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**The Body Composition Analysis Center at Tufts University  
Standard Operating Procedures for Whole-Body DXA Scans  
Performed for Body Composition Measurements and  
Regional (Hip and Spine) DXA Scans  
Performed for Bone Mineral Density Studies\***

**\* These procedures apply to scans that are sent to the Body Composition Analysis Center (BCAC) at Tufts University. Protocol-specific instructions supersede these procedures.**

**\*\*Please note that each site's HIPAA RAF should mention that you will be sending de-identified DXA and CT data to Tufts.**

## **1.0 General Instructions**

The following is a summary of procedures for whole-body DXA scans performed for body composition measurements and regional (hip and spine) DXA scans performed for bone mineral density studies. Please follow the manufacturer's instructions for operating your instrument. Whole-body, hip, and spine scans should be done using standard operating procedures defined by the manufacturer in order to allow comparability between study sites as well as generalizability to subjects outside the study conditions.

Before any scans are performed, please fax the **DXA Equipment Checklist form (Appendix 1)** as directed on the form to Tufts. Each department submitting scans to Tufts should complete a separate form, even if it is technically a sub-site for the study. ***Subjects should be scanned on the same instrument using the same version of software throughout the study.*** The Body Composition Analysis Center (BCAC) at Tufts and the protocol team should be notified as soon as possible if an instrument or software change is anticipated, and no scans should be performed without input from the team. The BCAC and the protocol team should also be notified if any adjustments are made to the scanner during service or maintenance.

If the computer is left on continuously, it is necessary to reboot the computer first thing in the morning. This will set the system date and time to the computer's internal clock and will perform basic checks on the computer system memory.

The subject should be asked about and examined for metal that could be in the scan path. Typical objects to look for are earrings, eyeglasses, wristwatches, coins, rings, buttons, buckles, zippers, body piercings, and support braces. The subject should remove shoes, and it may be necessary to remove skirts, slacks, etc. If in doubt, it is best to remove the object in question. If clothes are removed, a subject gown will be provided and a sheet made available to place over the subject during the scan. Rings or piercings that cannot be removed can be left on, but should be noted on the DXA Scan Case Report Form (DXA CRF- Appendix 3) in the "Comments" section, **and should always be left on in subsequent scans.** Small objects removed from the subject should be placed in a small box

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to keep them together and the box left in the room with the subject. After the scan is performed, the objects should be returned to the subject and the subject queried to make sure he/she has received all objects back.

### Lunar Systems

1. Perform the calibration procedure and quality control checks daily.
2. Enter the scan type from the main menu.
3. Enter basic subject information in the Lunar Mandatory Information screen: for **First Name enter “name of study”; for Last Name enter the participating subject’s Patient ID (PID); subject’s date of birth should be their actual month and year of birth with “15” as the day**, height, weight, sex, and ethnic type.

**DO NOT ENTER THE SUBJECT’S ACTUAL NAME or FULL DOB  
IN ORDER TO PRESERVE CONFIDENTIALITY!**

### Hologic Systems

1. The calibration procedure and quality control checks should be performed daily.
2. Go to “Patient” in the menu: for **First Name “name of study”; for Last Name enter the participating subject’s Patient ID(PID)**; then press Enter.
3. Enter the subject’s **actual month and year of birth with “15” as the day**, and their sex.
4. Press F10, and check that “name of study” and PID appear at the top of the screen.
5. Position the subject as discussed below, then press F3 (Scan), and choose the appropriate scan.
6. Press F10, and let the scan complete itself. Never move the subject off the table until the tabletop is centered over the base.

**DO NOT ENTER THE SUBJECT’S ACTUAL NAME or FULL DOB  
IN ORDER TO PRESERVE CONFIDENTIALITY!**

### Phantom Scanning

A special phantom, one used for calibrating your instrument for lean and fat mass, will be sent once to each site. Each department submitting scans to Tufts will complete a separate phantom calibration, even if it is technically a sub-site for the study. It is not necessary to perform this scan before the study starts, but it will need to be done before the completion of the study. The data obtained from scanning this phantom will allow the BCAC to analyze the data from your site with better accuracy.

Before sending the phantom to you, a coordinator from the BCAC will contact you to confirm where the phantom should be sent and who should receive it. The instructions for performing a scan of the phantom will be included with the phantom when it is shipped.

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The data from this scan should be sent back to the BCAC, and the phantom itself should be sent to the next site in line to receive the phantom. This information will be provided to you by the BCAC Research Coordinator. Refer to the Instructions for Submission of DXA Scans section of this manual for more information. ***Please be reminded that all costs of shipping for this study are the sole responsibility of each site, and will not be paid for by the BCAC.***

## **2.0 Radiation Safety**

As part of DXA evaluations, subjects are exposed to radiation. Most academic and private institutions have radiation safety committees that review clinical protocols in which subjects are exposed to any amount of radiation. Each institution has different requirements that need to be met. It is the responsibility of the site to meet all the local requirements to conduct these tests.

