

CARDIA

Cardiovascular Risk Development in Young Adults

CT Scan Site Manual of Operations:

Year 20

CT Exam

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Version 1

For copies of this document:

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Table of Contents

1. Introduction	4
2. Personnel, Facilities and Equipment Involved with CT Exam.....	4
3. CARDIA CT Exam Protocol and Procedures.....	6
3.1 Field Center Scheduling	6
3.2 CT Exam Overview	6
3.3 Entering Participant Identifying Information.....	7
3.4 Pre-CT Exam Activities	7
3.5 Participant Preparation at the CT Scan Site.....	8
3.6 Positioning the Participant and Calcium QCT Phantom on CT Couch ...	8
3.7 Scout Image of the Thorax	9
3.8 Heart 1 CT Scan Series	8
3.9 Breathing Instructions.....	10
3.10 Heart 2 CE Scan Series	11
4. Radiation Dose Estimates for the CARDIA CT Exam.....	11
4.1 Introduction	11
4.2 Informing Participants of Radiation Exposure	12
5. Image Transmission Procedures.....	12
5.1 CT Scan Site Procedures for Electronically Sending Exams.....	12
6. CT Scanner Quality Assurance Procedures	13
6.1 CT System Certification and QA Process.....	13
6.2 CT Initial Certification	13
6.3 CT Calibration	13
7. CT Technologist Training	
Appendices	16
A CT Central Training Curriculum.....	16
B CT Scheduling & Completion Forms	17
C Table of CT Scanner Specific Technical Parameters	20
D CT Technologist Training & Certification Logs	21
E Draft CT Technologist Electronic Training Material	*
F CARDIA/MESA CT Methods Paper.....	*

(* attached as separate files secondary to size considerations)

1. Introduction

- 1.1. The Cardiovascular Risk Development in Young Adults Study (CARDIA) is studying the relation between risk factors for heart disease early in life and calcified atherosclerotic coronary plaque (CACp) as measured by cardiac computed tomography (CT). Participants of prior CARDIA exams will be recruited for a cardiac CT exam as part of the CARDIA year 20 exam.
- 1.2. This document is the CT Scan Site manual of operations for the Year 20 CT exam of the Cardiovascular Risk Development in Young Adults (CARDIA) Study.

2. Personnel, Facilities and Equipment Involved with the CT Exam

A CT technologist from each of the CT Scan Site will be designate the “lead technologist” and will receive CARDIA CT examination-specific training at the WFUHS CTRC by Dr. J. Jeffrey Carr on April 20 and 21, 2005. The lead technologist at each CT scan site will coordinate the local CT activities related to CARDIA and will serve as a key liaison between the CT scan site and CTRC located in Winston-Salem, NC.

CT Scan Site technologists should have expertise with CT and their specific CT scanner as well as basic knowledge of anatomy related to the thorax and heart. It is recommended that technologists also have at least two years of experience in chest/cardiac computed tomography. The lead technologist should also have basic computer skills and access to a business email account.

The CTRC will develop training material to provide the CT technologists with detailed knowledge of the CT protocol as well as the quality control procedures required during the year 20 CT exam.

CARDIA CENTERS

- 2.1. Coordinating Center
 - O. Dale Williams, PhD – Principal Investigator
 - Sharina Person, PhD – Imaging CC Investigator
 - University of Alabama at Birmingham
- 2.2. CT Reading Center
 - J. Jeffrey Carr, M.D., M.S. – Principal Investigator
 - Wake Forest Univ. School of Medicine – Radiology and Public Health Sciences
 - Winston-Salem, NC
- 2.3. Field Center CT facilities
 - 2.3.1. Beth Lewis, MD

Univ. of Alabama at Birmingham (UAB)
General Electric Lightspeed16
UAB Kirklin Clinic
Birmingham, AL

2.3.2. Kiang Liu, Ph.D.
Northwestern University (NWU)
CT Site – Univ. of Illinois
George Kondos, MD (Cardiology)
GE-Imatron C-150
Chicago, IL

2.3.3. Steve Sidney, MD, MPH
Kaiser Permanente (USF)
HeartScan Walnut Creek
GE-Imatron C150
Oakland, CA

2.3.4. Pam Schreiner, Ph.D., M.S.
University of Minnesota at Minneapolis
Fairview UMC
Siemens Biograph 16 CT/PET with Cardiac Package
Minneapolis, MN (UMN)

Figure 1 - CARDIA CT Sites and Identifiers

Field Center state & ID#	CT System (OEM)	Participant ID #	Technologist ID #	Site Investigators
AB = 1	GE LS 16	1xxxx	123	C. Beth Lewis, MD Hrudaya Nath, MD
IL = 2	GE-Imatron-C150	2xxxx	223	Kiang Liu, PhD / George Kondos MD
MN = 3	Siemens Biograph 16	3xxxx	323	Pam Schreiner, PhD
CA = 4	GE-Imatron-C150	4xxxx	423	Steve Sidney, MD

