KNEE DECT

TABLE OF CONTENTS

1. Introduction

1.1 Background and rationale

MOST is a multicenter, longitudinal, prospective observational cohort study of risk factors for the development and progression of knee osteoarthritis (OA) and knee pain. This is a nationwide research study sponsored by the National Institute on Aging and coordinated by the San Francisco Coordinating Center. An existing cohort of 1500 men and women now aged 60+ have now been followed for 10 years. These participants along with a new cohort of 1500 younger men and women are currently being followed to help investigators better understand how to prevent and treat knee osteoarthritis, one of the most common causes of disability in adults. Dual Energy CT (DECT) of the knee will be performed at the 140-month follow-up visit to examine mineralization of the articular cartilage and menisci and to quantify three-dimensional bone mineral density and structure in the subchondral trabecular bone.

1.2 Purpose of the manual (Knee DECT)

This manual is intended for the CT technologists, principal investigators, and study coordinators at the clinical centers. The purpose of this manual is to standardize the imaging techniques and administrative procedures related to the DECT component of the MOST for evaluating the structure of the knee in study participants. The manual describes the CT techniques to be used along with the procedures for documentation and transfer of the CT data to the Coordinating Center at the University of California, San Francisco (UCSF).

The role of the UCSF Coordinating Center will be to:

- train and certify the clinic CT technologists
- monitor the performance of the CT technologists throughout the study
- check all CT scans for completeness, protocol adherence, and quality as soon as possible after they arrive at the UCSF Coordinating Center
- provide immediate feedback to the CT technologists and clinic coordinators when quality and protocol problems are detected
- request repeat CT scans as needed to correct problems
- inventory and archive all CT scans
- provide monthly Quality Assurance reports to the UCSF Coordinating Center and the MOST investigators on scans received, quality issues, and scans read in the previous month
- organize the CT scans for reading and measurements

1.3 Design of DECT study component

The DECT component of the MOST comprises bilateral knee imaging of the knee joints in about 3000 study participants who do not have contraindications for the CT examination (see Section 3).

1.4 Training of CT technologists

Each CT Center will identify radiology technicians who will be trained and certified to perform scans on the CT scanner chosen for the MOST Study. This person must read this manual, know how to complete Section 1 of the Knee CT Tracking form, successfully complete the training, and be certified by the UCSF Coordinating Center upon review of five participant bilateral scans. Certification will be based on the results of the training session and a review of 10 volunteer/participant knee scans (see Appendix 1 for certification form).

Only designated and certified technicians should perform the examinations for the MOST ancillary study. Each technician involved in the study will be identified by a unique MOST staff ID number assigned by the study coordinator.

2. Equipment and supplies

A Mindways QCT Phantom will be provided by each clinic coordinator to the CT facility which is to be used for the MOST Study.

3. Safety issues and contraindication for CT

Each site should follow their own internal procedures for addressing safety and contraindications for CT. For non-contrast CT as performed in MOST, the following are 2 known contraindications for CT:

- Pregnancy
- Weight over 350 lbs

4. Participant and exam room preparation

Proper participant set up should ensure correct positioning of the knees and sufficient participant comfort to limit motion artifacts. The Mindways QCT phantom should be positioned underneath the center of both knees

4.1 Participant positioning

Positioning of the participant's knee in the gantry must be reproducible from visit to visit to allow accurate comparison of serially acquired images. The participant should be imaged feet-

first and supine. The feet should be a few inches apart on either side from the center of the gantry, with the knees extended and the feet and patella pointing straight up.

If participants find that keeping their knees in this position difficult (e.g.: knee won't extend completely without pain), then a small pad can be placed under the knee and a small amount of flexion is allowed. Strapping feet together pointing vertically upwards is also useful to aid in consistent positioning, but again, if this is uncomfortable for the patient, it is better to let them position their feet in a comfortable position. Please note any knee flexion or internal/external rotation of the feet due to participant discomfort on the tracking form.

Table height should be chosen so that the knees are in the center of the gantry, with the left and right knees placed evenly either side of the center line.

