

# **Women's Health Initiative Coronary Artery Calcium Study (WHI-CACS)**

## **CT Scan Site Manual of Operations:**

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For copies of this document:

J. Jeffrey Carr, MD, MSCE  
Nancy Buchheimer, BS  
Section on Radiologic Sciences  
Wake Forest University Health Sciences  
Medical Center Blvd.  
PP2 – Suite 618  
Winston-Salem, NC 27157  
336-716-5620 (O); 336-716-4340 (fax)  
[jcarr@wfubmc.edu](mailto:jcarr@wfubmc.edu)  
[nbuchhe@wfubmc.edu](mailto:nbuchhe@wfubmc.edu)

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## **1. Introduction**

- 1.1. The WHI Coronary Artery Calcium Study (WHI-CACS) is a sub-study of the WHI E-Along Clinical Trial arm
- 1.2. The objective is to measure coronary atherosclerosis in women in the Estrogen-Along trial who were 50-59 at the time of enrollment and compare those who received estrogen to those who received placebo.
- 1.3. In WHI-CACS we will measure Coronary Artery Calcified Plaque (CACp) using a CT scanner with cardiac gating capability. The images will be analyzed at Wake Forest University Health Sciences in Winston-Salem, NC.
- 1.4. The WHI-CACS data will be analyzed at the central coordinating center for WHI located in Seattle, WA.
- 1.5. This document is the CT Scan Site manual for WHI-CACS.
- 1.6. Detailed background from the Clinical Site Manual:  
The WHI Coronary Artery Calcium Study (WHI-CACS) is a sub-study of the WHI E-Along Clinical Trial that seeks to assess the status of coronary atherosclerosis among women aged 50-59 years at baseline in the Estrogen-Along trial. The study utilizes electron beam computed tomography (EBCT) or multi-detector computed tomography (MDCT) to assess the presence and extent of calcification due to atherosclerosis in the coronary arteries. This measurement will allow for a comparison of atherosclerotic burden among women who had been randomized to estrogen-alone compared to women randomized to placebo after a mean of 7.1 years of treatment. The operational goal is to complete these measurements on 450 women randomized to estrogen-alone and on 450 women randomized to placebo at the 28 participating Clinical Centers (CCs). A total of 1,781 E-Along women are eligible at these CCs and will be invited to participate in this sub-study. A maximum of 950 participants will be enrolled in this study to ensure that we have complete calcium measurements on at least 900 eligible women. The primary analyses will be based on "intention-to-treat" and secondary ("sensitivity") analyses limited to women with good adherence to study pills (>80% adherence). The strategy is to complete the scans by July 10, 2005 to ensure that measurements are obtained as soon as possible after discontinuation of study meds, in order to minimize the dilution of treatment effect.

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

A CT technologist from each of the CT Scan Sites will be designated the "lead technologist" and will receive training through a series of conference calls scheduled in May 2005. The lead technologist at each CT scan site will

coordinate the local CT activities related to WHI-CACS and will serve as a key liaison between the CT scan site and the CT Reading Center (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 CT exam.

### **WHI-CACS Clinical Centers (CC-CT)**

- 2.1. In Appendix A is the list of Clinical Centers anticipated to be participating in WHI-CACS and available information related to the type of Cardiac CT system planned for the study.
- 2.2. In Appendix B is the Study Timeline

Each center will be responsible for scanning approximately 25-35 participants during the 2-month period that the CT exams will be obtained. Each participant will receive a scout followed by one non-contrast prospectively ECG gated series through the heart. The exam will then be completed, archived locally, burned to a CD and the CD sent via 2<sup>nd</sup> Day delivery to the CTRC at Wake Forest. Details of these procedures are contained in the following material.

### **TRAINING OF TECHNOLOGISTS**

The lead CT technologist from each of the four Field Centers will participate in a series of teleconferences with the CTRC scheduled for May 2005. The training sessions will review a PowerPoint slide presentation developed by the CTRC for the WHI-CACS. In addition a 3 ring binder with this material will be delivered to the lead tech to keep WHI-CACS study related material, which includes hardcopies of this manual of operations and the training presentation. After completing the training presentation, the technologist will complete a brief questionnaire. The CTRC will review the responses and issue a CT technologist identifier.