Field Center state & ID#	CT System (OEM)	CT Scan Site Lead CT Tech.	Field Center Principal Investigator	Field center Project Manager
AB = 1	GE LightSpeed 16	Jeff McGough, Kirklin Clinic	C. Beth Lewis, MD	Phil Johnson, UAB
IL = 2	GE-Imatron-C150	Annette Neuman Univ. Ill-Chicago	Kiang Liu, PhD NWU	Sue Jeriorny, 312-996-0862
MN = 3	Siemens Biograph 16 Install April 15 – CT same as Sensation 16	Bob Rickard, (612) 273-6632 Fairview	Pam Schreiner, PhD	
CA = 4	GE-Imatron-C150	Kathy Roach HeartScan	Steve Sidney, MD	

Each center will be responsible for scanning approximately one fourth of the cohort of 3200 participants. For purposes of increased reliability and quality

control, each participant will receive two sequential CT scans for the measurement of calcified coronary plaque during the year 20 CT exam.

TRAINING OF TECHNOLOGISTS

The lead CT technologist from each of the four Field Centers will come to WFUHS for a central training session at Winston-Salem by CTRC personnel on 4/20/05 and 4/21/05. The training sessions will include didactic, small groups and hands on training. During the course the lead techs will complete the certification test and observe CT scans of participants and QC procedures. They will leave with a comprehensive understanding of the CARDIA year 20 CT protocol. It is anticipated that upon completion they will be "Provisionally Certified". They will return to their local CT scan site with new knowledge and training material for the other technologists at their site. During the pilot phase the technologists will complete the 3 certification exams on their CT system. Each of these scans will also be rated on technical quality criteria and immediate feedback will be provided. These exams will be reviewed by the CTRC personnel and either further training or full certification will occur.

3. CARDIA CT Exam Protocol and Procedures

3.1. Field Center Scheduling

The CARDIA local investigators will arrange details of scheduling participants for the CT exam. Scheduling details will likely be unique to each site and will be mutually agreed upon between the CT scanning center and Field Center. ***A Field Center interviewer/scheduler will be responsible for explaining and obtaining consent for the CT examination including pregnancy screenings.*** Participants will be scheduled for a certain date and time, and transportation arrangements, if necessary, will be arranged by the Field Center interviewer/scheduler. A confirmation appointment letter will be sent, providing the time, date, and directions to the scanning center, and describing the procedure. The Field Center will fax or otherwise transmit to the CT scanning center the ***CARDIA CT Exam Form*** (CARDIA Form 76 – example Appendix B) along with a cover sheet which identifies the participant by name. The CT Technologists need to have the individuals real name to confirm identity. This cover sheet contains the appointment information for the CT exam, directions to the local CT facility and the participant's name and other identifying information necessary for communication between the participant and the CT scanning facility. Form 76 provides the detailed information required by the CT scanning sites for performing the exam. (See Appendix B)

Required information for the CARDIA CT scheduling form includes the participant's name (for scheduling and greeting purposes only), participant's weight (as recorded at the clinic visit), and date of birth, CARDIA study ID and CARDIA alpha numeric code.

3.2. CT Exam Overview

The CARDIA CT examination is designed to provide volumetric CT image data for measuring coronary calcified plaque. The exam consists of scout images and two ECG gated series of the entire heart. On average, 10 minutes of participant time will be spent within the CT scan suite; this includes instructions, setup and imaging. In rare cases, the exam may require 20 minutes. In many cases, the examination will be completed in less than 10 minutes. Participants will have ECG electrodes attached (according to your vendors recommendations) for cardiac gating and be instructed as to a standardized breath holding instructions.

Figure 2 CARDIA CT Series:

Series	Description	No. of images	Scan time	ECG gating
1	Scout of thorax ¹	2	7 sec x 2	no
2	Coronary scan 1 ²	40-50	20-40 sec	yes
3	Coronary scan 2 ²	40-50	20-40 sec	yes

¹Scout images will consist of a frontal and lateral low energy 2D scanogram when possible

²Duplicate scans will be obtained of the coronary circulation to improve the precision of the calcium measurement.

3.3. Entering Participant Identifying Information for CARDIA

The CT scanners to be used in this study store demographic, detailed scan technical information and the raw image data in the standard DICOM file format. Participant identifying information will be encrypted at each CT site for the following reasons:

- 1) Safeguard participant confidentiality.
- 2) Comply with federal requirements for medical information, Health Insurance Portability and Accountability Act of 1996 (HIPAA).
- 3) Provide positive and redundant participant identification for CT image files now and in the future.

