Multicenter Trial, Phase I Assessment of 2-D FFDM Versus Combo of 2-D and 3-D Tomosynthesis in Breast Cancer Screening

By looking at the breast slice by slice, tomosynthesis may be able to uncover hidden cancers.
# Table of Contents

Study Schema and Objectives ..... 3
Letter of Introduction and ACRIN Breast Imaging Core Laboratory Support Contacts ..... 4
Study Overview ..... 5
Sample Size and Eligibility ..... 6
Qualification Requirements Overview ..... 7-8
Study Procedures ..... 9-13
Imaging Parameters ..... 14
Image Acquisition Guidelines ..... 15
Assessment of Tomosynthesis-Imaging Parameters ..... 16
Image Submission Requirements ..... 17
Image Transmittal Worksheet Instructions ..... 18
Sample Image Transmittal Worksheet ..... 19
Quality Control Procedures ..... 20
Appendix 1: Z5 Form Example ..... 21
**STUDY SCHEMAS BY GROUP**
(Shaded boxes contain study-related procedures.)

### GROUP A

**PRIOR TO IMAGING:**
- Eligibility and Registration

**SCREENING IMAGING:**
- Standard digital mammography (both breasts)
- Study imaging, tomosynthesis (both breasts)

- No Findings
- Call Back for Diagnostic Imaging

**STANDARD CARE:**
- Clinical, standard diagnostic imaging

**FOLLOW UP**
Research staff will review your medical records and collect follow-up images for up to 18 months after your initial screening visit. You may be contacted if you have changed treating doctors.

### GROUP B

**STANDARD CARE:**
- Screening imaging finds suspicious findings

- Call Back for Diagnostic Imaging

**PRIOR TO IMAGING:**
- Eligibility and Registration

**DIAGNOSTIC IMAGING:**
- Standard digital mammography (one or both breasts, depending on screening results)
- Study imaging, tomosynthesis (both breasts)
- Possibly followed by additional standard imaging, such as ultrasound (one or both breasts, depending on previous imaging results)
Dear Breast Imaging Staff,

The Digital Breast Tomosynthesis Imaging Manual (DBTIM) contains breast image acquisition instructions for the ACRIN PA 4006 trial: Comparison of Full-Field Digital Mammography with Digital Breast Tomosynthesis Image Acquisition in Relation to Screening Call-Back Rate. This multicenter, phase I assessment will evaluate the specificity of 2-D FFDM versus a combination of 2-D and 3-D Tomosynthesis Imaging.

For the study objectives to be successfully met, it is critical that you acquire the breast images according to the imaging protocol detailed in this manual. This may be your first time supporting an ACRIN clinical trial; site training will be conducted by the American College of Radiology staff. During the training we will review the mandatory forms to be completed at the time of each breast imaging acquisition as well as the instructions included in the manual for submitting images to the core laboratory at ACRIN headquarters in Philadelphia, PA.

Part of ACRIN standard procedures is a quality control (QC) review of the images sent to the core laboratory. Should a core laboratory technologist performing the QC review identify any protocol violations or technical issues, he or she will provide expedient feedback so that you can make the necessary adjustments. Upon successful QC review, the images will be transferred to a third-party independent core laboratory for specialized analysis.

Thank you in advance for your diligent efforts in adhering to the procedures described in this manual and for helping us ensure the compliance and integrity of the image data collected for the ACRIN PA 4006 study. We look forward to collaborating with you!

Sincerely,

The ACRIN Breast Imaging Team

Kesha Smith, RT (R) (MR) (M) – 215-940-8810 or ksmith@acr.org

Dianne Munroe, RT (R) (M) - 215-940-8899 or dmunroe@acr.org
**Study Overview**

**Primary Aim**
The purpose of this investigation is to determine the reduced radiation exposure from tomosynthesis technology; recall rates of FFDM to the limited DBT set (digital breast two-view tomosynthesis with low-dose MLO) [Group A].

**Secondary Aims**
Aim 1: To determine the sensitivity of FFDM to the limited DBT set (digital breast two-view tomosynthesis with low dose MLO) [Group A and Group B].

