# IMAGE MANAGEMENT PLAN

**RESCUE: Randomized Evaluation of Patients with Stable Angina**  
*Comparing Utilization of Diagnostic Examinations*

Protocol Number: ACRIN 4701

<table>
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<tr>
<td>Document Status</td>
<td>DRAFT</td>
</tr>
<tr>
<td>Author</td>
<td>Rebecca Scaven, Cyndi Price</td>
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</table>

**Confidential**  
The information contained within this document is considered confidential/trade secret information. Further dissemination may only be made with the express written approval of American College of Radiology Imaging Network.
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## History of Revisions

<table>
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<td></td>
<td></td>
<td>Cyndi Price</td>
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1) Purpose

The Image Management Plan (IMP) is for use by ACR Diagnostic Imaging Core Lab personnel associated with the RESCUE Trial, to document image collection, image handling, image quality control and image archive for this study.

This IMP documents the processes and procedures employed by ACR Diagnostic Imaging Core Lab to promote consistent, efficient and effective image data management practices.

2) Creation and Maintenance

This IMP is created based upon the RESCUE Trial protocol, work scope, contract, analysis plans, data flow and the ACR Diagnostic Imaging Core Lab image management standards and practices. This IMP is to be approved by all responsible parties prior to commencement of the work described within this IMP. This IMP shall be considered a living document throughout the life cycle of the study, and shall be updated to address any procedural or protocol changes related to imaging management activities. The ACR Diagnostic Imaging Core Lab Imaging Technologist, or designee, shall ensure this IMP is kept current, including proper version control, and that all parties involved agree with the content, and approve and sign off on the document. Upon conclusion of the RESCUE Trial, the IMP shall be archived with all other pertinent study documentation.

3) Revisions to the Image Management Plan

Minor corrections encompassing only grammatical changes or personnel changes which will not affect image management processes may be approved by the ACR Diagnostic Imaging Core Lab Assistant Director. These will be designated as minor version changes i.e., Version 1.0 revised to Version 1.1. A copy of the revised document will be provided to all parties involved but will not require sponsor sign-off.

4) Study Overview

The RESCUE trial is funded by a grant for comparative-effectiveness research from the Agency for Healthcare Research and Quality (www.ahrq.gov).
This randomized, controlled, diagnostic, multicenter, phase III trial will assess two imaging technologies--coronary computed tomography angiography (CCTA) and single positron emission tomography (SPECT) myocardial perfusion imaging (MPI)--in diagnosing cardiac disease in patients with stable angina or angina equivalent.

Results from diagnostic imaging assessment will guide subsequent therapeutic approach. Participants with positive cardiac findings on diagnosis will be guided to optimal medical therapy (OMT) or diagnostic invasive coronary angiography (ICA) and possible revascularization, depending on extent and location of disease. Participants will be followed to collect healthcare utilization data, cardiac events, and quality-of-life questionnaires.

5) Criteria for Technical Site Qualification and Quality Assessment

During the pre study QA process, one (1) test image in each for each modality (that is, one for CCTA and one for SPECT MPI) will be submitted electronically from the sites to ACRIN core lab to ensure that: the recommended protocols are followed; image quality is adequate; and that all technical issues related to image transmission and receipt are resolved. The CCTA test case will be assessed for adequate test protocol adherence, radiation exposure, image quality, data/image reconstruction, and transfer capability for final certification. Images that are technically challenging or where quality is considered borderline may be delivered electronically to the respective collaborative core labs for consultation with experts in each modality. For sites with inadequate studies, the ACRIN core lab will review the test protocol with the site in detail and request an additional study for the modality until the site fulfills all requirements.

For institutions that are unable to submit a QA Test Cases for CCTA and SPECT MPI, the site will request and receive permission by the ACRIN Project Management team to waiver the test image requirement and will use the first case enrolled as their test case. The site will place a hold on further enrollment until the ACRIN Core Lab has reviewed the image data, provided feedback to the site, and has granted the site permission to continue accrual. The images will be submitted and the standard QC process will be completed by the ACRIN Imaging Technologist – (reference QC Appendices V and VI). Once evaluated, the images will be made available on TRIAD for the respective collaborative Core Lab at Tufts Medical Center (for SPECT exams) or MGH (for CCTA exams). The Core Lab will review the images and provide feedback to ACRIN regarding any concerns or issues with the image quality and/or technique. Any concerns or issues that may arise will be communicated to the site Study Coordinator and (or) Technologist on an ongoing basis to ensure that optimal imaging quality and technique has been performed.
Once a site has been approved in each modality for participant enrollment, prompt submission of all image data within five (5) days of completion of imaging is essential to ensure an adequate QC process.