The data coordinating system has assigned a unique study identification number for each CARDIA participant.

The study identification number (5 digits) will be entered in the field on the CT scanner where the local medical record numbers is typically placed. An "alpha code" (5 letters) will be entered in the name field followed by the participants weight in pounds.

Additional information such as the date-of-birth, ordering physician, CARDIA Year 20 should be entered on your "Patient Demographic"/"new exam screen".

*** It is very important that you enter your technician ID number that we assign to you somewhere on this “new exam” screen. This may vary between CT vendors, but most systems have a field for entering the CT technologists name/initials. Please type your tech ID in this location. If you do not have a field for this on your CT scanner please call the CTRC for additional help in resolving this issue.

Example CT Data Entry:

Name	BJDEC175 (get from form 76)
ID number:	12345 (get from form 76)
Date of Birth	03 MAR 1947
Technologist	432 (we will assign a tech ID)
Gender	Male
Weight	175 (also append wt. to the alpha code)
Ordering Phys.	Dr. Welby (optional but recommended- use site PI or alternate)
History	CARDIA Year 20 Coronary Exam

The series number and time stamp on each CT image will ensure proper identification of the first (series 2) and the second (series 3) heart /coronary CT scans. Scan technical data (site, CT scanner, kV, mA, fov, slice thickness, spatial resolution, kernel etc.) are automatically stored within the DICOM header as part of the DICOM standard for each image file and will be recorded and tracked by the CTRC.

3.4. Pre-CT Exam Activities

Subjects weighing more than 160 kg (352 lbs) will be excluded from the CT exam secondary to technical difficulties related to imaging individuals of this size and greater although this may vary by site.

Pregnancy Screening: The field center personnel will ask women if they have the potential to be pregnant and complete pregnancy screening process as detailed in the Clinic Exam procedures. This will be documented on the CT completion form. If the participant is not “Exempt” or has a “negative pregnancy test” documented on Form 76 – DO NOT DO THE CT EXAM and CALL the LOCAL CLINIC FOR FURTHER DIRECTIONS.

After CT technologist reviews Form 76 and determines that the Pregnancy Screening has been appropriately completed they will ask all female participants:

“Is there any chance you could be pregnant?”

If the answer is “NO chance of being pregnant” – continue with the CT exam

If the answer is “Yes or inconclusive” – terminate the CT exam and contact the local CARDIA clinic. This may appear to be repeating effort but just like in clinical practice we want to minimize any potential risk.

CT inclusion criteria:

1. Enrolled in CARDIA study
2. Pregnancy screen completed

CT exclusion criteria:

1. Weight greater than 160 kg (352 lbs), but may vary by site
2. Pregnant or pregnancy status unknown
3. Participant answers “Yes or indeterminate for pregnancy status” to the to the CT Technologist immediately prior to entering the CT scan suite.

3.5. Participant Preparation at the CT Scan Site

The CT Tech:

1. Reviews the CT scheduling cover sheet and Form 76 and matches the true identity with the Study ID and alpha code.
2. Confirms that the clinical pregnancy screen has been completed and documented on the CT Completion form.
3. Inquires as to the possibility that the female participant may be pregnant as discussed above.

The technologist will instruct the subject on the importance of breath holding and immobility during scanning. The technologist will attach 3-4 electrocardiography electrodes under the left clavicle and on either side of the thorax near the axilla (to maximize ECG signal) or as instructed by your equipment provider.

Example Script for instructing Participants:

Technologist: “Hello Ms. Smith I understand you are here for your Research CT exam for CARDIA. I see that the clinic has already tested to see if you could be pregnant – but is there any chance that you could be pregnant?”

Ms. Smith: “How many times are people going to ask me about that? – No chance at all.”

Technologist: “We are just being extra careful. The exam takes less than 15 minutes. You will be positioned on your back on a special table. I will connect ECG leads which allow us to track how your heart is beating during the CT scan. It is very important that you hold your breath for the 15-30 seconds that it takes to make the images of your heart and you will be asked to do this 3-4 times. Do you have any questions?”

3.6. Positioning the Participant and Calcium QCT Phantom on the CT couch

The participants can be positioned for the study feet first or head first. The rectangular calcium calibration QCT Phantom will be placed underneath the heart and included in the field-of-view for both CARDIA Cardiac CT scan series. A foam cushion is provided with the calibration pad phantom to provide for subject comfort. The calibration phantom will be placed inside the blue catcher bag with its long axis parallel to the long axis of the scanning table. The phantom is made of tissue equivalent plastic with rods of hydroxyapatite of known radiographic density. For the cardiac scans, the QCT phantom will be positioned directly behind the thoracic spine and the heart. The superior extent will be above the carina and inferiorly beyond the lower aspect of the heart.



