
The Body Composition Analysis Center at Tufts University Standard Operating Procedures for Abdominal Computed Tomography (CT) Scans

Performed for Body Composition Measurements*

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 DXA and CT data to Tufts.**

1.0 General Instructions

The following summarizes the procedures for site certification, subject preparation, obtaining the CT scan, and submitting the CT scan image to the BCAC. Please follow the manufacturer's instructions for operating your instrument. Scans should be performed using standard operating procedures defined by the manufacturer to allow comparability between study sites and generalizability to subjects outside the study conditions.

Subjects should be scanned on the same instrument using the same version of software throughout the study. The BCAC and the protocol team should be notified as soon as possible if an instrument or software change is anticipated or if any adjustments are made to the scanner during service or maintenance. Follow the protocol team's instructions on how these situations should be handled.

The preferred scanner setting is 120 kV; however, some scanners have fixed settings somewhat outside the 120 kV value, and some protocol teams may elect to choose lower settings, such as 90 or 100 kV. If the protocol follows the standard recommendation, the scanner should be set at 120 kV. If this is not possible, the setting closest to that value should be used. If the protocol recommends a different setting, the scanner should be set to that setting or the value closest to that setting. **OF CRITICAL IMPORTANCE: All post-baseline scans should be performed at the same setting as the baseline scan.**

The abdominal CT evaluation requires only a single image ("slice") and *does NOT require a full clinical abdominal CT scan, and does NOT require a professional radiologist's reading.*

2.0 Radiation Safety

As part of CT 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 CTs will be performed.
3. At the time of calculating the total amount of radiation, consider the following:
 - a. Include the amount of radiation necessary to do "scout" CTs (to identify anatomical sites that will be used for the cuts).
 - b. Remember that, in most cases, the number of cuts in an abdominal CT is limited, so the total amount of radiation is not equivalent to a normal abdominal CT.

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 an Abdominal and Thigh CT

ABDOMINAL: 1 lateral scout from T12 to mid-sacrum (120 kVp, 80 mA)
1 CT slice between L4-L5 (100 kVp, 170 mAs, 10 mm)

	<u>Effective Dose</u>	<u>Gonadal</u>	<u>Max Skin</u>
Abdominal	0.10 mSv (10 mrem)	0.02 mGy (2 mrad)	1.7 cGy (1.7 rad)
TOTAL:	0.10 mSv (10 mrem)	0.02 mGy (2 mrad)	1.7 cGy (1.7 rad)

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 Procedures for Site Certification and Scanner Approval

1. ***All CT scans must be performed on an approved scanner, and must be performed according to the specifications listed in Section 5.0 of this document.***
2. Fill in the CT Equipment Checklist form (Appendix 1) and fax it to the BCAC before scanning any study subjects. Each department submitting scans to Tufts should complete a separate form, even if it is technically a sub-site for the study.
3. To be approved, each site must send one Test CT scan to the BCAC that can be successfully read and analyzed. Each department submitting scans to Tufts must submit a separate Test CT scan, even if it is technically a sub-site for the study.
4. To be approved for the first time, or if there has been an equipment upgrade since the original approval, send:
 - a. One de-identified abdominal Test CT scan by the transfer method you prefer (CD-ROM or electronic upload to our DICOM server).
 - b. If your institution will not allow you to perform a CT Test scan on a patient before the study begins:

When the site performs the first patient's baseline scan, that scan needs to be saved to two disks. The first disk will be the actual patient baseline scan, and will be retained at the site until after scanner approval. The second disk will contain a de-identified version of the baseline CT scan, and will be sent to the BCAC. This de-identified scan will act as the CT Test scan. When the BCAC receives the CT Test scan, they will review it and communicate to the site immediately if there is a problem and therefore a need for a re-scan. *The site will*

need to be ready to re-schedule the patient immediately if the test scan is not approved. The site will also need to refrain from scanning any other patients until the CT Test scan is approved.

