COMPUTED TOMOGRAPHY – YEAR 10

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1. CT Scan Reading Center (LEDB)

1.1 Background and rationale

Significance of body composition CT scan: The purpose of the CT scan is to provide a means of quantifying the muscle and fat volumes in participants in the Health ABC protocol. Issues related to this are addressed in this manual. The CT body composition image will be used to calculate:

- Subcutaneous fat volume and density at L4-L5
- Visceral fat volume and density at L4-L5
- Abdominal muscle volume and density at L4-L5
- Thigh muscle volume and density at mid-femur.
- Subcutaneous fat volume and density at mid-femur
- Intramuscular fat volume and density at mid-femur

1.2 CT scan reading center purpose

The Laboratory of Epidemiology, Demography and Biometry (LEDB), IRP, NIA, NIH will be responsible for reading and analyzing the CT body composition scans obtained for the Health ABC protocol. The LEDB will store the spine images for future analysis. Objectives include:

- Review with the CT technologists collection, storage, and transmittal of the CT scans.
- Provide continuous technical support for each site.
- Provide quality control of the CT scans for each site.
- Analyze each body composition CT image obtained.
- Participate in protocol development and publication of results.

The methods used to acquire the CT must be consistent for each site to ensure accurate analysis at the CT Scan Reading Center. A standard technique for the acquisition will allow serial comparison and analysis of data should it be desired to re-image the participants at a later stage in the Health ABC protocol.

Please direct all CT protocol and data queries as directed in Section 5. in this chapter.

1.3 CT body composition scan collection

Axial CT scans at the L4-L5 and mid-thigh level will be obtained on each participant during their examination using the Health ABC protocol. It is important that the scans be transmitted to the LEDB on a timely basis so that image quality can be continually monitored. This will ensure that a minimum number of scans are compromised prior to resolution of any problems with quality. It is important that the site keep a backup of any images obtained in the event that the transfer media becomes damaged during shipment. All sites involved in collection of the scans must be certified as described in section 1.4.

1.4 Training and certification of CT sites and CT technologists

The protocol will be reviewed by investigators from LEDB and the University of Colorado Health Sciences Center (UCHSC). Technologists will be trained by the Principal Investigators of the LEDB during a telephone conference call. Prior to this training each site must be certified to ensure that it has the capability to perform the desired scan, that images are of acceptable quality, and that the site has the ability to transfer images in an acceptable manner to the LEDB.

Site certification

For each site, a letter will be mailed describing the project and expectations for the site. This mailing will include a site survey (Attachment A), this protocol manual, and a request for the following materials.

- A lateral abdominal scout and an axial CT scan, non-helical, in the area of L4-L5, from a routine participant, performed on the CT scanner to be used in the study.
- Example of an AP scout of the femur and a mid-thigh axial CT scan, non-helical, from a routine participant, performed on the CT scanner to be used in the study.
- Electronic "Save Screen" image of the scout images sent above, with the scan level of the abdominal and thigh scans electronically indicated.
- Example of a water phantom image obtained during normal QC within a month of the clinical images included above.
- Example of a linearity phantom image obtained during normal QC on the scanner to be used for this study.

All of the above materials should be sent to both the LEDB and UCHSC, at the addresses found on page 11, on the storage media (tape/disc) to be used for the study.

The above materials will be reviewed to assess the quality of the site's scanner, scan technique, and data transfer protocol. An assessment sheet (Attachment B) will be filled out for each study and will be reviewed during the site visit. When all recorded issues are satisfactorily resolved, the site will be certified.

The LEDB and UCHSC will continually review the image quality and technique as image data is submitted by the site during the course of the study. Specifically:

- Each water phantom will be analyzed for uniformity and calibration of CT values.
- Each scout will be evaluated for proper preparation and positioning of the participant.
- Each axial image will be evaluated for technique, appropriateness of chosen FOV, image quality and selection of level.

Any concerns will be discussed directly with the site CT coordinator.

Training of CT technologists

Technologists are trained in this protocol at the University of Pittsburgh as a similar protocol has been used on other studies. There will be a telephone conference call with the technologists during a meeting of the Pittsburgh site investigators to review the protocol.

Training will include:

- review of the scan protocol
- review of the site's recent QC logs
- assessment of the site's understanding of the protocol
- review of any questions that the site may have regarding the requirements for the study

It will be the responsibility of the lead CT technologist to train CT technologists not present at this session to perform this protocol. All certified technologists will receive a Staff ID# from their field center and should mark all scans performed with this ID#. It is desired that the number of technologists be limited so as to assure consistency in the scan technique. It is expected that technologists will be members of the normal staff of the facility performing the scans. The staff ID# of the technologist should be recorded on the daily inventory of Health ABC participants which is sent to the LEDB (Attachment D).

2. CT scanner equipment specifications

2.1 Equipment information

All images should be acquired using identical software for continuity and ease of analysis during the reading process.

All CT images will be acquired on the following scanner in Pittsburgh:

- GE HiSpeed NXi

CT image transfer to LEDB and UCHSC will be via

- CD

It is the responsibility of the site to keep an additional copy of the images on site.

3. CT body composition scan acquisition

The CT body composition scans consist of a lateral abdominal scout, 3 axial images at L4-L5, an AP thigh scout, and 3 axial images at mid-thigh.

3.1 Safety

A CT exam involves the use of ionizing radiation. A statement of radiation dose is included on the consent form signed by the study participant prior to involvement in the Health ABC study. Although it is the responsibility of the Health ABC study coordinator to have the participant sign the consent form, the CT technologist should check to be sure that this has happened. A summary of approximate radiation doses for the body composition protocol follows. Note that exact doses are scanner and protocol dependent.

	Absorbed Dose (mGy)	Effective Whole Body Dose (microSv)
Abdomen from lateral scout:	0.15	100
Abdomen, L4-L5 axial slice:	10	100
Thigh from AP scout:	0.15	15
Each mid-thigh from axial slice:	7.5	30
Each abdomen from spine CT	2.5	50

3.2 Exclusions

In this population, the only exclusion criteria shall be:

- Severe debilitation such that the participant is unable to lie supine.