## **3. WHI-CACS CT Exam Protocol and Procedures**

### **3.1. Field Center Scheduling**

The CC local investigators will arrange details of scheduling participants for the CT exam. The CC will fax or otherwise transmit the CT **Worksheet - Appendix B** to the CT scan facility. The worksheet contains the study

identifiers and name codes that will be used in place of the medical record number and participant's real name.

### 3.2. CT Exam Overview

The **WHI-CACS** CT examination is designed to provide volumetric CT image data for measuring coronary calcified plaque. The exam consists of scout images and one ECG gated series of the entire heart. On average, 6 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 15 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 1 WHI-CACS CT Exam by Series:**

| Series | Description                  | No. of images | Scan time | ECG gating |
|--------|------------------------------|---------------|-----------|------------|
| 1      | Scout of thorax <sup>1</sup> | 2             | 7 sec x 2 | no         |
| 2      | Coronary scan <sup>1,2</sup> | 40-56         | 10-40 sec | yes        |

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

<sup>2</sup>Scans times will vary based on CT system used and participants heart rate at the time of scanning.

### 3.3. Entering Participant Identifying Information for WHI-CACS

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 WHI-CACS participant.

***The study identification will be entered where the local medical record numbers is typically placed. An "alpha code" will be entered in the name field.***

Additional information such as the date-of-birth, ordering physician," **WHI-CACS Study**" should be entered on your "Patient Demographic"/"new exam screen".

\*\*\* It is very important that you enter your technician ID/initials 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 technologist's 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           | BJDEJPWE (from worksheet)                                   |
| ID number:     | 1201234L (from worksheet)                                   |
| Date of Birth  | 03 MAR 1947                                                 |
| Technologist   | 432 (we will assign a tech ID/initials)                     |
| Gender         | Female                                                      |
| Ordering Phys. | Dr. WHI (optional but recommended-use site PI or alternate) |
| History        | WHI-CACS                                                    |

The DICOM header will identify scanner location and exam date and time. 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 300 lbs will be excluded from the CT exam and not scheduled. This limit is secondary to study design and technical difficulties related to imaging individuals of this size and greater.

**Pregnancy Screening:** The women who are participants in WHI-CACS were required at study entry to have previously had a hysterectomy. Thus, by definition they cannot be pregnant during the CT exam. We realize that your local policies may dictate completing your local pregnancy screening procedures prior to CT scanning. If you have any questions concerning this please contact your local WHI clinical center or us.

**WHI-CAC CT Eligibility Criteria:**

1. Enrolled in WHI-CACS study – Individuals in this study have previously had a hysterectomy prior to being enrolled in the Estrogen alone arm of the trial.
2. Age 50-59 years at randomization to the Estrogen-Alone Trial.
3. Last data-entered weight 300 pounds or less and currently reported weight of 295 pounds or less.

### 3.5. Participant Preparation at the CT Scan Site

#### The CT Tech:

1. Reviews the CT Imaging Worksheet and matches the true identity individual with the Study ID and alpha code.
2. Confirms that the individual is part of the “Women’s Health Initiative Study”

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 clavicles and on the left side of the thorax near the axilla (to maximize ECG signal) or as instructed by your equipment provider.

Example Script for instructing Participants:

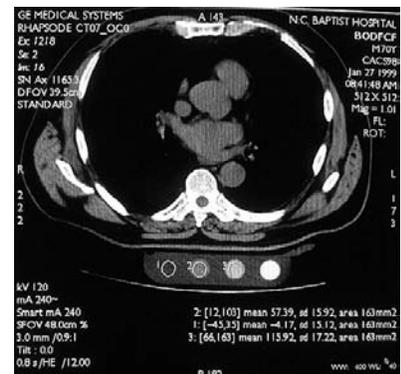
**Technologist:** “Hello Ms. Smith I understand you are here for your Research CT exam for **WHI-CACS**. During your CT exam you will be positioned on your back on a special table. I will connect ECG leads which allow us to track how your heart is beating during the CT scan. It is very important that 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. The entire exam should take about 10 minutes. Do you have any questions I could answer?”

### 3.6. Positioning the Participant on the CT couch

The participants can be positioned for the study feet first or head first. Center the individual on the CT couch and then within the CT gantry.

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

The technologist will check patient centering and position. If the individual is angled in the gantry – reposition and repeat the scout images. The technologist will then select the start position just below the carina of the trachea as viewed on the scout. 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.



