these results should be compared to results obtained by another person with experience in anthropometry.
    - i. Results obtained by the trainee for height must be within 0.5 cm of the results obtained by the certified technician and within 0.5 cm of each other.
    - ii. Results obtained by the trainee for weight must be within 0.2 kg of the results obtained by the certified technician and within 0.2 kg of each other.
    - iii. Results obtained by the trainee for waist circumference must be within 2.5 cm of the results obtained by the certified technician and within 1.0 cm of each other.

#### G. Certification

1. The following criteria must be met for a technician to be considered certified to perform anthropometric measurements for this study:
  - a. Completion of training out lined above.
  - b. Completed certification checklist given to center coordinator to be kept on file.

**DISC 2006**  
**Manual of Operations**  
**Blood Collection, Processing, Storage and Shipping**

A. Blood Collection Supplies

20G Needle

Vacutainer Needle Adapter

Vacutainer Tubes

3 Red-Top Tubes (no additive, glass 10 ml draw; BD 366430)

2 Purple-Top Tubes (K<sub>3</sub>EDTA glass, 7 ml draw; BD 366450)

1 Gray-Top Tube (NaFl plastic, 2 ml draw; BD 367587)

Tourniquet

Alcohol wipes

Sterile Gauze Pads

Band aids

Disposable gloves

B. Blood Collection

1. Blood will be collected by venipuncture. Record the date and time of venipuncture on the form.
2. Participants will have been asked to fast for 12 hours before the clinic visit. Ask the participant when she last ate or drank anything other than water and record the time and date on the form.
3. Assemble venipuncture equipment for the participant.
4. Phlebotomist should wash hands and put on gloves before beginning procedure.
5. Participant should be comfortably seated with both feet on the floor and arm resting on support extended with palm up. Inspect the arm. Venipuncture should not be performed on an arm with arterial access (e.g. fistula, shunt), with a rash or open sores or that is edematous or swollen.
6. Apply the tourniquet directly above the elbow.
7. Select a vein that is palpable and well-fixed to surrounding tissue. Palpate even when the vein can be seen. If veins do not distend pretty quickly, have the participant open and close her fist several times, massage the arm from wrist to elbow, tap the area sharply with the index and second finger 2-3 times. Examine the participants other arm to see if the veins are larger.
8. If the tourniquet has been applied for more than one minute before venipuncture, release the tourniquet for 1-2 minutes and then reapply.
9. Cleanse the area with an alcohol wipe. Repeat with a second alcohol wipe. Dry the area with a gauze pad or cotton ball. The area should be completely dry before venipuncture.

10. Attach a 20G needle to the vacutainer holder and insert the first red top tube up to the line on the adapter. Do not break the vacuum on the tube until the needle is securely in the vein.
11. Fix the selected vein about one inch below the site of puncture by pulling the skin taut. Point the needle, bevel up, in the direction of the vein at a 45° angle to the skin surface and about an inch below the puncture site.
12. Insert the needle into the vein and push the red top tube into the adapter. Hold the vacutainer below the puncture site. If no blood flows into the vacutainer remove the needle and switch to the other arm using a new sterile needle. If for some reason the same arm must be used for the repeat attempt, wait 10 minutes before beginning the procedure again. Three venipuncture attempts can be made.
13. When the tube is full, blood will stop flowing into it. Pull the tube off the adapter and replace it with the next tube and repeat until all tubes are full. Gently invert each tube 7-8 times to mix. Do not release the tourniquet until the last tube is filling.
14. Place a sterile 2x2 gauze pad over the puncture site with one hand and release the tourniquet with the other hand. Withdraw the needle with the adapter and tube still attached with a slow firm motion.
15. When the needle is out of the arm, have the participant hold the gauze pad with constant pressure over the puncture site for 2-4 minutes. When bleeding stops apply a band aid. Make sure the participant is not allergic to adhesives before applying the band aid.
16. Dispose of used needles in a 'sharps bottle' or similar container. Dispose of other blood drawing supplies as appropriate for contaminated biological waste.

C. Blood Collection Draw Order-- Samples to be collected in this order

1. Three 10-ml red top tubes for serum. Do not use serum separator tubes because they contain a gel that could interfere with some assays.
2. One 7-ml purple top tube for plasma and buffy coat (DNA).
3. One 7-ml purple top tube for whole blood.
4. One 2-ml gray tube for oxylated plasma.

D. Blood Processing Supplies

- Disposable Gloves
- Disposable Transfer Pipets (Fisher #13-711-20 or VWR #14670-114)
- Disposable Glass Serological Pipet (Fisher #13-678-27F or VWR #89005-108)
- Pipet Aid (Drummond 4000100; Fisher #13-681-19 or VWR #53498-103)
- P-1000 Pipetter (Finnpipette 4500-050; Fisher #21-377-195 or VWR #53515-044)
- Barrier Pipette Tips (Art Tips 2079EB; Fisher #21-402-83 or VWR #53225-748)
- 15 ml conical tubes with polyethylene caps (BD Falcon 352097; Fisher #14-959-70C or VWR #21008-918)

- 50 ml conical tube with polyethylene screw caps (BD Falcon 352098; Fisher #14-959-49A or VWR #21008-951)
- Applicator Sticks (Fisher #14-959-96B or VWR #10805-018)
- Cryovials (Nalgene 5000-0012; Fisher #03-337-7C)
- Cryovial Storage Boxes (Nunc 378247; Fisher #12-565-183 or VWR #55710-258)

Contact information for ordering:

Fisher Scientific 1-800-766-7000

VWR 1-800-932-5000

## E. Blood Processing Directions

1. Each participant's samples will be sent to the Fox Chase Cancer Center Biosample Repository in 2 separate shipments to protect against loss. To make it easier to pull samples from the freezer for shipping, each participant's samples will be evenly divided into 2 cryovial storage boxes at the time of processing.
2. Label cryovials
  - a. Five different cryovial labels (P for plasma, B for buffy coat, W for whole blood, G for glucose, S for serum) will be provided for each participant.
  - b. Affix the pressure sensitive labels securely to cryovials before aliquoting. The number of cryovials that you will need to prepare for each type of label is approximately:
    - 'P' for plasma – 6 cryovials
    - 'B' for buffy coat – 2 cryovials
    - 'W' for whole blood – 12 cryovials
    - 'G' for glucose – 2 cryovials
    - 'S' for serum – 28 cryovials
3. Purple-top Tube for Plasma and Buffy Coat
  - a. Plasma
    1. Centrifuge the purple top-tube at 1500 x g for 20 minutes at 4°C.
    2. Using either a disposable transfer pipet or a disposable glass serological pipet, transfer the plasma from the purple-top tube into one 15 ml conical tube; be careful not to disturb the cell layer below the plasma.
    3. Cap the conical tube tightly and invert 8 times to mix the plasma.
    4. Using the P-1000 pipetman with a new pipet, distribute 0.5 ml of plasma from the 15 ml conical tube into cryovials labeled 'P' for plasma and cap tightly. Place half of cryovials in one cryovial storage box and half in a separate box and store both boxes at -70°C or colder.
  - b. Buffy coat
    5. Using a new pipet (either disposable transfer pipet or disposable glass serological pipet), pull up the "buffy coat" layer of blood cells at the bottom of the purple-top tubes. The buffy coat is the thin white layer of cells between the plasma and red cells. When you pull up this layer, you will also pull some red cells – this is fine, just be sure to include as many of the white cells as possible. You should pull about 0.5 ml from the vacutainer.
    6. Place buffy coat from the purple-top tube into a 15 ml conical tube and invert gently 8 times to mix.

7. Distribute 1-1.5 ml buffy coat into each of 2 cryovials labeled 'B' for buffy coat and cap tightly. Place one of cryovials in one cryovial storage box and one in a separate box and store both boxes at -70°C or colder.
4. Purple-top Tube for Whole Blood
    - a. Using either a disposable transfer pipet or a disposable glass serological pipet, transfer the whole blood from the purple top tube into one 15 ml conical tube.
    - b. Cap the conical tube tightly and invert 8 times to mix the whole blood.
    - c. Using the P-1000 pipetman with a new pipet, distribute 0.5 ml of whole blood from the 15 ml conical tube into cryovials labeled 'W' for whole blood and cap tightly. Place half of the cryovials in one cryovial storage box and half in a separate box and store both boxes at -70°C or colder.
  5. Gray-Top Tube
    - a. Centrifuge the gray-top tube at 1500 x g for 20 minutes at 4°C
    - b. Using the P-1000 pipetman with a new pipet, distribute 0.5 ml of plasma from the gray-top vacutainer tube into cryovials labeled 'G' for glucose and cap tightly. Place one of cryovials in one cryovial storage box and remainder of cryovials into a separate cryovial storage box. Store both boxes at -70°C or colder.
  6. Red-Top Tubes
    - a. After venipuncture allow the red top tubes to stand for 45 minutes at room temperature to allow complete clotting.
    - b. Centrifuge samples at 1500 x g for 20 minutes at 4°C.
    - c. Remove the tube stopper and gently work a disposable applicator stick around the walls of the tube ("rim the tube") to remove any fibrin clots.
    - d. Using either a disposable transfer pipet or a disposable glass serological pipet, transfer the serum from the 3 red-top tubes into one 50 ml conical tube. Cap the tube tightly and invert 8 times to mix the serum.
    - e. Using the P-1000 Pipetman with a new pipet, distribute 0.5 ml of serum from the 50 ml conical tube into cryovials labeled 'S' for serum and cap tightly. Place half of cryovials in one cryovial storage box and half in a separate box and store both boxes at -70°C or colder.

## F. Shipping Directions

1. Shipments will be made monthly.
2. Never ship all of a participant's cryovials on the same day (This is why each participant's cryovials were stored in two separate boxes).
3. Shipments will be sent out only on a Monday or Tuesday.
4. Samples should be shipped only with an overnight carrier
5. When shipping, notify JoEllen Weaver, FCCC Biosample Repository, via email at [joellen.weaver@fcc.edu](mailto:joellen.weaver@fcc.edu) or fax 215-214-1635. Also notify Ryan Hopson via email at [ryan.hopson@fcc.edu](mailto:ryan.hopson@fcc.edu). Notification should include date of shipment, tracking number and list of each sample shipped as indicated on the shipping document.
6. To pack the shipping container:
  - a. Cryovial storage boxes should be placed into a plastic zip-seal bag and put into the bottom of the Styrofoam box.



- b. Dry ice pellets should cover the box and come up at least 2/3 of the height of the Styrofoam box.
- c. Place the lid on the Styrofoam box (but do not seal the lid with tape).
- d. Place a copy of shipping document on top of the Styrofoam box.
- e. Close the cardboard outer box and seal with tape.
- f. Mark the outer box with a Dry Ice Sticker, a Declaration of Diagnostic Specimens and the shipping waybill.

#### G. Training

1. To be certified, each technician who will be performing blood processing must complete the following:
  - a. Read the Manual of Operations chapter on blood processing.
  - b. Watch the video of the blood processing segment of the DISC '06 training session.
  - c. Practice pipetting water until comfortable using the equipment.
  - d. Process one blood collection according to the study procedures. The clinic coordinator must review and approve the processing of this sample.

#### H. Certification

1. The following criteria must be met for a technician to be considered certified to process blood for this study:
  - a. Completion of training outlined above.
  - b. Completed certification checklist given to center coordinator to be kept on file.

**DISC 2006**  
**Manual of Operations**  
**Blood Pressure**

A. Equipment needed:

Omron IntelliSense HEM-907 or 907XL Blood Pressure Monitor

B. Setting up the IntelliSense HEM-907XL Blood Pressure Monitor.

1. Attach the power cord to the DC jack on the lower left side of the monitor, labeled DC8V.
2. Plug in the monitor, but do not turn on the power.
3. Press and hold the on/off (power) button for more than three seconds while holding the start button; F1 is displayed.
4. F1 is the number of measurements the blood pressure monitor will record and average together for the final results. This value should be 3. If it is not, press the deflation button to cycle through the available options until “3” is displayed. Record this value on the Blood Pressure Measurement Form (Form 51) in field 1A, and then press the start button to go on.
5. F2 is the waiting time before the first measurement. For this study, we will use a 5 minute rest period before the first measurement is taken. If “5” is not displayed, again press the deflation button to cycle through the available options until “5” is displayed. Record this value on form 51 in field 1B, and then press the start button to go on.
6. F3 is the waiting time between individual measurements. We will use a 1 minute interval between measurements. If “1” is not displayed, again press the deflation button to cycle through the available options until “1” is displayed. Record this value on form 51 in field 1C.
7. Press the start button to again cycle through the three options, being sure that F1 is set to 3, F2 is set to 5, and F3 is set to 1.
8. Press the on/off (power) button to turn off the power and save these settings.

C. Before beginning

1. Make sure to use a quiet room. Avoid using a room near heavy vehicular and pedestrian traffic.
2. Make sure the room is well-lit, but not so bright that it bothers the participant.

3. Complete fields 2 and 3 on form 51.
4. Make sure that the room is comfortably warm, since temperature changes can affect the dilation and constriction of the small arterioles.
5. Ask the participant if she is experiencing any pain (headaches, muscle cramps, etc). Record this information in field 4 of form 51.
6. Ask the participant if she has smoked in the last 30 minutes. If necessary, wait to begin measuring the participant's blood pressure until at least 30 minutes have elapsed from the last time she smoked.
7. Ask the participant if she has exercised in the last 30 minutes. If necessary, wait to begin measuring the participant's blood pressure until at least 30 minutes have elapsed from the last time she exercised.
8. Ask the participant if she has had anything to eat or drink containing caffeine or alcohol in the last 60 minutes. If necessary, wait to begin measuring the participant's blood pressure until at least 60 minutes have elapsed from the last time she had anything to eat or drink containing caffeine or alcohol.

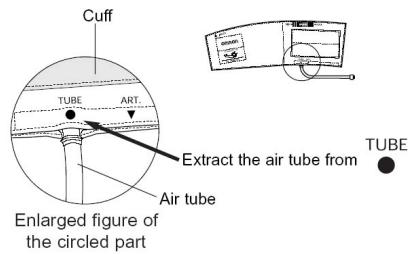
D. Applying the cuff.

1. Select the cuff according to the participant's approximate arm circumference:

Arm Circumference	Name of the cuff
17-22 cm	HEM-907-CS19 (Small)
22-32 cm	HEM-907-CR19 (Medium)
32-42 cm	HEM-907-CL19 (Large)
42-50 cm	HEM-907-CX19 (Extra Large)

2. Check the following before applying the cuff:
  - a. The bladder is correctly installed in the cuff.
  - b. The bladder is not twisted inside the cuff.

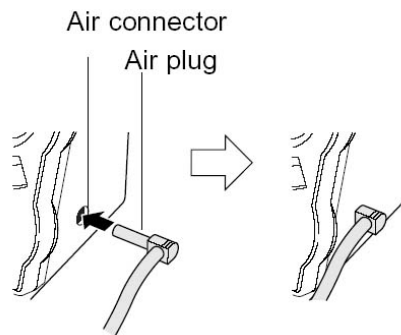
c. The bladder tube is protruding from the cuff as shown.



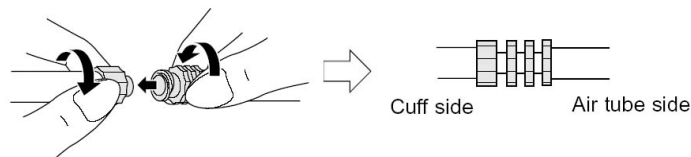
### 3. Connect the air tube securely

a. To use the small, medium, or large cuff

i. Connect the air tube to the main unit by securing the air plug to the base of the air connector.



ii. Securely connect the air tube and the cuff/bladder set by rotating the luer connection as shown.



b. To use the extra-large cuff – The extra-large cuff comes with an air tube with an integrated air plug. Connect the air plug of the cuff to the air connector securely when connecting to the main unit.

4. Place the right hand of the patient with the palm upward.

5. Palpate for the antecubital brachial pulse and align the artery position mark with the brachial artery.

6. Wrap the cuff snugly using both hands and securely fasten it with the Velcro™ tape. At this time, the lower edge of the cuff must be placed ½” to 1” above the inner side of the elbow joint.

- a. If after the cuff is wrapped the index marker at the top of the cuff does not point to an area inside the range indicated by the black range bar at the top of the cuff as shown, disconnect the current cuff and select the cuff suitable for the patient’s arm circumference.



- b. Be sure to wrap the cuff tightly enough so that you can insert only one finger between the cuff and arm.

7. Keep the level of the cuff at the same level as the heart during the measurement.

#### E. Measuring blood pressure

1. Complete questions 2-4 on the Blood Pressure Measurement Form.
2. Ask the participant not to speak or move during the five minute resting period or while the measurements are being taken unless necessary.
3. Push the on/off (power) button to turn on the power.
4. Set the MODE Knob (the dial on the right) to “AVG.”
5. Set the P-SET (inflation level setting) Knob to “AUTO.”
6. Push the START button to start the measurement. The monitor will wait for the five minute resting period to pass, and then begin inflating the cuff for the first measurement.
  - a. Do not push the start button without first wrapping the cuff
  - b. If you want to stop the measurement, push the STOP button. The unit will rapidly deflate.
7. When the measurements are completed, the monitor will display the average of the three readings.
  - a. If necessary, you can view the individual results by pressing the deflation button.
  - b. If the monitor determines that the pressure value is not correct, an error display appears (ER1 to 9). In this case, refer to Page 28 of the instruction

manual (included with your monitor and also available online at <http://www.omronhealthcare.com/enTouchCMS/FileUpFolder/HEM-907XL.pdf>) to determine the cause of the error and start the measurement again.