Pregnancy as an exclusion criteria will not be an issue in this population. If a participant's size is such that not all of the skin and subcutaneous fat can be captured in the CT image, the site is requested to perform the imaging anyway, using the largest display field of view available. Although a subcutaneous fat calculation cannot be made for such a participant, all other parameters will be measured.

3.3 Pre-examination procedures

All participants who arrive for CT scans should have already provided consent for this procedure. The technician responsible for performing the CT scan must confirm that the participant: (1) has already signed a consent form; (2) is not excluded based on the criterion described above; and (3) has a Health ABC participant number and form.

As with any CT of the abdomen, all metallic items such as clothes with zippers or hooks shall be removed from the area of interest. The participant should change into a hospital gown for the CT examination.

All CT studies should be identified on header fields and forms, as appropriate:

- Participant's Health ABC participant ID# as their ID#
- Participant's Health ABC acrostic as their name
- Date of Study
- Exam Number
- Performing technologist's Health ABC staff ID#

NOTE that the participant ID# has the format "HAnnnn" or "HBnnnn", where "nnnn" is a four digit number. The acrostic consists of the first letter of the participant's first name and the first three letters of the participant's last name. The staff ID# has the format "Ann" or "Bnn" where the "nn" is a two digit number. In the preceding, the "A" and "B" refer to the site's Health ABC ID#. Sites will be notified of any irregularity in header information via a letter stating the information received and requesting corrected information (Attachment E).

Participant positioning for performing <u>both</u> spine and body composition CT

Prepare the CT table and position the participant according to directions in Attachment G, entitled "Quick Reference for Health ABC Spine CT Scans." PRIOR to obtaining the spine axial scan at L3, obtain all body composition axial images (first the mid-thigh, then L4-L5 axial scans). Finally, obtain the spine CT scan.

<u>Order of Exams</u>

1. Position the spine phantom on the CT table so that the spine phantom will be in the FOV for the thigh CT scans. A position for the phantom under the legs is best.
2. Position the participant on the phantom, but do not raise the participant's legs with a cushion.
3. Obtain the thigh scout(s) and axial images.
4. Position the cushion under the participant's legs.
5. Re-position the spine phantom so that it can been seen in the FOV for the spine and abdominal images.
6. Obtain the abdominal and spine scout images.
7. Localize and obtain the abdominal, body composition images at the L4-L5 disc space.
8. If participant moves, obtain the abbreviated spine scout.
9. Localize and obtain the spine CT image (L3 preferred) (angle the gantry as appropriate) following similar scanning parameters as abdominal scans (refer to Attachment G).

Make sure that the participant's position is not changed between performing the axial abdominal CT and the axial spine CT scan. If it does, a second scout must be obtained to position the spine CT scan plane. (See attachment G for second scout parameters.) Also check for appropriate field of view.

3.4 Thigh at mid-femur image

Remember to position the spine phantom so that it is in the FOV under the participant's legs.

CT scanning parameters for mid-thigh body composition scan

An AP scout including the entire femur should be obtained. The femoral length is to be measured using the right leg as done previously, unless otherwise indicated on the exam referral sheet from the Health ABC clinic, in cranial-caudal dimension, and the mid point determined as illustrated in Figure 3. The scan plane chosen must be recorded electronically on the scout images shipped to LEDB. The acquisition at mid-thigh will include three (3) 10 mm slices centered on the midthigh: a 10 mm thick slice 15 mm above the midpoint, a 10 mm slice at the midpoint, and a 10 mm slice 15 mm below the midpoint. The entire circumference of both thighs are included in the field of view.

Problems:
Participant's femur does not fit within the field of view of the scout. For some participants, a single scout image will not display an image of the entire femur.

1. On some scanners, two slightly overlapping scouts can be obtained and the center of the femur determined from combining the information on the two scouts.

2. In some instances the scout field is shortened because the table extension limit is reached. In that instance one can shift the participant on the table between the abdominal and the thigh imaging. It is not critical that the table positions for the thigh and the abdominal images be correlated.

3. However, if neither of these techniques are possible, perform the thigh scout such that the top of the femur (medial edge of the greater trochanter as defined in Figure 3, Point 1) is visible as close to the top of the scout as possible. Locate the center of the line between this Point 1 and the bottom of the scout following the central axis of the femur. When we receive the image on site, we will record the distance between Point 1 and the scan plane so that this distance can be used in any subsequent imaging studies on this participant.

How to position the scan at mid-thigh (Refer to diagram on p. 15):

1. **Draw a line between the medial surface of the greater trochanter and the center of the intercondylar notch.**

2. **Find the midpoint of this line.**

3. **Set the scanner to obtain 3 slices (10mm thick), with the first 15 mm above the measured midpoint of the femur, the second at the midpoint, and the last 15 mm below the measured midpoint of the femur.**

Scout

- Level: To include proximal through distal femur. May require two scout images.
- Plane: AP
- mA: 40-100
- kVp: 120 -140
- speed: Normal

Axial images

- Level: Mid femur (see Figure 3)
- mAs: 200-250
- kVp: 120
- Slice: 10 mm
- Scan FOV: Largest.
- Display FOV: Variable - Image must contain all skin and subcutaneous tissue of both thighs. If in doubt, use largest available FOV.

3.5 Abdominal imaging

REMEMBER TO RE-POSITION THE SPINE PHANTOM SO THAT IT IS IN THE FOV FOR THE ABDOMINAL AND SPINE SCANS AND DOES NOT NEED TO BE FURTHER MOVED.

CT scanning parameters for body composition abdominal scans

A lateral scout (parameters below), covering T4 through the upper sacrum should be obtained. Note that this is an extended scout compared to the normal scout that you might perform. The L4-L5 disc space should be located on this scout by counting the (non rib-bearing) lumbar vertebrae. In general, the disc space closest to the iliac crest is L4-L5. In the unusual event that there are six non rib-bearing lumbar vertebrae, the interspace closest to the iliac crest should be considered to be L4-L5. See Figure 2.

