

Appendix I – Manual of Operations for HPTN 083 Study

HPTN 083: A Phase 2b/3 Double
Blind Safety and Efficacy Study
of Injectable Cabotegravir
Compared to Daily Oral
Tenofovir Disoproxil
Fumarate/Emtricitabine
(TDF/FTC), For Pre-Exposure
Prophylaxis in HIV-Uninfected
Cisgender Men and Transgender
Women who have Sex with Men



Body Composition Analysis Center

Tufts University

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The Body Composition Analysis Center at Tufts University

Manual for Hip and Spine DXA Scans

Performed for Body Composition Measurements

IMPORTANT NOTES:

- These guidelines apply to scans that are sent to Tufts University. Protocol-specific instructions may supersede these guidelines.
- Only sites with Hologic and Lunar scanners are eligible for the study. Array mode should be used for all scans.
- The DXA Scan Case Report Form (CRF- Appendix 2) must be completed in full and the form, printed image report, and CD/disk of the scan must be sent to the **Tufts Body Composition Analysis Center within three weeks of any scan date. Electronic transfers must also be uploaded within three weeks of any scan date.**
- Please note that each site's HIPAA RAF should mention that you will be sending de-identified DXA data to Tufts.

1.0 General Instructions Overview

The following is a summary of procedures for hip and spine DXA scans performed for body composition measurements. Please follow the manufacturer's instructions for operating your densitometer.

Before any scans are performed, please fax the **DXA Equipment Checklist form (Appendix 1)** as directed on the form to Tufts. A separate DXA Equipment Checklist form should be faxed for HPTN 083, even if a form has been sent to Tufts for other research studies. 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 densitometer 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 a hardware 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.

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 (CRF- Appendix 2) 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 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 “HPTN 083”; 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. Go to “Patient” in the menu: for **First Name “HPTN 083”; for Last Name enter the participating subject’s Patient ID (PID)**
2. Enter the subject’s **actual month and year of birth with “15” as the day**, and their sex.
3. Position the subject as discussed below, then choose the appropriate scan (hip or spine).
4. Start and complete the scan. 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 BIRTHDATE IN ORDER TO PRESERVE CONFIDENTIALITY!

IMPORTANT NOTE: All scans should be performed in array mode.

Phantom Scanning

A European Spine phantom, used for quality control, will be sent once to each site after the study is well underway. It is not necessary to perform these scans before the study starts, but they will need to be done before the completion of the study. Each DXA scanning site submitting scans to Tufts will complete a separate phantom calibration, even if it is technically a sub-site for the study. The data obtained from scanning these phantoms 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 them. The

instructions for performing phantom scans are included in **Appendix 3** of this manual. They will also be included with the phantom when shipped.

The data from the scans should be sent back to the BCAC, and the phantom will be sent to the next site in line to receive the phantom. This information will be provided to you by a BCAC coordinator. Refer to Appendix 3 section (pp.11-15) 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.***

1.1 Contrast Media Guidelines

Based upon ISCD official positions regarding contrast media, the BCAC recommends the following guidelines:

If the subject has undergone a procedure involving:

- Oral or IV contrast used for MRI or CT- delay DXA for **2 days**
- Barium- delay DXA at least **1 week**
- **No calcium supplements to be administered on the day of DXA scanning**

If the subject has undergone nuclear medicine exams:

- Technetium (99m)- delay DXA **48 to 72 hours**
- Iodine 131- delay DXA at least **1 week**

2.0 DXA Scan Positioning Techniques and Scan Acquisition

Hip DXA scans will be conducted on the LEFT side of the body. For 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.

Acceptable Femur image

- Make sure that the Femur image shows the greater trochanter, the femoral neck, the femoral head and the ischium
- The entire femoral head must fit within the scan window or Total Hip BMD cannot be measured
- The femoral shaft should be straight and parallel to the edge of the scan image
- The greater trochanter should be centered vertically in the window
- 3-5cm of tissue (2-3 sweeps of the detector) must be visible above the greater trochanter and below the ischium
- A triangular foot restraint should be used to ensure that the leg has the proper 25 degrees of internal rotation
- A minimal amount of the Lesser Trochanter should be visible in the scans

Acceptable AP Spine image

- Make sure the spine is in the center of the image
- All of L4 must be shown
- The top of L5 should be shown
- Approximately ½ of T12 must be shown
- In the rare instance that a subject has 6 lumbar vertebrae, start counting from the bottom up. L5 is always between the iliac crests and L4 is the first one above it
- The extra vertebrae is normally located between L1 and T12 (the extra may even have floating ribs attached to it)

For purposes of this research protocol, **no professional reading is required**. Remember to **ARCHIVE all scans** to your machine in case of reporting errors.