8. Record the systolic and diastolic blood pressures, and the pulse on the Blood Pressure Measurement Form in fields 5-7, respectively.
9. Push the ON/OFF (power) button to turn off the monitor.
10. If necessary, report any problems or special occurrences in question 8 on the Blood Pressure Measurement Form.

#### F. Equipment maintenance

1. While the HEM-907XL is designed so that calibration should not be necessary, to ensure accuracy it should be checked monthly against a calibrated mercury manometer.
2. To perform these checks, you will need
  - a. a calibrated mercury manometer (including inflation bulb)
  - b. a T-tube
  - c. two air tubes
  - d. a sturdy cylindrical object on which the cuff can be wrapped
3. Connect the manometer, inflation bulb, cuff, and the monitor with the T-tube as shown in the figure.



4. Tightly wrap the cuff over a sturdy cylinder.
5. Release the valve of the inflation bulb to remove the air inside the cuff completely.
6. Push the ON/OFF (power) button to turn on the monitor.
7. Set the MODE selector to “CHECK”.
8. Close the valve of the inflation bulb and inflate the cuff to the pressure to be checked, based on the manometer read.
9. Compare the pressure values displayed on the monitor to the one on the manometer.
10. Record these values on the Weekly Equipment Inspection and Maintenance Log.
11. Accuracy of the monitor is validated to be  $\pm 3$  mmHg or 2% of standard manometer reading. If your result shows a difference exceeding the tolerance, alert the center director, make a note of it on the Weekly Equipment Inspection and Maintenance Log and contact Omron repair department (1-877-216-1336).

#### G. Training

1. To be certified, each technician who will be measuring blood pressure must complete the following:
  - a. Read the Manual of Operations chapter on blood pressure.
  - b. Watch the video of the blood pressure training session from the DISC '06 Philadelphia meeting.
  - c. Measure the blood pressure of 3 adult volunteers. These same volunteers should also have their blood pressure measured by a previously certified technician. The results obtained by the trainee must be within 4 mmHg of the results obtained by the certified technician. For the first technician certified, these results should be compared to results obtained by another person at the center with experience measuring blood pressure.

#### H. Certification

1. The following criteria must be met for a technician to be considered certified to measure blood pressure for this study:
  - a. Completion of training out lined above.

- b. Completed certification checklist given to center coordinator to be kept on file.



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**1. Overview of the 24-Hour Dietary Recall**

The purpose of the DISC dietary recall (DR) is to obtain a record of the type and amount of foods and beverages consumed by DISC participants during a complete 24-hour period (from midnight-to-midnight) for the day preceding the interview. An in-person 24-hour dietary recall will be conducted at the clinic visit. Two additional 24-hour dietary recalls will be conducted by telephone in the following two weeks. Dietary interviewers who are masked to treatment assignment will conduct the dietary recalls.

Interviewers will be trained and certified by the University of Minnesota Nutrition Coordinating Center (NCC) to use Nutrition Data System for Research (NDSR) dietary data collection software to collect 24-hour dietary recalls. The software includes a food database of over 18,000 foods, with many ethnic foods and over 8,000 brand-name foods. It features built-in, standard interview prompts for obtaining detailed food descriptions, including preparation method and ingredient information. The NDSR requires specialized training and extensive practice in order to effectively utilize it to conduct a research interview. The NDSR software will calculate the nutrients consumed by each participant and will provide Food Group Serving Counts for 166 subgroups including fruit, vegetables, grains, dairy, meat, fats, non-dairy beverages and miscellaneous other foods consumed for each participant on a per food, per meal and per day basis.

As much as possible, the dietary recalls collected for each participant should take place within a two-week window and include representation of week and weekend days. Two 24-hour dietary recalls will be collected to obtain information for weekday intake (Monday-Friday). The third 24-hour dietary recall will be collected to obtain information about weekend intake (Saturday-Sunday). A standardized multiple-pass approach will be used by all DR interviewers to collect the 24-hour dietary recalls.

Each clinic will designate a DR coordinator who will oversee the collection and quality assurance of the 24-hour dietary recall. Quality assurance of the dietary data will be conducted locally by staff at each clinic and centrally by quality assurance scientists at NCC.

When the final phase of quality assurance has been completed, NDSR backup files will be sent to NCC to generate nutrients and food group information. Resulting output files will be sent to Maryland Medical Research Institute (MMRI) for statistical analysis.

## **2. Dietary Interviewer Training and Certification**

To achieve standardization and accuracy of the research interview, DR interviewers must fully understand the DISC protocol and their individual responsibilities for the study. Clinical center staff will attend a central 2 day NCC sponsored NDSR training workshop to become familiar with NDSR program features, understand the NDSR database structure, gain skill at data entry, editing and data management, increase or enhance their dietary interviewing skills, and learn their responsibilities for the DISC specific dietary assessment protocol. Consistent use of the multiple-pass approach, a DISC-specific introduction script, and DISC Food Amounts Booklet will be used to promote standardization of the DR collection. Each trainee will bring a laptop computer to the training with the NDSR program installed. An LCD projector will be provided for use by the NCC trainer. Following the training and prior to collecting DISC dietary recalls, all DR interviewers will successfully complete NCC certification activities and be certified by NCC staff. The certification includes:

- Attendance at NCC 2-day training workshop.
- Completion of a scripted baseline recall with NCC staff per telephone.
- Collection of 10 unscripted recalls from subjects whom represent age, gender and ethnic diversity of the clinical center of the DISC participants.
- Completion of a scripted follow-up recall with NCC staff.

The Nutrition Coordinating Center will notify the DISC clinics and the coordinating center with the certification status of each DR interviewer.

## **3. Quality Assurance**

Clinical center DR coordinators are responsible for ensuring the overall quality of the dietary data collected by the DR interviewers in their charge. Specific procedures for checking the dietary data, observing interviews, documenting unusual foods and amounts, and flagging unreliable recalls will be provided at the training workshops.

## **4. Software Licensing**

Each clinic will license the Nutrition Data System for Research (NDSR) software. Included in the initial annual support is the resolution of 50 new foods for the first copy and 5 per year for each additional copy. Unlimited technical support is provided as needed for supported users. Data will be collected beginning in spring 2006 using the most current version of NDSR. Each year as new versions of NDSR become available, sites will switch to the new version to take advantage of the most current food database which best reflects the food marketplace.

## **5. Site of Data Collection**

Dietary recalls will be conducted in-person and over the telephone. The space provided for the dietary interviews should be quiet and free from distractions.

## **6. Advance Preparation**

Prior to collecting the dietary recalls, DISC clinics will obtain written consent from each participant.

**7. Materials Needed**

**7.1 Documentation**

1. 24-Hour Dietary Recall Manual of Procedures (1 per interviewer)
2. NDSR User Manual (1 per licensed copy of NDSR)
3. Two dimensional food models - DISC Food Amounts Booklet (1 copy per interviewer with sizes next to pictures, 1 copy per participant with pictures only)
4. Dietary Intake form (used for backup)
5. In-person and telephone interview introduction script
6. Quality assurance procedures
7. Folder for dietary recall information for each participant
8. Dietary Recall Forms

**7.2 Computer and Other Items**

1. Laptop and/or desktop computer(s) with NDSR dietary data collection software program installed
2. Formatted computer diskettes, recordable CD, or portable storage device, etc.
3. Computer printer
4. Headset for telephone (1 per interviewer)

**7.3 Amount Estimation Tools**

A Food Amounts Booklet will be provided to each participant who will be instructed to keep it near the telephone for 24-hour dietary recalls. Each clinic will receive one original copy of the DISC Food Amounts Booklet with the sizes next to the pictures, and copies of this should be given to each DR interviewer. A second version is posted on the study website and clinics should make as many copies as needed of this form to give to each participant. As much as possible, a recall should not be collected without a Food Amounts Booklet. If a booklet is lost, a replacement booklet should be provided to the participant prior to collecting the 24-hour dietary recall.

NASCO Food Models will be used at the in-person interview to help teach the participant how to recall serving sizes. The specific models include:

Catalog Number	NASCO Food Model Description
<b>For use with "Meats" Diagrams (use both)</b>	
WA12531HR	Eye of Round Roast, Cooked, 3 oz. (85 g)
W05820HR	Perch, 3 oz. (85 g), Broiled
<b>For use with "Squares and Rectangles" and "Thickness" Diagrams (select one)</b>	
WA18319HR	Brownie, 2" Square (5 cm)
WA20492HR	Cake, Sheet, Yellow with Icing, 2" x 2" (5 cm x 5 cm)
W06634HR	American Cheese, Slice, 1 oz. (30 g)
<b>For use with "Circles" Diagram (select one)</b>	
WA05260HR	Cookie, Chocolate Chip, 2" Dia. (5 cm)
WA18282HR	Cookie, Chocolate Chip, 4" Dia. (10 cm)
WA13623HR	Bagel, 3 oz. (85 g)
WA23104HR	Tortilla, Flour, One 6" (15 cm) dia.
W05772HR	Bologna, Large, Round Slice, 1 oz. (30 g)

<b>For use with "Mounds" Diagrams (select one)</b>	
WA13612HR	Ice Cream, Chocolate, One Size 8 Scoop, 1/2 Cup (120 ml)
W05830HR	Ice Cream, Vanilla, One Size 8 Scoop, 1/2 Cup (120 ml)
WA18285HR	Potatoes, Mashed, 1 Cup (240 ml)
<b>To illustrate "measured" amounts (select one)</b>	
W05644HR	Corn, Whole Kernel, Canned, 1/2 Cup (120 ml)
W05647HR	Peas, Frozen, 1/2 Cup (120 ml)
W05646HR	Beans, Green, Cooked or Canned, 1/2 Cup (120 ml)
WA04172HR	Cornflakes/Dry Cereal in Bowl, 3/4 Cup (180 ml)
W07402HR	Applesauce in Bowl, Canned, Unsweetened, 1/2 Cup (120 ml)

The models will be used only during an instructional period prior to collecting the first in-person dietary recall. After this instructional period, the NASCO models are put away and the Food Amounts Booklet is used to estimate amounts during the recall.

## **7.4 Dietary Recall Forms**

### **7.4.1 DR-Form 1, Telephone Recall Availability Form**

Prior to data collection, each participant must complete a telephone recall availability form including her name, phone number, and suggested days and times to call. The participant must identify several best days and times since the telephone recall is unannounced. The participant ID number will be added to the form by the DR coordinator before assigning the participant to the DR interviewer.

### **7.4.2 DR-Form 2, Telephone Contact Log**

The telephone contact log is used to record all attempts to contact the participant. Detailed notes should be made about hard to reach participants. If the interviewer is not able to collect both recalls in the designated time window the telephone contact log serves as a record of their attempts.

### **7.4.3 DR-Form 3, Recall Checklist**

The 24-Hour Recall Checklist is initiated after the completion of each dietary recall and serves to document each step of local quality control for the DR interviewer and coordinator. A copy of the 24-hour Recall Checklist is kept on file at each clinic attached to the printed food report. After completion of the recalls, a folder with the telephone recall availability form, telephone contact log, the DISC 24-hour recall checklist, and corresponding NDSR Reports will be forwarded to the DR coordinator for local quality assurance and management of dietary record data.

### **7.4.4 DR-Form 4, New Food Request Form**

A New Food Request Form is used to record information about a food that cannot be located in the NDSR database (e.g., the item is a new product that hasn't been added to the database, the interviewer doesn't recognize the food, etc.). When the DR interviewer is unable to locate a food reported during the 24-hour dietary recall interview, it will be entered as an NDSR Missing Food. During a quality assurance review, the clinic DR coordinator will consult study-specific and NDSR Data Entry Rules for a possible solution or will confirm that the missing food cannot be entered into NDSR without further assistance from NCC database scientists. If the food cannot be entered, a New Food Request Form is completed by

the DR coordinator and sent to NCC for data entry instructions or filled out online at <http://www.ncc.umn.edu/Newfoods/index.htm>

**7.4.5. DR-Form 5, 24-hour Dietary Supplement Recall Script**

Following each dietary recall, a recall of dietary supplements consumed in the previous 24-hours will be conducted. Standard prompts are provided on the script to elicit information about the use of dietary supplements and over the counter antacid products taken yesterday. Participants will be asked to bring their supplement containers for the in-person visit. The containers will be used to complete information on the Dietary Supplement Form. Information on the completed script form will be used to complete the Dietary Supplement Form.

**7.4.6. DR-Form 5.1, 24-Hour Dietary Supplement Information Form**

The 24-hour Dietary Supplement Form is completed for all dietary supplements and antacid products reported during the 24-hour Dietary Supplement Recall. Following the interview with the participant, dietary supplement information will be entered in NDSR.

**7.4.7. DR-Form 6, 30-day Dietary Supplement Recall Script**

After the in-person 24-hour dietary supplement recall, information about usual supplement intake will be obtained using the 30-day Dietary Supplement Recall Script. Standard prompts are provided on the script to elicit information about the use of dietary supplements and over the counter antacid products taken in the past 30 days. Information on the completed script form will be used to complete the Dietary Supplement Form.

**7.4.8. DR-Form 6.1, Usual (Past 30 Days) Dietary Supplement Information Form**

The Usual (Past 30 days) Dietary Supplement Form is completed for all dietary supplements and antacid products reported during the Usual Dietary Supplement Recall. Following the interview with the participant, dietary supplement information will be entered in NDSR. Completed forms will be filed in the Dietary Recall Information Folder for each participant and will be used to provide a supplement intake record corresponding with each of the three days of dietary intake for the study and for the 30-day dietary supplement intake.

**8. Data Transfer Procedures**

NDSR backup files of the DISC dietary recalls will be sent from the clinical center to NCC via email after completion of local quality assurance activities. An NDSR Record Listing Report will be faxed to NCC to document the recalls included in the shipment.

**9. General Guidelines for Working With Participants**

**9.1 Creating Rapport**

Because each participant is the primary respondent for the 24-hour dietary recall, it is important for the DR interviewer to be able to motivate her to provide complete and accurate information. Every effort should be made to keep 24-hour dietary recall collection as objective and non-judgmental as possible. The interviewer should avoid congratulating participants for eating certain foods or reacting with dismay to reports of other foods. The interviewer can stress that he/she wants to know what the participant really ate and that honesty is appreciated. DR interviewers must maintain a demeanor of neutrality to all participants and should adapt a style and approach to make the participant comfortable. The DR interviewer should look for both verbal and non-verbal responses, be a good listener, and thank the participant for the information provided.

## **9.2 Confidentiality**

The DR interviewer will gain trust by assuring the participant before the recall begins that there are no right or wrong answers and that what they say is confidential. Dietary intakes will not be discussed with other participants. Any necessary discussion about a specific 24-hour dietary recall should be conducted in private and not in the presence of others.

Furthermore, the participant's personal information (such as contact information) is kept in a secure location at the clinical center. All information that is sent on to NCC, and the coordinating center is labeled with the participant's study ID number only.

## **10. General Guidelines for Conducting the 24-hour Dietary Recall**

### **10.1 Interview Tools and Techniques**

#### **10.1.1 General documentation for using NDSR to collect the 24-hour dietary recall**

Rules and procedures for administering the 24-hour dietary recall interview are used to help ensure standardization and to facilitate gathering the dietary data. Many of these are imbedded in the NDSR program and documented in the NDSR User's Manual. DISC specific procedures to ensure consistency of data collection among study clinics will be highlighted at the training workshop.

#### **10.1.2 Using a script**

A standard script is used to introduce the 24-hour dietary recall interview and start the recall process. The script provides continuity between interviews. The remainder of the dietary recall will be guided by NDSR interview prompts and is ad hoc in nature due to the variability of participant responses.

#### **10.1.3 Using NDSR interview prompts**

NDSR displays on-line prompts to help interviewers ask standardized questions.

#### **10.1.4 Use of the Food Amount Booklet (Two-Dimensional)**

Participants will be allowed to freely select from items in the Food Amounts Booklet. Coaching in the use of this booklet will occur as needed during each interview to make sure that this tool is used appropriately. Participants should be allowed to select the most appropriate picture but interviewers may suggest additional options if the participant needs assistance or chooses an inappropriate option. Notes should be made to indicate how the amount was estimated in the NDSR Notes field.

#### **10.1.5 Two-dimensional food amount training using NASCO models**

The NASCO models will be used only during an instructional period prior to collection of the in-person dietary recall. The models will be used to help participants visualize actual food portions and compare them to the graphic representations in the Food Amounts Booklet. The NASCO models also help the participant understand the nature of the recall process and how to accurately assess portion size. The dietary interviewer should use the NASCO models during a "mock" interview where the procedure is explained. Then the Food Amounts Booklet should be introduced as the standard for future data collection. The NASCO models help to make the transition to two-dimensional models.

For use with "Meats" Diagrams (use both)

Eye of Round Roast, Cooked, 3 oz. (85 g)

Perch, 3 oz. (85 g), Broiled

For use with "Squares and Rectangles" and "Thickness" Diagrams (select one)

Brownie, 2" Square (5 cm)

Cake, Sheet, Yellow with Icing, 2" x 2" (5 cm x 5 cm)

American Cheese, Slice, 1 oz. (30 g)

For use with "Circles" Diagram (select one)

Cookie, Chocolate Chip, 2" Dia. (5 cm)

Cookie, Chocolate Chip, 4" Dia. (10 cm)

Bagel, 3 oz. (85 g)

Tortilla, Flour, One 6" (15 cm) dia.