A series of abdominal images comprising the abdominal volume at L4-L5 during suspended respiration, (parameters below) should be obtained. For suspended respiration, the participant should breathe in, let the air out until it stops naturally, and stop breathing. The participant should not forcefully exhale. Participants should relax their abdomen and make no attempt to "pull it in." Care must be taken to include the skin and all subcutaneous tissues on this image as illustrated in Figure 1.

For spine CT measurements, refer to Attachment G, "Quick Reference for Health ABC Spine CT Scans" for instructions on performing this scan. Do not let the participant move so that the same scout can be used for localizing the spine CT scan.

How to position the abdominal scan correctly (Refer to diagram on page 14):

1. Draw a line along the inferior face of L4.
2. Draw a line along the anterior face of L5. This line should meet the first line.

3. The angle created by the line on the inferior face of L4 and the superior face of L5 is called the *angle of lordosis*.
4. The scan position should bisect this angle midway between L4 and L5.

Scout:

- Level: Approximately T4 through upper sacrum. You **must** include upper sacrum even if you have to exclude T4. This may require two scout acquisitions.
- Plane: LAT
- mA: 100
- kVp: 140
- Speed: Slow speed to provide the lowest noise scout.

Axial abdominal images for body composition:

- Level: L4 - L5 disc space.
- mAs: 300 - 360
- kVp: 140
- Slice: 10 mm (display on the image)
- Scan FOV: Largest available.
- Display FOV: Variable - Image must contain all skin and subcutaneous tissue. If in doubt, use largest available FOV.
- Algorithm: Standard

3.6 Image storage

All images should be double archived: once on media to be transferred to the LEDB and once on media to be stored at the imaging site at full resolution.

3.7 Post scanning quality check for body composition images

Prior to completing the examination, all images should be checked for the following:

- Scout films cover the desired areas and a set has been created with scan planes marked at the endpoints and midpoint of the acquired volume of scans.
- Axial images were obtained at L4-L5 and at mid thigh, with any possible deviation from protocols explicitly noted.
- All skin and subcutaneous fat are visible on the axial images.
- There is no perceptible participant motion artifact in the image.
- If applicable, recorded that no thigh scans were done due to bilateral prostheses.

Axial abdominal images showing movement artifacts from breathing. Although the goal is still to obtain these images during suspended respiration, if the images show artifact from breathing, the participant should NOT be re-imaged. The primary data loss in this instance will be the area of the anterior rectus muscles and it is felt that this information is not

beneficial enough to warrant the additional dose from re-imaging. Images so compromised will be marked in the dataset at the LEDB.

3.8 Post scanning quality check for spine CT image

Prior to completing the examination, spine CT images should be checked for the following:

- Spine CT volume obtained at L4, L3, L2, L1, or T12.
- Spine CT volume is mid-vertebral body and angled to compensate for lordosis.
- Angle of lordosis compensation recorded by the technician.
- Spine CT phantom is in FOV and centrally positioned against back.
- All soft tissue is visible on the axial images.
- Absence of image artifacts in vertebral body or calibration cylinders.

4. CT scan image transmission

4.1 Image transfer

Images to be transferred include water phantom images from the current month for monitoring of scanner calibration as well as all scouts (with and without scan planes marked), axial images, and the spine CT. Scans from the Pittsburgh site will be transferred via CD. All media should be mailed on a weekly basis to:

Michael A. Nalls
Laboratory of Epidemiology, Demography and Biometry
Gateway Building. Suite 3C-309.
7201Wisconsin Ave.
Bethesda, MD 20892-9205

The site CT coordinator will be notified if a weekly mailing has not been received.

Weekly submissions should include images of all of the following for each participant undergoing scans each the week:

1. Spine scans (preferably at the L3 level)
2. Abdominal scans
3. Mid-thigh scans
4. All scouts in DICOM format
5. Screen captures of scan localizer screens associated with the thigh, abdomen and spine.
6. Most recent monthly water phantom scan
7. Most recent monthly calibration (torso) phantom scan
8. Abbreviated spine scout (if necessary due to movement of participant)

4.2 Shipment notification and confirmation

As soon as the media is mailed, the site should fax a Body Composition Substudy CT Scan Shipment Notification Form (Attachment D) to the LEDB at (301) 496-4006.

The site's media will be read and returned along with a letter confirming the contents of the media (Attachment F). Discrepancies in Participant ID# information will be handled via a letter to the CT coordinator (Attachment E). Note that the site is required to keep an on-site backup of all the images including scout scans, so that discrepancies can be resolved. This process should take no more than one week from receipt of the media.

4.3 Transfer checklist

Before transferring or mailing please be sure that:

- Each disk contains the current month's water phantom image from the scanner used for participant images, scout images, scout images with electronic markers indicating the scan planes, and the axial images at L4-L5, mid-thigh, and at L3.
- Data for the monthly water phantom imaging and calibration phantom imaging will be forwarded to Ann Scherzinger, Ph.D as well as to LEDB.
- A copy of the Body Composition Substudy CT Scan Shipment Notification Form and Participant Logs (Attachment D) is included, which contains a list of the participants and exams included on the media.
- A back-up of all studies on the storage medium including the appropriate water phantom has been retained by your site.
- A clear return address is on the package.

5. CT Scan Reading Center Directory

For questions regarding protocol requirements for the abdomen and thigh body composition images contact Michael Nalls or Ann Scherzinger by fax or e-mail.

For questions regarding protocol requirements for the spine BMD measurement contact Tom Lang at UCSF.

Susan Averbach at the Coordinating Unit must be copied on all queries regarding procedures, protocol, or data quality.

For questions regarding data receipt or confirmation reports contact Michael Nalls.