Technical performance for CCTA and SPECT MPI QA exams, as well as all trial participants’ exams, will be judged by ACRIN technologists according to the criteria for each test listed in Table 1 below:

**Table 1. Technical Performance/Image Criteria**

<table>
<thead>
<tr>
<th>Modality</th>
<th>Criteria</th>
</tr>
</thead>
</table>
| CCTA          | 1) Complete data set without major motion artifacts and sufficient contrast enhancement, additional data sets if motion artifacts are present (retrospective ECG gating), and protocol description with radiation dose details;  
                2) Use of heart-rate lowering drug and retrospective ECG gating for heart rate > 65 bpm, unless a dual-source CCTA scanner is available. |
| SPECT MPI     | 1) High quality non attenuated-corrected AND attenuated-corrected raw rest and stress projection images with attention to minimal motion and acceptably low levels of hepatic and bowel uptake.  
                2) Reconstructed files (short axis, vertical long axis, and horizontal short axis).  
                3) Screen capture of quantitative analysis results page displaying “% of LV ischemia or “% LV reversibility” from a commercial quantitative software program (i.e. Emory Cardiac Toolbox, 4D-MSPECT, QPS (Cedars Sinai) … etc.).  
                4) High quality gated SPECT MPI with Beat Length Histogram (if available) |

**6) Overview of Investigational Site's Submission Process via TRIAD**

Each participating site is required to submit all acquired CCTA and SPECT MPI images to the ACRIN core laboratory. The image transfer method is via TRIAD-OA, the American College of Radiology’s web-based software solution which allows sites participating in the RESCUE trial a secure method to review and submit clinical trial images. This software application includes a rich client and a
site server (DICOM file cache). ACRIN will provide TRIAD software for electronic image submission and anonymization to participating institutions.

**Randomized trial participants are to be submitted using the assigned four digit ACRIN case number.** Images can be transferred to the ACRIN central archive by inserting a CD or DVD in the drive of a PC with the TRIAD rich client installed. The TRIAD software anonymizes, encrypts, and applies compression to the images before they are transferred to the ACRIN image archive in Philadelphia, PA.

The first TRIAD submission will be your IT “Test Submission”. Test exams are submitted with the assistance of our IT department, and should be labeled TA_“4 digit site number”. The next submission (usually within a few days) will be a “Quality Assurance” submission which is to assure ACRIN DICOM validity and quality of imaging. These exams are to be labeled QA_“4 digit site number”. Once ACRIN is satisfied with the sites’ QA submission(s) and notified to start patient enrollment, all exams will be submitted as “Clinical Trial” subjects utilizing the 4 digit Subject ID (ex. 0004).

Please note: sites will be asked to resubmit data should the exams be submitted with the incorrect Subject ID number.

**Current TRIAD users must contact TRIAD support to be linked to the RESCUE trial before you are able to submit any images via TRIAD.**

For TRIAD installation, please call 215-940-8820 or e-mail TRIAD-Support@acr.org

1. Preparing for TRIAD Installation

A. Identify the necessary personnel: Prior to scheduling a time with the ACR site technical specialist, please identify the following key TRIAD personnel contacts:

- The TRIAD user(s): individual(s) who will conduct the transfer and/or review of images using TRIAD. These individuals will need to register a TRIAD account at: https://triad.acr.org/Web/UserAccount/Register.aspx
- IT Administrator(s): individual(s) that will participate in the installation and basic testing of the TRIAD software.
- PACS Administrator(s): individual(s) who will transfer the case images internally from a c-store based scanner to the machine running TRIAD.
B. Designate a Computer for TRIAD use: Identify the computer that will be used to run the TRIAD software (this machine does not need to be used solely for TRIAD). Please review the hardware requirements (listed below) with your IT department to ensure the selected computer meets the minimum requirements. User guides are also located on the TRIAD website at: https://triad.acr.org/Learning.htm

C. Confirm User Permissions and Network/Connectivity permissions:

- To install the TRIAD software on the designated computer, an individual with administration rights to the machine must be present during the TRIAD installation. If a shared login is nonexistent on the machine chosen for TRIAD, the software must be configured under the logon of the person who will be submitting or reviewing images. The installation is user specific and does not install for all users.
- Please make sure that the necessary connectivity permissions are in place to allow the DICOM transfer of images from the PACS scanner to the TRIAD designated machine. Please make sure that you are allowed to transfer electronic files from the site via the Internet. This ability is needed to submit images from the TRIAD server to the ACRIN HQ Central Server. Please make sure that the designated computer has the necessary firewall permissions to allow access to Citrix “GoToMeeting” and will be needed for you to receive remote assistance from a TRIAD site technical analyst.