At the time of submitting the protocol application, it is important to consider the following issues:

1. Review with your radiologist the calculated amount of radiation that the subject will be exposed to as part of the trial.
2. If more than one radiation center is going to be used, this applies to each one of the different sites where DXAs will be performed.
3. At the time of calculating the total amount of radiation, remember that DXA can be whole body or localized. Adjust the amount of radiation to the total number and the types of DXAs to be done.

As an example, consider the following calculations. These calculations are specific for the individual machine where they were developed and should be adapted to the site-specific situation.

### **EXAMPLE: Subject Dose Estimates for a Whole-Body DXA**

DXA (dual energy x-ray absorptiometry) measurements will be performed with a total body scanner (QDR-2000 Hologic, Waltham, MA) generating x-rays at two energy levels (40 and 70 kVp). Participants will be lying down on the device and the x-ray will pass through the body in a fine beam. A series of transverse scans will be made from head to toe at 1-cm intervals. Data will be collected for approximately 120 pixel elements per transverse, with pixel size being approximately 5 x 10 mm. The total scan area with this instrument is approximately 60 x 200cm. Scan speed is 16 cm/s (8 cm/s if body weight is greater than 70 kg). This gives a maximum scan of approximately 25 minutes. The maximum radiation dose for the total body measurement will be 5 mrem, the amount of radiation a person receives during 5 days of normal background radiation. Percent body fat will be derived from the DXA using computer algorithms provided by the manufacturer.

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The maximum radiation doses allowed in human research subjects vary by IRB. The guidelines below are based on the Food and Drug Administration's allowable dose limits for radioactive drugs used in research.

Title 21 CFR (Code of Federal Regulations) Part 361.1 (b)(3) "Limit on radiation dose" states:

"The amount of radioactive material to be administered shall be such that the subject receives the smallest radiation dose with which it is practical to perform the study without jeopardizing the benefits to be obtained from the study.

- (i) Under no circumstances may the radiation dose to an adult research subject from a single study or cumulatively from a number of studies conducted within 1 year be generally recognized as safe if such doses exceed the following:

Whole body, active blood-forming organs, lens of the eye, and gonads:

Single dose	3 Rems (3,000 mRems)
Annual and total dose commitment	5 Rems (5,000 mRems)

Other organs:

Single dose	5 Rems (5,000 mRems)
Annual and total dose commitment	15 Rems (15,000 mRems)

- (ii) For a research subject under 18 years of age at his last birthday, the radiation dose shall not exceed 10 percent of that set forth in paragraph (b)(3)(i) of this section.
- (iii) All radioactive material included in the drug either as essential material or as a significant contaminant or impurity shall be included when determining the total doses and dose commitments. Radiation doses from x-ray procedures that are part of the research study (i.e., would not have occurred but for the study) shall also be included. The possibility of follow-up studies shall be considered for inclusion in the dose calculations."

### **3.0 Subject Positioning Techniques and Scan Acquisition**

#### Whole Body

1. When prompted by the program, ask the subject to lie down on the scan table.
2. The centerline on the table pad should divide the subject's body in half. Use the lines on the table pad to assure the subject is lying straight on the table. The subject's head

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should be directly below (about 1") the horizontal line located along the top of the table pad.

3. Have the subject tilt his/her head back slightly during the scan. This makes placement of the head region cut line easier to place.
4. A foam wedge (or pillow) **may not** be used under the subject's head as it will affect the body composition results.
5. Have the subject place hands palms down alongside the body with fingers together. **DO NOT OVERLAP HANDS AND LEGS.** If the subject cannot lie flat without thighs overlapping, position hands laterally and secure with masking tape. Note this technique for use in follow up scans. The subject's entire body should fit within the scan lines on the table pad.
6. If the subject is too wide to fit within the boundary lines, the technician should proceed to the Hemiscan Protocol section of this manual. For tall subjects, please proceed to the Tall Subjects section of this manual.
7. The subject's feet should be angled inwards, toes touching, and secured using a Velcro strap. The subject should be asked not to move until directed to do so.
8. Continuing the scan will cause the x-ray tube to ramp up to the appropriate current and voltage. The operator should check to make sure the orange "X-Ray On" light is lit, and remain in the room to check the progress of the scan acquisition as it appears on the screen.
9. The subject's head should appear with a few blank scan lines above it. As the scan proceeds, the total-body image should be in a straight line vertically on the screen. If these conditions are not met, the scan should be stopped. The scan arm will move to the original start position and the localizer light will come on. The subject should be repositioned as needed.
10. When the detector moves past the subject's feet, the auto stop feature then interrupts the scan and closes the shutter. A message appears on the screen, allowing the operator to continue the scan or shut down the system. After the scan ends, the shutter closes, the voltage and current ramp down and a messages appears for the operator to wait. The scan arm moves to the home position and a screen message appears to inform the operator that the scan is over and to remove the subject from the table. The technician should click to the Total-body Scan Options screen, then save the scan file.
11. The operator may now exit the Total-body portion of the program to perform another type of scan. If you plan to analyze the scan for local purposes, this is allowable, but please save an unanalyzed scan as well. For purposes of this research protocol, **no professional reading is required.**

**IMPORTANT NOTE: MAKE SURE TO SAVE THE SCAN FILE TO THE HARD DRIVE AND TO THE FLOPPY DISK OR CD-ROM FOR THE BCAC. SAVE THE DATA IN RAW FORM – DO NOT SEND ANALYZED SCAN FILES!**

#### *Hemiscan Protocol for Obese Subjects*

Overweight subjects may not fit between the normal scanning parameters. This poses an important problem with respect to whole-body DXA scanning which does not appear when spine or hip scans alone are contemplated. Often part of the left and right arms is cut off

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during DXA scans. This creates a problem during the analysis since the software can only acquire partial values for BMC, fat, lean tissue, etc.