IMPORTANT NOTE: MAKE SURE TO SAVE THE SCAN FILE TO THE HARD DRIVE AND TO THE FLOPPY DISK OR CD-ROM FOR THE BCAC.

3.0 Instructions for Submission of DXA Scans

- ❖ 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.

Sites may either MAIL or UPLOAD DXA scans to Tufts University:

The DXA Scan Case Report Form (CRF- Appendix 2) must be completed in full; the form and scan must be sent or uploaded to the Tufts BCAC within three weeks of the scan date.

A. To send scans via **MAIL**, sites must send the following:

1. The formatted disk (floppy or CD ROM) containing scan files for each study subject. Data from more than one scan or subject can be sent on one disk. **Double-check that the disk indeed contains the scans you intend to send!**
2. The floppy disk or CD ROM needs to be clearly labeled with the following:
 - Name of the study (HPTN 083)
 - Site #
 - Patient ID Number (PID)
 - Visit Month
 - Date of scan
 - Scanner type and software version

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!

3. Send one hard copy paper printout of the DXA image reports and
4. The floppy disk or CD-ROM and
5. The DXA Scan Case Report Form (CRF- Appendix 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! **All costs associated with shipping DXA scans will be paid for by the sites or the study.** Mail your scans to:

Andrea D. Miller
Program Administrator
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.miller@tufts.edu

- B. To send scans via **UPLOAD**, sites must follow the steps as follows in Appendix 4.

PLEASE REMEMBER

- ❖ **Be sure that you are uploading the raw scan files, not images of the report.**
- ❖ **Please be neat! Do not forget to clearly label each scan with PID # and Site # just as you would a disk or CD.**
- ❖ **Create a site folder on the server so that your scans are easily identified! Folder labeling and file placement will help us to know that your scans have been uploaded. If they are not filed correctly, your scans may be lost otherwise.**
- ❖ **Please FAX or EMAIL a copy of the CRF immediately BEFORE uploading files to our server.**

Appendix 1 DXA Equipment Checklist

STUDY NAME: HPTN 083 Study

Site #: _____

Principal Investigator's name: _____

1. Who is the primary **DXA technician** for your study site?

Name: _____

Address: _____

Phone: _____

Fax: _____

Email: (ALL CAPS please)

2. Who is the primary **Study/Research Coordinator** for your site?

Name: _____

Address: _____

Phone: _____

Fax: _____

Email: (ALL CAPS please)

3. Have you (DXA Technician) received and read the Manual and are you confident that you can follow the procedures outlined? YES NO

4. Scanner model and serial number: _____

5. Scanner software version: _____

6. Have you (DXA Technician) completed DXA training by either manufacturer (Hologic/Lunar) or ISCD certification? YES NO

DXA Certificate Date: _____

DXA Tech Signature: _____ Date: _____

Please return this form by fax or email to (617) 636-3662/ andrea.miller@tufts.edu BEFORE PERFORMING ANY SCANS. If there are any updates to this form at any point, re-fax the updated form. Please include copy of certification.

Appendix 3
INSTRUCTIONS FOR USING THE
EUROPEAN SPINE PHANTOM (ESP) FROM
TUFTS UNIVERSITY

HPTN 083 STUDY PHANTOM INSTRUCTIONS

Contact for Questions

Should you have any questions, please contact:

Andrea Desilets Miller
Program Administrator
Tufts University
Body Composition Analysis Center
Jaharis Building, # 212
150 Harrison Avenue
Boston, MA 02111
Phone: 617-636-3497
Fax: 617-636-3662
Email: Andrea.Miller@tufts.edu

For any technical questions or assistance, please contact:

Justin Wheeler
Body Composition Scan Technologist
Tufts University
Body Composition Analysis Center
Jaharis Building, # 211
150 Harrison Avenue
Boston, MA 02111
Phone: 617-636-3745
Fax: 617-636-3662
Email: Justin.Wheeler@tufts.edu

European Spine Phantom Description

The phantom's main body consists of a water-equivalent resin. The three inserts contain varying amounts of calcium hydroxyapatite (CaHA) to cover the full physiological range of spongy and cortical bone densities for all age groups.