4.2 Participant comfort and prevention of motion artifacts

Comfortable positioning of the participant at the beginning of the examination is critical to limiting motion artifacts. Padding or other measures such as taping the feet in a fixed position to ensure no external rotation should be considered.

The participant should be told to not move during the scan. **When the technologist sees motion during the scan, the sequence(s) should be repeated (at most, repeat one time).**

If the participant feels pain or is uncomfortable with their patellae and feet pointing straight up, allow them to externally or internally rotate or flex/extend their knees until comfortable and then immobilize before scanning.

When the ideal position has been altered for participant comfort, please make a note on the Knee CT Tracking Form.

5. DECT scanning protocol

After a scout scan from the superior part of the pelvis to the feet, dual energy scan will be performed of both knees.

Bilateral (280mm) as well as unilateral (120mm) reconstructions of both knees will then be created using both high and low resolution reconstruction kernels.

The following 2 sections give the details for the GE scanner in Alabama (section 5.1) and the Siemens scanner in Iowa (section 5.3).

Sections 5.2 and 5.4 describes the details of the scan planning at each site.

5.1 Scan protocol – Alabama

The CT scan parameters should be set for Dual Energy CT as follows:

- 80 KEV + 140 KEV
- 260 mAs
- Pitch 0.9mm
- Table speed 39mm/s
- 0.8 second exposure
- 0° gantry tilt

The entire exam will comprise:

- a scout scan/topogram (from the pelvis to the feet)
- spiral CT imaging (both knees including 9 cm of distal femur, and 9 cm of proximal tibia)
- reconstruction of axial slices of both knees at a field of view (FOV) of 28 cm – in which the Mindways phantom cross-section should be completely visible
- reconstruction of axial slices of the right knee at a field of view (FOV) of 14 cm*
- reconstruction of axial slices of the left knee at a field of view (FOV) of 14 cm*

All reconstructions should be performed at 0.6mm slice thickness with 0.3mm slice spacing, using the “STANDARD” kernel.

Low energy (80 KEV) and high energy (140 KEV) reconstructions, should be saved in all cases.

> *It is permissible to increase the FOV up to 15 cm in very large knees to ensure complete coverage of bony anatomy, especially the posterior of the femoral condyles. Please try to use the smallest FOV to achieve this.

5.2 Scan set-up – Alabama

Place the Mindways phantom centrally underneath the middle of the right and left knees and perform a scout scan of the entire lower body from slightly above the pelvis to the feet.

When planning the axial extent of the scan, Start Location should be 9 cm above the joint line at the knee, and End Location should be 9 cm below the joint line of the knee.

5.3 Scan protocol – Iowa

The CT scan parameters should be set for Dual Energy CT as follows:

- 80 kVp + 150 kVp with Sn Filtration
- Tube A: 250 mAs Tube B: 180 (eff.), but since CareDose is being used, the actual mAs will differ for each subject.
- Pitch 0.8mm
- CareDose ON
- 1 second exposure
- 0^0 gantry tilt

The entire exam will comprise:

- a scout scan/topogram (from the pelvis to the feet)
- spiral CT imaging (both knees including 20% of distal femur, and 20% of proximal tibia)
- reconstruction of axial slices of both knees at a field of view (FOV) of 28 cm – in which the Mindways phantom cross-section should be completely visible
- reconstruction of axial slices of the right knee at a field of view (FOV) of 12 cm*
- reconstruction of axial slices of the left knee at a field of view (FOV) of 12 cm*

All reconstructions should be performed at 0.6mm slice thickness with 0.3mm slice spacing, using the Qr40 kernel.

Low energy (80 kVp) and high energy (Sn150 kVp) reconstructions, should be saved in all cases

*It is permissible to increase the FOV up to 15 cm in very large knees to ensure complete coverage of bony anatomy, especially the posterior of the femoral condyles. Please try to use the smallest FOV to achieve this.