Please note the website for go to meeting:
https://www1.gotomeeting.com/t/URL/g2m/joingotomeeting?Target=/m/join_gotomeeting.tmpl

D. Communicate With Your IT organization: Please forward the information below to your IT group to confirm that the selected computer meets TRIAD’s minimum requirements prior to scheduling a TRIAD technical specialist appointment.

1. System HARDWARE Requirements for a TRIAD Installation
- Model: PC
- Processor: Intel P-IV 3GHZ minimum; Intel Core Duo 2 GHZ is recommended
- RAM 1 GB is minimum; 4GB is recommended
- HDD: 200 MB for Rich client GUI client application up to 22GB-for local image cache, the size required will depend on the amount of images stored by the system

TRIAD site server HDD depends on the amount of images received from the scanner before they are sent to TRIAD. Image Storage 10 GB
minimum; 200GB is recommended.

2. **System SOFTWARE Requirements for a TRIAD Installation:**

   - Microsoft Windows XP SP3 and or Windows Server 2003 SP2 Operating systems
   - Microsoft Windows 7 Operating system
   - MS SQL 2005 Express *This will need to be installed and configured by an ACR site technical specialist*

3. **System NETWORK Requirements for a TRIAD Installation:**

   - For all traffic except image transfer (e.g. metadata search, security attributes exchange, etc.) the minimum client Internet connection speed should be at least 128kbps. For image transfer, additional Internet connection bandwidth of at least 256 kbps is required. *Client connection speed of at least 1 Mbps is suggested.*
   - Speed between TRIAD Site Server and Internet should be at least 256 kbps. *Client connection speed of at least 1 Mbps is suggested.*
   - Internet channel bandwidth of TRIAD Web Server and TRIAD application server should be at least 256 Kbps x MAX number of online users sending or receiving data simultaneously.
   - ACR Server side components should be connected through fully switched fabric with full-duplex links with a speed of at least 1Gbps.

**E. Scheduling TRIAD Installation**

If you feel your site is ready to proceed with the TRIAD installation, please call 215-940-8820 or submit an e-mail to TRIAD-Support@acr.org. Please include the following information in your e-mail: your site name and number, study number, preferred installation date and time, names of individuals participating in the installation and their contact information.

**II. CD/DVD media via mail**

The other option for image submission includes submitting images via a CD/DVD and ship to the ACRIN Imaging Core Laboratory.
7) **Overview of ACRIN Image Management / Processing**

Upon confirming receipt of the site’s submitted image datasets and Image Transmittal Worksheet (ITW), the ACRIN Core Laboratory will conduct standard Quality Control (QC) assessment of images submitted into TRIAD. Copies of modality-specific ITW forms are available in the appendices within this document.

During this QC assessment, the Imaging Technologist will evaluate the datasets for quality and imaging protocol compliance. A QC form will be completed, signed and dated by an ACRIN technologist for every submitted case. The QC process will begin by ensuring all required datasets are present and the ITW form is completed in its entirety. Specifically, the case #, institution #, image exam series, date of study and CCTA/SPECT MPI Imaging Parameters are checked for accuracy when compared to the submitted exam.

Once QC has been completed, the images and accompanying QC forms will be credited into CTMS database. Copies of modality-specific QC forms are available in the appendices within this document. The original forms will be given to Data Management. The exam will then be published in the TRIAD archive and the case will be tracked in an Excel spreadsheet by the ACRIN Technologist.