Scanning the Phantom

- 1) Setup a new patient biography. Set the Last Name and Patient ID to “ESP” followed by your site number (e.g. “ESP Site 14”). Set the birth date to May 21, 1989. Set the gender to Male.
- 2) Leave the height and weight fields blank.
- 3) After the biography is complete, enter a new exam. The scan will be performed in both Whole Body and Spine array modes.
- 4) The spine scan will be completed first. Select spine scan array mode and place the phantom within the scan region (remember, this phantom simulates the L1-L3 region). Use the laser crosshairs as a guide to ensure that the phantom is situated squarely and is in the correct location. The foot end of the phantom should be just above the horizontal laser beam. **The QRM logo should be facing the foot end of the table.**



- 5) Start the scan. Stop and reposition as needed.
- 6) Without moving the phantom, perform **2** more spine scans. This will give you a **total of 3** scans.
- 7) Next, without repositioning the phantom, scan it **3** times in Whole Body array mode. This will give you a **total of 6** scans.
- 8) Save the **6 scan files** for transmission to Tufts (via mail, email, or FTP upload).

IMPORTANT:

Please ensure that the phantom is positioned squarely on the bed. Use a square object for alignment if necessary. If the phantom appears to be tilted in the scan image, stop the scan and start again.

Submission of European Spine Phantom Data

All together there should be a total of **6** scans performed and saved. Verify that all scans are saved to the disk/CD for sending to Tufts; or verify that all scans are properly saved for electronic transmission. If saved to disk/CD, please label with the Study Name (HPTN 083), Site number, and the scanning date.

Analysis is not necessary.

DO NOT SHIP THE PHANTOM BACK TO TUFTS unless you are instructed to do so.

1. Via Mail: Send **ONLY** the disk or CD and the completed ESP Data Form back to Tufts for analysis just as if it were patient information.
2. Via Email: Send the 6 scan files in a zip folder and attach the ESP Data Form to your email.
3. Via FTP Upload: Transfer 6 scan files electronically through our FTP server: <http://www.fiberftp.com/tufts/> and send the Data Form by either email or fax.
4. Once the analysis has been deemed successful, Tufts will contact you and provide shipping instructions to forward the phantom to the next scheduled site.

Please be certain that ALL materials are returned to the shipping case:

1 ESP body block (wrapped carefully in provided bubble wrap)

HPTN 083 European Spine Phantom Data Form

FROM: Andrea Desilets Miller
Program Administrator
Body Composition Analysis Center
Tufts University
150 Harrison Avenue
Jaharis Building, # 212
Boston, MA 02111
(617) 636-3497
Andrea.Miller@tufts.edu

RE: HPTN 083 European Spine Phantom

In order to make sure that the differences between the DXA instruments at the various clinical sites are minimized and accounted for, we are sending around to each site the European spine phantom. Please scan this phantom according to the directions enclosed. We are requesting a five day turn around period in order to reach all the sites in a timely manner.

Enclosed is a set of instructions. Please **fill out** the bottom of this sheet and return it along with **all 6 of the DXA phantom scans via email, FTP upload, or mail.**

Thank you for your support. If I can be of further assistance, please do not hesitate to contact me.

SITE # _____

DATE OF SCAN _____

TECHNICIAN PERFORMING SCAN _____

MAKE/MODEL SCANNER AND SOFTWARE VERSION

Appendix 4

Electronic Scan Upload

Sites wishing to send DXA scans to Tufts electronically may do so using the Tufts BOX file transfer server. BOX uses an intuitive drag-and-drop interface which allows users to upload DXA scans and other relevant files to a unique site folder.

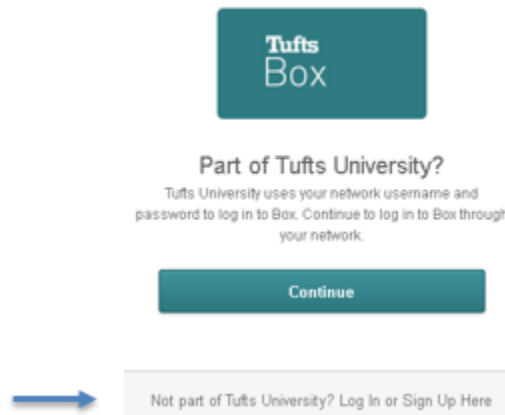
Each individual at site locations requiring upload privileges must submit their name, email address, site number, and institution affiliation as listed on the DXA Equipment Checklist(s) (Appendix 1). Multiple checklists may be submitted for additional users as needed.