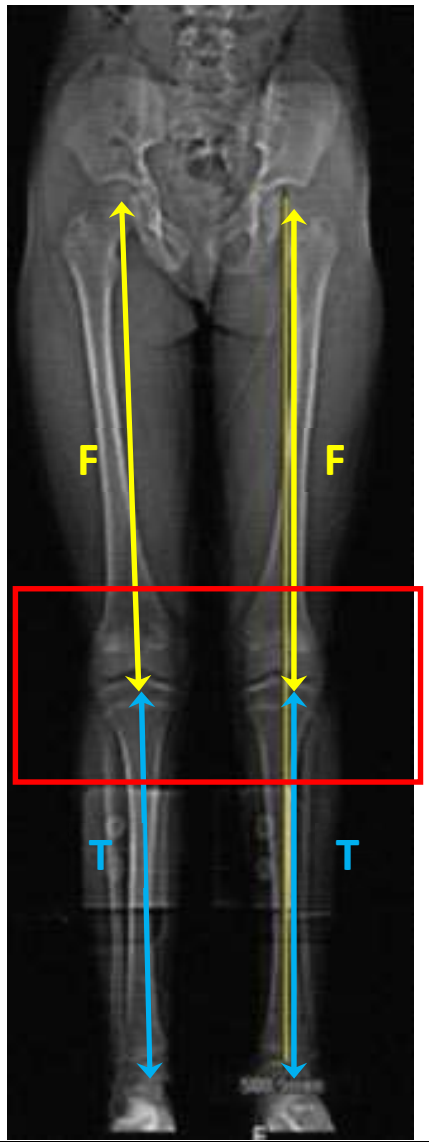
5.4 Scan set-up – Iowa

Place the Mindways phantom centrally underneath the middle of the right and left knees and perform a scout scan of the entire lower body from slightly above the pelvis to the feet.

Use the scout scan/topogram to measure the lengths of the left and right femurs and left and right tibias (see below). These measurements are used to determine the axial extent of the CT scan above and below the knee in the following manner:

1. Add together the left and right femur lengths and divide by 10. The scan prescription should start this distance above the joint line of the knee.
2. Add together the left and right tibia lengths and divide by 10. The scan prescription should end this distance below the joint line of the knee.

Figure 1. Showing planning for selecting volume of interest for knee CT



Calculating 20% Average Length of Femur and Tibia

(cm)	Right	Left	20% Average Length
Femur	FR	FL	(FR+FL)/10
Tibia	TR	TL	(TR+TL)/10

(mm)	Right	Left	20% Average Length
Femur	524	532	106
Tibia	418	408	83
		Total =	189