Aim 2: To assess lesion-type characterization by sensitivity and specificity in participants (calcification-only lesions versus soft-tissue lesions, as well as lesions subgroups masses, calcifications, architectural distortions, asymmetries) in FFDM versus DBT (two-view tomosynthesis set with low-dose MLO [Group A and B].

Aim 3: To estimate the agreement of FFDM and DBT with determination of the adjudication committee on lesion-type characterization.

Aim 4: To use the sequential interpretation results [Group A and B] in order to compare the two-view limited tomosynthesis set (with low-dose MLO view alone) with the tomosynthesis plus set (low-dose MLO view plus addition of low-dose CC view) on the basis of: Call-back rate; Identification of new lesion(s); Lesion characterization; and Triangulation.

Aim 5: To calculate and compare the radiation dose of the FFDM and the DBT sets.

Aim 6: To identify the determinants of participant radiation dose and clinical image quality including factors such as kVp, mAs, target/filter combination, and breast thickness and composition.
Sample Size and Eligibility

A total of 550 participants will be enrolled into two groups (Group A and Group B).

Group A
500 participants will be recruited to screening mammography. Group A participants will be asymptomatic women 25 years and older with no history of breast cancer will be recruited from a prospective population.

Group B
50 participants will be recalled for diagnostic assessment after positive screening findings. The initial screening study from which the call-back recommendation was generated must have been completed within 30 days prior to the call-back diagnostic imaging visit. The initial screening FFDM that led to the patient call back will need to be submitted to ACRIN for study-related assessment.

Exclusion Criteria
- Pregnant women,
- Women unable to tolerate compression of the breast associated with mammography,
- Women with implants, and
- Women with breasts too large to accommodate adequate positions of the breast for digital breast tomosynthesis (DBT)
Qualification Requirements Overview

- To participate in the ACRIN PA 4006 trial, a site must submit to the imaging core laboratory phantom images for 2D full field digital mammography (FFDM) and 2D and 3D tomosynthesis. **Please note:** The qualifying phantom scans must have been performed on the digital mammography and Hologic Selenia Dimensions Tomosynthesis systems that will be used for the duration of the trial.

- An initial QC log should be submitted along with the qualification images. The log should include the results from the Artifact Evaluation and the Phantom Image Quality Evaluation quality control tests performed by the technologists.

- During the course of the trial the sites are required to perform the quality assurance tests as mandated by the manufacturer. In addition the site must submit to ACRIN a copy of the quality assurance documents. ACRIN must be notified when service has been completed on the scanners, as re-qualification of the machine may be necessary depending on the service requirements. Refer to the Hologic quality control standards as outlined in the Hologic quality control manual for more information.

Image Qualification Review
Qualification scans will be reviewed by the trial physicist to ensure they are protocol compliant and of high quality. Qualification scans should not be completed by the trial physicist who will be determining whether images are compliant. The site PI and research associate will receive feedback by e-mail regarding the review results. If the phantom scans are approved, the site has successfully demonstrated the ability to acquire tomosynthesis mammograms; a certificate will be included in the e-mail documenting the approved scanner type(s) and model(s). If the scans are not approved, a form that explains required corrections will be e-mailed. Please note: Approval of the test/qualifying scans is mandatory prior to a site registering a participant onto the trial.

Test Case Submission
The qualifying cases must be submitted electronically in DICOM format. (No film, please.) Please affix a label to the media (CD, DVD) jacket that includes: study name, site name, site number, and scanner make and model. Do not apply adhesive labels directly to the CD or DVD.
Mail the images to:
American College of Radiology Imaging Network
Core Laboratory
Attn: ACRIN PA 4006
1818 Market Street, 16th Floor
Philadelphia, PA 19103

If you have any questions, please do not hesitate to contact the ACRIN PA 4006 Imaging Team:
Kesha Smith, 215-940-8810 or ksmith@acr.org
Dianne Munroe, 215-940-8899 or dmunroe@acr.org
**Study Procedures**

All participants will be consented and registered prior to their screening or diagnostic evaluation, which may be same day. If an eligible patient decides not to join the trial, her reason should be documented on a Screening Log to assist in identifying recruitment barriers. Participants will undergo both routine screening full field digital mammogram (FFDM) and the tomosynthesis imaging set (DBT) comprising: FFDM only (from screening in Groups A and B), as well as diagnostic imaging (FFDM, +/- ultrasound and other) when obtained on call-back in Group A and on all Group B patients; low-dose DBT—two-view limited tomosynthesis set with low-dose 2-D MLO view (limited tomosynthesis set) and low-dose low-dose CC view (tomosynthesis plus set). However, the timing of the study-related imaging visits will be segregated into two cohorts, screening (Group A) and diagnostic (Group B).