5. The BCAC will notify the site by email if the Test CT scan has been approved. (Please include the correct contact email address on the CT Equipment Checklist form [Appendix 1].)
6. **Do NOT send X-Ray films to Tufts!**

4.0 Instructions on Subject Preparation

It is preferable that the CT scans be scheduled the same day as the study visit. Follow the protocol-specific instructions as to the allowable time difference between the study visit and the actual scan. NOTE: The clinic visit is defined as the visit at which the medical history and targeted physical examination occur.

It is preferable that the abdominal CT scans be conducted while the subject is fasting. If there is a need for the subject to eat for medical reasons, a small snack (e.g., two crackers or a piece of toast and 8 oz. or less of a beverage) rather than a large meal prior to the scans is preferable.

5.0 Procedures for Performing CT scan of the Abdomen

Have the subject change into a gown. Brassieres and underpants should be removed prior to the abdominal CT scan. Any type of girdle, control stockings, or other garments that add support must also be removed prior to the scan.

IMPORTANT NOTE: Please do not identify the scan using the subject's name. Use the Patient Identification Number (PID), and date ONLY on the images. Study visit number should also be included on the CT Scan Case Report Form (CT CRF- Appendix 3). No subjects' names should appear on any materials sent to Tufts.

Baseline Abdominal Scans

1. Dye injection is not needed for the abdominal CT scan.
2. Place a small triangular wedge pillow under the subject's knees to help tilt the spine in the correct position. Have the subject cross his/her arms over the chest/neck with the elbows up and out of the way of the abdomen.
3. The technician will position the bed in the scanner so that a lateral tomogram can be taken that will include at least T12 through L5 of the spine. Record the picture on disk.
4. Identify the location of the interspace between L4 and L5.
5. Have the subject hold his/her breath (just have the subject stop breathing; do not have subject take deep breath, blow out, and then hold) and then take a 10-mm slice at the

level of the interspace between L4 and L5 (angle must be zero so that the slice will be perpendicular to scanning table).

Settings:

kV = 120 (preferred)

MA = 170

1 second scan time

10 mm slice thickness

DFOV = the size that will fit the entire slice into the field of view. It is critical that none of the abdomen is cut off.

Algorithm = standard

Store data on disk in RAW or non-compressed format, and as a DICOM file.

These settings are for a GE scanner. Settings for your scanner may be slightly different. The settings must be standardized so as to give the greatest definition to fat and lean tissue. Once the technician has determined the appropriate setting for your scanner, use the SAME settings for every follow-up scan. The only change in the settings will be for the DFOV. If a person is large or small, the DFOV will have to be changed accordingly. **Make sure to record the DFOV on the CT Scan Case Report Form (CT CRF- Appendix 3).**

6. The entire cross-section of the abdomen must be on the screen. If the entire abdomen is not on the screen, the picture must be reconfigured. Once the entire abdomen is on the screen, the technician will download it on the disk. Verify that the image is actually on the disk.
7. Record the **study name, PID number, date, and study visit number** on the scan. These unique numbers need to be recorded. Please remove patient names, birthdates, and any other identifying information.
8. Have the subject get off the table.
9. Verify that all data have been collected. Fill out the information requested on the CT Scan CRF and send it along with the CT scan and a copy of the CT CRF.

Repeat CT scan of Abdomen

Follow the same procedures for repeat abdominal scans. Identical settings and location **must** be used for the repeat scans. It is crucial to position the subject and identify the scan landmarks as uniformly as possible to obtain useful data.

Instructions for Sending CT Scan Electronically or via CD-ROM

6.0 There are 2 ways to transfer the image to Tufts:

- a. Electronic transfer by FTP or DICOM Protocol (PREFERRED). If you send the file electronically, you do NOT also have to send it by CD ROM. You may send the completed CT Scan CRF as well via fax or email. See the address information below.
- b. Copy the image to a CD-ROM using a read/write CD-ROM player and send the CD-ROM. If you cannot transfer files electronically, this is the

best alternative. YOU MUST SAVE THE FILE AS A DICOM FILE BEFORE COPYING IT TO THE CD-ROM. ONLY DICOM FILES SHOULD BE SENT ON CD-ROMs. SEE INSTRUCTIONS BELOW FOR HOW TO MAKE SUCH FILES.

c. DO NOT SEND X-RAY FILMS TO TUFTS!!