**3.8. Heart : Cardiac CT Scan Series with Prospective ECG Gating**

Scanning procedure for cardiac gated CT scans of the coronary arteries are modified from those developed as part of NHLBI’s MESA and CARDIA studies (Carr, 2005). 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 27 cm.

**Technical Parameters for each CT system is in Appendix D.**

**Participant Weight and the CT exam:**

**Participants weighing more than 300 lbs 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.

**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 27 cm (or 270 mm). *It is very important when prescribing the scan to make sure that the anterior-posterior center is offset anterior and to the left so that the entire heart is included in the images. Be sure to check your images and if for some reason portions of the heart are not included in the images perform a reconstruction (not an additional CT scan) to center the heart in the display field-of-view.*

**Figure 2 - Table CT Image Reconstruction Parameters**

| Series  | Scan FOV             | Display FOV | Kernel                                       | Recon. type                     |
|---------|----------------------|-------------|----------------------------------------------|---------------------------------|
| Heart 1 | Large / Body / 55 cm | 270 mm      | GE=standard<br>Siemens=b30f<br>Imatron=Sharp | 240°<br>(partial)<br>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"

The total imaging time will be approximately 15 to 40 seconds depending upon CT system used. The technologist will then acquire one entire series of image slices through the heart with ECG gating. The technologist will instruct the subject to relax on the table while he/she reviews the reconstructions and assesses the adequacy of positioning, ECG gating and lack of respiratory motion. If the scan completed successfully, the technologist will escort the participant out of the CT imaging suite.

After the Exam:

1. Complete the WHI-CACS CT Imaging Worksheet.
2. Fax the worksheet to the numbers on the bottom – your local WHI clinic.
3. Fax the worksheet to the CTRC at 336.716.4340

**4. Radiation Dose Estimates for the 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 participant are the potential for (1) hereditary defects, (2) developmental defects for exposure of a fetus/embryo in utero and (3) cancer induction. The WHI-CACS 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 and the WHI-CACS participants have all previously had a hysterectomy.
2. To reduce the risk of any radiation induced cancer, we are using as low a radiation dose scan as possible to obtain the information necessary to accomplish the goals of this research. This will be approximately < 2mSv, which is much less than the 3.6 mSv U.S annual average and the 7.0 mSv annual exposure for residents of Denver, Colorado.

Participants in this study will receive a one-time exposure of less than 3 mSv with the typical exposure of ~ 1 mSv. This level of radiation exposure is equivalent to less than one year 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.

### **5.1. CT Scan Site Procedures for Sending Exams to the CTSC at Wake Forest in Winston-Salem, NC**

CT exams will be archived locally and then saved to a CD labeled with the ID number. These CD will then be sent by courier (FedEx, US Express Mail, etc...) to us via 2<sup>nd</sup> Business Day Service. We will assist you with preprinted mailing labels so that the charges will be billed to us. Look at your schedule, and, if participants are clustered during the week, we recommend sending them together. However, if no additional WHI-CACS participants are scheduled in the next 3-4 days mail the CD's to us without further delay.

Send to the following address:

Attention: Chris O'Rourke  
Imagelab – Div. of Radiological Sciences  
Piedmont Plaza 2, Suite 618  
2000 West First Street  
Winston-Salem, NC 27103

Telephone: 336.716.7234

Fax: 336.716.4340

## **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) & Torso/QCT phantom 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.

The purpose of the CT scanner certification process is validate the CT scanner ability to measure the know amounts of calcium contained in the phantom. We will then use this information as part of our quality control procedures.

## **7.1 CT Technologist Training Material**

CT protocol training material will be provided for all technologists. 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 WHI-CACS study
2. Train and maintain skills of each CT technologist
  - a. Identify and train a "Lead" technologist from each site via a teleconference in May 2005
  - b. Provide training material and exam for each scan site
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. 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.