Bologna, Large, Round Slice, 1 oz. (30 g)

For use with "Mounds" Diagrams (select one)

Ice Cream, Chocolate, One Size 8 Scoop, 1/2 Cup (120 ml)

Ice Cream, Vanilla, One Size 8 Scoop, 1/2 Cup (120 ml)

Potatoes, Mashed, 1 Cup (240 ml)

To illustrate "measured" amounts (select one)

Corn, Whole Kernel, Canned, 1/2 Cup (120 ml)

Peas, Frozen, 1/2 Cup (120 ml)

Beans, Green, Cooked or Canned, 1/2 Cup (120 ml)

Cornflakes/Dry Cereal in Bowl, 3/4 Cup (180 ml)

Applesauce in Bowl, Canned, Unsweetened, 1/2 Cup (120 ml)

#### **10.1.6 Guidelines for probing**

Probing is the technique used by the interviewer to stimulate discussion and obtain more information. DR interviewers probe when a participant's response is not meaningful or is incomplete, i.e., when it does not adequately answer the question.

Probing can be used to gather information about additional meals and snacks as well as additions to reported foods. The quality of the interview depends a great deal on the interviewer's ability to probe meaningfully and successfully. Probing techniques are covered extensively in the training workshop.

#### **10.1.7 Unconsumed portions**

The amount the participant actually consumed is what should be entered, not what she was served. Double check to ensure that the amount reported is what was consumed. Asking "Were you able to finish that?" or "Did you eat all of it?" helps to identify and eliminate the unconsumed portions.

#### **10.1.8 Unusual portions**

If something sounds unusual, the DR interviewer should clarify it and not blindly accept the initial response. Redirecting questions and presenting appropriate alternatives from the Food Amounts Booklet permits the participant to restate her initial response and allows the interviewer to verify, confirm, or correct an unusual portion. Confirmation of any unusual intake or portions should be documented using the NDSR Notes Field by stating which picture in the Food Amounts Booklet was used. Specific information about confirming portions and documenting unusual portions will be provided at the training workshop.

#### **10.1.9 Evening snack**

If the participant was fasting the night before the in-person dietary recall because of the need to collect a fasting blood sample, the DR interviewer should probe for the previous

night's snack to add to the fasting days intake. Note in the NDSR note field that this snack is for the previous day.

#### **10.1.10 How to handle sick days/insufficient intake for the telephone recalls**

While instructing the participant about upcoming telephone recalls at the in-person visit, the DR interviewer should tell the participant that she should inform them immediately of illness the prior day. At the time of the telephone recall, begin with an open-ended question such as, "How was yesterday?" rather than leading the response with a question about whether or not the participant was sick. If the participant says yesterday's intake was highly unusual due to illness, the DR interviewer should call back on another day to collect the 24-hour recall.

### **10.2 Conducting the Interview using the Multiple-Pass Approach**

#### **10.2.1 PASS 1: Using the NDSR Quick List**

The Quick List will be used to collect an outline of the previous day's intake. It is designed to get participants to begin thinking about what and when they ate. Foods and beverages as reported by the participant are entered on the Quick List screen along with time eaten and meal name if provided by the participant at this time. Quick List is the first pass in the NDSR multiple-pass approach.

If the participant does not volunteer the time of the meal or give a specific meal name during the Quick List, the DR interviewer need not interrupt to ask for this information. NDSR will prompt for this information during the third pass.

#### **10.2.2 PASS 2: Reviewing the Quick List**

A review of the Quick List permits the DR interviewer to obtain an overview of the day's intake to note if there are large gaps in time, missed meals or missing beverages, and to insert the meals and or foods recalled during this pass. This review is the second pass of the NDSR multiple-pass approach.

#### **10.2.3 PASS 3: Collecting complete meal, food, and amount detail**

To help the participants remember what they ate, information about the time, name, and location of the meal are provided in the Meal Information Window.

Complete descriptive detail for foods and beverages is obtained during the third pass of the NDSR multiple-pass approach. The participant is asked about additions to foods and beverages entered on the Quick List. The DR interviewer asks probing questions based on the information displayed in the NDSR window and utilizes the NDSR food search feature to obtain complete detail for food descriptions, preparation methods, and variable ingredients.

After specifying the food, an open-ended question "How much did you eat (drink)?" is asked to obtain the amount eaten. The participant will be encouraged to use the Food Amounts Booklet to describe the amount consumed.

The DR interviewer should allow the participant to choose pictures in the Food Amount Booklet without help. If they have difficulty or select an inappropriate item, they should be encouraged to use a more appropriate item for the food eaten. The DR interviewer should always refer to the ruler when the participant gives dimensions in inches.

After entering the amount specified by the participant, NDSR displays a conversion to a common unit. The DR interviewer needs to be able to visualize the amount reported and subsequently confirm with the participant any questionable amounts by using the Food Amounts Booklet (e.g., 1 FO of juice or 4 cups of ice cream). The NDSR Note field will be



used to enter information to confirm atypical amounts as well as other unusual information (e.g., no beverage with a meal or no condiments and/or bread for sandwiches).

#### **10.2.4 PASS 4: Reviewing the recall**

The fourth and final pass of the NDSR multiple-pass approach occurs after entering all of the food detail. During this review, the interviewer probes for missed meals, beverages, and snacks and any other information that was earlier omitted. Edits are made as needed and notes are provided.

Foods not found in the database are flagged as missing and complete detail is collected from the participant in a corresponding note field including descriptions of what the food looks like as well as ingredients and the amount eaten. Clinic DR coordinators will determine which foods are truly missing and will contact NCC for resolutions. Upon receipt of the resolution, clinics will edit the 24-hour dietary recall accordingly.

#### **10.2.5 Documentation using NDSR Note Field**

Notes are used to clarify contradictory, questionable or unusual food items or amounts, or document cases where typical companion foods are not consumed. Notes serve as communication between the DR interviewer, the DR coordinator, and the DR administrator at NCC. NDSR forces a note when the amount reported is questionably large (i.e., exceeds what has been established in the database as more than the usual amount reported at one time). In this case, a meaningful note should be added to explain how the large amount was determined to be correct. NDSR food notes should match the amounts entered. For example, if the dietary interviewer enters 6 cups of ice cream, the note should describe how the participant determined that she ate 6 cups and the amount 6 cups should be retyped in the note field to ensure that a typographical error did not occur. Perhaps the participant reported two 3D bowls of ice cream for a total of 6 cups. Further probing might reveal that the ice cream was scooped into the bowl and consequently a reduction in the 6 cups to account for the air space between the scoops will need to be factored in. Redirecting the participant to the mounds or measuring cups might result in a more realistic amount for the ice cream.

Important information to include in notes includes missing meals or drinks, Food Amounts Booklet picture and size used to estimate unusually larger or small portions, missing condiments, and modifications of food such as McDonald's cheeseburger when only half of the bun was eaten. Notes allow the clinic DR coordinator to make appropriate changes to the recall to reflect what was actually eaten as well as confirming that the interviewer entered what the participant reported.

#### **10.2.6 Printing NDSR Reports**

As soon as possible following the interview, the Foods Report and the Record Properties Reports should be printed and placed in the participant folder.

### **11. Special Instructions**

#### **11.1 Entering Meal Time**

In general, the approach to collecting the 24-hour dietary recall is to find out when people eat and what they eat versus asking what they ate for specific meals. The NDSR program does require a time for each eating occasion. Exact eating times are not important and a best guess of the approximate time may be used.

## **11.2 Entering the Meal Name**

NDSR meal names include Breakfast, Lunch, Dinner/Supper, Snack, School Lunch, and Other. If the meal name is not stated by the participant, the DR interviewer may ask the participant the meal name saying: “Was this your (*insert most obvious meal name*)?” Or “What would you call this meal?” A meal name may be repeated several times in the context of a recall. For example, the participant may report snacks several times throughout the day. If the name of the meal is obvious to the DR interviewer, it is not necessary to ask the participant this question. For example, the first meal of the day may be labeled as breakfast, between meal items may be labeled as snacks without probing.

## **11.3 Entering the Meal Location**

NDSR meal locations (where the meal is eaten) include Home, Work, Friend’s Home, School, Day Care, Restaurant/Cafeteria/Fast Food, Deli/Take-out/Store, Community Meal Program, Party/Reception/Sporting Event, and Other. The meal location helps to determine which food variables to enter during the 24-hour dietary recall. For example, many foods in NDSR differentiate between home prepared and restaurant prepared foods.

## **11.4 Entering the Visit Number**

Visit numbers will be used for each measure as follows:

Visit 1 Baseline recall #1

Visit 2 Baseline recall #2

Visit 3 Baseline recall #3

## **11.5 Entering the Site ID Number**

Clinical Centers will use the following ID numbers for NDSR site ID.

1- Johns Hopkins Children’s Center, Baltimore, MD

2- Northwestern University, Chicago, IL

3- University of Iowa, Iowa City, IA

4- New Jersey Medical School, Newark, NJ

5- Children’s Hospital of New Orleans, LA

6- Kaiser Permanente Center for Health Research, Portland, OR

## **11.6 Minimizing the Response Burden**

### **11.6.1 Selecting NDSR default foods**

As a general rule, the DR interviewer should accept the participant’s level of detail or opinion about the foods and beverages eaten. When it becomes clear that the participant is unable to provide the level of detail that the NDSR program permits, the DR interviewer will select defaults without asking further questions about a specific food. If the participant is not able to provide the information that NDSR requires, an NDSR unknown should be selected.

### **11.6.2 Default preparation methods and details**

When participants would not be expected to be able to provide the answers to the NDSR prompts, especially regarding preparation methods or other details as part of a restaurant meal, interviewers should select the “unknown” defaults provided in NDSR. Asking too many questions that cannot possibly be answered may lead the participant to respond inappropriately just to provide an answer to the question.

### **11.6.3 Unknown brand name products and fast food items**

If the DR interviewer is unable to locate a food item that is a national brand name product or a food from a national fast food restaurant chain, it should be entered as an NDSR Missing

Food and forwarded to the DR coordinator. A resolution will be provided by the coordinator or by staff at NCC.

#### **11.6.4 Entering sandwiches, tacos, and similar assembled foods**

While NDSR contains many default sandwiches, tacos, and similar assembled foods, it is important for the DR interviewer to probe to find out if the participant can describe the item eaten in terms of the ingredients and the amounts of each ingredient. If the participant can report the amount of ingredients in the sandwich, the sandwich is entered using the NDSR Assembled Food or Recipe feature, entering each ingredient and amount. If the sandwich or taco is reported to be from a national fast food restaurant chain, the corresponding NDSR entry is selected. Any modifications made to national fast food restaurant meals, such as not eating the bun for a McDonald's hamburger or ordering a Subway sandwich with only ham and lettuce, should be recorded in the Note Field for adjustment after the recall is completed.

#### **11.6.5 Entering tossed salads, mixed dishes, soups, and similar foods**

If a participant reports a tossed salad, mixed dish, or soup, the DR interviewer will select the closest database match based on the description of the food. As a rule, amounts of the individual ingredients in these foods need not be entered.

The DR interviewer will have the participant estimate the total amount consumed and the NDSR standard recipe will determine the amounts of the individual ingredients. For most food combinations, generic entries based on the types of ingredients are available. When unable to find a database food that is a good fit, the DR interviewer should collect as much detail as possible from the participant, including the amount eaten. This detail is entered as an NDSR Missing Food. It is critical that with the written description, other reviewers can visualize the food and the amount eaten. Vague descriptions and incomplete amounts are unlikely to be interpreted correctly during data cleaning and quality assurance.

### **11.7 Entering Amounts**

#### **11.7.1 Food Specific Units (e.g., slice, each, small, single serving bag, piece)**

Food Specific Units (FSU) are available for many foods in the NDSR database. FSU are most frequently available for packaged items such as an ice cream bar or a frozen commercial entree. However, foods that may seem "standard" can come in several sizes (e.g., nugget, regular, extra large). These units are all options in NDSR. In general, it is preferable to have the participant describe the portion consumed using the Food Amounts Booklet and use the information about FSU in NDSR as a guide to help quantify the food. Because the use of the Food Amounts Booklet often results in using dimensions and suggests entering the food using a shape, the DR interviewer should look at the dimensions associated with the food specific units to get a sense of how realistic the dimensions reported might be. In general, it is better to use the "small", "medium" or "large" FSU to describe pieces of chicken and fruit. These foods tend to be overestimated when dimensions are used because the visual image includes refuse (e.g., bone, core, peel). FSU should also be considered for many baked goods when dimensions result in unrealistic amounts as compared with the standard amounts per the NDSR common unit.

#### **11.7.2 Food shapes (e.g., circle, rectangle, wedge, cube)**

Shapes allow the participant to use two or three dimensions to describe the amount of food eaten. Food shapes in NDSR are measured using inches to describe the length, width, height, or diameter, depending on the food. Notes should be used for any unusual

dimensions, making clear that the interviewer has visualized the food and is aware of any unusual dimensions and has probed sufficiently to be sure the participant has given the best description for the food item. Shapes are not appropriate for describing liquid or non-solid foods or for all solid foods and in many situations the FSU is a better way to quantify the food item.

### **11.7.3 Weight measures (e.g., ounce, pound, gram)**

Weight measurements should only be used if the exact weight is available from a package label or if the participant reported an amount using one of the meat or fish fillet pictures. Picture meat replicas can be used to assist participants in describing their portion sizes of cooked meat including roast, steak, pork chop, and ham. (Note: chicken parts/pieces do not have weights associated with them and are considered food-specific units.) The meat replica pictures (page 13) should not be used to represent cold cuts, sausage, meat loaf, or fish because the same volume for these items (meat replicas) will have different weight. NDSR will require the interviewer to determine if the meat portions include either bones or fat, and if the fat was eaten, consequently, the DR interviewer should clarify with the participant if the amount of meat or fish envisioned by looking at the picture of meat or fish includes bone or other refuse.

### **11.7.4 Volume measures (e.g., cup, fluid ounce, tablespoon, pint)**

Volume measures are used to describe amounts for all liquid items, beverages, and non-liquid foods served or quantified in bowls, cups, or glasses. Examples in the Food Amounts Booklet include the pictures of measuring cups and spoons, bowls, and glasses. When volume measurements are being used to describe non-liquid foods, NDSR will first prompt the interviewer to select an amount unit (e.g., cup, teaspoon, tablespoon), and then the quantity and form in which the food was eaten (e.g., sliced, diced, solid). The form determines the amount that can be placed in a particular container and factors in the density of the food item. For most beverages, NDSR will prompt the interviewer to ask if the amount included ice, consequently the DR interviewer should clarify if the amount the participant reports includes ice.

## **11.8 Dietary supplements**

After the final pass of the dietary recall, a recall of dietary supplements taken during the previous 24-hours will be collected. The participant responses are recorded on paper and when dietary supplements are reported for the previous day, the information is entered in NDSR after the participant leaves.

## **12. Administering the 24-Hour Dietary Recall**

### **12.1 Set up the NDSR Program**

#### **12.1.1 Set up a project**

Before beginning the 24-hour dietary recalls a project is created to organize the information. A new NDSR project will be set up for each DR interviewer. DISC project information includes:

Project Name = *Insert name of interviewer* DISC Recalls

Project Abbreviation = Interviewer ID (1-3 characters locally assigned) + computer ID (2 characters locally assigned)

Record Type = Recall

### 12.1.2 Set the preferences

The following Methods preferences will be set for DISC recalls:

#### Require on record header

*Select:*

Date of birth  
Gender  
Interviewer ID  
Visit number  
Site ID

*De-select:*

Participant name, Life Stage Group

#### Display

*De-select:*

Show non-required fields in record header

*Select:*

Meal time format: Standard

#### Food Entry

*Select:*

Use Quick List  
Require note if amount exceeds max  
Require meal name  
Require meal location

Nutrients Per Food and User Preferences will be set according to the specific activities being conducted by the DR interviewer. For example, for daily backup of data the User Preferences may be set for the Backup folder to the external disk drive or network drive. Nutrients Per Food will be set according to each specific quality assurance task being performed by the DR interviewer or clinic DR coordinator.

## 12.2 Creating an Intake Record

Using the information provided about the participant by the clinic study staff, the DR interviewer will complete a Header tab to create an NDSR dietary recall intake record. The interviewer will enter the participant ID, date of intake, date of birth, interviewer ID, site id and visit number into the appropriate fields.

## 12.3 Introduction

The interviewer begins by introducing himself or herself to the participant. He/she should be friendly and relaxed. The interviewer should always give neutral responses to whatever the participant tells them. The interviewer will say: **Hi** (*insert participant's name*). **My name is** (*insert your name*). **How are things going today?** Pause, wait for their response, spend a minute or so to establish rapport, and proceed: **During this part of the visit, I'm going to be asking you about what you ate and drank yesterday and I'll enter the information in the computer as we go. What you say is confidential and there are no right or wrong answers. Whatever you ate is okay. Do you have any questions for me? Are you ready?** Or if this is a phone interview say: **I'm calling to collect the 24-hour recall for DISC. This will take about 30 minutes. Do you have time right now and do you have your Food Amounts Booklet?** If she doesn't have time right now, try to schedule the recall for another time later today. If later today doesn't work, say: **Thanks, I will try again another day.** If she doesn't have the Food Amounts Booklet, arrange for her to get another before making the call.