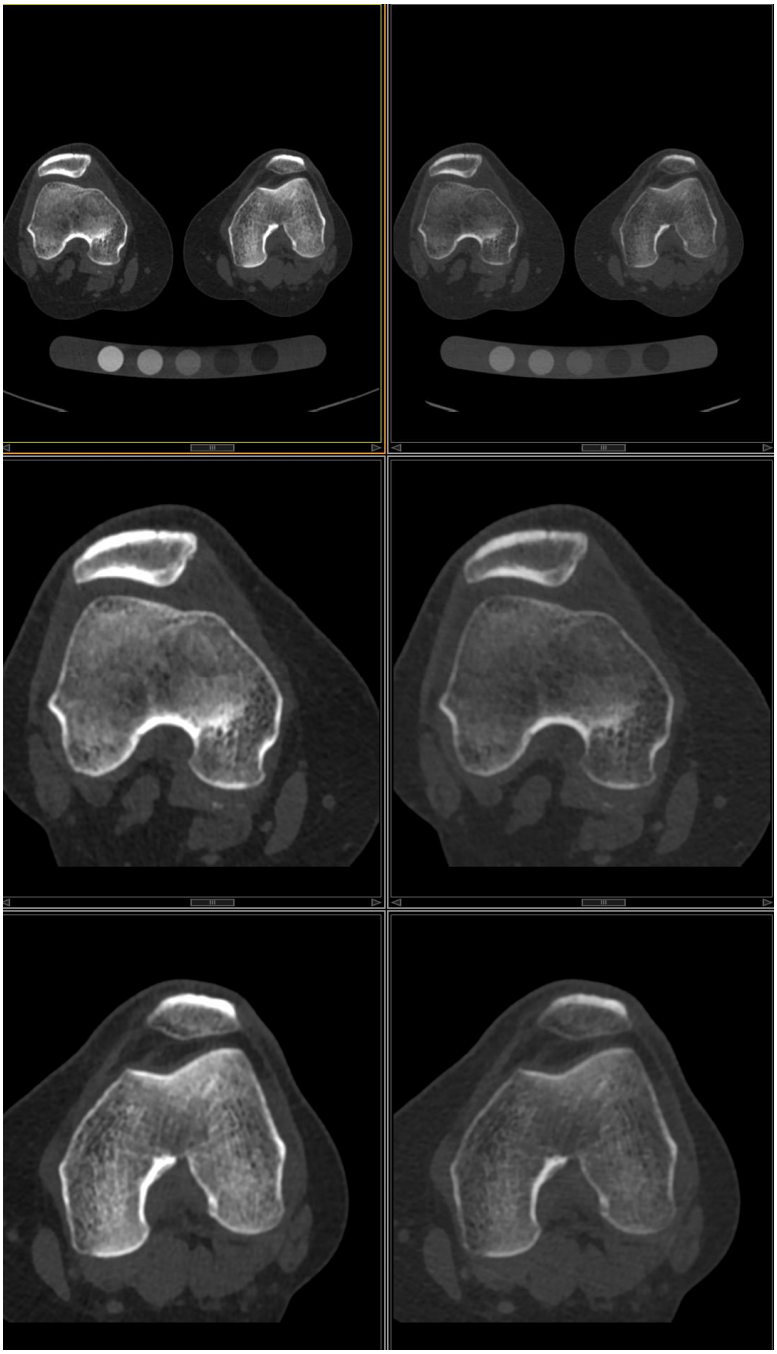
So axial slices should run from 106mm above knees to 83mm below knees (a total of 189mm or 378 slices at 0.5mm slice thickness)

When one knee is higher than the other, plan the upper extent based on the highest knee and the lower extent on the lowest knees.

NB: If the scout/topogram shows a knee replacement in either knee, then no CT or reconstructions should occur and note the fact that a replacement was seen on the knee CT data collection form.

5.5 Example images of the different reconstructions required

Figure 2. Showing example Siemens Force scanner images from Iowa with low energy (80kVp) images [left] and high energy (150kVp+Sn) images. The top row shows the 28cm field of view reconstruction of both knees plus the Mindways phantom. The middle row, shows 12cm reconstruction of the right knee, and the bottom row shows the 12cm reconstruction of the left knee. At Iowa the Siemen's Qr40 reconstruction kernel is used, and at Alabama, the GE Standard kernel is used. At Alabama the energy settings used are 80 KEV and 140 KEV, and the field of view is 14cm.



6. Entering patient and scan details

6.1 Labeling the images

If possible, use the following information when performing the scan, otherwise, use this information when blinding images prior to sending to UCSF:

The following information should be entered as the study is started and prescribed so that the information will appear on the images sent to the Coordinating Center at UCSF.

Patient Entry Screen

1. Patient ID = Use your own internal ID /MRN if needed
2. Patient Name = MOST Participant ID# + 4-letter MOST Acrostic
3. Birth Date – leave blank or 01/01/1950 (Enter true date if required by site)
4. Sex = enter gender (male or female)
5. Age = leave blank if possible (Enter if required by site)
6. Weight = leave blank if possible (Enter if required by site)
7. Operator = enter staff MOST ID#

For the bilateral, large field of view reconstructions of both knees, ensure a label "Bilateral Knees" or "Both knees" is recorded. For the smaller field of view reconstructions of only one knee, ensure the correct label "Left Knee" or "Right Knee" is recorded. If possible ensure that the relevant reconstruction kernel name is also recorded with the relevant reconstructed series.