- 3.7. **Scout Image of the Thorax** The technologist will instruct the participant using the standard breathing instructions, (at end-inspiration), while acquiring two scout images of the thorax (Frontal and lateral scout images, aka scanograms or tomograms).

The technologist will check patient centering and position of the Calcium CT Calibration Phantom (See Appendix B, arrows indicate location of rectangular phantom). The technologist will then choose the start position for the highest group of four slices just below the carina of the trachea. The end location of the volume acquisition will be beyond the diaphragmatic aspect of the heart so that the entire coronary arterial system will be imaged. The CT couch will be moved to the start position. The technologist will confirm correct positioning of the calcium phantom on the scout image and reposition if necessary.

3.8. Heart 1 CT Scan Series

Scanning procedure for cardiac gated CT scans of the coronary arteries are based on the standard protocols developed during the year 15 exam {Carr, 2005 #2252}. To ensure complete coverage of the entire heart, a minimum of 10.5 cm of image data in the z direction (head-to-foot) will be acquired with each scan. This coverage results in 45-55 slices depending upon the length of the heart. The heart scans will be reconstructed centered on the heart using a display field-of-view of 35 cm. This will include the Calcium QCT phantom within the images as well as the majority of the lungs.

****** One of the CT quality factors is inclusion of the phantom on the cardiac CT images – the technologist should confirm that the entire QCT phantom (i.e. all four cylinders) are visible on each slice – if not reconstruct the images altering the left-right or anterior-posterior positioning while maintaining a 35 cm DFOV to include the entire phantom. *******

Technical Parameters for each CT system is in Appendix C.
Participant Weight and the CT exam:

Participants weighing more than 160 kg (352 lbs) or your locally determined limit will be excluded from the CT exam. As individuals become larger more X-ray photons are stopped or attenuated by their tissue. This means that there are fewer photons making the trip through the participant to make an image. This results in decreased image quality. To compensate, **the tube current (or mA) will be adjusted upwards (25%) for participants who weigh more than 100 Kg (220 lbs.) at their clinic visit. This is why clinic personnel must record weight on the CT completion form, in addition the CT tech must append the weight after the name.**

This adjustment, although imperfect, will maintain a more constant signal-to-noise ratio (or photon flux) across participants of varying weights and result in improved image quality and calcium measurement. Note that this along with all the additional technical and demographic information including individual time stamps for the scan, scan series and individual image is recorded in the DICOM header which is part of each image and will be available on the CT image library of all the CARDIA studies as part of our quality control procedures.

Reconstruction Parameters:

The following technical parameters should be entered into a memorized protocol on each CT system, which should greatly facilitate protocol compliance. All series will be performed using the large scan field-of-view. This may also be referred to as the “body” as opposed to the “head” scan field-of-view. The technologist will reconstruct using a display or reconstruction field-of-view of 35 cm (or 350 mm). *Why are we scanning the heart with a 35 cm fov? By reconstructing with a 35 cm fov we insure that the QCT phantom is included in the reconstructed images. It is very important when prescribing the scan to make sure that the anterior-posterior center is such that the entire phantom is included in the image. You will have to center AP behind the heart on individuals with very large chest. If while reviewing*

your images you see that the phantom is partially clipped off, reconstruct the series with the appropriate AP offset. Be sure to check this on the first heart scan. The standard reconstruction kernel will be used for the two cardiac series. For the cardiac series, the 240 degree (scan reconstruction algorithm will be used (note that this option has various names depending on vendor (segmented, ultrafast)).

Additional Reconstructions: We would like for both heart 1 & heart 2 for you to program into the protocol two additional reconstructions.

- 1) "5-50 recon" 5 mm slices with 50 cm DFOV. These images we will use along with the scout to obtain information about the chest wall, muscles and fat.
- 2) "Hi-res Recon" Thin slice recon at 1 mm – 1.5 mm with a 26 cm DFOV around the heart.

Figure 3 - Table CT Image Reconstruction Parameters

Series	Scan FOV	Display FOV	Kernel	Recon. type
Heart 1&2	Large / Body / 55 cm	350 mm	GE=standard Siem=b30f Imatron=Sharp	240° (partial) quick scan

3.9. Breathing Instructions

All CT scan sequences will be performed with suspended respiration and a single breath hold. The two cardiac scan series will require participants to suspend respiration a variable amount of time, ranging from 10 to 30 seconds, depending upon the combination of heart rate and heart length. The technologist will instruct the participant as described above and then a standardized digitally recorded voice will provide breathing instructions. Breathing will be suspended at end inspiration to depress the diaphragm and liver for improved imaging of the heart.