To overcome this problem, the patient should be positioned on the table so that the entire right side of their body fits on the scan table. Any overflow should be directed off the left side of the table.

**\*Overflow should occur on the left side of the table instead of the right because the scanner arm moves along the right side and poses a danger to the patient's safety.**

1. Position the patient so that the entire right side of their body fits on the scan table.
2. Only exclude parts of the left side that are necessary to fit the patient on the table. For example, sometimes it may be possible to fit the patient on the table by excluding only part of their left forearm. Other times it may be necessary to exclude their entire left arm and part of their left leg.
3. Any left-sided body regions that cannot fit entirely within the scan i.e. left arm, left leg, etc. will be estimated by doubling the corresponding right sided data.

**\*If the left arm is cut off from the scan, then the right arm values will be multiplied by 2 when calculating body composition data.**

### Tall Subjects

If a person is too tall to fit within the lines, some of the feet or legs may extend outside of the scan view. Position the subject's head in the usual manner (about 1 inch below the top line on the table) and allow their feet to overhang. Please note the parts that were cut off on the "technical problems or additional comments" line of the DXA CRF and make sure that follow-up scans are performed in exactly the same manner.

### Hip and Spine

Hip and spine DXA scans will be conducted on the side on the side of the body specified in the study protocol. For these hip and spine scans, the subject-positioning techniques and the scan acquisition procedures should be done using the standard operating procedures defined by the instrument manufacturer.

## **4.0 Instructions for Submission of DXA Scans**

1. Sites should send the following:
  - a. The formatted disk (floppy or CD ROM) containing **raw unanalyzed data** for each study subject. \*Occasionally scans are analyzed accidentally on site and cannot be unanalyzed. This does not present a problem for Tufts, since all scans are reanalyzed by the scan technician. Data from more than one scan or subject should not be sent on one disk. Saving the scan files to new disks will greatly reduce the likelihood of needing to resend the scans due to disk corruption. Please do not compress scan files into .zip files. Double-check that the disk indeed contains the scans you intend to send!

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- b. The floppy disk or CD ROM needs to be clearly labeled with the following:
- Name of study
  - Site #
  - Patient ID Number (PID)
  - Visit Month (Baseline, 6 month, 12 month, etc.)
  - Date of scan
  - Scanner type (Hologic, Lunar) and software version (v. 5.76, etc.)

NOTE: Before mailing a disk, take it to a computer, put it in the drive, and confirm that the file is indeed on the floppy disk or CD-ROM!

- c. Send one hard copy paper printout of the subject's DXA reports and
- d. The floppy disk or CD-ROM and
- e. The DXA Scan Case Report Form (DXA CRF- Appendix 3)
- f. Fax the DXA Equipment Checklist (Appendix 1) only once at the beginning of every study; it will only need to be faxed another time if there are contact or equipment changes and it has been updated.
2. Scans can be shipped by your preferred carrier (e.g., FedEx, UPS, DHL, Express Mail, etc.), but a traceable shipping method must be used! Mail your scans to:

Andrea Desilets  
Research Coordinator  
Body Composition Analysis Center  
Tufts University Friedman School of Nutrition Science and Policy  
150 Harrison Avenue, Room #212  
Boston, MA 02111  
Phone: 617-636-3497  
Fax: 617-636-3662  
Email: Andrea.Desilets@tufts.edu

***All costs associated with shipping DXA scans will be paid for by the sites or the study. Do not ship scans to be billed to the recipient, as these scans will be rejected.***

Appendix 1

**DXA Equipment Checklist**

**STUDY NAME:** \_\_\_\_\_

Site #: \_\_\_\_\_

Investigator's name: \_\_\_\_\_

1. Who is the primary DXA contact person for your study site?

Name: \_\_\_\_\_

Address: \_\_\_\_\_

\_\_\_\_\_

Phone: \_\_\_\_\_

Fax: \_\_\_\_\_

E-mail: \_\_\_\_\_

2. Have you received and read the SOP and are you confident that you can follow the procedures outlined?

A. Yes

B. No

3. What type of DXA equipment will be used?

A. Lunar

B. Hologic

4. Which model and serial number? \_\_\_\_\_

5. Which software version? \_\_\_\_\_

Please return this form by fax to (617) 636-3662 BEFORE PERFORMING ANY SCANS. If there are any updates to this form at any point, re-fax the updated form.