#### 12.4 Entering the NDSR Quick List

The interviewer proceeds by asking the participant to make a list of all the foods and beverages they had yesterday. Say: **First, we'll make a list in the computer of what you ate yesterday starting with when you got up. Then I will ask you some more questions and we'll figure out how much you had to eat.** Then say: **Please think about yesterday and then tell me what was the first time you had something to eat or drink?** Enter the response then as needed say: **What did you have at that time?**

The interviewer enters the information reported by the participant on the NDSR Quick List screen, not requiring the participant to give time, meal name, or meal location. The interviewer will use a slash to mark each eating occasion and NDSR will prompt later for the time and meal name. Above all, the interviewer should let the participant think and say what ever comes to mind about the previous day's intake, avoiding interruptions that may be distracting to the participant.

#### 12.5 Reviewing the NDSR Quick List

The interviewer verifies all of the entries on the Quick List and probes for missed items by reading the list back to the participant saying: **I am going to read back what you have told me. If you think of anything else you are or drank yesterday or if I have missed anything, let me know.** Start by saying **I have nothing between midnight and *(the first time a food or beverage is reported)*. Do you remember if you got up during the night (after midnight) and had anything to eat or drink?** Look for long periods of time between reported eating occasions and probe to see if anything was missed. **Did you have anything between your breakfast at 7am and your lunch at 12 Noon?**

Any errors should be corrected, and any additional foods the participant may report are added at this time.

#### 12.6 Collecting Meal Information Detail

The interviewer begins by saying: **Next we'll go over our list and I will ask you some questions about each food. You can use the Food Amounts Booklet at any time to let me know much you had.** NDSR will bring up the Meal Information window. The interviewer will use this opportunity to ask questions about meal time, meal name, and meal location if this information was not provided earlier during the Quick List.

#### 12.7 Asking About Additions

The DR interviewer will be asking about additions to every food. An on-line prompt will remind you to say: **The first thing on your list is *(NDSR inserts the name of each food)*.** Then, reading from the NDSR screen the interviewer will say: **Did you add anything to the *(NDSR inserts the name of the food)*?** Ask the additions question until you receive a "no" response.

#### 12.8 Collecting Complete Food and Amount Detail

The NDSR Food Search window prompts the DR interviewer for each available level of detail during this third pass. An on-line prompt will remind you to begin by saying: **What type of *(insert name of food)* was it?** The interviewer continues to define the food, selecting food variables as required on each screen. Unknown should be entered if the participant cannot describe food in detail (e.g., if it was prepared at a restaurant). An on-line prompt for the amount will remind you to say: **How much did you eat (drink)?**

Some foods require additional quantity details, with required fields indicated in yellow. After entering the amount provided by the participant, the NDSR displays a conversion to a common unit. At this time, the interviewer must be able to visualize the amount reported and confirm as needed any questionable amounts using the Food Amounts Booklet or by making

reference to other familiar items or recognizable standards. For example, 1/16 of a hamburger should have a note saying, “ate only one bite” or 8 cups of popcorn should have a note saying, “ate entire **box** at the movies”. The interviewer should ask if the complete amount described was eaten: **Were you able to finish that? or the (*insert name of food*)?**

Note: Foods that do not have complete descriptive and/or complete amount information are indicated with a blue question mark to the left of the food. When the interviewer has completely described a food, NDSR replaces the question mark with a green check mark to the left of each completed item.

As the interviewer conducts the 24-hour dietary recall, he/she will provide positive reinforcement by stating “**thanks, you are doing a great job, a big help**” as appropriate. The interviewer should maintain a pleasant tone of voice and avoid responding to the participant in any negative ways. If it is necessary to ask the participant to repeat what she said, the interviewer should ask him/her to do so in a gentle way and take ownership by saying: **Sometimes it’s hard for me to hear things. Could you please tell me that again?**

### 12.9 Reviewing the Recall

During the fourth and final pass of the NDSR multiple-pass approach, the interviewer will probe for missed meals, beverages, and snacks, making sure no information was inadvertently omitted. The DR interviewer will try to get a mental picture of the day, looking especially for time gaps of more than four hours between eating. The interviewer should look at the most likely snack times for example, after work, before bed, etc. Notes should be made to indicate skipped meals or not consuming a beverage or condiments with food. During the review, the interviewer reads back each food and amount, asking for confirmation from the participant. For example: **Now we’ll go over what I’ve put in the computer one last time. The first thing that I have is at (*insert meal name and time*) when you had (*insert food name*).** When the interviewer notices a large time gap he/she should ask: **Did you have anything to eat or drink after work? Anything before your (*insert time e.g., evening meal*) and (*before bed*)?**

Additional foods and meals are inserted at any time. If the participant hesitates and can’t remember eating anything for a long period of time, the interviewer may say: **Can you think what you were doing (*after work, at dinner/supper time, etc.*)? Sometimes if we think about where we were or whom we were with, it helps to remember what we ate.**

### 12.10 Completing the Trailer Tab

When complete, the system presents the Trailer tab and DR interviewer ends the recall saying: **Next (*insert name of participant*), in terms of the amount of food you ate, would you say this was close to the amount that you usually eat, a lot more than you usually eat, or a lot less than you usually eat? \_\_\_\_\_,**

This question refers to the overall amount of food for the day, not the type of food. The DR interviewer records the participant response to the last question on the Trailer tab. If the participant reports a lot more, check “considerably more than usual” or a lot less than usual, check “considerably less than usual”. In either case, NDSR requires the DR interviewer to provide a note that briefly states why the intake was not usual. For example, a celebration meal with lots of food or participant not feeling well and not eating much can result in eating a lot more or a lot less than usual. If needed the interviewer can say: **What makes you say it’s (*a lot more or a lot less than usual*)?**

The DR interviewer will determine the reliability of the data. If the dietary recall is unreliable because the participant was unable to recall one or more meals or for some other reason question the reliability, he/she will click the appropriate NDSR button and add the required NDSR Note. The interviewer does not ask the participant this question, nor share

their opinion with them. Thank you. Next I will ask you a few questions about dietary supplements.

#### 12.11 Collect the Dietary Supplement Recall

The interviewer proceeds to ask about intake of dietary supplements. **“In this portion of the interview I am going to ask questions about your use of dietary supplements and over the counter antacid products that you took yesterday.”** Each question on the script is asked and responses are listed on the form along with the number of times the product was taken yesterday.

After going through the listed probing questions, the interviewer proceeds by saying “Next we will use the containers that you brought in with you to complete the information.” A separate Dietary Supplement Form is used for each supplement listed. The list of dietary ingredients and amounts is required only for supplements not in NDSR.

Following the 24-hour Dietary Supplement Recall, a 30-day dietary recall will be conducted to get at usual intake.

#### 12.12 Thank the Participant

The interviewer thanks the participant and ends the recall: **Thanks so much for your help. Do you have any questions?** Pause, wait for and response to questions, and proceed: **You did a great job and I really enjoyed talking with you. Remember to keep the Food Amounts Booklet. We will need to use it when we do this again Thanks for your help.**

#### 12.13 Editing the Recall

The DR interviewer should review and edit the 24-hour dietary recall as soon as possible after its administration. During editing, special attention is paid to NDSR Missing Foods and NDSR Notes.

**12.13.1** Foods not found in the database will be indicated by NDSR as missing with capital M instead of the green check. Complete detail about the missing food should be reviewed and edited to ensure that adequate information has been provided for the clinic DR coordinator, or the staff at NCC to make a resolution. Remember another person should be able to picture the reported food so information about the color, size, shape, ingredients, and preparations should be included in the note.

**12.13.2** The NDSR Note field provides on-line documentation to clarify or confirm contradictory, questionable or unusual food items. Notes serve as communication between the DR interviewer, the clinic DR coordinator and the NCC quality assurance scientist when reviewing the data. Notes should be made to clarify unusual portion sizes, modifications to foods (e.g., not eating the crust of a piece of pizza), and eating foods without anticipated companion foods (e.g., hamburger without a bun or condiments).

#### 12.14 Special Considerations for Administering the Unannounced 24-hour Dietary Recall by Telephone

Because the telephone recalls are not scheduled in advance, the Telephone Recall Availability Form is used to identify best days and times for the participant to be reached. After the completion of each recall, the participant is asked to confirm their availability in the upcoming days. Notes should be made of any special plans or activities. The DR interviewer can attempt to obtain another telephone number for a participant if she indicates that she will be at another location (e.g., work).

The Telephone Introduction Script for the Telephone Recall will be used to start the recall and serves to remind the DR interviewer that the participant must have a copy of the Food Amounts Booklet for use in estimating food amounts during the recall. If the participant does not have the booklet, say you will send another one and will call back in a



few days. If this will be outside the second week of the intervention, collect the recall, make a note on the recall header that it was collected without the Food Amounts Booklet and advise the clinic DR coordinator who will review the foods and amounts and consult with the NCC DR administrator to determine if the recall can be used. Depending on the foods reported, amounts may be quantified without the usage of the Food Amounts Booklet (e.g., fast food sandwiches) and the recall may be acceptable. The Telephone Contact Log is completed each time the DR interviewer attempts contact with the participant. The clinic DR coordinator will review the Telephone Contact Logs daily or consult daily with the DR interviewer to monitor the progress towards collection of the 24-hour dietary recalls for each eligible participant within the time window.

The dietary interviewer may need to confirm that yesterday was atypical because the participant was ill and didn't eat. Probing questions such as "Were you at work yesterday?" can be used to identify when the participant was out sick. Sometimes it isn't clear until completion of the recall that the day was atypical. The DR interviewer should consult with the clinic DR coordinator regarding the possible need to collect an additional recall if the intake reported represents extreme under-reporting and an additional day should be collected. When this occurs, the highly questionable day would be deleted from the NDSR program.

### **13. Dietary Supplement Data Entry**

Upon completion of the 24-hr dietary recall, a separate NDSR dietary supplement record will be created for the participant to facilitate the analysis of nutrients both with and without supplements. Completed Dietary Supplement Forms will be entered. A separate NDSR project should be created to enter the supplement data. The time is not important for supplement data entry. Use 12pm for the mealtime, other for the meal name and other for the meal location. Enter each supplement and/or antacid at the same meal, regardless of when they are actually taken. For the 30-day dietary supplement record, if a supplement is taken not taken daily, enter a fraction of the supplement recorded. E.g., a One-A-Day tablet taken 20 times over the past 30 days would be entered as 20/30 tablet.

### **14. Clinical Center (Local) Quality Assurance**

On-site quality control of the NDSR dietary recall data will be the responsibility of the DR interviewers and the DR coordinator at each clinic. On-site quality control will include:

- Review and editing of each dietary recall by interviewer within 1-2 days.
- Review of each dietary recall by clinic DR coordinator within 1 week, with feedback provided to the respective DR interviewer.

#### **14.1 Daily Review of 24-Hour Recall Data**

At the end of each recall, the DR interviewer will initiate the 24-hour Recall Checklist (DR-Form 3) and proceed to review each 24-hour dietary recall collected. Obvious errors may be corrected on the spot (e.g., entry of 10 hamburgers consumed when the DR interviewer knows that it was only one.) Should the DR interviewers have questions, they should discuss these with the clinic DR coordinator to reach a consensus. Clinic DR coordinators may consult with NCC for more guidance. The following steps will be taken during the daily review by the DR interviewer:

- **Check the Header tab on-line or print and review the Record Properties Report.** Review and confirm information about the project name, record type, and date of intake.
- **Check the Food tab on-line or print and review the Foods Report.** Each food and amount should be carefully reviewed and confirmed. Unusually small or large portions

are verified and any justification or rationale is documented in the note field. Missing food information is checked for completeness.

- **Edit the dietary recall.** The DR interviewer will conduct edits for each intake record within one to two days of initial data collection or after input from the clinic DR coordinator.

## 14.2 Weekly Review of 24-hour Recall Data

At least once per week, the DR coordinator will review all 24-hour dietary recalls collected for the clinic. The coordinator may make or recommend changes in the 24-hour dietary recalls only after discussing the proposed change(s) with the DR interviewer. It is the responsibility of the clinic DR coordinator to document and communicate clinic-specific consensus decisions to the NCC and to the DR interviewers within his/her clinic.

Weekly checks by the DR coordinator should address the information in the header, trailer, and food tabs.

### 14.2.1 Record Properties Report

The record properties report can be used to check information entered in the header and trailer fields.

- Check the header tab information against the DISC 24-hour Recall Checklist.  
Confirm:
  - Participant ID number
  - Interviewer ID number
  - Visit number
  - Site ID number
  - Date of intake
- Review the trailer tab information:
  - Trailer tab is complete and note is provided if necessary
  - Meal patterns and calories from past recalls can be compared for participants who report more than or less than usual intake

### 14.2.2 Food Report

The food report should be checked for common mistakes:

- Missed meals or beverages. A note should be provided if there is a missed meal or if a meal does not contain a beverage.
- Unusually large or small servings. Check the unit of serving size reported, the selected amount with parenthesis following it, and the note field to clarify unusually small or large servings.
- Food entry incorrect per note. Check the database to be sure the most appropriate choice was selected based on the note (e.g., entered unknown margarine when note says Country Crock).
- Food entry or size incorrect per location. Check to be sure the preparation is reasonable based on location (e.g., they should enter unknown for type of fat used to fry foods if purchased in a restaurant). Check for a reasonable size based on the reported location.
- Missed companion foods per note and location. Check to see that foods are entered with appropriate companion foods and condiments and look for a note about unexpected omissions (e.g., spaghetti noodles without sauce).
- Incorrect amount per information recorded in the NDSR Note Field.
- Converting fractions to decimals or decimals to fractions when not necessary.
- Selecting inappropriate/incorrect forms of food.

- Check to see that fluids/liquids are entered as FO instead of OZ.
- Check the form of food (e.g., applesauce is ½ cup solid while ½ cup of turkey should be entered as ½ cup cut pieces).
- Enter pieces of fruit and chicken as food specific units instead of dimensions.
- Enter baked goods as small, medium or large based on reported dimensions.
- Modifications of fast foods or mixed dishes. Use the output file to determine the exact food and amount to subtract or add to fast foods or mixed dishes (e.g., subtract off the half bun from a McDonald's cheeseburger if the note indicated the participant did not eat it).
- Inappropriate picture in Food Amounts Booklet. Check to see that the graphic or picture used to estimate the size makes sense (e.g., you can't have a heaping TS of hot sauce because it is liquid but a heaping TS of peanut butter is probable).

### **14.2.3 Output Files**

Output files can be generated for a group of recalls or an entire project and used to check the accuracy of information in the header, trailer and food tabs.

- Single food items greater than 400 Kcal, 25 g of fat, or 500g.
- Daily totals less than 500 kcal.
- Daily totals greater than 5,500 kcal.

### **14.3 Continuing Education**

DR interviewers are encouraged to review the MOP throughout the project period in order to remain well versed on specific issues and procedures. The NDSR Quarterly ([www.ncc.umn.edu/newsletter](http://www.ncc.umn.edu/newsletter)) is also a useful source of information.

## **15. Study-wide Dietary Data Quality Assurance**

### **15.1 Receipt of 24-hour Recall Data at NCC**

Upon receipt at NCC, the NCC data flow technician confirms the successful transmission of the electronic file, and via e-mail notifies the person sending the data from each clinic accordingly.

### **15.2 Review and Verification of Data**

A 20% random sample of recalls will be designated and checked to identify questionable foods and/or unreasonable amounts which will be called to the attention of the clinic DR coordinators with a recommendation regarding editing when it is thought that the DR interviewer selected an inappropriate food or amount. In addition, NCC quality assurance reports are run on 100% of the data to identify food and nutrient outliers and results will be provided to the clinical centers for confirmation.

### **15.3 Generation of Inquiries**

Clinics are contacted on a weekly basis regarding questionable items noted during the quality control review. The queries serve to resolve the immediate questions and to alert the interviewers to the types of issues that are questioned and require confirmation and documentation on the NDSR dietary intake record.

### **15.4 Editing 24-hour Dietary Recall Data**

Final edits are made to the dietary intake records by staff at the clinical centers. Cleaned copies of the recalls are stored at each clinic and resent to NCC.

## **16. Clinic Data Management**

### **16.1 Backup of 24-hour Recall Data**

NDSR backup of projects containing the 24-hour dietary recall interviews will be routinely conducted by the DR interviewer to ensure the security of the data. Daily backup copies of the data are made to a computer diskette, or other portable storage device, and stored in a location separate from the computer. At the end of each week, the last backup copy made of each interviewer's recalls will be given to the clinic DR coordinator.

### **16.2 Restoring 24-hour Recall Data**

The clinic DR coordinator will restore the 24-hour dietary recall projects to a computer with NDSR program installed. This computer should be connected to a printer so that reports can be printed and reviewed. This computer should also be connected to the Internet so that backup files can be sent electronically sent to NCC.

### **16.3 Transmission of 24-hour Recall Data to NCC**

On a weekly basis, after quality assurance activities have been completed, the clinic DR coordinator will combine the recalls collected and submit to NCC via e-mail

### **16.4 Archive 24-hour Recall Data at Clinic**

Completed dietary recalls should be archived at each clinic by removing them from the laptops and storing them in the desktop computer and disks. An archived copy of all data should be kept until the study is complete. Frequent archival keeps the number of stored recalls at a minimum, increasing the efficiency of the NDSR and the DR interviewer.

### **16.5 Clinic Storage of Paper Documentation**

The clinic DR coordinator will file copies of the all materials related to the dietary interview. The participant ID number will be used for record retrieval in the event of questions.