IMPORTANT:
If real patient name, medical record number (MRN), age and date of birth are required for scanning at your facility, make sure to replace any MRN and patient name with the MOST Participant ID and 4-letter MOST ACROSTIC before sending image to UCSF.

6.2 QA checks of CT images by the CT technologist

The CT technologist is responsible for ensuring that the quality of the examination and images is evaluated *before* the participant is released from the examining room. Poor quality images (those that exhibit any of the quality problems described below) should be repeated.

If the image cannot be improved, the reason should be stated in the "Comments" field on the Knee CT data collection form. Please detail any participant or equipment issues, e.g. large knee/thigh or knee pain/participant cannot stay still.

Each participant's scans should be checked for:

1. Completeness
   Were all of the reconstructions performed? If not, record which were not obtained and why on the Knee CT data collection form. Check "No" and enter the reason not acquired.

2. Protocol adherence
   The data has been acquired using the correct parameters in strict accordance to this Knee CT manual (see Section 5). Please indicate non-standard parameters and explain why on the "Comments" section of the Knee CT data collection form.
   Note: Please indicate any deviation from the CT protocol and explain the reason for deviation on the Comments section of the Knee CT data collection form.

3. Image quality
   Images should be checked at the time of the exam by the CT technologist for possible problems listed below before the participant is released. Images that do not meet these quality criteria should be reacquired. If the problem cannot be resolved with reacquisition, record the reason for the problem on the Knee CT data collection form for each knee (right/left) affected, and indicate the reason on the Comments section of the form.
   - **Incomplete coverage of anatomy**
     Complete coverage of bony anatomy is very important, otherwise the examination will be incomplete and the scans might not useful for radiologist reading. If anatomy is insufficiently covered, the reconstruction should be repeated. It does not matter if some soft tissue around the knee is outside the field of view (FOV) in the reconstructions of either knee, but the center of the knee joint should be in the center of the reconstructions' FOV. The example images in section 5.5 show that bony anatomy is all within the FOV, and it is OK even though soft tissue is outside the reconstructed volume. For large knees, you may want to increase the FOV to ensure complete coverage of bony anatomy.
   - **Motion artifacts**
     Positioning the participant comfortably using cushions and pads around the knees, immobilizing the feet, and emphasizing the importance of lying still can minimize participant motion artifacts (Refer to section 4.1 Participant positioning). Images degraded by participant motion artifacts should be repeated after correcting any causes of participant discomfort or anxiety. Often verbal reassurance is sufficient to allay mild participant anxiety. This is particularly important for people with painful knees.

6.3 Completing the knee CT data collection form

If the knee CT data collection form can be completed online at the time of the scan and transfer of images to UCSF, the CT technologist can complete the entire Knee CT data collection form as soon as the images are acquired and transferred. This may be done electronically online at https://keeptrack.ucsf.edu but paper forms are available if necessary.

If electronic data entry is used, print or save the completed form to a PDF file **BEFORE clicking the submit button** and then e-mail the PDF version to the MOST Clinic Coordinator.

If the CT scanning facility cannot transfer images at the time of acquisition (e.g.: if the scans have to be sent to a PACS system and then blinded and transferred to UCSF later), a paper data collection form will have to be used and only Section 1 is completed at the time of acquisition by the CT Technologist:

- The MOST ID# and Acrostic will be preprinted on the form, but must be verified by matching the ID badge the participant is wearing and the ID, ACROSTIC and name in the participant's study chart before the CT is completed.

- If scan parameters were changed (e.g.: the reconstruction field of view or axial extent of the scan were less that specified in the protocol), or there were technical problems, enter the relevant information at the "Comments:" for the relevant knee and reconstruction.

- If there were any other problems affecting image quality (e.g., participant couldn't stay still, participant required internal/external rotation of knee for comfort), record those at the "Comments:".