**CCTA Overview of Quality Control (QC) Process**

CCTA image data will be evaluated for completeness and quality. A complete dataset consists of the following series/images:

- Localizer
- Dose Report/Patient Protocol
- Calcium scoring sequence (optional)
- Full FOV imaging
- Multiphase reconstructions, if acquired

The CCTA image quality will be evaluated based on the following guidelines:

- Absence of major motion artifacts
- Sufficient contrast enhancement
- Less than 15 mSv radiation dose

**SPECT MPI Overview of Quality Control (QC) Process**

SPECT MPI image data will be evaluated for completeness and quality. A complete dataset consists of the following series/images:

- Non attenuated-corrected AND attenuated-corrected raw rest and stress projection data
- Reconstructed files (short axis, vertical long axis, and horizontal short axis)
- Screen capture of quantitative analysis results page displaying “% of LV ischemia or “% LV reversibility” from a commercial quantitative software program (i.e. Emory Cardiac Toolbox, 4D-MSPECT, QPS (Cedars Sinai), etc.).
- Gated SPECT MPI data with Beat Length Histogram (if available)

The SPECT MPI image quality will be evaluated based on the following guidelines:

- The entire Left Ventricle is in the Field of View
- High Quality Raw data projection images are evaluated with attention to minimal motion and low levels of hepatic and bowel uptake
- Gated nuclear images with attention to beat-length histogram (if available) are evaluated to ensure optimal gating was achieved.
Image Query Process/Data Clarification

If the submitted exams are not protocol complaint, missing any of the required datasets, associated imaging forms, or if the forms are not completed correctly or in their entirety, an imaging query (Z5 Image Query Form) will be issued to the site Study Coordinator. A copy of the Z5 Image Query form is available in the appendices within this document.

The site must respond to the query form and take corrective action to provide the missing datasets, forms and/or elements on the forms. The site’s corrective action must be documented on the Z5 Image Query Form along with the signature and date of the person responsible for completing the form. GCP guidelines will also be enforced.
Appendices

Appendix 1: Site Initiation Process Flow

PSA is approved and added to folder by Project Manager
\home1\acrin\Protocols\4701 RESCUE\Site Specific

TRIAD Letter (Explaining TRIAD and PC requirements)
Is sent by Clinical Trials Associate assigned to RESCUE Trial
To Study Coordinator, Principle Investigator, and IT contact at participating sites

Once site has a PC that meets requirements, they contact ACRIN to schedule an
appointment to install TRIAD
TRIAD is then installed by MWebware

QA Instruction Transfer Letter (including ITW forms) is sent by Clinical Trials Associate
to the Study Coordinator at site where TRIAD was installed

QA data sets (sent through TRIAD) and ITW’s (faxed) received and approved for CTA
and SPECT
(Imaging Technologists send approval letter to Study Coordinator
for specific modality once QC’d)

Final QA Approval letter is sent by Clinical Trials Associate once both modalities are
approved to Study Coordinator and RESCUE Project Manager and the site is activated.
Appendix 2: CCTA Image Transmittal Worksheet

CCTA Image Transmittal Worksheet ACRIN 4701

All anonymized exams should be submitted to the ACRIN-Image Management Center after each visit. A completed, signed Image Transmittal Worksheet MUST accompany all imaging exams submitted to ACRIN. Please mail or fax this completed ITW with each case submission.

American College of Radiology
1818 Market Street, Suite 1600
Philadelphia, PA 19103
Fax 215-923-1737

☐ Check box if this is a QA submission (no need to complete subject ID, Year of Birth, BMI, or Date of Exam)

Section I: Image Data Demographics

<table>
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<tr>
<th>ACRIN Site ID:</th>
<th>Subject ID:</th>
<th>Subject Year of Birth:</th>
<th>Subject BMI:</th>
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Section II: Exam Data

Date of Exam: ___/___/___

Exam Start Time: ___ : ___ AM/PM

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<th>Type of Gating</th>
<th>Comments</th>
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<td>Dose Report/ Patient Protocol</td>
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<td>Scout</td>
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<td>☐ Retrospective</td>
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Name of Technologist who performed the exam: __________________________

Form Completed By: __________________________

Email: __________________________

Phone: (____) ________

Date: ___/___/___

American College of Radiology Image Management Center

ACRIN Study #4701

RESCUE Trial

Image Management Plan

12/5/2011

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Appendix 3: Nuclear Medicine SPECT MPI Image Transmittal Worksheet

## Nuclear MPI SPECT Image Transmittal Worksheet (ITW)

ACRIN 4701

All anonymized exams are submitted to the ACRIN-Image Management Center at the American College of Radiology within 5 business days of the visit. The images are transferred using a predefined method established prior to enrollment. An Image Transmittal Worksheet (ITW) is completed during imaging and signed by the technologist. A copy of the ITW is faxed or mailed to ACRIN on the day the images are transferred.