**Group A: Screening Tomosynthesis**

Group A comprises 500 asymptomatic women with no history of breast cancer who are scheduled for routine screening of the breasts with FFDM. The Group A component of the trial is powered to show a 30% reduction in call-back rate from screening including DBT. Participants in Group A will undergo both FFDM and DBT. Initial interpretation from local readers will determine call back for diagnostic evaluation based on positive (abnormal) findings from either the conventional two-view digital mammography study—“FFDM only”—or the tomosynthesis imaging sets (limited tomosynthesis set and then a sequential read with the low-dose CC view added for the tomosynthesis plus set). Participants will be biopsied or followed as recommended by the physician who evaluated the participant at diagnostic call back. Local readers will be randomly assigned images to assess per institutional standard procedures and are blinded to the results of the complementary image set for the participant. Local readers also will be asked to assess image quality. Any necessary diagnostic evaluation from positive screening findings should be conducted within 30 days after screening visit. Follow up will include medical record review, review of conventional imaging results, and images collection at approximately 1-year post-screening assessment. Follow-up data may be collected up to 18-months post-screening depending on participant’s scheduling; data may be collected over a shorter time period due to funding constraints.
GROUP A: Imaging Procedures

Screening (FFDM with DBT)
- Confirm/collection current participant and proxy contact information;
- FFDM per institutional standard of care;
- Study-related tomosynthesis imaging sets (limited and tomosynthesis plus sets) according to parameters provided in the ACRIN PA 4006 Imaging Manual
- Assessment for AEs.

Local Reader Clinical Assessment
Local radiologists will be responsible for the clinical read of screening FFDM and DBT under the following restrictions:
- Site PI will randomly assign images to local readers;
- Readers will be blinded to the complementary imaging for a participant (i.e., no local radiologist will read both FFDM and DBT for an individual);
- Images will be assessed for clinical significance, lesion(s) location and type (broadly as soft-tissue or calcification-only lesions for monitoring purposes, as well as subgroup analysis of mass, asymmetry, architectural distortion and calcifications), and quality;
- Image-positive results from either FFDM or DBT, or both, will require call back for diagnostic imaging follow up (BI-RADS = 0, additional imaging needed).

Diagnostic Imaging (Positive Screening Results Only) Within 30 Days After Screening
- Follow-up diagnostic imaging and possible biopsies will be per institutional standard of care (diagnostic FFDM, ultrasound, and/or other procedures);
- Follow-up diagnostic imaging must be completed within 30 days after screening imaging is completed;
- Further evaluation or follow-up procedures will be conducted per institutional standard of care;
- Results of diagnostic assessment and follow up will be submitted to ACRIN.
**Group B: Diagnostic Tomosynthesis in an Enriched Population**

Approximately 50 asymptomatic women with no history of breast cancer who have been informed of positive (abnormal) findings from a recent (within 30 days) FFDM screening will be recruited to Group B prior to their diagnostic imaging (e.g., diagnostic FFDM and/or ultrasound and/or other). Group B participants will consent to DBT of both breasts as part of their diagnostic imaging work up; all screening and diagnostic images will be collected for study-related analysis. Participants will be biopsied or followed as recommended by the physician who evaluated the participant at diagnostic call back. Study-related follow up will include medical record review and images collection at approximately 1-year post-screening assessment. Follow-up data may be collected up to 18-months post-screening depending on participant’s scheduling; data may be collected over a shorter time period due to funding constraints.

Enrollment to Group B will concentrate initially on calcification-only lesions (based on the report of the initial screening study), under the assumption that Group A will comprise predominantly soft-tissue lesions. Recruitment of call-back cases based on lesion type will be monitored to achieve 75%-to-50% soft-tissue lesions and 25%-to-50% calcification-only lesions within the enriched cohort.