Standardized Script for breathing instructions:

- "Take a deep breath in... <5 sec. pause>
- "Blow it all the way out... <5 sec. pause>
- "Take a deep breath in... <5 sec. pause>
- "Blow it all the way out... <5 sec. pause>
- "Take a deep breath in and hold your breath
- <15-40 scan acquisition>
- "Breathe and relax"

Though total imaging time will be approximately 15 to 40 seconds, performing the repeated measure of the heart (Heart 2) will require about 5 to 7 minutes to complete. The technologist will first acquire one entire series of image slices. The technologist will instruct the subject to relax on the table while he/she

reconstructs and assesses the adequacy of positioning, ECG gating and lack of respiratory motion. A two-minute recovery period is required for the participants in between the repeated scan series of the heart.

3.10. Heart 2 CT Scan Series

The procedures for the heart 2 CT scan series are identical to heart 1. Prior to performing this series the technologist will review the images of Heart 1 CT scan series during the participant's 2 minute recovery period. If these are acceptable as to participant positioning and scan coverage, the technologist will immediately acquire another series of image slices while the subject remains immobile and in an identical position. If adjustments to the prescription are needed, these will be made on the Heart 2 scan series. *A repeat of Heart 1 CT series is not required and should not be performed. If an unrecoverable error is made (i.e. cannot be fixed through a retrospective reconstruction) then to reduce participant radiation exposure the study will rely on one measurement of coronary calcium.*

4. Radiation Dose Estimates for the CARDIA CT EXAM

4.1 Introduction

The CT exam involves the use of ionizing radiation (X-rays) to generate images of the participants, which are then analyzed to provide quantitative information for scientific investigation. The level of exposure utilized in the CT exam is on the same magnitude as that typically used in diagnostic imaging. The next section describes the potential risks of exposure to low levels of radiation and where along the continuum from the average natural exposure of 3.6 mSv annually the dose for participants in this study is located. The radiation exposure in this CT exam is well below the threshold for any observable direct dose related effects of ionizing radiation. Therefore the concerns of low-level radiation exposure for participants of CARDIA are the potential for (1) hereditary defects, (2) developmental defects for exposure of a fetus/embryo in utero and (3) cancer induction. The CARDIA CT Exam is designed to minimize or eliminate these potential risks. Specifically the following steps have been implemented:

1. To reduce the risk of any radiation induced hereditary effects, the gonads (testes and ovaries) are not directly irradiated in the CARDIA CT exam.
2. To in all likelihood eliminate the potential risk of any radiation induced developmental defects to an embryo/fetus as a result of an CARDIA CT exam, female participants who have the potential to be pregnant (i.e. functioning ovaries and uterus) will be required to have a pregnancy test prior to being eligible for an CARDIA CT exam. In addition, the pelvis receives negligible exposure since it is not imaged.
3. To reduce the risk of any radiation induced cancer, we are using a low radiation dose scan as possible to obtain the information necessary to accomplish the goals of this research. This will be approximately 3.6 mSv,

which is much less than the 7.0 mSv annual exposure for residents of Denver, Colorado.

Participants in this study will receive a one-time exposure of less than 5 mSv with the typical exposure of less than 2 mSv. This level of radiation exposure is equivalent to less than two years of average annual background exposure (secondary to natural and man-made sources of radiation) and much less than the 50 mSv annual exposure allowed for radiation workers.

4.2 Informing Participants of Radiation Exposure:

To provide participants with a concise and understandable explanation of the radiation involved with the CT exam we have chosen to present the effective dose. The effective dose estimates the exposure by organ irradiated and allows the values to be compared directly with the annual exposure to natural sources of radiation (3.6 mSv) and the annual allowance for radiation workers(50 mSv). We believe that the alternatives of (1) simply providing a number out of context or (2) comparing the dose to other medical procedures, while informative to scientists and healthcare professionals, is less informative to the lay public. The following language is recommended to the field centers for informed consent concerning the CT exam. Local requirements or standard language may require modifications as appropriate.

Recommended Language for Informed Consent or for questions that may arise from participants during the clinic of CT exam:

The estimated amount of radiation (effective dose) the average participant in this study will receive is less than 6 mSv. This amount of radiation exposure can be compared to the amount of radiation exposure you get each year from natural and man made sources which is 3.6 mSv (average annual background exposure). If you are located in Denver Co. the annual exposure is 7 mSv. The actual amount you receive for the CT exam depends on several factors such as how big you are and if you are a man or women; however, the range of these values is between 1.5 and 2 times the average U.S. background exposure you receive each year. People who have jobs in which they work with radiation have a yearly limit of 50 mSv. The amount of radiation you will receive by participating in this study is approximately 13% of this annual limit for radiation workers.