Mailing address:

Michael A. Nalls
Laboratory of Epidemiology, Demography and Biometry
Gateway Building. Suite 3C-309.
7201Wisconsin Ave.
Bethesda, MD 20892

Ann Scherzinger, Ph.D.	Phone:	(303) 372-6166
	Pager:	(303) 266-3631
	e-mail:	Ann.Scherzinger@uchsc.edu
	Fax:	(303) 372-6148
Tamara Harris, M.D., M.S.	Phone:	(301) 496-6044
	e-mail:	harris99@mail.nih.gov
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UCSF Coordinating Unit Contact

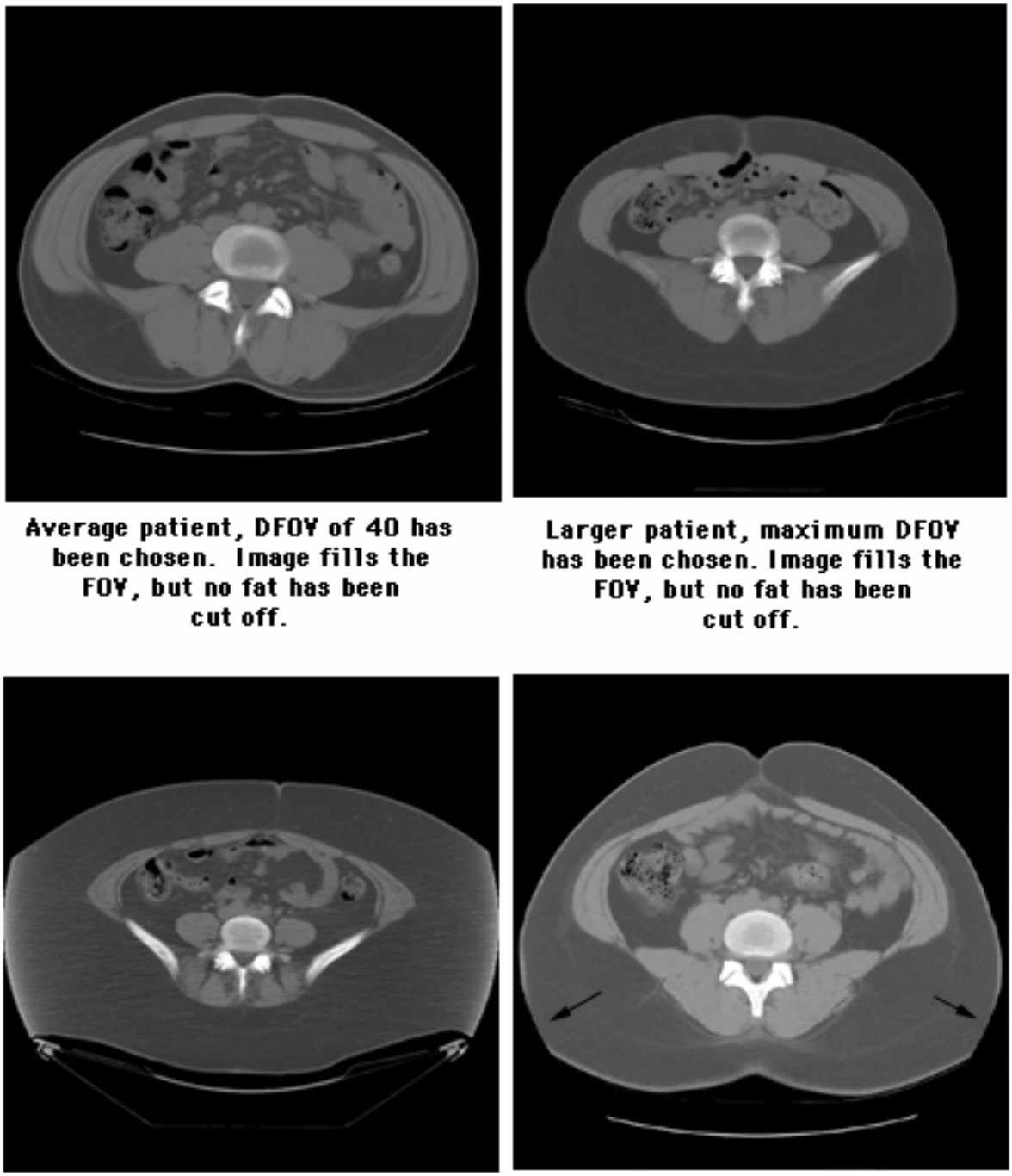
Susan Averbach	Phone:	(415) 514-8088
	e-mail:	saverbach@psg.ucsf.edu
	Fax:	(415) 514-8150
Thomas Lang, PhD	Phone:	(415) 502-4698
	e-mail:	thomas.lang@radiology.ucsf.edu
	Fax:	(415) 353-4552

6. List of figures

1. Selection of Display Field of View (DFOV)
2. Location of Abdominal Scan Plane localized from scout images.
3. Location of Mid-Thigh Scan Plane localized from scout images.

7. List of attachments

A. Site Survey
B. Review of Materials
C. Site Visit Checklist
D. CT Scan Shipment Notification
E. ID Verification Request
F. Confirmation of Receipt of Data
G. Quick Reference for Health ABC Spine CT Scans
H. Image Submission Suggestions
I. Year 10 CT Tracking Form



Average patient, DFOV of 40 has been chosen. Image fills the FOV, but no fat has been cut off.

Larger patient, maximum DFOV has been chosen. Image fills the FOV, but no fat has been cut off.

Very large patient. Maximum DFOV has been chosen but not all subcutaneous fat is visible. Acquire all images anyway and transmit to center.

Large patient. DFOV chosen is too small. Re-reconstruct image with larger DFOV.

Figure 1 - Selection of Display Field of View (DFOV).