The enriched Group B population is designed to increase the number of true-positive and false-positive cases for comparison of the two imaging modalities at the lesion level. Images for lesion level analysis will comprise approximately 100 image-positive cases collected from both study cohorts (all of Group B and approximately 50 cases from Group A that result in call backs for diagnostic assessment). Analysis of the images performed at the lesion level will also assess the added contribution of the low-dose CC view when added to the two-view tomosynthesis plus low-dose MLO view image set.
GROUP B: Imaging Procedures

Call-Back Diagnostic Imaging (Standard-of-Care Imaging, Including FFDM, and DBT) Within 30 Days After Screening

Participants enrolled to Group B, who have had image-positive screening results (abnormal findings, BI-RADS = 0, additional imaging needed), will undergo the following procedures on both breasts during routine call-back diagnostic imaging:

- Diagnostic FFDM and/or ultrasound (and any other standard imaging and procedures) per institutional standard of care;
- Confirm/collect current participant and proxy contact information;
- Study-related tomosynthesis imaging sets (limited and tomosynthesis plus sets) according to parameters provided in the ACRIN PA 4006 Imaging Manual
- Assessment for AEs.

Local Reader Clinical Assessment: Sequential Reads

Local radiologists will be responsible for the clinical read of diagnostic imaging under the following restrictions:

- Diagnostic images will be read sequentially:
  1. FFDM (screening and diagnostic; historical patient imaging will be available per institutional standard of care);
  2. Two-view limited tomosynthesis image set with low-dose MLO view only;
  3. Two-view tomosynthesis plus image set with low-dose MLO and addition of low-dose CC view;
  4. Any other standard imaging and procedures (e.g., ultrasound).

- Images will be assessed for clinical significance, lesion(s) location and type (broadly as soft-tissue or calcification-only lesions, as well as subgroup analysis of mass, asymmetry, architectural distortion and calcifications), and quality;
- Further evaluation or follow up procedures will be conducted per institutional standard of care.
GROUPS A and B FOLLOW UP

Medical Records Review and Images Collection at Approximately One (1) Year Post-Screening

Follow-Up Responsibilities
Sites will be responsible for follow-up data collection, including images from examinations, at approximately one (1) year post-screening for Groups A and B. Study-related follow up may be necessary up to 18 months post-screening depending on participant accessibility and clinical follow-up scheduling. Study-related follow up may be truncated due to funding and related trial-completion limitations.

Follow-Up Procedures
- Participant status will be determined at approximately one (1) year post-screening;
- Research staff will contact the participant’s treating physician for medical records extraction—including follow-up examination images—and to assist in submission of follow-up images to ACRIN;
- If treating physician is no longer overseeing participant care, telephone contact will be made with the participant or proxy to facilitate contact with new treating physician or to determine current breast cancer-related status at minimum;
- One-Year Follow-Up Guidelines detailing the specifics of contact and other procedures is available at www.acrin.org/PROTOCOLSUMMARYTABLE/ACRINPA4006/4006DataForms/tabid/717/Default.aspx.
- All participant data from image-positive call-back cases and interval cancers will be reviewed in adjudication to classify them as calcification-only or soft-tissue lesions (further delineated by subtype—e.g., mass, asymmetry, architectural distortion); this classification will serve as basis for comparison with local reader results.
**Imaging Parameters**

Imaging parameters for the tomosynthesis sets have been developed in accordance with Hologic’s guidelines and the overall strategy of maintaining the tomosynthesis dose at approximately 1.2 mGy and the low-dose FFDM dose at approximately 1.0 mGy for a 4.2 cm thick breast in the combined tomosynthesis+FFDM acquisition. The exams must be acquired using automatic exposure control (AEC).

**For Participants**

The tomosynthesis images should be acquired in the “Combo” mode, in which 3D and 2D image data are acquired in rapid succession while the breast is held in compression.

The 2D and 3D portions of the combo image should be photo timed with the "Auto Filter" AEC mode and the density set to the "-1" (minus one) density setting. The AEC sensor location should be set appropriately for the participant’s breast size and glandular tissue distribution.

When performing the weekly phantom images, the clinical technique (above) should be used. The AEC sensor should be set to "Position 2".