### **16.6 Computer Failure**

NDSR automatically saves all data as entered. In the event of a temporary interruption in operating NDSR, recovery will likely go unnoticed by the participant. With long-term power failure or the failure of the hard drive of the computer, the interview may be resumed later the same day or delayed until another day. In the event of computer hardware or software problems, DR interviewers will notify clinic DR coordinators immediately. Clinic DR coordinators will report problems as follows:

- Problems with the NDSR software are reported to the NCC. Names and telephone contact for hardware and software related problems are included in the computer hardware and software documentation.
- Problems with the computer must be dealt with on a local basis.

## **17. Sending Data to NCC for final quality assurance and nutrient calculations**

Following completion of final quality assurance procedures, individual clinics will send final cleaned NDSR backup files to NCC. NCC will generate output files to include nutrients and Food Group Serving Counts and send to the coordinating center when data have been received from all of the individual clinics. The latest version of the NDSR database will be used to calculate final nutrients for the study.

**18. Sending Data to Maryland Medical Research Institute (MMRI)**

Following completion of final quality assurance procedures, NCC will generate output files to include nutrients and Food Group Serving Counts and send to MMRI for analysis. Backup files of the recalls will also be sent so that MMRI maintains the participant record files that can be recalculated as desired when future versions of the NDSR database become available.

**OPERATORS' MANUAL FOR DISC STUDY**

**SCANNING AND ANALYSIS PROCEDURES  
FOR HOLOGIC SYSTEMS**

**DIETARY INTERVENTION STUDY IN CHILDREN**

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## **Introduction to Quality Assurance**

This manual serves as the official Hologic Prodigy Dual X-ray Absorptiometry (DXA) Operator's Guide for the Dietary Intervention Study in Children (DISC). The purpose of this manual is to standardize the DXA scanning acquisition procedures between the clinical centers participating in the DISC study. The success of the DXA study will depend on several factors, including the qualifications and dedication of the scanner operators, clear specification and understanding of the study requirements as set forth in this manual, and good lines of communication between the sites participating in the metabolic study, the Musculoskeletal and Quantitative Imaging Research Group (MQIR), Fox Chase Cancer Center (FCCC), and the Maryland Medical Research Institute (MMRI).

This manual is intended to serve as the DXA operator's guide for the DISC and builds upon (rather than replaces) the operator training and documentation provided by Hologic Corporation. It is expected that each person performing scan acquisition for the DISC is familiar and competent with the scanning system employed at their study site. In addition, the material in this manual should be read and understood before beginning to scan participants for this study. The MQIR will certify that each DXA technologist is qualified by Expert Review of 3 DXA scans each of AP spine, proximal femur and whole body acquired and analyzed by each technologist. These scans can be from volunteers or from recent patients with patient identifiers removed.

Other important requirements for DXA in this study are as follows:

- 1) No scanner hardware changes**
- 2) No scanner software upgrades**
- 3) No scanner relocation**

**Without proper notification and request for approval from FCCC and MQIR.**

Request for the above can be made by e-mail to MQIR and approval or denial will be issued using MQIR specific forms.

**Any questions or comments concerning the DXA procedures of this study should be directed to the UCSF, Musculoskeletal and Quantitative Imaging Research Group (MQIR):**

**Chyi Huang  
UCSF / MQIR  
Attn: DISC  
185 Berry Street, Ste. 350  
San Francisco, CA 94107  
Tel: (415) 353-4938  
Fax: (415) 353-9425**

**e-mail: [chyihuang@radiology.ucsf.edu](mailto:chyihuang@radiology.ucsf.edu)**





## Introduction to the DISC Protocol

This follow up of the DISC study will include 301 young women between 6 sites. The DXA scans to be performed will be AP spine, proximal femur and whole body, one visit only. All scans will be analyzed at MQIR at UCSF. This manual will describe the procedures to be followed for participant scanning and longitudinal calibration.

Please read this manual carefully before scanning participants. These instructions assume you are familiar with correct scanning and analysis procedures.

## Participant Registration

Enter the participant's 6 digit **letter code** into the *last name field* exactly as it is entered on the DXA Form. Enter the participant's 6 digit **ID** in the Patient ID field. For this reason, you should always get the participant's letter code and ID number from the Study Coordinator to ensure consistency. (Figure 1)

All leading zeroes must be included. Be sure to use zeroes (Ø) and not the letter "O" when entering the Participant ID into the Participant ID field.

On the Scan Property page following the entry fields are the fields for Operator's Initials and participant's height and weight. Because there is only one visit, no visit code is necessary. (Figure 2)

DOB, sex, ethnicity, height and weight should be entered in the appropriate fields. DISC should be entered into the Ref MD field. Be sure to use zeroes (Ø) and not the letter "O."

The 'Patient' window has a title bar with a close button. It contains two tabs: 'Biography' (selected) and 'Insurance'. The Biography tab includes the following fields:

- Last Name:
- First Name:
- Middle Initial:
- Ethnicity:
- Patient ID:
- Identifier2:
- Sex:
- DOB: Month:  Day:  Year:
- Referring Physician:
- Menopause Age:  Weight:  lb Height:  in
- Patient Comment:

Buttons at the bottom:

**Figure 1 Participant Biography**

The 'Scan Properties' window has a title bar with a close button. It contains two tabs: 'Details' and 'Identification' (selected). The Identification tab includes the following fields:

- Patient Name: ABCDEF, DISC
- Patient ID: 0-1234-5
- Scan ID: D04090612
- Operator:
- Height:  in
- Weight:  lb
- Scan Comment:

Buttons at the bottom:

**Figure 2 Scan Comment Field**

## **DXA Scan Acquisition**

The following sections describe in detail the MQIR's requirements for acquiring participant scans for the DISC study, above and beyond those mentioned in the Hologic operator's manual.

In order to get the most consistent participant results it is important to follow consistent procedures in acquiring all scans. These include the following:

- 1) Use the same scan mode for all participants. (Fast Array)
- 2) Remove all radio-opaque objects from the scan areas. (underwire bras, jewelry, belts, etc.)
- 3) The participant should be dressed in a hospital gown or scrubs wearing only underpants and, if necessary, thin socks. A thin sheet may be placed over the participant for warmth.
- 4) Ensure correct positioning of the participant.
- 5) Ensure that no movement occurs during scanning.
- 6) Monitor the scan during acquisition. If positioning is not correct, or the participant moves, etc., abort the scan, reposition the participant if necessary and restart the scan.

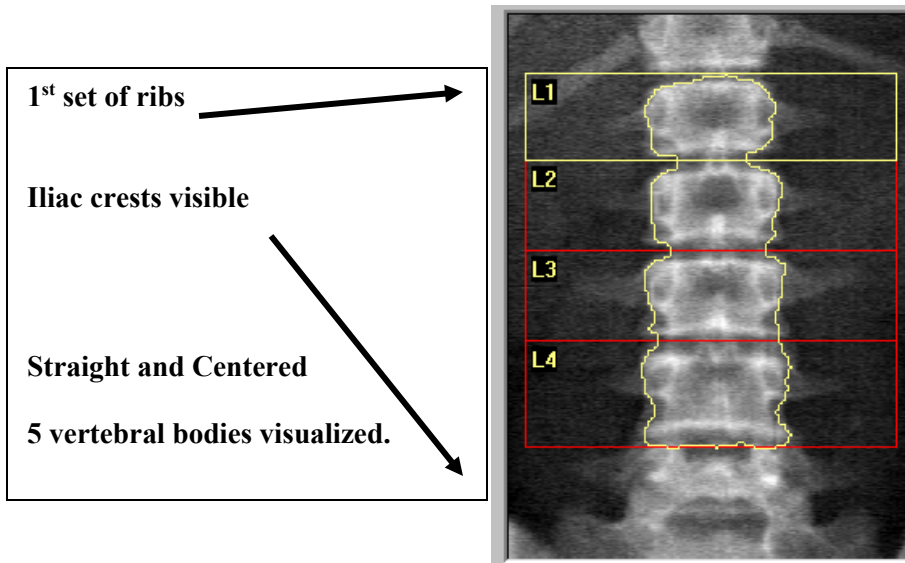
**NOTE:** when scanning participants it is important to keep in mind that it is much less time consuming to rescan the participant immediately if a problem is detected, rather than having to recall the participant for a repeat of the scan on another day.

Please note any problems with scan acquisition in the comment field of the electronic DXA log sheet.

### **AP Spine Scans:**

Details Specific to the DISC study are noted below.

1. Select **fast array** scan mode
2. Keep the scan width and length set to the default settings.
3. Scan the Lumbar spine to include L1 through L4. Make sure that the AP spine scan includes both iliac crests at the bottom of the image and at least one vertebra with ribs at the top (Figure 3). \* To assist in positioning the spine correctly, use the spinal positioning block. Ensure optimal participant positioning by consistently using the same positioning cushions for each scan.



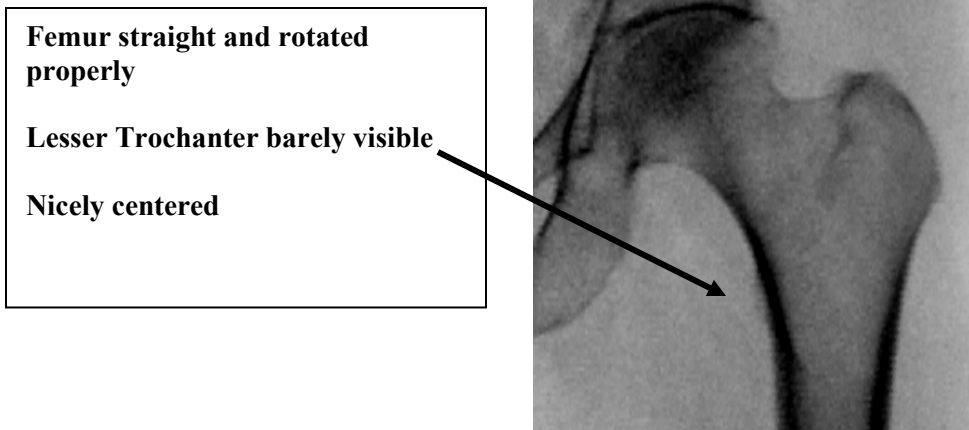
**Figure 3: Properly Positioned AP Spine Scan**

\*(The common default length is 8 inches or 20 cm, depending on the set up of a particular scanner. When a participant measures 5'7" in height, the length of the scan may be increased by 2 inches (4 cm.) to assure inclusion of the crests and the first set of ribs. Always terminate the scan upon viewing the first set of ribs. )

## Femur Scans

Details Specific to the DISC Study are noted below.

1. **Scan the LEFT hip.** If the left hip is not appropriate for scanning, please scan the right. Please note the reason for not scanning the left hip on the DXA form.
2. Select **fast array** scan mode. Keep the scan width and length set to the default settings.
3. Make sure the leg to be scanned is properly rotated and abducted. Ensure optimal participant positioning by consistently using the hip scan positioning fixture for every scan. Always position the participant's leg by applying rotating force **above the knee**. This will ensure that the hip itself is rotated, not just the lower leg. Proper rotation and abduction will alleviate many analysis problems. With optimal positioning the lesser trochanter will be barely visible (Figure 4).

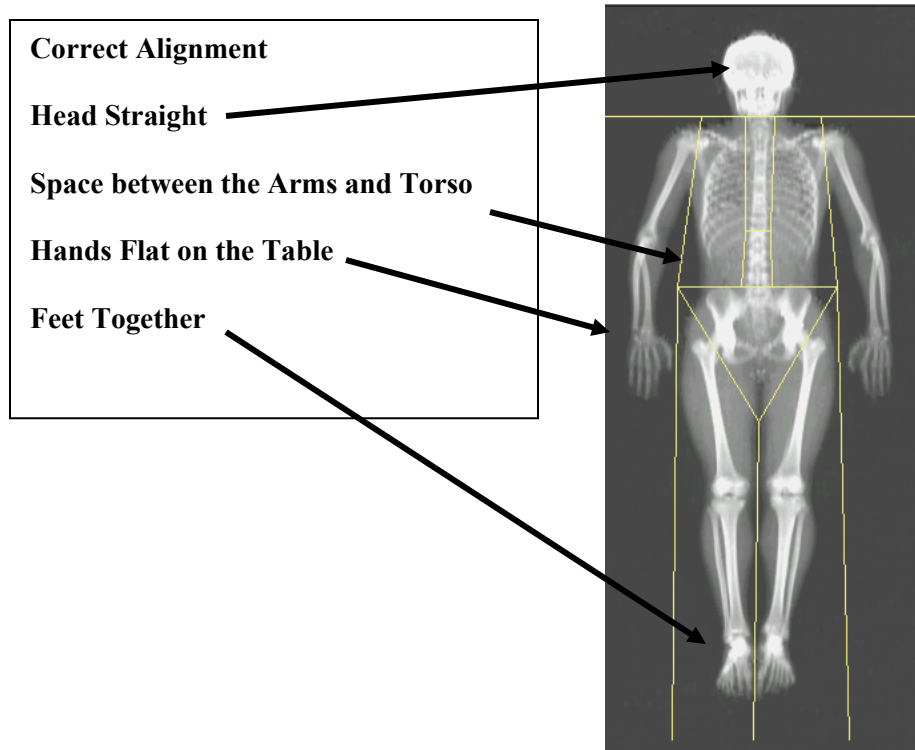


**Figure 4: Correctly Positioned Femur Scan**

### **Whole Body Scans**

Details Specific to the DISC Study are noted below.

1. Keep the scan width and length set to the default settings – scan the entire table.
2. Position the participant in the center of the table aligned with the long axis of the scanner, head near the head end of table. The participant’s head should face straight up, not turned to the left or right. If required for participant comfort, use only radiolucent pillows.
3. The legs and feet **must** be positioned together with a Velcro strap around the ankles to help avoid movement. **Please keep the feet relaxed with the toes pointed upwards.** (Figure 5)
4. Position hands with palms flat against the scan table. **Please maintain space between the arms and the torso when possible.** If necessary, with larger or heavier participants, the hands may be placed in a lateral position next to the hips. **Do not** tuck the hands under the hips to keep them in the scan field. If necessary, tape the participant’s hands to the scan table. For participants who are too tall to fit within the scanning limits, it is acceptable for the feet to extend beyond the lower scan limit line. Do not bend the knees to keep the feet within the scan field.
5. Monitor the scan during acquisition for participant movement so the scan may be stopped and restarted. Do not engage the participant in conversation because it may cause motion, but give them encouragement and updates on the scan’s progress.
6. No analysis.



**Figure 5: Correctly Positioned Whole Body Scan**

## Data Security

The Archive function in Hologic scanners is used to store scan files on diskettes, CD's, optical disks or electronic storage. For data security all scan files should be archived soon after scanning in case of a computer failure.

For data security, archive your scan files on a regular basis.

The System Backup function is used to back up your Hologic database. The Hologic database contains all biography, report summaries and, location information for all participants scanned on your system. Your site should perform a System Backup on a weekly basis.

When preparing to send participant scan files to UCSF, use the **Copy** command to transfer participant scan files to diskettes, CD's, or USB stick. Do **not** use the Archive command.

## Quality Control Data (Longitudinal and Cross-Calibration)

Scanner Quality Control (QC) procedures are used to monitor scanner performance throughout the course of the study. Longitudinal QC procedures consist of daily procedures used to monitor the performance of a single scanner over time. Cross-calibration procedures are used to monitor scanner variation from machine to machine. An additional QC measure is the use of the "DXA Bone Densitometer Report" (pages 14 and 17). The investigator site completes and sends this report monthly to UCSF along with copies of the QC scans on diskette, CD, or USB stick. Both longitudinal Quality Control and cross-calibration will be discussed in this section.

## Normal Longitudinal QC Procedures

This study will make use of data obtained by your standard daily QC procedures using the Hologic Spine Phantom, the Hologic Whole Body Phantom and an Air Scan procedure.

### Hologic Spine Phantom

(Assumption is made that a biography already exists)

Make sure that the phantom serial number is entered in the Pat ID field. The phantom number may be read from the label on the side of the phantom.

Scan the Hologic Spine phantom at least every day that a study participant is scanned, but at a minimum of three days per week for the duration of the study.

These scans are analyzed automatically and added to the QC database.

Review the QC plot for BMD. If the BMD for L1-L4 falls outside acceptable limits, rescan the phantom. If the BMD from the second scan also falls outside the limits, call for service at Hologic. If the BMD from the second scan falls within the limits, continue with normal scanning for the day.

### Hologic Whole Body Phantom

Perform a scan of the Whole Body Phantom 3 times per week on 3 different days. Create a Participant Biography in the following manner: Please use zeros (Ø) in the biography and not the letter "O."

Name: **WBP-YYYY**

'W' denotes the Whole Body Phantom

Replace 'YYYY' with the phantom serial number

Participant ID: **XXX**

Replace 'XXX' with your site #

Sex: **F**

Participant Comment: **LONGITUDINAL QC – WHOLE BODY SCAN**

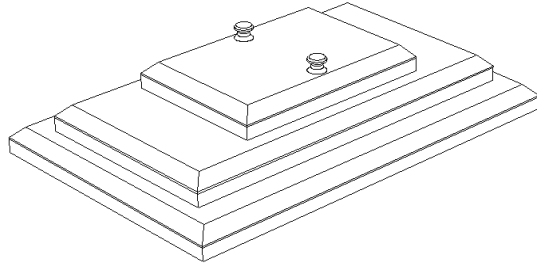
All other fields in the Participant Biography should be left blank.