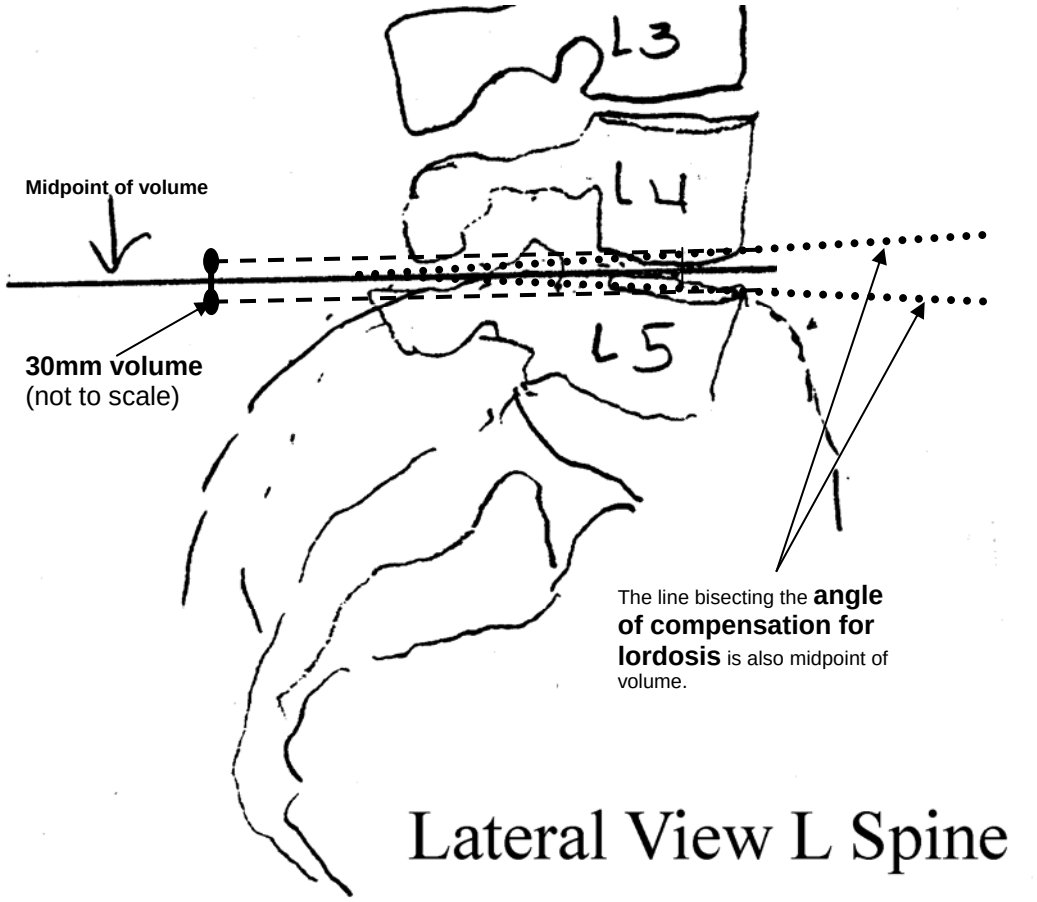
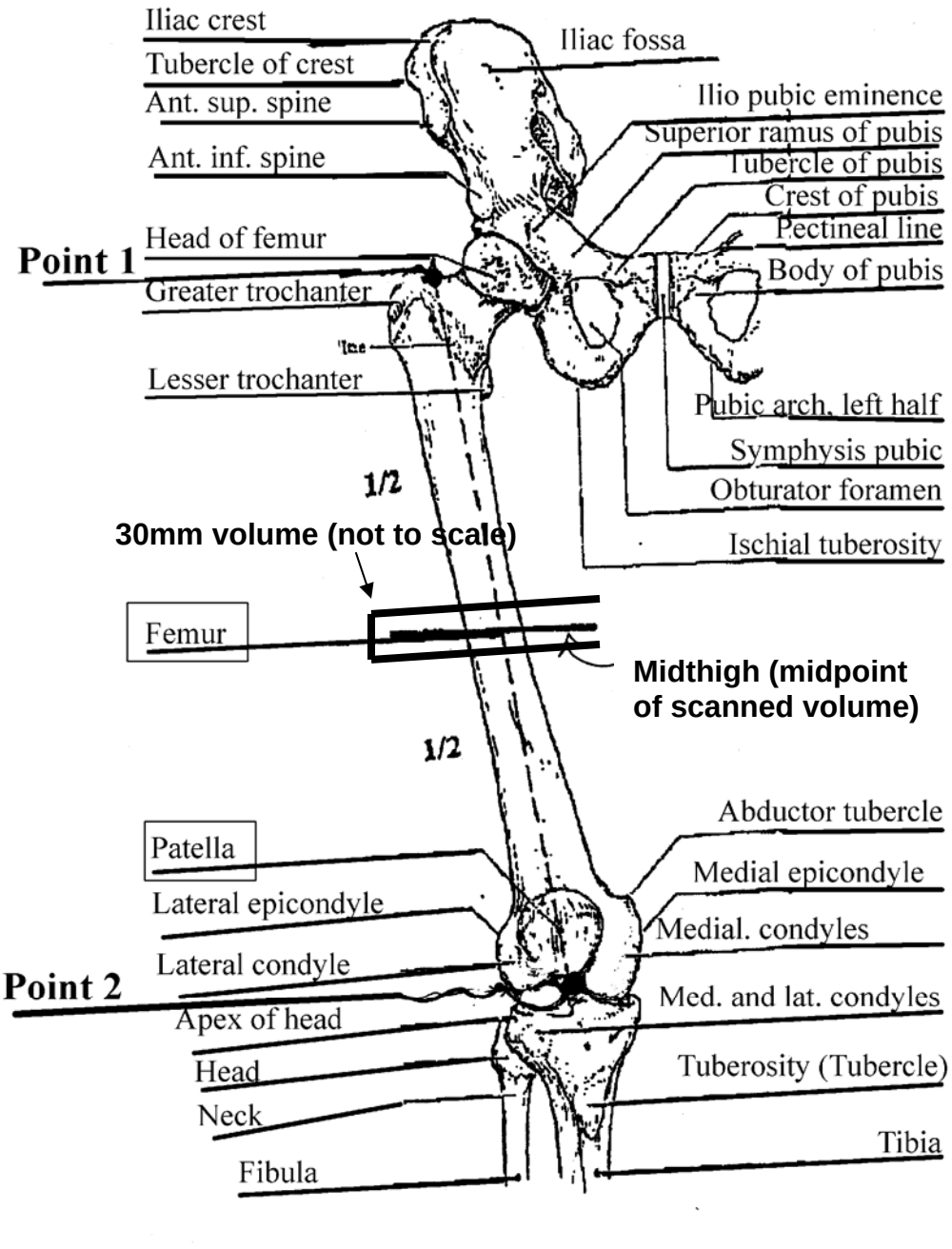


Figure 2 - Location of Abdominal Scan Plane



Location of the mid-thigh scan: Measure the distance between the medial edge of the greater trochanter (Point 1) and the intercondyloid fossa (Point 2). Choose the plane lying midway between these points (Scan Plane).