## Appendix A – List of Clinical Centers

| <b>Clinical Center</b>   | <b>WHI-CACS PI</b> | <b>EBCT</b> | <b>MDCT</b> | <b>CT System Details</b>           |
|--------------------------|--------------------|-------------|-------------|------------------------------------|
| <b>Atlanta</b>           | Phillips           | N           | Y           | Siemens 64                         |
| <b>Birmingham</b>        | Lewis              | N           | Y           | GE LightSpeed-4                    |
| <b>Boston</b>            | Manson             | N           | Y           | Siemens 16 & 64                    |
| <b>Buffalo</b>           | Wactawski-Wende    | Y           | N           | Siemens 16                         |
| <b>Chapel Hill (UNC)</b> | Heiss              | N           | Y           | Siemens 16                         |
| <b>Chicago</b>           | Greenland          | Y           | N           | GE-Imatron C150                    |
| <b>Cincinnati</b>        | Gass               | N           | Y           | Siemens 64                         |
| <b>Columbus</b>          | Jackson            |             |             | GE LightSpeed 16                   |
| <b>Detroit</b>           | Hendrix            |             |             |                                    |
| <b>GWU</b>               | Hsia               | Y           |             | GE-Imatron C150                    |
| <b>Hawaii</b>            | Curb               | Y           | Y           | GE-Imatron?<br>Toshiba Aquillion 4 |
| <b>Iowa</b>              | Robinson           | N           | Y           | Siemens 4<br>Siemens 4             |
| <b>LA</b>                | Nathan             | N           | Y           | Siemens 64                         |
| <b>La Jolla</b>          | Langer             | Y           | Y           | GE-ImatronC150                     |
| <b>Madison</b>           | Sarto              | N           | Y           | GE LightSpeed 16                   |
| <b>Medstar</b>           | Thomas             | N           | Y           | Phillips 16                        |
| <b>Memphis</b>           | Johnson            | N           | Y           | GE LightSpeed 16                   |
| <b>Miami</b>             | O'Sullivan         | N           | Y           | Siemens 16                         |
| <b>Milwaukee</b>         | Kotchen            | Y           | N           | GE-Imatron C150                    |
| <b>Minneapolis</b>       | Margolis           | N           | Y           | Phillips 40                        |
| <b>New York City</b>     | Smoller            | N           | Y           | Phillips 16                        |
| <b>Newark</b>            | Lasser             | N           | Y           |                                    |
| <b>Oakland</b>           | Sidney             | Y           | N           | GE-Imatron C150                    |
| <b>Pawtucket</b>         | Eaton              | N           | Y           |                                    |
| <b>Pittsburgh</b>        | Kuller             | Y           | N           | GE-Imatron C150                    |
| <b>Portland</b>          | Whitlock           | N           | Y           | Toshiba 64                         |
| <b>Rhode Island</b>      |                    |             |             | Toshiba 16                         |
| <b>Stony Brook</b>       | Lane               |             |             |                                    |
| <b>San Antonio</b>       | Brzyski            | N           | Y           | Siemens 4                          |
| <b>Stanford</b>          | Stefanick          | N           | Y           | Siemens 64                         |
| <b>UCDavis</b>           | Robbins            | N           | Y           | GE LightSpeed 16                   |
| <b>Worcester</b>         | Churchill          | N           | Y           | Phillips 32                        |

## Appendix B – WHI-CACS Timeline

|                    |                                                                                                                      |
|--------------------|----------------------------------------------------------------------------------------------------------------------|
| Jan 14, 2005       | Determine Clinical Center interest in participating                                                                  |
| Feb. 1             | Submit RFP to NHLBI for final review and approval.<br>Submit approved RFP to FHCRC purchasing to add legal language. |
| Feb 10             | Reading Center RFP released                                                                                          |
| Feb 14             | Submit materials to FHCRC IRB                                                                                        |
| Mar 11             | Responses to Reading Center RFP due                                                                                  |
| April 1            | Select Reading Center                                                                                                |
| April 20           | Distribute IRB-approved materials to Clinical Centers for local IRB approval                                         |
| April 29<br>(2 wk) | Reading Center provides protocols for imaging and QC                                                                 |
| Week of<br>May 2   | Conference calls with Clinical Centers to review study procedures and respond to questions                           |
| May 23             | CCs begin mailing invitational letters and packets to eligible participants                                          |
| May 27<br>(6 wk)   | Complete initial Imaging Center training<br>Reading Center provides Reading Center Manual for CCC and PO.            |
| June 1<br>(8 wk)   | Begin imaging pilot with 3 scans at each site.                                                                       |
| June 10            | First CCs approved for imaging remaining participants.                                                               |
| June 17            | Reading Center submits first data to CCC and results to CCs.                                                         |
| July 29            | Complete participant CT imaging                                                                                      |
| Aug 15             | WHILMA database closes down<br>CCs complete WHILMA data entry                                                        |
| Sept 2             | Complete review of images by Reading Center                                                                          |
| Sept 15            | [CCs forward any remaining data]                                                                                     |
| Sept 30            | Reading Center completes final data entry, QC, and data transfer to the CCC.                                         |
| Sept-Dec           | [CCC: Transition to Extension study, complete DM and CaD primary and priority papers.]                               |
| Jan-Mar '06        | Data analysis of WHI-CACS data.                                                                                      |