We believe the above language accurately and conservatively presents the information related to radiation exposure with the CARDIA CT exam and will allow our participants and potential participants to make an informed decision about involvement in this study.

The investigators of CARDIA are aware that local review and approval of the CT protocol, as for other aspects of the study, must be made through the appropriate local Investigational Review Boards (IRB). In some cases additional review by radiation safety committees may be required. The CT Reading Center will provide assistance and the material contained in the manual of operation to the

field center principal investigator and imaging investigator to facilitate and enhance the process as requested.

5.1. CT Scan Site Procedures for Electronically Sending Exams to the CTRC

The objective is for each CT field site to perform a “DICOM send” to WFU CT Reading Center. The exact configuration and procedures may vary depending upon your local network environment. In most cases CARDIA CT protocol can be preconfigured on the CT scanner so that the images will be automatically routed upon completion of the exam to our secure PACS in Winston-Salem. In some cases the exams may need to be networked to a workstation that is then configured to send to the CTRC. Our objective is for you to send the exam upon completion of the study as part of your routine work flow. The CTRC can receive images continuously and simultaneously from all CARDIA sites. We are able to receive exams 24 hours a day, 7 days a week. The coordinating center at UAB will be monitoring and providing real-time tracking of the work flow.

**** CT technologists should “send” the exam to CTRC upon completion ****

6. CT Scanner Quality Assurance Procedures

6.1 CT Scanner Certification and Quality Assurance

The CT Scanners will complete a certification process prior to the pilot exam. During this process measurement of scan quality will be obtained concerning spatial resolution and contrast resolution with particular attention directed to the calibration of CT numbers.

6.2 CT Certification Process:

1. CT images will be sent to the CTRC to provide format of DICOM header and additional CT scanner specific information.
2. CTRC will ship the Cardiac CT phantom (QRM-Germany) to the site and a series of scans of this phantom will be obtained, burned to a CD and returned to the CTRC for analysis .
3. The QCT phantom & torso phantom used in the year 15 exam will be scanned according to protocol burned to CD and then shipped to the CTRC.

The purpose of the CT scanner certification process is validate the CT scanners ability to measure the know amounts of simulated calcified plaque contained in the CARDIA CT phantom. We will then use this information to fine-tune the CT protocol for each CT system. It will also allow us to understand potential biases between the CT sites as well as confirm the protocol prior to the pilot & cohort exams. It is likely that we will need to repeat this process if changes are made to the protocol.

6.3 CT Calibration

Calibration to Air (Baseline, then daily) - An initial baseline followed by daily scans will be obtained. This calibration is part of the daily scanner start-up routine. These procedures will follow the manufacturer's recommended procedure.

Calibration to Water (Baseline)

An initial baseline calibration will be obtained and analyzed using a water phantom. These procedures will follow the manufacturer's recommended procedure and will include zeroing and calibrating the scanner unit.

Calibration to Calcium (Baseline, then bi-weekly)

Each CT scanning site will be provided a standardized Calcium QCT Calibration Phantom which includes a Torso QA phantom for scanner calibration (Image Analysis Inc, Lexington, KY). The center plug of the Torso QA phantom contains a region with a known concentration of calcium hydroxyapatite (100mg/ml). The Calcium QCT Calibration phantom contains four cylindrical rods with the following concentrations of calcium: 0, 50, 100, 200 mg/ml calcium hydroxyapatite. On the first and 15th of each month quality assurance scans of the torso phantom will be performed at the CT scan site. The analysis of these scans by the CT Reading Center allows convenient and quick verification of accuracy and precision of the CT scanners at different sites.

Positioning the Calibration and Torso Phantoms.

The table height of the CT couch will be positioned such that the center of the Torso Calibration phantom will be located at isocenter of the scanner field of view.

Place the torso phantom on top of the calibration phantom (positioned in couch pad) and using your laser alignment light; adjust the table height until the torso center insert is at the location of isocenter on the CT scanner. This is the table height you will use for QA scans with your Torso phantom.

Scanning the TORSO QA Phantom

After the correct position has been determined, take a vertical axial slice through the center of the TORSO phantom. Use the same parameters as with participant exams. Each site will perform a scout of the phantom followed by an axial scan (identical parameters to the heart series). Reconstruction should be done with the same parameters as in scanning study subjects. Then display your axial image on your CT monitor and examine it to ensure that it is free of artifacts, such as air gaps and streaks. Ensure that the calibration phantom is included in the field of view.

If there are significant artifacts over the calibration phantom, you should discard the image and rescan the phantom.