Figure 3 - Location Mid-Thigh Scan Plane

Attachment A: Site Survey

SITE SURVEY - CT IMAGING SITES FOR HEALTH ABC STUDY

ATTACH TO REQUESTED SAMPLE IMAGES

TO BE FILLED OUT BY SITE:

Site Name:_____ Site ID: _____

Address: _____

_____

_____

Contact Name: _____ Phone: _____
Alternate contact: _____ Phone: _____

E-Mail address: _____

Make/Model of CT used: _____

Transfer Media: _____

List of participants/images on media:

_____
_____
_____
_____
_____
_____

Date of water phantom image: _____

Date of calibration (torso) phantom image: _____

Attachment B: Review of Materials

REVIEW OF SUBMITTED SAMPLE SCANS

Site Name:_____ Site ID: _____

Address: _____

_____

Phantom Quality Measures

Water Calibration:_____

Uniformity: _____

Linearity: _____

Calibration (torso) phantom: _____

Scout

Technique: _____

Positioning: _____

FOV: _____

Participant prep: _____

Axial Images

Technique: _____

Positioning: _____

FOV: _____

Image quality: _____

Selection of level: _____

Header Demographics

Site Id: _____

Participant ID#: _____

Study Date: _____

Other problems or comments:

Attachment C: Site Visit Checklist

SITE VISIT CHECKLIST

SITE: _____ Date: _____

I. Imaging Protocol Issues

_____ Confirm survey information.
Name, address, contact, phone number

_____ Review routine maintenance schedule for scanner.
Maintenance schedule:

_____ Site protocol regarding consent form.
Who is responsible for consent form:

_____ Review exclusion criteria.

_____ Discuss participant preparation and positioning.
Review guidelines in the manual.

_____ Discuss labeling of images with appropriate demographics.

Participant ID#:
Participant Name:
Staff ID#:

_____ Discuss what images are required and imaging parameters.

Review the two groups (Spine CT versus Body Composition).
Review technique in sample images.
Review any concerns from sample images.

_____ Discuss how to identify imaging levels.
Review any concerns from the sample images.

SITE VISIT CHECKLIST - PAGE 2

SITE: _____ Date: _____

_____ Discuss how to choose appropriate fields of view.
Review procedure if participant is too large.
Review any concerns from sample images.

_____ Give site name of contact for protocol questions.

_____ Discuss training of additional CT technologists.

Site Questions:

SITE VISIT CHECKLIST - PAGE 3

SITE: Date:

II. Image Transfer and Storage Protocols

_____ Confirm water and calibration (torso) phantom scan protocol and timing. Review any concerns from sample images.

_____ Confirm facility for retaining local backup of images.
Site procedure:

_____ Confirm protocol for image storage.

_____ Confirm schedule for mailing of data to LEDB.

Schedule:
Contact person:

_____ Confirm schedule for returning media to site.
Schedule:
Contact person:

_____ Confirm site addresses for mailing.
Address:

_____ Discuss any issues seen in review of site's sample images regarding transfer format.

_____ Give site name of contact for transfer protocol questions.

Site Questions:

Attachment D Health ABC Body Composition Substudy CT Scan Shipment Notification

TO: Michael Nalls and Tamara Harris, MD.
FAX: (301) 496-4006

FROM: _____
SITE ID: _____
FAX: _____

RE: CT Shipment of Health ABC Participant Data

Message

The following data is being sent to you today _____
(today's date)

For delivery on _____
(date)

VIA: Mail Delivery service: _____ Airbill #_____
(airbill number)

Exam Date Range of Participants Included: _____

Please call me at _____ if you have any questions. Thank you.
(telephone number)

Daily Inventory of Health ABC Participants

Exam Date: _____

Participant ID	Acrostic	Staff ID	Exam # (UP)	Leg used for femur length		Vertebra for BMD
_____	_____	_____	_____	L	R	_____
_____	_____	_____	_____	L	R	_____
_____	_____	_____	_____	L	R	_____
_____	_____	_____	_____	L	R	_____
_____	_____	_____	_____	L	R	_____
_____	_____	_____	_____	L	R	_____
_____	_____	_____	_____	L	R	_____
_____	_____	_____	_____	L	R	_____
_____	_____	_____	_____	L	R	_____
_____	_____	_____	_____	L	R	_____
_____	_____	_____	_____	L	R	_____
_____	_____	_____	_____	L	R	_____
_____	_____	_____	_____	L	R	_____
_____	_____	_____	_____	L	R	_____

Exam Date: _____

Participant ID	Acrostic	StaffID	Exam # (UP)	Leg used for femur length		Vertebra for BMD
_____	_____	_____	_____	L	R	_____
_____	_____	_____	_____	L	R	_____
_____	_____	_____	_____	L	R	_____
_____	_____	_____	_____	L	R	_____
_____	_____	_____	_____	L	R	_____
_____	_____	_____	_____	L	R	_____
_____	_____	_____	_____	L	R	_____
_____	_____	_____	_____	L	R	_____
_____	_____	_____	_____	L	R	_____
_____	_____	_____	_____	L	R	_____
_____	_____	_____	_____	L	R	_____
_____	_____	_____	_____	L	R	_____
_____	_____	_____	_____	L	R	_____
_____	_____	_____	_____	L	R	_____

Attachment E: ID Verification Request.

(Site CT Coordinator)
(Date)

Dear: (Site CT Coordinator)

Would you please provide written verification that the information in the headers (participant identification) for the CT studies you have sent matches the assigned Health ABC ID numbers on the following participant(s) as the CT studies did not originally include the proper ID code:

(List of Participant[s])

For subsequent studies, please make sure that the CT image header information follows protocol procedures in identifying participants by Health ABC Participant ID# as the Participant ID#, and the Participant Acrostic as the Participant's Name. If your site, for medico-legal reasons, must include the full participant name, please remember to include the identifying information from the header along with the Exam Number and Date on the Daily Inventory of Health ABC Participants form that you fax to the CT Scan Reading Center prior to shipment of the study.

Thank you in advance for your immediate attention in this matter. If you have any questions, please feel free to call me at (301) 496-6443.