After receiving this information, Tufts will create a unique site folder for each institution and individual requesting access. Individuals who have submitted their email addresses for uploading access will receive a BOX invitation via email. This email will contain a link that will bring the user to the BOX portal and will allow them to set up their own username and password to access the server.

Below is a detailed walkthrough of the setup process:

(Individual BOX accounts may look slightly different from the one shown in this example.)

- 1) From your email invitation, click the View Folder link.
- 2) Locate the “not part of Tufts University?” link at the bottom of the page



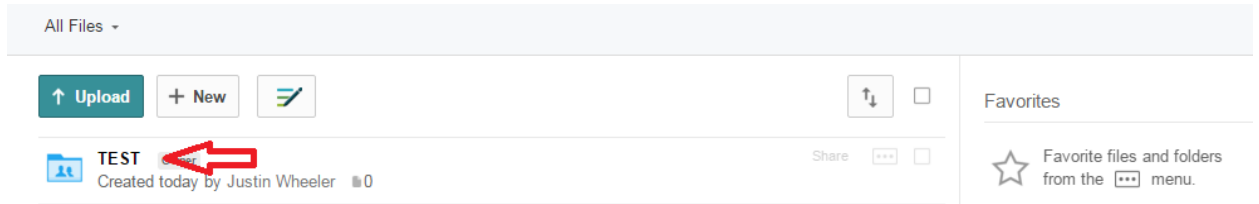
- 3) Click the “Login or Sign Up Here” link
- 4) Follow the prompts to create your Box account

Once you’ve created an account, you can upload DXA files and/or CRFs to your designated folder.

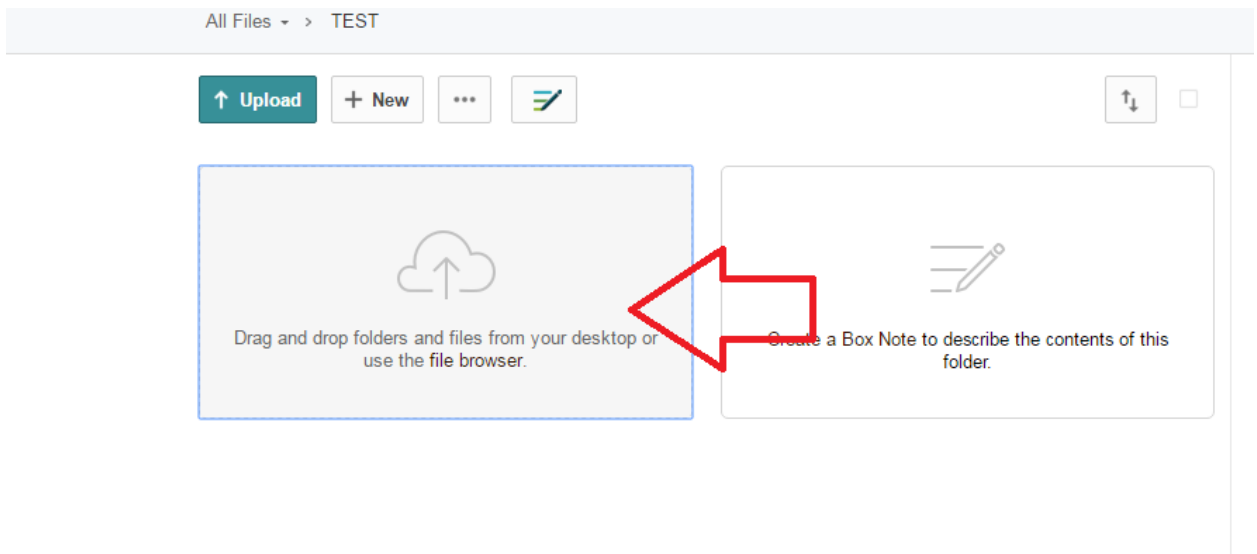
Uploading Files

Follow the following steps to upload DXA scan files to BOX.

- 1) Sign in to your Box account
- 2) Click on your site's folder (the example here is "test")



- 3) From the saved location, drag and drop DXA scan files into the drag and drop upload icon. Alternatively, you can click on this icon and it will open Windows Explorer from where you can browse to locate your files to be uploaded.



- 4) Once your files have been uploaded, a message similar to the one pictured below will pop up indicating that your files have been successfully transferred to Tufts.