**For Phantom Imaging**

Furthermore, when imaging the phantom, the compression height should be set to exactly 4.2 cm, or the "ACR Phantom Combo" view should be selected from the Acquisition Station, rather than "RCC Combo" or "LCC Combo". This will ensure that the appropriate technique factors are applied to the phantom.

**Radiation Dose Monitoring**

Monitoring of radiation dose will be a part of the image quality assurance program for this trial, and sites with higher average doses will be given feedback by the core lab and PI concerning methods to reduce dose.
**Image Acquisition Guidelines**

1. Employ proper positioning and compression.  
   *It is desired that the same operator acquire both the FFDM and DBT images using identical positioning.*

2. FFDM examinations will be acquired as prescribed by each site's own departmental protocol. The DBT exams are acquired as outlined in the ACRIN PA 4006 protocol and imaging manual.

3. Operate FFDM and DBT system in accordance with the Manufacturer's Instructions for Use.

4. Employ exposure factors (kVp and AEC settings) as recommended by the manufacturers (dose not to exceed state or federal limits). FFDM and DBT examinations should be acquired using an optimized technique for each system within the allowable radiation dose highlighted in this manual.

5. Complete required Image Transmittal Worksheet (ITW).
Assessment of Tomosynthesis-Imaging Parameters

Radiation Exposure and Quality
Analysis will compare combinations of tomosynthesis sets on all cases to set the radiation exposure per breast to approximately 3.4 mGy on average. The 3.4 mGy exposure would be equivalent to the national average for two-view mammography radiation exposure. Additional assessments will allow for subsequent analyses of image quality and specificity as compared with the adjudication results (see Section 15.5 of the protocol).

In this evaluation, 500 image sets from Group A will be used to compare two-view FFDM with the tomosynthesis image sets in the following combinations:

- FFDM only (average dose per average breast = approximately 3.4 mGy).
- Two-view limited tomosynthesis image set with low-dose MLO view only (low-dose 2-D MLO and two-view DBT average dose = approximately 3.4 mGy).
- Two-view tomosynthesis plus image set with low-dose MLO and addition of low-dose CC view (low-dose projection CC and MLO plus two-view DBT average dose = approximately 4.4 mGy). FFDM plus all diagnostic mammographic imaging at call-back versus the tomosynthesis image sets. The approximate dose per breast for two-view, 2-D mammography is 3.4 mGy. The dose for the complete DBT (two-view tomosynthesis at approximately 1.2 mGy each, plus two simultaneously acquired low-dose 2-D CC and MLO views at 1.0 mGy each) is approximately 4.4 mGy which is comparable to conventional mammography.

Quality and Lesion Subtypes
In addition to comparison between imaging modalities, quality of images (including spatial completeness, linear and feature sharpness, etc) will be assessed based on local reader and adjudication assessments for lesion subtypes.
Image Submission Requirements

Image Submission Instructions

Sites have two options for submitting the FFDM and DBT exams to ACRIN’s image archive:
- Using ACRIN’s image transfer application (TRIAD)
- Express mailing images on a CD-ROM or DVD

Please note: All FFDM and DBT images for this protocol must be provided in DICOM format.

TRIAD Software for Secure File Transfer Protocol (sFTP) Submission

The preferred image transfer method is via TRIAD, a software application that ACRIN provides for installation on a site’s PC. One or several computers of choice within the institutional “firewall” and on the institutional network may be equipped with TRIAD software; Internet access is also required. The TRIAD application can then be configured as a DICOM destination on either scanner(s) and/or PACS system for direct network transfer of study related images into the TRIAD directory. When properly configured, the TRIAD software anonymizes, encrypts, and performs a lossless compression of the images before they are transferred to the ACRIN image archive in Philadelphia. Once equipment-readiness has been determined, imaging personnel from ACRIN will coordinate installation and training for the software.

For more information, contact: TRIAD-support@phila.acr.org or call 215-940-8820.

Upon electronically submitting the FFDM and DBT exams, sites should fax the Image Transmittal Worksheet (ITW; see “Image Transmittal Worksheet Instructions” on next page) to the ACRIN core lab at 215-923-1737 or e-mail it to ksmith@acr.org.