Sincerely,

Michael A. Nalls
Health ABC CT Scan Reading Data Coordinator

Attachment F: Confirmation of Receipt of Data

(Site CT Coordinator)
(Date)

Dear: (Site CT Coordinator)

Enclosed you will find the recirculating CD your study site is using for the Body Composition Substudy of the Health ABC. Please continue to use the disk for subsequent CT scans. Your original list of the contents of the enclosed disk is attached. Unless noted below, all data was transferred successfully.

(Detail concerning problems)

Please continue to keep a permanent on-site digital copy of your CT data.

We appreciate your efforts to date and look forward to continued contact with you. If you have any questions, please do not hesitate to contact one of the CT Reading Center personnel.

Sincerely,

Michael A. Nalls
Health ABC CT Scan Reading Data Coordinator

Attachment G: Quick Reference for Health ABC Spine CT Scans

Quick Reference for Health ABC Spine CT Scans

Prepared by

Cynthia Hayashi
Mary Sherman
Vesta March
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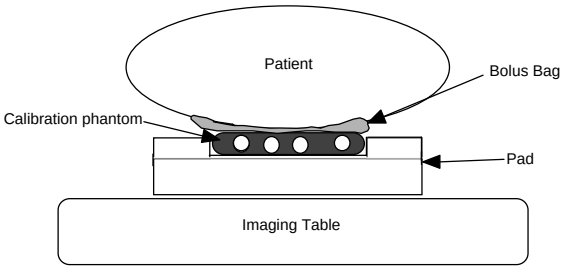
Attachment G: Quick Reference for Health ABC Spine CT Scans - Page 2

Introduction: An outline of the general procedure for performing both spine and body composition CT scans follows:

- Place spine CT phantom in proper position on the CT table for the thigh and thigh content scans (this page).
- Position the participant (this page).
- Perform the thigh scout and thigh axial image (main manual).
- Move and re-position the phantom so it will be in the FOV for both the abdomen and spine.
- Acquire the extended scout and L4-L5 body composition image (main manual).
- If participant has moved, perform an abbreviated scout (this attachment).
- Perform spine CT axial image at L3 (this attachment).

Phantom and participant positioning:



Cross-sectional view of phantom positioning

The participant will be scanned supine, feet first in the scanner. Before placing the participant on the table, place the blue foam pad on the table and put the recessed area in the the phantom inside phantom, marked “top”, pad. The end of the the head of the should point toward the centerline of the participant. Align laser light on the phantom with the scanner. The long axis of the phantom should be centered on the table’s longitudinal line. Smooth out the gel in the blue gel bags evenly. Cover the phantom with the gel bags. These bags must remain centered on the phantom to prevent air gaps between the participant and the phantom. Be very careful in positioning the participant on the phantom to assure the gel bags do not move. Place an additional pad or rolled sheet just below the blue pad so that the participant will have something to sit on prior to lying down on the blue pad and phantom. This avoids having the participant place all of their weight on the lower end of the blue pad which can cause the misalignment of the phantom.

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You may now place the participant on the table. The bottom of the phantom should be at the level of the anterior superior iliac spine (ASIS). This will assure that the phantom will cover L1 to L4.

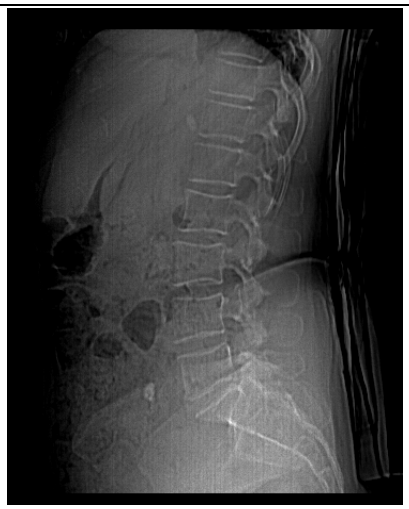
At this point proceed to the main manual to obtain the thigh and abdominal body composition CT images. Elevate the legs on a large cushion to reduce the lordotic curve in the back. This also ensures no air gap between the phantom and the participant. Position the participant's arms over the head. You may support the arms with cushions if necessary. When finished, return to this section to perform the spine CT imaging.

Localization for spine CT axial scan: You should use the same scout that was obtained for the body composition scan to localize the spine CT scan. If the participant moved after the body composition scan, you may need to obtain a new scout for localization. If so, you should obtain a "standard" lateral scout that primarily covers the lumbar region, as illustrated below.

ABBREVIATED SCOUT PARAMETERS (ONLY if needed):

Azimuth: 90
- Table speed: Normal
- Starting location: 50 mm above the Xyphoid
- Ending location: -250 (approximately)
- Kv...default is OK
- mA: 100
- Tilt....0

The gantry should be at 0 angle for the scout. Usually 50 to -250 will cover an average sized participant. Magnify the image so that you can see the image well.



Lateral scout view

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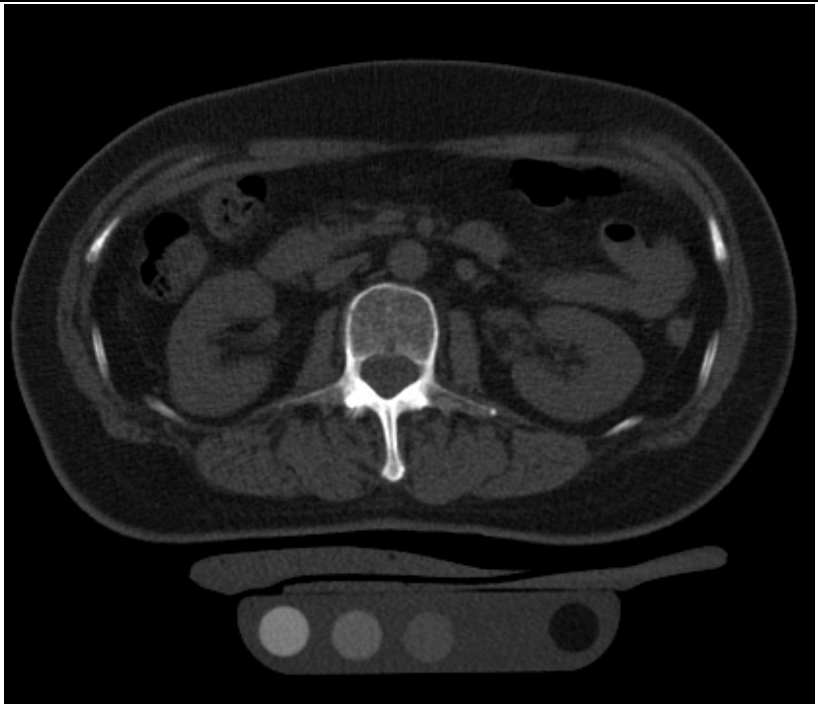
Axial scan of L3 for spine CT measurement: The slice should be centered in L3. Using the lateral scout, position the cursor on an endplate, angle to match the angle of the endplate. Now move the cursor to the center of the L3 vertebra. If L3 is compressed or you see abnormalities within the vertebral body that would result in analysis problems (i.e., areas of high density, calcified nodes etc...), select an alternate vertebra to scan. L4 will be the first choice as an alternate. If L4 is abnormal, choose (in order of priority) L2, L1, T12.