**ASSEMBLY:** Figure 6: Hologic Whole Body Phantom

Assemble according to the instructions that accompany the phantom.

**Caution: Do not attempt to lift the entire phantom assembly.**





**Figure 6 Hologic Whole Body Phantom**

**POSITIONING:**

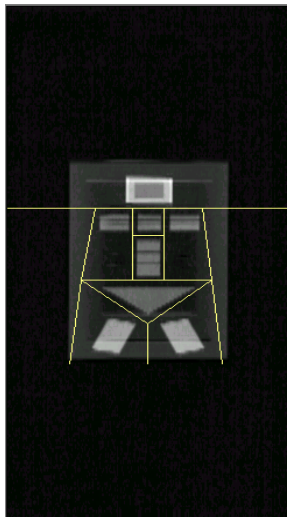
Center the table. Position the WB phantom in the center of the table with the ends marked ‘head’ towards the head of the table. Align the laser centering lights with the centering marks on the surface of the phantom. The phantom should be parallel with the long axis of the table in the center.

**SCANNING:**

Be sure there is nothing else on the table. Scan the phantom using the standard adult WB scan mode. Scan the entire table.

**ANALYSIS: Figure 7**

Analyze the scan using the Regions of Interests pictured in Figure 7. Compare all future scans to the first baseline scan.



**Figure 7. Whole Body Phantom Scan**

## Air Scan Procedure (Table Top Radiographic Uniformity)

Perform a scan of the table once per week, the same day that the tissue bar is scanned. For users with software version 12.1 or higher, this is an automatic procedure called "Table Top Radiographic Uniformity". No biography needs to be created. Users with a software version less than 12.1 need to create an Air Scan Biography in the following manner:

Please use zeros (0) in the biography and not the letter "O."

Name: **Air Scan**

Participant ID: **XXX**

Replace 'XXX' with your site #

Sex: **F**

Participant Comment: **AIR SCAN**

Remove everything from the table and perform a scan of the entire table using the whole body scan mode.

### Analysis: (Note: automatic with versions 12.1 and higher) Windows/Delphi 11.2

Using Windows Explorer, go to the **C:\QDR\Utilities** directory

- Copy the Service icon onto your desktop as a shortcut (This should remain there.)
- Enter the Delphi Software in the usual manner.
- Acquire an Air Scan

Exit without shutting down from the Delphi software.

- double click on the SERVICE Icon Shortcut. This puts you back into the Delphi software in service mode.

- From the Menu on top of the screen, select Utilities->Service Utilities->Table Top Radiographic Uniformity

- Select the most recent air scan and press ok.

- You will be presented with an image of the air scan and a scan printout similar to the output below. The image will typically not look very pretty. It should ideally look like random white noise (i.e. static on a TV set). You may see streaks.

Report Date: 8/8/05

Selected scan = P:\DXA\_DATA\DISC\[PA02626A.R0P

Total points per phase in row: 109

Total lines in column: 150

Lines with a standard deviation greater than 2.0

Phase Line	mean	stdev	min	max
<b>Global Stats:</b>				
1	586.92	<b>1.03</b>	587	590

Columns with a standard deviation greater than 2.0

phase line	mean	stdev	min	max
------------	------	-------	-----	-----

**Note:** If the global standard deviation is less than 2.0, the scanner is functioning properly. If the results are above 2.0, please repeat the air scan and review results. If the SD remains over 2.0, the scan needs to be emailed to Chyi Huang for immediate review. The number to look at is shown above in bold. (1.03 in this example.)

**No further analysis using Hologic or Delphi software should be performed on these scans.**

### Typical Schedule for Phantom Scanning – Longitudinal QC

	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Tissue Bar		X					
Hologic Spine Phantom		X	X	X	X	X	
Whole Body Phantom		X		X		X	
Air Scan		X					

### Copying and Archiving:

Use **Copy** for copying scans to diskette, CD or USB stick. Archive to your site's regular archive modality.

### Scanner Cross-Calibration Plan

In order to accurately assess differences in scanner performance among investigator sites, cross-calibration phantoms will be sent to each site at least once during the course of the study. Coordination will be made in advance between the QA Center and each site for delivery of the cross-calibration phantoms. Phantoms used will be the: Hologic Block Phantom, Hologic Femur Phantom, European Spine Phantom, and, Hologic Whole Body Phantom. Detailed scanning and analysis procedures will accompany the phantoms.

### DXA Bone Densitometer Report (BDR):

The BDR is completed at the end of each month by the technologist and submitted to the Study Coordinator. It provides a record of additional information about each study scanner. The BDR tracks scanner maintenance and repairs as well as technologist changes, which are then reviewed by the MQIR. Two critical pieces of identifying information are the scanner serial number and the Hologic spine phantom serial number. For reference purposes, an original blank BDR form is supplied with this DXA Operator's Guide.

**IMPORTANT:**

**Changes in scanners, software, or location of scanners can have a large impact on the integrity of study data. For this reason, such changes are NOT ALLOWED for the duration of this study without prior notification and approval from MQIR and the FCCC. Requests for changes may be made by telephone or e-mail to MQIR (Chyi Huang at 415-353-4938, [chyi.huang@radiology.ucsf.edu](mailto:chyi.huang@radiology.ucsf.edu)).**

**Operator Qualification**

All technologists must be qualified by the QA Center prior to scanning any study participants. Qualification consists of on-site training by a QA Center staff person and the QA Center's evaluation of print-outs of 3 AP spine scans, 3 hip scans and, 3 total body scans acquired before the study and analyzed by the technologist. Each study technologist should provide a copy, if available, of their manufacturer's training certificate and license to the QA Center. Please forward with a copy of the Hologic Operator's Form found at the beginning of this section as soon as possible after receiving this Procedures Manual. When a new technologist is employed, please follow the above instructions. When someone leaves employment, please note the date.

**Data Export Procedures / Timelines****Participant Data**

All participant scans are to be sent on labeled diskettes, CD or USB stick along with a copy of DXA form, to UCSF for analysis by the UCSF Study Coordinator on a monthly basis.

**Instrument Quality Control Data**

Instrument Quality Control data should be sent to UCSF once monthly. QC data transfers should consist of the following:

- 1) Completed "QC Data Transfer Checklist."
- 2) Completed DXA Bone Densitometer Report (BDR) (Page 17).
- 3) Copies of all the monthly QC scans (Hologic Spine, Hologic WB, and Air Scans) .  
**Please do not send the Daily Flat or the Tissue Bar scans.** Use a labeled diskettes, CD, or USB.

Please Note:

You may copy both participant and QC scans onto the same medium. Please check the appropriate data types on the FED EX Form (page 18) and/or on the label (Figure 8).

DISC- Data
Study Site #: _____
Date: ____/____/____ D D M M M Y Y
Participant Data: __
QC Data: __
Disk # ____ of ____

**Figure 8 – Label (example)**

Data to be submitted on a monthly basis to:

**Address:**

**Chyi Huang**  
**MQIR, University of California, San Francisco**  
**Attn: DISC**  
**185 Berry Street, Ste. 350**  
**San Francisco, CA 94107**

**Telephone:** (415) 353-4938  
**FAX:** (415) 353-9425  
**E-Mail:** [chyh.huang@radiology.ucsf.edu](mailto:chyh.huang@radiology.ucsf.edu)

**IMPORTANT: ALWAYS USE COPIES OF THE FORMS PROVIDED  
 IN THE APPENDIX FOR ALL DXA DATA TRANSFERS**

**Bone Densitometer Report**

**USE ONE FORM FOR EACH SCANNER IN THIS STUDY**

THIS FORM ONLY PERTAINS TO STUDIES IN WHICH DXA DATA ARE SENT TO UCSF. DXA SCANNER OPERATORS SHOULD SEND THIS FORM ALONG WITH A COPY OF THE QC SCANS AND BMD, BMC, AND AREA PLOTS FOR THE SPINE PHANTOM FOR THE MOST RECENT SIX MONTHS.

**DXA Bone Densitometer Report • DISC**

Site number \_\_\_\_\_

Scanner Serial Number \_\_\_\_\_ Spine Phantom Number \_\_\_\_\_

- 1) Has a new / different scanner been used for any study patients?  Yes  No If yes, explain:  
 Was scanner change approved in advance by UCSF?  Yes  No By Whom? \_\_\_\_\_

- 2) Have there been any software changes ?  Yes  No If yes, indicate:  
 Old software version: \_\_\_\_\_ New software version: \_\_\_\_\_ Date installed: \_\_\_\_\_  
 Was software change approved in advance by UCSF?  Yes  No By Whom? \_\_\_\_\_

3) Were there any technologist changes?  Yes  No If yes, indicate:

Technologist	Added / Departed	Date of Change	Date of Manufacturer's Training
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

- 4) Were there any maintenance/recalibration/repair problems?  Yes  No If yes, indicate:
- | Service performed | Date of Service |
|-------------------|-----------------|
| _____             | _____           |
| _____             | _____           |
| _____             | _____           |
| _____             | _____           |

5) Additional comments (Use reverse side) :

Main Technologist: \_\_\_\_\_ Date: \_\_\_\_\_ Telephone: \_\_\_\_\_

Please make copies of this blank form. Complete this form each reporting period and send the original to the UCSF Quality Assurance Center and keep a copy for your records.

**FED EX Transfer Log**

## FEDEX TRANSFER LOG

Complete this form and place it on top of the contents in the FedEx package. Send to an email to: [chyi.huang@radiology.ucsf.edu](mailto:chyi.huang@radiology.ucsf.edu) with the expected delivery date and tracking # for the package.

FedEx to: Chyi Huang  
UCSF/Musculoskeletal and Quantitative Research Imaging  
185 Berry Street, Ste.350  
San Francisco, CA 94107  
Tel: 415-353-4938

**Participant Data Enclosed in this FedEx:**

PARTICIPANT ID #	LETTER CODE
<input type="checkbox"/> - <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> - <input type="checkbox"/>	
<input type="checkbox"/> - <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> - <input type="checkbox"/>	
<input type="checkbox"/> - <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> - <input type="checkbox"/>	
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<input type="checkbox"/> - <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> - <input type="checkbox"/>	
<input type="checkbox"/> - <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> - <input type="checkbox"/>	

*Note: For each PARTICIPANT ID listed above, a participant intake sheet must be included in FedEx; All CD's, diskettes, USB sticks, etc. must be labeled!*

\_\_\_ Tot. # transfer media (CD's, diskettes, etc.)

**Quality Control Data Enclosed in this FedEx:**

**DXA:** (all of the following should be included):

- QC Archive data diskette/superdisc with label  
 Bone Densitometer Report

**Study Coordinator/DXA Technologist Signature:** \_\_\_\_\_ **Site#** \_\_\_\_\_

**DATE:**   /   /





# **OPERATORS' MANUAL FOR DISC STUDY**

## **SCANNING AND ANALYSIS PROCEDURES FOR GE/LUNAR PRODIGY SYSTEMS**

### **DIETARY INTERVENTION STUDY IN CHILDREN**

GE-Lunar Corp.  
313 West Beltline Hwy.  
Madison, Wi 53713

MQIR  
University Of California, San Francisco  
185 Berry Street, Ste. 350  
San Francisco, Ca 94107

Draft 1  
MAY 2006

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## **Introduction**

### **Introduction to Quality Assurance**

This manual serves as the official GE/Lunar Prodigy Dual X-ray Absorptiometry (DXA) Operator's Guide for the Dietary Intervention Study in Children (DISC). The purpose of this manual is to standardize the DXA scanning acquisition procedures between the clinical centers participating in the DISC study. The success of the DXA study will depend on several factors, including the qualifications and dedication of the scanner operators, clear specification and understanding of the study requirements as set forth in this manual, and good lines of communication between the sites participating in the metabolic study, the Musculoskeletal and Quantitative Imaging Research Group (MQIR), Fox Chase Cancer Center (FCCC), and the Maryland Medical Research Institute (MMRI).

This manual is intended to serve as the DXA operator's guide for DISC and builds upon (rather than replaces) the operator training and documentation provided by GE/Lunar Corporation. It is expected that each person performing scan acquisition for the DISC is familiar and competent with the scanning system employed at their study site. In addition, the material in this manual should be read and understood before beginning to scan participants for this study. The MQIR will certify that each DXA technologist is qualified by Expert Review of 3 DXA scans each of AP spine, proximal femur and whole body acquired and analyzed by each technologist. These scans can be from volunteers or from recent patients with patient identifiers removed.

Other important requirements for DXA in this study are as follows:

- 1) No scanner hardware changes**
- 2) No scanner software upgrades**
- 3) No scanner relocation**

**Without proper notification and request for approval from FCCC and MQIR.**

Request for the above can be made by e-mail to MQIR and approval or denial will be issued using MQIR specific forms.

Any questions or comments concerning the DXA procedures of this study should be directed to the UCSF, Musculoskeletal and Quantitative Imaging Research Group (MQIR):

**Chyi Huang**  
**UCSF / MQIR**  
**Attn: DISC**  
**185 Berry Street, Ste. 350**  
**San Francisco, CA 94107**  
**Tel: (415) 353-4938**  
**Fax: (415) 353-9425**  
**e-mail: [chyh.huang@radiology.ucsf.edu](mailto:chyh.huang@radiology.ucsf.edu)**

Other questions regarding the study protocol should be directed to the site Project Director.

**GE/LUNAR PRODIGY DXA OPERATOR'S LOG**

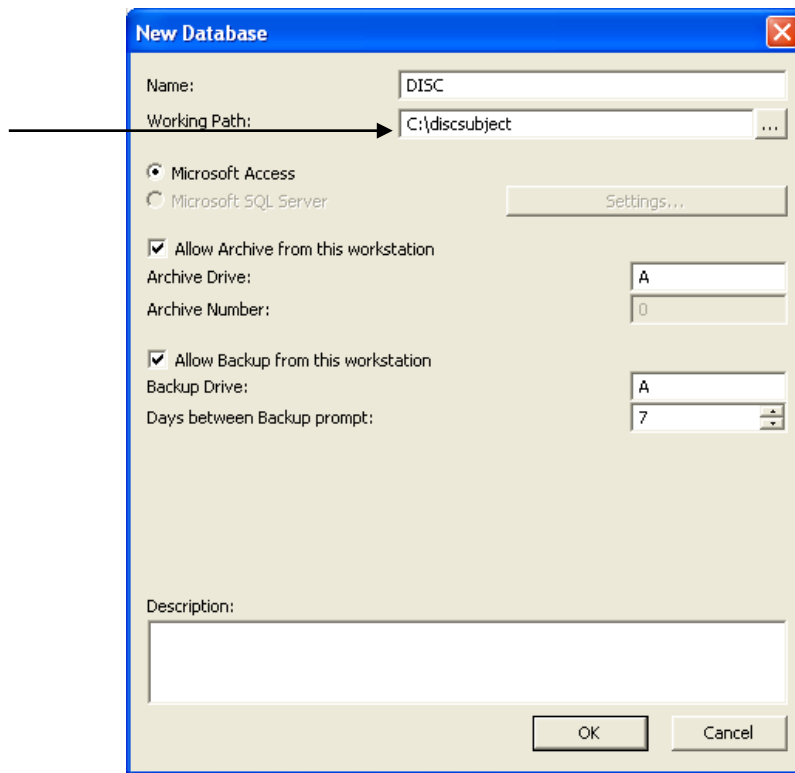


scans will be analyzed at MQIR at UCSF. This manual will describe the procedures to be followed for participant scanning and longitudinal calibration.

Please read this manual carefully before scanning participants. These instructions assume you are familiar with correct scanning and analysis procedures.

## **Creation of New Database**

Create a DISC database (see Figure 1, New Database), which will allow you to easily locate and compare all future scans of the same participant to their original scans. Please note the name of the Working Directory for future reference. This will be different for each site. We suggest that the name of the working directory be changed to DISC for easier recall. Ie: C:\discsubject.



**Figure 1. New Database**

## **New Participant Registration**

This section describes in detail the specific procedures to be conducted for the DISC with respect to entering the participant's biography. Be sure to read and understand the material in this section

before scanning any participants for DISC. Any questions you may have regarding the acquisition of DXA scans should be directed to MQIR.

### Participant Name and ID Fields

Select the DISC Database and New (patient). The Mandatory Information screen appears. Enter the following data in the information fields. At the end of each field press Tab to move the cursor to the next field. (See Figure 2, New Patient Directory)

Enter **DISC** in the *First Name* field. Enter the participant's 6 digit **letter code** in the *Last Name* field **exactly** as it is entered on the DXA Logsheet. Enter the participant's 6 digit **ID code** in the *ID Field*. For this reason, you should always obtain the participant's number and ID code from the Study Coordinator to ensure accuracy. An example of the Prodigy Biography Screen is shown in Figure 2.

Enter the DOB, sex, ethnicity, weight and height in the appropriate fields. As there is only one visit, no visit code is necessary .

First Name:	DISC
Middle Initial:	None
Last Name:	Participant's Code Name – 6 digits
Patient ID:	Participant's ID number (0-1234-5)
Birth Date:	Participant's BD
Height:	Participant's height
Weight:	Participant's weight
Sex:	Female
Ethnic Group:	As appropriate
Operator's Initials:	

**Note from this example that all leading zeroes must be included. Be sure to use zeroes (Ø) and not the letter "O" when entering the Participant ID into the *Name and Pat ID*. Enter the operator's initials on the 2<sup>nd</sup> page.**

The screenshot shows a 'Patient' form with the following fields and values:

- Last Name: ABCDEF
- First Name: DISC
- Middle Initial: (empty)
- Ethnicity: Hispanic
- Patient ID: 0-1234-5
- Identifier2: (empty)
- Sex: Female
- DOB: Month: April, Day: 14, Year: 1982
- Referring Physician: DISC
- Menopause Age: (empty)
- Weight: 141 lb
- Height: 67 in
- Patient Comment: (empty text area)

Buttons at the bottom: OK, Cancel, Help.