Media Delivery Instructions

FFDM and DBT images for this protocol can be submitted to ACRIN via a CD/DVD-ROM in DICOM format. Please affix a label to the CD jacket that includes: study name, site name, site number, subject number, date of scan(s), and type of imaging. Do not apply adhesive labels directly to the CD.

Complete the ITW (see “Image Transmittal Worksheet Instructions” on next page) and include with the media shipment.

Mail the images and ITW to:
American College of Radiology Imaging Network
MRI/CT Core Laboratory
Attn: ACRIN PA 4006
1818 Market Street, 16th floor
Philadelphia, PA 19103
Image Transmittal Worksheet Instructions

The Image Transmittal Worksheet (ITW), provided on the following page, can also be downloaded on the protocol-specific page of the ACRIN Web site: www.acrin.org/4006_imagingmaterials.aspx

1. The full field digital mammogram and digital tomosynthesis exam must be submitted to ACRIN. Each imaging submission must include an ITW for each participant/study.

Please keep a copy of the ITW within the study participant’s records

2. The ITW must be completed in its entirety and signed by the person completing the worksheet. When the study has been submitted to ACRIN via the electronic database (TRIAD), please submit the ITW to ACRIN via fax 215-923-1737 or by email to Diane Munroe at dmunroe@acr.org. Studies submitted by mail (CD or DVD) must contain a printed ITW in the mailed package.

3. An ACRIN Core Laboratory imaging specialist will review the ITW to confirm:
   a. The number of images identified as being submitted on the ITW actually arrived at ACRIN;
   b. The appropriate identifying/de-identified information was included for the imaging study.

4. The person that completes and signs the image transmittal form will receive feedback regarding image transmission discrepancies. Please make sure the signature and email address are legible.

For further information or questions, contact the ACRIN Core Laboratory at: (215) 940-8810

A sample ACRIN PA 4006 Mammography ITW follows on the next page. For full-scale PDFs, visit www.acrin.org/4006_imagingmaterials.aspx.
**Instructions:** Standard of care and study imaging exams must be submitted to the American College of Radiology Image Network (ACRIN) in DICOM format. Each imaging submission must include an Image Transmittal Worksheet (ITW) for each participant/study. The ITW must be completed in its entirety and signed by the person completing the worksheet. When the study has been submitted to ACRIN via the electronic database (TRIAD), please submit the ITW to ACRIN via fax 215-923-1737 or by email to Diane Munroe at dmunroe@acr.org. Studies submitted by mail (CD or DVD) must contain a printed ITW in the mailed package.

Please keep a copy of each ITW within the study participant’s records

For further information or questions contact the ACR Imaging Core Laboratory:
1818 Market Street, 16th Floor
Philadelphia, PA 19103
(215) 940-8899
Fax: 215-923-1737 or email dmunroe@acr.org

### Section I: Image Data Demographics

<table>
<thead>
<tr>
<th>ACRIN Site Number:</th>
<th>ACRIN Case Number:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Participant Initials:</th>
<th>Participant DOB:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>-</strong>-<strong>-19</strong></td>
</tr>
</tbody>
</table>

### Section II: Image Submission (select one)

#### Group A

<table>
<thead>
<tr>
<th>Imaging Exam</th>
<th>Date of Imaging (MTH-DD-YYYY)</th>
<th># Images Submitted</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study-FFDM</td>
<td>[ ] [ ] [ ]- [ ]- [ ]- 20[ ]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Study-DBT</td>
<td>[ ] [ ] [ ]- [ ]- [ ]- 20[ ]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Screening Exam Group B only</td>
<td>[ ] [ ] [ ]- [ ]- [ ]- 20[ ]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diagnostic Call Back Exam</td>
<td>[ ] [ ] [ ]- [ ]- [ ]- 20[ ]</td>
<td>Modality (Diagnostic Mammogram, US, MRI)</td>
<td></td>
</tr>
<tr>
<td>Follow-up Exam</td>
<td>[ ] [ ] [ ]- [ ]- [ ]- 20[ ]</td>
<td>Modality (FFDM, US, MRI, other)</td>
<td></td>
</tr>
</tbody>
</table>