Axial scan

SCAN PARAMETERS:

- Single energy, 80 KV
- Level: L3
- mA: 70
- sec: 2
- Slice thickness: 10 mm
- Scan FOV: Large
- Display FOV: 40 or 48 cm, depending upon participant size. Scan should encompass all soft tissue and the calibration phantom. You must re-scan the participant if the soft tissue and/or the calibration phantom is clipped.
- Algorithm: Standard
- Matrix: 512
- Table height: to be determined using guidelines provided: 180 is used at UCSF.

SCAN QUALITY PARAMETERS:

Prior to completing the study, please check the spine CT images for the following:

- Spine CT slice was mid-vertebral body and angled to compensate for lordosis.
- Phantom was in the field of view and centrally positioned against back.
- All soft tissue is within the field of view.
- Absence of image artifacts in vertebral body or calibration cylinders.

Attachment H: Image Submission Suggestions

Image Submission Suggestions

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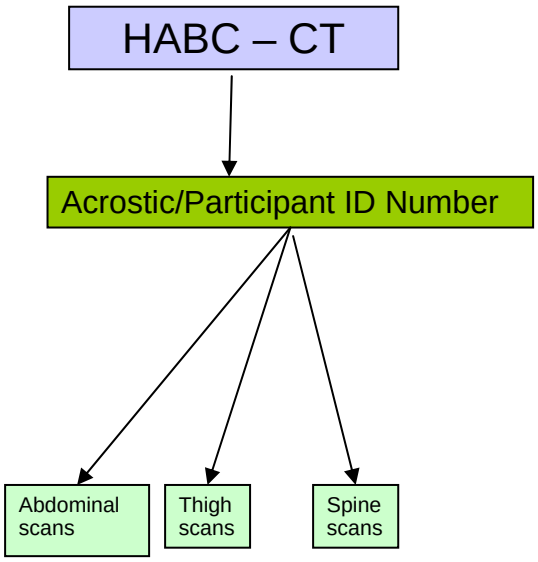
General Suggestions:

- ❑ Include HABC ID.
- ❑ DICOM header should include accurate acquisition date information, particularly in studies that have multiple rounds of images per participant
- ❑ CT machine, model and acquisition software versions should also be included in DICOM header information
- ❑ For multiple disk submissions, please order by participant name or ID number.
  - Example: Disk 1, Participants A-E; Disk 2, Participants F-Z or Disk 1, Participants 00-09; Disk 2, Participants 10-21.

For participants with only one set of images.

- ❑ Each individual should have their own folder labeled by their acrostic code or participant number.
- ❑ The next set of folders will be for each area of the body scanned i.e., thigh or abdomen or L3 vertebra.
  - ❑ Within these folders should be the actual images themselves.

Studies with single sets of scans per participant: Flowchart of data organization.



1st. Health ABC CT folder created.

2nd. Subfolder created for each participant.

3rd. Subfolders for scans grouped by region of the body imaged.

Attachment I: CT Tracking Form

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Health ABC

HABC Enrollment ID #	Acrostic	Date Visit Completed	Staff ID #
		Month / Day / Year	

YEAR 10 CT Tracking

1. What is your...?

First Name | M.I. | Last Name

2. Which thigh was measured for the last CT scan?
(Note: Refer to Data from Prior Visits Report to see which thigh was measured for the last CT scan.)

- Right → Measure right thigh.
- Left → Measure left thigh.
- Neither → Measure right thigh.
- Don't know → Measure right thigh.

3. Were any Year 10 CT scans acquired?

- Yes
  - **a.** Record CT exam #: ____ (Exam number)
  - **b.** Date CT scan(s) obtained: ____ / ____ / ____ (Month / Day / Year)
  - **c.** Health ABC staff ID# for the CT technologist: ____
- No → Go to Question #6.

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Health ABC

HABC Enrollment ID #	Acrostic

YEAR 10 CT TRACKING

4. Which scans were obtained?
(Note: Mark only one in each category.)

a. Thigh scout(s)	O one scout	O two scouts		O not obtained
b. Thigh scans	O one scan	O two scans	O three scans (protocol)	O not obtained
c. Extended abdominal/ spine scout(s)	O one scout	O two scouts		O not obtained
d. Abdominal scans (at L4-L5)	O one scan	O two scans	O three scans (protocol)	O not obtained
e. Abbreviated spine scout(s) (only obtained if participant moves)	O one scout	O two scouts	O not required (participant didn't move)	O not obtained
f. Spine scan O T12 O L1 O L2 O L3 (preferred) O L4				O not obtained

5. Were any of the required CT scans not obtained (i.e., the "not obtained" bubble is marked in any of Questions #4a through #4f)?

O Yes → Go to Question #6.

O No → STOP

6. Why weren't the Year 10 CT scans done?
(Note: Mark all that apply.)

- O Participant did not show up for appointment
- O Participant refused
- O Participant cannot lie supine
- O CT stopped at participant's request
- O Equipment failure
- O Other ***(Please specify:*** _____ ***)***

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