**Figure 2. New Patient Directory**

### **DXA Scan Acquisition**

In order to get the most consistent participant results it is important to follow consistent procedures in acquiring all scans. These include the following:

- 1) Use the **“Thick”** scan mode for each participant in the study to compensate for possible weight issues.
- 2) The patient must be dressed in a hospital gown or pajamas wearing only underpants and thin socks if necessary. Remove all radiopaque objects possible from the scan areas.
- 3) Ensure correct positioning of the participant on all exams.
- 4) Monitor the scan during acquisition. If positioning is not correct, or the participant moves, etc., interrupt the scan, reposition the participant if necessary and restart the scan.

Please note any problems with scan acquisition in the comment field of the DXA Log Sheet.



### AP Spine Scans

The GE/Lunar Prodigy Operator's Manual should be consulted for the proper AP Lumbar Spine scanning and analysis procedures. Clarifications for DISC are noted below.

- 1) Use the “**Thick**” Scan Mode.
- 2) Keep the scan width and length set to defaults. “Smart” scan should be on.
- 3) Make sure that each AP scan includes both iliac crests at the bottom of the image and at least one vertebrae with ribs at the top. Also, make sure the spine is straight and centered in the scan-field. Ensure optimal participant positioning by consistently using the positioning cushions for each scan. (Figure 3)
- 4) No analysis.

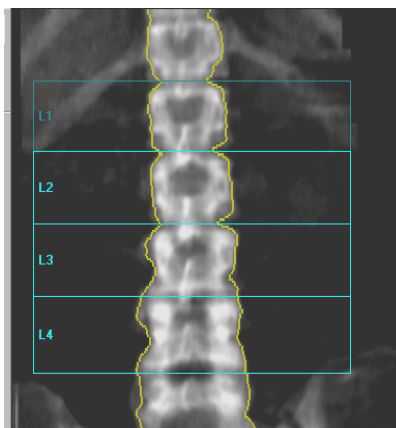
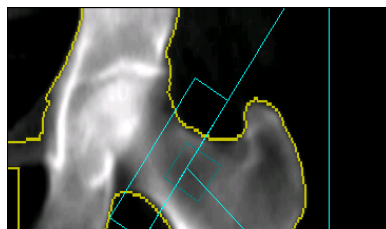


Figure 3. Properly acquired and analyzed AP Spine Scan

### Femur Scans

The GEG/Lunar Prodigy Operator's Manual should be consulted for the proper hip acquisition procedures. Clarifications and exceptions for the DISC are noted below.

- 1) Scan the **LEFT** hip. If you scan the right hip, then note on the log sheet the reason(s) why the left hip was not usable.
- 2) Use the “**Thick**” Scan Mode to compensate for possible weight issues. Keep the scan width and length set to its default. “Smart” scan should be on.
- 3) Make sure the leg to be scanned is properly rotated and abducted. Ensure optimal patient positioning by consistently using the hip scan positioning fixture. Always position the patient's leg by applying rotating force **above the knee**. This will ensure that the hip itself is rotated, not just the lower leg. Proper rotation and abduction will alleviate many analysis problems. With optimal positioning the lesser trochanter will be barely visible. (Figure 4)
- 4) No Analysis

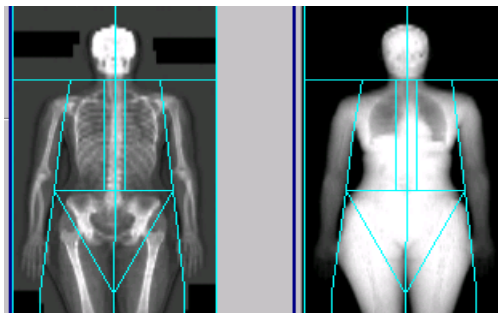


**Figure 4. Properly acquired and analyzed proximal femur**

### Whole Body Scans

The GE/Lunar Prodigy Operator's Manual should be consulted for the proper whole body acquisition procedures. Clarifications and exceptions for DISC are noted below.

- 1) Ask the patient if any metal implants are present and note presence on participant DXA log sheet.
- 2) Position the patient in the center of the table aligned with the long axis of the table. The head towards the head end of table within the scan limit line. The participant's head should look straight up, not turned left or right. If required for participant comfort, use only radio-lucent pillows. If pillows are used, make a note to use the same pillow again during follow-up measurements.
- 3) Feet and legs should be placed together with no internal rotation of the hips. Use a velcro strap around the ankles to avoid movement. Position hands with palms flat against the scan table. . If necessary with larger or heavier participants, the hands may be placed in a lateral position next to the hips. **Do not** tuck the hands under the hips to keep them in the scan field. If necessary, tape the participant's hands down to the scan table. For patients who are too tall to fit within the scanning limits, it is acceptable for the feet to extend beyond the lower scan limit line. **Do not** bend the knees to keep the feet in the scan field.
- 4) Use the “**Thick**” Scan Mode to compensate for possible weight issues. Keep the scan width and length set to its default. “Smart” scan should be on.
- 5) Monitor the scan during acquisition. If the patient moves, the scan may be interrupted and restarted. (Figure 5)
- 5) No Analysis



**Figure 5: Properly acquired whole body scans.**

### **Longitudinal Quality Control and Cross Calibration**

Scanner Quality Control (QC) procedures are used to monitor scanner performance throughout the course of the study. Longitudinal QC procedures consist of daily procedures used to monitor the performance of a single scanner over time. Cross-calibration procedures are used to monitor scanner variation from machine to machine. An additional QC measure is the use of the "DXA Bone Densitometer Report" (page 18). The investigator site completes and sends this report monthly to UCSF along with copies of the QC scans on Zip disk, CD, or USB stick. Both longitudinal Quality Control and cross-calibration will be discussed in this section.

Use the existing QA database for GE/Lunar Phantom. (Either the water bath or the Plastic enclosed) This phantom must be scanned every day a participant is scanned or at least 3 times per week. An Hologic Whole Body Phantom must be scanned 3 times per week.

#### **Scanner Quality Control**

##### **Aluminum Spine Phantom:**

*(Assumption is made that a biography already exists)*

- Make sure that the phantom serial number is entered in the Pat ID field. The phantom number may be read from the label on the bottom of the phantom.
- Scan the Lunar Aluminum Spine phantom at least every day that a study subject is scanned, but at a minimum of three days per week for the duration of the study.
- These scans should be analyzed for L1-L4. Always use *copy* for comparing back to the baseline scan. If a QA database has not been created, please do so. All future aluminum spine scans and WB phantom scans should be scanned using that database.

Review the QC plot for BMD. If the BMD for L1-L4 falls outside acceptable limits, rescan the phantom. If the BMD from the second scan also falls outside the limits, call for service at GE/Lunar. If the BMD from the second scan falls within the limits, continue with normal scanning for the day.

##### **Whole Body Phantom:**

Perform a scan of the Whole Body Phantom 3 times per week on 3 different days. Please use zeros (0) in the biography and not the letter "O."

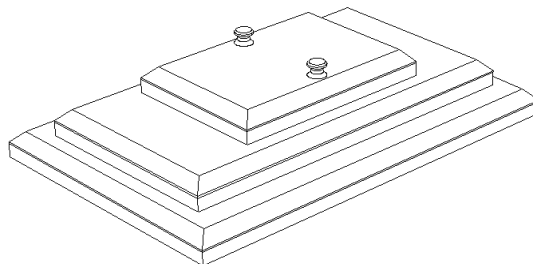
Select the QA Database and New (patient). The Mandatory Information screen appears. Note the serial number on the phantom. Enter the following data in the information fields. At the end of each field press Tab to move the cursor to the next field.

First Name:	WBP
Middle Initial:	None
Last Name:	Serial Number
Patient ID:	Site Number
Birthdate:	Birth Date: Present date minus 40 years*
Height:	170cm (or 67 inches)
Weight:	70kg (or 154 lbs.)
Sex:	Female
Ethnic Group:	White

\*For example, if the date is April 14, 2006, enter April 14, 1966. Do not change this date on future scans of this phantom.

**ASSEMBLY:** Figure 6: Hologic Whole Body Phantom  
Assemble according to the instructions that accompany the phantom.

**Caution: Do not attempt to lift the entire phantom assembly.**



**Figure 6. Whole Body Phantom**

### **POSITIONING:**

Center the table. Position the WB phantom in the center of the table with the ends marked 'head' towards the head of the table. Align the laser centering lights with the centering marks on the surface of the phantom. The phantom should be parallel with the long axis of the table in the center.

### **New Measurement**

1. Select Measure, then Total Body. Use the default scan mode (standard). Manually set the length to 91cm. and use the default scan width. Turn off “Analyze When Done” and “Smart Scan.” (Figure 7, Hologic Whole Body Phantom New Measurement.)

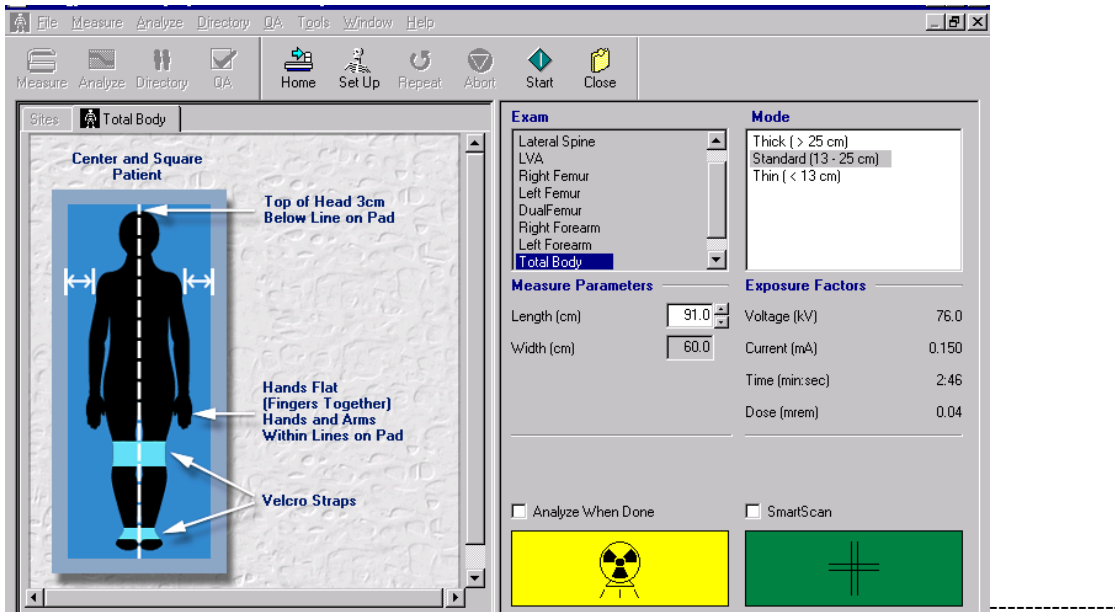
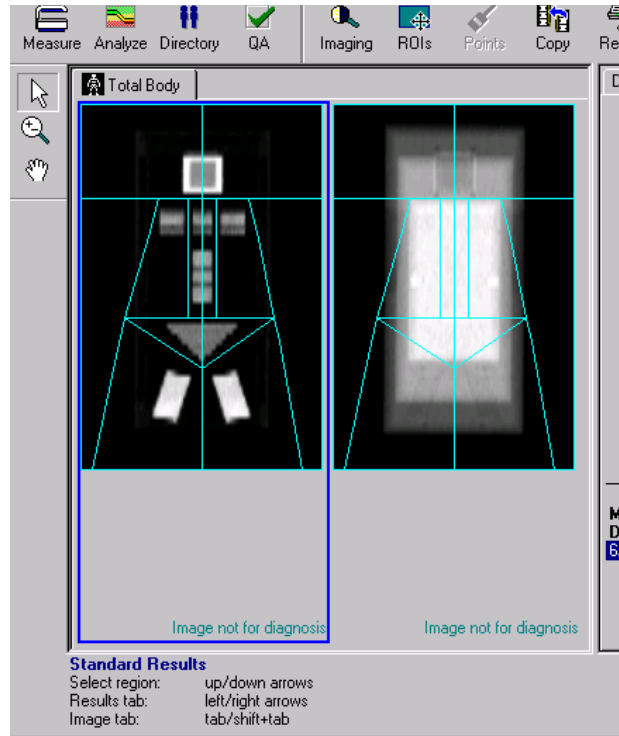


Figure 7: Hologic Whole Body Phantom

2. Position the Whole Body phantom at the head end of the scanner table with the end of the phantom marked “head” toward the head of the table. Allow approximately 1” of space from the head of the table to the top of the phantom. Position the phantom in the center of the table parallel with the long axis.
3. Be sure there is nothing else on the table. Monitor the first few sweeps to verify that the detector and phantom are properly positioned. Scan the length of the phantom allowing the scanner to automatically stop.



**Figure 8: Hologic Whole Body Phantom Scan**

### **Hologic Whole Body Phantom Scan Analysis**

Define the ROI's as demonstrated in Figure 8, Hologic Whole Body Phantom Scan. Complete the analysis. The first scan will be the baseline scan. Compare all subsequent scans to this scan. Print a copy of the first scan for reference.

### **Data Shipment and Scan Archival of Participant and QC Data**

When preparing to send participant and/or QC scan files to MQIR, use the below procedure to transfer the scan files to transfer media . Do not use the Archive command. Archive the scans to the archive system only after they have been *copied* to the transfer media for shipping.

#### **To Copy Scan Images Transfer Media (ZipDisc,diskettes, CD, USB, etc.)**

- Within the Database, choose the scans you want to copy.
- Click on the 1<sup>st</sup> scan in the series. Hold down the Shift key and click on the last scan.
- All scans for a selected participant or phantom should then be highlighted. **Right** click on the shaded area. (See Figure 9, Patient Scan Directory.)
- A small command box will appear.
- Select “Send Image File To → Disk...”

- At “My Computer,” select A:\ (3 ½ Floppy A): (see Figure 10, Browse for Folder) to send scans to the transfer media. Repeat until all scans for all desired participants and phantoms have been copied for shipping.

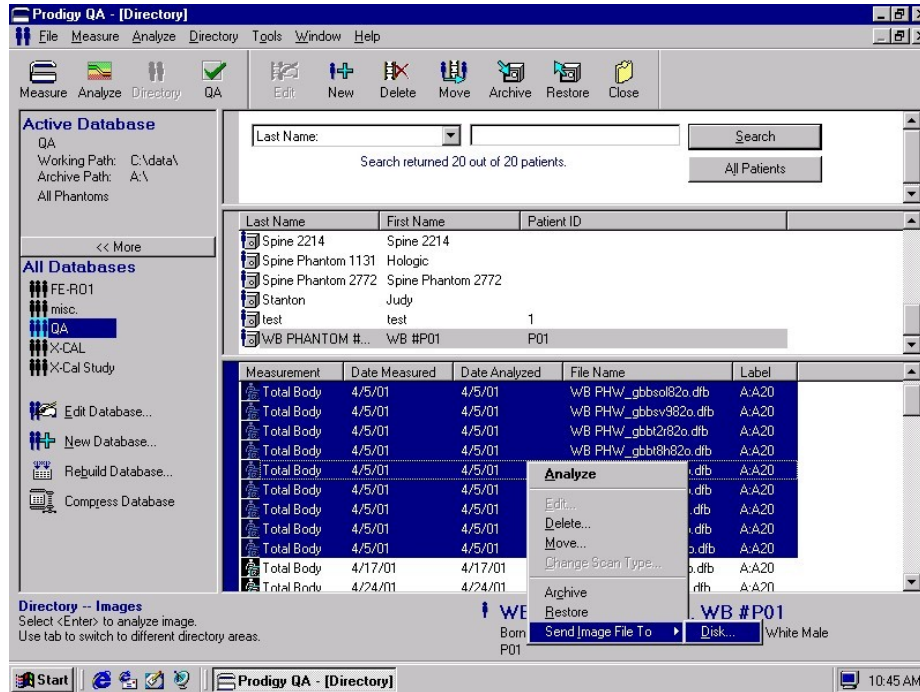


Figure 9. Directory – example of choosing scans from the database.



Figure 10 Browse for Folder

### Labeling copy diskettes

All transfer media must be labeled (Figure 11) using the labels provided by the Study Coordinators, prior to mailing to MQIR.

<b>DISC Data Transfer Label</b>	
Number of Participants:	_____
QC Data	_____
Date:	___ / ___ / ___
	D D M M M Y Y
Diskette #	_____ of _____

**Figure 11 Data label for diskettes/superdisc**

### Scanner Cross-Calibration

In order to accurately assess differences in scanner performance among investigator sites, cross-calibration phantoms will be sent to each site at least once during the course of the study. Coordination will be made in advance between the QA Center and each site for delivery of the cross-calibration phantoms. Phantoms used will be the: Hologic Block Phantom, Hologic Femur Phantom, European Spine Phantom, and, Hologic Whole Body Phantom. Detailed scanning and analysis procedures will accompany the phantoms.