Using your CT software place ROIs on the calibration phantom reference samples (0, 50, 100, 200 mg/cc). The 0 sample will be an apparent blank space on one end of the calibration phantom. Then place an ROI in the TORSO vertebral sample. The ROIs should be as large as practical while remaining completely within the reference cylinder. (We recommend ROIs about 70% of the sample area.) Record the five mean CT numbers within these five ROIs and send these numbers by FAX or E mail to the CARDIA reading center (Email, fax) using the standard QA forms provided (attached QA Data Sheet). Record the five mean CT numbers within these five ROIs. The QA data sheet will then be filed in the local CARDIA study 3-ring binder for your records.

The QCT & Torso phantom scans provide valuable information concerning the CT scanner and any change over time (temporal drift). It is critical that these scans be performed and the results & images be sent to the CTRC.

******* Torso QCT scans will be performed on or about the 1st & 15th of each month*******

Some common sources that cause poor results include: inappropriate table height (TORSO plug should be at isocenter when scanned); mal-positioning of the phantom; old or improper CT calibrations; use of improper scan parameters.

7.1 CT Technologist Training Material

CT protocol training material will be provided for all technologists from each field site. The curriculum for the CARDIA CT Training is presented in Appendix A and a draft of the electronic education material is in Appendix D. The instructional material will provide the technologist who will perform the CARDIA CT studies an overview of the study objectives, study organization and an introduction to the CARDIA CT Reading Center personnel. It will detail the study protocol and quality control procedures. It will complement this manual of operation and provide pictures to facilitate learning the CARDIA CT protocol.

The experience in MESA and CARDIA with CT technologists is that in some cases multiple technologists at each site are performing protocol exams as part of their work schedule. Although it is desirable to minimize the number of technologists involved, this is, in most cases, outside the ability of investigators to designate. The WFU Reading Center has designed a program to accomplish the following:

1. Identify the technologist performing each CARDIA study
2. Train and maintain skills of each CARDIA CT technologist
 - a. Train a “Master” technologist from each site at WFUHS CTRC
 - b. Provide pre-certification material and exam for each technologist
 - c. Provide Preliminary Certification until completion and review of the 3 studies on protocol.
 - d. Time-limited certification for 6 months
3. Provide feedback to CT technologist on an individual and by site basis
4. Identify protocol variances / violations /and violations impacting participant safety
 - a. Retrain / enhanced training as needed
 - b. Stop CT exams if needed to resolve problem

The training material will consist of a CD with a PowerPoint presentation, this CT manual of operations and a pre-certification exam. Technologists will be required to read the PowerPoint training material and answer the pre-certification exam. Hypertext links will allow the technologist to link directly to the relevant material in the MOO. The pre-certification exam will allow the Reading Center to assign a unique technologist identification which will be entered on every scan performed by the technologist. After successful pre-certification, the next three exams will be performed in conjunction with the Master technologist. After these have been reviewed and accepted, the technologist will be given full certification for 6 months. Every 6 months the Reading Center will create a new training presentation in PowerPoint focusing on core issues and any potential problems identified across all scan sites in the study. A brief questionnaire directed at these issues must be completed by each technologist and returned to the Reading Center to maintain certification. If problems are identified at a specific site, additional training by Dr. Carr may be required. He will review selected studies completed to date and discuss issues related to protocol compliance. Feedback will be provided to the technologists concerning their scan technique for the heart. Questions and issues they may have will be discussed and resolved as appropriate. These visits will take one working day each and will concentrate on obtaining adequate and optimal scan images using the CARDIA CT scanning protocol.

Appendix A

The central training curriculum for CT Technologists:

**CARDIA Year 20 CT Training Course Schedule Itinerary
Wake Forest University Baptist Medical Center, Winston-Salem, NC
April 20-21, 2005**

- **Location:** Wake Forest University Baptist Medical Center, Winston-Salem, NC
- **Local Airport:** Greensboro, High-Point, Winston-Salem (GSO)
- **Transportation from airport to Hawthorne Inn:** PTI Airport Transportation:
1-877-796-5466 (LIMO)
E-mail: www.ptiairporttransportation.com/
- **Hotel:** Hawthorne Inn & Conference Center, 420 High St. Winston-Salem, NC 27101
Phone: (336) 777-3000 or Toll Free: 800-972-3774
Fax: (336) 777-3144
E-mail: www.hawthorneinn.com
When you make your reservations, please mention Sheila Sprigg or Jeff Carr. There is a block of rooms reserved. However, you must still make your reservation. Once made, please call Sheila Sprigg at 336-716-7234.

Wednesday, April 20th

- Travel to Winston Salem
- Arrive by 4 pm Wednesday April 20th
- 6:00 pm – 9:00 pm - Pizza Dinner, Introductions and Lectures

Thursday, April 21st

- 8:00 am - Take free shuttle to the MRI building at Wake Forest Baptist Medical Center
- 8:00 am – 1:00 pm: Training
- 1:00 pm – transport to airport ~ 1 hour

Technologists will need to arrive on 4/20/05. Sheila Sprigg will be the contact person for coordination of housing and scheduling. Each site is asked to pay initially for flights, lodging, meals, and miscellaneous and then submit vouchers to Sheila Sprigg at the end of the training for reimbursement. Sheila Sprigg's e-mail is ssprigg@wfubmc.edu.