American College of Radiology  
1918 Market Street, Suite 1600  
Philadelphia, PA 19103  
Fax 215-923-1737

For further information or questions email rescven@acr.org

### Section I: Image Data Demographics

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<tr>
<td></td>
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<td></td>
<td>M</td>
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### Section II: Exam Data

Test Submission: □ (Check only if sample study)

Date of Visit: __/__/____ (DD-MM-YYYY)

Site Name: __________

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<th>Exam Series</th>
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<th># of Raw Gated Image Data</th>
<th>Reconstructed/Processed Image Data</th>
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<td>□ Rest Summed</td>
<td>□ Rest Gated</td>
<td>□ Short Axis, Vertical Long Axis &amp; Horizontal Long Axis</td>
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<tr>
<td></td>
<td>□ Stress Summed</td>
<td>□ Stress Gated</td>
<td>□ Screen Capture of Results Page Displaying “% of Ischemia” or “% of Reversibility”</td>
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</tbody>
</table>

| Attenuation Corrected Projection Files | □ Rest Summed | □ Rest Gated | □ Short Axis, Vertical Long Axis & Horizontal Long Axis |
|                                       | □ Stress Summed | □ Stress Gated | □ Screen Capture of Results Page Displaying “% of Ischemia” or “% of Reversibility” |

Heart Rate Histogram: □ Yes □ No
### Nuclear MPI SPECT Image Transmittal Worksheet (ITW)

**ACRIN Study #4701**

**ACRIN Site ID:** □ □ □ □ □ □

**ACRIN Subject ID:** □ □ □ □ □ □

#### Section III: SPECT MPI Acquisition Parameters

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<tr>
<td>□ Tetrofosmin _______ mCi/MBq</td>
<td>□ Tetrofosmin _______ mCi/MBq</td>
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<th>Time per Stop</th>
<th>Patient Motion Detected</th>
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<td>□ 64x64</td>
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<td>:</td>
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<td>□ Other</td>
<td></td>
<td>(seconds)</td>
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<th>Images Repeated</th>
<th>Gated</th>
<th>Number of frames/cycles/bins</th>
<th>Bad Beat Rejection</th>
<th>R-R Window used</th>
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<tbody>
<tr>
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<td>□ Yes □ No</td>
<td>□ Yes □ No</td>
<td>□ Yes □ No</td>
<td>□ Yes □ No</td>
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<tr>
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<td>□ 8 □ 16</td>
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<td>□ Yes □ No</td>
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</table>

#### Complete Following only if Gated Study Performed

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<th>Gated</th>
<th>Number of frames/cycles/bins</th>
<th>Bad Beat Rejection</th>
<th>R-R Window used</th>
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<td>□ Yes □ No</td>
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<td>□ 8 □ 16</td>
<td>□ Yes □ No</td>
<td>□ Yes □ No</td>
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**Name of Technologist:**

**Form Completed By:** ____________________________

**Email:** @ ____________________________

**Phone:** ( ) __________

**Date:** __/__/_______

*American College of Radiology Image Management Center: RESCUE SPECT ITW Version 2 Page 2*
### Appendix 4: Z5 Imaging Query

#### ACRIN 4701 - RESCUE Trial

**Z5 Imaging Query**

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<th>Z5 Requester Information</th>
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<td>Date of Request: 1/1/2011</td>
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<table>
<thead>
<tr>
<th>Exam Information</th>
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<tbody>
<tr>
<td>Site Number - Subject Number:</td>
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<tr>
<td>Study Date: 1/1/2011 (mm/dd/yyyy)</td>
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<tr>
<td>Modality: [ ] CCTA [ ] SPECT</td>
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<table>
<thead>
<tr>
<th>Z5 Query Explanation</th>
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<tbody>
<tr>
<td>[ ] No ITW Submitted</td>
</tr>
<tr>
<td>[ ] ITW Form Incomplete - Missing information/data</td>
</tr>
<tr>
<td>[ ] No Dose Report Submitted</td>
</tr>
<tr>
<td>[ ] Administered Isotope and/or Dose not Recorded</td>
</tr>
<tr>
<td>[ ] Region of Interest was not Covered</td>
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<tr>
<td>[ ] Study Incomplete - Missing views/images/series</td>
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<tr>
<td>[ ] Problem with De-Identifying Patient Data</td>
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<td>[ ] Problem with DICOM Format</td>
</tr>
<tr>
<td>[ ] Images in Secondary Screen Capture Format - No raw data submitted</td>
</tr>
<tr>
<td>[ ] No Reconstructions Submitted/or were Done Improperly</td>
</tr>
<tr>
<td>[ ] Significant Artifact/Poor Image Quality</td>
</tr>
<tr>
<td>[ ] Radiation Dose Above Protocol Maximum Value</td>
</tr>
<tr>
<td>[ ] Other:</td>
</tr>
<tr>
<td>ACRIN Comments:</td>
</tr>
</tbody>
</table>