### Bone Densitometer Report (page 18)

The BDR is filled out monthly by the technologist and submitted to the Study Coordinator. It provides a record of additional information about each study scanner. The BDR tracks scanner maintenance and repairs as well as technologist changes, which are then reviewed by MQIR. Two very important pieces of identifying information are the scanner serial number and the GE/Lunar phantom serial number. A blank BDR form is supplied with this GE/Lunar DXA Operator's Guide for reference. Make copies of this form for future use



**IMPORTANT: Changes in scanners, software, or location of scanners can have a large impact on the integrity of study data. For this reason, such changes are NOT ALLOWED for the duration of this study without prior approval from MQIR and notification of DISC. Requests for changes may be made by telephone or e-mail to MQIR (Chyi Huang, 415-353-4938 or [chyihuang@radiology.ucsf.edu](mailto:chyihuang@radiology.ucsf.edu)).**

### Operator Qualification

All technologists must be qualified by the QA Center prior to scanning any study participants.



Qualification consists of on-site training by a QA Center staff person and the QA Center's evaluation of print-outs of 3 AP spine scans, 3 hip scans and, 3 total body scans acquired before the study and analyzed by the technologist. Each study technologist should provide a copy, if available, of their manufacturer's training certificate and license to the QA Center. Please forward with a copy of the Hologic Operator's Form found at the beginning of this section as soon as possible after receiving this Procedures Manual. When a new technologist is employed, please follow the above instructions. When someone leaves employment, please note the date.

### **Archive**

The **Archive** function on Prodigy scanner is used to store scan files onto floppy diskettes or zip disk. . **Archive your scan files on a regular basis.** See your Prodigy Operator's manual for instructions. **Do not** use the archive command to transfer participant scan files to disk.

### **Shipping of Data**

Shipping of data should be done monthly. Participant and QC data can be included on the same transfer media. Please include the Fed Ex Transfer Log. (page 19)

### **Bone Densitometer Report**

**USE ONE FORM FOR EACH SCANNER IN THIS STUDY**

THIS FORM ONLY PERTAINS TO STUDIES IN WHICH DXA DATA ARE SENT TO UCSF. DXA SCANNER OPERATORS SHOULD SEND THIS FORM ALONG WITH A COPY OF THE QC SCANS FOR THE MOST RECENT MONTH.

**DXA Bone Densitometer Report • DISC**

Site number \_\_\_\_\_

Scanner Serial Number \_\_\_\_\_ Spine Phantom Number \_\_\_\_\_

1) Has a new / different scanner been used for any study patients?  Yes  No If yes, explain:

Was scanner change approved in advance by UCSF?  Yes  No By Whom \_\_\_\_\_

2) Have there been any software changes ?  Yes  No If yes, indicate:

Old software version: \_\_\_\_\_ New software version: \_\_\_\_\_ Date installed: \_\_\_\_\_

Was software change approved in advance by UCSF?  Yes  No By Whom?

3) Were there any technologist changes?  Yes  No If yes, indicate:

Technologist	Added / Departed	Date of Change	Date of Manufacturer's Training
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

4) Were there any maintenance/recalibration/repair problems?  Yes  No If yes, indicate:

Service performed	Date of Service
_____	_____
_____	_____
_____	_____
_____	_____

Additional comments (Use reverse side if necessary) :

Main Technologist: \_\_\_\_\_ Date: \_\_\_\_\_ Telephone: \_\_\_\_\_

Please make copies of this blank form. Complete this form each reporting period and send the original to the MQIR and keep a copy for your records.

**FED EX Transfer Log**

FEDEX TRANSFER LOG

Complete this form and place it on top of the contents in the FedEx package. Send to an email to: [chyi.huang@radiology.ucsf.edu](mailto:chyi.huang@radiology.ucsf.edu) with the expected delivery date and tracking # for the package.

FedEx to:  
 Chyi Huang  
 UCSF/Musculoskeletal and Quantitative Research Imaging  
 185 Berry Street, Ste.350  
 San Francisco, CA 94107  
 Tel: 415-353-4938

**Participant Data Enclosed in this FedEx:**

PARTICIPANT ID #	LETTER CODE
□-□□□□-□	
□-□□□□-□	
□-□□□□-□	
□-□□□□-□	
□-□□□□-□	
□-□□□□-□	
□-□□□□-□	
□-□□□□-□	

*Note: For each PARTICIPANT ID listed above, a participant intake sheet must be included in FedEx; All transfer media must be labeled!*

\_\_\_ Tot. # transfer media (CD's, disks, etc.)

**Quality Control Data Enclosed in this FedEx:**

**DXA:** (all of the following should be included):

- QC Archive data # transfer media with label
- Bone Densitometer Report

**Study Coordinator/DXA Technologist Signature:** \_\_\_\_\_ **Site#** \_\_\_\_\_

DATE: □□ / □□ / □□□□



DISC 06  
Questionnaire and  
Form Clarifications

**COMPLETE FORM 16 BEFORE ANYTHING ELSE TAKES PLACE**

Before each participant's visit, have a number of blank Pregnancy Outcome Questionnaires (# 20) available for those participants who have had multiple pregnancies.

For any form that asks for specific information help the participant by asking probing questions about that time in her life, how she was feeling, was she in school or working, was she in a relationship, her living arrangements, etc. all to get the most accurate information possible.

????For estimations always round to nearest age, amount, day, month or year.

<u>Form #</u>		<u>Clarification</u>
16	1 page	<b><u>ASK AND COMPLETE THIS BEFORE ANYTHING ELSE TAKES PLACE</u></b>
1	1 page	# 2 Age – record the participant's current age. If she currently is 25 and will turn 26 the following month, write 25 in the spaces provided. Make sure the participant's age recorded in #2 agrees with her date of birth recorded in #1.  # 3 Race – <b>answer 'yes' or 'no' for each race.</b> Note that there are 2 columns that need to be completed.  # 5 Ancestry/ethnic origin – list as many ancestries as desired
2	1 page	# 2 If the participant does not recall her age at the time of her first menstrual period try to help her remember by thinking of the grade she was in school, was it summer or winter, etc. If she is unsure, she should record her best guess.  # 3 "regular" is what is regular for the participant, for some it could be a 26 day cycle, for others it could be 32 days. The participant should answer for times when she was not taking hormones for birth control, pregnant or breast feeding. "expected" is within about $\pm 3$ days.  # 5 Answer 'yes' only if the participant brought her calendar showing the date she started her last period. If she returns a blank calendar, answer 'no'.
3	2 pages	#3 Answer 'Yes' or 'No' to each option. Note that there are 2 columns to be completed.  # 5-8 If the participant cannot recall the name of the medication write 'unknown'. Try to help her remember the age she started taking the medication and duration of use by probing about whether she was in school, where she was working, what season it was, etc. If she is unsure, she should record her best guess.

#10 All pregnancies including live births, still births, miscarriages, tubal, ectopic or molar pregnancies and induced or elective abortions should be counted.

# 12-18 Space is provided to record 7 pregnancies. If the participant has been pregnant more than 7 times record the information for additional pregnancies on a separate sheet. Record the most recent or current pregnancy in line #12, since this is the only line that has the option for recording a current pregnancy. If currently pregnant fill in the bubble and the number of weeks pregnant, the other parts (A, C, D, E and F) are not relevant. If other pregnancies get out of order, do not worry about it. We will have the dates and can order them in the computer. If the participant breastfed for less than 1 week, answer 'yes' under column E 'Did you breastfeed' and record '00' in column F 'Number of weeks breastfed'.

- 4      6 pages      The hormone questionnaire may be a difficult form to complete so spend time with the participants before they complete the form, let them know there are 6 pages for different types of birth control, the most common form of birth control are pills on the first page. The participant should record information about the brand name of the pills on the line for column A. Pictures of birth control pills are provided to help the participant identify the brand. If she cannot remember she should fill in the bubble before 'unknown'. If the participant is currently using this pill she should fill in the bubble in front of 'Currently taking' and leave 'Age stopped' blank. If the participant has difficulty remembering ages started and stopped and duration of use, tell her to think about what else was going on in her life at that time. For example, who was she dating when she started, was she dating the same person when she stopped, how long did she date this person, etc. All the columns need to be completed for each pill the participant used, so if she doesn't recall, she should give her best guess. Remind the participant that she should record birth control pills that she used for reasons other than to prevent pregnancy such as to regulate her periods. The birth control pill that the participant is currently using needs to be recorded on line #3, but if others get out of order do not worry about it. We can sort it out in the computer. There are all sorts of different birth control pills on the market today. Seasonal pills are typically taken continuously for 12 weeks with a period every 3 months or 4 periods per year. Some of the participants may be taking the 'mini' pill and not have a period for a year or more in which case she would record '00' under frequency of periods per year. This questionnaire contains one page for each type of hormone; the format is the same for pages 2 – 6.
- 5      5 pages      # 1-25 The participant should answer 'yes' or 'no' to each and provide any descriptive information on the line provided.
- # 26 If the participant has any other health conditions, she should record 'yes' and specify the condition on the line provided.
- # 32, 34 and 39 record the procedure date OR age, not both.
- 6      2 pages      # 1-16 The participant should answer 'yes' 'no' or 'unknown' for each prescription and non-prescription medication they have ever taken four or more times a week for at least two weeks. List the names of all drugs taken under each category. Make sure that

the participants **do not** list vitamins, minerals, herbs or dietary supplements; these are captured on other forms.

Try to help the participant remember the age when she first took any medication in this category and duration of use by probing about whether she was in school, where she was working, what were her symptoms, etc. If she is currently taking this medication complete the bubble for 'Currently taking' 'Aged stopped' will be blank and the 'Total years' will be the total years she has been taking the medication up to this date. Several different medications may have been taken in one category with different start and stop dates, make sure they combine all medications in a category. 'Age started' is the first time a medication was taken in the category. 'Age stopped' is the most recent time a medication in this category was stopped. 'Total years' is the combined length of time medications in this category were taken.

- 7 1 page # 1 100 cigarettes is equal to 5 packs in their entire life.
- # 2 The participant should give her best estimate to document all smoking activities even if she considers herself to be a social or occasional smokers.
- # 3 Help the participant remember when she started smoking on a regular basis by asking probing questions about what grade she was in, what activities was she doing when she first started smoking, etc. On a regular basis includes social smoking and could be a couple times a month, once a week or daily.
- 8 1 page # 2 Help the participant remember the first time she had an alcoholic beverage by asking probing questions about what grade she was in, if she was at a party or social event, etc.
- #3 Please note that part A refers to the frequency of drinking and part B refers to the amount consumed on each occasion.
- #4 Please note that part A refers to the frequency of drinking and part B refers to the amount consumed on each occasion.
- 9 1 page # 1 – 3 To help the participant give her best estimate on her weight, ask probing questions about school activities, involvement in sports, was she thin or heavy, how much she weighed in comparison to her friends etc. These questions are being asked to see how well young women can recall their weights at earlier ages to address a methodological question. If you have old DISC forms or other sources of this data, please do not refer to it when completing these questions.
- # 4 – 8 The hours for these activities **MUST ADD UP TO 24 HOURS** for a typical weekday and weekend day.
- # 5 Also includes driving and office work.
- 10 2 pages This questionnaire asks about health of the participant's biological parents. If she does not know her biological parents, she should complete the questionnaire by responding 'do not know' to each question.

- 11 1 page # 2 Answer ‘Yes’ or ‘No’ to each option. Note that there are 2 columns to be completed, if the answer is ‘yes’ make sure the number of people for that category is marked in column 3.
- # 3 has 2 columns, column A asks about the participant’s income for the past year and column B asks about the total household income. The past year is the past 12 months, not the last calendar year. Household income is the sum of incomes of all people living in the household. If the participant lives alone or is the only person in the household who earns any money, household income will be the same as personal income. Household income may be difficult to estimate if there are other working adults, but ask the participant to provide her best estimate.
- 12 1 page This questionnaire elicits characteristics of the participant’s birth and infancy. To help the participant complete the questionnaire accurately, it should be sent to the participant before her clinic visit so that she can consult with her mother or other caregiver, look for the information in birth records or her baby book, etc.
- # 3 and 4 term of pregnancy may also be known as ‘weeks gestation’ or ‘gestational age’.
- # 5 participants who were **ever** fed breast milk, regardless of the duration should answer ‘Yes’ to this question and round the duration to the nearest whole week or month.
- 13 1 page To help the participants complete the Prescription Medication Inventory they were asked to bring containers of all medicines that they are **currently** taking. For someone to be currently taking a medication, she does not necessarily have to have taken it the day of the visit. Some medicines are taken less frequently than daily. Please record the duration that the participant has taken the medication for the current indication only. If she is currently taking antibiotic A for an infection, record the duration she has been taking the antibiotic for that infection (maybe 7 days), do not record all antibiotics she has ever taken. If she is currently taking antibiotics for acne, she may refill her prescription many times. Record the duration since she started taking the antibiotic for acne (it may be several months), not just the most recent prescription refill. Try to help the participant remember how long she has been taking the medication by asking probing questions about when she started taking the medication...whether she was in school, where she was working, what were her symptoms, etc.
- The prescription medications entered on this questionnaire may also be listed on the Hormone Use Questionnaire (# 4) and the Medication Use Questionnaire (# 6) for prescriptions **ever** taken.
- 14 1 page To help the participants complete the Non-Prescription Medication Inventory they were asked to bring containers of all medicines that they are **currently** taking. For someone to be currently taking a medication, she does not necessarily have to have taken it the day of the visit. Some medicines are taken less frequently than daily. Please record the duration that the participant has taken the medication for the current indication only. If she is currently taking an antihistamine for a cold, record the



duration she has been taking the antihistamine for that cold (maybe 7 days), do not record all antihistamines she has ever taken. If she is currently taking antihistamines for allergies, she may get many refills over the season. Record the duration since she started taking the antihistamine for the allergy (it may be several months), not just the time she purchased her last container of antihistamines. Try to help the participant remember how long she has been taking the medication by asking probing questions about when she started taking the medication...whether she was in school, where she was working, what were her symptoms, etc.

The Non-prescription medications entered on this questionnaire may also be listed on the Hormone Use Questionnaire (# 4) and the Medication Use Questionnaire (# 6) for non-prescriptions **ever** taken.

- 15 1 page # 1 asks if the participant **ever** used supplements in their entire life. Items 2 through 34 ask if the supplements were used in the **last 12 months and, if yes, in the last 30 days**, all items must be answered. Licorice supplements and peppermint do not include candy.
- 16 1 page **MUST BE ADMINISTERED BEFORE ANYTHING ELSE TAKES PLACE**
- 19 2 pages # 1-30 all of these questions should have a bubble filled in for one of the 6 choices. # 30 if the participant has been treated multiple times for an eating disorder ask her to list the first time she was ever treated, if she needs help remembering the first time, ask what grade of school she was in, about her job or relationships.
- 20 1 page The Pregnancy Outcome Questionnaire is designed to learn about pregnancy outcomes experienced by DISC study participants. Participants should complete a separate questionnaire for each pregnancy that resulted in a live birth, stillbirth, or miscarriage. Please do not have women complete this questionnaire for pregnancies that ended due to induced or elective abortions. The coordinator needs to complete the header by filling in the # of the current pregnancy outcome questionnaire and the total number of questionnaires completed.
- # 1 Please enter the month and year that this pregnancy ended (i.e. the date of live birth, stillbirth, or miscarriage)
- # 2 This question asks about prenatal care received. Answering “Yes” indicates that women had prenatal visits at least once per month during the time they knew they were pregnant.
- # 3 This question asks about prenatal vitamins specifically, which contain folic acid, not just multivitamins.
- # 4 This question refers to smoking habits that either continued or started once the woman discovered she was pregnant.
- # 5 The most recent weight that women recall before this pregnancy.
- # 6 This should be the total amount of weight gained or lost during this pregnancy (please be sure that the bubble is marked to indicate gain or loss of weight). This weight measurement should be the weight at the time of delivery/loss minus the pre-pregnancy weight.

# 7 This question is designed to obtain information regarding health problems during the pregnancy. Women should report diagnosis of the listed problems. Please use the lines provided to describe specific bleeding or placental problems, infections, or other problems that are not included in this list.

# 8 Participants should specify how the pregnancy ended by marking the appropriate bubble.

**Women who experienced a live birth or a stillbirth should proceed to # 9-11.**

**Women who had a miscarriage should stop after answering question 8.**

# 9 This question is to determine whether this pregnancy resulted in the birth of a single baby or multiple babies. Participants should record the number of babies born even if there were different outcomes for multiple babies.

# 10 For single births, please complete Parts A,B,C, and D and do not proceed to question 11.

# 11 Parts A,B,C, and D should be completed for the second-born baby in the case of multiple births.

In the event of multiple births greater than twins (i.e. triplets, etc.), please complete questions 10 and 11 on another questionnaire and make a note on page 1 that there are subsequent forms.

Please have women complete separate forms for each pregnancy (multiple births at the same time are considered a single pregnancy).

- 21 2 pages Coordinators must be certified to administer this questionnaire. Refer to the detailed instructions about completing this form on the DISC 06 web site under the Forms heading.
- Page 1 **DO NOT FAX** the first page of this questionnaire to MMRI with the other questionnaires. This list is for the participants to circle activities they have done more than 10 times from high school through the past year, not including time spent in school physical education classes.
- Page 2 The header asks for a Sequence #, because some participants may be very active and will need more than 10 places (one page) to list all their activities. The first page would be 1, the second page would be 2, etc.