Appendix B – CT Scan Completion Form Draft

Form 76
28March05
Page 1 of 1

Participant ID Barcode

Study ID Number:

12345

Name Code:

ABCDE

Y20 - CARDIA VII Scan Completion Form

This box to be completed by <u>Field Center Staff</u>			
Date of Birth: _____		Weight: <input type="text"/> <input type="text"/> <input type="text"/> lbs. (limit 352 lb – round down)	
Sex: Male Female		Signed consent: Yes No	
Pregnancy Test? Exempt	Yes No	Test date: <input type="text"/> / <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	Results: Negative Positive

Remainder of form to be completed by <u>CT Technologist</u>
(If pregnancy test information above not complete, ask participant to complete now.)
Ask female participants: <i>Is there any chance you could be pregnant?</i> Yes No
If answer is “YES” cancel CT exam and call CARDIA Clinic

CT Scanner ID:

Date of Scan: / /

CT Technologist ID:

Exam Number:

Archived locally: Yes No

Where:

GE LightSpeed 16 @ Kirklín Clinic:

axial, ECG@50%, KV: 120, 8i x 2.5 mm, recon std. @ 35 cm dfov.

Set mA by weight →	< 220 lbs	≥ 220 lbs
	320 mA (160 mAs)	400 mA (200 mAs)

	Series #	#images	Heart rate
Scout			
Heart scan 1			
Heart scan 2			

Comments:

Appendix C

The CT Technical Settings for Coronary Scan Series:

At the time of this draft the CTRC has not yet received sample images as phantom scans. Once we receive these images we will update the tables with the specific parameters for each CT scanner.

System	Mode	FOV	Multi-slice	Kernel / recon	time	ECG gating
GE Imatron C-150	Axial	35 cm	1 slice by 3 mm	Sharp / Partial	0.1 s	Prospective
GE LightSpeed 16	Axial Cine	35 cm	8 slice by 2.5 mm	Std / Partial	0.4 s	Prospective
Siemens Sensation 16 Biograph 16	Axial Quick Scan	35 cm	6 slice by 3 mm	B30F / Partial	0.4 s	Prospective

Heart Scans: Adjusting mA / mAs based on Weight					
System	KVp	Gantry speed [s]	Exposure Time [s]	Weight < 220 lbs	Weight = > 220 lbs
Siemens Sensation 16 Biograph 16 TBD Minnesota	120	TBD*			
GE Imatron C150	130	NA	0.1 s	630 mA	NA
GE LightSpeed 16 UAB	120	0.50 s	0.326 s	320 mA 106 mAs	400 mA 133 mAs

*The Sensation/Biograph 16 can rotate at either 0.42 sec. per 360 degree rotation with Akron Tube and 0.37 sec. for the Straton tube. Once installed at Fairview this will need to be determined and the accurate mA/mAs settings determined.

Appendix D:

CT Technologist Training and Certification Procedures:

The WFU CT Reading Center will coordinate with FC personnel for the training of CARDIA technologists. The process will consist of:

- 1) pre-certification training material
- 2) pre-certification test
- 3) detailed review and successful completion of three complete CARDIA CT exams
- 4) quarterly recertification test completion

The lead technologist at each Field Center site will visit the CTRC at WFUHS on April 21, 2005 for certification training.. This visit provides an opportunity for hands-on training and relationship building for the CT exam. During this visit a lead CT tech for the project is designated and trained. Detailed training is provided by an animated and graphical PowerPoint course provided by the RC on CD or via the Internet. This course is based on the CARDIA MOO but includes actual CT exam images and pictures documenting critical aspects of the CT exam and quality control procedures. A written exam must be completed. Following the successful completion of the pre-certification exam the RC will issue a technologist ID number and preliminary certification. The RC will then review each exam by the Technologist and provide full certification once three exams have been completed with complete protocol adherence. Written quarterly recertification will be required to maintain skills.

Figure 4 CARDIA CT Technologist by Site

Field Center state & ID#	Name	Years Exp.	Licensing	CARDIA (MESA) Tech ID #
UAB = 1				
NWU = 2				
UMN = 3				
USF = 4				

Figure 5 CARDIA Technologist Training Record:

Field Center	Name	Tech ID #	Cert. Exam	Pre-cert. date	Full-cert. Date	Re-cert 1	Re-cert 2
UAB=1							
NWU=2							
UMN=3							
USF=4							