**Site Corrective Action Taken:**

| Site Staff (E)Signature: | Date: 1/1/2011 |

**IMPORTANT:** The case listed above from your institution is incomplete and/or requires a clarification.

Please sign and date this form and return to ACRIN via Email or FAX (215) 923-1737

If imaging is incomplete, please forward all missing data within 5 days.

ACRIN Study #4701 12/5/2011
RESCUE Trial Image Management Plan Page 17 of 19
# Appendix 5: Internal CT Quality Control Form

<table>
<thead>
<tr>
<th>ACRIN Site Number:</th>
<th>Subject ID:</th>
<th>Date of Exam:</th>
<th>ACRIN Technologist performing QC:</th>
<th>Date of ACRIN QC:</th>
</tr>
</thead>
</table>

## Computed Tomography Angiography - Technical Quality Assessment

<table>
<thead>
<tr>
<th>Completeness:</th>
<th>Submitted:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Dose Report/Patient Protocol</td>
<td>No</td>
</tr>
<tr>
<td>2. Localizer</td>
<td>No</td>
</tr>
<tr>
<td>3. Calcium Scoring Series</td>
<td>No</td>
</tr>
<tr>
<td>4. Contrast Enhanced CCTA</td>
<td>No</td>
</tr>
<tr>
<td>5. Full field of view for incidental findings</td>
<td>No</td>
</tr>
<tr>
<td>6. Multiphase axial reconstructions</td>
<td>No</td>
</tr>
</tbody>
</table>

## Quality:

| Absence of major motion artifacts | No | Yes |

## Radiation Exposure:

<table>
<thead>
<tr>
<th>Total DLP for CTA sequence only</th>
<th>mGy x cm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Radiation dose, CTA sequence only (Mean DLP x 0.17^a)</td>
<td>mSv</td>
</tr>
<tr>
<td>Total DLP for entire exam</td>
<td>mGy x cm</td>
</tr>
<tr>
<td>Total Radiation Effective Dose entire exam (Mean DLP x 0.17^a)</td>
<td>mSv</td>
</tr>
</tbody>
</table>

Comments:

Initials of person completing this form: [15]

Date Form Completed (mm-dd-yyyy): [16]

---

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Appendix 6: SPECT QC Form

QS
ACRIN 4701
Randomized Evaluation of Patients with Stable Angina Comparing Utilization of Noninvasive Examinations
SPECT Quality Control Form

If this is a revised or corrected form, please ✓ box.

1. RESCUE Case #: __________ [1]
2. ACRIN Core Lab Technologist performing QC: ___________________________ [3]
5. Gender: [ ] Male [ ] Female
6. Was the Study submitted in its entirety? [1] [ ] No [ ] Yes
   If no, what files are missing?
   ____________________________________________________________ [6]

Overall Image Quality:
7. High Quality Raw data projection images with attention to minimal motion and acceptable low levels of hepatic and bowel uptake? [6] [ ] No [ ] Yes
   Comments:
   ____________________________________________________________ [10]
8. Gated nuclear images with attention to beat-length histogram [11] [ ] No [ ] Yes
   Comments:
   ____________________________________________________________ [12]
9. Was a Query (25) issued to the site? [13] [ ] No [ ] Yes
   If Yes, please complete Qb:
   9a. Name of Site Personnel Notified: __________________________ [14]
       Date Site Notified: _____ / _____ / ________ [14]
   9b. Specify the reason why a Query was issued:
       ____________________________________________________________ [16]
   Comments:
   ____________________________________________________________ [17]
   Initials of person completing this form [18]
   Date Form Completed (mm-dd-yyyy) [19]

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