2. If you have just completed scanning a subject, the radiology technician may transfer the image to a workstation that you will use to do the electronic scan transfer. If you need to send images by CD-ROM, have the CT technician load the image on one of their scanners or another workstation and then it can be pushed (by the CT technician) or pulled over to the workstation (see below).
3. If someone has been using the workstation for analysis, press "front" on the right hand side of the keyboard to bring up the window you want.
4. You can pull the images you need from the CT computer to the workstation:
 - a. Under "Network" click on "Select Remote Host" and choose the CT scanner that the image was obtained from or stored on.
 - b. Next, under "Network" choose, "Query Host." This will bring up all the scans currently located on that CT scanner.
 - c. Highlight the scan that you are interested in pulling over, then under "GET" select "Get Examination."
 - d. Now you can "Quit" under "Application" and you will be back to a window that lists all the scans on that workstation.
 - e. In the main window of the workstation, identify the subject (protocol number and subject's initials will be used), date, and examination number of the image you want to transfer. Using the left side of the mouse, highlight the Protocol number and subjects initials you want (on the left window of the screen). On the right window of the screen highlight the image and series that correspond to the prospective (PROSP) image. Hold the shift key if you need to highlight more than one image. You do not need the scout image, although you may push that over if you want.
 - f. Under Network click on "Select Remote Host" and select "Phy-dicom." Press OK
 - g. Under Network click on "Push Image." Press OK.
 - h. You will see the word "ACTIVE" next to Network, which means that the transferring is taking place.
 - i. For confirmation look under Message and you will see that the image was sent.

NOTE: You may need to discuss with your hospital or University Information Systems people how to send these files without violating their firewall. This is well worth the bother as it will simplify your life enormously once it is in place!

For technicians, this is what you need to know:

[1] Using DICOM protocol:

HostName: dicom_phy

AE Title: DIGITAL_JACKET

Protocol: DICOM 3.0

IP Address: 130.64.44.46

Port No.: 104

1. The CT scans can be shipped on CD-ROM to the address below.
2. To create a DICOM file on a CD-ROM:

From CT console or workstation:

[1] From the Patient's List console, select (or highlight) the CT exams to be transferred.

[2] Choose the "Archive" mode from the top menu.

[3] Select target as "CD-ROM" or "CD-RW," depending on scanner type.

[4] Choose "All Exams" or "Copy All" function, depending on scanner type.

[5] Click "OK" to confirm the archiving process.

From Personal PC (if available):

[1] Send CT exams to a stand-alone PC via DICOM 3.0 protocol.

[2] Run Adaptec CD burning application via the following PC commands

"/Start/Program/Adaptec Easy CD Creator/Easy CD Creator"

[3] Select "Data CD."

[4] Select (drag and drop) all the CT exams to the destination window (lower right).

[5] Click the "Create CD" icon button (looks like a red dot).

[6] Select speed at "4X" and "Disk at once" options.

[7] Click "OK" to confirm the archiving process.

3. All images should be stored on the system's hard drive or a disk at the time the CT scan is completed until the study is over.
4. Send the CT scan and the CT Scan Case Report Form for every patient scanned.

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

MAKE SURE THERE IS A LABEL ON THE DISK INDICATING THE STUDY NUMBER, YOUR SITE NUMBER, PATIENT ID NUMBER, STUDY

TIMEPOINT (BASELINE, WEEK 24, ETC.), DATE OF SCAN, AND CT SCANNER MAKE AND MODEL.

Please do not include patient names, birthdates, or any other identifying information. Also, please do not send scouting scans to Tufts. Only the L4 / L5 slice is needed for analysis.

All costs associated with shipping CT 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

CT Equipment Checklist

STUDY NAME: _____

Site #: _____

Investigator's name: _____

1. Who is the primary CT 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 CT scanner will be used?

4. How will you transfer the data to Tufts?

a. On CD-ROM

b. By Optical Disk (What type of disk? _____)

c. By DICOM (electronic transfer)

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.