#### Group B

<table>
<thead>
<tr>
<th>Imaging Exam</th>
<th>Date of Imaging (MTH-DD-YYYY)</th>
<th># Images Submitted</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Screening Exam Group B only</td>
<td>[ ] [ ] [ ]- [ ]- [ ]- 20[ ]</td>
<td>Modality (FFDM, US, MRI, other)</td>
<td></td>
</tr>
</tbody>
</table>

Form Completed By: [ ] [ ] [ ] [ ]

Date Form Completed: [ ] [ ] [ ]- [ ]- [ ]- 20[ ]

(MM-DD-YYYY)
Quality Control Procedures

The ACRIN PA 4006 protocol explicitly requires participating centers to meet technical specifications for uniformity and maintain quality control/quality assurance programs to the tomosynthesis and mammography units used to obtain images. Specific parameters for image acquisition are outlined in the protocol and provided in this manual. This routine imaging will occur only at accredited centers that have successfully demonstrated their competence during the site qualification process. ACRIN will provide ongoing quality control through the ACRIN core lab. Specifically, the ACRIN core lab will receive and conduct quality control evaluations on all images to help centers maintain trial grade quality. In addition to these guidelines, all participating sites are required to document that they have performed the weekly Quality Assurance processes per the manufacturer’s recommendations by submitting to ACRIN a copy of QA documents. Sites must notify ACRIN when service has been completed on the mammography units, as requalification of the machine may be necessary depending on the service requirements.

The ACRIN core lab specialists will provide feedback to sites, especially during early trial imaging to ensure high-quality imaging per protocol. However, re-imaging will not be requested once the trial is under way. Furthermore, the imaging manual contains specific language for image capture (how to scan) and diagnostic (how to read), with specific imaging submission requirements.

Should the specialist discover that images or image-related data are missing, inaccurate, or inconsistent with the imaging protocol, sites are notified through the following process:

1. An imaging query describing the problem is e-mailed to the study coordinator. Such a query is referred to as a Z5 form (see example on the following page).

2. The site should resolve the problem as quickly as possible and must maintain a hard copy of the completed and signed query at the site.

3. A site receives up to three reminders to resolve a query. After that time, an outstanding query is reported to the trial leadership for assistance with resolution.

A sample Z5 Query form is located in the appendix.
## Z5 Form Example

**ACRIN Imaging Query**

**Request for Additional Imaging Information**

**DATE of this request:** __________________________

**TO:** __________________________  **Inst.##:** __________________________  **Inst. Name:** __________________________

**FROM:** __________________________  **Subject:** ACRIN IMAGING QUERY RESPONSE REQUEST  **Study No./Name:** __________________________

The above mentioned case from your institution is incomplete or requires a clarification. Kindly supply the missing images and/or subject information described, to make the case evaluable for final review. Please print this form and return to ACRIN via FAX No. 215.923-1737.

**Queries requiring the submission of incomplete image data will not be resolved until the missing image data is received here at ACRIN.**

<table>
<thead>
<tr>
<th>X</th>
<th>Case</th>
<th>Image Type</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Study Date</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Explanation</th>
<th>Site Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Missing Images/VIEWS - Study incomplete. (<strong>See Comments</strong>)</td>
<td></td>
</tr>
<tr>
<td>Date of Birth (DOB) on Images does not match DOB in Clinical DB. Please Confirm correct DOB. (<strong>See Comments</strong>)</td>
<td></td>
</tr>
<tr>
<td>Digital Image files damaged. (<strong>See Comments</strong>)</td>
<td></td>
</tr>
<tr>
<td>Exam not in DICOM format. (<strong>See Comments</strong>)</td>
<td></td>
</tr>
<tr>
<td>Incorrect Case # assigned to images. (<strong>See Comments</strong>)</td>
<td></td>
</tr>
<tr>
<td>Incorrect technical factors utilized. (<strong>See Comments</strong>)</td>
<td></td>
</tr>
<tr>
<td>Anatomy Not Covered (ANC). (<strong>See Comments</strong>)</td>
<td></td>
</tr>
<tr>
<td>OTHER. (<strong>See Comments</strong>)</td>
<td></td>
</tr>
</tbody>
</table>

**ACRIN Comments:**

**SITE Comments:**

**Institution Representative:** __________________________  **Phone No.:** __________________________  **Email:** __________________________

---

*ACRIN Imaging Query*