## Appendix C – CT Worksheet Draft



### WHI-CACS Participant CT Worksheet

|                                                                                                                                                 |
|-------------------------------------------------------------------------------------------------------------------------------------------------|
| <<participant name>><br><<participant address>><br><<participant home phone>><br><<participant date of birth>><br><<participant weight in lbs>> |
|-------------------------------------------------------------------------------------------------------------------------------------------------|

|          |                |
|----------|----------------|
| WHI ID # | <<alpha code>> |
|----------|----------------|

|                                                                                                                                                                                                                                                                                        |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>WHI-CACS Scan Protocol:</b> <ul style="list-style-type: none"><li>• K-V I2D (MDCT) - I3D (EBCT), slice 2.5-3 mm, 27-30 sec</li><li>• ECG-gated EBCT @ 30%, GE-MDCT 70%, Siemens 30%</li><li>•</li><li>•</li></ul> Technical questions? Contact Chris, Nancy or Jeff at 336.716.7234 |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|                                                                                                               |
|---------------------------------------------------------------------------------------------------------------|
| Date Scan Completed: ____-__-____<br>CT Technician's Initials: ____-____<br>Comments or Notes about the Scan: |
|---------------------------------------------------------------------------------------------------------------|

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| If scan not completed, please select reason (mark <u>one</u> only):<br><input type="checkbox"/> Equipment malfunction<br><input type="checkbox"/> Participant too large to fit on scanning table<br><input type="checkbox"/> Participant physically unable to continue for other reason<br><input type="checkbox"/> Participant too anxious to continue (e.g., claustrophobic)<br><input type="checkbox"/> Other: _____<br><input type="checkbox"/> Participant needs to be re-scheduled (e.g., cancellation, no-show, too anxious) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

When scan is completed, fax this form to:

|                                                |
|------------------------------------------------|
| Label and CC name, staff name,<br>phone number |
|------------------------------------------------|

## Appendix D

### The CT Technical Settings for Coronary Scan Series:

At the time of this version the CTSC has not yet received sample images from phantom scans at each CT site. Once we receive these images we will update the tables with the specific parameters for each CT scanner and a specific protocol page will be sent to each site. Note that factors such as mA/mAs are dependent upon gantry speed, which varies across vendors and even within models.

| System                              | Mode                | FOV | Multi-slice       | Kernel / recon  | time         | ECG gating      |
|-------------------------------------|---------------------|-----|-------------------|-----------------|--------------|-----------------|
| GE Imatron C-150                    | Axial               | 27  | 1 slice by 3 mm   | Sharp / Partial | 0.1 s        | Prospective 80% |
| GE LightSpeed 16                    | Axial<br>Cine       | 27  | 8 slice by 2.5 mm | Std / Partial   | 0.4 s / 0.25 | Prospective 70% |
| Siemens Sensation 16<br>Biograph 16 | Axial<br>Quick Scan | 27  | 6 slice by 3 mm   | B30F / Partial  | 0.4 s / 0.25 | Prospective 50% |
| Toshiba Aquillon 64                 |                     | 27  | 6 slice by 3 mm   | FC01            | 0.4 s / 0.25 | Prospective 50% |

| 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<br>Biograph 16 TBD         | 120 | 0.42             | .25               | 80 mAs                  | 100 mAs                  |
| GE Imatron C150                                 | 130 | NA               | 0.1 s             | <b>630 mA</b>           | <b>NA</b>                |
| GE LightSpeed 16                                | 120 | 0.42 s / 0.3326s | 0.25s             | <b>320 mA</b><br>80 mAs | <b>400 mA</b><br>133 mAs |
| Phillips                                        | 120 | TBD              |                   |                         |                          |
| Toshiba Aquillon 64                             | 120 | TBD              |                   |                         |                          |

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