If images are being sent on physical media (e.g.: an external hard drive), send paper copies of the data collection form to the MOST Clinic Coordinator with only section 1 complete, and section 2 blank, at the same time that images are sent.

6.4 Transfer of images from the CT scanner to the MOST Clinic Coordinator

Iowa: The radiology technologists will be transferring the CT data to UCSF via secure FTP. The radiology center will keep all data until they are informed that it can be deleted.

Alabama: Ensure that any Knee CT data collection forms are returned from the CT scanning facility to the MOST Clinic Coordinator. Images should be kept on the PACS system until UCSF has confirmed receipt and, after that, for the period of time required by the UAB's own policy.

7. Transfer of images to UCSF

A secure (FTPS) protocol will be used to transfer the images to UCSF. Ensure that the MOSTID/ACOSTIC are recorded as the PatientID/PatientName of the images prior to transfer.

The ftp server details are as follows:

Server:	mostftps.sfcc-cpmc.net
Port:	990
Encryption:	implicit FTP over TLS required

The username/password for each clinic will be provided by the MOST Coordinating Center.

Please e-mail MOST Coordinating Center every time images are transferred along with a list of the MOSTIDs of the participants with images being transferred.

8. Image QA at the UCSF Coordinating Center

8.1 QA review of participant images

Upon receiving the images, the UCSF Coordinating Center will check the images to confirm that all PHI/PII has been removed. This includes reviewing the DICOM headers. In addition, the UCSF Coordinating Center will check the images against the data received from the Knee CT Data Collection Form to ensure that the protocol has been followed. The images will also be checked for adequate anatomical coverage and the presence of artifacts.

UCSF Coordinating Center staff will send the repeat and/or resend requests for CT scans to the clinical sites regularly. Resend requests should be performed from the ClearCanvas workstation software as soon as possible. Participants identified for repeat scans should be scheduled as soon as possible, and if a repeat proves impossible, the Coordinating Center should be informed.

If problems with image quality or protocol adherence are encountered, the UCSF Coordinating Center will work directly with the clinical site to correct the problem.

Request for repeat scans, in the event that the initial scan is unusable or missing, will be sent as a MOST numbered memo. While it is important to have usable scans on all eligible participants, we realize that practical considerations may make it difficult for some participants to return for a repeat CT. Therefore, it will be left up to the clinical and professional judgment of the study coordinator and onsite investigator to decide whether to re-contact the participant. If a participant is not re-contacted or refuses to undergo a repeat CT, the study coordinator must notify the CT QA and Reading Center, so that this can be noted in the database comments field, and the repeat request cancelled.

9. Questions and contact information

Removed for public release

Appendix 1 Knee CT Technologist Certification Form

This section to be completed by the MOST Clinic Coordinator:

This form is to be used to request Knee CT technologist certification. Each technologist will receive a technologist ID for the MOST study. Be certain that each knee CT is obtained according to the protocol. Knee CT scans should be sent to the Coordinating Center in the usual manner. The images will be reviewed for image quality and protocol adherence.

After a new technologist has completed 5 scans which pass QC, Felix Liu at the MOST Coordinating Center will contact the MOST Clinic Coordinator with the information that needs to be completed in the following section. Use that information to complete the form and then e-mail the form to Felix Liu at the above address.

1. MOST Field Center: ☐ University of Alabama ☐ University of Iowa
2. Clinic Coordinator: _____
3. Certification of a Knee CT technologist is requested for:

Name: _____MOST Staff ID#_____

4. Date(s) CT scans were sent: _____
5. The 5 sets of Knee CTs submitted to the Coordinating Center for certification are:

	Participant ID	Knee CT Date
1.		
2.		
3.		
4.		
5.		

6. Clinic Coordinator signature:_____ Date _____

This section to be completed by the Reading Center:

1. Date Request Received: _____
2. Action Recommended:
   - Pass without comment: _____
   - Pass with comment: _____
   - Fail: resubmit _____
3. Comments:_____
4. Signature of certifier: _____ Date_____
5. This completed form has scanned and archived. Date:_____